Complete range for dura substitution

Neurosurgery products

B|BRAUN
AESCULAP

Dura substitutes

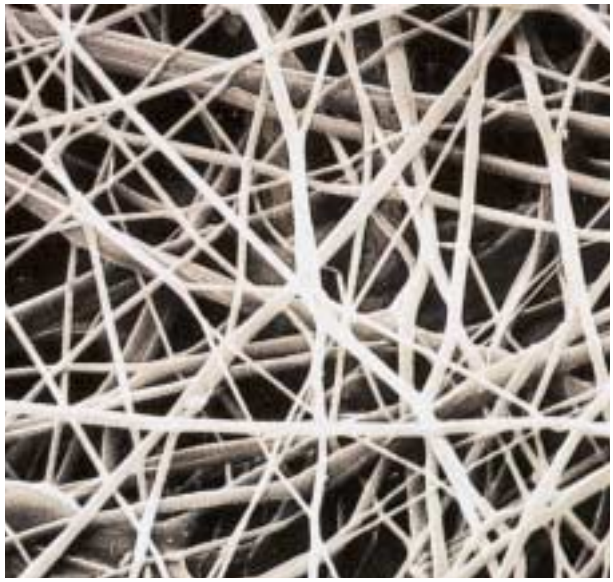
To prevent cerebrospinal fluid loss in dura mater defects, a substitute material is indicated to cover the defect. The aim is to prevent the formation of adhesions between the underlying nerve tissue and the cranium, thus avoiding the symptoms of neurological deficit potentially associated with this. These dural gaps can be the result of congenital malformations or be caused by lengthy surgical interventions (contraction), or by trauma and tumours. Since the first duraplasty with exogenous tissue, performed by Abbe in 1895, a multitude of materials have been used as plastic dura substitutes. These include alloplastic material as well as autologous tissue, homologous dura, and heterologous materials. Dura substitutes are among B. Braun's most successful product developments. Since 1994, the range available from B. Braun Surgical GmbH has included two neurosurgery products with a proven track record. Lyoplant, produced from bovine pericardium, is a biological absorbable substitute. **Neuro-Patch®**, a non-absorbable fleece made from aliphatic polyester urethane, is a synthetic alternative to bioimplants.

Neuro-Patch®, non-absorbable dura

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

Product description

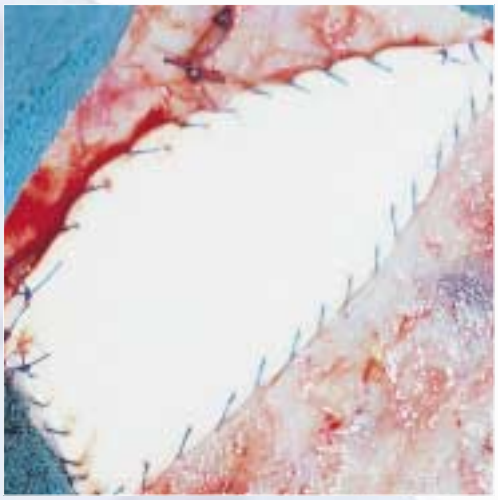
Neuro-Patch® is a new type of microporous fabric manufactured from a highly purified polyester-urethane. A technologically advanced, electronically controlled procedure has been developed for producing the **Neuro-Patch®**, in which a dissolved polyster-urethane polymer is sprayed from special jets.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



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

substitute

functional, well tolerated, biostable



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

Indications

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

- for closing cerebral an cerebellar dural defects
- for decompressing procedures in raised intracranial pressure
- for closure of spinal dural defects
- for spinal decompression procedures

Contra-indications

Neuro-Patch® should not be used:

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

Warning note

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

Compatibility

Animal experiments and clinical studies have confirmed that **Neuro-Patch®** is extremely well tolerated by tissues. No adverse cellular or immunologic reactions are experienced.
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 strenth 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.

