



*Advanced solutions for
peripheral nerve repair*

Rebuilding connections

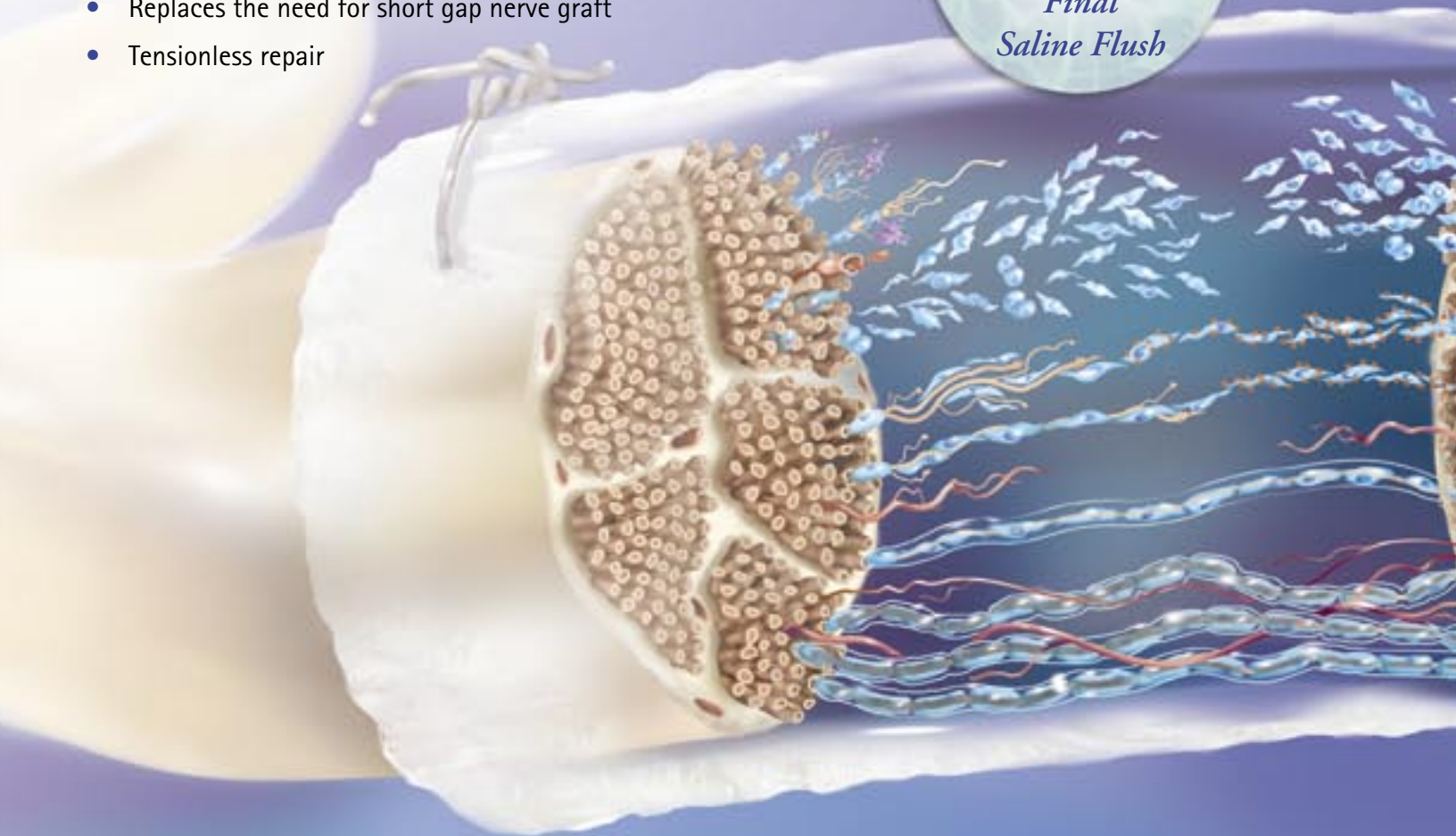
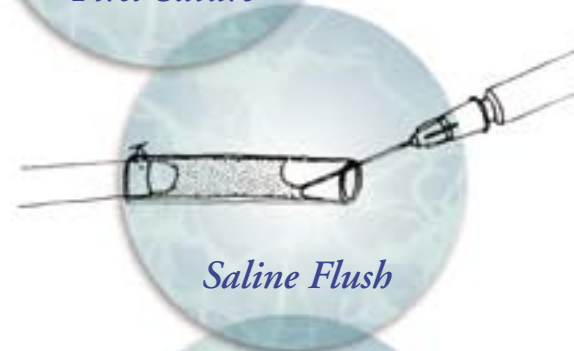


