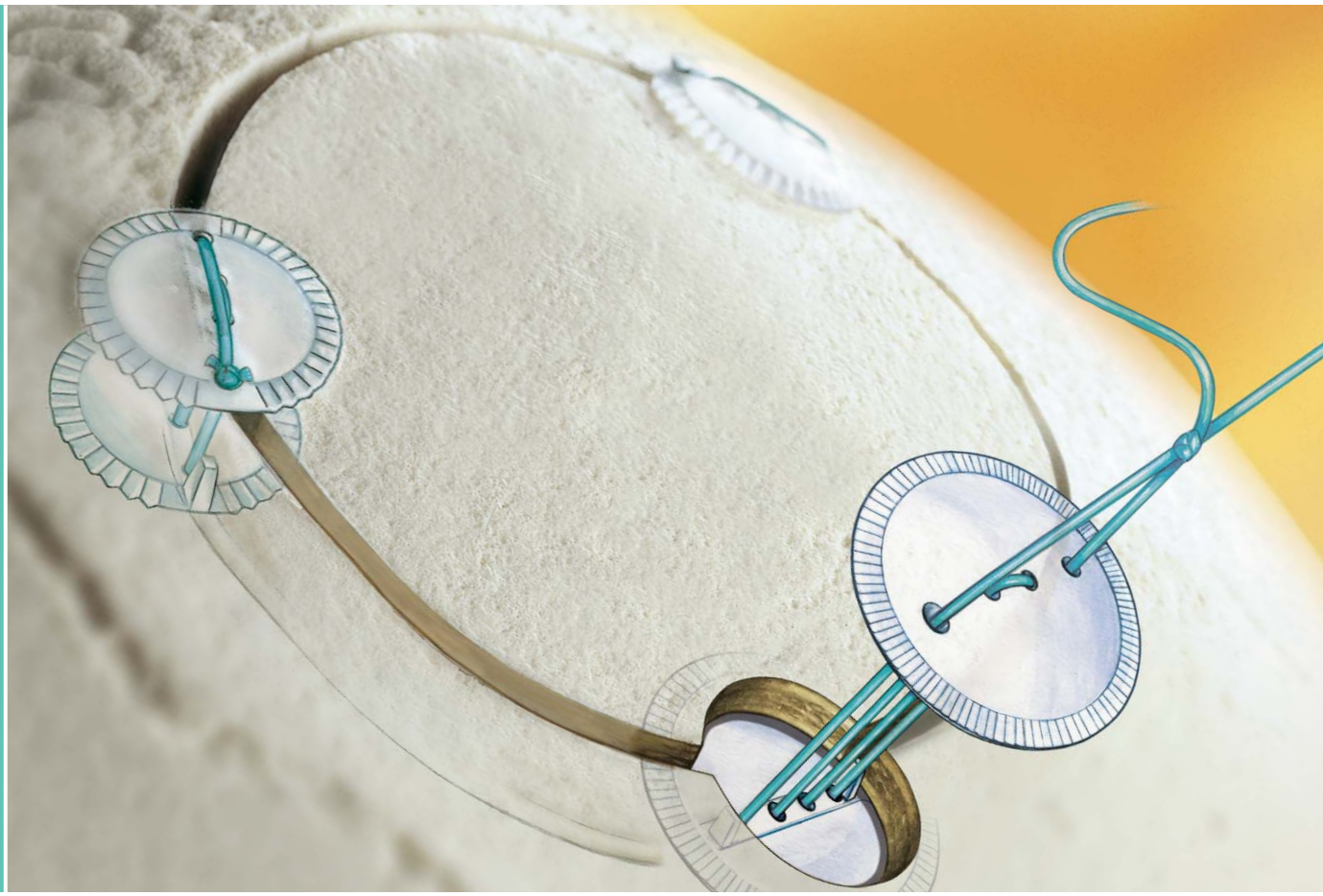
Aesculap® CranioFix® absorbable

Absorbable cranial fixation system



Aesculap Neurosurgery

B BRAUN
SHARING EXPERTISE

Aesculap® CranioFix® absorbable

"CranioFix absorbable" – instrument-free, absorbable fixation system for cranial bone flaps