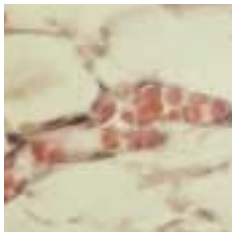
Vitalisation and healing

Neuro-Patch® completely heals without irritating the surrounding tissue. It is covered by a very delicate neomembrane wich 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.

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 an 26 months, capillaries also grow out into the pores. (450 x)

The choice is yours!

B. Braun substitutes are produced in conformity with the very latest technical standards. Precision instruments and experienced staff guarantee that these standards remain consistently high. Equipped with all the necessary technical facilities, the production areas meet GMP requirements, and every raw material used in production is subjected to rigorous incoming goods inspections.

Quality assurance and CE mark

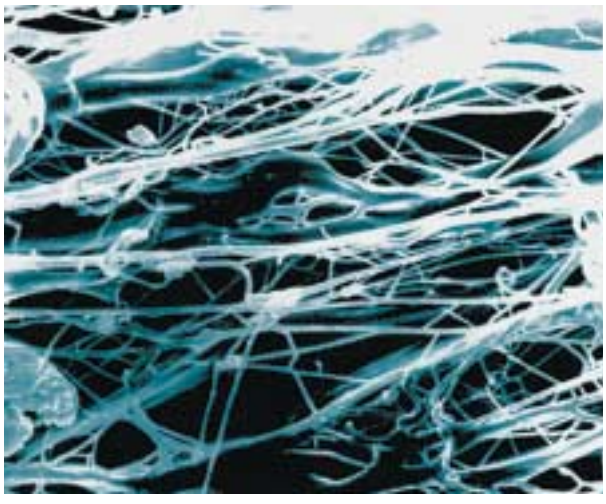
All B. Braun Surgical GmbH products carry the CE mark, testifying to their conformity with the highest medical device safety and suitability standards.
B. Braun Surgical's quality assurance system ensures detailed product documentation. The high product quality is therefore verifiable at every single stage of production.

Lyoplant®, absorbable dura substitute

- excellent tissue compatibility
- rapid and regular ingrowth of autologous connective tissue (revitalisation)
- good union with local host tissue (integration)
- outstanding handling properties such as rapid rehydration, high flexibility and conforminng to anatomical contours

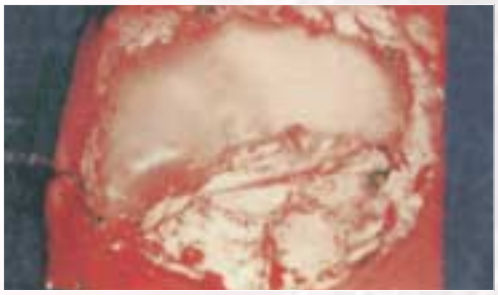
Product description

Lyoplant® is a pure collagen implant that is produced from bovine pericardium. This collagen is a Type I collagen and is known for its low propensity to cause immunological reactions. The special and comprehensive manufacturing process eliminates all non-collagenous substances such as fats, enzymes and other non-collagenous proteins. Controlled lyophilisation (freeze-drying) process ensures that the loose fibre structure of **Lyoplant®** ist preserved to offer the optimum conditions for integration after implantation.



Lyophilized **Lyoplant®** (Magnification 4000 x). Loosely connected skeins of collagen fibres, which are surrounded by a network of fine fibres.

Pure collagen implant



The good shape adaption of **Lyoplant®** on application

Indications

The substitution and enlargement of connective tissue structures in neurosurgery:

- for covering cerebral and cerebellar dural defects
- in cerebral decompression operations to relieve elevated intracranial pressure
- to cover spinal dural defects
- for spinal decompression operations

Contra-indications

Lyoplant® should not be employed

- in infected areas
- in substitution of mechanically stressed connective tissue structures
- for substitution of parts of the arterial system or the heart walls

Tissue compatibility

Improved, extensive manufacturing processes have resulted in a product consisting of pure collagen which, in comparison with other collagen products for dura-substitution has superior tissue compatibility. Animal experiments and clinical studies have proved the excellent tissue compatibility of **Lyoplant®**.

