

ReFeel[®]

Nerve Repair Solution



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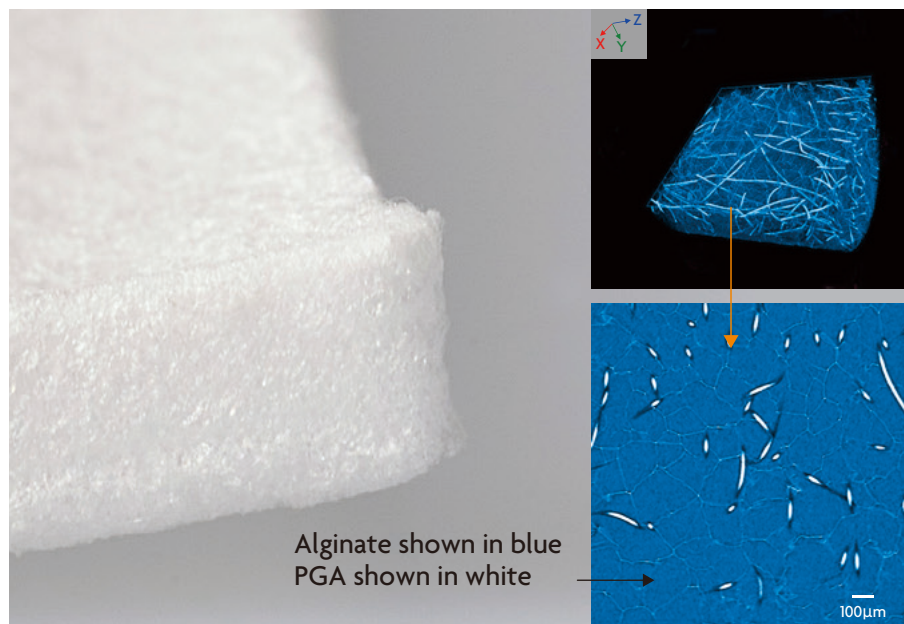
ReFeel[®] provides a solution for nerve regeneration, using a proprietary sodium alginate and PGA formula in sheet form to treat injured nerves with discontinuity or no substantial loss of nerve tissue.

Why sodium alginate?

Alginate is a natural polysaccharide derived from brown algae, that is commonly used in other medical applications as a protective barrier that promotes healing. Upon implantation, the alginate takes hydrogel form that surrounds and protects damaged nerves from invading fibroblasts, preventing scarring of the damaged area and maintaining an ideal environment for regeneration^{1), 2)}.

Why PGA?

Polyglycolic acid or PGA non-woven fabric is used as a reinforcement material that provides structure for suturing and a scaffold to guide nerve regeneration. Together, these components resorb by 26 weeks once nerve regeneration has occurred*.

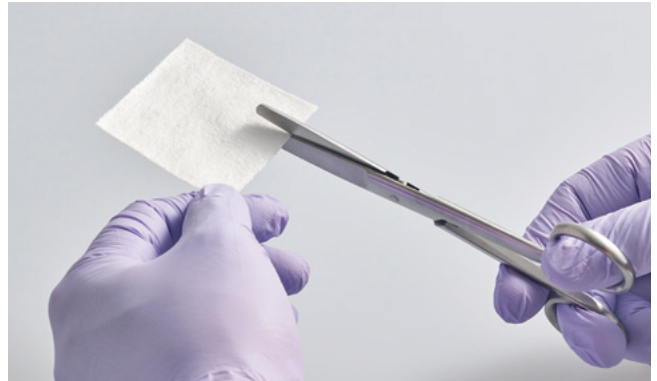


*Animal studies on file. The results of preclinical and in vitro studies may not be indicative of human clinical outcomes.

Features of the ReFeel® Nerve Repair Solution

Simple in design & application :

- Minimizing suturing required may lead to minimize damage to the nerve and saving time
- Versatile, cut to size sheet catering for nerves of all sizes and anatomic locations
- One SKU can be used in place of conduits, wraps and allografts for minimal inventory management



The sheet swells due to water absorption, bringing the nerve and duct into close contact.