developed in cooperation with
K.-D. Lerch, M.D.
Dortmund, Germany

for craniotomy gap

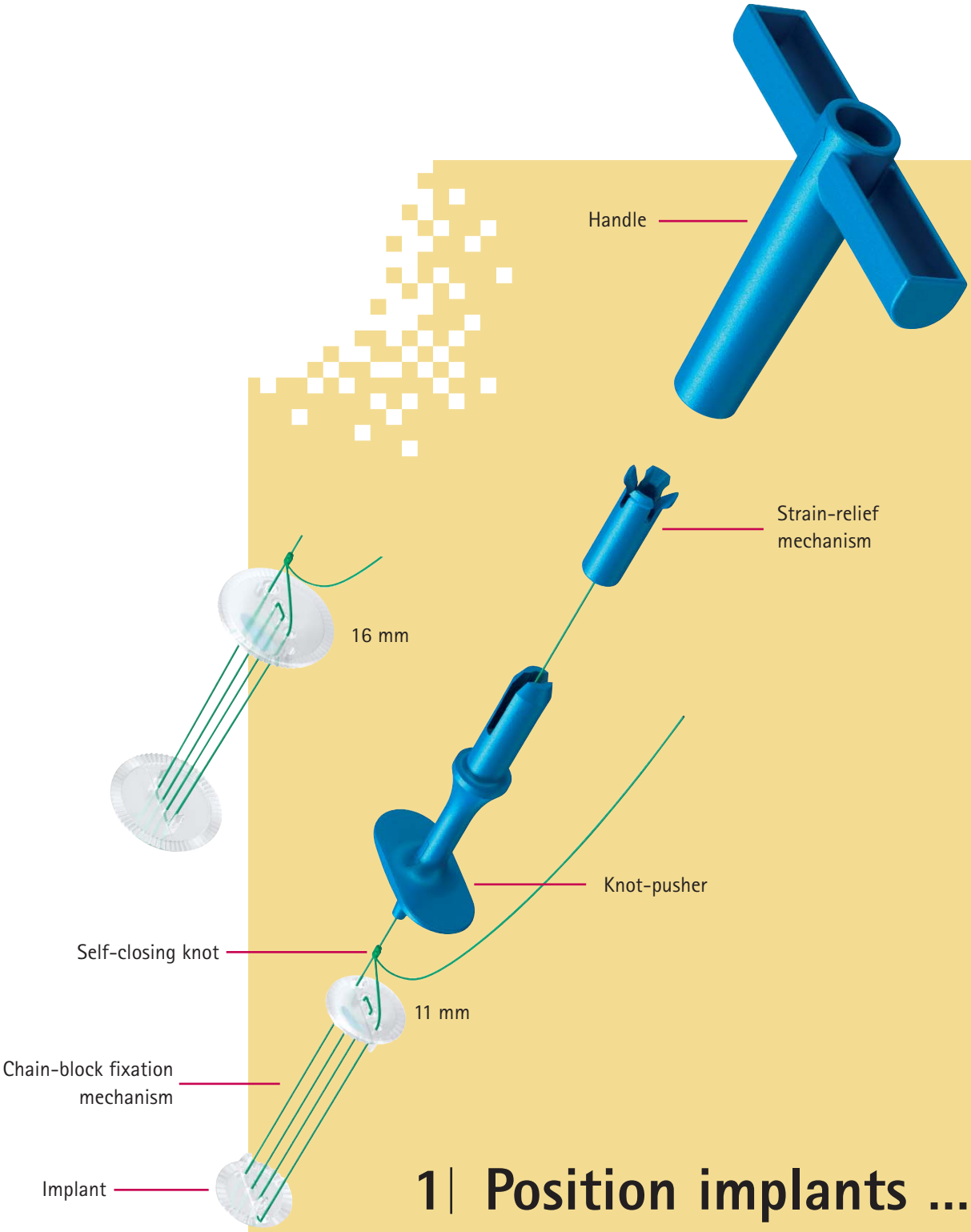
for drill hole and craniotomy gap

CranioFix absorbable is a double sided, clamp based system for the fixation of craniotomised bone flaps. The patented thread chain-block mechanism (DE 19952359C and DE 10161724A1) offers instrument-free application. The integrated automatic strain-relief mechanism ensures a reproducible fixation with defined force. The implants are made of absorbable polyester [Poly (L-lactide-co-D, L-Lactide) 70:30], which is a standard material for absorbable fixations in neurosurgery. The fixation retains approximately 90 - 95% of its initial strength after 8-12 weeks. The implants are absorbed completely after 2-3 years and the material is metabolized by the body. The stability characteristics of CranioFix absorbable support the complete osseo-integration of cranial flaps in paediatric and adult patients.

