MOCHIDA PHARMACEUTICAL CO., LTD.

ReFeel®

Nerve Repair Solution

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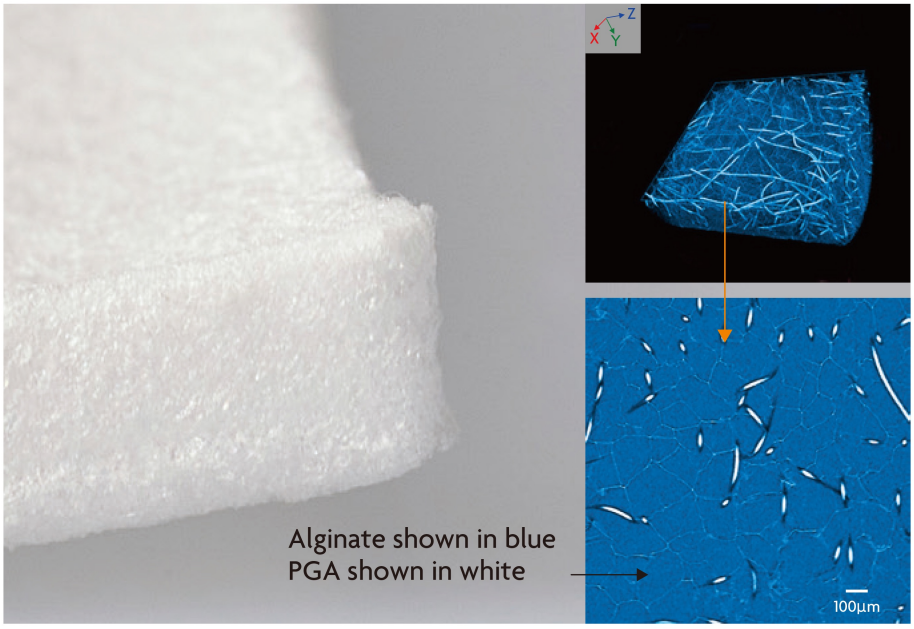
ReFeel® provides a solution for nerve regeneration, using a proprietary Sodium Alginate and PGA formula in sheet form to treat injured nerves with discontinuity or no substantial loss of nerve tissue.

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.

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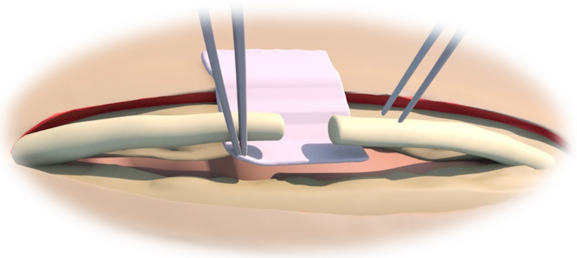
Product Features & Benefits



Clinical Versatility

- Can be used for the repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity.
- Applicable for management of peripheral nerve injuries in which there has been no substantial loss of nerve tissue.
- Flat sheet can be customized in anatomies that are challenging to address with preformed conduits or wraps, such as peripheral nerves near a joint.

Improved Surgical Efficiency

- Minimal suturing required.
- Microsurgery is not required.
- Cost-effective option for both hospital and ASC operating rooms.
- Ambient storage required (1°C and 28°C - avoid excessive humidity.) - one SKU for easy inventory management.
- Eliminates need for multiple SKUs - one sheet that can be cut to size, replacing allografts, conduits and wraps.

Bio-Compatible

- Creates bridge for nerve regeneration, using proprietary Alginate and PGA formula.
- Provides protected environment in which the natural healing process of the nerve occurs.

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Simple in Design & Application:

- Minimal suturing required

- Versatile sheet format, which can be cut to size and used as both a conduit and a wrap

- One SKU for easy inventory management

Nerve Cushioning Feature:

The alginate in the sheet swells once hydrated, which creates a cushioning layer around the nerve when applied.

In the case of 3mm DIA. of nerve

Start Completion

In the case of 5mm DIA. of nerve

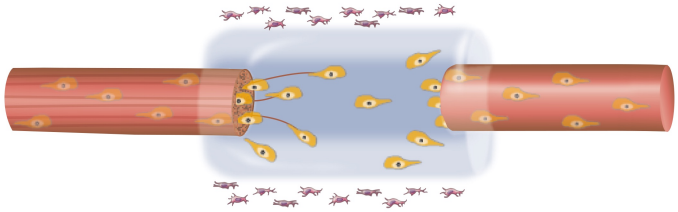
Start Completion

Mechanism of Action

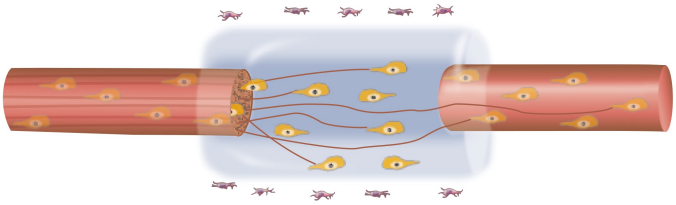
How it Works:

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.

