



introducing axoguard nerve cap



surgically address
neuropathic pain

reduce neuroma formation, reduce pain

revolutionizing the science of nerve repair™



understanding the clinical challenge

Every nerve that is cut and not reconstructed forms a neuroma.

A neuroma is an entangled mass of disorganized nerve and fibrous tissue that can cause debilitating pain.^{1,2}

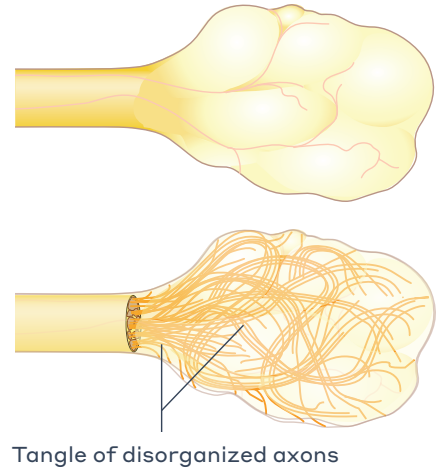
Neuromas are the #1 cause of pain in amputees, also leading to an inability to use prosthesis.^{9,10}

Causes of neuroma pain^{1,3,4}

- Mechanical stimulation
- Pathologic axon interaction
- Constriction

Neuroma symptoms (ICD 10)^{5-7,23}

- Post traumatic pain (G89.21)
- Post surgical pain (G89.28)
- Other chronic pain (G89.29)
- Allodynia/hyperesthesia (R20.3)
- Paresthesia (R20.2)
- Residual limb pain (G54.6)



difficulties in neuroma management

Despite more than 30 different treatment methods, neuromas continue to be an unresolved problem in microsurgery. These methods include pharmacotherapy, chemical injections, traction neurectomy, and burying in muscle, vein, or bone.¹¹⁻¹³

It is reported that 46% of patients who had a neuroma excised saw no improvement in symptoms and only 33–40% of patients were satisfied with treatment after burial into bone or muscle.^{3, 14-16}

Limitations of burying in muscle or bone^{3,8,17}

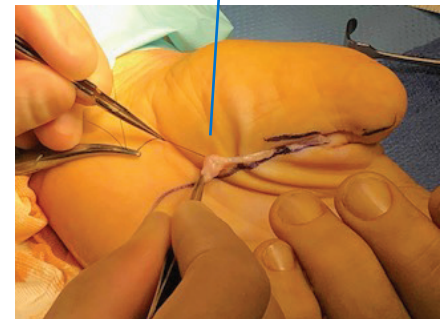
- Pain due to muscular contraction or localized pressure
- Larger surgical dissection
- Risk of secondary surgery

Shortcomings of pharmacologic intervention^{8,11,18-20}

- Chemical injections are only successful 40% of the time
- Temporary solution that has a reduced benefit over time
- May cause considerable side effects



Neuroma



Photos courtesy of Mark Rekant, MD

introducing axoguard nerve cap

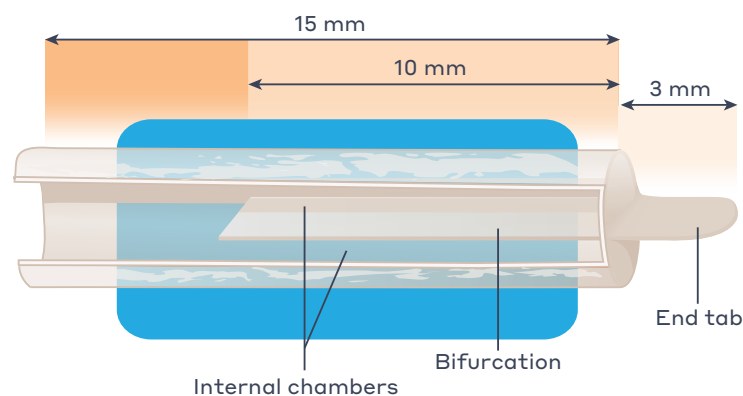


an innovation in neuroma management

Proprietary bifurcation provides the nerve adequate space to exhaust subsequent outgrowth, and reduces pathologic axon interaction.²¹

The Axoguard porcine small intestine submucosa (SIS) matrix isolates and protects the nerve end from surrounding tissue, neurotrophic factors and mechanical stimulation.