CranioFix absorbable is delivered sterile as a ready-to-use assembly. It can be used without any additional instruments.

CranioFix absorbable - for easy and fast fixation of cranial bone flaps

- Particularly suitable for paediatric patients, recurrent tumour patients and MRI follow-up patients
- No artefacts or obstructions in postoperative MRI or CT imaging
- No secondary surgery for removal of metal implants (especially in paediatric patients)
- No palpable, noticeable or visible implants, especially in frontal area, delivering the best cosmetic results and increased patient acceptance
- No growth restrictions and screw migrations in paediatric patients
- No MRI security issues (no Tesla limitation), simplifying future medical treatment especially for MRI follow-up patients
- No screwing, pre-drilling or drilling, in contrast to micro titanium plates & screws



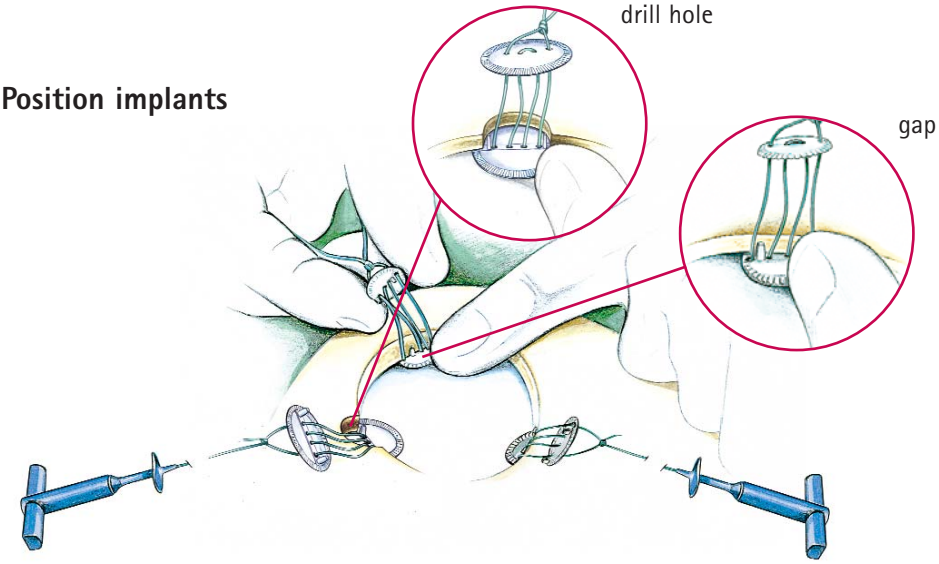
1| Position implants ...

2| Pull handle ...

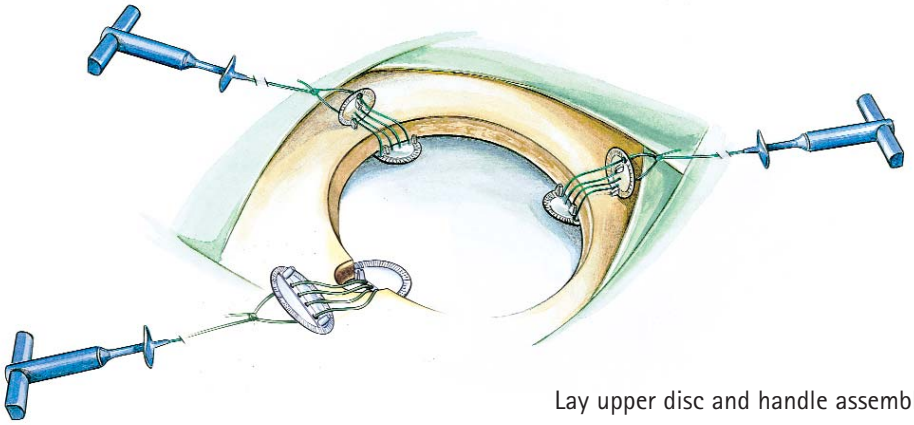
3| Cut suture.

