Part No. 030-1335
Rev. R

OSTEOMED
OSTEO-FLAP
Cranial Flap Fixation System

Product Information and Instructions For Use

Description

The *OSTEOMED* Cranial Flap Fixation System is comprised of a clamping device which has a threaded post attached to an inferior disk and a superior disk that threads down the post to secure a sandwich fit of the Cranial flap and cranium between the inferior disk and the superior disk. Desired fixation is achieved by threading the superior disk down the threaded post and against the cranial bone by the surgeon using the tightening tool. These clamps are available in a range of sizes, 11mm, 17mm, and 22mm. Device is magnetic resonance (MR) conditional. Running the MRI using a spin-echo rather than a gradient-echo approach, at 1.5T rather than 3.0T, will yield the smallest artifact.

Material

The device is made of Titanium Alloy (ASTM-F-136). The instrumentation is made from various grades of stainless steel, aluminum, and/or medical grade plastic.

Clinical 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. OsteoMed single use devices/instruments cannot be reused and/or reprocessed. The product has been labeled as single use only for patient safety. The design of the device and the intricacies of the surfaces may not facilitate cleaning and sterilization after contact with body tissues or fluids, so there is an increased risk of contamination if reused. This may lead to potential risks of cross infection/contamination associated with using inadequately cleaned and sterilized devices. For cutting instruments the cutting efficacy may be reduced requiring the surgeon to use increased force that might cause patient harm and/or increase the risk of thermal necrosis. Because these products have not been validated for multiple use, OsteoMed cannot guarantee the safety and effectiveness of the device if it is used on more than one patient.

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.
5. Evaluation of the safety and compatibility of the device in the MR environment, the following concerns were determined based on the implant material, MDD 93/42/EEC and ISO14630: magnetically induced displacement force and torque, radio frequency (RF) heating and image artifacts.
6. The *OSTEOMED* Cranial Flap Fixation System has not been tested for safety and compatibility in the MR environment, nor has it been tested for heating or migration in the MR environment.

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 replaced or sent to OsteoMed for disposition and repair.
7. OsteoMed recommends the use of OsteoMed products in a sterile environment.

Cleaning

- Products must be carefully cleaned prior to sterilization, unless supplied in an autoclavable pouch directly from OsteoMed. Trained personnel must perform cleaning and mechanical inspection prior to sterilization.
- Compliance is required with the equipment manufacturer's user instructions (manual and/or machine cleaning, ultrasound treatment, etc.) and recommendations for chemical detergents.

Sterility

- Product is supplied NON-STERILE unless expressly labeled as STERILE.
- *OSTEOMED* Cranial Flap Fixation device is also packaged STERILE (gamma sterilized). DO NOT USE IF STERILE PACKAGE IS DAMAGED. DO NOT USE AFTER EXPIRATION DATE.
- Use of the sterilizer shall comply with the manufacturer's user instructions for sterilizers.
- The user facility must clean and disinfect devices prior to sterilization per standard hospital procedures.
- Non-sterile devices are sterilizable by steam sterilization (autoclaving). For sterilization of OsteoMed implant systems, the following parameters should be used.

OSTEOMED Cranial Flap Fixation device must be in autoclavable pouch for steam sterilization.

Pre-Vacuum Steam Sterilization

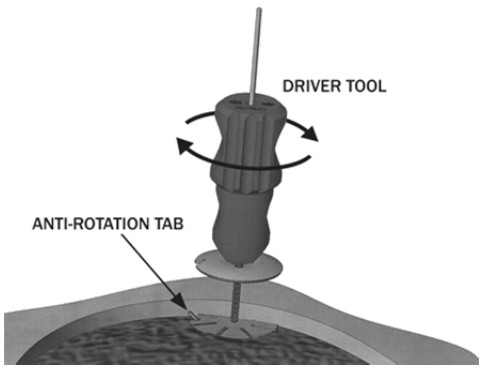
Temperature:	270°F (132°C)
Time:	6 minutes
Dry Time:	0 minutes
Configuration:	Pouched (Autoclavable)

Caution

- 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.

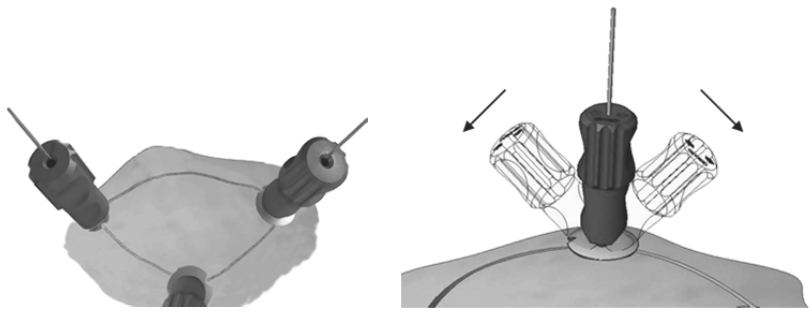
Instructions for use

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.

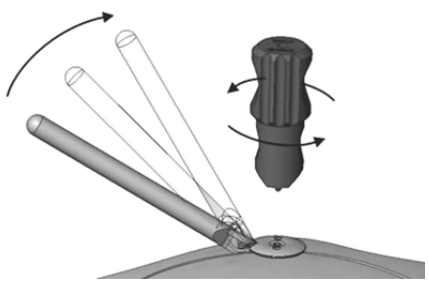


2. The superior disks are threaded down on each device with the use of the attached driver tool. Tighten the superior disk by pulling the rod in a superior direction with one hand, and turning the driver tool with the other hand. DO NOT secure any single device until all of the devices are loosely tightened 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 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.



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Symbols and Definitions

	Single Use Only	REF	Catalogue Number
	Use By (Date)		Do not use if sterile package is damaged
LOT	Batch Code (Lot Number)		Consult Instructions for Use
	Date of Manufacture		Manufacturer
	Attention, See Instructions for Use Caution, Consult Accompanying Documents	EC REP	Authorized Representative in the European Community
Rx ONLY	Federal Law (U.S.A) Restricts this device to sale by or on the order of a physician.	STERILE R	Sterile, Method of Sterilization Using Irradiation
MR	Magnetic Resonance Conditional		

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