

# Aesculap Neurosurgery

## CranioFix® absorbable

Absorbable cranial fixation system



Instrument-free, absorbable fixation system for cranial  
bone flaps

# CRANIOFIX® absorbable

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



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



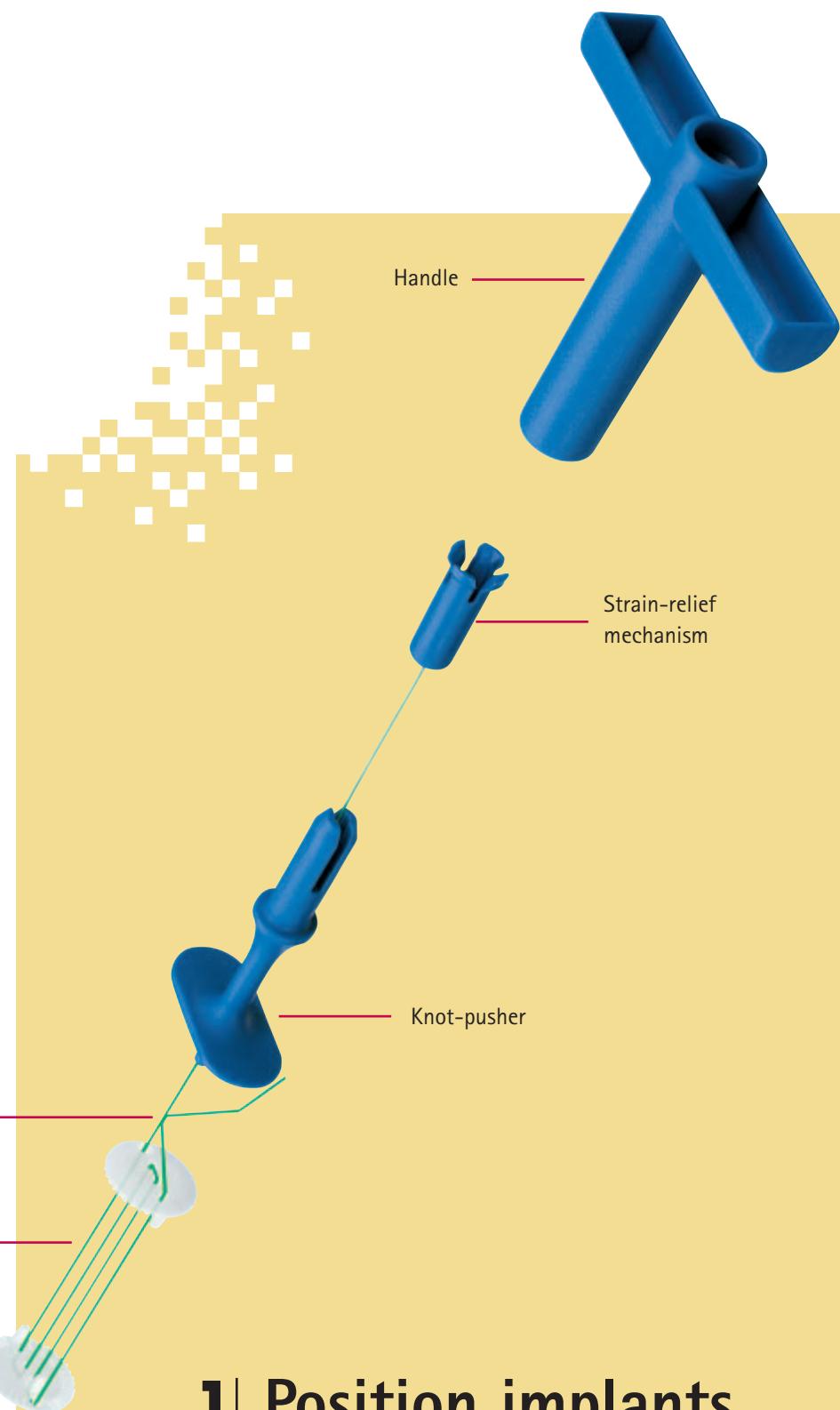
for all craniotomised  
bone flaps

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
- 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