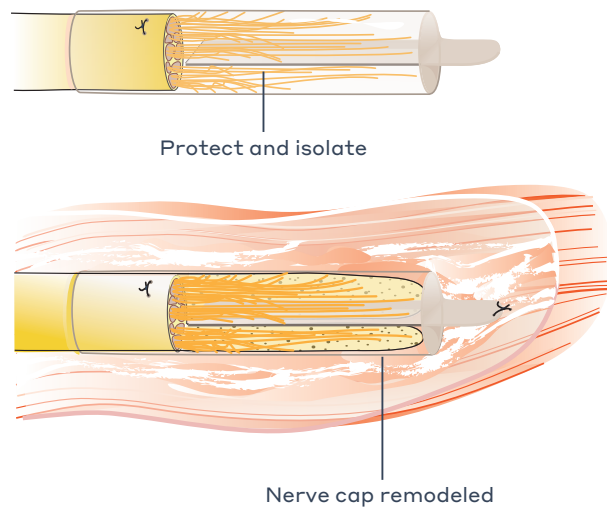
The end tab allows for suture placement to anchor the device to surrounding tissue, away from the surgical incision.



designed for patients with surgeons in mind

Reduces the development of painful neuroma.

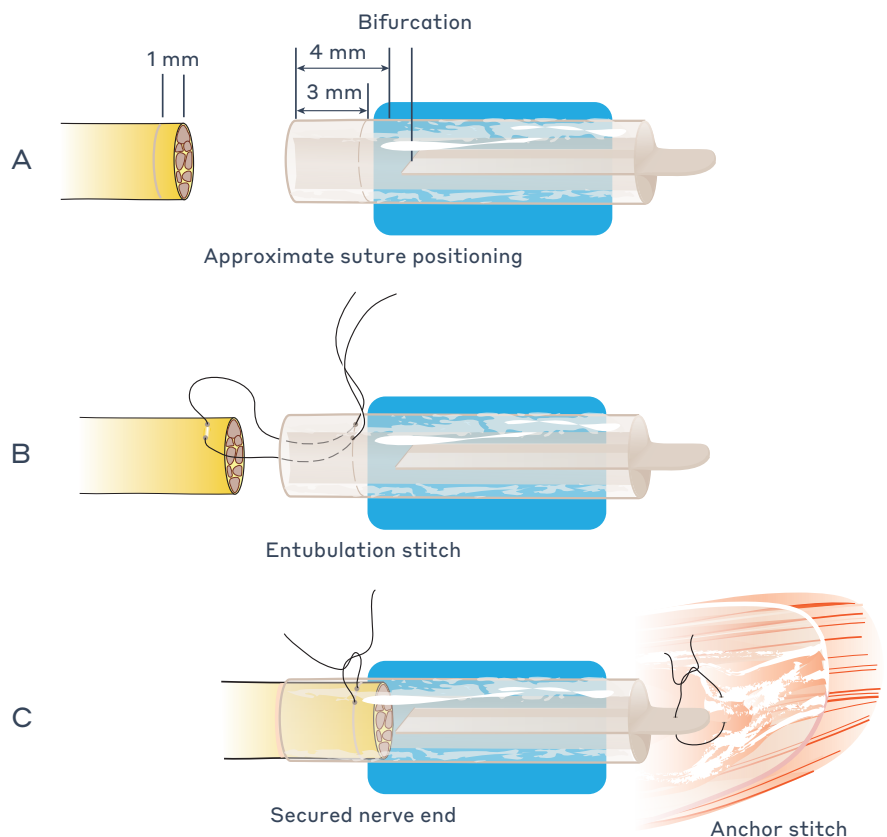
Material gradually remodels into the patient's own tissue to protect the nerve end.



Offers alternative to muscle-burying technique in anatomic areas with limited or no musculature.

Semi-translucent to allow for easy visualization of the nerve end during entubulation.

