Instructions for use/Technical description

CranioFix absorbable
Aesculap® CranioFix absorbable
CranioFix absorbable

Legend
1 Plastic applier
2 Handle
3 Spring piece
4 Knot pusher
5 Pre-knotted suture
6 Implant
7 Outer disk
8 Inner disk
9 Spacer pins

Intended use
The absorbable CranioFix implants are used for fixating bone flaps after a craniotomy. The implants support the stability for the required healing time before resorbing into smaller molecules, which are metabolized in the body.

The absorbable CranioFix implants comprise:
- one inner and one outer disk, made of absorbable material, as fixation elements,
- a pre-knotted suture connecting the two disks,
- a plastic applier, which is connected to the implant by the pre-knotted suture.

Materials
- Inner and outer disks:
  - Absorbable polyester [Poly(L-lactide-co-D, L-lactide) 70:30]
- Pre-knotted suture:
  - B. Braun PremiCron polyester suture

CranioFix absorbable implants do not contain any metals and do not impair the diagnostic power of MRT and CT images.

Indications
Surgically installed implants are designed to support the normal healing process. They are not intended for use either as replacements for natural body parts or to bear loads over the long term if healing does not occur. They serve to fixate the bone flaps and can bear loads up to the dead weight of the head.
**Contraindications**

The following list shows some, but not all conceivable contraindications:

- Systemic illnesses and metabolic disorders, allergies to the implant materials, inflammations in the region of the implant site, insufficient compliance and co-operation of the patient
- Bone conditions that rule out the application of CranioFix absorbable
- Alloplastic bone flap
- Degenerative bone diseases
- Missing dura mater
- Application in the facial skull (viscerocranium) and in the orbita or skull-base region
- Patients with existing fracture treatment of bone fragments
- Patients with a decompressed bone flap
- Acute or chronic infections in the region of the craniotomy, or systemic infections
- Severe damage to bone structures that could prevent a stable implantation of implant components (inadequate quality of the bone tissue)
- Bone tumors in the region where the implant is to be fixated
- Anticipated overload on the CranioFix absorbable implant

**Side effects and interactions**

- Changes in position, loosening, wear and tear on, or fracture of implant components
- Delayed or failed fracture healing, delayed or failed formation of connective tissue
- Primary and secondary infections
- Tissue reaction to implant materials
- Injury to blood vessels and nerves
- Hematomas and wound healing disorders
- Implantation failure due to:
- Loosening
- Inadequate fixation

**Safety notes**

**CAUTION**

Federal law restricts this device to purchase by, or on instruction by a physician!

- MRI examinations do not present any additional risk to implant wearers due to magnetically induced forces, heat and artefacts.
- It is the operating surgeon’s responsibility to ensure that the surgical procedure is performed properly.
- General risk factors associated with surgical procedures are not described in the present instructions for use.
- The operating surgeon must have a thorough command of both the hands-on and conceptual aspects of the established operating techniques.
- The operating surgeon must be fully conversant with bone anatomy, including the pathways of nerves, blood vessels, muscles, and tendons.
- It is the operating surgeon’s responsibility to ensure the correct combination of implant components and their implantation.
- Aesculap is not responsible for any complications arising from incorrect diagnosis, choice of incorrect implant, incorrectly combined implant components and/or operating techniques, the limitations of treatment methods, or lack of asepsis.
- Do not, under any circumstances, combine implant components from different manufacturers.
- Do not, under any circumstances, use damaged or surgically removed components.
- The implant components applied, along with their article numbers, the name of the implant, as well as the batch number and serial number (if available) must be documented in all patient records.
- Postoperatively, individual patient information, as well as mobility and muscle training, is of particular importance.
- To prevent implant damage, postoperative radiotherapy using neutrons, protons or heavy ions (particle radiation) must be avoided.
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Damage to the load-bearing structures of the implant may result in loosening of components, their dislocation and migration, and other severe complications.

To ensure the earliest possible detection of such factors favoring implant malfunction, the area of the craniotomy must be inspected postoperatively through the appropriate procedures.

