Cranial Clamps with Crimping Device.
Quick and stable fixation of cranial bone flaps following a craniotomy.
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Cranial Clamps with Crimping Device

One instrument. 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. 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 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.

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**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.

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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.

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 cranial 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 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

**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.

**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

### Instrument

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>398.96.98</td>
<td>Stagbeetle Forceps, 125 mm</td>
</tr>
</tbody>
</table>

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 reattach the cranial bone flap.
### Titanium Cranial Flap Tube Clamps

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Diameter</th>
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<tbody>
<tr>
<td>460.100</td>
<td>11 mm</td>
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<tr>
<td>460.001</td>
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<tr>
<td>460.002</td>
<td>18 mm</td>
</tr>
<tr>
<td>460.003</td>
<td>22 mm</td>
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### Titanium Cranial Flap Tube Clamps, textured

<table>
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<tr>
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<tbody>
<tr>
<td>460.107</td>
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</tr>
<tr>
<td>460.008</td>
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<tr>
<td>460.009</td>
<td>18 mm</td>
</tr>
<tr>
<td>460.010</td>
<td>22 mm</td>
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</tbody>
</table>

◊ 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

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<tr>
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<tr>
<td>304.760</td>
<td>Universal Instrument Tray, large, deep</td>
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<tr>
<td>304.761</td>
<td>Neuro Instrument Tray Lid, large</td>
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<tr>
<td>304.773</td>
<td>Neuro Insert Tray, for Cranial Clamps</td>
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<tr>
<td>304.775</td>
<td>Neuro Multi Clamp Insert Tray</td>
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<tr>
<td>304.776</td>
<td>Label Sheet for Cranial Clamps</td>
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<td>329.315</td>
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<tr>
<td>398.96.98</td>
<td>Stag beetle Forceps, 125 mm length</td>
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Implants

Titanium Cranial Flap Tube Clamps

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

Note: For additional information, please refer to package insert.

For detailed cleaning and sterilization instructions, please refer to http://us.synthes.com/Medical+Community/Cleaning+and+Sterilization.htm or to the below listed inserts, which will be included in the shipping container:

—Processing Synthes Reusable Medical Devices—Instruments, Instrument Trays and Graphic Cases—DJ1305
—Processing Non-sterile Synthes Implants—DJ1304