NeuraGen is an absorbable implant designed for peripheral nerve repair⁷

- NeuraGen is a semi-permeable, Type I collagen tube for peripheral nerve repair^{1,6}
- Provides a protective environment and conduit for axonal regrowth across a nerve gap^{1,6,7}
- Biocompatible and completely resorbed^{1,6}
- Open collagen structure facilitates suture placement
- Resilient structure that maintains an open lumen throughout the process of axonal regrowth³

NeuraGen Repair

- Simple, rapid technique
- Replaces the need for short gap nerve graft
- Tensionless repair

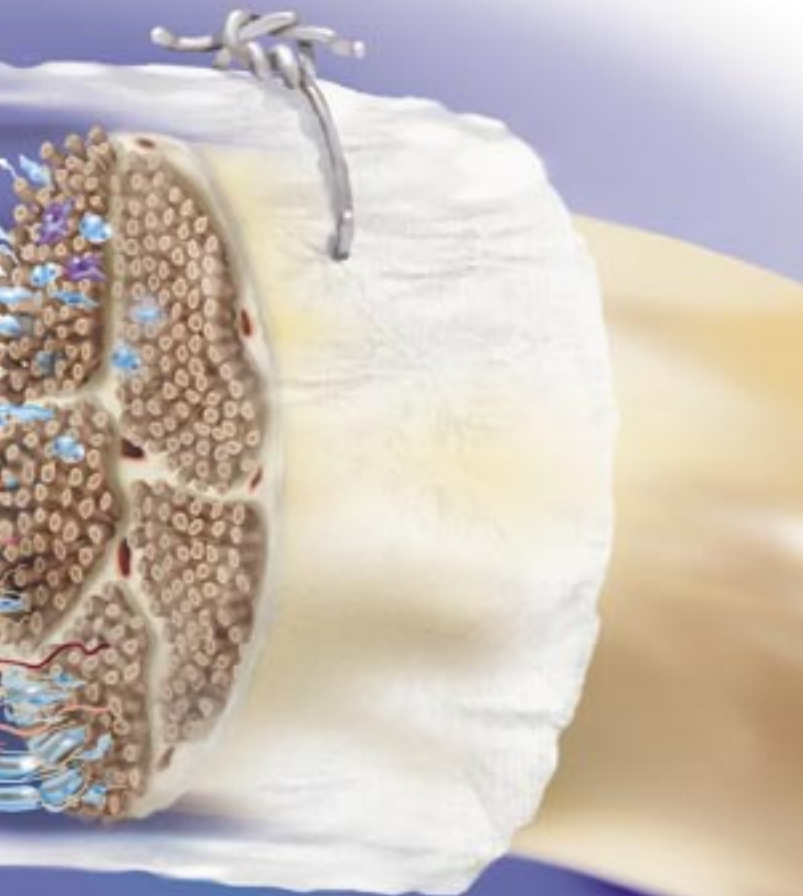


NeuraGen Nerve Guide Animal Study¹

NeuraGen is simple, safe and easy to use

- Pliable and resilient once rehydrated⁷
- Excellent handling characteristics
- Efficient alternative to direct suture

Below: Diagrammatic representation of Schwann cells outgrowth and axonal extension (after Göran Lundborg)⁵

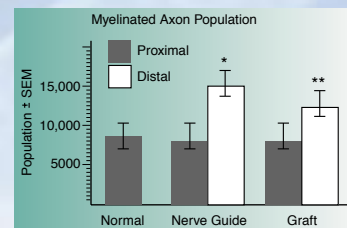


The technology behind the NeuraGen™ Nerve Guide is based on a semi-permeable collagen tube that isolates and provides an environment for the extension of axons and growth of Schwann cells that are the elements responsible for functional recovery following nerve injury. The fibrillar structure of the collagen is maintained throughout the manufacturing process, permitting the construction of a tubular matrix that has great mechanical strength and defined permeability.^{2,3} The collagen of the nerve guide is processed to increase mechanical stability and control the rate of resorption.

