OSTEOMED®

A TRADITION OF QUALITY AND INNOVATION

OSTEOFLAP™

SURGICAL TECHNIQUE GUIDE

Cranial Clamp System

OsteoFlap™ Cranial Clamp System

SURGICAL TECHNIQUE GUIDE

DANGER indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.

WARNING indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury.

CAUTION used without the safety alert symbol indicates a potentially hazardous situation which, if not avoided, may result in property damage.

INDICATIONS

The **OSTEOMED** Cranial Flap Fixation System is indicated for the re-attachment of the bone flap after a craniotomy. The **OSTEOMED** Cranial Flap Fixation System is intended for single patient use only.

CONTRAINDICATIONS

Use of the **OSTEOMED** Cranial Flap Fixation System is contraindicated in cases of active or suspected infection, in patients previously sensitized to nickel or titanium, in patients with certain metabolic diseases, or patients who are immune compromised. It is further contraindicated in patients exhibiting disorders which would cause the patient to ignore the limitations of rigid fixation. The **OSTEOMED** Cranial Flap Fixation System has not been designed for use in pediatric neurosurgery. The effect of skull growth on retention is unknown.

WARNINGS

1. **ONLY** install the superior disk with a two finger technique to avoid excess torque force during the installation procedure.
2. **DO NOT** over torque the superior disk.
3. The use of three **OSTEOMED** Cranial Flap Fixation devices placed in a triangular formation is recommended for maximum stability.
4. Improper fixation may result in formation of cranial ridges, changes in the position of the cranium and loosening and fracture of implant components.

CAUTIONS

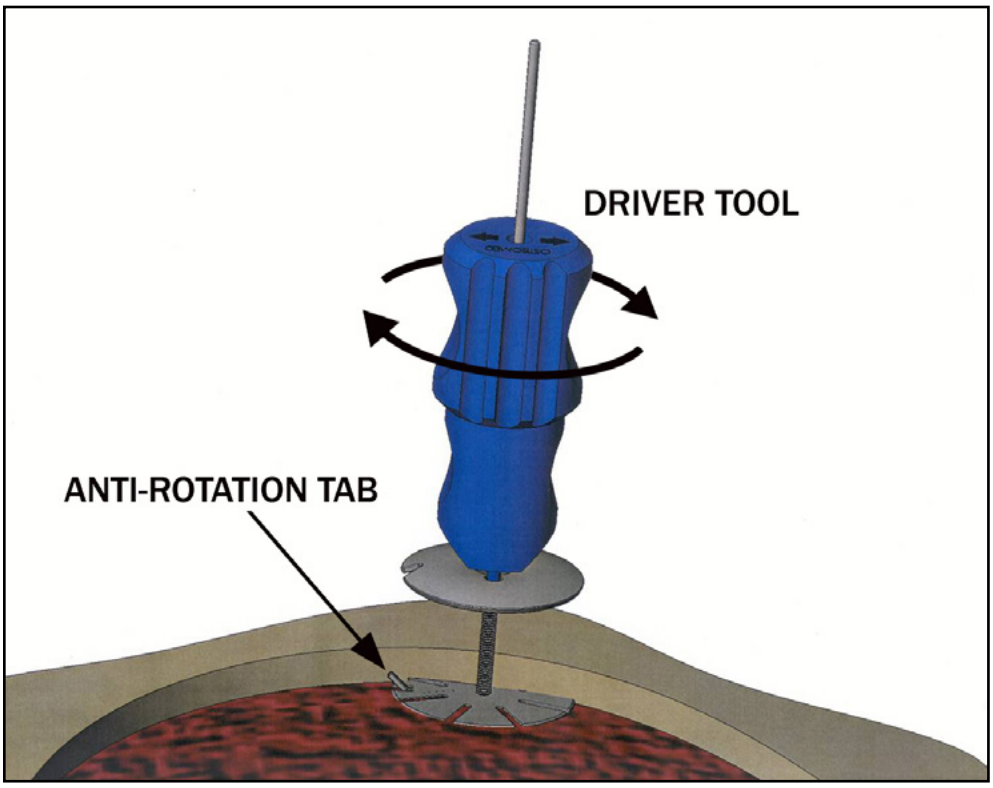
- Federal (United States) law restricts this device for sale by or on the order of a medical practitioner licensed to do so.
- Do no attempt a surgical procedure with faulty, damaged, or suspect **OSTEOMED** instruments or implants. Inspect all components preoperatively to assure utility. Alternate fixation methods should be available intraoperatively.

