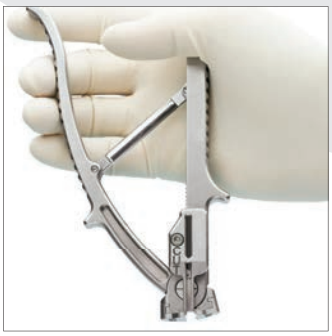
For fixation of cranial bone flaps following a craniotomy

FlapFix

Surgical Technique



DePuy Synthes

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

Image intensifier control

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

Processing, Reprocessing, Care and Maintenance
For general guidelines, function control and dismantling of multi-part instruments, as well as processing guidelines for implants, please contact your local sales representative or refer to:
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance
For general information about reprocessing, care and maintenance of Synthes reusable devices, instrument trays and cases, as well as processing of Synthes non-sterile implants, please consult the Important Information leaflet (SE_023827) or refer to:
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance

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FlapFix. For fixation of cranial bone flaps following a craniotomy.

The Synthes FlapFix System is cranial clamping solution that allows surgeons to apply implants with a single instrument in a single 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 each individual leaf of 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

Application instrument (ref. 329.323)
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, simple 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 simple "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.

[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

Intended Use, Indications, Contraindications, General Adverse Events, Device Specific Adverse Events, Warnings and MRI Information

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.

General Adverse Events
As with all major surgical procedures, risks, side effects and adverse events can occur. While many possible reactions may occur, some of the most common include: Problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, dental injuries, neurological impairments, etc.), thrombosis, embolism, infection, nerve and/or tooth root damage or injury of other critical structures including blood vessels, excessive bleeding, damage to soft tissues incl. swelling, abnormal scar formation, functional impairment of the musculoskeletal system, pain, discomfort or abnormal sensation due to the presence of the device, allergy or hypersensitivity reactions, side effects associated with hardware prominence, loosening, bending, or breakage of the device, mal-union, non-union or delayed union which may lead to breakage of the implant, reoperation.

Device Specific Adverse Events
Device Specific Adverse Events include:
- Dural laceration or injury
- Eyelids swelling and bruising
- Seroma

Warnings: **These devices can break during use (when subjected to excessive forces or outside the recommended surgical technique). While the surgeon must make the final decision on removal of the broken part based on associated risk in doing so, we recommend that whenever possible and practical for the individual patient, the broken part should be removed. Medical devices containing stainless steel may elicit an allergic reaction in patients with hypersensitivity to nickel.**

MRI Information

Torque, Displacement and Image Artifacts according to ASTM F2213-06, ASTM F2052-14 and ASTM F2119-07
Non-clinical testing of worst case scenario in a 3 T MRI system did not reveal any relevant torque or displacement of the construct for an experimentally measured local spatial gradient of the magnetic field of 3.65 T/m. The largest image artifact extended approximately 34 mm from the construct when scanned using the Gradient Echo (GE). Testing was conducted on a 3 T MRI system.

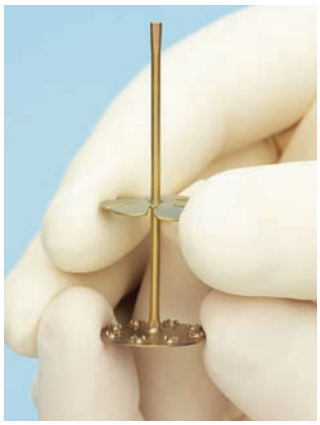
Radio-Frequency-(RF-)induced heating according to ASTM F2182-11a
Non-clinical electromagnetic and thermal testing of worst case scenario lead to temperature rises of 1.5 °C (1.5 T) and 2.0 °C (3 T) under MRI Conditions using RF Coils (whole body averaged specific absorption rate [SAR] of 2 W/kg for 15 minutes).

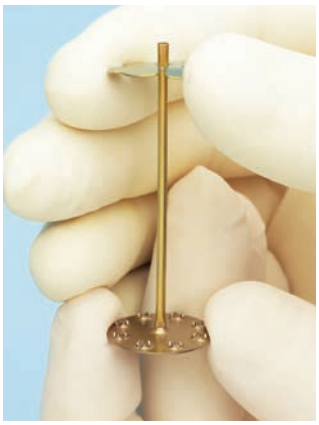
Precautions: **The above mentioned test relies on non-clinical testing. The actual temperature rise in the patient will depend on a variety of factors beyond the SAR and time of RF application. Thus, it is recommended to pay particular attention to the following points:**
- **It is recommended to thoroughly monitor patients undergoing MR scanning for perceived temperature and/or pain sensations.**
- **Patients with impaired thermoregulation or temperature sensation should be excluded from MR scanning procedures.**
- **Generally, it is recommended to use an MRI system with low field strength in the presence of conductive implants. The employed specific absorption rate (SAR) should be reduced as far as possible.**
- **Using the ventilation system may further contribute to reduce temperature increase in the body.**

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.

