Cranial Clamps with Application Instrument. Quick and stable fixation of cranial bone flaps following a craniotomy.
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Cranial Clamps with Application Instrument

One instrument. One step. Quick fixation.
The 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 listed below, which have become the guidelines for internal fixation. 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, active mobilization
Early and safe mobilization of the part and patient.

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.

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.

2

Position 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 cranial bone flap

Replace the bone flap to its original position.

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.
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.
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

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.
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.

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.
Instrument Maintenance

Prior to sterilization, add one drop of Synthes Special Autoclavable Oil to the highlighted areas.

After oiling, activate lever five times.
### Implants and Instruments

#### Implants

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Diameter</th>
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<tbody>
<tr>
<td>460.100</td>
<td>11 mm</td>
</tr>
<tr>
<td>460.001</td>
<td>13 mm</td>
</tr>
<tr>
<td>460.002</td>
<td>18 mm</td>
</tr>
<tr>
<td>460.003</td>
<td>22 mm</td>
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</tbody>
</table>

Titanium Cranial Flap Tube Clamps

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Diameter</th>
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<tbody>
<tr>
<td>460.107</td>
<td>11 mm</td>
</tr>
<tr>
<td>460.008</td>
<td>13 mm</td>
</tr>
<tr>
<td>460.009</td>
<td>18 mm</td>
</tr>
<tr>
<td>460.010</td>
<td>22 mm</td>
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Titanium Cranial Flap Tube Clamps, textured

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

#### Instruments

<table>
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<tr>
<th>Product Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>329.323</td>
<td>Application Instrument, with Alignment Guide, for Titanium Cranial Flap Tube Clamps</td>
</tr>
<tr>
<td>398.96.98</td>
<td>Stagbeetle Forceps, 125 mm</td>
</tr>
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Titanium Cranial Flap Tube Clamp Set with Alignment Guide Instrument (01.503.123)

**Trays and Accessories**
- 304.760 Universal Instrument Tray, large, deep
- 304.761 Neuro Instrument Tray Lid, large
- 304.775 Neuro Multi Clamp Insert Tray
- 304.776 Label Sheet for Cranial Clamps
- 306.534 Cranial Clamp Insert Tray, for Application Instrument
- 306.535 Label Sheet for Insert Tray, Cranial Clamp Instrument

**Instruments**
- 329.323 Application Instrument, with Alignment Guide, for Titanium Cranial Flap Tube Clamps
- 398.96.98 Stagbeetle Forceps, 125 mm length

**Implants**

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**Additional Item**
- 519.97 Special Autoclavable Oil

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

For detailed cleaning and sterilization instructions, please refer to:
www.synthes.com/cleaning-sterilization

In Canada, the cleaning and sterilization instructions will be provided with the Loaner shipments.