Aesculap® CranioFix® absorbable

1. Position implants

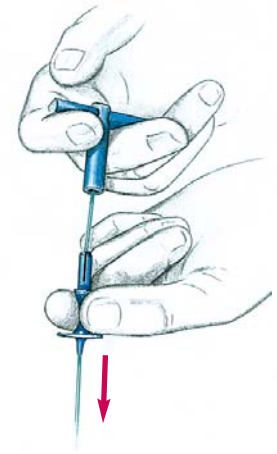


Place the lower disc of CranioFix absorbable between dura and skull.



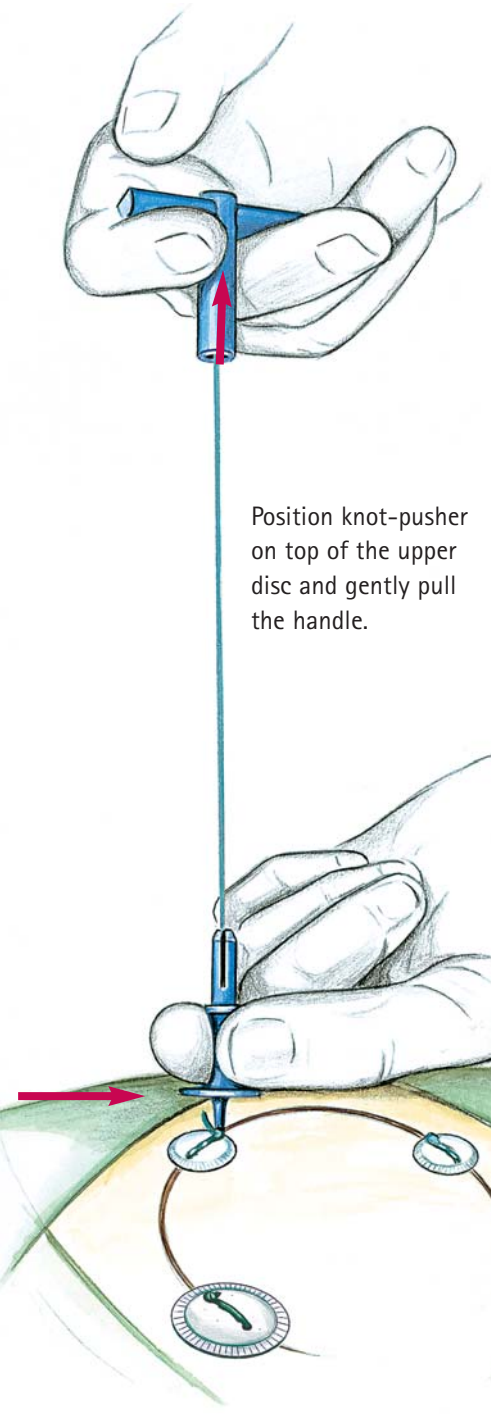
Lay upper disc and handle assembly down beside craniotomy. Replace the bone flap in its original position.

2. Pull handle

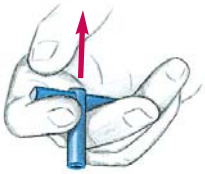


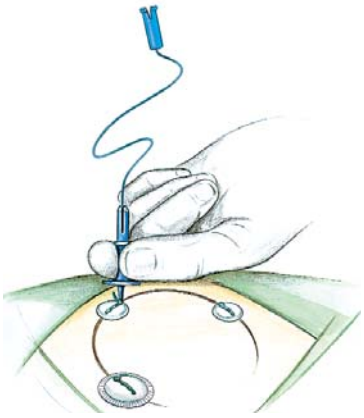
Release knot-pusher from handle.

The application – easy and fast.