Start



Completion

In the case of 3mm DIA. of nerve



Start



Completion

In the case of 5mm DIA. of nerve

Mechanism of Action

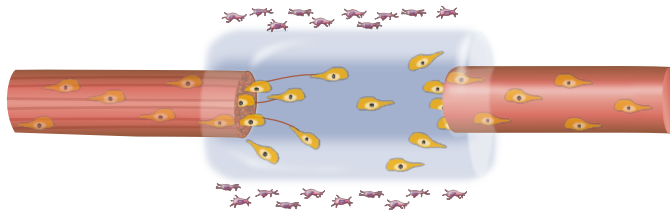
How it works

A



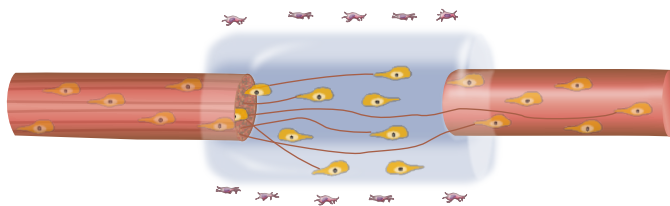
The alginate sheet is implanted to bridge the gap in the injured nerve. The alginate turns to gel form following absorption of water, creating the optimal environment for nerve regeneration to take place. The gel protects the nerve endings from highly proliferative fibroblasts.

B



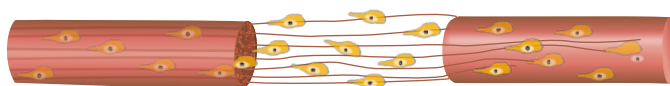
The alginate begins resorbing gradually from the surface area towards the center and together with the PGA mesh, continues to promote/facilitate nerve regeneration across the gap. Schwann cells migrate from both nerve endings, while axons grow from the proximal stump along the surface area where the alginate has been resorbed.

C



The alginate gel continues to resorb towards the center. The axons from the proximal stump continue to grow and enter the distal stump, being led by Schwann cells.

D



After the gel has fully resorbed, the regenerated axons continue to grow, joining the two nerve endings. By 26 weeks the PGA mesh has also fully resorbed*.

Histological Evaluation

Reference: Evaluation of Nerve Repair, Article Degradation and Local Response to Mochida Nerve Cuff in a Rat Sciatic Nerve Model – 1, 8, and 26 Weeks*:

NAMSA Study Number: 21T_50464_02/AnaPath Phase Number: 13678B

Test Article: ReFeel®, Comparative Conduit

Figure 1

ReFeel®. Week 26. HE stain.

Regenerated nerve fascicles(*) surrounded by collagen fibers and fatty infiltrate (arrow).

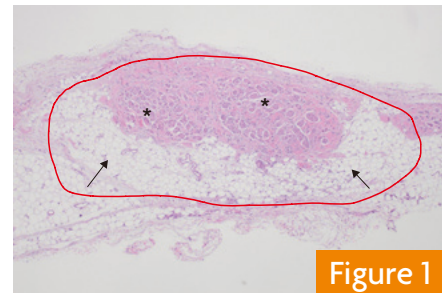


Figure 1

Figure 2

Comparative Conduit Week 26. HE stain.

Cross section of the partially degraded reference article (RA) and regenerated nerve fascicles(*)

The Reference Article showed regrowth of nerve fascicles, but not adipose tissue.

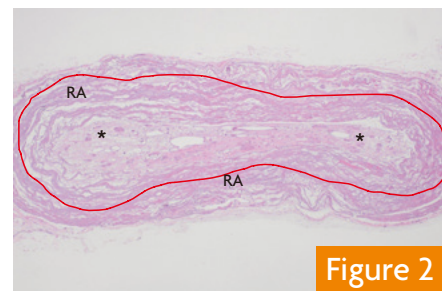


Figure 2

Figure 3

Comparative Conduit Week 26. HE stain.

Cross section of the reference article (RA) with mineralization (arrow) and the distal end of the conduit.

Indicates the calcification and mineralization that was observed in the Reference Article.

