POLYGANICS
TRANSFORMING PATIENT RECOVERY

NEUROLAC® peripheral nerve guide

INSTRUCTIONS FOR USE - GB

Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in complications

STERILE

Sterilized with ethylene oxide gas. For single use only. Do not autoclave.

CAUTION

Federal (USA) law restricts this device to sale by or on the order of a physician.

STORAGE

- Store in a dark, dry place between -18°C and 8°C (39°F).
- Use the device prior to the 'use by' specified on the package.

DESCRIPTION

The NEUROLAC nerve guide is composed of the bioresorbable copolyester poly(DL-lactide-ε-caprolactone). The NEUROLAC nerve guide provides guidance and protection to regenerating axons.
The NEUROLAC nerve guide elicits a minimal acute inflammatory reaction of the surrounding tissue, which is followed by gradual encapsulation of the tube by fibrous tissue. Degradation of the NEUROLAC nerve guide occurs through hydrolysis leading to gradual reduction of molecular weight. The NEUROLAC nerve guide retains its initial mechanical properties up to at least 8-10 weeks, whereafter rapid loss of mechanical strength and gradual mass loss occur. NEUROLAC nerve guide is resorbed within approximately 16 months.

The NEUROLAC nerve guide inner diameter is indicated on the label, and is packed in a tray placed in a Tyvek pouch. The Tyvek pouch is sealed in an aluminium pouch including silica gel, and then packed in a carton box with an IFU. The NEUROLAC nerve guide is indicated for single-use.

INDICATIONS

The NEUROLAC nerve guide is indicated for the reconstruction of a peripheral nerve discontinuity up to 20 mm in patients who have sustained a complete division of a nerve.

CONTRA INDICATIONS

There are no known contraindications.

WARNINGS

- The NEUROLAC nerve guide is for single use only. Do not resterilize or re-use. Structural integrity and/or function may be impaired through cleaning, resterilization, or re-use and may cause adverse patient reactions. Accordingly, Polyganics will not be responsible for any direct or consequential damages or expenses resulting from re-use of (or any part of) the NEUROLAC nerve guide;
- Sterile unless package has been opened or damaged. Discard open unused nerve guides;
- The NEUROLAC nerve guide should only be used by physicians who are trained in nerve defect repair techniques. Accordingly, Polyganics will not be responsible for any direct or consequential damages or expenses resulting from use by untrained personnel. The physician should consult recent literature on current medical practice on peripheral nerve repair;
- Nerve regeneration may be suboptimal in elderly, malnourished or debilated patients or in patients suffering from cancer, anaemia, obesity, diabetes, infection or other conditions which may delay wound healing, infected wounds, or moderate tissue inflammatory response characteristic of foreign body response.

PRECAUTIONS

- Do not expose the nerve guide to organic solvents (e.g. chloroform, acetone);
- Do not use absorbable sutures for fixation of the nerve stumps into the nerve guide;
- Avoid crushing, crimping, kinking or other damage due to application of surgical instruments such as forceps, needleholders and scissors or during handling of the device;
- Avoid tension on the nerve ends;
- Prevent compression and/or kinking of the NEUROLAC after the procedure. The use of a protective splint is recommended.
- Ensure sufficient healthy soft tissue is available to cover the NEUROLAC® device in order to avoid protrusion or wound dehiscence;
- Avoid applying wound dressings or protective splints with too much pressure.

ADVERSE EVENTS

Adverse events associated with the use of a NEUROLAC nerve guide may include but are not limited to:

- Failure to provide adequate nerve regeneration at sites where too much tension or compression occurs;
- Failure to provide adequate/complete nerve regeneration;
- Transitory local irritation;
- Infection;
- Allergy;
- Delayed wound healing.

OPENING OF THE PACKAGE

Open the aluminum pouch. **Attention**: the outside of white/transparent pouch is not sterile. The Tyvek pouch is opened in such a way that the tray remains sterile. The tray can be opened by sliding the lid. By clasping the nerve guide at one of its ends between a pair of tweezers, it can be taken from the tray. The lid contains a ruler that may be used as a reference to estimate the gap length or nerve stump diameter.
Inspect the tube; do not use if the tube is kinked, brittle, or degraded.

NOTE: These recommendations are designed to serve only as a general procedure. They are not intended to supersede the institutional protocols or professional clinical judgment concerning patient care.

SURGICAL PROCEDURE

1. Surgically expose the injured nerve.
2. Resect the injured segment distally and proximally until a nerve stump is identified with no residual intrafascicular scarring.

NOTE: Do not crush the nerve stumps as this can cause extrusion of intra-fascicular components.

3. Measure the length of the defect with all joints in an extended position.
4. If the gap length is between 0 and 20 mm, the injured nerve can be reconstructed with a NEUROLAC nerve guide.
5. Select the NEUROLAC nerve guide with the proper internal diameter.

