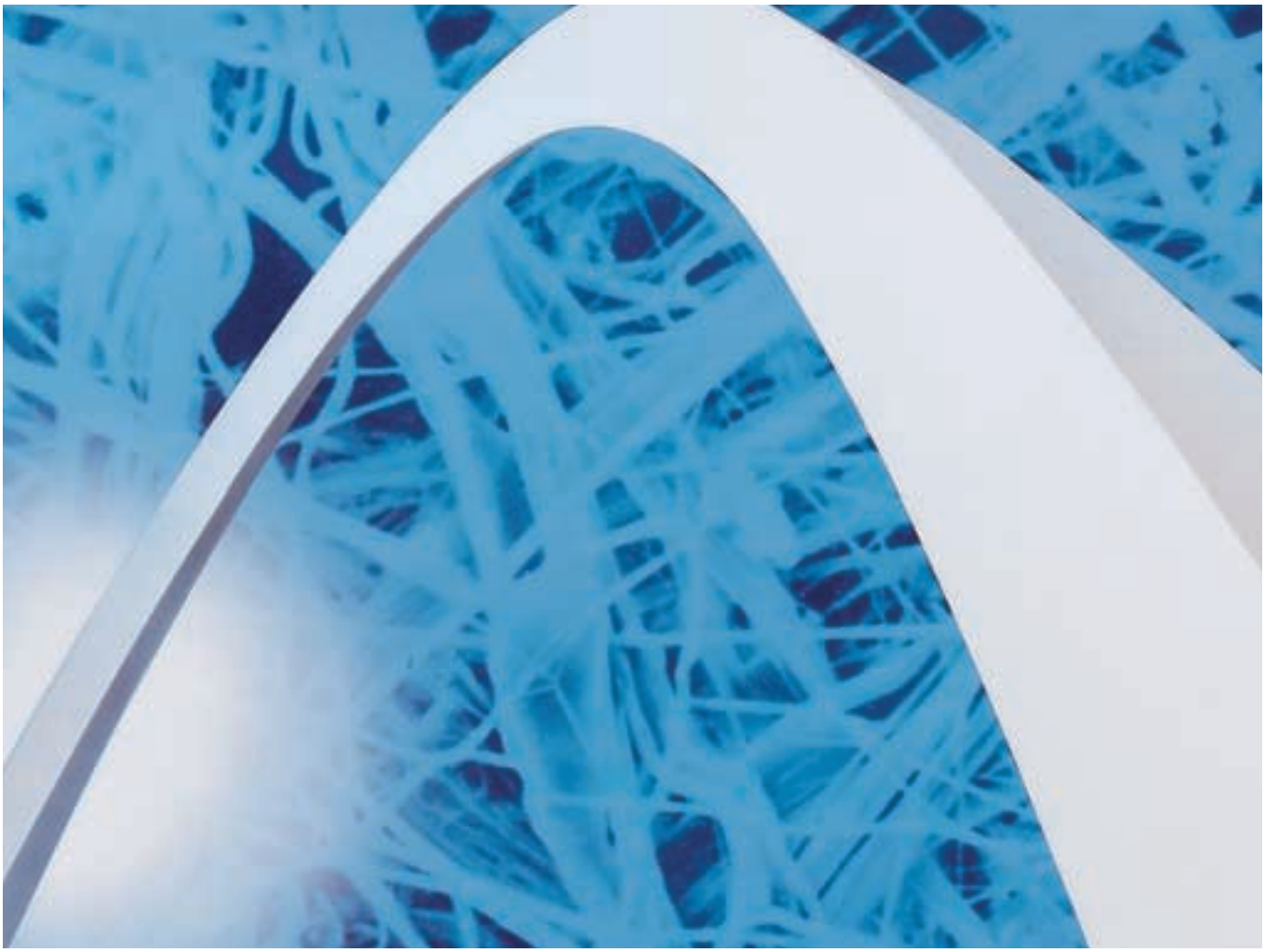
Neuro-Patch®

The bridge for new connective tissue



The synthetic dura substitute –
functional, well tolerated, stable

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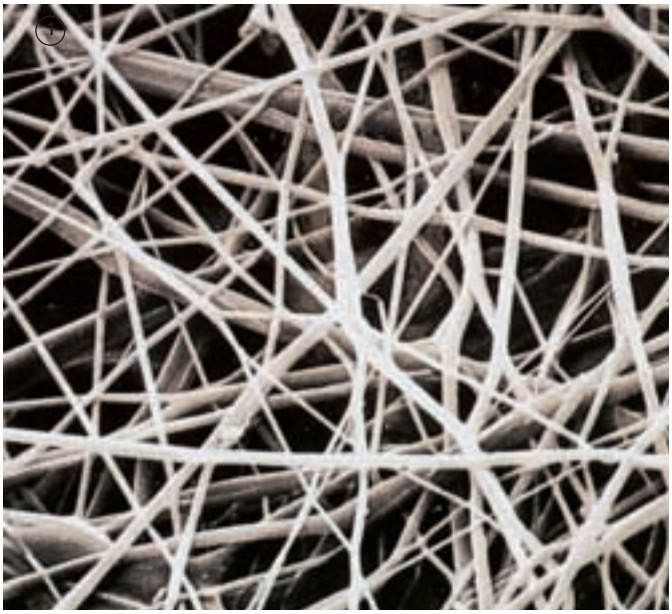


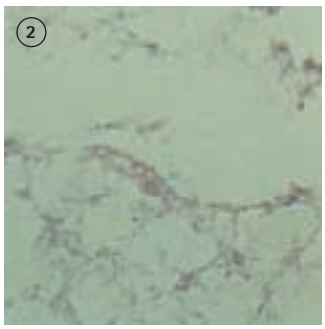
Scanning electron micrograph of the microporous structure (1000 x).

Product description

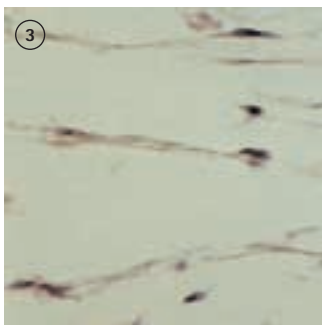
Neuro-Patch® is a new type of microporous fabric manufactured from a highly purified polyester-urethane.
A technologically advanced, electronically controlled procedure has been developed for producing the **Neuro-Patch®,** in which a dissolved polyester-urethane polymer is sprayed from specialised jets. This produces fibres which are captured at defined angles, producing a fleece-like structure.
The fine fibred microstructure supports the rapid infiltration of connective tissue cells.

Vitalisation and healing

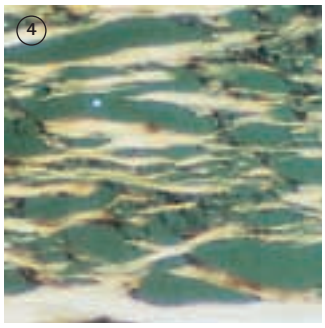
Neuro-Patch® heals in completely without irritating the surrounding tissue. It is covered by a very delicate neomembrane which separates the patch from adjacent tissues. The neo-membrane adheres closely to the microporous surface of the patch.
One to three days following implantation, cells from the surrounding connective tissue (mainly fibroblasts with a few histiocytes) begin to migrate into the pores of the implant. After three to four weeks, most of the **Neuro-Patch®** is interpenetrated by a population of fibroblasts. These fibroblasts produce collagen. Twelve months after implantation, even capillaries have grown into the newly formed dense collagen bundles. Adhesions with the surface of the brain related to the implant have not been observed.
(Figs. 2 – 7, functional implantation in dogs)



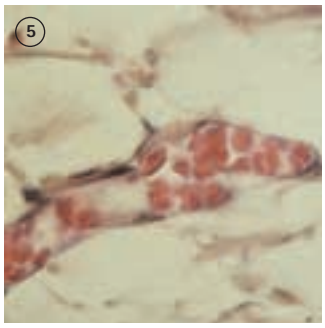
After implantation, the pores of **Neuro-Patch®** are initially plugged with low-protein exsudate, preventing fluid leakage (400 x)



After 2 months, the pores of the **Neuro-Patch®** are populated by fibroblasts. (250 x)



After 18 months, all pores are filled with a dense network of collagen fibres. (polarised light, 135 x)



Between 12 and 26 months, capillaries also grow out into the pores. (450 x)