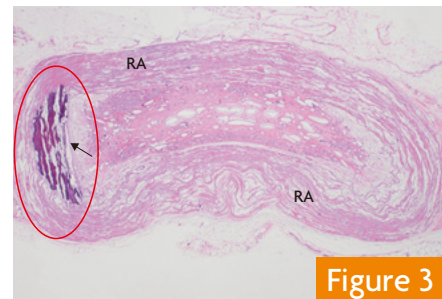
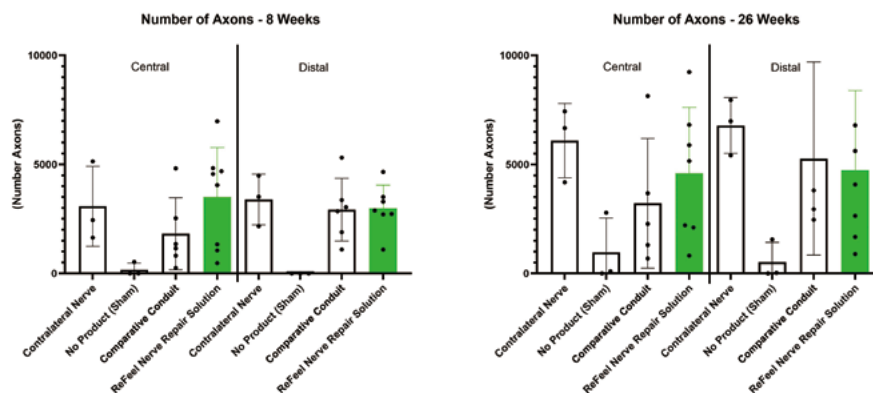


Figure 3

Results: Both articles showed almost equivalent nerve regeneration in the central and distal sections of the implant, 8 and 26 weeks after the 1cm nerve transection (nerve gap) in the left sciatic nerve of male Sprague Dawley Rats.

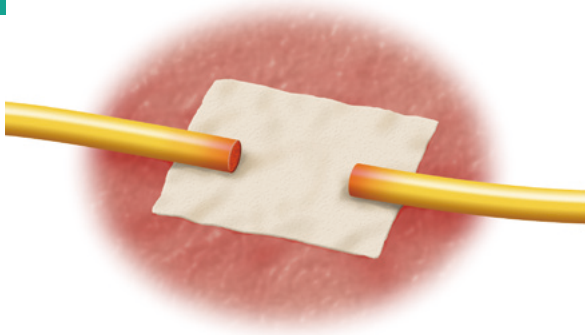


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Surgical Technique

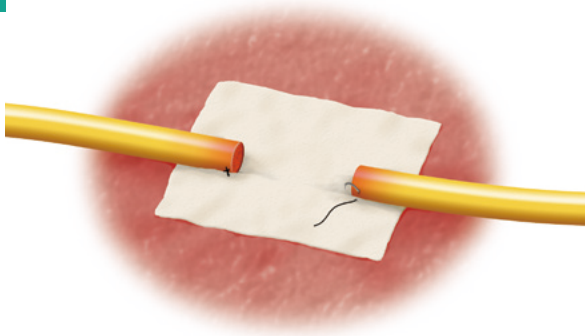
(1) Repair of Nerve with Discontinuities

1



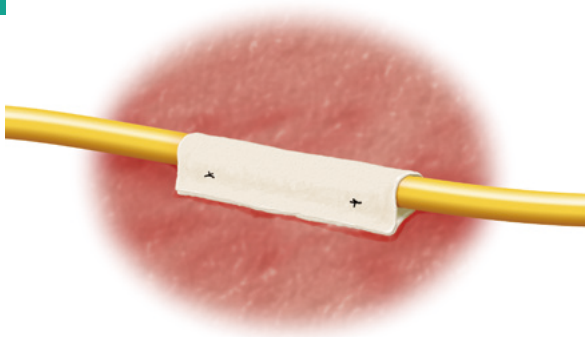
Place the sheet under the nerve.

2



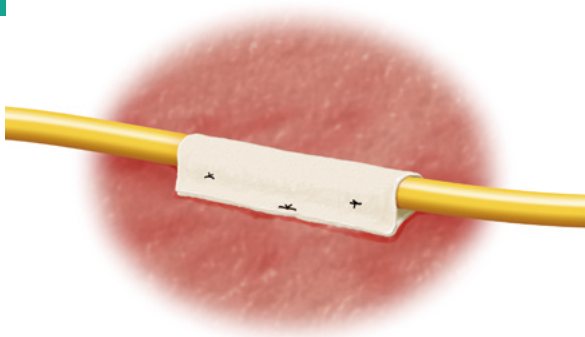
Suture the sheet to the epineurium.

3



Fold the sheet.

