Patient Information NEUROLAC®

What is NEUROLAC® Used For

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.

NEUROLAC® is a bioresorbable product that will be completely resorbed in time and is not influenced by the behavior of the patient prior or following the surgery.

Product Description

NEUROLAC® nerve guide is composed of the bioresorbable copolyester poly(DL-lactide-ε-caprolactone). NEUROLAC® provides guidance and protection to regenerating axons. NEUROLAC® elicits a minimal acute inflammatory reaction of the surrounding tissue, which is followed by gradual encapsulation of the tube by fibrous tissue. Degradation of NEUROLAC® occurs through hydrolysis leading to gradual reduction of molecular weight. NEUROLAC® 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. Expected device lifetime is 24 months if stored between -18°C and 8°C.

NEUROLAC® is available in 10 sizes:

Catalogue #	Type (Nerve Diameter)
NG02-015/03	NEUROLAC-TW 1.5 mm
NG02-020/03	NEUROLAC-TW 2.0 mm
NG02-025/03	NEUROLAC-TW 2.5 mm
NG02-030/03	NEUROLAC-TW 3.0 mm
NG01-040/03	NEUROLAC 4.0 mm
NG01-050/03	NEUROLAC 5.0 mm
NG01-060/03	NEUROLAC 6.0 mm
NG01-070/03	NEUROLAC 7.0 mm
NG01-080/03	NEUROLAC 8.0 mm
NG01-100/03	NEUROLAC 10.0 mm

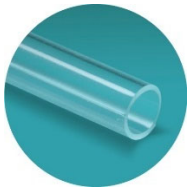

Figure 1 NEUROLAC®

Components

DL-Lactide monomer,
L-Lactide monomer, $C_6H_6O_4$
Ɛ-Caprolactone monomer
Tin(II) *2-ethylhexanoate*

When NEUROLAC® Should Not be Used

There are no contra-indications.

Precaution

Despite extensive testing of the product, adverse effects may occur as with any product and surgery. Any adverse outcomes potentially attributable to NEUROLAC® must be reported promptly to your doctor. You should also report it to Polyganics at +31 50 5886598 or directly to the Therapeutic Goods Administration at this link: https://www.tga.gov.au/reporting-problems

Adverse Effects

Adverse events associated with the use of NEUROLAC® 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.

Seek medical advice if you experience any of these symptoms.

MRI Information

NEUROLAC® is non-conducting and non-magnetic and poses no risk in the Magnetic Resonance Imaging (MRI) environment.

Usage

The product is for single patient use only. The cutting to the correct size in each procedure is determined by the judgment of the clinician.
No specific instructions for use are applicable for the patient, besides the surgery specific instructions provided by the hospital to the patient.

Record Keeping

It is important that you keep a record of your implant. You will be sent a small card similar to a credit card that you can keep in your wallet which will have the details of your implant printed on it.

Manufacturer

Legal Manufacturer and Manufacturing Facility
Polyganics Innovations BV
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The Netherlands
Phone (worldwide): +31 (0)50 5886588
This information sheet is available for download at:
https://polyganics.com/media/downloads/

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