

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

Technique Guide
with Application
Instrument



Table of Contents

Introduction	FlapFix	2
	AO Principles	4
	Indications and Contraindications	4

Surgical Technique	Surgical Technique	5
	Implant Removal	11

Reprocessing, Care & Maintenance		12
---	--	----

Product Information	Implants and Instruments	14
	Set	15

Warning

This description alone does not provide sufficient background for direct use of the instrument set. Instruction by a surgeon experienced in handling these instrument is highly recommended.

Reprocessing, Care and Maintenance of Synthes Instruments

For general guidelines, function control and dismantling of multipart instruments please refer to: www.synthes.com/reprocessing

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

One instrument. One step. Quick fixation.

The Synthes FlapFix System is an innovative cranial clamping solution that allows surgeons to apply implants with a single instrument in a single, simple motion. The specially designed application instrument provides surgeons with the ability to affix cranial bone flaps quickly and with only one hand.

The titanium implants are textured or smooth, in four sizes, and can be shipped sterile or non-sterile.

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 non-sterile packaging



Application instrument

The application instrument is the only instrument needed to perform all aspects of craniotomy closure. With only a single hand action, a clamp can be closed quickly and smoothly.

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



Features/Benefits

- Only one instrument is needed for crimping, tensioning, and cutting of the FlapFix
- Pre-crimping of implants is performed in a single, easy hand movement with a specially designed crimping side. Crimping allows the bone flap to be held in place and repositioned, if necessary, before the final tightening
- Tensioning to a secure fit and cutting the tube is done with a single and easy “closing hand” action
- Side insertion of the implant into the application instrument prevents depression of the dura
- Ergonomic design for either right or left handed operation



Crimping side



Cutting side

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 mobilization

Early and safe mobilization of the part and patient.

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, haematoma, aneurysm or other cranial indication.

Contraindications

FlapFix is not intended for use in paediatrics.

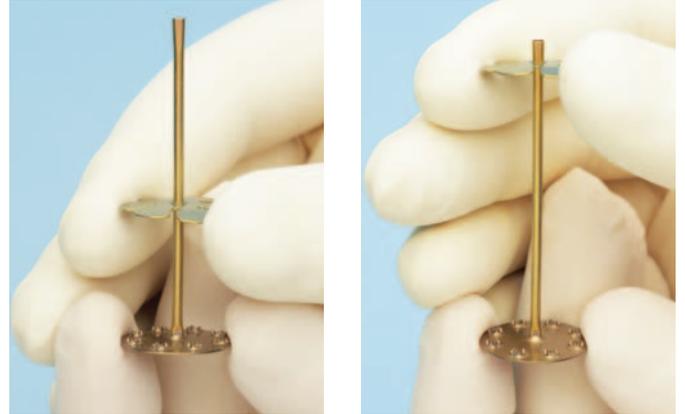
¹ Müller ME, Allgöwer M, Schneider R, Willenegger H (1995) Manual of Internal Fixation. 3rd, expanded and completely revised ed. 1991. Berlin, Heidelberg, New York: Springer

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

1

Position the 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 the 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 the cranial bone flap

Replace the bone flap to its original position.



4

Lower the 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

Precrimp implants

Instrument

329.323 Application Instrument

Place the tube between the blades of the "CRIMP" side of the instrument and lower to the surface of the top disk.

Important: Pull up gently on the exposed tube using your second hand until the lower disk is up against the cranial table.

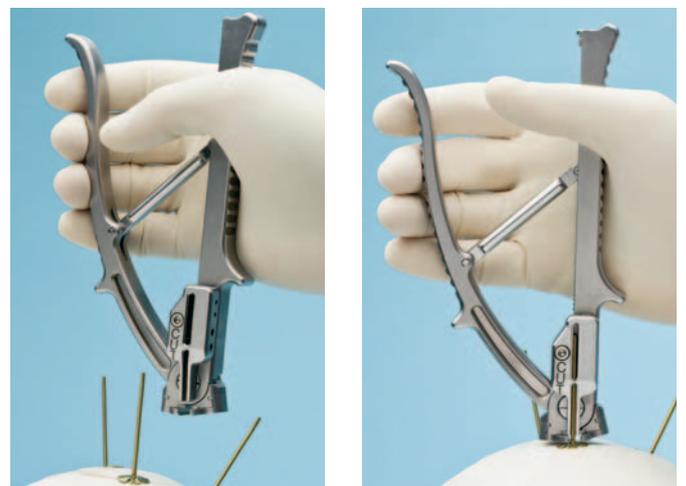
Press the handles of the application instrument together. Repeat this procedure for the remaining implants. This procedure will allow the bone flap to be held in place during the final tightening.



