



FP 0067-01B

Description

The AxoGuard[®] Nerve Protector is an implant that provides nonconstricting protection for peripheral nerves. AxoGuard[®] Nerve Protector is designed to be an interface between the nerve and the surrounding tissue. AxoGuard[®] Nerve Protector is comprised of an extracellular matrix (ECM) and is fully remodeled during the healing process. When hydrated, AxoGuard[®] Nerve Protector is easy to handle, soft, pliable, nonfriable, and porous. AxoGuard[®] Nerve Protector is flexible to accommodate movement of the joint and associated tendons, and has sufficient mechanical strength to hold sutures. AxoGuard[®] Nerve Protector 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 Protector is intended for the repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity. The 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 a known sensitivity to porcine material.

NOTE: This device 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.

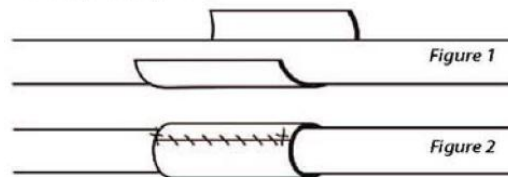
Sterilization

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 Protector using aseptic technique. Minimize contact with latex gloves.

1. Follow standard operating procedures for exposure and mobilization (mm) using a suitable measuring instrument. If necessary, repair the nerve using standard operating procedures. Select an AxoGuard[®] Nerve Protector of sufficient diameter to account for normal edema following traumatic nerve injury. The AxoGuard[®] Nerve Protector diameter should be at least 1-2mm larger than the measured nerve diameter and long enough to cover the affected area.
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. If necessary, trim the AxoGuard[®] Nerve Protector to the appropriate dimensions for covering the damaged portion of the nerve.
4. 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 Protector for 10 seconds or until the desired handling characteristics are achieved.
5. Position the AxoGuard[®] Nerve Protector around the nerve (Figure 1). If desired, gently flush the device with sterile saline or Lactated Ringer's solution to improve conformability with the nerve. Secure the device as necessary. This may include placing running sutures along the longitudinal slit to enclose the nerve, and/or stay suture through the nerve epineurium. See Figure 2. for complete repair.



6. Discard any unused portions of the AxoGuard[®] Nerve Protector according to institutional guidelines for biological waste. Do not resterilize.

How Supplied.

AxoGuard[®] Nerve Protector 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 Protector 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 Service:

888-AXOGEN1 (888-296-4361)

E-mail: Customerservice@AxoGeninc.com

Returned Goods Policy

Authorization from AxoGen Customer Service 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 number



Caution: Federal (USA) law restricts this device to sale by or on the order of a physician



Manufacturer



Sterile unless package opened or damaged. Method of sterilization – ethylene oxide.



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