INTEGRA®

NeuraWrap™

Nerve Protector

CE 2797

ENGLISH

DESCRIPTION

NeuraWrap™ nerve protector is an absorbable collagen implant that provides a non-constricting encasement for injured peripheral nerves for protection of the neural environment. NeuraWrap nerve protector is designed to be an interface between the nerve and the surrounding tissue. When hydrated, NeuraWrap nerve protector is an easy to handle, soft, pliable, nonfriable, porous collagen conduit. The wall of the conduit has a longitudinal slit that allows NeuraWrap nerve protector to be spread open for easy placement over the injured nerve. The resilience of the collagen conduit allows NeuraWrap nerve protector to recover and maintain closure once the device is placed around the nerve. NeuraWrap nerve protector is provided sterile, non-pyrogenic, for single use only, in double peel packages in a variety of sizes.

INDICATIONS FOR USE

NeuraWrap nerve protector is indicated for the management of peripheral nerve injuries in which there has been no substantial loss of nerve tissue.

CONTRAINDICATIONS

NeuraWrap nerve protector is not designed, sold or intended for use except as described in the indications for use and is contraindicated for patients with a known history of hypersensitivity to bovine derived materials.

INSTRUCTIONS FOR USE

Follow standard procedures for exposure and mobilization of the injured nerve (Figure 1). Determine the nerve diameter in millimeters (mm) using a suitable measuring instrument. If neurolysis is performed measure the nerve diameter after neurolysis. Select a NeuraWrap nerve protector of sufficient diameter to allow wrapping of the injured nerve. The diameter of the NeuraWrap nerve protector must be at least 2mm larger than the measured nerve diameter. Hydrate the NeuraWrap nerve protector in sterile saline for a minimum of 10 minutes before use. NeuraWrap nerve protector must be long enough to cover the affected area. After hydration, the NeuraWrap nerve protector may be cut to an appropriate length as required. For nerve injuries longer than 2cm more than one NeuraWrap nerve protector may be used end-to-end.

Application Procedure: NeuraWrap nerve protector should be opened at the slit and placed over the injured nerve (Figure 2). If needed, NeuraWrap nerve protector may be trimmed to desired width. The slit may then be closed with a running suture technique (Figure 3), using an atraumatic suture. NeuraWrap nerve protector may be rotated (Figure 4) such that the suture line is away from the injured soft tissue (i.e. the skin suture line). An additional stay suture or sutures (Figures 5 & 6) may be placed to prevent migration. The stay suture should be placed through the NeuraWrap nerve protector and the epineurium to anchor the NeuraWrap nerve protector at each end.

Figure 1

Figure 2

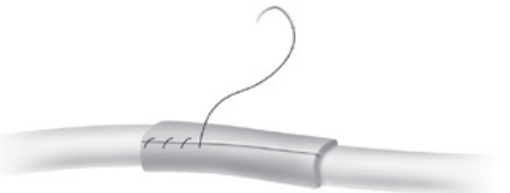


Figure 3

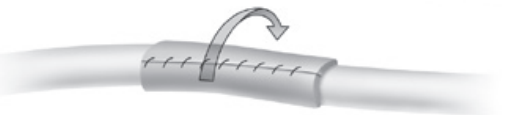


Figure 4

Figure 5

Figure 6

Postoperative Procedure: Application of NeuraWrap nerve protector does not modify postoperative treatment.

SAFETY

NeuraWrap nerve protector is manufactured from collagen obtained from bovine deep flexor tendon, which is classified by European Standards as Category C material (no detectable infectivity for Bovine Spongiform Encephalopathy (BSE)). Bovine Tendon is known to be one of the purest sources of Type I collagen

that is commercially available.

The collagen used to manufacture NeuraWrap nerve protector is currently used in the manufacture of artificial skin, absorbable hemostatic sponges, and absorbable wound dressings. The manufacturing process for NeuraWrap nerve protector meets USA and European Standards for animal tissue sourcing, handling and inactivation of viruses and transmissible agents. This process involves a treatment with sodium hydroxide that is a recognized method of inactivation of Spongiform Encephalopathy pathogens.

