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

Surgical Technique

Instruments and implants approved by the AO Foundation.
Image intensifier control

This description alone does not provide sufficient background for direct use of the instrument set. Instruction by a surgeon experienced in handling these instruments 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 an innovative cranial clamping solution that allows surgeons to apply implants with a single instrument in a single motion. The specially designed application instrument or application forceps 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 (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

Application Forceps for FlapFix (optional)
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, simple “firm handshake” action
– Ergonomic design for either right- or left-handed operation prevents slippage
– Ease of 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.\textsuperscript{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.


**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 but are not limited to:
- 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 F2052-06e1 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 5.4 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 simulations of worst case scenario lead to temperature rises of 10.7 °C (1.5 T) and 8.0 °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.
**Surgical Technique**

**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.
Surgical Technique

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.
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.
Optional Technique using Application Forceps (ref: 329.315)

Steps 9 to 11 are to be followed when using the application forceps, instead of steps 5 to 8 that are relevant to the application instrument.

9
Prepare application forceps

**Instrument**

| 329.315 | Application Forceps for FlapFix |

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

**Precaution:** Necessary tension to the implant can only be achieved when the ratchet of the application forceps is pushed forward prior to applying tension.

10
Apply tension to implant

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).

Excessive tension does not need to be applied to the implants to ensure stable fixation of the bone flap.

**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.

Ensure that the application forceps lies flush against the cranial surface during the entire procedure.
Crimp and cut tube

While maintaining tension on the implant, crimp and cut the tube of the implant by squeezing the application forceps trigger (see arrow).

Release the ratchet to close the device.

Repeat steps 9–11 for the remaining implants.

Precautions:
– Ensure that the forceps are placed flush to the implant for cutting.
– 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 reattach the cranial bone flap.

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

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<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>05.001.095</td>
<td>Synthes Maintenance Oil, 40 ml, for EPD and APD</td>
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### FlapFix*

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<tr>
<th>Product Number</th>
<th>Diameter</th>
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<tr>
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<td>460.001</td>
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<tr>
<td>460.002</td>
<td>18 mm</td>
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<tr>
<td>460.003</td>
<td>22 mm</td>
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### FlapFix, textured*

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<tr>
<td>460.008</td>
<td>13 mm</td>
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<tr>
<td>460.009</td>
<td>18 mm</td>
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<tr>
<td>460.010</td>
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* Available nonsterile or sterile-packed. Add ".01S" to product number for sterile product.
### Instruments

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<td>Application Instrument with Alignment Guide for FlapFix</td>
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<table>
<thead>
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<th>Code</th>
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### Optional Instrument

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<td>Application Forceps for FlapFix</td>
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</table>
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