AxoGuard®
NerveConnector
FP0068-02B

CANADA ONLY

Description

The AxoGuard® Nerve Connector is an implant that provides protection for peripheral nerves. AxoGuard® Nerve Connector is designed to be an interface between the nerve and the surrounding tissue. AxoGuard® Nerve Connector is comprised of an extracellular matrix (ECM) and is fully remodeled during the healing process. When hydrated, AxoGuard® Nerve Connector is easy to handle, soft, pliable, nonfriable, and porous. AxoGuard® Nerve Connector is flexible to accommodate movement of the joint and associated tendons, and has sufficient mechanical strength to hold sutures. AxoGuard® Nerve Connector is provided sterile, for single use only, and in a variety of sizes to meet the surgeon's needs.

Indications for Use

The AxoGuard® Nerve Connector is indicated for the repair of peripheral nerve injuries where gap closure can be achieved by flexion of the extremity. This device is supplied sterile and is intended for single use.

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

Contraindications

This device is derived from a porcine source and should not be used for patients with known sensitivity to porcine material.

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

Precautions

- **Do not resterilize.** Discard all open and unused portions.
- Device is sterile if the package is dry, unopened and undamaged. Do not use if the package seal is broken.
- Discard device if mishandling has caused possible damage or contamination, or if the device is past its expiration date.
- Do not suture 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
- Acute or chronic inflammation (initial application of surgical graft materials may be associated with transient, mild, localized inflammation)
- Allergic reaction

Storage

This device 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: These recommendations are designed to serve only as a general procedure. They are not intended to supersede the institutional protocols or professional clinical judgment concerning patient care. Always handle AxoGuard® Nerve Connector using aseptic technique. Minimize contact with latex gloves.

1. Follow standard operating procedures for exposure and mobilization of the nerve (see Figure 1). Determine the nerve diameter in millimeters (mm) using a suitable measuring instrument. Select an AxoGuard® Nerve Connector of sufficient diameter to account for normal edema following traumatic nerve injury and to allow easy insertion of the nerve stumps into the device.

Figure 1

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.

3. Hemostasis of both nerve stumps must be achieved prior to beginning the entubulation procedure. If a tourniquet is used, release the tourniquet and achieve homeostasis before entubulating.

4. If necessary, trim the AxoGuard® Nerve Connector to a length that is appropriate for the nerve gap. Allow at least 3mm on the proximal and distal stumps for insertion into the connector (at least 6mm total).

5. Open the tray and fill the pre-molded rehydration reservoir with room temperature sterile saline or sterile Lactated Ringer's solution. Hydrate the AxoGuard® Nerve Connector for 10 seconds or until the desired handling characteristics are achieved, but not more than 20 minutes.

6. Use non-absorbable suture to secure the AxoGuard® Nerve Connector in place. Pass the suture through the wall of the tube from outside to inside, at least 1mm from the edge (see Figure 2). Then pass the suture transversely through the epineurium of one nerve stump at a distance of at least 2mm from the cut nerve face. Reverse the suture and pass it through the wall of the nerve guide by pulling the suture so that the nerve stump is drawn into the tube. Tie the suture so that it is secure but

(continued on back)

avoid generating tension in the suture itself. If desired, add additional suture to secure the device.

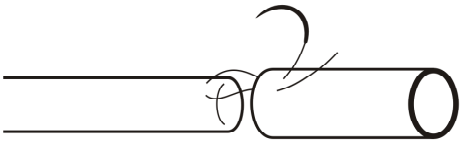

Figure 2

7. Use a syringe to gently flush the lumen of the nerve protector with sterile saline or Lactated Ringer's solution (Figure 3). Repeat the suturing procedures described above with the opposite nerve stump (Figure 4). Fill the interior of the nerve connector with saline or Lactated Ringer's solution (Figure 5). See Figures 6 and 7 for completed repair.

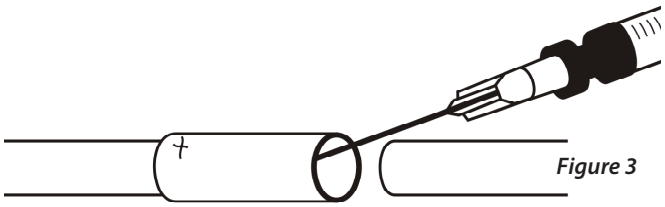

Figure 3

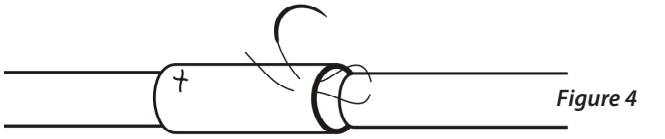

Figure 4

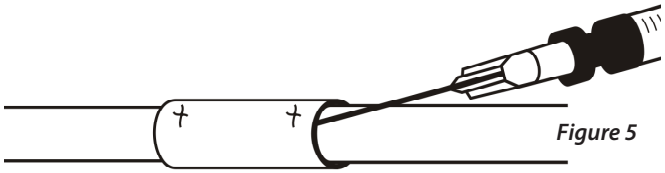

Figure 5

Figure 6

Figure 7

8. Discard any unused portions of the AxoGuard® Nerve Connector according to institutional guidelines for biological waste. Do not resterilize.

How Supplied

AxoGuard® Nerve Connector is placed into a plastic tray and then inserted into a 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. The AxoGuard® Nerve Connector and packaging do not contain natural rubber latex. *Do not use if the peel pouch appears to be open or damaged.*

Inquiries

For additional information, to place an order or to report adverse events, contact:

AxoGen Customer Care:
888-AXOGEN1 (888-296-4361)
E-mail: CustomerCare@AxoGenInc.com

Returned Goods Policy

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

Symbols Used on Labeling

	See instructions for use
	Expiration date
	Do not reuse after opening
LOT	Lot number
Rx ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician
	Manufacturer
STERILE EO	Sterile unless package opened or damaged. Method of sterilization – ethylene oxide.

AxoGen® Nerve Regeneration

Distributed by:
AxoGen Incorporated
13631 Progress Blvd. Suite 400
Alachua, Florida 32615
Phone: (386) 462-6880
Toll Free: (888) 296-4361
Fax: (386) 462-6801
CustomerCare@AxoGenInc.com
www.AxoGenInc.com

Manufactured by:
Cook Biotech Incorporated
1425 Innovation Place
West Lafayette, Indiana 47906 U.S.A.
Phone: (765) 497-3355
Toll Free: (888) 299-4224
Fax: (765) 497-2361

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