Instructions for use/Technical description
CRANIDFX2 titanium clamps Ø 11 mm, Ø 16 mm, Ø 20 mm

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Sharing Expertise

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CE mark - DIR 93/42/EEC
Aesculap®
CRANIOFIX2 titanium clamps Ø 11 mm, Ø 16 mm, Ø 20 mm

Legend
Fig. 1
1 CRANIOFIX2 titanium clamps FH49T/FH49T-UNI, Ø 11 mm
CRANIOFIX2 titanium clamps FH49T/FH49T-11, Ø 16 mm
CRANIOFIX2 titanium clamps FH49T/FH49T-20, Ø 20 mm
Fig. 2
1 CRANIOFIX2 titanium clamps FH49T/FH49T-11, Ø 11 mm
2 CRANIOFIX2 titanium clamps FH49T/FH49T-20, Ø 20 mm
Fig. 3
1 Correct position of CRANIOFIX2 titanium clamps FH49T/FH49T-11, Ø 11 mm
2 Incorrect position of CRANIOFIX2 titanium clamps FH49T/FH49T-20, Ø 11 mm
Fig. 4
1 CRANIOFIX2 titanium clamps
2 New craniotomy line
3 Old craniotomy line

Symbols on product and packages

STERILE: R
Stereile using Irradiation

This product is not for reuse in terms of its proper applications as defined by the manufacturer.

Use by

Caution, general warning symbol
Caution, see documentation supplied with the product

Product description
The Aesculap CRANIOFIX2 Titanium clamp system comprises sterile CRANIOFIX2 Titanium clamps for single use and diverse reusable neurosurgical instruments for applying titanium clamps.

Intended use
The Aesculap CRANIOFIX2 Titanium clamp system is used for fixing craniostereotized bone flaps and fractures at the brain skull (neurocranium). The CRANIOFIX2 Titanium clamp FH49T/FH49T-UNI, Ø 11 mm, is applied in the craniotomy gap (see Fig. 2) or in the fracture gap. The CRANIOFIX2 Titanium clamp FH49T/FH49T-11, Ø 16 mm, is applied in a trepanation hole of Ø 12 mm (see Fig. 3) or for bridging the defect in case of a fracture. The CRANIOFIX2 Titanium clamp FH49T/FH49T-20, Ø 20 mm, is applied in a trepanation hole of Ø 15 mm (see Fig. 3) or for bridging the defect in case of a fracture.

Materials
The CRANIOFIX2 Titanium clamps are made of titanium alloy (Ti6Al4V) acc. to ISO 5832-3. This titanium alloy is a biocompatible material. The CRANIOFIX2 Titanium clamps are non-ferromagnetic and MR-Conditioned up to 3T Tesla. Consequently, the magnetic fields applied during MRT tomography do not present any risk. Stronger magnetic fields or an enlargement of the imaging field can lead to a dramatically increased incidence of positioning errors and artifacts.

The size of the artifacts can vary considerably, depending on the MRT pulse-frequency, and compensate the significance of the MRT image if the area concerned is in the immediate vicinity (within a distance of some millimeters) of the clamp position.

Contraindications
The following list shows some, but not all conceivable contraindications:
- Patients with systemic diseases and operative disorders, susceptibility to metals or allergies against the implant materials, inflammations in the region of the implant site, and patients that show insufficient compliance and cooperation.
- Bone conditions that rule out the application of CRANIOFIX2 Titanium clamps.
- Artificial cranial bone flaps
- Bone tumors in the area on which the implant is supported
- Degenerative bone diseases
- Missing dura mater
- Application in the facial skull (viscerocranium) and in the orbita or skull-base regions

Notes
The following list shows some, but not all, conceivable contra-indications:
- Improper fixation or combination with other fixation methods (bolts, mini plates or clamp systems from other manufacturers) can lead to step formation, position shifts of the skull calotte and loosening or breakage of imperfections. For maximum stability of a craniofixated bone flap, we recommend using three CRANIOFIX2 Titanium clamps in a triangular arrangement. Larger bone flaps or multiple fragments of a skull fracture, additional CRANIOFIX2 Titanium clamps may be required to ensure adequate stability.
- During application of CRANIOFIX2 titanium clamps, friction between the upper titanium disc and the pin indentation can lead to spark formation. Appropriate safety measures must be taken in order to prevent this. Because of the fire hazard, surgical interventions of this kind must not be carried out in rooms where flammable anesthetics or other flammable gases, liquids, objects or oxidizing agents are stored.
- After the operation, exceptionally high mechanical loads on the fixed bone flap must be avoided.