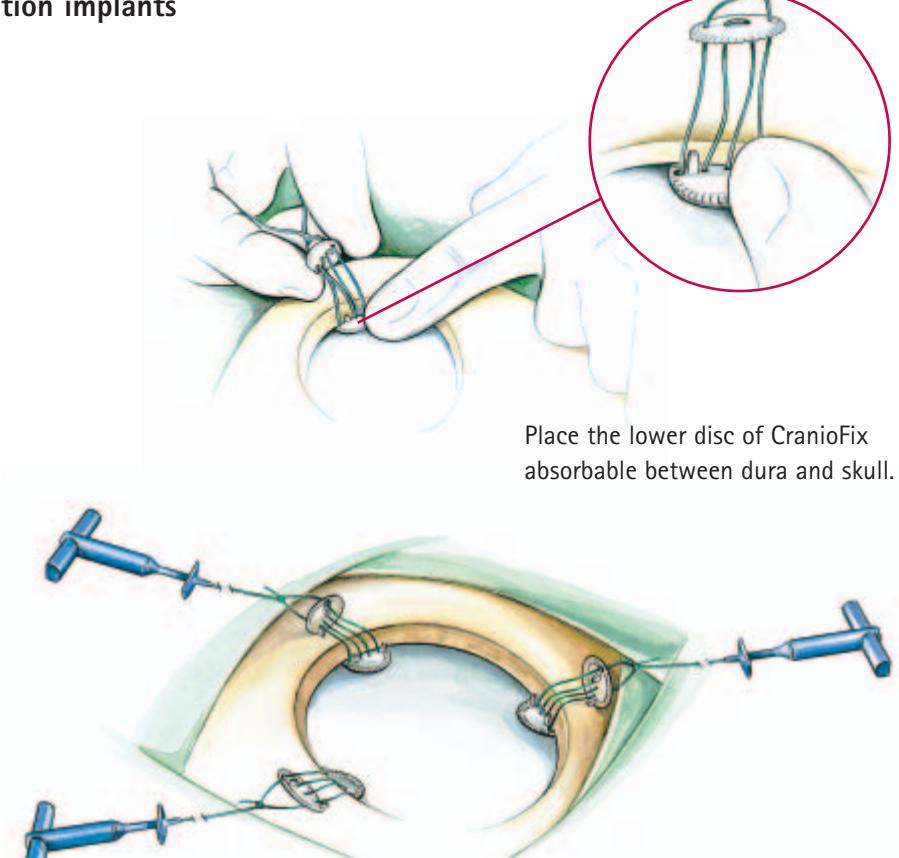
**1 | Position implants ...**

**2 | Pull handle ...**

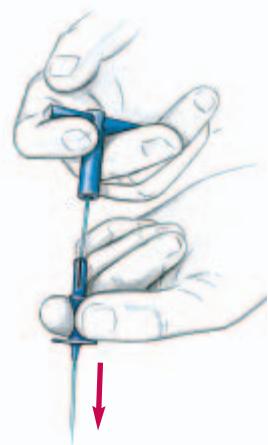
**3 | Cut suture.**

# CRANIOFIX® absorbable

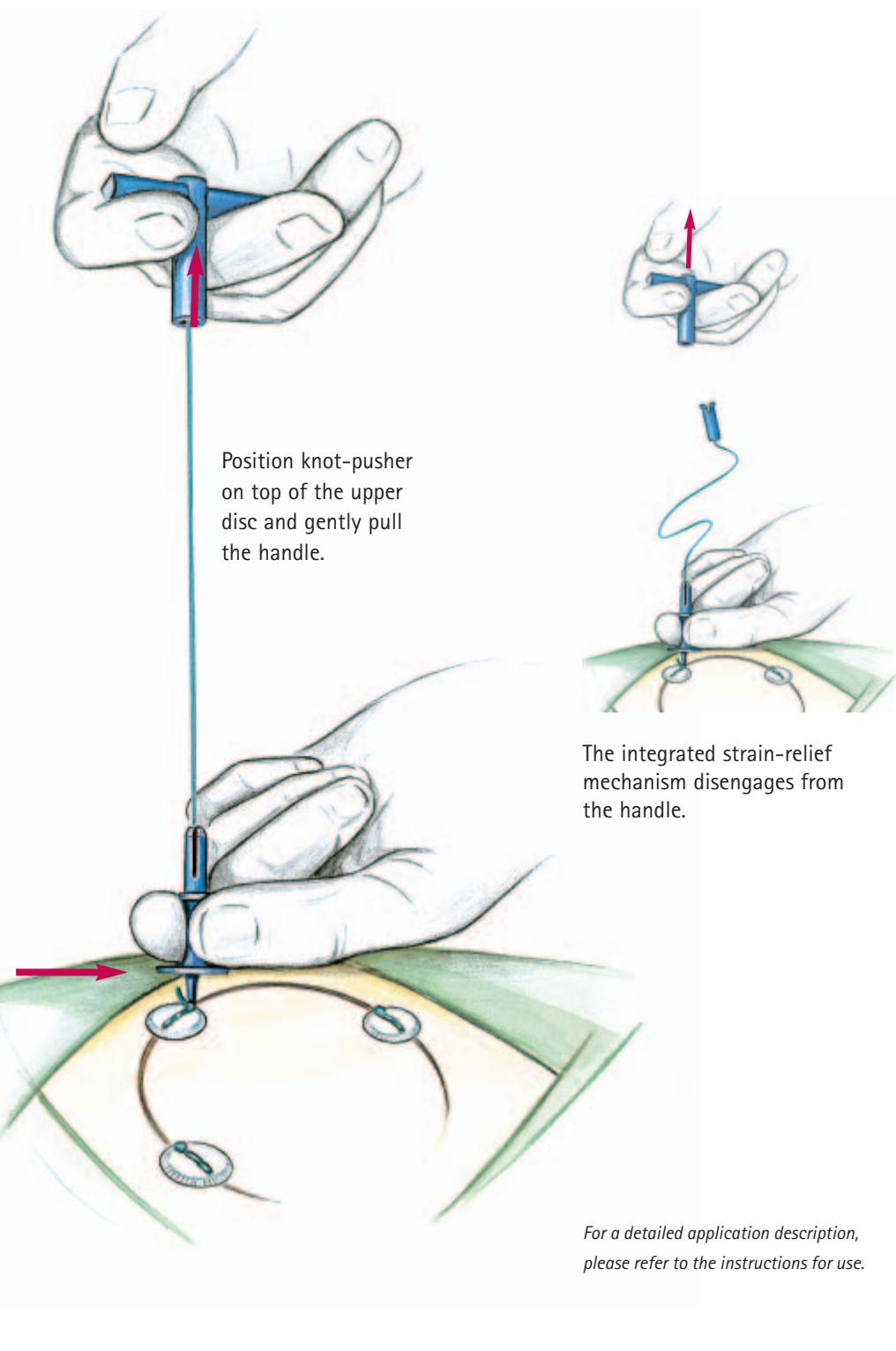
## 1. Position implants



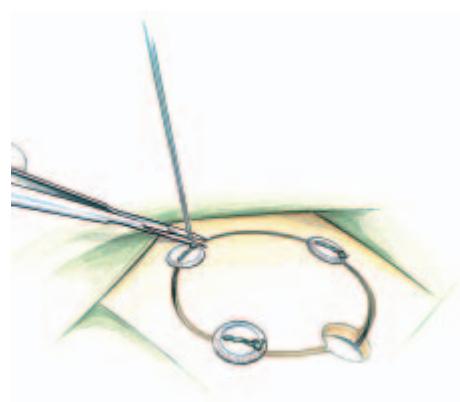
## 2. Pull handle



**The application – easy and fast.**



### 3. Cut suture



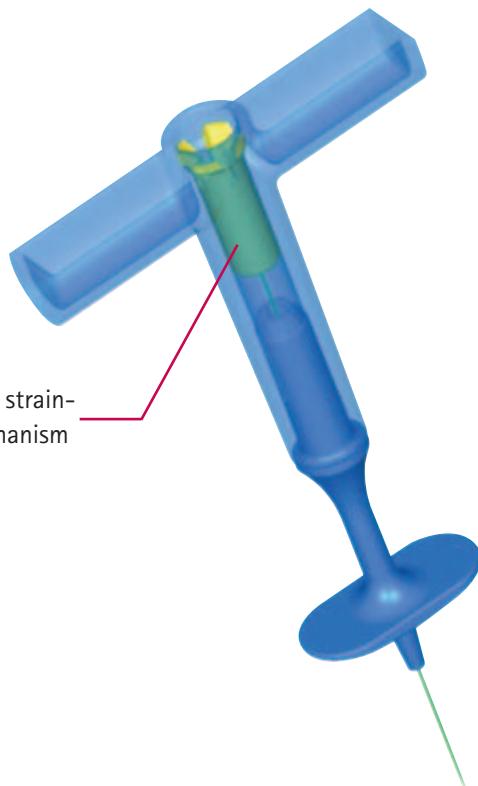
