Quick and Stable Fixation of Cranial Bone Flaps Following a Craniotomy

Cranial Clamps With Application Instrument

Surgical Technique
MR Information
The Cranial Clamps With Application Instrument have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration or image artifact in the MR environment. The safety of the Cranial Clamps With Application Instrument in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.
Cranial Clamps With Application Instrument

One instrument. One step. Quick fixation.
The DePuy Synthes Cranial Flap Tube Clamp 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 available textured or smooth, in four sizes, and can be shipped sterile or nonsterile.

Cranial Flap Tube Clamps
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 nonsterile 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 Cranial Flap Tube Clamp
- Precrimping 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 of the tube is done with a single, 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
AO Principles

In 1958, the AO formulated four basic principles, which have become the guidelines for internal fixation.\(^1,2\)

**Anatomic reduction**
Fracture reduction and fixation to restore anatomical relationships.

**Early, active mobilization**
Early and safe mobilization and rehabilitation of the injured part and the patient as a whole.

**Stable fixation**
Fracture fixation providing absolute or relative stability, as required by the patient, the injury, and the personality of the fracture.

**Preservation of blood supply**
Preservation of the blood supply to soft tissues and bone by gentle reduction techniques and careful handling.

Indications

The DePuy Synthes Cranial Flap Tube Clamp is intended to reattach a cranial bone flap to the surrounding cranium after a craniotomy procedure.

Please refer to package insert for the full list of indications, contraindications, warnings and/or precautions.

**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.

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Position 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.

Position 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
Replace cranial bone flap

Replace the bone flap to its original position.

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

4
Lower 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.

**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 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.

**Precautions:**
- Excessive force can cause the lower disk to be pulled out.
- Irrigate and apply suction for removal of debris potentially generated during implantation or removal.
6
Insert implant into instrument

Instrument

329.323  Application 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.
Tighten and cut tube

Instrument

329.323 Application Instrument

With the tube in the gripping box, press the handles together until the 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 excess tube from instrument

Instrument

329.323 Application 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.

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

Implant removal

Instrument

398.96.98 Stagbeetle Forceps, 125 mm

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

## Implants

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Titanium Cranial Flap Tube Clamps

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Titanium Cranial Flap Tube Clamps, textured

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

## Instruments

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Titanium Cranial Flap Tube Clamp Set With Alignment Guide Instrument (01.503.123)

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For detailed cleaning and sterilization instructions, please refer to www.synthes.com/cleaning-sterilization or sterilization instructions, if provided.
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Not all products may currently be available in all markets.

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West Chester, PA 19380

Synthes USA, LLC  
1101 Synthes Avenue  
Monument, CO 80132

To order (USA): 800-523-0322  
To order (Canada): 855-946-8999

Note: For recognized manufacturer, refer to the product label.

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