A viral inactivation study for the NeuraWrap nerve protector manufacturing process was conducted by an independent certified laboratory. In this study, the sodium hydroxide reduced the viral titer to non-detectable levels for the following viral strains: Human Immunodeficiency Virus Type I (HIV), Bovine Viral Diarrhea (BVD), Infectious Bovine Rhinotracheitis (IBR), Parainfluenza Virus Type 3 (PI3), Vesicular Stomatitis (VSV).

WARNINGS

- Do not use if the product package is damaged or opened.

PRECAUTIONS

- Rinse surgical gloves to remove any glove powder prior to handling NeuraWrap nerve protector.
- After application, NeuraWrap nerve protector must fit loosely around the injured nerve to avoid constriction of the nerve tissue.

- NeuraWrap nerve protector should be used with caution in infected regions.

ADVERSE EVENTS

Possible complications can occur with any peripheral nerve surgical procedure including pain, infection, decreased or increased nerve sensitivity, and complications associated with use of anesthesia.

SINGLE USE DEVICE

NeuraWrap nerve protector is supplied in a single-use package and is guaranteed to be sterile and non-pyrogenic unless opened or damaged. The product is intended for use as an absorbable implant and is not to be reused. Reuse of the device can result in contamination and/or disease transmission. Any attempt to resterilize or reuse the product/components will damage the matrix and impair its ability to function as intended. All unused pieces must be discarded.

STORAGE

Store at room temperature. Avoid excessive heat or humidity. Do not refrigerate.

HOW SUPPLIED

NeuraWrap nerve protector is supplied sterile, in single use, double peel packages. Contents of the package are guaranteed sterile and nonpyrogenic unless the package is opened or

damaged. The NeuraWrap nerve protector product and packaging do not contain natural rubber latex.

Reference Number:	Size:	Quantity:
NW320	3.0 mm ID x 2cm length	single unit
NW520	5.0 mm ID x 2cm length	single unit
NW720	7.0 mm ID x 2cm length	single unit
NW1020	10.0 mm ID x 2cm length	single unit
NW340	3.0 mm ID x 4cm length	single unit
NW540	5.0 mm ID x 4cm length	single unit
NW740	7.0 mm ID x 4cm length	single unit
NW1040	10.0 mm ID x 4cm length	single unit

PRODUCT INFORMATION DISCLOSURE

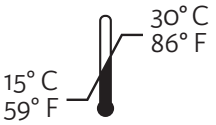
INTEGRA LIFESCIENCES CORPORATION HAS EXERCISED REASONABLE CARE IN THE SELECTION OF MATERIALS AND THE MANUFACTURE OF THESE PRODUCTS. INTEGRA LIFESCIENCES EXCLUDES ALL WARRANTIES, WHETHER EXPRESSED OR IMPLIED, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. INTEGRA LIFESCIENCES SHALL NOT BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL LOSS, DAMAGE, OR EXPENSE, DIRECTLY OR INDIRECTLY ARISING FROM USE OF THIS PRODUCT. INTEGRA LIFESCIENCES NEITHER ASSUMES NOR AUTHORIZES ANY PERSON TO ASSUME FOR IT ANY

OTHER OR ADDITIONAL LIABILITY OR RESPONSIBILITY IN CONNECTION WITH THESE PRODUCTS.

RETURNED GOODS POLICY

- Authorization, from customer service, must be obtained prior to returning product.
- Sterile product must be returned in unopened, undamaged cartons, packed to prevent damage.
- Custom or special order products will not be accepted for credit.
- Credit will be issued for goods returned prior to ninety days from ship date with a restocking charge. This assumes that the product returned is not damaged and can be verified to have not been used or opened.

SYMBOLS USED ON LABELING

	Consult Instructions for Use
	Expiration date
	Do not re-use
LOT	Lot number
	Do not use if package is damaged
EC REP	Authorized representative in the European Community
STERILE EO	Sterilized using Ethylene Oxide.
CE 2797	Product complies with requirements of directive 93/42/EEC
Rx ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician or practitioner
	Manufacturer
REF	Catalog number
	Do not re-sterilize
	Temperature Limit

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EC REP

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