

FlapFix. Quick and stable fixation of cranial bone flaps following a craniotomy.

Technique Guide
with Application
Forceps



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FlapFix. Quick and stable fixation of cranial bone flaps following a craniotomy.

One instrument. Quick fixation.

The Synthes FlapFix system is an innovative cranial clamping solution that allows surgeons to apply implants with a single instrument. The specially designed Application Forceps provides surgeons with the ability to affix cranial bone flaps quickly and with only one hand. The titanium implants are available textured or smooth, in four sizes, and can be shipped sterile or nonsterile.

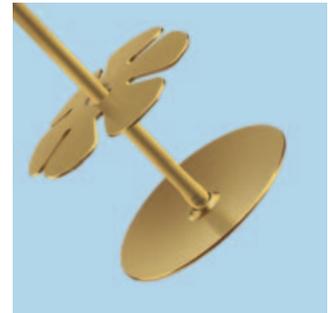
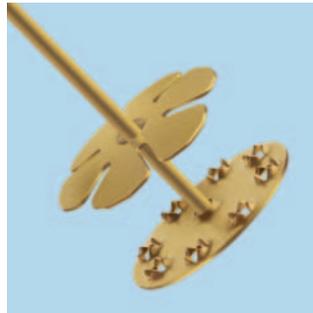
FlapFix

The implants combine a low profile and an anatomical fit.

The implants are made of pure titanium and are available in various sizes, including a textured version.

Features/benefits

- A low profile for minimal palpability
- An anatomic fit is achieved by the clover-leaf design of the top disk. This allows the implant to adapt to the shape of the cranium
- Available in four diameters: 11 mm, 13 mm, 18 mm, and 22 mm
- Offered with smooth or textured bottom disks
- Specially designed smooth disk edges
- Available in sterile and nonsterile packaging



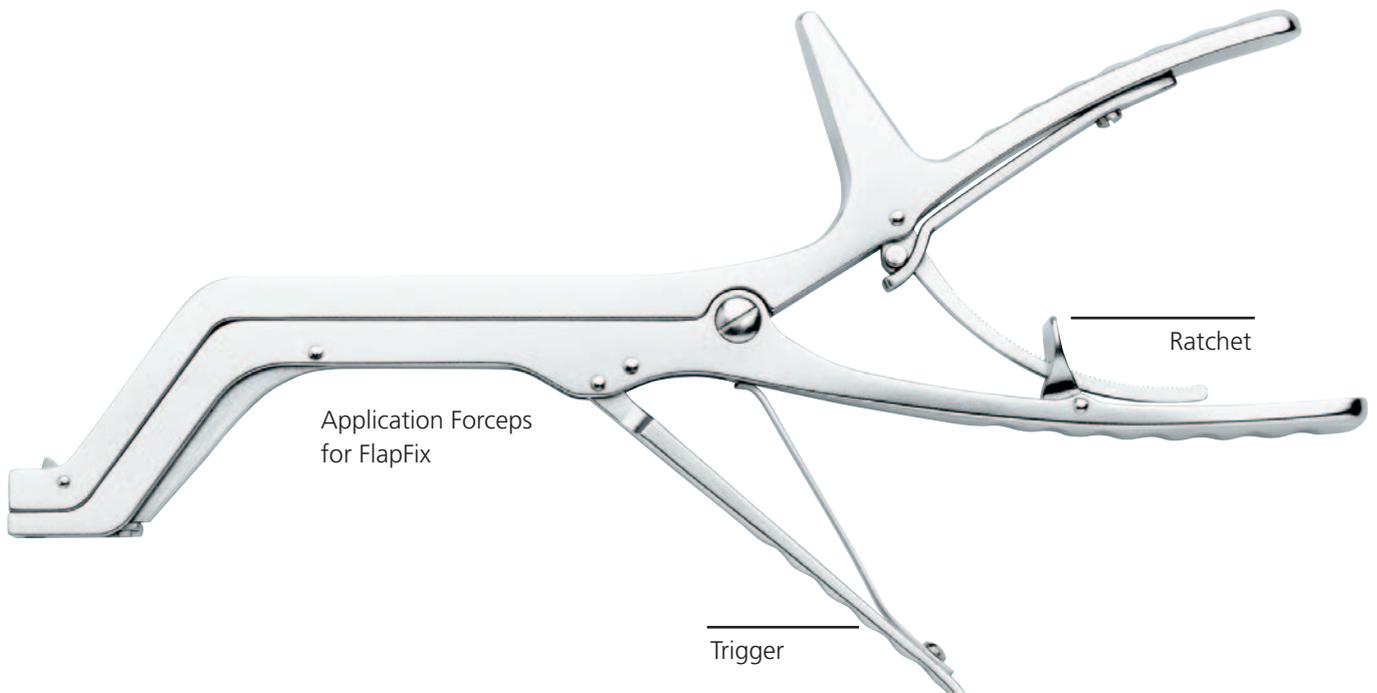
Application Forceps for FlapFix

The Application Forceps is the only instrument needed to perform all aspects of craniotomy closure.

