

Quick and Stable Fixation of Cranial Bone Flaps
Following a Craniotomy

Cranial Clamps With Crimping Device

Surgical Technique



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MR Information

The Cranial Clamps With Crimping Device 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 Crimping Device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

 Image intensifier control

Cranial Clamps With Crimping Device

One instrument. 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. The specially designed Crimping Device 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.

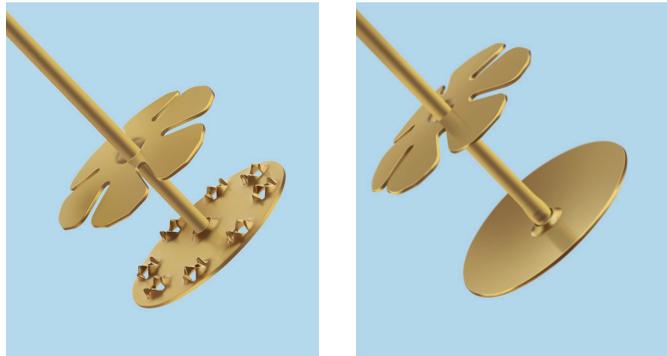
Cranial Flap Tube Clamps

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

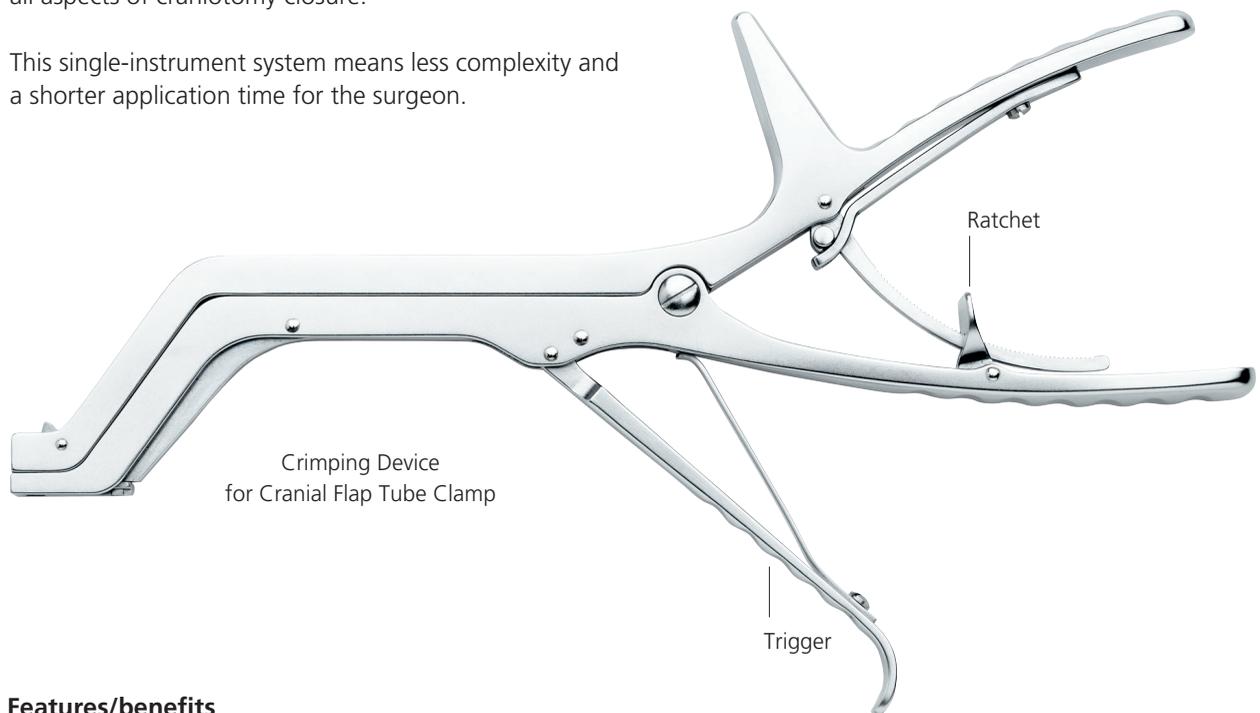
- A low profile for minimal palpability
- An anatomic fit is achieved by the clover-leaf design of the top disk. This allows the implant to adapt to the shape of the cranium
- Available in four diameters: 11 mm, 13 mm, 18 mm, and 22 mm
- Offered with smooth or textured bottom disks
- Specially designed smooth disk edges
- Available in sterile and nonsterile packaging



Crimping Device

The Crimping Device is the only instrument needed to perform all aspects of craniotomy closure.