Product safety

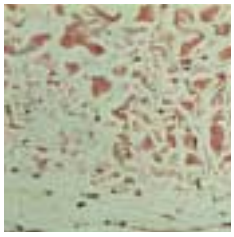
Lyoplant® is produced from bovine pericardium. In order to avoid the theoretically possible risk of transmission of BSE (bovine spongiform encephalopathy) the following measures are taken:

- pericardium is a tissue that is regarded as safe
- New Zealand, the country of origin of the pericardium, is free from BSE
- **Lyoplant®** is treated with sodium hydroxide solution

Revitalization by endogenous connective tissue

The high porosity of the **Lyoplant®** surface permits rapid inward migration of fibrocytes and good anchorage to the neomembrane with which the body tries to surround the implant. In porous membranes of biological origin, such as **Lyoplant®**, the fibrocytes that migrate in as part of the "revitalization" do not initially synthesize collagen, but adapt their metabolisms to contribute to the maintenance of the collagen fibres of the Lyoplant already present. It is only months later that there is a certain degree of collagenase-induced degradation of the **Lyoplant®**. This collagen experiences successive degradation and is replaced by the "new" endogenous fibrocytes. These "revitalized" structures are supplied with essential nutrients by capillaries that grow into the structure.

1 month postoperative (polarized light). **Lyoplant®** is partly absorbed and replaced by young connective tissue.



7 months postoperative. **Lyoplant®** is completely vitalised. At the lower border a thin neo-membrane is visible.

Skin incision

The initial incision is marked using a **Cutfix®** disposable scalpel, Fig. 10.
For ease of skin, fascia and muscle exposure, another scalpel, Fig. 10, should be used. The periosteum is incised with **Cutfix®** and reflected with the rasp.

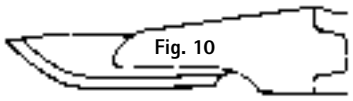
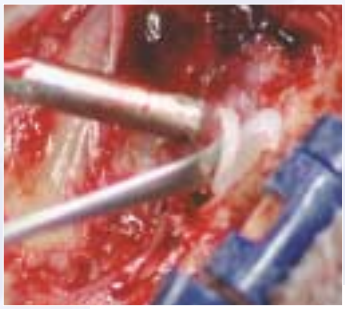


Fig. 10

Use	Product	Size	Cat. No.
	Cutfix® disposable scalpel	Fig. 10	**55 180 59**



Craniotomy

Severe bleeding from the drill holes or wound margins of the bone flap can be quickly and reliably stemmed by the application of **Bone Wax.**

Use	Product	Cat. No.
	Bone Wax	**10 297 54**

Exposure of the dura mater

To expose the dura mater, **Cutfix®** disposable scalpel, Fig. 11, is used

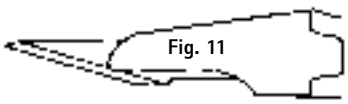


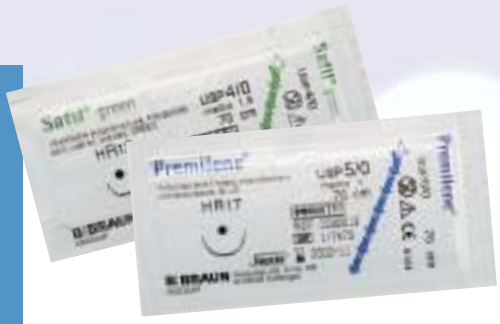
Fig. 11

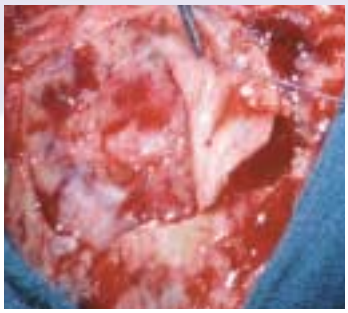
Use	Product	Size	Cat. No.
	Cutfix® disposable scalpel	Fig. 11	**55 180 40**