CranioFix absorbable is suitable for bone flap fixation under the following conditions:

### Implant position

<table>
<thead>
<tr>
<th>Skull thickness &gt; 2.5 mm</th>
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<tr>
<td>Craniotomy gap</td>
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<td>1.3 mm to 2 mm</td>
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</table>

| FF016 | X | Ø 11 mm |
| FF017 | X | Ø 16 mm |

### Sterility

- The implant components come individually packed in protective packaging that is labeled according to its contents.
- The implant components are EO-sterilized (ethylene oxide).
- Store implant components in their original packaging. Remove them from their original protective packaging only just prior to application.
- Prior to use, check the product expiry date and verify the integrity of the sterile packaging.
- Do not use implant components that are past their expiration date or whose packaging is damaged.

- Avoid brief temperature peaks.
- Check the temperature indicator on the packaging. If the temperature indicator has changed color from gray to black, do not use the product and set it aside.

![Damage to implants caused by processing and resterilization!](image)

**WARNING**

Do not reprocess or resterilize the implants.

### Storage

- Do not expose product to direct sunlight.

![Product damage due to excessively high transportation and storage temperature!](image)

**WARNING**

Do not transport or store at a temperature permanently in excess of 25°C.
Application

The operating surgeon shall devise an operation plan that specifies and accurately documents the following:
- Selection of the implant components and their dimensions

The following conditions must be fulfilled prior to application:
- All requisite implant components are ready to hand.
- Operating conditions are highly aseptic.
- The operating surgeon and operating room team are thoroughly familiar with the operating technique and with the available range of implants and instruments; information materials on these subjects must be complete and ready to hand.
- The operating surgeon is fully conversant with the rules governing medical practice, the current state of scientific knowledge, and the contents of relevant scientific articles by medical authors.
- The manufacturer has been consulted if the preoperative situation was unclear and if implants were found in the area operated on.

The surgical procedure and following information has been explained to the patient, and the patient’s consent has been documented:
- The patient is aware of the risks involved in neurosurgery, general surgery, orthopedic surgery, and general anesthesia.
- The patient has been informed of the advantages and disadvantages of an absorbable implant and has been made aware of possible alternative materials (e.g. CranioFix made of titanium alloy).
- Excessive load or infection can lead to implant malfunctions.
- The fixation achieved with CranioFix absorbable is fundamentally inferior to the natural osseous bond.
- This is an absorbable implant that supports the fixation of the bone plate during the healing period of approx. 12 weeks.

- The patient must be made aware of the limits to the allowable load on the implant, and be informed of the appropriate rules concerning his or her behavior while carrying the implant. The risks of transgressing these rules must be explained to the patient.
- If the bone fusion is delayed or fails completely, the beginning resorption and resulting loss of rigidity of the implants mean that the implants will no longer be able to absorb the holding force and thus loose their holding functionality.
- The implant components must not be subjected to overload or to extreme strains from physical labor or sports activities.
- The patient must undergo regular medical follow-up examinations of the implant components.

WARNING

Loosening of the implant due to excessive strain!

- The patient must be warned of the risk of implant breakage or loosening caused by excessive physical activity, weight load on the operating site in excess of the dead weight of the head, or as a result of non-adherence to postoperative care instructions.
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Setup and handling of CranioFix absorbable

Keep CranioFix absorbable in its original packaging until immediately before application. This also applies for the aluminum packaging, which protects the product from humidity and light.

CranioFix absorbable is prepared through the following steps:

- Prior to use, check the expiry date and make sure that the sterile packaging is intact.
- Check the temperature indicator on the packaging. Do not use the product if the temperature indicator has changed color from gray to black.
- Unpack CranioFix absorbable.
- Check to make certain that the surfaces of CranioFix absorbable are not bent or damaged.

Application of the implants

The operating surgeon is responsible for the proper application of CranioFix absorbable.

Unstable bone flap fixation on the skull!