Safety measures
The operating surgeon should be thoroughly familiar with the surgical techniques required for using this product. The operating surgeon is responsible for the proper application of the CRANIOFIX2 titanium clamps. The operating surgeon is also responsible for complications resulting from misdiagnosis and flawed operation techniques.

Possible side effects
Infections, damage to nervous tissue, hematoma and wound dehiscence are among the general perioperative risks. The patient should be made aware of these risks as well as other risks of neurosurgery, general surgery and the administration of anesthetics.

MRI Information
Non-clinical testing demonstrated that the CRANIOFIX2 System is MRI Conditional. A patient with this device can be scanned safely, immediately after placement under the following conditions:
- Static magnetic field of 1.5-Tesla or less
- Maximum spatial gradient magnetic field of 3,000 Gauss/cm or less
- First Level Controlled Operating Mode, with a maximum whole-body averaged SAR of 4-W/kg

MRI-Related Heating
In non-clinical use, the CRANIOFIX2 System produced the following temperature rises during MRI performed for 15 min of scanning (e.g., per pulse sequence) in 1.5 Tesla MRT (Magnetom, Siemens Medical Solutions, Malvern, PA). Numerical Simulation 2002 BHS Active-shielded, horizontal field scanner) and 3 Tesla (T2, Tesla/1.5T MRI, Excite, HDx, Horizon, Neuroguide, Mri, General Electric Healthcare, Milwaukee, WI) MRT Systems:
- First Level Controlled Operating Mode, scaled to whole body averaged SAR of 4-W/kg, highest temperature change

Material Information
The image quality must be compromized if the area of interest is in the exact same area or relatively close to the position of the CRANIOFIX2 System. Therefore, in case of possible exposure, observe the indications for the presence of this device may be necessary. The maximum artifact size (e.g., as seen on the gradient echo pulse sequence) extends approximately 6 mm relative to the size and shape of this implant.

Artificial bone
The bone material must not be disintegrated or altered with any instruments, as these instruments may alter the bone material. The bone material must not be disintegrated or altered with any instruments, as these instruments may alter the bone material.

Delivery format
Aesculap CRANIOFIX2 titanium clamps are delivered in sterile condition and are designed for single use only. The CRANIOFIX2 titanium clamps must not be sterilized.

Provision and handling of the implants

CAUTION
Federal law restricts this device to sale by or on the order of a physician

Damage to destruction of the titanium clamps caused by using a non-compatible applicator:
- Use the CRANIOFIX2 applicator (FH49T) only for CRANIOFIX2 titanium clamps (FH49T/FH49T-UNI). If used, the CRANIOFIX2 titanium clamps may become damaged.
- Use the CRANIOFIX2 applicator (FH109R, FH106R, and FH107R) only for the CRANIOFIX2 titanium clamps (FH90T/FH90T).

Prior to the surgical intervention, the operating surgeon must prepare an operation plan in order to ensure that a sufficient number of sterile CRANIOFIX2 titanium clamps are available. Aesthetically appropriate conditions are in place, the CRANIOFIX2 applicator required and other CRANIOFIX2 instruments are complete and ready for operation, and the operating surgeon and the OR team are familiar with the instruments and operation technique. The craniotomy incisions must be performed in an osteodense fashion.

Proper handling of the CRANIOFIX2 titanium clamps before and during the operation is essential for successful bone flap fixation.

Application of CRANIOFIX2 titanium clamps

CAUTION
The Aesculap CRANIOFIX2 titanium clamp Ø 16 mm may only be applied in a trepanation hole of Ø 12 mm (see Fig. 3) or for bridging the defect in case of a fracture.

The Aesculap CRANIOFIX2 titanium clamp Ø 20 mm may only be applied in a trepanation hole of Ø 15 mm (see Fig. 3) or for bridging the defect in case of a fracture.

The operating surgeon is responsible for the proper application of the CRANIOFIX2 titanium clamps. For maximum stability of one bone flap approx. 20 cm² in size, we recommend applying three CRANIOFIX2 titanium clamps in the craniofixation gap or the trepanation hole, respectively, at equal distances from each other. Figure 2 shows a typical application of a craniofixated bone flap.