Precaution: **Care should be taken not to nick or tear gloves when handling an implant with a textured bottom disk.**





2. Position the implant

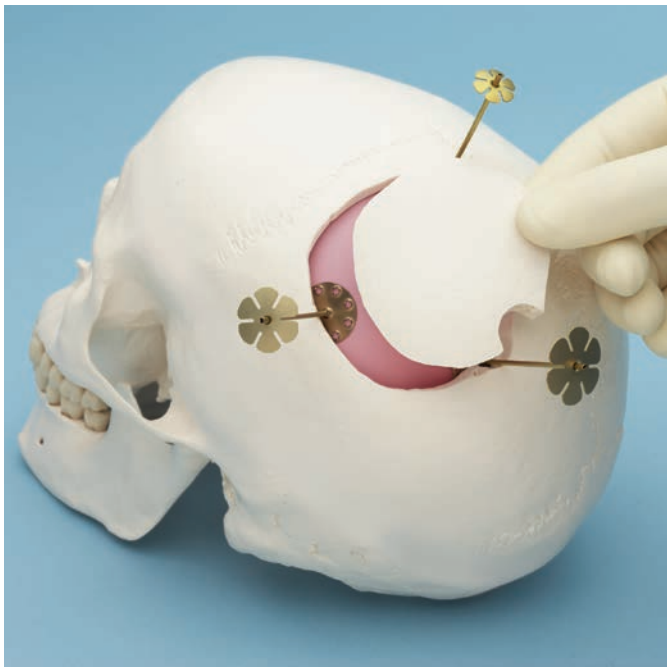
Arrange at least three implants equidistant around the craniotomy by inserting the bottom disks between the dura and the cranium.

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

3. Place the cranial bone flap

Replace the bone flap to its original position.

Precaution: **FlapFix is designed to fixate the bone flap on the cranium and should not be used to hold any other implant.**



4. Lower the top disk

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.

Precaution: **Prevent the bottom disk from pressing against the dura.**

5. Precrimp implants

Instrument	
329.323	Application Instrument

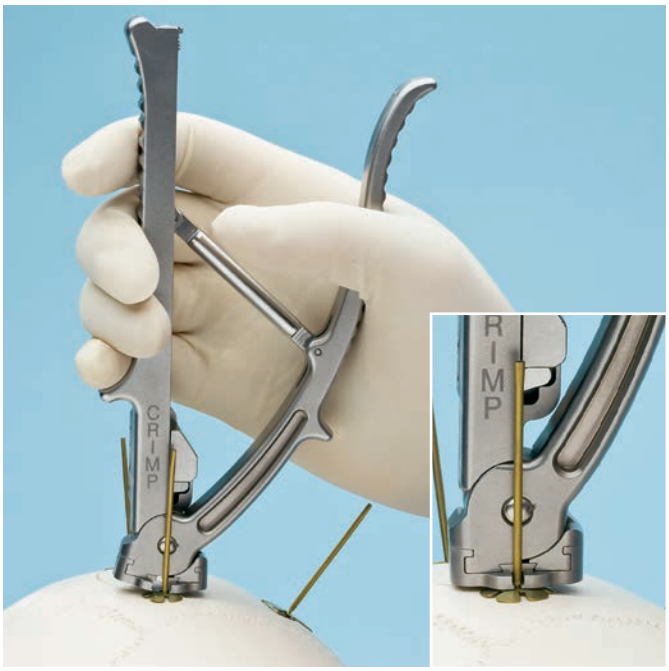
Place the tube between the blades of the "CRIMP" side of the instrument and lower to the surface of the top disk.

Pull up gently on the exposed tube using your second hand until the lower disk is up against the inner surface of the cranium.

