

ConformaWrap™

Manufactured For:



BIOCIRCUIT TECHNOLOGIES, INC.

1819 Peachtree Road, Ste 205
Atlanta, Georgia 30309 USA
Phone: 1-800-905-2204
www.biocircuit.com
support@biocircuit.com

Patent: www.biocircuit.com/patent

Description

ConformaWrap™ is a surgical implant designed to protect a damaged peripheral nerve, serving as a non-constricting interface between the nerve and the surrounding tissue. ConformaWrap is composed of an extracellular matrix (ECM), which is fully remodeled during the healing process. When hydrated, ConformaWrap is easy to handle, soft, pliable, nonfriable, and porous. ConformaWrap is provided sterile, for single use only, and in a variety of sizes to meet the surgeon's needs.

Indications for Use

ConformaWrap™ is indicated for the management of peripheral nerve injuries where there is no gap. ConformaWrap is supplied sterile and is intended for one-time use.

Rx 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.

Contraindications/Precautions/Warnings

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

- ConformaWrap™ is derived from a porcine source and should not be used for patients with known sensitivity to porcine material.
- 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.

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)

Storage

ConformaWrap™ should be stored in a clean, dry location at room temperature.

Sterilization

This device has been sterilized with ethylene oxide.

Suggested Instructions for Use













NOTE: Always handle ConformaWrap™ using aseptic technique. Minimize contact with latex gloves.

1. Follow standard operating procedures for exposure, mobilization, and preparation of the nerve.
2. Open the outer carton and remove the sterile pouch. Using standard aseptic technique, open the pouch and remove the clamshell. The clamshell should only be opened in the sterile field.
3. ConformaWrap may be trimmed, before or after hydration, to the appropriate dimensions for covering the intended portion of the nerve. Size the ConformaWrap to account for normal edema associated with nerve injury and tourniquet removal.
4. Hydrate ConformaWrap with sterile saline or Lactated Ringer's solution until the desired handling characteristics are achieved, but not more than 20 minutes. Note: the clamshell may be used as a rehydration reservoir.
5. Position ConformaWrap around the injured nerve allowing for normal edema associated with nerve injury. Add sterile saline or Lactated Ringer's solution as needed.
6. Secure ConformaWrap if necessary. This may include optional placement of one or more sutures.
7. Discard any unused portions of ConformaWrap according to institutional guidelines for biological waste. Do not re-sterilize.

How Supplied

ConformaWrap™ is provided in a plastic clamshell 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. Do not use if the peel pouch appears to be open or damaged. ConformaWrap and packaging do not contain natural rubber latex.

Symbols Used on Labeling

	Reorder/Catalogue Number		Refer to Instructions for Use		Do Not Resterilize
	Lot Number		Ethylene Oxide Sterilized		MR Safe
	Expiration Date		For Sale on the Order of a Physician Only		Manufacturer
	Single Use Only		Do Not Use if Packaging is Damaged		
			Inspect Packaging Prior to Use		

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.

Inquiries

For additional information, to place an order or to report adverse events, contact BioCircuit Technologies Customer Care: Phone: 1-800-905-2204
www.biocircuit.com - support@biocircuit.com