ReFeel® Nerve Repair Solution
Instructions for use

Caution:
Prescription use only. Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.
Read and understand all the information in these instructions.

Device description:
ReFeel® Nerve Repair Solution (hereafter referred to as ReFeel®) is a press-molded sheet of xerogel made by lyophilizing a gel made from Sodium Alginate, which is covalently cross-linked with Ethylene diamine, embedded with a Polyglycolic acid sheet. The sheet size is approximately 5.5 x 5.5 cm.

When used, the device is cut according to the size of the nerve axon injury site, and fixed in place to cover the nerve axon injury site.

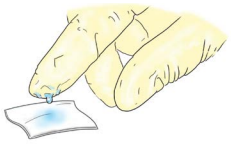
ReFeel® is in a sheet form, and can cover the nerve injury site by folding. In addition, the sheets can be freely bent to fit areas that are not flat or smooth.

Indications/Intended 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.

Contraindications:
ReFeel® is not designed, sold or intended for use except as described in the Indications/Intended use. ReFeel® is contraindicated in patients with:
- Known history of hypersensitivity to Alginate, Polyglycolic acid or ethylene diamine materials.
- Known history of allergic reactions to the laminaria or seaweed derived products.
- Acute infections or have a contaminated wound in the immediate area surrounding the peripheral nerve discontinuity or injury.

Directions for use:
Note: Physicians should follow best clinical practices when performing peripheral nerve repair procedures. Clinical decisions are not affected by the information and references in these instructions for use.

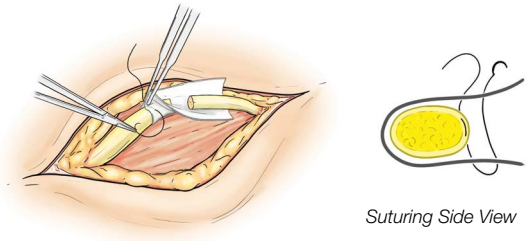
Warning: Do not submerge. Wet with fingers or use dry for optimal handling.



Repair of nerve with discontinuities

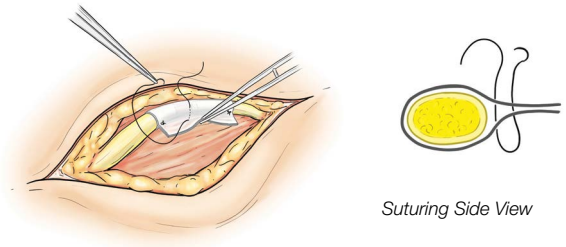
1. Expose, isolate and prepare the nerve at the appropriate incision site according to physician's standard procedure.
2. Determine the nerve diameter and the nerve gap distance in millimeters (mm) using a suitable measuring instrument. Assess the gap that could be closed by flexion.
3. Prior to treatment it should be ensured that a sufficient volume of ReFeel® is available to the surgeon for complete filling of the nerve defect.
4. Inspect package for damage, open carton, and remove pouch.
5. Open outer pouch and remove inner pouch ensuring that it remains in the sterile field.
6. Open inner pouch and remove ReFeel® from the pouch.
7. Cut ReFeel® to the desired size, based on the length of nerve gap and the diameter of nerve ending on each end.
   I. Cut the ReFeel® to a length to create a suitable overlap of the ReFeel® on each of the nerve ending for suturing. An overlap of >3x the nerve diameter is recommended. In the case of smaller nerves, this overlap should be maximised based on the available space at the surgical site.
   II. Cut the ReFeel® to a width of approximately 6-7 times the nerve diameter to give sufficient material to wrap around the nerve and leave sufficient material to create an overlap for suturing.

   ReFeel® can be implanted in its dry state but can also be used with minimal hydration (a few drops of saline).
   Note: ReFeel® can be implanted either side up.
8. Place a sheet of ReFeel® under the nerve defect using micro-forceps, ensuring both the proximal and the distal ends of the injured nerve are covered, once the gap has been closed as the anatomy will allow.
9. Sutures should be used to fix the ReFeel® to the Epinureum of each end of the nerve to prevent migration. When suturing, use non-absorbable monofilament suture material (a USP 4-0 to 8-0 suture is recommended).



Suturing Side View

10. Fold ReFeel® to enclose the nerve defect, and then if required, suture the folded ends in the center so that they do not open.



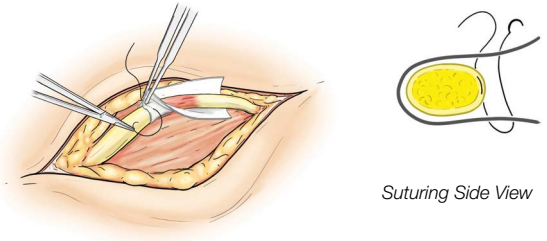
Suturing Side View

11. Trim ReFeel® as needed.
12. Dispose any unused portions of the device and packaging materials in accordance with clinical standards.
13. Evaluate and close the wound according to physician's standard procedure.