Tie an additional knot and cut the remaining suture.

# The result – reliable and safe.

# 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 applicators necessary
- No heating or contouring pen necessary



Integrated strain-relief mechanism

Self-closing knot sinks into indentation

## 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.



## Material

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

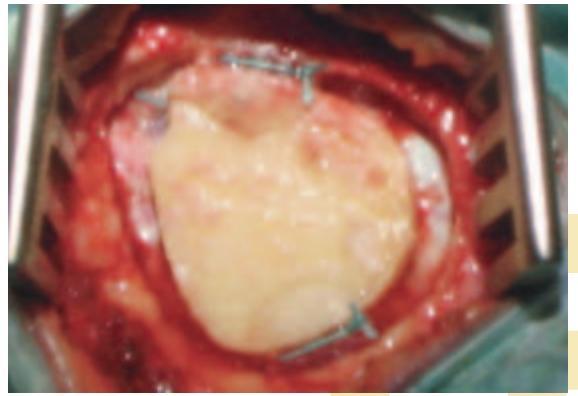
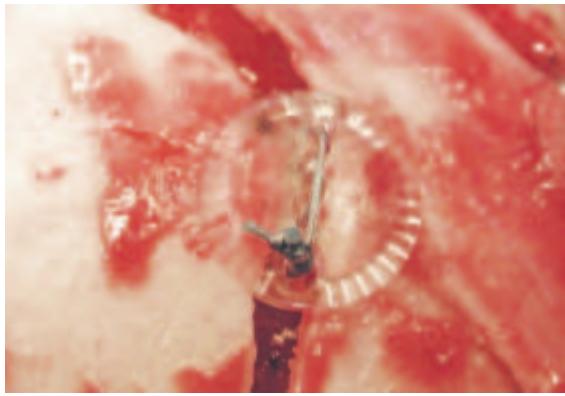
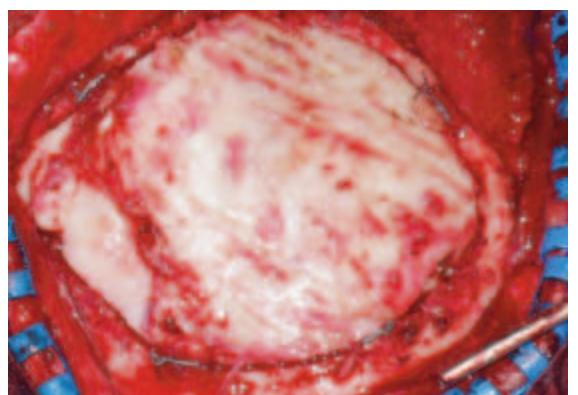
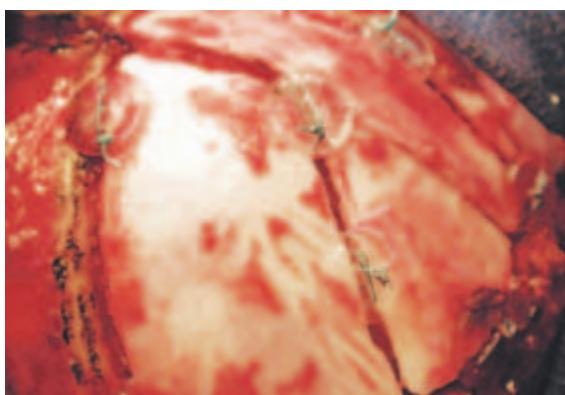
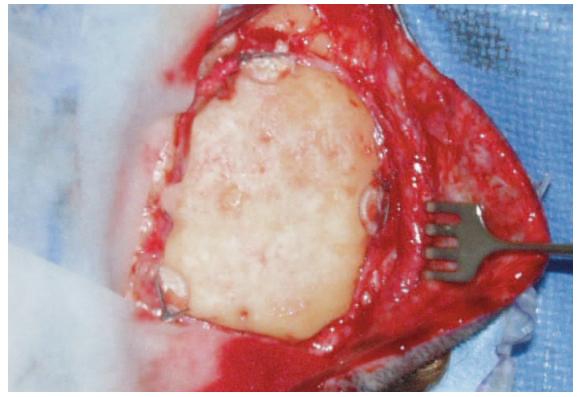
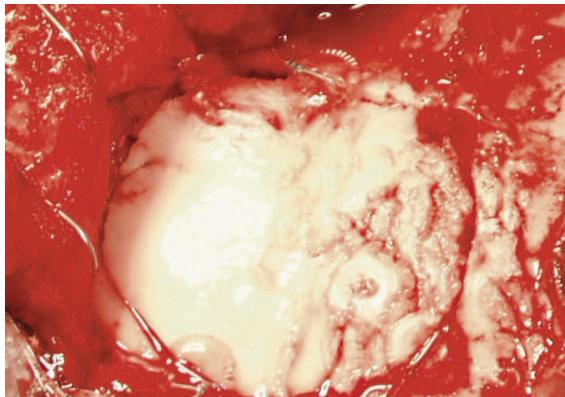
## No cleaning, reprocessing or sterilisation

