Instructions for Use
FlapFix

This instruction for use is not intended for distribution in the USA.

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DePuy Synthes
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

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Instructions for Use

FlapFix
460.001 FlapFix ∅ 13.0mm
460.002 FlapFix ∅ 18.0mm
460.003 FlapFix ∅ 22.0mm
460.008 FlapFix textured ∅ 13.0mm
460.009 FlapFix textured ∅ 18.0mm
460.010 FlapFix textured ∅ 22.0mm
460.100 FlapFix ∅ 11.0mm
460.107 FlapFix textured ∅ 11.0mm
460.001.01S FlapFix ∅ 13.0mm, single pack, sterile
460.002.01S FlapFix ∅ 18.0mm, single pack, sterile
460.003.01S FlapFix ∅ 22.0mm, single pack, sterile
460.008.01S FlapFix textured ∅ 13.0mm, single pack, sterile
460.009.01S FlapFix textured ∅ 18.0mm, single pack, sterile
460.010.01S FlapFix textured ∅ 22.0mm, single pack, sterile
460.100.01S FlapFix ∅ 11.0mm, single pack, sterile
460.107.01S FlapFix textured ∅ 11.0mm, single pack, sterile
329.323 Application Instr.w/Alignment Guide f/FlapFix
398.960 Stagbeetle Forceps, ratchet lock, L 125 mm
Please read these instructions for use, the Important Information leaflet (SE_023827) and the FlapFix surgical technique (DSEM/CMF/1015/0097) carefully before use. Ensure that you are familiar with the surgical technique.

Material(s)

Part(s):	**Material(s):**	**Standard(s):**
Implants:	Titanium (TiCP)	ISO 5832-2
Instruments:	Stainless Steel	ASTM A276
		ASTM 899
		ISO 10088-1-3

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 pediatrics.

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

Sterile device

STERILE R Sterilized using irradiation

Store implants in their original protective packaging, and do not remove them from the packaging until immediately before use.
Prior to use, check the product expiration date and verify the integrity of the sterile packaging. Do not use, if the package is damaged.

Non Sterile Device

Devices provided non-sterile need to be processed according to the information provided in document SE_023827 Important Information prior to use.
During the initial processing or reprocessing of FlapFix implants perform a functional test (i.e. sliding of discs along the tube). This functional test should be performed after cleaning and disinfection and prior to steam sterilization.

Single-use device

 Do not re-use

Products intended for single-use must not be re-used.
Re-use or reprocessing (e.g. cleaning and resterilization) may compromise the structural integrity of the device and / or lead to device failure which may result in patient injury, illness or death.
Furthermore, reuse or reprocessing of single-use devices may create a risk of contamination e.g. due to the transmission of infectious material from one patient to another. This could result in injury or death of the patient or user.

Contaminated implants must not be reprocessed. Any Synthes implant that has been contaminated by blood, tissue, and/or bodily fluids/matter should never be used again and should be handled according to hospital protocol. Even though they may appear undamaged, the implants may have small defects and internal stress patterns that may cause material fatigue.

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.

Precautions
- Care should be taken not to nick or tear gloves when handling an implant with a textured bottom disk.
- Select the appropriate sized disk to ensure there is adequate overlap of the disk and bony surfaces.
- Irrigate and apply suction for removal of debris potentially generated during implantation or removal.
- FlapFix is designed to fixate the bone flap on the cranium and should not be used to hold any other implant.
- Prevent the bottom disk from pressing against the dura.
- Excessive force can cause the lower disk to be pulled out.
- Ensure that the instrument is 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.

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 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.

Special operating instructions

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.

3 Place the cranial bone flap
Replace the bone flap to its original position.

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.

5 Precrimp implants
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 until the lower disk is up against the inner surface of the cranium. Press the handles 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.

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.
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
Use the stagbeetle forceps to grasp the clover-leaf disk between its petals. Remove the disk 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 disks.
Note: The FlapFix are for single use only and must be discarded after removal. Use new FlapFix to reattach the cranial bone flap.

Troubleshooting
Please replace worn or damaged instruments if the cutting function or tube retention is not adequate.

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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