NEUROCAP®

Capping symptomatic end-neuroma

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NEUROCAP®

Management of symptomatic nerve-end neuroma

Symptomatic neuroma

Symptomatic neuroma may develop after a nerve dissection following any trauma to a peripheral nerve, whether accidental or planned (i.e. surgery). Neuroma-induced neuropathic pain and morbidity seriously affect the patient's daily life and socioeconomic functioning[1]. The incidence of symptomatic neuromas after peripheral nerve injury is estimated to be 3-5%, however certain surgeries (e.g. autograft procedures, amputations) may have up to a 30% incidence rate[2].

There are several surgical procedures possible to treat symptomatic end-neuromas, but none are considered gold standard for both treatment and prevention. The most common procedure is surgical removal of the neuroma and surrounding scar tissue, and placing the proximal stump into an area subjected to minimal mechanical stimulation.

Covering the nerve stump

Different ways of pain treatment are available, however with an average of 2.8 re-operations[1] and the surgeries have a failure rate of 10% or more[5].
Covering the nerve stump with a cap of autologous material prevents both neuroma development and regeneration[3], but has its limitations.

- Suitable veins need to be available and sacrificed and the stability of the treatment depends upon consistent venous integrity (i.e. no vein collapse).
- Muscle capping is often performed as this tissue is easily available, however the recurrence of very painful sensory neuroma has been reported[3]. Replacing the refreshed nerve end into bone is a technically demanding option.
  The nerve stump must be properly placed into a drilled hole, with no kinking at the hole entrance, and requires the nerve to be fixed to prevent dislocation.
- Use of vascularized flaps is technically very demanding and only considered in specific cases[4].

Research on better fixation techniques and covering the nerve stump with synthetic material bypassing possible biocompatibility issues of animal derived materials led to the idea to develop NEUROCAP®, a nerve capping device for the treatment of neuromas.
Its composition is based on the same synthetic polymers used in NEUROLAC® nerve guide for treatment of peripheral nerve lesions.

NEUROCAP®

Management Of Neuroma

NEUROCAP® is intended to protect a peripheral nerve-end and to separate the nerve from surrounding environment to reduce the development of a symptomatic end-neuroma.

NEUROCAP® is a tubular device with one open end and one closed end. Dislocation of the nerve stump is prevented by suturing the nerve end into the cap. A hole at the sealed end of the tube allows easy fixation of the nerve stump with a suture to the surrounding tissue. This allows an effective capping technique without the necessity of drilling a hole into bones, or sacrificing other tissue.
The application of NEUROCAP® and the available device dimensions are illustrated in figure 1 and table 1.

Figure 1:
NEUROCAP® Product Application

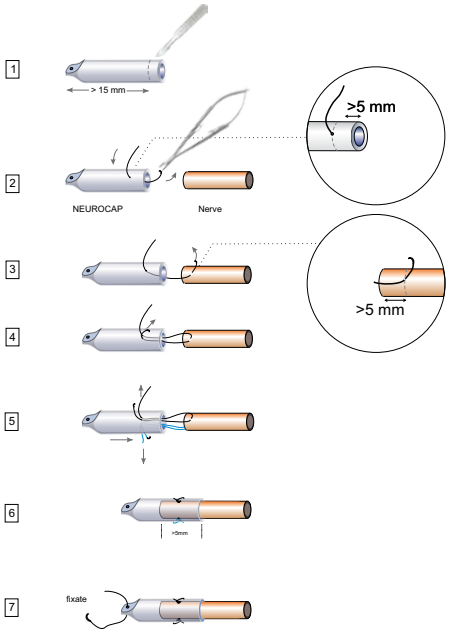

Table 1:
NEUROCAP® Product Description

Ø (mm)	Catalogue number	Recommended Needle & Suture size
1,5	NC01-015/03	• 7,0 or 6,0 Polypropylene with smallest needle possible • Tapered needle: 3/8 (9 - 11 mm)
2,0	NC01-020/03	
2,5	NC01-025/03	
3,0	NC01-030/03	
4,0	NC01-040/03	• 5,0 or 6,0 Polypropylene or mono-filament with 11 mm tapered needle • 5,0 or 6,0 polyamide/nylon with 13 mm needle or with the smallest tapered needle available
5,0	NC01-050/03	
6,0	NC01-060/03	
7,0	NC01-070/03	
8,0	NC01-080/03	

STOP Neuroma Trial

This safety and performance study underlines the effectiveness of Neurocap by demonstrating significant pain reduction, improvement of quality of life and reduction in pain medication use (12 Month data).

PROTECT NEURO Trial

This ongoing study, regarding the long term performance of Neurocap, demonstrates significant pain reduction and reduction in pain medication use, as well as significant improvement of quality of life at 12- and 24-months follow-up (final 24-months data are being collected).

NEUROCAP® is available in 1 unit per box.
It is packed in a plastic tray and a Tyvek pouch and subsequently placed in a aluminum pouch.
NEUROCAP® is transparent, indicated for single-use and should be stored in a dark, dry place between -18 °C (0 F) and 8 °C (46 F).
The shelf life 24 months.

1. Van Der Avoort DJJC, Hovius SER, Selles RW, Van Neck JW, Coert JH. The incidence of symptomatic neuroma in amputation and neurorrhaphy patients. J Plast Reconstr Aesthetic Surg. 2013;66(10):1330-1334.
2. Stokvis A, van der Avoort D-JJC, van Neck JW, Hovius SER, Coert JH. Surgical management of neuroma pain: a prospective follow-up study. Pain. 2010;151(3):862-869.
3. Lewin-Kowalik J, Marcol W, Kotulska K, Mandera M, Klimczak A. Prevention and management of painful neuroma. Neurol Med Chir (Tokyo). 2006;46(2):62-67; discussion 67-68.
4. Watson J, Gonzalez M, Romero A, Kerns J. Neuromas of the hand and upper extremity. J Hand Surg Am. 2010;35(3):499-510.
5. Elliot D, Sierakowski A. The surgical management of painful nerves of the upper limb: a unit perspective. J Hand Surg Eur Vol. 2011;36(9):760-770.

NEUROCAP® is FDA cleared under number K152684, and CE-marked as a bioresorbable device for peripheral nerve injury treatment and management.

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