This single-instrument system means less complexity and a shorter application time for the surgeon.



Features/benefits

- Only one instrument is needed for tensioning and cutting of the Cranial Flap Tube Clamp
- Tensioning to a secure fit and cutting of the tube is done with a single, easy “firm handshake” action
- Ergonomic design for either right- or left- handed operation prevents slippage
- Easy access to the operation site due to deflected tip

AO Principles

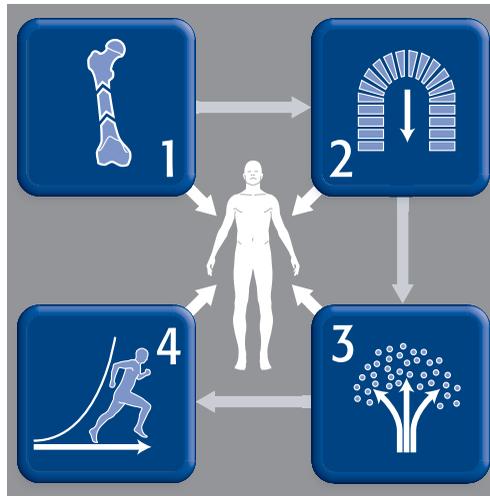
In 1958, the AO formulated four basic principles, which have become the guidelines for internal fixation.^{1,2}

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 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.

1. Müller ME, Allgöwer M, Schneider R, Willenegger H. *Manual of Internal Fixation*. 3rd ed. Berlin, Heidelberg, New York: Springer-Verlag; 1991.
2. Rüedi TP, RE Buckley, CG Moran. *AO Principles of Fracture Management*. 2nd ed. Stuttgart New York: Thieme; 2007.

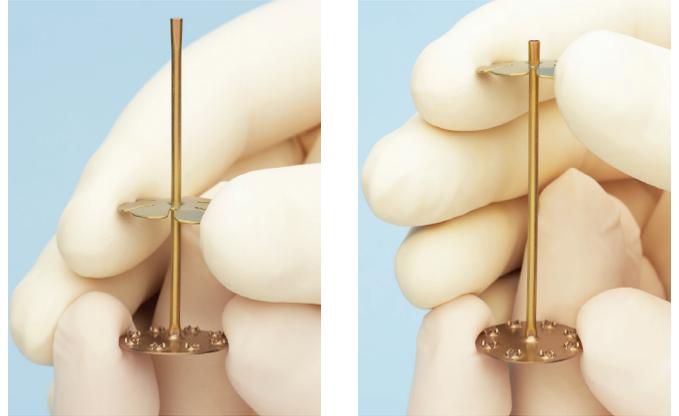
Operating Technique

1

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.



2

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 cranial 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.

