axoguard nerve cap®

Instructions for Use

axogen®

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DESCRIPTION

The Axoguard Nerve Cap is a surgical implant that is a tubular device with one open end, one sealed end (cap) and internal channels designed to provide protection for a peripheral nerve end or stump where repair is unattainable or not desired. The device isolates the nerve stump from the surrounding soft tissue bed by pulling the nerve into the tube and suturing the nerve within the cap. The end of the cap has a suturable tab to allow the surgeon to suture the device to surrounding tissue.

Axoguard Nerve Cap is an extracellular matrix (ECM) and is fully remodeled during the healing process. When hydrated, Axoguard Nerve Cap is easy to handle, soft, pliable, nonfriable and porous. Axoguard Nerve Cap is flexible and pliable to accommodate movement of the joints and surrounding soft tissues and has sufficient mechanical strength to hold appropriately sized non-absorbable suture. Axoguard Nerve Cap is provided sterile, for single use only, and in a variety of sizes to meet clinical needs.

INDICATIONS FOR USE

Axoguard Nerve Cap is indicated to protect a peripheral nerve end and to separate the nerve from surrounding environment to reduce the development of symptomatic or painful neuroma.

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 Nerve Cap is derived from a porcine source and should not be used for patients with known sensitivity to porcine derived materials. Axoguard Nerve Cap is contraindicated for use in any patient for whom soft tissue implants are contraindicated; this includes any pathology that would limit the blood supply and compromise healing or evidence of a current infection.

Axoguard Nerve Cap should not be implanted directly under the skin. *NOTE: This device is not intended for use in vascular applications.*

PRECAUTIONS

- This device is designed for single use only. Do not re-sterilize the 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 peel pouch appears to be damaged or open.
- Discard device if mishandling has caused possible damage or contamination, or if the device is past its expiration date.
- Device should be hydrated prior to suturing.

Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in complications.

- Avoid crushing, crimping, kinking or other damage due to application of surgical instruments such as forceps, needle holders and scissors during handling of the device.
- Avoid tension on the nerve end.
- Ensure sufficient healthy soft tissue is available to cover the Axoguard Nerve Cap in order to avoid protrusion or wound dehiscence.

POTENTIAL COMPLICATIONS

As with any surgical procedure, complications can occur such as 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).

ADVERSE EVENTS

Adverse events associated with the use of Axoguard Nerve Cap may include but are not limited to:

- Failure to reduce symptomatic neuroma pain;
- Transitory local irritation;
- Infection;
- Allergy;
- Delayed wound healing;
- Protrusion.

STORAGE

Axoguard Nerve Cap should be stored in a clean, dry location between 10 – 30°C/50 – 86°F. Use the device prior to the “Use-by” date specified on the package. The “Use-by” date is in the form Year- Month-Day.

STERILIZATION

Axoguard Nerve Cap has been sterilized with ethylene oxide (EO).

HOW SUPPLIED

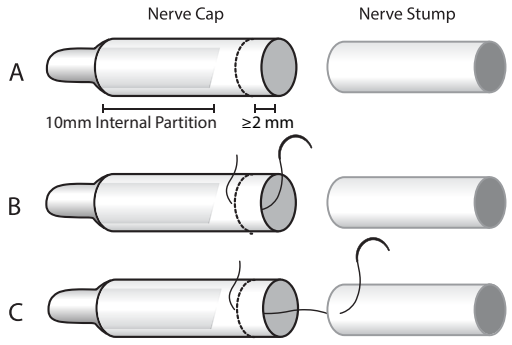
Axoguard Nerve Cap is supplied in a plastic tray within a sterile pouch. The pouch is heat-sealed to provide a sterile barrier and has a peelable seal. Contents of the package are guaranteed sterile unless the package is opened or damaged. Axoguard Nerve Cap and packaging do not contain natural rubber latex.

Do not use if the peel pouch appears to be open or damaged. Multiple patient labels with product code, lot number and expiration date are provided for patient records. A Product Feedback Form is also provided and can be returned back to Axogen as indicated on the card.

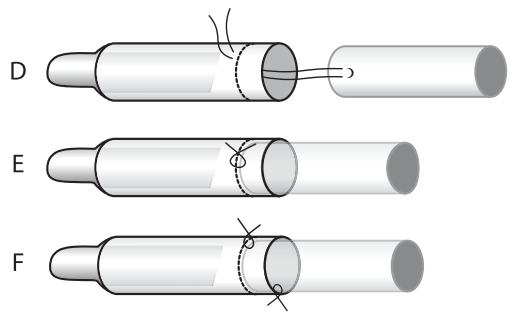
Suggested Instructions for Use (General Procedure). These recommended Instructions for Use are designed to serve as a general procedure. They are not intended to supersede the institutional protocols or professional judgment concerning patient care.