Repair nerve with no substantial loss of nerve tissue

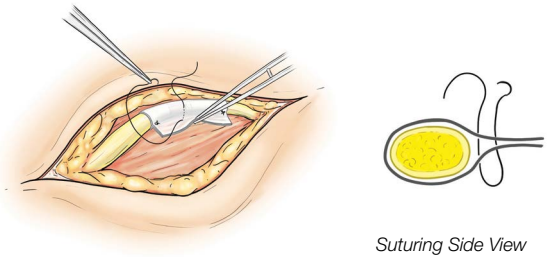
1. Expose and isolate the nerve at the appropriate incision site according to physician's standard procedure.
2. Determine the nerve diameter and the length of the injured nerve area in milimeters (mm) using a suitable measuring instrument.
3. Prior to treatment it should be ensured that a sufficient volume of ReFeel® is available to the surgeon for complete covering of the injured nerve.
4. Inspect package for damage, open carton, and remove pouch.
5. Open outer pouch and remove inner pouch ensuring that it remains in the sterile field.
6. Open inner pouch and remove ReFeel® from the pouch.
7. Cut ReFeel® to the desired size, based on the length of injured area and the diameter of non-injured area on each side.
   I. Cut the ReFeel® to a length to create a suitable overlap of the device on each side of the injured area for suturing. An overlap of >3x the nerve diameter is recommended. In the case of small nerves, this overlap should be maximised based on the available space at the surgical site.
   II. Cut the ReFeel® to a width approximately 6-7 times the nerve diameter to give sufficient material to wrap around the nerve and leave sufficient material to create an overlap for suturing.

   ReFeel® can be implanted in its dry state but can also be used with minimal hydration (a few drops of saline).
   Note: ReFeel® can be implanted either side up.
8. Place a sheet of ReFeel® under the injured nerve using micro-forceps, ensuring both the non-injured areas are covered.
9. If required, sutures should be used to fix the ReFeel® to the Epinureum of the nerve to prevent migration. When suturing, use non-absorbable monofilament suture material (a USP 4-0 to 8-0 suture is recommended).



Suturing Side View

10. Fold ReFeel® in the center to enclose the injured nerve, and if required, suture the folded ends in the center so that they do not open.



Suturing Side View

11. Trim ReFeel® as needed.
12. Dispose any unused portions of the device and packaging materials in accordance with local clinical standards.
13. Evaluate and close the wound according to physician's standard procedure.

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 the 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 the ReFeel® has not been evaluated in pregnant women and children.

Interactions
No interactions between ReFeel® and medicinal products or other medical devices have been reported to date.

How supplied
ReFeel® is supplied in a single product size, sterile, in single use, non-pyrogenic, and double peel pouches. Contents of package are guaranteed sterile and non-pyrogenic unless the package is opened or damaged. Inner pouches remain sterile when handled with proper sterile technique.

Storage
Store ReFeel® at temperature between 1°C and 28°C. Humidity range between 0% and 65%. Avoid excessive temperature and humidity.

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

Information
For additional information, please contact your local representative. Any serious event related to the device should be reported to the distributor.

Warranty
Suitability for use of the medical device for any surgical procedure shall be determined by the health care provider. Mochida Pharmaceutical Co., Ltd. shall not be liable for incidental or consequential damages of any kind.

Returns
PBC Biomed Inc.
150 Peabody Place, Ste. L1007
Memphis, TN 38103
www.pbcbiomed.com
Tel: 888.813.5511

Open products cannot be returned for credit.

Manufactured/Distributed
Manufactured for:
Mochida Pharmaceutical Co., Ltd.
1-7 Yotsuya, Shinjuku-ku
Tokyo, Japan

Distributed by:
PBC Biomed Inc.
150 Peabody Place, Ste. L1007
Memphis, TN 38103
Tel: 888.813.5511
E-mail: customerservice@pbcbiomed.com
www.pbcbiomed.com

Symbols

	Manufacturer.
	Use by date.
LOT	Lot number.
REF	Catalogue number.
STERILE R	Sterilization by irradiation.
	Do not re-sterilize.
	Do not use if package is damaged.
	Keep dry.
	Single use only. Do not reuse.
	Consult instructions for use.
Rx Only	Prescription use only: US Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.
1°C 28°C	Storage temperature between 1°C and 28°C.
0% 65%	Humidity range between 0% and 65%.
QTY	The quantity and the size.

Information last updated 2024-09-18