This single-instrument system means less complexity and a shorter application time for the surgeon.

Features/benefits

- Only one instrument is needed for tensioning and cutting of the FlapFix
- Tensioning to a secure fit and cutting of the tube is done with a single, easy "firm handshake" action
- Ergonomic design for either right- or left- handed operation prevents slippage
- Easy access to the operation site due to deflected tip



AO Principles

In 1958, the AO formulated four basic principles listed below, which have become the guidelines for internal fixation.^{1,2} These products were designed with these principles in mind.

Anatomic reduction

Fracture reduction and fixation to restore anatomical relationships.

Stable fixation

Stability by fixation or splintage, as the personality of the fracture and the injury requires.

Preservation of blood supply

Preservation of the blood supply to soft tissue and bone by careful handling.

Early, active mobilization

Early and safe mobilization of the part and patient.

1 Müller ME, Allgöwer M, Schneider R, Willenegger H (1995) Manual of Internal Fixation. 3rd, expanded and completely revised ed. 1991. Berlin, Heidelberg, New York: Springer

2 Rüedi TP, Buckley RE, Moran CG (2007) AO Principles of Fracture Management. 2nd expanded ed. 2002. Stuttgart, New York: Thieme

Indications and Contraindications

Intended Use

Closure of craniotomies due to fixation of the bone flap.

Indications

Closure of craniotomies in adult patients with cranial tumors, hematoma, aneurysm or other cranial indication.

Contraindications

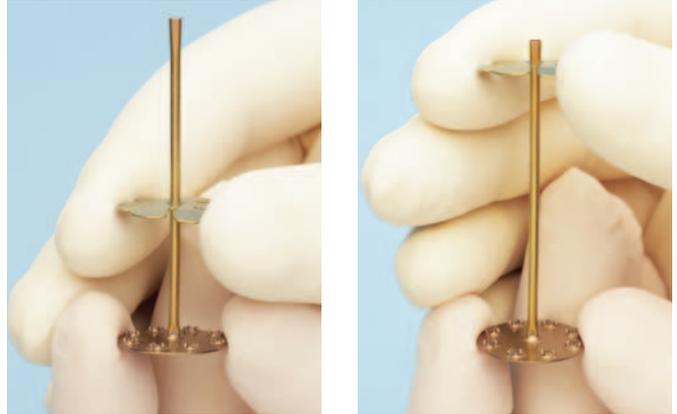
FlapFix is not intended for use in pediatrics.

Surgical Technique

1

Position top disk

Manually slide the top disk toward the upper end of the tube until it locks in place. Repeat this procedure for the remaining implants.



2

Position implant

Arrange at least three implants equidistant around the craniotomy by inserting the bottom disks between the dura and the cranium.

Note: Select the appropriate sized disk to ensure there is adequate overlap of the disk and bony surfaces.



3

Replace cranial bone flap

Replace the cranial bone flap to its original position.



4

Lower top disk

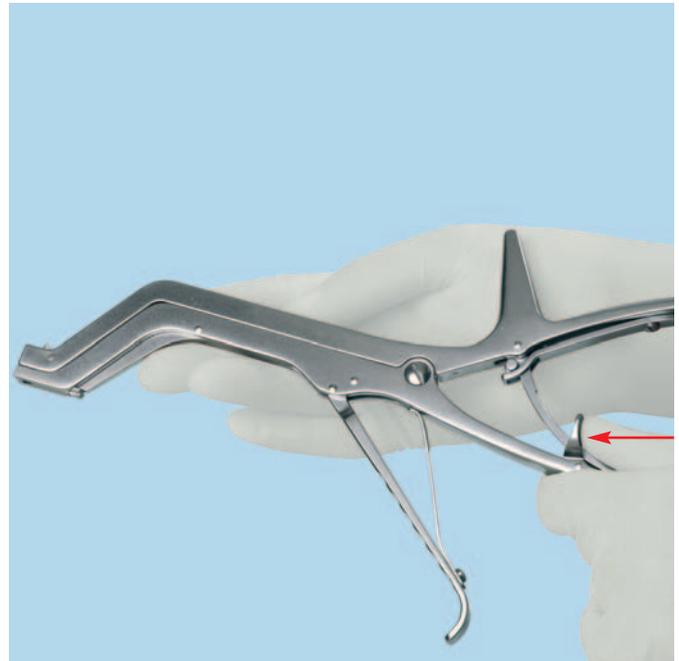
To prevent the bottom disk from pressing against the dura, grasp the connecting tube with two fingers while gently loosening the top disk. Slide the top disk down to the cranium. Repeat this procedure for the remaining implants.