surgical technique

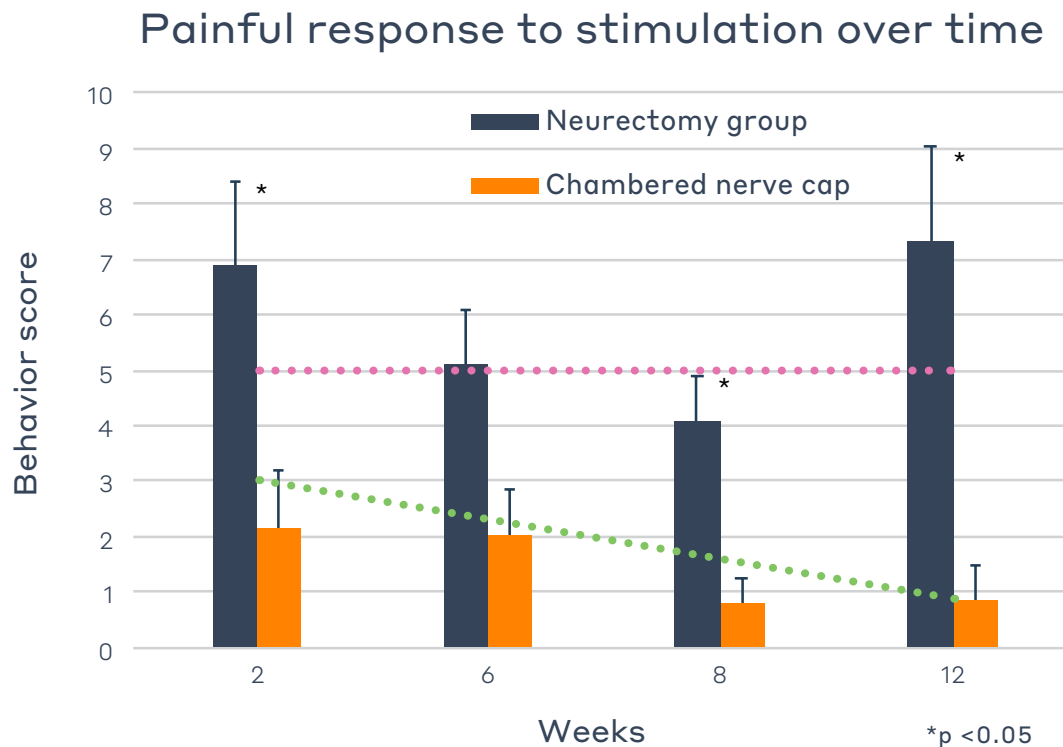


See Instructions for Use for full procedure details

reduces painful neuroma formation

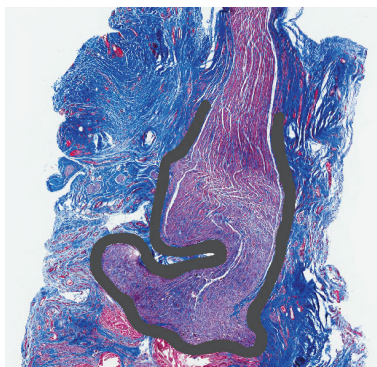
pre-clinical: conclusions from behavioral testing²²

Application of the Axoguard Nerve Cap effectively reduced hyperalgesia from mechanical stimulation of peripheral nerve end neuroma in a rodent model.

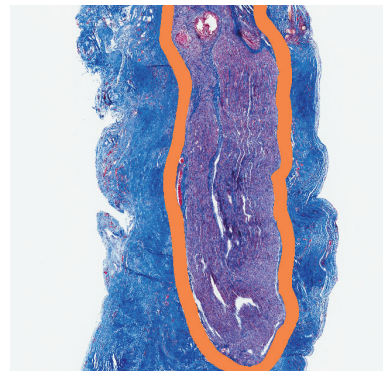


Mean behavior score was measured using the methods described by Dorsey et al 2008. At 12 weeks the pain response in the nerve cap group was statistically lower than the neurectomy group (p-value < 0.05).

Neuroma – Image A










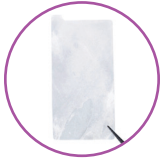


Nerve cap – Image B




12-week histology images: neurectomy image with dark outline(A) is indicative of disorganized neuroma formation; nerve cap outlined in orange(B) confines subsequent nerve outgrowth.

one company for all your surgical nerve repair solutions

 avance® nerve graft	 axoguard® nerve connector	 axoguard® nerve protector	 axoguard® nerve cap	 avive® soft tissue membrane
				
Biologically active, processed human nerve allograft developed for bridging nerve discontinuities up to 70 mm	Semi-translucent coaptation aid for nerve transections up to 5 mm	Extracellular matrix that remodels to protect injured nerves and reinforce nerve reconstructions	Separates nerve end from surrounding environment to protect from mechanical stimulation and reduce painful neuroma formation	Resorbable soft tissue covering to separate tissue layers for at least 16 weeks

ordering information

Code	Dimensions	Approximate size
AGT215	2 mm Nerve Cap	
AGT315	3 mm Nerve Cap	
AGT415	4 mm Nerve Cap	

citations

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- Patent pending.
- Data on file at Axogen Corp.
- 2019 ICD-10, www.cms.gov.

indications and trademark disclaimers

Axoguard Nerve Cap

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

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.

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