Precautions:

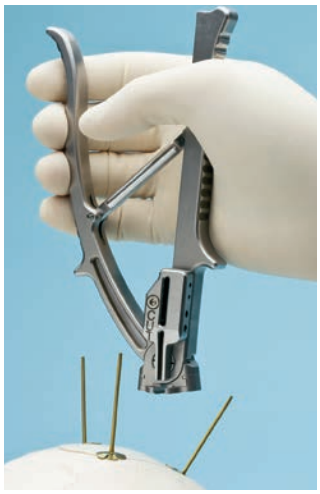
- **Excessive force can cause the lower disc to be pulled out.**
- **Irrigate and apply suction for removal of debris potentially generated during implantation or removal.**

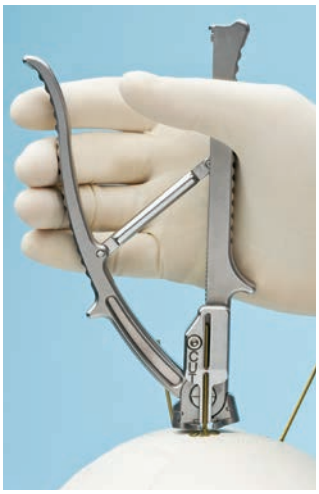
Press the handles of the application instrument together. Repeat this procedure for the remaining implants. This procedure will allow the bone flap to be held in place during the final tightening.



6. Insert implant into instrument

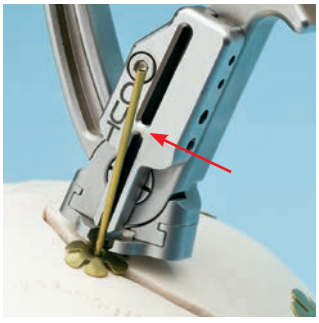
Insert the tube laterally into the gripping box on the "CUT" side of the instrument.





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.

Precaution: **Ensure that the instrument is placed flush to the implant for cutting.**

8. Remove remaining tube from instrument

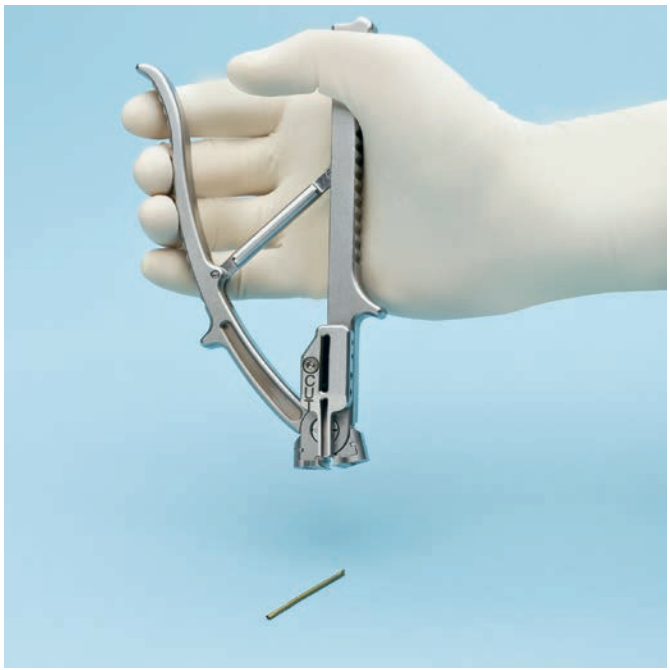
Remove the instrument from the surgical field and release the handles to dispose of the excess tube.

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.

Precautions:

- **After implant placement is completed, discard any excess tube in an approved sharps container.**
- **Do not release the instrument handles while still in the surgical field.**



Implant Removal

Instrument

398.960	Stagbeetle Forceps, 125 mm

Use stagbeetle forceps to grasp the clover-leaf disc between its petals. Remove the disc by tilting the forceps slightly towards the center of the cranial bone flap. Repeat this procedure for the remaining implants. 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 re-attach the cranial bone flap.**

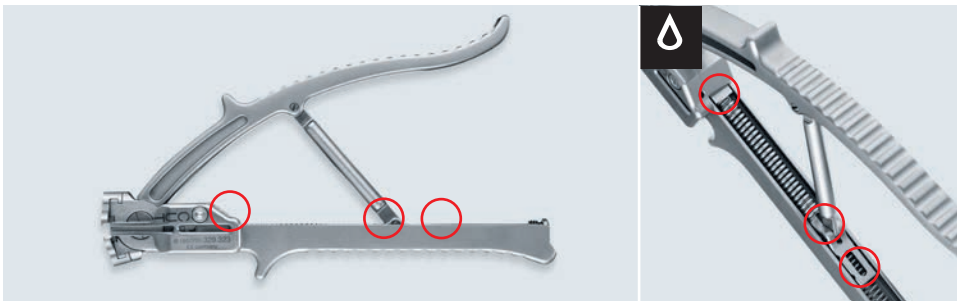
Precaution: **Irrigate and apply suction for removal of debris potentially generated during implantation or removal.**

Maintenance of the Application Instrument

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.