5

Prepare application forceps

Push the ratchet forward (see arrow). During this procedure, the application forceps must be closed at the front.



6

Apply tension to implant

Instrument

329.315 Application Forceps, for FlapFix

Thread the implant tube through the instrument tip and lower the instrument to the top disk. Squeeze the instrument to apply tension to the implant (firm handshake).

Note: Excessive tension does not need to be applied to the implants to ensure stable fixation of the bone flap. Excessive force can cause the lower disc to be pulled out. Ensure that the application forceps lies flush against the cranial surface during the entire procedure.



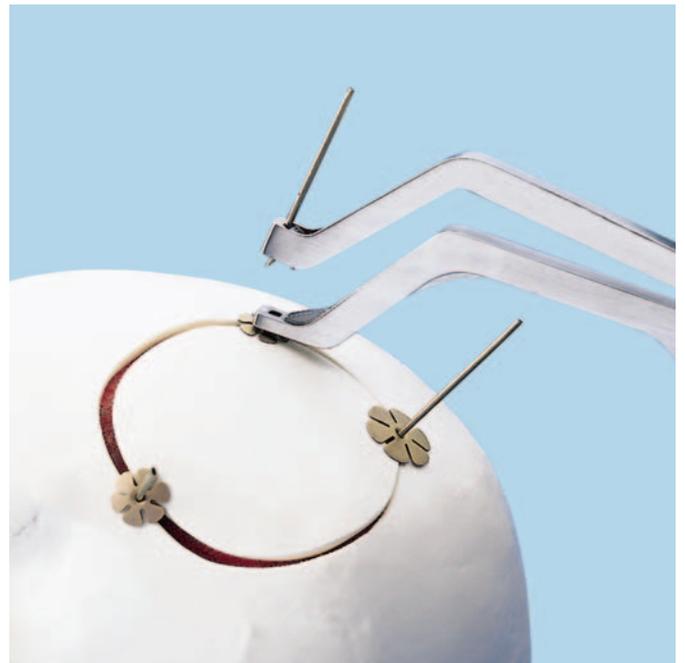
7

Crimp and shear center tube

While maintaining tension on the clamp, crimp and shear the center tube of the clamp by squeezing the crimping device trigger (see arrow).

Release the ratchet to close the device.

Repeat steps 5–7 for the remaining implants.



Implant Removal

Implant removal

Instrument

398.960 Stagbeetle Forceps, 120 mm

Use stagbeetle forceps to grasp the clover-leaf disc between its petals. Remove the disc by tilting the forceps slightly toward the center of the cranial bone flap. Repeat this procedure for the remaining clamps. Lift off the bone flap and remove the lower discs.

Note: The FlapFix are for single use only and must be discarded after removal. Use new FlapFix to reattach the cranial bone flap.



Implants

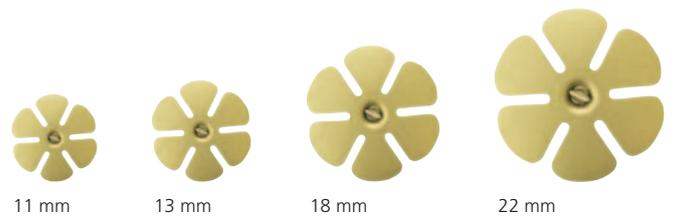
FlapFix*

460.100	11 mm diameter
460.001	13 mm diameter
460.002	18 mm diameter
460.003	22 mm diameter



FlapFix, textured*

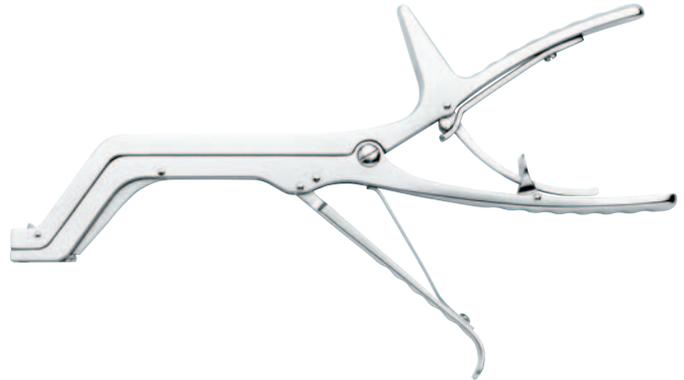
460.107	11 mm diameter
460.008	13 mm diameter
460.009	18 mm diameter
460.010	22 mm diameter



* Available nonsterile or sterile-packed. Add ".015" to product number for sterile product.

Instruments

329.315 Application Forceps, for Cranial Flap Tube Clamp



398.960 Stagbeetle Forceps, 120 mm





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