axoguard HA+ nerve protector

Instructions for Use

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DESCRIPTION

Axoguard HA+ Nerve Protector is a surgical implant that provides non-constricting protection for peripheral nerve injuries. Axoguard HA+ Nerve Protector is designed to aid in coaptation and protection of peripheral nerve injuries by serving as an interface between the nerve and the surrounding tissue and also provides tension relief when used as a coaptation aid. Axoguard HA+ Nerve Protector is comprised of an extracellular matrix (ECM) and is fully remodeled during the healing process. When hydrated, Axoguard HA+ Nerve Protector is easy to handle, soft, pliable, nonfriable, and porous. The lubricant coating on Axoguard HA+ Nerve Protector is composed of sodium hyaluronate and sodium alginate. When hydrated, the lubricant coating reduces friction between the nerve and the surrounding tissue. Axoguard HA+ Nerve Protector is flexible to accommodate movement of the joint and has sufficient mechanical strength to hold sutures. Axoguard HA+ Nerve Protector is provided sterile, for single use only, and in a variety of sizes to meet the surgeon's needs.

INDICATIONS FOR USE

Axoguard HA+ Nerve Protector is indicated for the management and protection of peripheral nerve injuries where there is no gap, or following closure of the gap.

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

Axoguard HA+ Nerve Protector base membrane is derived from a porcine source and the lubricant coating is composed of sodium hyaluronate and sodium alginate. The Axoguard HA+ Nerve Protector should not be used for patients with known sensitivity to porcine, alginate, or hyaluronate materials.

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

PRECAUTIONS

- This device is designed for single use only. Attempts to reprocess, resterilize, and/or reuse may lead to device failure and/or transmission of disease.
- Do not resterilize 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 suture device prior to rehydration.

POTENTIAL COMPLICATIONS

Possible complications can occur as with any surgical nerve 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:

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

STORAGE

Axoguard HA+ Nerve Protector should be stored in a clean, dry location at room temperature. Do not store in direct sunlight due to risk of heat.

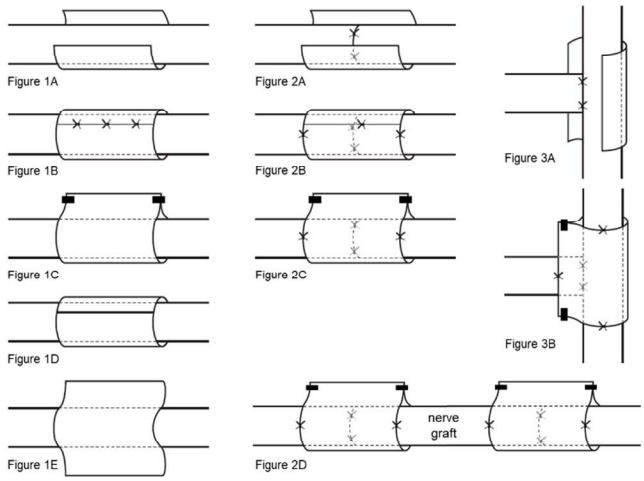
STERILIZATION

This device has been sterilized with ethylene oxide.

SUGGESTED INSTRUCTIONS FOR USE

NOTE: Always handle Axoguard HA+ Nerve Protector using aseptic technique. Minimize contact with latex gloves because of potential patient allergy.

1. Follow standard operating procedures for exposure, mobilization, and/or repair of the nerve. Determine the nerve diameter in millimeters (mm) using a suitable measuring instrument.
   a. Select an Axoguard HA+ Nerve Protector device of sufficient dimensions to account for normal edema following traumatic nerve injury and tourniquet removal.
   b. As placed the Axoguard HA+ Nerve Protector is to be oversized to allow for the normal edema discussed above; specifically, the device should be 1-2 mm larger in diameter than the nerve.
   c. Close any gap prior to the application of the device as, for example, illustrated in Figures 2A, 2B, 2C, 2D, 3A, and 3B.
2. Open the outer carton and remove the foil pouch. Using standard aseptic technique, open the outer pouch and pass the inner pouch to the sterile field.
3. Within the sterile field, open the inner pouch and, if necessary, trim the Axoguard HA+ Nerve Protector to the appropriate dimensions for covering the intended portion of the nerve. The Axoguard HA+ Nerve Protector may be trimmed after hydration, if desired.
4. Hydrate Axoguard HA+ Nerve Protector in a sterile container with room temperature sterile saline or sterile Lactated Ringer's solution for 10 seconds or until the desired handling characteristics are achieved, but not more than 20 minutes.
5. Position Axoguard HA+ Nerve Protector around or over the nerve or around the coaptation site (Figures 1A, 2A, and 3A). If desired, add sterile saline or Lactated Ringer's solution to improve conformability. Secure the device as necessary. Examples of applied devices are shown in Figures 1B, 1C, 1D, 1E, 2B, 2C, 2D, and 3B.



Examples of securing Axoguard HA+ Nerve Protector

6. Discard any unused portions of Axoguard HA+ Nerve Protector according to institutional guidelines for biological waste. Do not resterilize.

HOW SUPPLIED

Axoguard HA+ Nerve Protector is provided in a dual, inner, 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. Axoguard HA+ Nerve Protector and packaging do not contain natural rubber latex. *Do not use if the Axoguard HA+ Nerve Protector 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), or Email: customercare@axogeninc.com

RETURNED GOODS POLICY

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

SYMBOLS USED ON LABELING

STERILE EO	Sterilized using ethylene oxide		Manufacturer
	Temperature limit	MD	Medical device
	Consult instructions for use	MR	MR safe
	Do not re-use	LOT	Batch code
	Use-by date	REF	Catalogue number
	Keep dry	US	Country of manufacture
BIO	Contains biological material of animal origin		Keep away from sunlight
	Single sterile barrier with protective packaging inside		Do not use if package is damaged
	Do not resterilize	UDI	Unique device identifier

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Patent www.axogeninc.com/patents

Made in the USA