Recommendations for craniotomy

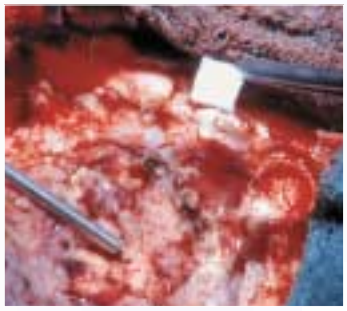
Dura supra suture and dura retention suture

Dura supra suturing can be performed with non-absorbable monofilament polypropylene sutures - **Premilene®** - HR 17, USP 5/0, 4/0, 3/0, or with absorbable braided polyglycolic acid sutures - **Safil®** - HR 17, USP 5/0, 4/0, 3/0. Any necessary retention sutures can be applied using the same needle and suture combinations.





Use	Product	Size	Cat. No.
	Premilene® monofilament polypropylene suture	USP 5/0, HR 17, 75 cm USP 4/0, HR 17, 75 cm USP 3/0, HR 17, 75 cm	**C 00 900 12** **C 00 900 13** **C 00 900 14**
	Safil® polyglycolic acid suture, braided, coated	USP 5/0, HR 17, 70 cm USP 4/0, HR 17, 70 cm USP 3/0, HR 17, 70 cm	**C 00 480 12** **C 00 480 13** **C 00 480 14**



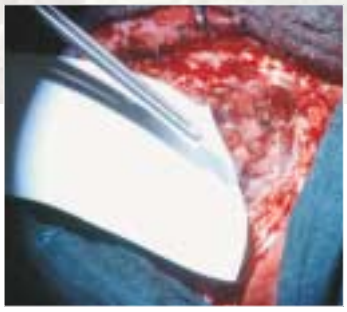
Tumour removal

Bleeding can be controlled at any time with **Lyostypt®**.

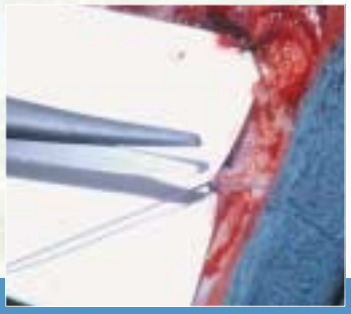
Use	Product	Size	Cat. No.
	Lyostypt® collagen haemostyptic, absorbable	3 x 5 cm 5 x 8 cm 10 x 12 cm	**10 691 28** **10 691 52** **10 692 09**

Dural closure

To cover the dural defect, use the synthetic substitute **Neuro-Patch®** or the native substitute **Lyoplant®**.



Use	Product	Size	Contents	Cat. No.
	Neuro-Patch® synthetic dura substitute	12 x 14 cm	1 piece	**10 640 02**
		6 x 14 cm	1 piece	**10 640 10**
		6 x 8 cm	1 piece	**10 640 29**
		4 x 10 cm	1 piece	**10 640 37**
		4 x 5 cm	2 pieces	**10 640 45**
		2 x 10 cm	2 pieces	**10 640 53**
		1,5 x 3 cm	2 pieces	**10 640 61**
	Lyoplant® bovine dura substitute	12 x 14 cm	1 piece	**10 662 00**
		6 x 14 cm	1 piece	**10 660 21**
		6 x 8 cm	1 piece	**10 662 42**
		4 x 10 cm	1 piece	**10 660 48**
		4 x 5 cm	2 pieces	**10 660 64**
		2 x 10 cm	2 pieces	**10 660 80**
		1,5 x 3 cm	2 pieces	**10 661 02**
		ø 1,4 cm	2 pieces	**10 661 61**
		ø 0,9 cm	2 pieces	**10 661 53**



