

Patient Information NEUROCAP®

What is NEUROCAP® Used For

NEUROCAP® is a bioresorbable device to protect a peripheral nerve end and separate the nerve from surrounding environment to reduce the development of a symptomatic neuroma (growth of nerve tissue) in patients where nerve tissue has been damaged.

Product Description

NEUROCAP® is composed of the bioresorbable copolyester poly(DL-lactide-ε-caprolactone). NEUROCAP separates the nerve from the surrounding environment and protects the nerve end. NEUROCAP elicits a minimal acute inflammatory reaction of the surrounding tissue, which is followed by gradual encapsulation of the cap by fibrous tissue. Degradation of NEUROCAP occurs through hydrolysis leading to gradual reduction of molecular weight. NEUROCAP retains sufficient mechanical properties to act as a barrier up to at least 10 weeks, whereafter rapid loss of mechanical strength and gradual mass loss occur. NEUROCAP is resorbed in approximately 16 months.

NEUROCAP is a tubular device with one open end and one end sealed, the tip, as indicated in figure 1. An additional hole is included in the tip for easy tissue fixation with a suture. The size of the products is 3cm in length, and NEUROCAP is available in different diameters for different nerves, see table 1. Expected device lifetime is 24 months if stored between -18°C and 8°C.

NEUROCAP® is available in 8 sizes:

| Catalogue # | Type (Nerve Diameter) |
|-------------|-----------------------|
| NC01-015/03 | NEUROCAP 1.5 mm |
| NC01-020/03 | NEUROCAP 2.0 mm |
| NC01-025/03 | NEUROCAP 2.5 mm |
| NC01-030/03 | NEUROCAP 3.0 mm |
| NC01-040/03 | NEUROCAP 4.0 mm |
| NC01-050/03 | NEUROCAP 5.0 mm |
| NC01-060/03 | NEUROCAP 6.0 mm |
| NC01-070/03 | NEUROCAP 7.0 mm |
| NC01-080/03 | NEUROCAP 8.0 mm |



Figure 1 NEUROCAP®

Components

DL-Lactide monomer,
L-Lactide monomer, C₆H₆O₄
ε-Caprolactone monomer
Tin(II) 2-ethylhexanoate

When NEUROCAP® 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 NEUROCAP® 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 a NEUROCAP may include but are not limited to:

- Failure to reduce symptomatic neuroma pain
- Transitory local irritation;
- Infection;
- Allergy;
- Delayed wound healing;
- Protrusion

Seek medical advice if you experience any of these symptoms.

MRI Information

NEUROCAP® 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

Blauwborgje 32

9747 AC Groningen

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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