- Do not use CranioFix absorbable if the skull is exposed to loads beyond its dead weight.
- Only apply CranioFix absorbable in the cranial region.
- Do not use CranioFix absorbable in operations in which a permanent implant must be used.
- Use at least three implants.
- Place the spacing pins of the implants in the craniotomy gap.
- When using a FF017 in the burr hole: Position the suture line at an angle of 90° to the craniotomy gap.
- Do not turn the upper and lower disk of the implant.
- Make certain the implant is positioned correctly.

To ensure sufficient stability of a craniotomized bone flap, at least three CranioFix absorbable implants must be placed in an equilateral triangle arrangement, see Fig. 1.

Larger craniotomized bone flaps may require a larger number of CranioFix absorbable implants to ensure sufficient stability.
Inappropriate fixation or any combination with other fixation methods can result in the formation of steps, shifts within the calvarium and loosening and breakage of implant components.
Positioning the inner disk and pins in the craniotomy gap

- Slide in inner disk 8 between dura mater and lamina interna of the skull calotte. Apply outer disk 7 and the applier extracranially, see Fig. 5.

Fig. 5

- Position both pins of inner disk 8 at the wall of the craniotomy gap.

Arranging all implants in the craniotomy gap

- Position three CranioFix absorbable implants in an equilateral triangle arrangement.
- Do not turn the upper and lower disk of the CranioFix absorbable implants against each other, see Fig. 6.

Fig. 6

Positioning the bone flap

- Insert the bone flap in its original position.

Provisional fixation of the implants

- Pre-fixate the inner and outer disks (8 and 7) by gently pulling on plastic applier 1.
- Inner and outer disks (8 and 7) have to be positioned directly opposite to each other in the craniotomy gap.
- Both pins of the inner and outer disks must now be in the craniotomy gap.
- Repeat this procedure for all other implants.
- Pull off knot pusher 4 from handle 2, see Fig. 7.
Hold handle 2 in such a way that the suture is under slight tension and use knot pusher 4 to push the Röder knot into the knot depression in outer disk 7, see Fig. 8. Both pins of the inner and outer disks must now be in the craniotomy gap.

Final fixation of the implants

Hold knot pusher 4 with one hand while holding handle 2 with the other, see Fig. 9. Both pins of the inner and outer disks must now be in the craniotomy gap.

Carefully pull handle 2 until the automatic strain relief mechanism engages and handle 2 is released, see Fig. 10.

Repeat this procedure for all other implants.
Repeat this procedure for all other implants.

**Applying the safety knot**

**WARNING**

- Impaired stability caused by implantation without a safety knot!
  - Make certain that the automatic strain relief mechanism has been triggered.
  - Tie another safety knot with the free proximal ends of the suture.
  - Cut off the proximal ends of the suture in such a way that at least 3 mm are left between the safety knot and the suture ends.
  - Apply at least one more safety knot above the previously tied Röder knot; put the safety knot into the recess provided for this purpose.

**WARNING**

- Implant failure caused by suture rupture during the application of the safety knot!
  - Remove implant components and bone flap; remove other implant components.
  - Repeat application with new implants.
Cut off any excess suture length, see Fig. 11. When doing this, take care that the implant is securely fixated.

Fig. 11

- Repeat this procedure for all other implants.
- Carry out a stability check.

This completes the fixation of the bone flap in the craniotomy.

Handling CranioFix absorbable in a repeat intervention

The operating surgeon is responsible for any repeat surgical intervention and the appropriate procedure in this regard.

- Damage to the CNS and poor cosmetic results due to unstable fixation!
  - Carry out a stability check of the surgical provision.
  - Insert additional implants.

- Heating up of remaining plastic chips of CranioFix caused by milling of the implant!
  - Do not carry out any incision through a CranioFix absorbable implant.
  - Preferably carry out the second incision outside the original craniotomy incision. Alternatively, apply the second incision inside the original craniotomy incision (e.g. for anatomic reasons).

Further information on implant systems is available from B. Braun/Aesculap or the appropriate B. Braun/Aesculap office.

Distributor in the US/Contact in Canada for product information and complaints

3773 Corporate Parkway
Center Valley, PA, 18034,
USA