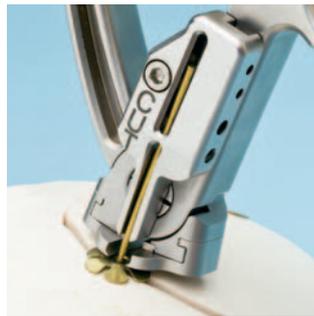
6

Insert implant into instrument

Insert the tube laterally into the gripping box on the "CUT" side of the instrument.



Ensure the blades are flush with the top disk.



Correct



Incorrect

7

Tighten and cut tube

With the tube in the gripping box, press handles together until implant is tensioned and the cut is achieved. Continue to hold the handles together.



8

Remove remaining tube from instrument

Remove the instrument from the surgical field and release the handles to dispose of the excess tube.

Note: The excess tube is held inside the instrument gripping box only while the handles are compressed. When the handles are released, the excess tube will fall out of the gripping box.

Repeat steps 6–8 for remaining implants



Implant Removal

Instrument

398.960 Stagbeetle Forceps, 120 mm

Use the stagbeetle forceps to grasp between the petals of the top disk. Tilt the forceps towards the center of the bone flap to release. Repeat this procedure for the remaining implants. Remove the bone flap and lower disks.

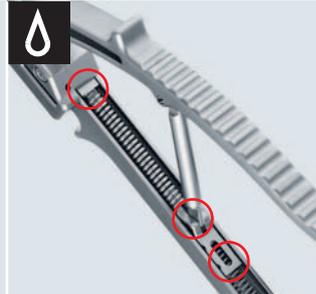
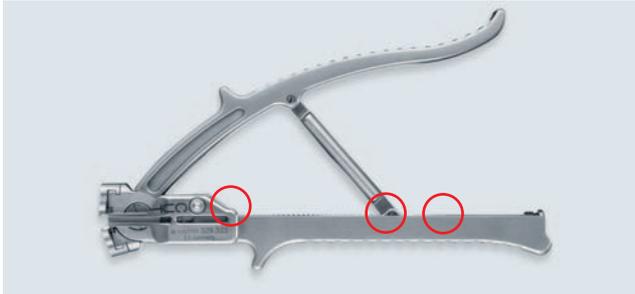


Reprocessing, Care & Maintenance

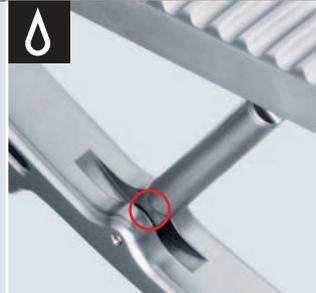
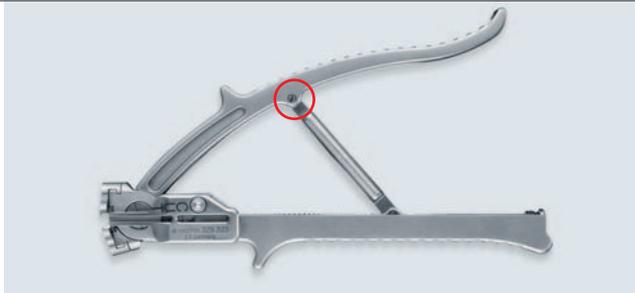
The Application Instrument (329.323) for FlapFix must be lubricated following each use as part of the reprocessing procedure.

Place one drop of oil at each lubrication point as shown.

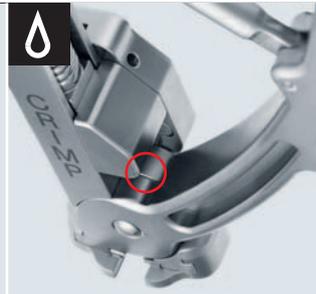
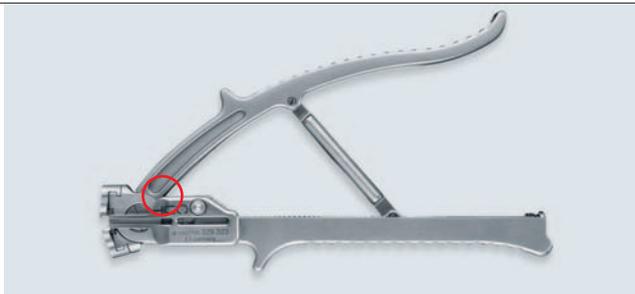
1



