Product description

**Neuro-Patch®**

**Product description**
Neuro-Patch® is a microporous fabric, manufactured from specially polyester urethane and used as a dura substitute. The fine-fiber microstructure is characterized by intercommunicating pores and many openings on the surface. This allows immigration of the body's own connective tissue cells. The device is provided sterile, for single use only.

**Composition**
Neuro-Patch® consists of specially purified aliphatic polyester urethane. It is EtO sterilized.

**Indications for use**
Neuro-Patch® is indicated as a dura mater substitute in neurological procedures for soft tissue reconstruction of damaged, impaired, or missing tissue, such as for:
- Closing cerebra l and cerebellar dural defects, such as after excision of tumors, operations on the posterior cranial fossa and after the removal of basal meningiomas;
- Decompressive surgery in the presence of increased intracranial pressure;
- For closure of spinal dural defects after removal of spinal tumors and after spinal trauma; and
- Spinal decompressive surgery.

**Contraindications**
Do not implant in infected areas, open cranial trauma or open spina bifida.

**How supplied**
The product is supplied sterile, non-pyrogenic and packaged as single or double pieces. The products are available in various dimensions ranging from 1.5 x 3 cm sections to as large as 6 x 14 cm pieces. Specific sizes are noted by catalog number below.

**Precautions**
Before using Neuro-Patch®, the surgeon should be familiar with the surgical technique, special applications and the properties of Neuro-Patch® in vivo.
**Warnings**

Neuro-Patch® should not be used together with bone cement as the patch material could be damaged depending on the application. Neuro-Patch® should only be used if the package is intact. Visually inspect the packaging; do not use product if the package is found opened, punctured, torn or tampered with as sterility may be compromised. Do not resterilized, as the sterilization process may alter the structure of Neuro-Patch® and thus its properties in vivo. U.S.A. Federal Law restricts this device to sale by or on the order of a physician.

**Possible adverse reactions**

Hypersensitivity or an immune response to Neuro-Patch® may occur. The physician should closely monitor the patient for such a reaction and treat accordingly. Postoperative adjacent tissue adhesions in situ may occur.

**Directions for use**

The correct size of Neuro-Patch® should be chosen and cut as closely as possible to fit the defect. The Neuro-Patch® should be fixed with non-absorbable suture material (polyester, polypropylene). To improve suture security, non-absorbable suture material (polyester, polypropylene) is recommended. The use of atraumatic round-bodied needles will allow suturing without significant damage to the implant.

**Storage**

Store the Neuro-Patch® box in a clean, dry and protected area with protection from extreme changes in temperature and humidity. Storage conditions should not exceed temperature of 25 ± 5 °C. (68 °F – 86 °F)
Product range

<table>
<thead>
<tr>
<th>Packs of 1 piece</th>
<th>Packs of 2 pieces</th>
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</thead>
<tbody>
<tr>
<td>Dimensions</td>
<td>REF</td>
</tr>
<tr>
<td>12 x 14 cm</td>
<td>106 4002</td>
</tr>
<tr>
<td>6 x 14 cm</td>
<td>106 4010</td>
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<tr>
<td>4 x 10 cm</td>
<td>106 4037</td>
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<tr>
<td>6 x 8 cm</td>
<td>106 4029</td>
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</tbody>
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Distributor in the US/Contact in Canada for product information and complaints

Aesculap Inc.
3773 Corporate Parkway
Center Valley, PA 18034
USA

Symbols used on labelling

- Do not reuse!
- Use until Year + Month
- Date of manufacture
- Temperature limitation
- Sterile unless package is opened or damaged.
  Method of Sterilization – Ethylene oxide
- CE-mark and identification number of notified body. Product conforms to the essential requirements of the Medical Device Directive 93/42/EEC.
- Batch Number
- See Instructions for Use
- Cat. No.
- Size

Date of information: 09/2014