The level of functional recovery achieved with the NeuraGen™ Nerve Guide is equivalent to direct suture repair (animal trials) and is stable over long time periods (3 to 4 years).¹ In animal trials, there were no episodes of compression neuropathy reported with other more rigid or non-biodegradable materials.⁴ A critical property of the NeuraGen™ Nerve Guide is that the absorption process is complete and operates via normal metabolic pathways. In these studies, there was no reported scar tissue or inflammatory response to this material.^{2,3} The results of the animal study demonstrated that the complete resorption of the collagen nerve guide minimized the possibility of nerve entrapment and thereby degradation of the repair.



Implantation of NeuraGen Nerve Guide for the repair of 2cm deficit of the median nerve in the primate animal model. (Macaca Fascicularis)



Quantified total populations of myelinated axons in the proximal and distal nerve trunks are indicated for the two repair groups compared to normal median nerve. Both repair groups had significantly more myelinated axons in the distal nerve trunks compared to proximal values or to control values. Error bars show standard error of the mean (* = $p < 0.05$, ** = $p < 0.005$, paired t-tests).¹

NeuraGen™ Ordering Information



| CATALOG NUMBER | SIZE | UNIT/CASE | ACTUAL SIZE (length shown 3 cm) |
|----------------|---------------------------|-----------|---------------------------------|
| PNG130 | 1.5mm (ID) x 3cm (length) | 1 | |
| PNG220 | 2mm (ID) x 2cm (length) | 1 | |
| PNG230 | 2mm (ID) x 3cm (length) | 1 | |
| PNG320 | 3mm (ID) x 2cm (length) | 1 | |
| PNG330 | 3mm (ID) x 3cm (length) | 1 | |
| PNG420 | 4mm (ID) x 2cm (length) | 1 | |
| PNG430 | 4mm (ID) x 3cm (length) | 1 | |
| PNG520 | 5mm (ID) x 2cm (length) | 1 | |
| PNG530 | 5mm (ID) x 3cm (length) | 1 | |
| PNG620 | 6mm (ID) x 2cm (length) | 1 | |
| PNG630 | 6mm (ID) x 3cm (length) | 1 | |
| PNG720 | 7mm (ID) x 2cm (length) | 1 | |
| PNG730 | 7mm (ID) x 3cm (length) | 1 | |

NeuraGen is supplied sterile, nonpyrogenic, in single use, double peel packages.

Adverse Events:

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.⁷

NeuraGen™, your first choice for peripheral nerve repair.



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References:

- 1 Archibald, S. J., Shefner, J., Krarup, C., and Madison, R.D. Monkey median nerve repaired by nerve graft or collagen nerve guide tube. *J. Neurosci.* 1995;15(5):4109-4123.
- 2 Archibald, S. J., Krarup, C., Shefner, J., Li, S.T. and Madison, R.D. Collagen-based nerve guide conduit for peripheral nerve repair: an electrophysiological study of nerve regeneration in rodents and non-human primates. *J. Comp. Neurol.* 1991;306(4):685-696.
- 3 Li, S.T., Archibald, S.J., Krarup, C., and Madison, R. Peripheral Nerve repair with collagen conduits. *Clinical Materials.* 1992;9:195-200.
- 4 Mackinnon, S.E., Dellon, A.L., Hudson, A.R. and Hunter, D.A. A primate model for chronic nerve compression. *J.Reconstr.Microsurg.* 1985;1:185-194.
- 5 Lundborg, G. *Nerve Injury and Repair.* 1988. New York: Churchill Livingstone.
- 6 Archibald, S. J., Krarup, C., and Madison, R.D. Factors that influence peripheral nerve regeneration: electrophysiological study of the monkey median nerve. *Annals of Neurology.* 2002;51(1):69-81.
- 7 NeuraGen™ Instructions For Use, Integra LifeSciences Corporation; 2001.

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