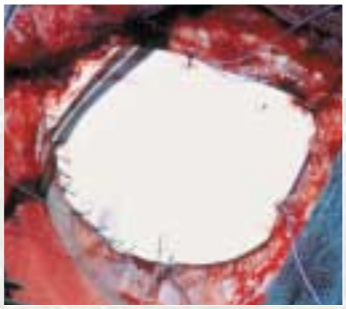
Dura substitute fixation

We recommend fixing **Neuro-Patch®** or **Lyoplant®** with **Premilene®**, size HR 17, USP 5/0, 4/0, 3/0.

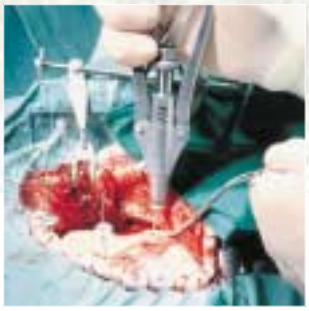
Use	Product	Size	Cat. No.
	Premilene® monofilament polypropylene suture	USP 5/0, HR 17, 75 cm	**C 00 900 12**
		USP 4/0, HR 17, 75 cm	**C 00 900 13**
		USP 3/0, HR 17, 75 cm	**C 00 900 14**
	Safil® polyglycolic acid suture, braided, coated	USP 5/0, HR 17, 70 cm	**C 00 480 12**
		USP 4/0, HR 17, 70 cm	**C 00 480 13**
		USP 3/0, HR 17, 70 cm	**C 00 480 14**

Dura substitute – continuous suture

Depending on user preference, we offer absorbable suture material - **Safil®** - or non-absorbable suture material - **Premilene®** - in the sizes HR 17, USP 5/0, 4/0, and 3/0.



Recommendations for craniotomy



Bone flap closure

Bone flap fixation using **Craniofix**® is characterised by rapid and easy application compared with plates, screws and bone flap threads.

Use	Product	Leaflet
	Craniofix® System for bone flap fixation	For more information, see our AESCULAP leaflet **C 471 11**

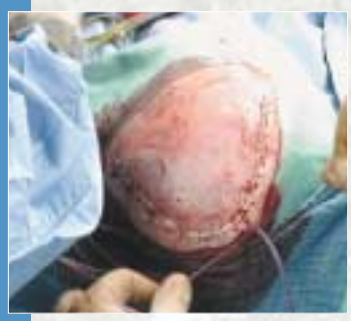
Layer-by-layer wound closure

Muscle sutures are applied using **Safil**®, HR 22 or HR 26. Subcuticular and cutaneous sutures can be applied with either **Premilene**® or **Safil**® in sizes 4/0 and 3/0 using cutting needle DS 19.

Use	Product	Size	Cat. No.
	Premilene®	USP 4/0, DS 19, 45 cm USP 3/0, DS 19, 45 cm	**C 00 902 20** **C 00 902 21**
	Safil®	USP 4/0, DS 19, 45 cm USP 3/0, DS 19, 45 cm	**C 00 482 20** **C 00 482 21**
	Safil®	USP 0, HR 22, 70 cm USP 0, HR 26, 70 cm	**C 00 480 37** **C 00 480 43**

Wound drain fixation

Use **Premilene**® in sizes 4/0 and 3/0 with cutting needle DS 19.