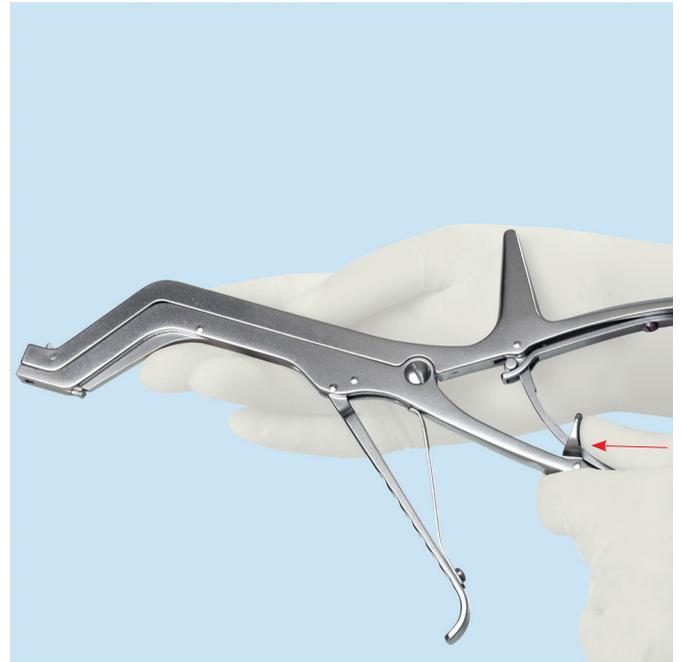


5

Prepare crimping device

Push the ratchet forward (see arrow). During this procedure, the crimping device 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.



6

Apply tension to implant

Instrument

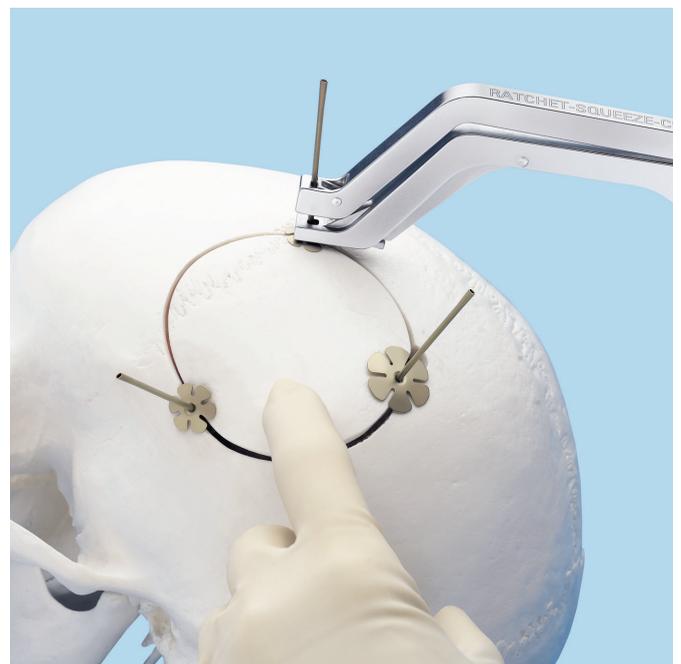
329.315 Crimping Device, for Cranial Flap Tube Clamp

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.

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.



7

Crimp and shear center tube

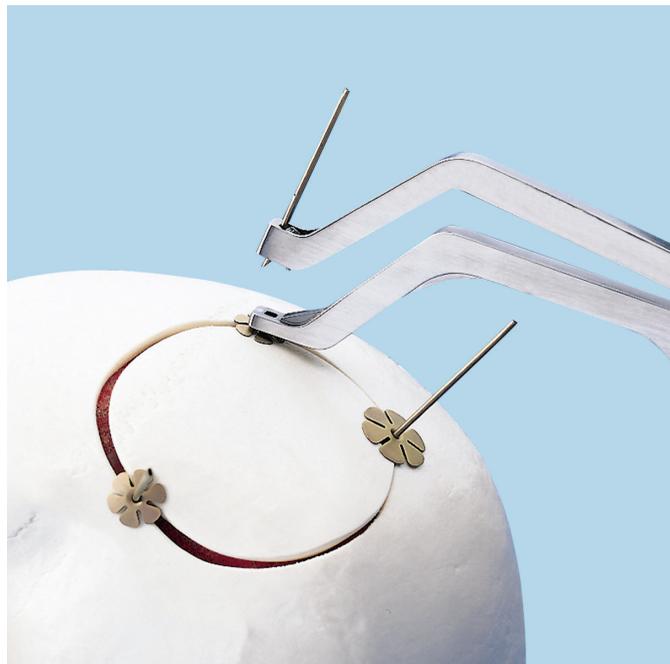
While maintaining tension on the clamp, crimp and shear the center tube of the clamp by squeezing the crimping device trigger. (See arrow).

Release the ratchet to close the device.