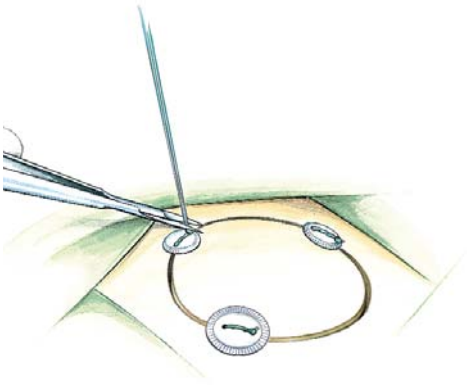
Position knot-pusher on top of the upper disc and gently pull the handle.





The integrated strain-relief mechanism disengages from the handle.

3. Cut suture



Tie an additional knot and cut the remaining suture.

For a detailed application description, please refer to the instructions for use.

The result – reliable and stable.

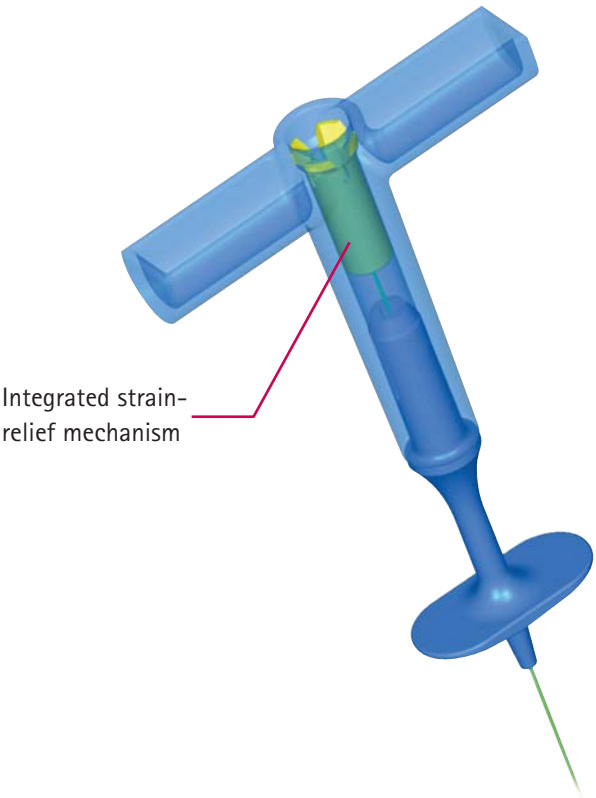
Aesculap® CranioFix® absorbable

Integrated strain-relief mechanism

- Integrated, patented strain-relief mechanism
- Reproducible fixation with defined force

Instrument-free application

- Sterile product assembly is ready for use
- No additional cutting instruments or appliers necessary
- No heating or contouring pen necessary