NOTE: Always handle Axoguard Nerve Cap using aseptic technique. Minimize contact with latex gloves. Do not trim the tab of the Axoguard Nerve Cap prior to implantation.

1. After debridement and mobilization of the nerve stump, determine the nerve diameter in millimeters (mm).
2. Select an Axoguard Nerve Cap to fit the nerve stump, accounting for post-operative swelling and to allow easy insertion of the nerve stump into the device. If there is no Axoguard Nerve Cap that matches the diameter of the nerve stump, select the device that is one size larger.
3. Hemostasis of the proximal nerve stump must be achieved prior to beginning the entubulation procedure. If a tourniquet is used, release the tourniquet and achieve hemostasis before entubulating.
4. Open the outer carton and remove the chevron pouch. Using standard aseptic technique, open the pouch and pass the inner tray into the sterile field for further handling.
5. Open the tray and fill the pre-molded reservoir with room temperature sterile saline or sterile Lactated Ringer's solution. Allow the Axoguard Nerve Cap to hydrate for at least 10 seconds or until the desired handling characteristics are achieved, but not more than 20 minutes. NOTE: Small diameter Axoguard Nerve Caps may need to be hydrated by flushing the lumen of the cap with solution. Care should be taken to avoid puncturing the Axoguard Nerve Cap during this process.
6. Transfer the Axoguard Nerve Cap from the reservoir to the operative field. Use micro-pickups to temporarily entubulate the nerve end into the Nerve Cap, ensuring proper Nerve Cap size was selected. Once confirmed, remove the nerve from the Nerve Cap and initiate the entubulation via vertical mattress suture, by passing the suture (non-absorbable) through the wall of the Nerve Cap from outside to inside at least 2 mm from the tube edge. Then pass the suture transversely through the epineurium of the nerve stump at a distance of at least 2 mm from the cut nerve end. Reverse the suture and pass it through the wall of the Axoguard Nerve Cap by pulling the suture so that the nerve stump is drawn into the cap, ensuring that the nerve end is entubulated approximately 3-5 mm into the Nerve Cap. When suturing is completed, ensure that the nerve stump face is linearly aligned within the cap. To reduce the potential risk for misalignment, avoid abutting the nerve stump up to or inserting past the internal partition.



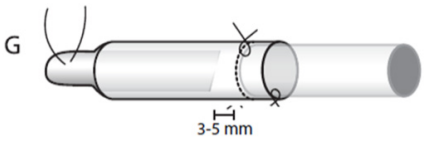
7. Tie suture securely being careful not to generate excess tension at the suture site. At least one additional simple epineurial suture at the nerve-tube edge site to secure the device to the nerve stump is required. **See Figure D, E and F.**



See Figure A, B and C.

8. The lumen of the Axoguard Nerve Cap may be gently filled/flushed with sterile saline or Lactated Ringer's solution. Ensure the nerve stump is not expelled from the tube while irrigating the lumen.
9. Once the Axoguard Nerve Cap is securely sutured onto the nerve stump, the distal tab of the Nerve Cap may be used to drag the entubulated nerve and the Axoguard Nerve Cap to a deeper anatomical plane of surrounding soft tissue if desired (e.g., between or under muscle). As an option, the Axoguard Nerve Cap distal tab can be suture secured to deeper soft tissues, although not required.

See Figure G.



10. Prior to surgical site closure, visually confirm final alignment of the nerve within the cap.
11. Close the surgical site as required by your institutional practices or professional judgement concerning patient care.
12. Discard any unused portions of the Axoguard Nerve Cap according to institutional guidelines for biological waste.

INQUIRIES

For additional information, to place an order, or to report errors, accidents or adverse reactions, 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 product to Axogen Corporation. Sterile product must be returned in unopened, undamaged cartons and packaged to prevent damage.

SYMBOLS USED ON LABELING

STERILE EO	Sterilized using ethylene oxide		Manufacturer
10° C 30° C	Temperature limit		Date of Manufacture
	Caution	MR	MR Safe
	Do not re-use	LOT	Batch code
	Use-by date	REF	Catalogue number
	Keep dry		

Manufactured for:

axogen®

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