The following is a brief description of the surgical procedure:
1. Position the three CRANIOFIX2 titanium clamps in equal distances to each other at the bone flap.
2. The lower discs are positioned in the dura mater and the calvarium.
3. Replace the bone flap in its original position.
4. Apply the holding forces on the CRANIOFIX2 titanium clamp. To ensure a safe fixation and avoid damage to the pin indentation, the pin of the CRANIOFIX2 titanium clamp must be held in the recess intended for this purpose.
5 Position the CRANIOFIX2® applicator over the pin of the CRANIOFIX2® titanium clamps.
6 Compress the handle of the CRANIOFIX2® applicator so that the upper disk approaches the lower disc along the pin indentation.

The spring needs engage in the pin indentation of the CRANIOFIX2® titanium clamp, with an audible "click."
7 Do not remove the holding forceps until immediately before closing the CRANIOFIX2® titanium clamp.
8 The CRANIOFIX2® applicator is equipped with an automatic strain relief mechanism, which ensures that the CRANIOFIX2® applicator is disengaged as soon as the maximum allowable force is applied. Once the CRANIOFIX2® applicator has disengaged, the handle should be fully compressed several times until there is no more audible clicking of the spring rods as they engage in the indentation of the pin of the CRANIOFIX2® titanium clamp.

![CAUTION]
The top disk can loosen after application if the pin is not cut off properly!  
- After tightening the top disk, cut the excess pin off at a right angle to the pin's axis using the CRANIOFIX cutting forceps.
- Be sure that the indentation above the top disk remains completely intact.

9 Use the cutting forceps to remove the remaining, outward projecting portion of the pin. When doing so, the protruding pin of the CRANIOFIX2® titanium clamp must be held securely to prevent the pin from snapping off into the operation field in an uncontrollable manner.

10 The same procedure is carried out with the other CRANIOFIX2® titanium clamps.

The surgical procedure for applying CRANIOFIX2® titanium clamps is described in the CRANIOFIX2® brochure and in the literature kit (www.anculap.de). Please address any inquiries in this respect to your Anculap Medical Products Consultant, or contact us directly:

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Patient ID
The patient ID serves to keep a written record of important information on the implanted CRANIOFIX2® titanium clamps and the surgical intervention that was carried out:

- Patient data
- Hospital data
- Date of provision
- Physician in charge and hospital
- Art. no. and lot no. of the CRANIOFIX2® titanium clamps implanted

To facilitate the postoperative radiological examination, each patient should be issued with a Patient ID, which can be ordered separately from Anculap. Please address any inquiries in this respect to your Anculap Medical Products Consultant, or contact Anculap directly.

Accessories

<table>
<thead>
<tr>
<th>Art. no.</th>
<th>Designation</th>
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<tbody>
<tr>
<td>FF480T</td>
<td>CRANIOFIX2® titanium clamp ø 11 mm</td>
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<tr>
<td>FF480T-UNI</td>
<td>CRANIOFIX2® titanium clamp ø 11 mm</td>
</tr>
<tr>
<td>FF491T</td>
<td>CRANIOFIX2® titanium clamp ø 16 mm</td>
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<tr>
<td>FF491T-UNI</td>
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<td>FF492T</td>
<td>CRANIOFIX2® titanium clamp ø 20 mm</td>
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<tr>
<td>FF492T-UNI</td>
<td>CRANIOFIX2® titanium clamp ø 20 mm</td>
</tr>
<tr>
<td>FF494T*</td>
<td>CRANIOFIX2® applicator, cannot be disassembled</td>
</tr>
<tr>
<td>FF105R*</td>
<td>CRANIOFIX2® holding forceps</td>
</tr>
<tr>
<td>FF103R*</td>
<td>CRANIOFIX2® cutting forceps</td>
</tr>
<tr>
<td>FF104R*</td>
<td>CRANIOFIX2® removal forceps</td>
</tr>
<tr>
<td>FF84P</td>
<td>CRANIOFIX2® storage tray</td>
</tr>
</tbody>
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* Concerning the handling, functioning and reprocessing of this product, the instructions for use TAC 01161 must be observed.

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

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