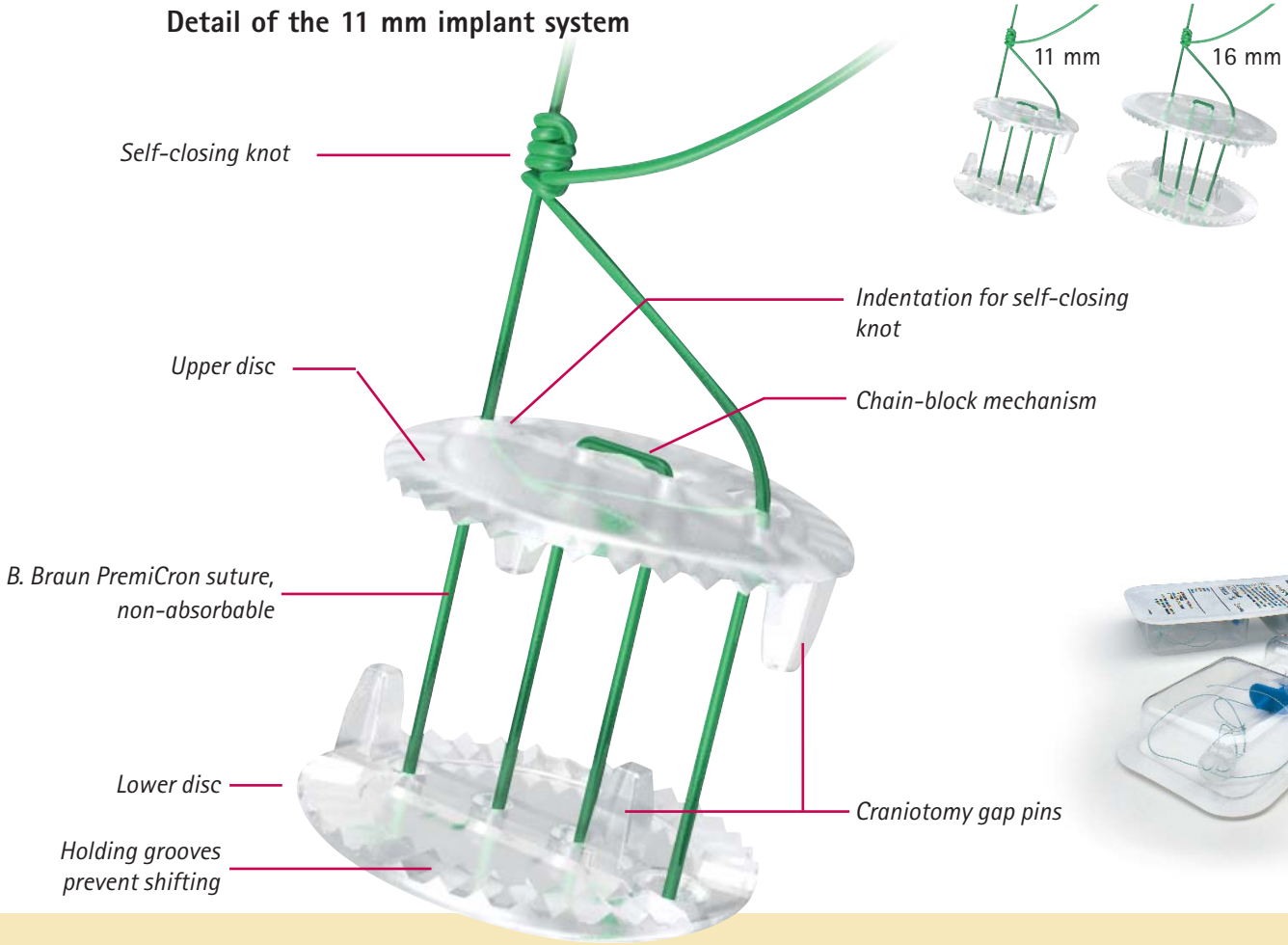
Osteoplastic outcome

- Smooth flat surface of low-profile implant
- Pre-fabricated knot sinks into indentation
- Knot is not palpable or visible

The smart art of cranial fixation.

Cranial chain-block fixation system.

Detail of the 11 mm implant system



Material

- Absorbable polyester implants [Poly (L-lactide-co-D, L-Lactide) 70:30]
- Non-absorbable suture (B. Braun PremiCron, USP 2/0)
- High biocompatibility

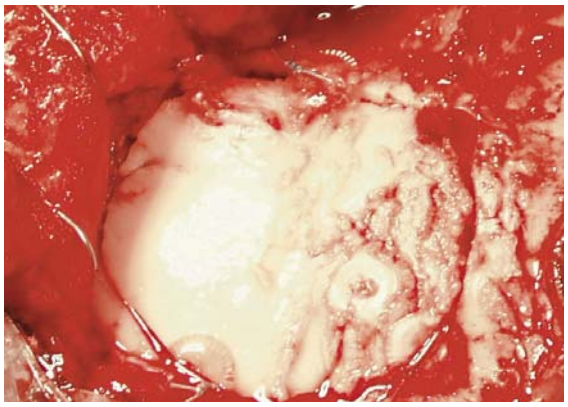
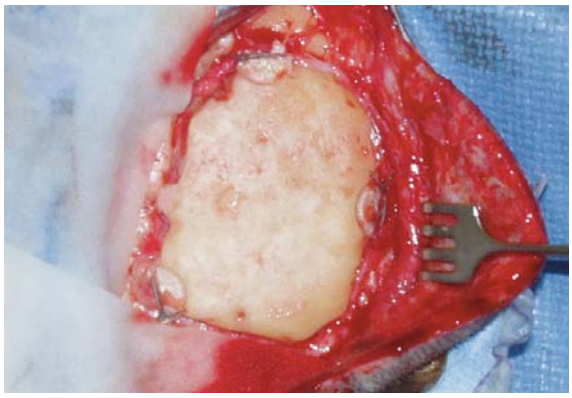
Craniotomy gap pins