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

## Craniotomy gap pins

- Simplify positioning and centring of implants in craniotomy gap

# CRANIOFIX® absorbable



The result is impressive.



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

Thomas A. Kopitnik, M.D.  
Professor, Department of Neurosurgery  
Wyoming Medical Center  
Casper, 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

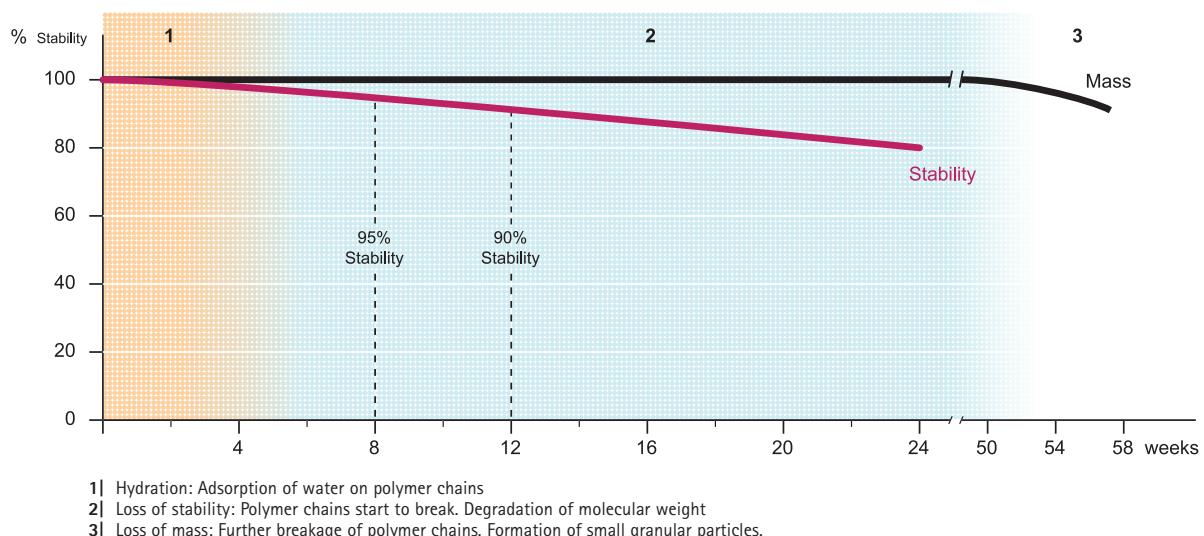
*"The chain-block mechanism of CranioFix absorbable works efficiently and delivers a very stable fixation."*