Craniotomy

For meningioma and duraplasty

Recommended uses	Material	Size	Cat. No.
Marking surgical field	**Cutfix®**	Fig. 10	**55 180 59**
Exposure of skin down to galea	**Cutfix®**	Fig. 10	**55 180 59**
Haemostasis at bone	**Bone Wax**		**10 297 54**
Exposure of dura mater	**Cutfix®**	Fig. 11	**55 180 40**
Dura supra suture and dura retention suture	**Premilene®**	USP 5/0; HR 17, 75 cm USP 4/0; HR 17, 75 cm USP 3/0; HR 17, 75 cm	**C 00 900 12** **C 00 900 13** **C 00 900 14**
Haemostasis and lining of tumour cavity	**Lyostypt®**	3 x 5 cm 5 x 8 cm 10 x 12 cm	**10 691 28** **10 691 52** **10 692 09**
Dural closure	**Neuro-Patch®**	12 x 14 cm 6 x 14 cm 6 x 8 cm 4 x 10 cm 4 x 5 cm 2 x 10 cm 1,5 x 3 cm	**10 640 02** **10 640 10** **10 640 29** **10 640 37** **10 640 45** **10 640 53** **10 640 61**
	Lyoplant®	12 x 14 cm 6 x 14 cm 6 x 8 cm 4 x 10 cm 4 x 5 cm 2 x 10 cm 1,5 x 3 cm ø 1,4 cm ø 0,9 cm	**10 662 00** **10 660 21** **10 662 42** **10 660 48** **10 660 64** **10 660 80** **10 661 02** **10 661 61** **10 661 53**
Dura substitute fixation	**Premilene®**	USP 5/0, HR 17, 75 cm USP 4/0, HR 17, 75 cm USP 3/0, HR 17, 75 cm	**C 00 900 12** **C 00 900 13** **C 00 900 14**
Dura substitute - continuous suture	**Premilene®**	USP 5/0, HR 17, 75 cm USP 4/0, HR 17, 75 cm USP 3/0, HR 17, 75 cm	**C 00 900 12** **C 00 900 13** **C 00 900 14**
	Safil®	USP 5/0, HR 17, 70 cm USP 4/0, HR 17, 70 cm USP 3/0, HR 17, 70 cm	**C 00 480 12** **C 00 480 13** **C 00 480 14**
Bone flap closure	**Craniofix®**	AESCULAP-Brochure	**C-471-11**
Drill hole lining	**Lyostypt®**	3 x 5 cm 5 x 8 cm 10 x 12 cm	**10 691 28** **10 691 52** **10 692 09**
Layer-by-layer wound closure	**Safil®**	USP 0, HR 22, 70 cm USP 0, HR 26, 70 cm	**C 00 480 37** **C 00 480 43**
Cutaneous suture	**Premilene®**	USP 4/0, DS 19, 45 cm USP 3/0, DS 19, 45 cm	**C 00 902 20** **C 00 902 21**
Wound drain fixation	**Premilene®**	USP 4/0, DS 19, 45 cm USP 3/0, DS 19, 45 cm	**C 00 902 20** **C 00 902 21**

Spinal

For meningioma and duraplasty

Recommended uses	Material	Size	Cat. No.
Marking of surgical field	**Cutfix®**	Fig. 10	**55 180 59**
Cutaneous, subcutaneous and fascia exposure	**Cutfix®**	Fig. 10	**55 180 59**
Haemostasis at bone	**Knochenwachs**		**10 297 54**
Exposure of dura mater	**Cutfix®**	Fig. 11	**55 180 40**
Dura retention suture	**Premilene®**	USP 5/0; HR 17, 75 cm USP 4/0; HR 17, 75 cm	**C 00 900 12** **C 00 900 13**
Dura closure	**Neuro-Patch®**	4 x 5 cm 2 x 10 cm 1,5 x 3 cm	**10 640 45** **10 640 53** **10 640 61**
	Lyoplant®	4 x 5 cm 2 x 10 cm 1,5 x 3 cm	**10 660 64** **10 660 80** **10 661 02**
Dura substitute fixation	**Premilene®**	USP 5/0, HR 17, 75 cm USP 4/0, HR 17, 75 cm	**C 00 900 12** **C 00 900 13**
Dura substitute - continuous suture	**Premilene®**	USP 5/0, HR 17, 75 cm USP 4/0, HR 17, 75 cm	**C 00 900 12** **C 00 900 13**
	Safil®	USP 5/0, HR 17, 70 cm USP 4/0, HR 17, 70 cm	**C 00 480 12** **C 00 480 13**
Muscle approximitaion suture	**Safil®**	USP 0, HRT 22, 70 cm USP 0, HRT 26, 70 cm	**C 00 483 32** **C 00 483 43**
Fascia	**Safil®**	USP 0, HRT 22, 70 cm	**C 00 483 32**
Subcuticular suture	**Safil®**	USP 3/0, DS 19, 45 cm	**C 00 482 21**
cutaneous suture	**Premilene®**	USP 3/0, DS 19, 45 cm	**C 00 902 21**
Wound drain fixation	**Premilene®**	USP 4/0, DS 19, 45 cm USP 3/0, DS 19, 45 cm	**C 00 902 20** **C 00 902 21**