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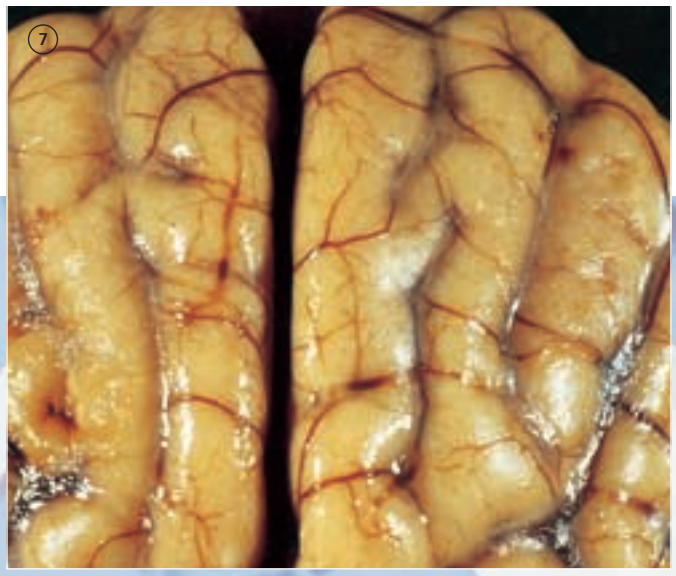


Macroscopic picture of the cerebral surface in a dog: The cerebral surface below the implant remains free of irritation and adhesions. (2 months)

Compatibility

Animal experiments and clinical studies have confirmed that **Neuro-Patch®** is extremely well tolerated by tissues. No adverse cellular or immunologic reactions are seen.
The absence of multinucleated giant cells demonstrates that the **Neuro-Patch®** is not recognised as a foreign body by the host.

Biostability

The absolute biostability of the **Neuro-Patch®** has been documented by histological studies and by the results of physical strength and dry weight measurements (showing no material loss even after implantation for many years).
The **Neuro-Patch®** cannot be degraded within the body either enzymatically or by direct cellular activity.

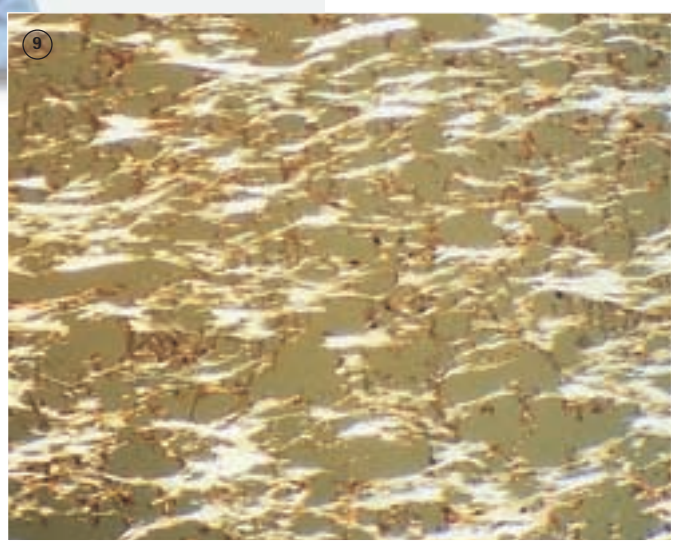
2 months

6 months

12 months

Macroscopic findings after experimental implantation as a dura mater substitute in dogs. At no point do implants show deposits or adhesions.
As the interval after implantation increases, the only change is masking of increasing numbers of sutures by neo-membrane.

Even 6 years after implantation, histology shows no loss of material fibrils, and no cellular infiltration to suggest irritation. (220 x)



Polarised light demonstrates the dense and uniform collection of collagen fibres in the pores of the same implant (cf. Fig. 8). (135 x)

Neuro-Patch®

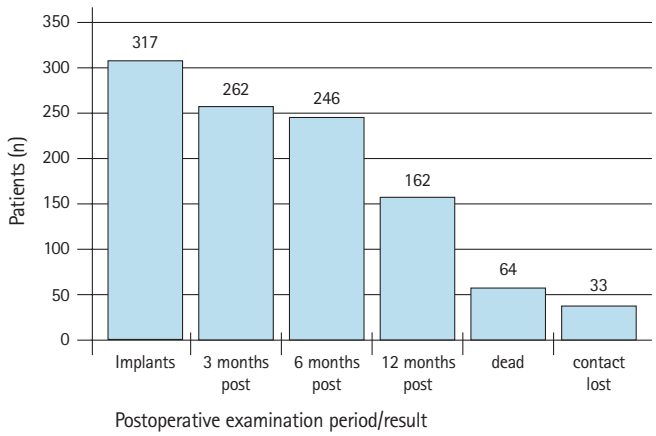
Scientific documentation

Clinical experience and results of a multicentre study

The liquor-tight closure of the dura is a basic principle in cranial neurosurgery. If it is not possible to create a seal by suture, replacement materials become necessary.
The surgeon would certainly prefer to use endogenous tissue but this is frequently not possible so then an alternative becomes necessary.
A new, synthetic material, the polyester urethane nonwoven **Neuro-Patch®,** has been available since the beginning of 1994.
The aim of the present study was to check how far the patch can be employed in neurosurgical head operations. The target criteria were handling during the operation, immediate postoperative complications and long-term toleration.