NOTE: It is essential that the internal nerve guide diameter is slightly larger than the diameter of the transected nerve to guarantee optimal nerve regeneration.

6. Cut the selected nerve guide with a pair of scissors or a knife so that the nerve guide is 1 cm longer than the nerve gap.

Tension on the nerve ends should be avoided as much as possible. In some cases mobilization of the nerve ends may be employed at the discretion of the surgeon to reduce the tension. To secure adequate fixation of the nerve ends in the nerve guide, it is required to use the accepted surgical technique of flat, square ties with additional throws as warranted by surgical circumstance and the experience of the surgeon.

SUTURING TECHNIQUE

1. Place the NEUROLAC nerve guide in warm saline (37°C) for approximately 1 minute before implantation. This will make the tube more flexible and ease needle passage during suturing.

See Figure 1. *Schematic representation of suture technique for suturing the nerve ends into the nerve guide.*

2. Suture the NEUROLAC nerve guide by passing the suture (8-0 suture recommended) first through the tube from the outside to the inside and then transversally and superficially through the epineurium and back through the tube from the inside to the outside, after which a tie is made (Fig. 1.1-1.3).
3. When positioning optimization of the nerve ends in the nerve guide is required, it is recommended to place a second suture in the same nerve end (Fig. 1.4).
4. Pull the proximal nerve stump into the nerve guide.

NOTE: It is recommended that the nerve ends are pulled into the tube for at least 3 mm for optimal nerve regeneration.

5. Fill the tube with heparinized saline, using a solution containing 1000 units of heparin per 100 ml of normal saline (Fig 1.5).
6. Subsequently, use the same procedure, to pull the distal nerve stump into the nerve guide.
7. A minimum space of 5 mm should be left between the nerve ends in the nerve guide.
8. Fill any remaining space with heparinized saline (Fig 1.6) by injecting along the nerve into the lumen of the tube or by penetrating the tube (not the nerve).

CAUTION: Ensure that no blood enters the nerve guide lumen since this may hinder nerve recovery.
CAUTION: The nerve guide should be implanted and sutured with all joints in an extended position as to assure that no tension occurs on the proximal or distal nerve end when joints are being mobilized.

If placed near a joint, immobilize the joint upon discretion of the surgeon to avoid dislocation, migration and/or kinking of the device. Pressure on the repair side should be avoided since this can cause closure and kinking of the device.

DISPOSAL

Dispose contaminated implantation and packaging materials utilizing standard hospital procedures and universal precautions for bio-hazardous waste.

USED SYMBOLS

	=	Consult instructions for use.
	=	Caution
	=	Do not use if package is damaged
	=	Manufacturer
	=	Use by
	=	Catalog number
	=	Do not reuse
	=	Do not re-sterilize
	=	Lot number
	=	Sterilized with ethylene oxide gas
	=	Keep dry
	=	Keep away from sunlight
	=	Limit of storage temperature
	=	MR safe

DISCLAIMER OF WARRANTY AND LIMITATION OF REMEDY

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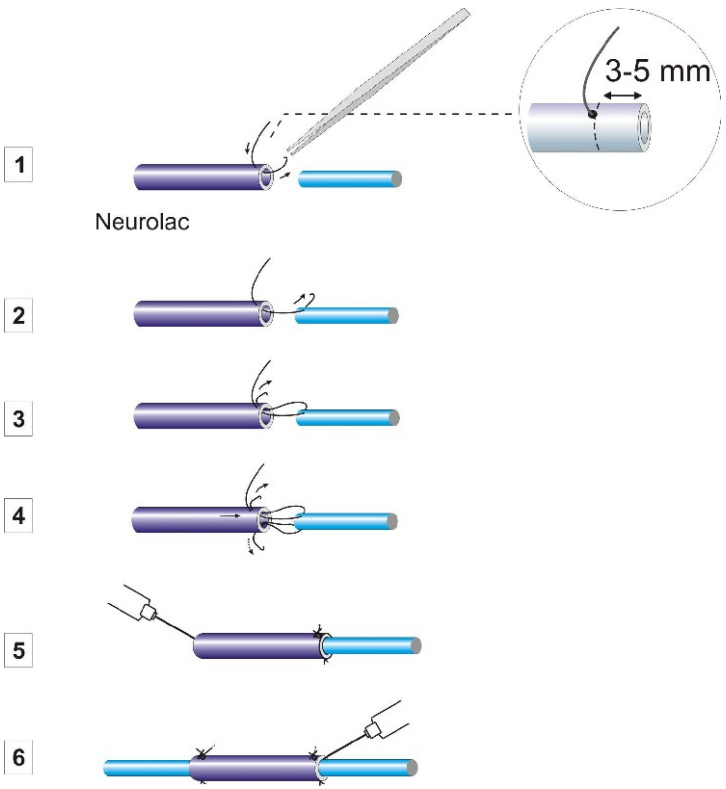
Figure 1



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