Instructions for Use
FlapFix

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

DePuy Synthes
CMF
COMPANIES OF Johnson&Johnson

CE
0123

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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
329.315 Application Forceps f/FlapFix
329.323 Application Instr.w/Alignment Guide f/FlapFix
398.960 Stagbeetle Forceps, ratchet lock, L 120 mm
Please read these instructions for use, the Synthes brochure "Important Information" and the corresponding surgical techniques FlapFix (036.000.932/036.000.086) carefully before use. Ensure that you are familiar with the appropriate surgical technique.

Material(s)
Material(s): Standard(s):
Implants
Titanium: ISO 5832-2

Instruments
Stainless Steel: ASTM A276, ASTM 899, ISO 10088-1-3

Indications
Craniotomies in adult patients with cranial tumors, haematoma, aneurysm or other cranial indication.

Contraindications
FlapFix is not intended for use in pediatrics.

Side effects
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.

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.
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.

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

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 crimping device lies flush against the cranial surface during the entire procedure.

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

Magnetic Resonance environment
CAUTION:
Unless stated otherwise, devices have not been evaluated for safety and compatibility within the MR environment. Please note that there are potential hazards which include but are not limited to:
– Heating or migration of the device
– Artifacts on MR images

Treatment before device is used
Synthes products supplied in a non-sterile condition must be cleaned and steam-sterilized prior to surgical use. Prior to cleaning, remove all original packaging. Prior to steam-sterilization, place the product in an approved wrap or container. Follow the cleaning and sterilization instruction given by the Synthes brochure "Important Information".

Special operating instructions
For Instrument 329.323 (036.000.932)
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
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 cranial table. 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. 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.

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
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.

For Instrument 329.315 (036.000.086)
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 Prepare crimping device
Push the ratchet forward (see arrow). During this procedure, the crimping device must be closed at the front.

6 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).
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 crimping device 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
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.
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 of the device
Detailed instructions for processing implants and reprocessing reusable devices, instrument trays and cases are described in the Synthes brochure “Important Information”. Assembly and disassembly instructions of instruments “Dismantling multipart instruments” can be downloaded from http://www.synthes.com/reprocessing

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