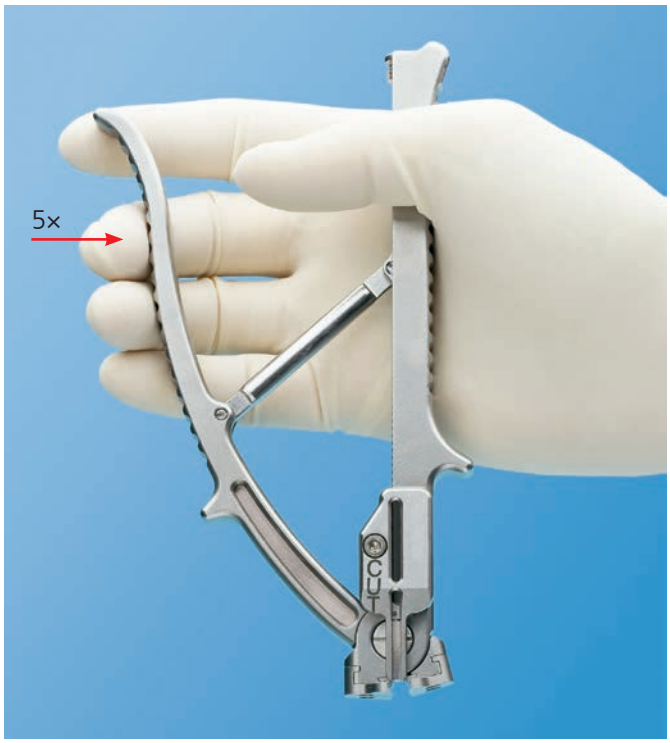
1



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	Synthes Maintenance Oil, 40 ml, for EPD and APD

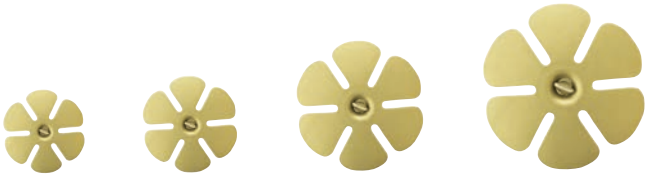
Implants and Instruments

FlapFix*

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

FlapFix, textured*

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



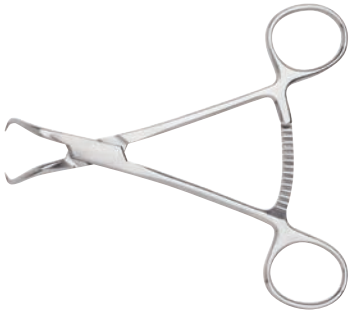
11 mm 13 mm 18 mm 22 mm

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

Instruments

329.323	Application Instrument with Alignment Guide for FlapFix

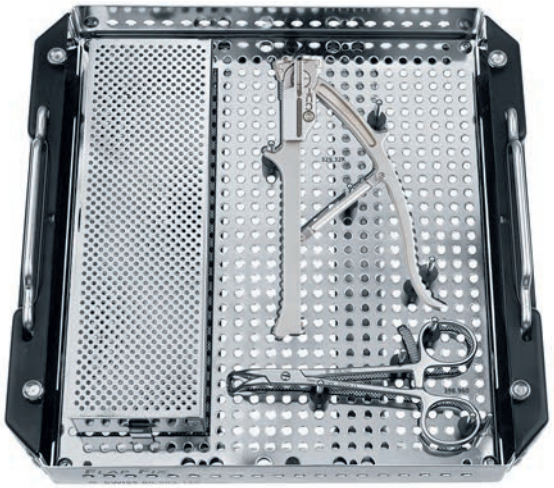
398.960	Stagbeetle Forceps, 125 mm



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, 125 mm



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