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

# CRANIOFIX® absorbable

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

The in-vitro study measures the stability and mass of CranioFix absorbable implants with 2mm depression depth of the bone flap under hydrolysis conditions [Internal study, Aesculap AG & Co. KG, idealized curves, 2003-2005]

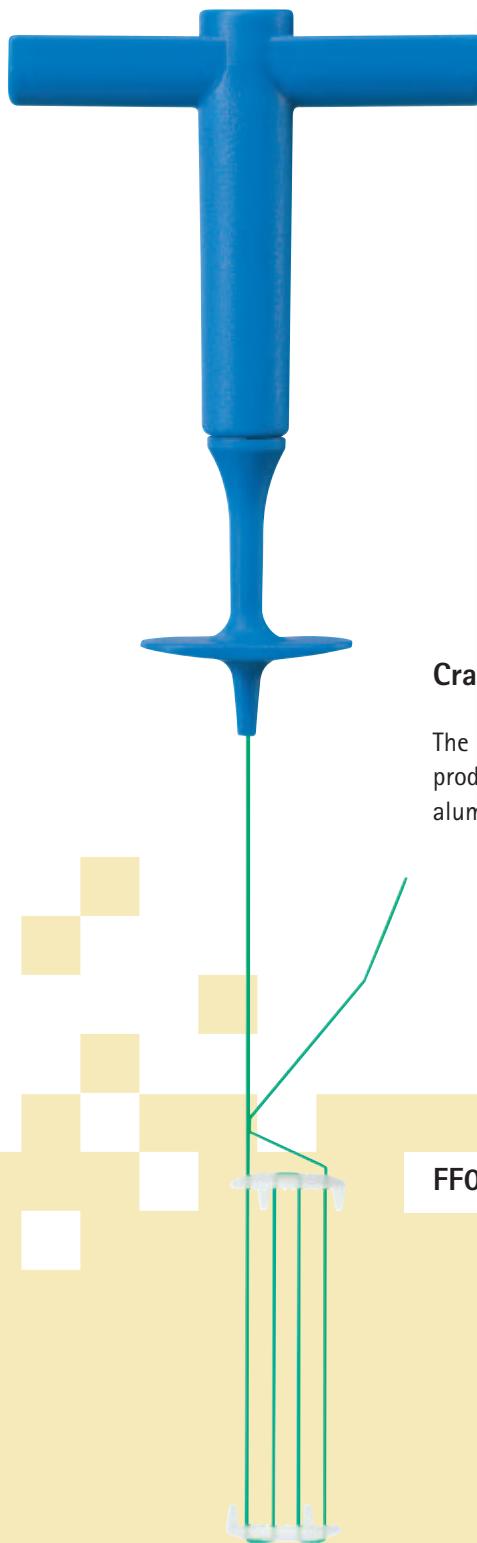


### Stability

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 osseointegration process for adult and paediatric patients.

### Degradation

The degradation of the co-polymer material occurs through hydrolysis and metabolism. 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, box of 6 implants**





# AESCALAP®

**B|BRAUN**  
SHARING EXPERTISE

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