BIOCIRCUIT TECHNOLOGIES	**Document Number:**	05-MAR-001
	Effective Date:	07/01/2022
	Revision:	03
	Instructions for Use	

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

STERILE: Sterilized with ethylene oxide gas. **DO NOT** use if the package is open or damaged.

STORAGE: Store in a cool, dry place.

SINGLE USE: Nerve Tape is intended for single patient use only. DO NOT re-sterilize and/or reuse, as it may result in compromised device performance and risk of improper sterilization and cross contamination.

1 Distribution and manufacturing information

Distributed by: BIOCIRCUIT TECHNOLOGIES, INC.
1819 Peachtree Road NE, Ste 205
Atlanta, Georgia 30309 USA
Phone: (770) 468-7700
www.biocircuit.com
info@biocircuit.com

Manufactured by: COOK BIOTECH INC.
1425 Innovation Place
West Lafayette, Indiana 47906 USA
Phone: (765) 497-3355

2 Description

Nerve Tape™ is a surgical implant designed to align and connect peripheral nerves. Nerve Tape is designed to be an interface between the nerve and the surrounding tissue. Nerve Tape is comprised of an extracellular matrix (ECM), which is fully remodeled during the healing process, and nitinol microhooks, which bind coapted nerve ends together. When hydrated, Nerve Tape is easy to handle, soft, pliable, nonfriable, and porous. Nerve Tape has sufficient mechanical strength to hold the ends of the nerve together. Nerve Tape is provided sterile, for single use only, and in a variety of sizes to meet the surgeon's needs.

3 Indications for Use

Nerve Tape™ is indicated for the repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity. Nerve Tape is supplied sterile and is intended for one-time use.

R_x ONLY This symbol means the following: CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician. This product is intended for use by trained medical professionals.

4 Contraindications/Precautions/Warnings

Note: This device is not intended for use in vascular applications.

- Nerve Tape is derived from a porcine source and should not be used for patients with known sensitivity to porcine material.
- The microhooks are composed of NiTiNOL, an alloy of nickel and titanium. Persons with allergic reactions to these metals may suffer an allergic reaction to this implant. Prior to implantation, patients should be counseled on the materials contained in the device, as well as potential for allergy / hypersensitivity to these materials.
- This device is designed for single use only. Attempts to reprocess, re-sterilize, and/or reuse may lead to device failure and/or transmission of disease.
- Do not re-sterilize device.
- Discard all open and unused portions of the device.
- Device is sterile provided the package is dry, unopened and undamaged. Do not use device if the package seal is damaged or open.
- Discard device if mishandling has caused possible damage or contamination, or if the device is past its expiration date.
- Do not implant device prior to rehydration.
- Ensure an accurate nerve diameter is obtained using an appropriate measuring device prior to selection and application of Nerve Tape. Improper measurement and/or selection of an incorrect device size carries a potential risk of nerve injury.

5 Potential Complications

Possible complications can occur with any nerve repair surgical procedure including pain, infection, decreased or increased nerve sensitivity, and complications associated with use of anesthesia. If any of the following conditions occur and cannot be resolved, careful removal of the device should be considered:

- Infection
- Allergic reaction
- Acute or chronic inflammation (initial application of surgical graft materials may be associated with transient, mild, localized inflammation)

6 Storage

Nerve Tape should be stored in a clean, dry location at room temperature.

7 Sterilization

This device has been sterilized with ethylene oxide.

8 Suggested Instructions for Use

NOTE: Always handle Nerve Tape® using aseptic technique. Minimize contact with latex gloves.

8.1 Follow standard operating procedures for exposure, mobilization, and preparation of the nerve for repair (Figure 1). Determine the nerve diameter in millimeters (mm) using a suitable measuring instrument. **Ensure nerve diameter measurement and device size selection are accurate. Failure to do so carries the risk of potential nerve injury.** Select the Nerve Tape size closest to the nerve diameter.

