NeuroShield

INSTRUCTIONS FOR USE

PRODUCT DESCRIPTION

NeuroShield™ is a chitosan membrane to provide a non-constricting protection for peripheral nerves. NeuroShield™ is designed to be an interface between the nerve and the surrounding tissue for uses to treat nerve injuries. When hydrated, NeuroShield™ is easy to handle, soft, pliable, non-friable, porous and transparent.

INDICATION

NeuroShield™ is indicated for the repair of peripheral nerve injuries in which there is no gap or where a gap closure can be achieved by flexion of the extremity.

CONTRAINDICATIONS

No contraindications are yet known. There are no data on the use of NeuroShield™ in children.

STERILIZATION

NeuroShield™ has been sterilized with ethylene oxide gas.

STORAGE

Store NeuroShield™ in a clean, dry environment at room temperature.

PRECAUTIONS/PRECAUTIONARY MEASURES

- NeuroShield™ and its parts are designed exclusively for single use. Do not re-sterilize or re-use. Re-using this product can potentially cause serious harm to the health of the patient. Examples of the dangers associated with re-using NeuroShield™ include significantly reduced product performance, cross infection and contamination.
- Allergic reactions to medical products containing chitosan are not yet known. However, since chitosan is derived from shellfish, individuals with known shellfish allergies should exercise caution in the use of any product containing chitosan.
- NeuroShield™ is sterile as long as the packaging has not been opened or damaged. Please dispose of open, unused NeuroShield™. Do not use if the sterile packaging is damaged.
- Do not use after the expiration date.
- Do not re-use. Unused portions of NeuroShield™ should be disposed of.

ADVERSE EVENTS

The adverse events listed below may occur following any surgery of injured nerves and can therefore also appear after the implantation of NeuroShield™ like

- Abnormal reddening of the operation scar,
- abnormal swelling at the site of the operation,
- temporary local irritation,
- delayed wound healing.

Risks such as infections, blood loss, healing disorders and complications related to the anesthetic are associated with any surgical procedure. In the case of nerve reconstruction, adverse effects such as pain, decreased sensitivity and impairment of motor and sensory functions can occur. As with all procedures carried out on peripheral nerves, there is a risk of the nerve not regenerating.

INQUIRIES

For further information, orders or to report adverse effects, please contact:

Monarch Bioimplants GmbH
Platz 4
CH-6039 Root D4
Switzerland
Tel.: +41 (0)41 4552261
Fax: +41 (0)41 4552264
www.monarchbioimplants.com

NeuroShield™ is a trademark of Monarch Bioimplants GmbH.

DATE OF INSTRUCTIONS FOR USE

2018-08

EXPLANATION OF THE SYMBOLS USED

	Expiration date: Year-Month-Day		Consult instructions for use
77°F 59°F	Temperature limits for storage		Do not use if package is damaged
LOT	Lot number		Do not re-sterilize
REF	Catalog number		Do not re-use
STERILE EO	Sterilized using ethylene oxide		Manufacturer
Rx Only	Prescription only		Keep dry
	NeuroShield™ is MR safe		

USE

Note: Instructions for use provide general information regarding the proper use of the device. 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.

1. When unpacking NeuroShield™ ensure that the internal pouch remains sterile.
2. Remove NeuroShield™ and place in sterile, physiological saline or Ringer's solution for at least ten minutes to hydrate it. This will make NeuroShield™ flexible and facilitates folding, trimming and suturing if needed.
3. Use anatomical forceps to grip NeuroShield™.
4. If necessary, cut the membrane in half or trim to the desired size.
5. Apply NeuroShield™ between the nerve to be protected and/or repaired and the adjacent tissues.
6. NeuroShield™ may be fixed as necessary with sutures to prevent migration. If positioned around a nerve this may include placing running sutures along the longitudinal slit to enclose the nerve, and/or stay sutures placed through NeuroShield™ and the epineurium to anchor the device at each end.
7. Use non-absorbable monofilament suture material (a USP 8-0 suture is recommended).
8. Dispose any unused portions of the device and packaging materials in accordance with clinical standards. Do not re-sterilize.
9. Close the wound.