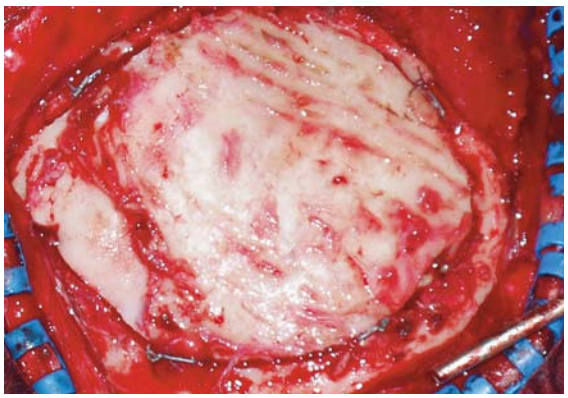
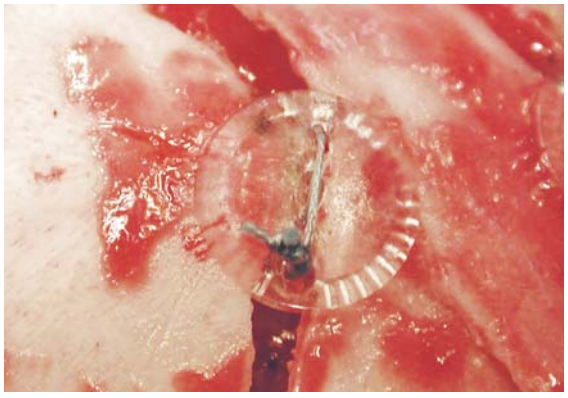
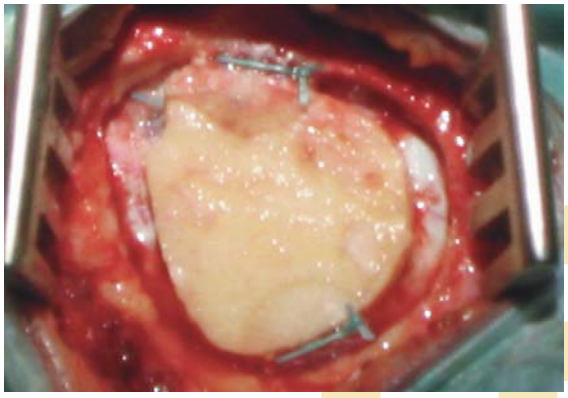
- Simplify positioning and centring of implants in craniotomy gap

No cleaning, reprocessing or sterilisation

- Product is delivered sterile
- All components are disposable
- No cleaning, reprocessing or sterilisation of additional instrumentation

Aesculap® CranioFix® absorbable

The results are impressive.

"CranioFix absorbable is very user friendly, very simple to use and has superior cosmetic results."

Thomas A. Kopitnik, Jr., M.D.
Professor, Department of Neurosurgery
Central Wyoming Neurosurgery
Mountainview Regional Hospital
Casper, WY, USA

"CranioFix absorbable is amazingly stable and easy to apply. Therefore, it is splendidly suitable as an absorbable fixation system."

Martin Bettag, M.D.
Professor and Head of the Department of Neurosurgery
Hospital of Barmherzige Brüder Trier
Trier, Germany

„I believe most neurosurgeons will find CranioFix absorbable the fastest and easiest system to use. The application does not require a drill or additional instrumentation. It is extremely useful in young children."