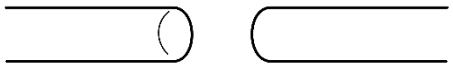


Figure 1

8.2 Open the outer carton and remove the sterile pouch. Using standard aseptic technique, open the pouch and pass the inner tray to the sterile field for further handling.

8.3 Fill the pre-molded rehydration reservoir with room temperature sterile saline or sterile Lactated Ringer's solution. Hydrate Nerve Tape for 10 seconds or until the desired handling characteristics are achieved, but not more than 20 minutes.

8.4 Hemostasis of both nerve stumps must be achieved prior to beginning the entubulation procedure. In the event a tourniquet is used, release the tourniquet and achieve hemostasis before beginning the entubulation procedure.

8.5 Place Nerve Tape underneath intended repair site **with the microhook side facing upward and the metal columns oriented parallel to the nerves**, as illustrated in Figure 2.

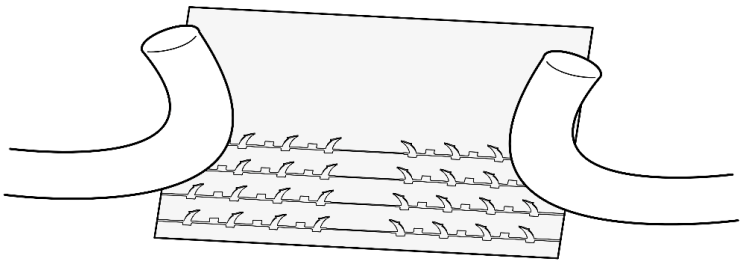


Figure 2

8.6 Position the first nerve stump slightly past the midpoint of the device, place onto one of the central microhook columns and apply a gentle reverse and downward tug to engage the underlying microhooks into the epineurium. The cut surface of the nerve stump should end up at the midpoint of the device (Figure 3).

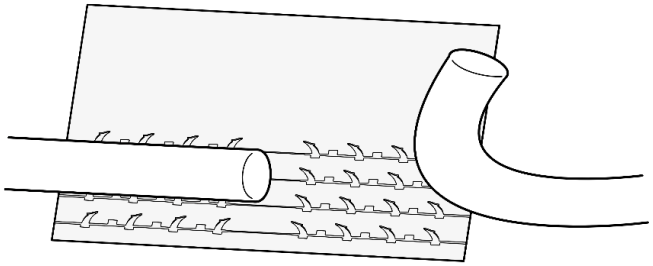


Figure 3

8.7 Repeat this process with the second nerve stump on the opposite side of the device, such that the two nerve stumps are positioned in close approximation (Figure 4).

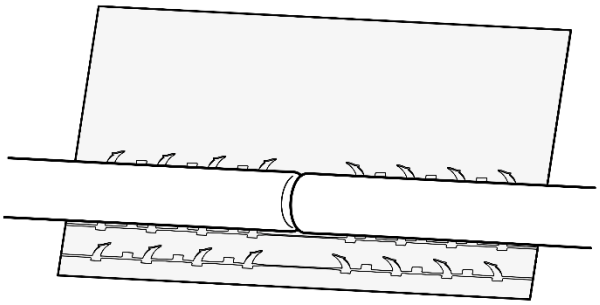


Figure 4

8.8 Irrigate Nerve Tape device with sterile saline or Lactated Ringer's solution.

8.9 Engage additional microhooks by wrapping the shorter leaf of the device around the approximated nerve stumps (Figure 5).

8.10 Next, engage remaining microhooks and continue entubulation by wrapping the longer leaf of the device around the approximated nerve stumps (Figure 6).

8.11 To complete entubulation, continue wrapping so that the longer leaf overlaps and coheres with the underlying material. The leaf can be trimmed if desired, maintaining an overlap of at least ¾ of the device circumference to achieve device closure.

8.12 Secure the longer leaf if necessary. This may include optional placement of one or more sutures, allowing for normal edema following traumatic nerve injury.