A total of 317 patients (160 female, 157 male) were observed.

The duration of observation and the study for the whole patient population are shown in the figure.



Summary of the results

As can be seen from the present study **Neuro-Patch®** can be recommended without restriction for permament dura replacement; this applies both with respect to its handling properties and also with respect to any reservations concerning plastic materials.
No product-specific complications were observed during this investigation. Specifically there were no early or late infections, which were associated with the product. The numbers of complications, such as "inflammation" and "cerebrospinal fluid fistula" were remarkably low, so that the patch can be recommended for all neurosurgical interventions, apart from use in already infected areas or when there is potential contamination of the area of operation (open cerebrocranial trauma), where fundamentally the use of plastics should be regarded with caution.
The scientific evidence does not reveal currently any further contra-indications for the use of **Neuro-Patch®** as dura replacement.

The scientific documentation is available on request.

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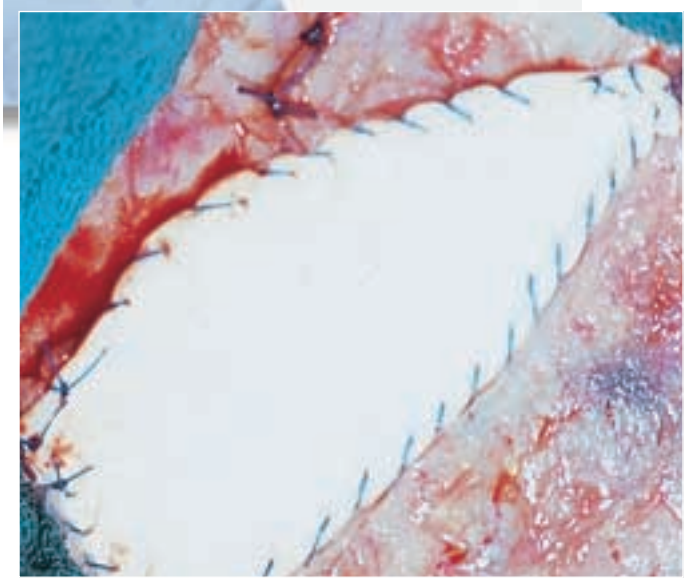
Advantages

- fluid-tight to prevent CSF leakage
- microporous structure –
  hence rapid population with "vital"
  endogenous fibroblasts
- extraordinarily
  well tolerated by tissue
- absolute biostability and
  permanent tensile strength
- protection against suture pull-out, even when
  sutured in place under tension
- optimum handling properties, e.g.:
  - impressive elasticity and flexibility
  - modelling qualities
  - very easy to suture
  - can be cut to any size desired

Mode of application

To achieve tension-free embedding, the **Neuro-Patch®** should be cut as closely as possible to the defect size. The **Neuro-Patch®** should be fixed with non-absorbable suture material (polyester, polypropylene). Additionally, it may be secured with fibrin glue. Atraumatic round-bodied needles allow suturing without significant damage to the implant.



Closure of a dural defect
with **Neuro-Patch®**

Indications

Neuro-Patch® is used as a dura substitute in neurosurgery:

- **for closing cerebral and cerebellar dural defects:**
  - after excision of tumours, operations on the posterior cranial fossa and after removal of basal meningiomas
  - for closure of CSF fistulae, e.g. after frontobasal fractures
- **for decompressing procedures in raised intracranial pressure**
- **for closure of spinal dural defects:**
  - after removal of spinal tumours
  - after spinal trauma
- **for spinal decompression procedures**

Contraindications

Neuro-Patch® should not be used:

- **in open cranial trauma**
- **in open spina bifida**
- **in infected areas**

Warning notes

Neuro-Patch® should not be used together with bone cement als the patch material could be damaged depending on the application.

