NEUROCAP
Bioresorbable Peripheral Nerve Capping Device

NEW
510(k) Regulatory Clearance

POLYGANICS
TRANSFORMING PATIENT RECOVERY
www.polyganics.com
Symptomatic neumora
Symptomatic neumora may develop after a nerve dissection following any trauma to a peripheral nerve, whether accidental or planned (i.e. surgery). Neurona-induced neuropathic pain and morbidity seriously affect the patient’s daily life and socioeconomic functioning. 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.

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 neumora and surrounding scar tissue, and placing the proximal stump into an area subjected to minimal mechanical stimulation.

Covering the nerve stump
Covering the nerve stump with a cap of autologous material prevents both neumora development and regeneration, 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 neumora has been reported. 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. Unfortunately, this way of pain treatment in amputation has an average of 2.8 re-operations and the surgeries have a failure rate of 10% or more.

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

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

<table>
<thead>
<tr>
<th>Needle &amp; Suture size</th>
<th>Recommended</th>
<th>Catalogue number</th>
</tr>
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<tbody>
<tr>
<td>1.5</td>
<td>7.0 or 6.0 Polypropylene with</td>
<td>NC01-015/03</td>
</tr>
<tr>
<td>2.0</td>
<td>smallest needle possible</td>
<td>NC01-020/03</td>
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<tr>
<td>2.5</td>
<td>Tapered needle: 3/8 (9 - 11 mm)</td>
<td>NC01-025/03</td>
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<tr>
<td>3.0</td>
<td>needle available</td>
<td>NC01-030/03</td>
</tr>
<tr>
<td>4.0</td>
<td>5.0 or 6.0 Polypropylene or mono-filament with 11 mm tapered needle</td>
<td>NC01-040/03</td>
</tr>
<tr>
<td>5.0</td>
<td>5.0 or 6.0 polyamide/nylon with 13 mm needle</td>
<td>NC01-050/03</td>
</tr>
<tr>
<td>6.0</td>
<td>7.0 or 6.0 polyamide/nylon with 13 mm needle</td>
<td>NC01-060/03</td>
</tr>
<tr>
<td>7.0</td>
<td>needle with the smallest tapered</td>
<td>NC01-070/03</td>
</tr>
<tr>
<td>8.0</td>
<td>NC01-080/03</td>
<td></td>
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To prove safety and effectiveness of performance of NEUROCAP, Polyganics is engaged with several European hospitals in an open non-randomized clinical investigation called STOP NEUROMA Trial.

STOP NEUROMA Trial
This study will be conducted to obtain data on the clinical performance of NEUROCAP ability to isolate the nerve end, resulting in a reduction of pain of experienced from the symptomatic neumora and prevention of the recurrence of a symptomatic neumora. If you need more information please contact us through info@polyganics.com

NEUROCAP is available in 1 unit per box as is packed in a plastic tray, an aluminum pouch and subsequently placed in a Tyvek 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 is 12 months. NEUROCAP is a class II device which obtained 510(k) clearance (K152684).