8.13 The finished repair is illustrated in Figure 7a (and with optional suture closure in Figure 7b).

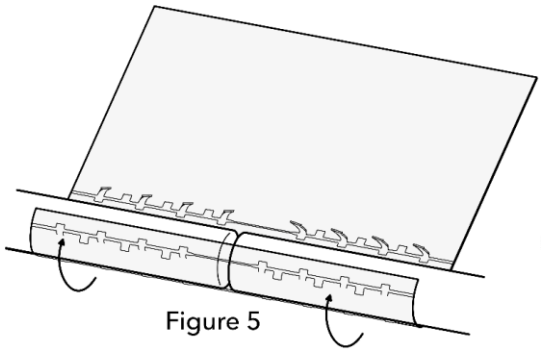


Figure 5

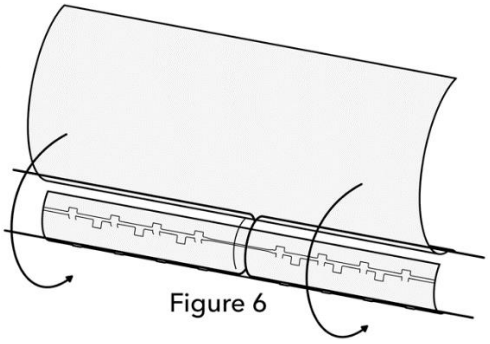


Figure 6

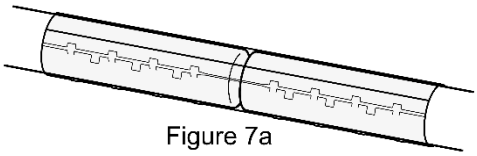


Figure 7a

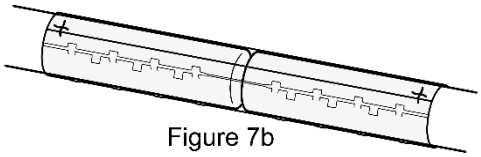


Figure 7b

8.14 Discard any unused portions of Nerve Tape according to institutional guidelines for biological waste. Do not re-sterilize.

9 How Supplied

Nerve Tape is provided in a plastic tray and outer sterile pouch. The pouch is heat-sealed to provide a sterile barrier and has a peelable seal. Contents of the package are guaranteed sterile unless the package is opened or damaged. Nerve Tape and packaging do not contain natural rubber latex. *Do not use if the peel pouch appears to be open or damaged.*

10 MRI Safety Information

A person implanted with the Nerve Tape device may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

Nominal value(s) of Static Magnetic Field [T]	1.5 T or 3 T
Maximum Spatial Field Gradient [T/m and gauss/cm]	20 T/m (2000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
Maximum Whole-Body SAR [W/kg]	4.0 W/kg
Limits on Scan Duration	4.0 W/kg whole body average SAR for 15 minutes of continuous RF (a sequence or back-to-back series / scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact of 1 mm
Operating Mode	First Level Control Mode
If information about a specific parameter is not included, there are no conditions associated with that parameter.	

11 Inquiries

For additional information, to place an order or to report adverse events, contact BioCircuit Technologies Customer Care:

Phone: (770) 468-7700
www.biocircuit.com
info@biocircuit.com

12 Returned Goods Policy

Authorization from BioCircuit Technologies Customer Care must be obtained prior to returning product. Sterile product must be returned in unopened, undamaged cartons, packed to prevent damage.

13 Symbols Used on Labelling


Inspect Package Prior to Use


Manufacturer

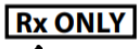

Expiration Date

Ethylene Oxide Sterilized


Single Use Only, Do Not Reuse


Do not Use if Packaging is Damaged

Lot Number



For Sale on the Order of a Physician Only

Catalogue Number

Magnetic Resonance Imaging Conditional


Refer to Instructions for Use

14 VERSION HISTORY

The following table describes the version history of this Instructions for Use document for the nerve repair wrap.

Version	Date	Description
00	07.09.20	Original release – refer to CR-20-003
01	02.05.21	Revised to reflect Design Verification output – refer to CR-21-002
02	03.03.21	Revised according to testing results – refer to CR-21-004
03	07.01.22	Revised according to FDA feedback – refer to CR-22-006