Repeat Steps 5–7 for the remaining implants.

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

Implant removal

Instrument

398.96.98 Stagbeetle Forceps, 125 mm

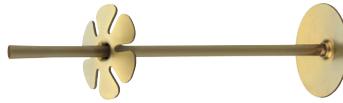
Use stagbeetle forceps to grasp the clover-leaf disc between its petals. Remove the disc by tilting the forceps slightly toward the center of the cranial bone flap. Repeat this procedure for the remaining clamps. Lift off the bone flap and remove the lower discs.

Note: The cranial flap tube clamps are for single use only and must be discarded after removal. Use new clamps to re-attach the cranial bone flap.



Implants

-
- 460.100 Titanium Cranial Flap Tube Clamps[◇]
460.001 11 mm diameter
460.002 13 mm diameter
460.003 18 mm diameter
460.003 22 mm diameter



- 460.107 Titanium Cranial Flap Tube Clamps, textured[◇]
460.008 11 mm diameter
460.009 13 mm diameter
460.010 18 mm diameter
460.010 22 mm diameter



11 mm



13 mm



18 mm



22 mm

[◇] Available nonsterile or sterile-packed. Add .01S to product number for sterile product.

Instruments

329.315 Crimping Device, for Cranial Flap Tube Clamp



398.96.98 Stagbeetle Forceps, 125 mm



Titanium Cranial Flap Tube Clamp Set (145.830)

Trays and Accessories

304.760	Universal Instrument Tray, large, deep
304.761	Neuro Instrument Tray Lid, large
304.773	Neuro Insert Tray, for Cranial Clamps
304.775	Neuro Multi Clamp Insert Tray
304.776	Label Sheet for Cranial Clamps

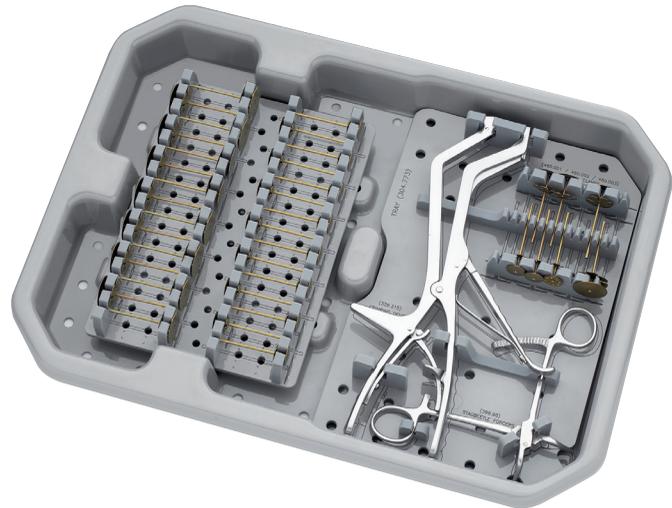
Instruments

329.315	Crimping Device, for Cranial Flap Tube Clamp
398.96.98	Stagbeetle Forceps, 125 mm length

Implants

Titanium Cranial Flap Tube Clamps [◇]		
	Diameter (mm)	Qty.
460.100	11	3
460.001	13	6
460.002	18	6
460.003	22	3

Titanium Cranial Flap Tube Clamps, textured [◇]		
	Diameter (mm)	Qty.
460.107	11	3
460.008	13	6
460.009	18	6
460.010	22	3



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

Note: For additional information, please refer to the package insert or www.e-ifu.com.

For detailed cleaning and sterilization instructions, please refer to www.depuySynthes.com/hcp/cleaning-sterilization or sterilization instructions, if provided in the instructions for use.

Limited Warranty and Disclaimer: DePuy Synthes products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

Please also refer to the package insert(s) or other labeling associated with the devices identified in this surgical technique for additional information.

CAUTION: Federal Law restricts these devices to sale by or on the order of a physician.

Some devices listed in this technique guide may not have been licensed in accordance with Canadian law and may not be for sale in Canada. Please contact your sales consultant for items approved for sale in Canada.

Not all products may currently be available in all markets.



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To order (USA): 800-523-0322

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

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