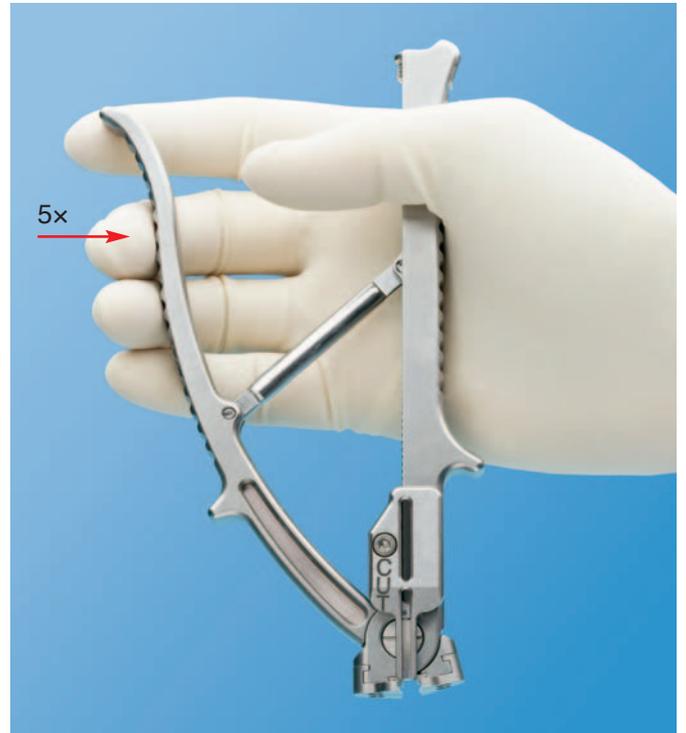
2



3



Distribute the oil over the moving surfaces by squeezing the instrument handles together and releasing. Repeat this procedure 5 times.



Use only the following product for lubrication.

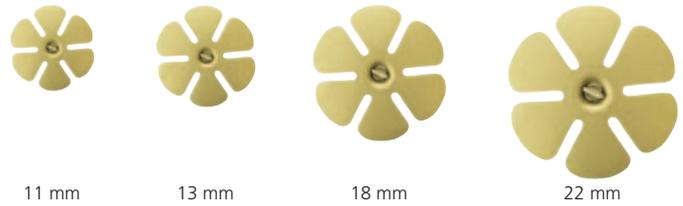
05.001.095 Oil Dispenser with Synthes Special Oil,
50 ml, for EPD and APD

For sterilization parameters, general guidelines, function control and dismantling of multipart instruments please refer to:
www.synthes.com/reprocessing

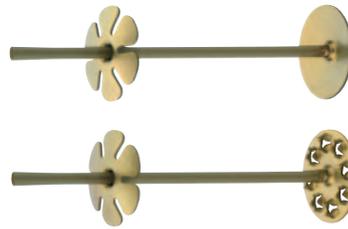
Implants and Instruments

Implants

FlapFix



460.100	11 mm diameter
460.001	13 mm diameter
460.002	18 mm diameter
460.003	22 mm diameter
460.107	Textured, 11 mm diameter
460.008	Textured, 13 mm diameter
460.009	Textured, 18 mm diameter
460.010	Textured, 22 mm diameter



Instruments

329.323 Application Instrument for FlapFix



398.960 Stagbeetle Forceps, 120 mm



Available nonsterile or sterile-packed. Add ".01S" to product number for sterile product.

FlapFix Set with Application Instrument (145.850)

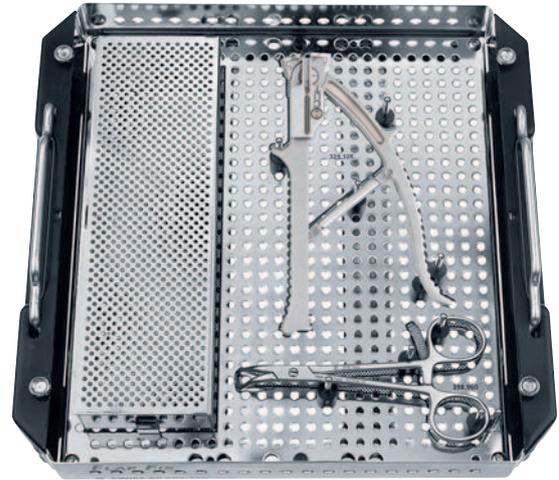
Vario Case

60.503.120 Vario Case for Application Instrument for FlapFix

Instruments

329.323 Application Instrument for FlapFix

398.960 Stagbeetle Forceps, 120 mm





Synthes GmbH
Eimattstrasse 3
CH-4436 Oberdorf
www.synthes.com

All technique guides are available as PDF files at
www.synthes.com/lit



CE
0123

036.000.932.AB 60100020 © 06/2010 Synthes, Inc. or its affiliates. All rights reserved. Synthes, FlapFix and Vario Case are trademarks of Synthes, Inc. or its affiliates.