MAINTAINING DEVICE EFFECTIVENESS

1. The surgeon should have specific training, experience, and thorough familiarity with the use of rigid fixation products and techniques.
2. The surgeon must exercise reasonable judgment when deciding which size to use for specific indications.
3. The **OSTEOMED** Cranial Flap Fixation device is not intended to endure excessive abnormal functional stresses.
4. The **OSTEOMED** Cranial Flap Fixation device is intended for temporary fixation only until osteogenesis occurs.
5. All **OSTEOMED** plates, screws, and instrumentation may be required for each surgery. Failure to use dedicated, unique **OSTEOMED** instruments for every step of the implantation technique may compromise the integrity of the implanted device, leading to premature device failure and subsequent patient injury. Failed devices may require re-operation and removal.
6. Carefully inspect the **OSTEOMED** implants prior to use. Inspect the instruments before and after each procedure to assure they are in proper operating condition. Instruments which are faulty, damaged, or suspect should not be used. They should be re placed or sent to **OSTEOMED** for disposition and repair.
7. **OSTEOMED** recommends the use of **OSTEOMED** products in a sterile environment.

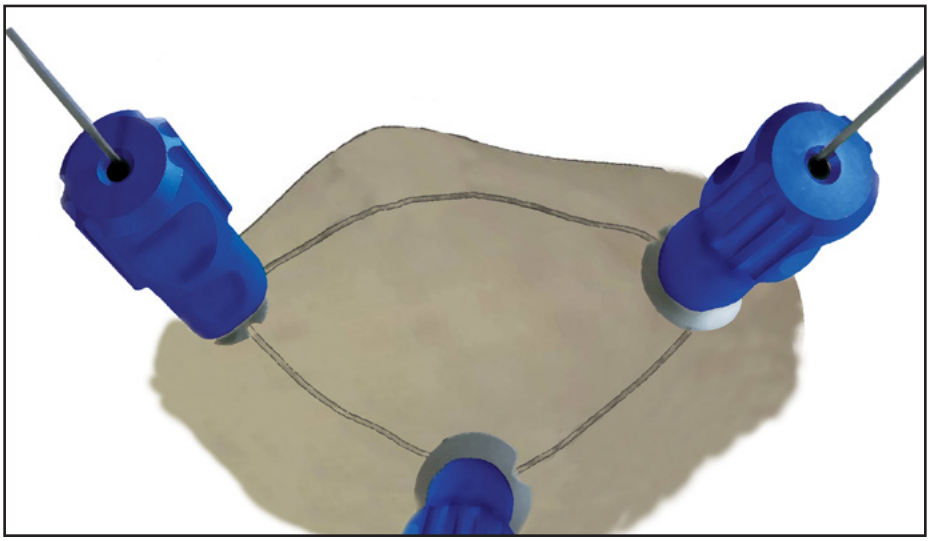
Instructions for Use

1 After the surgical intervention, position Cranial Flap Fixation Disks equally spaced on the dura. Position the inferior disk so that the anti-rotation tab on the inferior disk falls within the kerf width. Replace the bone flap, allowing it to rest between the inferior and superior disks.