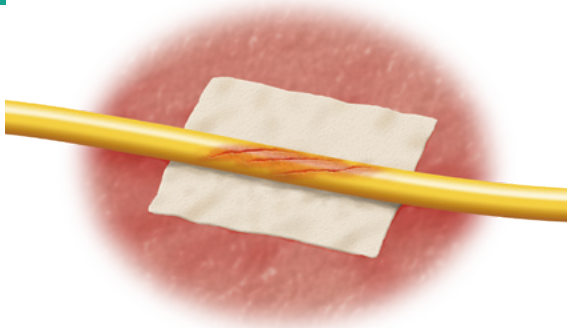
4



Suture the folded end of the sheet, cut and remove any excess sheet.

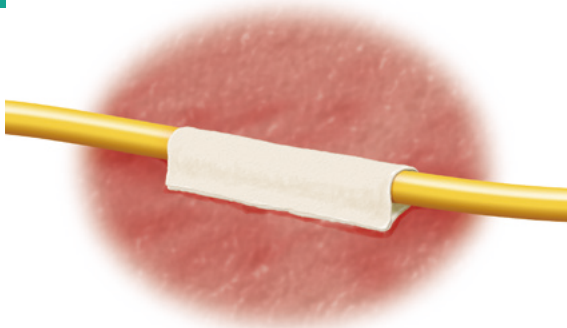
(2) Repair of Nerve with No Substantial Loss of Nerve Tissue

1



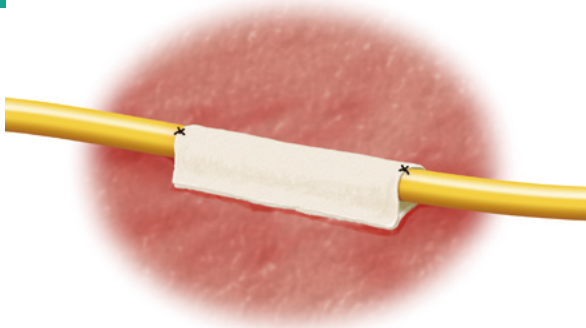
Place the sheet under the nerve.

2



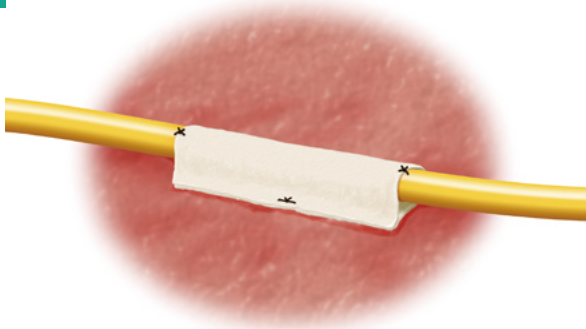
Fold the sheet.

3



Suture the sheet to the epineurium.

4



Suture the folded end of the sheet, cut and remove any excess sheet.

Ordering Information

Item Number	Description	Spec.
802-01	ReFeel® Nerve Repair Solution	55 mm x 55 mm

References

- 1) Hashimoto T, Suzuki Y, Kitada M, Kataoka K, Wu S, Suzuki K, Endo K, Nishimura Y, Ide C. Peripheral nerve regeneration through alginate gel: analysis of early outgrowth and late increase in diameter of regenerating axons. *Exp Brain Res* 2002; 146: 356–68
- 2) Ohsumi H, Hirata H, Nagakura T, Tsujii M, Sugimoto T, Miyamoto K, Horiuchi T, Nagao M, Nakashima T, and Uchida A. Enhancement of Perineurial Repair and Inhibition of Nerve Adhesion by Viscous Injectable Pure Alginate Sol. *Plast. Reconstr. Surg.* 2005; 116: 823-30

Indication for Use

ReFeel® is indicated for the repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity, or the management of peripheral nerve injuries in which there has been no substantial loss of nerve tissue.

Warnings

Single use only. Do not re-sterilize. Do not use if packaging is damaged.

Complete postoperative wound closure is essential.

ReFeel® must not be used to repair nerve defect where full coverage of the defect site cannot be achieved.

ReFeel® should not be implanted in combination with other products (other than products where the instructions for use of these products allow combination with ReFeel®).

Heavy bleeding may reduce performance of ReFeel®.

Adverse Reactions

Possible complications that can occur with any peripheral nerve surgery may include pain, swelling, infection, decrease or increase in nerve sensitivity, wound healing disorders, hypersensitivity that may be caused by alginate and/or polyglycolic acid and complications associated with use of anaesthesia.

Minor discomfort in the surgical site may occur for a few days.

For more information on ReFeel® or product complaints/queries contact:

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www.pbcbiomed.com

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