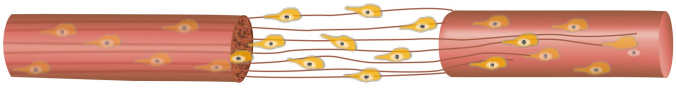
B. The alginate begins resorbing gradually from the surface area towards the center and together with the PGA mesh, continues to promote/facilitate nerve regeneration across the gap. Schwann cells migrate from both nerve endings, while axons grow from the proximal stump along the surface area where the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



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Histological Evaluation

Test Article:

ReFeel®, Comparative Conduit

Figure 1

ReFeel®. Week 26. HE stain.

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

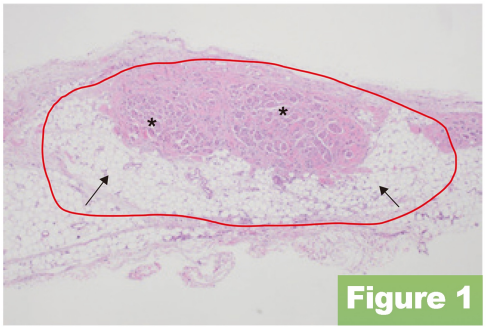


Figure 2

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.

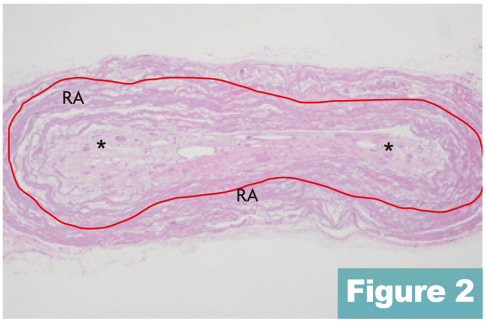
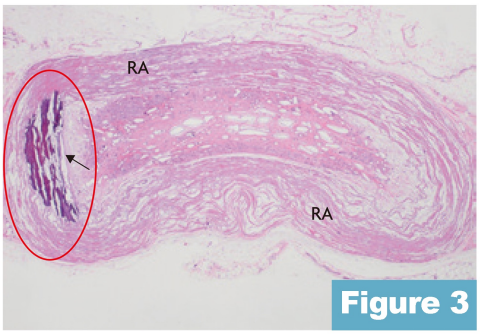


Figure 3

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.



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*:

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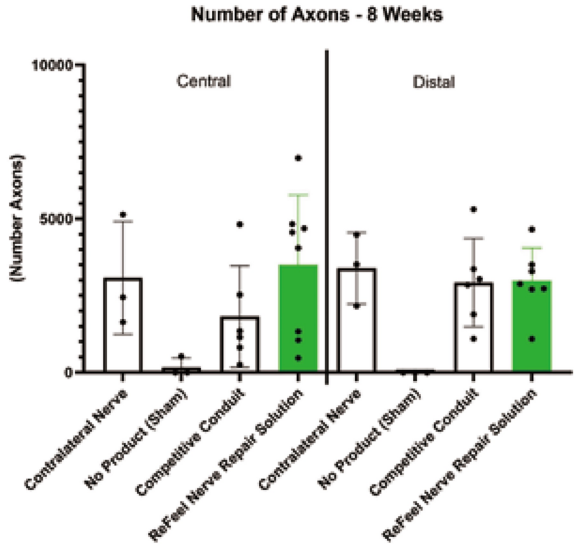
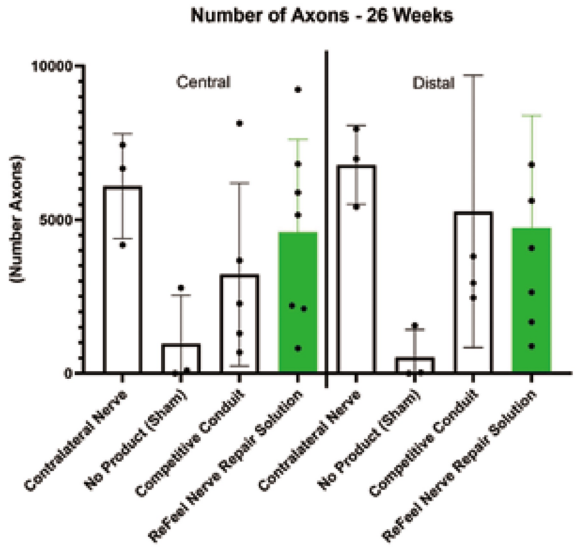
Results:

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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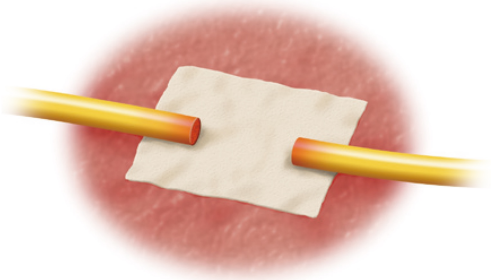
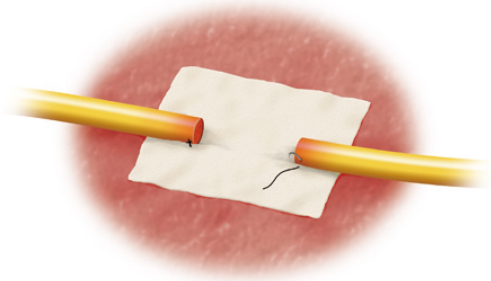
Surgical Technique

(1) Repair of Nerve with Discontinuities

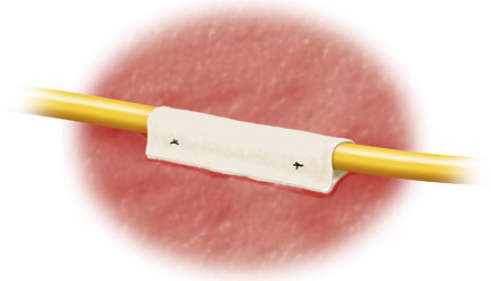
1. Place the sheet under the nerve.



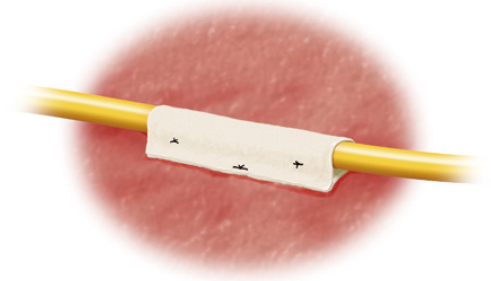
2. Suture the sheet to the epineurium.



3. Fold the sheet, cut and remove any excess sheet.

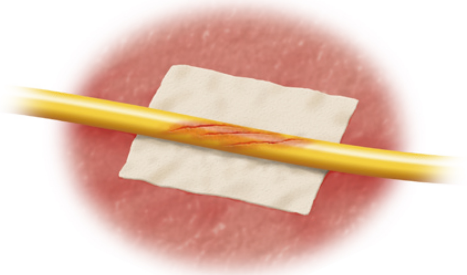


4. Suture the folded end of the sheet.

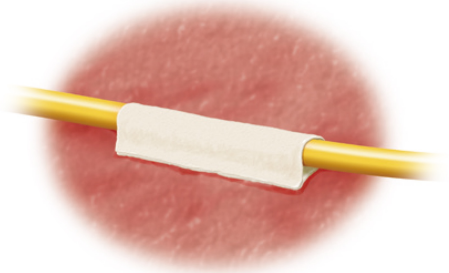


(2) Repair of Nerve with No Substantial Loss of Nerve Tissue

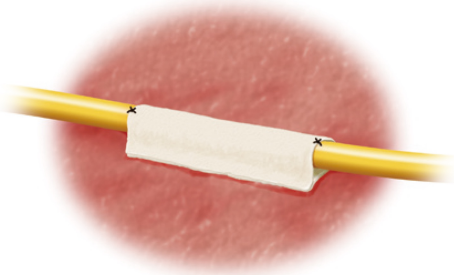
1. Place the sheet under the nerve.



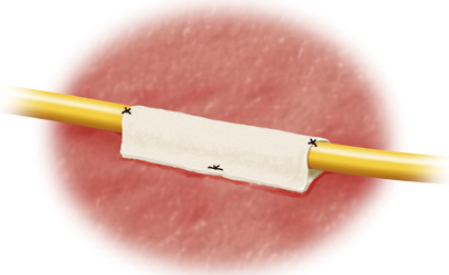
2. Fold the sheet, cut and remove any excess sheet.



3. Suture the sheet to the epineurium.



4. Suture the folded end of the sheet.



Ordering Information

SKU:	Description:	Size:
802-01	ReFeel®	55mm x 55mm

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 PureAlginate Sol. Plast. Reconstr. Surg. 2005; 116: 823-30

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. Transient, mild, or localized inflammation may occur as a result of standard surgical procedure.

Precautions

Use of ReFeel® is intended only for surgeons that are experienced in performing nerve repair surgery and who are familiar with the appropriate surgical techniques.

Aseptic handling techniques are required during all phases of device handling.

Do not wash the treatment area containing ReFeel® until the application of the device has been completed and the nerve is fully wrapped and sutured.

Do not use contaminated ReFeel® for surgery.

The safety and effectiveness of ReFeel® has not been evaluated in pregnant women and children.

Disposal

The used device along with any waste materials should be disposed of in accordance with local requirements.

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

Tel: 888.813.5511
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www.pbcbiomed.com

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Tokyo, Japan

Distributed By

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Caution: Prescription use only. Federal law (USA) restricts this device to sale by or on the order of a physician. See Instructions for Use for complete indications, warnings, contraindications and adverse events.