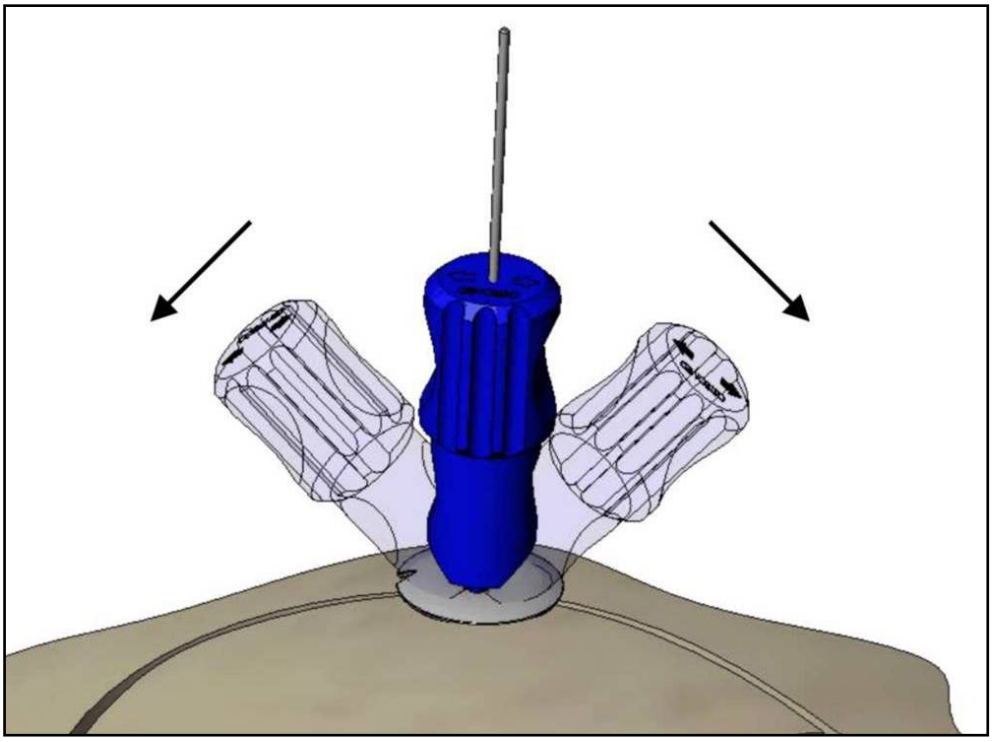


2 The superior disks are threaded down on each device with the use of the attached driver tool. Tighten the superior disk by pulling the rod in a superior direction with one hand, and turning the driver tool with the other hand (Fig. A). DO NOT secure any single device until all of the devices are loosely tightened and the flap is correctly oriented. Final tightening should be firm and represent the maximum force of the fingers. Avoid capturing soft tissue or debris between the disks and the bone.

NOTE: If the tab on the superior plate is not in the kerf width when the device is secured, continue to turn the driver tool until the tab is in the kerf width.

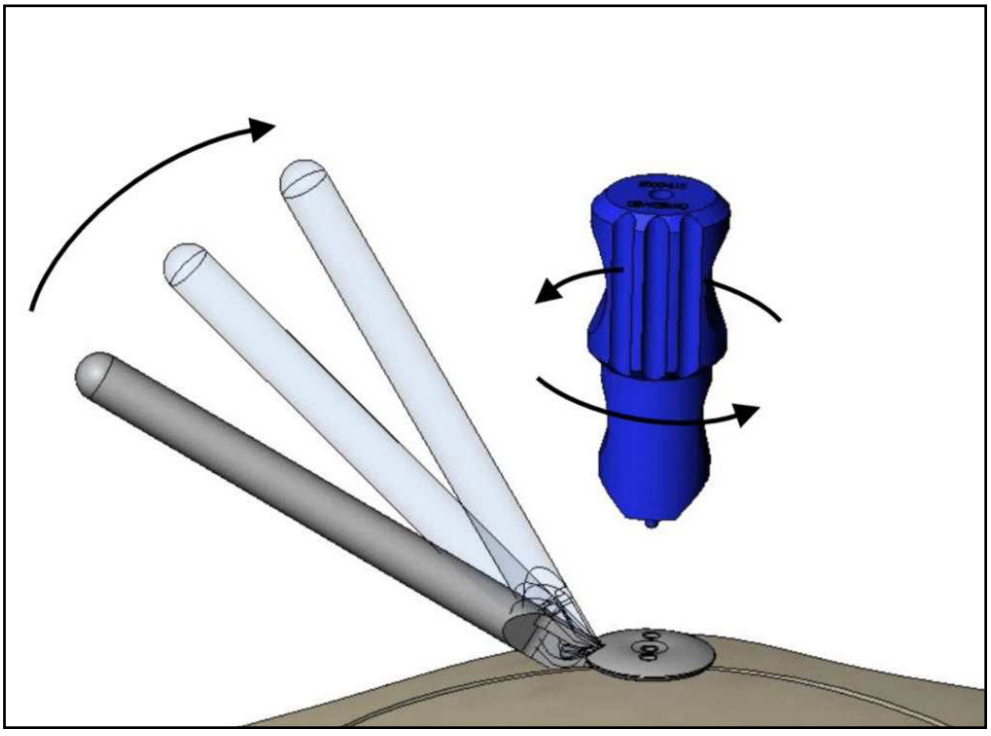


3 Once all the implants have been secured, rock the disposable driver tool in the direction of the arrows on the driver tool. The center rod should break clean. Dispose of the driver tool and broken center rod according to standard hospital procedure. Repeat for all implants.



4 **Removal of Implant:**
NOTE: Removal Tool Kit is required for removal.

Using the Tab Bending Tool from the Removal Tool Kit , lift up on the anti rotation tab until the tab clears the kerf. Engage the removal tool with the superior plate and turn counter-clockwise to remove superior disk.



OSTEOMED®

A TRADITION OF QUALITY AND INNOVATION

Customer Service: 800.456.7779

3885 Arapaho Road I Addison, TX 75001 I Phone: 972.677.4600 I Fax: 800.390.2620

A COLSON ASSOCIATE

www.osteomedcorp.com

P/N 030-1337 Rev.B