Product range neurosurgery

Cat. No. **B 055 02**
Neuro-Patch®

Cat. No. **B 076 02**
Lyoplant®

Cat. No. **B 003 02**
Cutfix®

Cat. No. **B 022 02**
Bone wax

Premilene® Easyslide

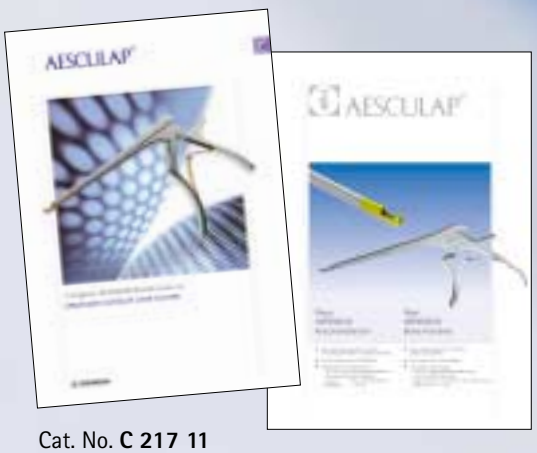
Safil® Easyslide

Cat. No. **B 026 02**
Lyostypt®

AESCULAP

Cat. No. **C 201 11**
Aesculap product range

Cat. No. **O 134 02**
HILAN-High-Speed
Motor System



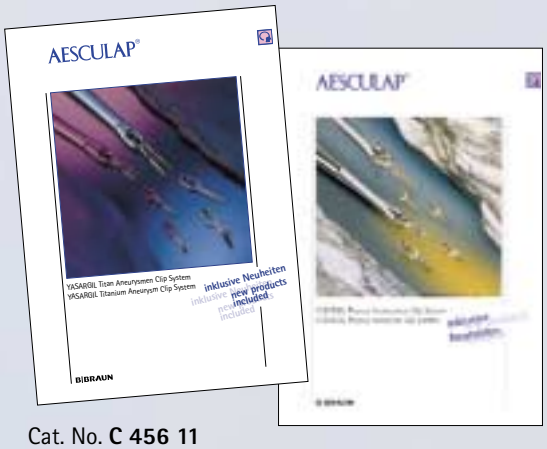
Cat. No. **C 217 11**

Cat. No. **C 721 11**

KERRISON Rongeur
Standard model and/or dismantable version

Pros.-Nr. **C 207 11**
CASPAR Scalp Clip System
Temporary haemostasis of
galea flap

Cat. No. **C 302 11**
HF Surgical Instruments,
bipolar



Cat. No. **C 456 11**

Cat. No. **C 202 11**

YASARGIL Aneurysm Clip Systems
Titan or Phynox

Cat. No. **C 465 11**
GN 090 - JET Irrigation
Instrument, bipolar
irrigating forceps

Cat. No. **C 471 11**
CRANIOFIX®
System for refixation of
craniotomised bone flaps

B|BRAUN

AESCULAP

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