Kerry R. Crone, M.D.
Associate Professor of Neurosurgery and Paediatrics
Director of Paediatric Neurosurgery
Cincinnati Children´s Hospital Medical Center
Cincinnati, USA

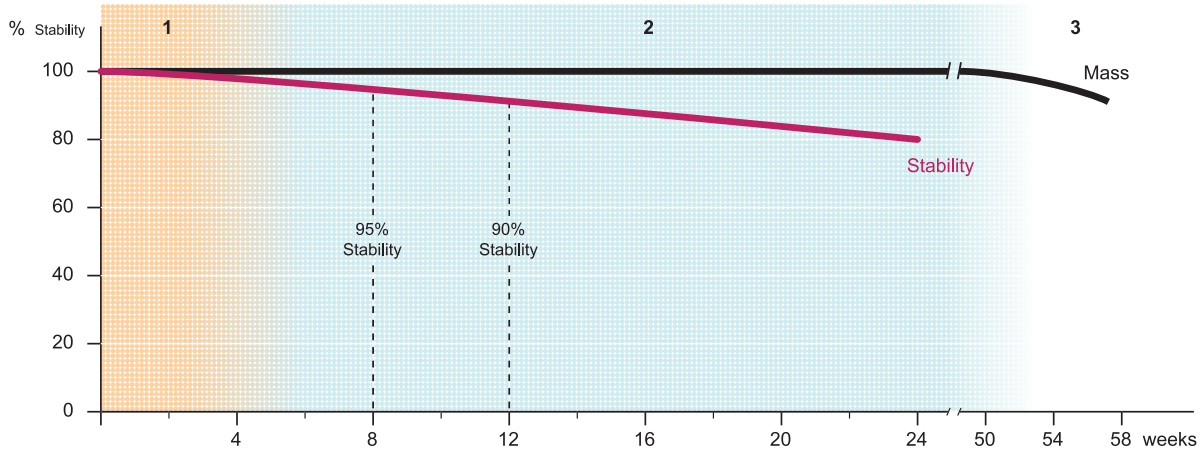
"The chain-block mechanism of CranioFix absorbable works efficiently and delivers a very stable fixation."

Nikolai Hopf, M.D.
Professor and Chairman
Department of Neurosurgery
Katharinenhospital Stuttgart
Stuttgart, Germany

Aesculap® CranioFix® absorbable

CranioFix absorbable in-vitro study: **stability and mass**

The in-vitro study measures the stability and mass of CranioFix absorbable implants (only for FF016) with 2 mm depression depth of the bone flap under hydrolysis conditions
[Internal study, Aesculap AG, idealized curves, 2003-2005]



1 | Hydration: Adsorption of water on polymer chains
2 | Loss of stability: Polymer chains start to break. Degradation of molecular weight
3 | Loss of mass: Further breakage of polymer chains. Formation of small granular particles.

Stability

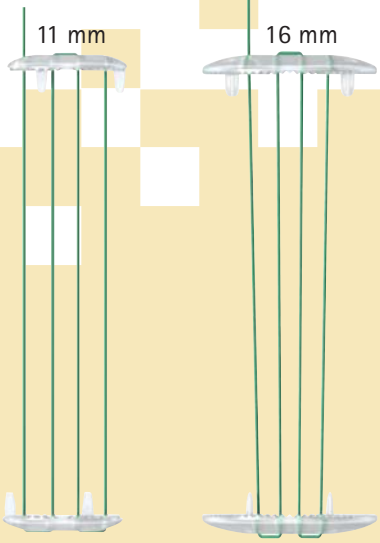
CranioFix absorbable is made from the clinically proven absorbable polyester material [Poly (L-lactide-co-D, L-Lactide) 70:30]. The non-crystalline material is characterized by high strength, excellent tissue compatibility and appropriate periods of degradation for the cranial skeleton. The in-vitro study has shown that CranioFix absorbable retains approximately 95% of its initial strength after 8 weeks and approximately 90% after 12 weeks. This provides enough strength during the osseo-integration process for adult and paediatric patients.

Degradation

The degradation of the co-polymer material occurs through hydrolysis and metabolization. During hydrolysis water (body fluids) enters the implant and breaks the polymer chains. Metabolization occurs as the single lactic acid molecules are finally metabolized by the citric acid cycle. The absorbable material completely disappears within 2-3 years.

CranioFix absorbable – packaging

The box contains 6 CranioFix absorbable implants. The products are individually double sterile packed in an aluminium foil pouch and an inner plastic blister pack.



FF016 **CranioFix absorbable, 11 mm, box of 6 implants**

FF017 **CranioFix absorbable, 16 mm, box of 6 implants**

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