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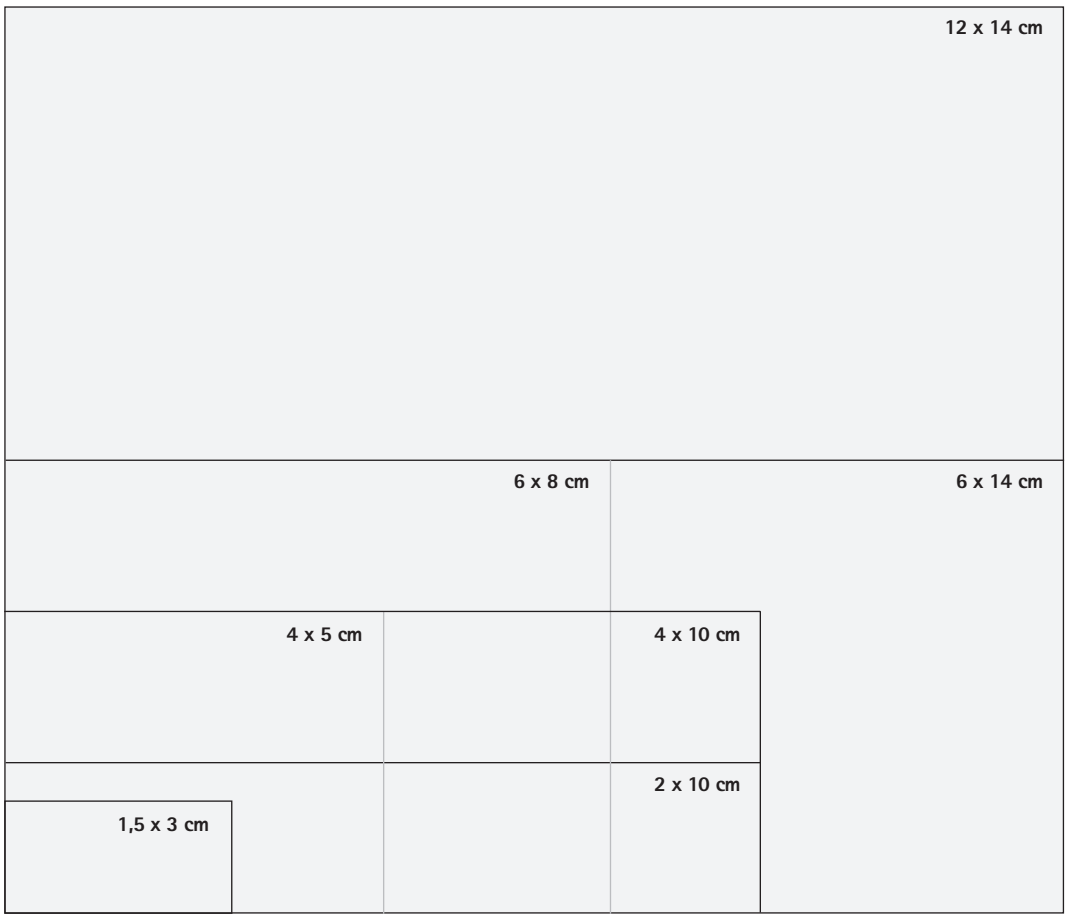
Chart of original dimensions



List of the scientific evidence:

(available on request)

- Plets C, van Loon J (1995)
  Introduction to Symposium "Modern concepts of dural substitution"; 10th European Concress of Neurosurgery, Berlin 1995.
- Ernestus RI, Ketter G, Klug N (1995)
  Current concepts of duraplasty in cranial neurosurgery
  Symposium "Modern concepts of dural substitution";
  10th European Congress of Neurosurgery,
  Berlin 1995.
- Heiss E, Sievert T (1995)
  Clinical experiences with synthetical dura substitution
  Symposium "Modern concepts of dural substitution";
  10th European Congress of Neurosurgery,
  Berlin 1995.
- van Loon J, Plets C, Goffin J, van Calenberg F (1995)
  A prospective study of polyesterurethane (Neuro-Patch®) as dura-substitute
  Symposium "Modern concepts of dural substitution";
  10th European Congress of Neurosurgery,
  Berlin 1995.

Further literature on Neuro-Patch® is available on request.

Product Range Neuro-Patch		
Dimensions	**Contents (pieces)**	**Cat. No.**
12 x 14 cm	1	10 640 02
6 x 14 cm	1	10 640 10
6 x 8 cm	1	10 640 29
4 x 10 cm	1	10 640 37
4 x 5 cm	2	10 640 45
2 x 10 cm	2	10 640 53
1,5 x 3 cm	2	10 640 61

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