Part No. 030-1752
Rev. D

OSTEOMED Oracle Cranial Distraction System

Product Information and Indications for Use

Description

The *OSTEOMED Oracle Cranial Distraction System* is a distraction osteogenesis system consisting of distractors, spacers, screws, distractor tool, drills, screwdriver, holding forceps, plate bending forceps, plate cutters, and distractor rod removal tool. The distractor is anchored to the cranium using 1.2mm diameter standard screws or 1.2mm diameter Auto-Drive screws. The distractor gradually distracts the bone segments by the activation of the distractor rod with the distractor tool. The system also contains 1.5mm diameter safety screws. The distractors can distract up to 25mm in length.

Material

The distractor assembly is made from Titanium (ASTM-F-67) and Titanium Alloy (ASTM-F-136). Spacer is made from Titanium (ASTM-F-67). The screws are made from Titanium Alloy (ASTM-F-136). The instrumentation is made from various grades of stainless steel, anodized aluminum, and/or medical grade plastic.

Clinical Indications

The *OSTEOMED Oracle Cranial Distraction System* is indicated for use in the treatment of cranial conditions such as syndromic craniosynostosis and congenital deficiencies in which osteotomies and gradual bone distraction are indicated. This device is intended to provide temporary stabilization and gradual lengthening of the cranial bones. This device is intended to be removed after consolidation. The *OSTEOMED Oracle Cranial Distraction System* is intended for single patient use only.

Contraindications

- Use of the *OSTEOMED Oracle Cranial Distraction System* is contraindicated in cases of active or suspected infection, in patients previously sensitized to 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 distraction osteogenesis.
- The *OSTEOMED Oracle Cranial Distraction System* is also contraindicated in those cases where there is an inadequate volume or quality of bone to place the distractor securely.

Warnings

1. Distractors, plates, spacers, screws, or other appliances of dissimilar metals should not be used together in or near the implant site.
2. Multiple plate bending may weaken the device and could result in implant fracture and failure.
3. Use of screws in high density bone may lead to implant fracture or failure upon insertion.
4. Use of excessive torque during insertion of screws may lead to implant failure.
5. Do not remove distractor rod before the consolidation period has been completed.
6. Distractor must be fixated with a minimum of 3 screws on each arm of the moving plate and the stationary plate.
   Note: not adding 3screw in each arm may cause pressure in the subcutaneous plate during removal of the distraction rod.
7. The distractor rod must be turned in the direction of the arrow as indicated on the handle of the distractor tool.
8. Patient's activities must be governed according to the limitations of the device.
9. During distraction and consolidation period, the soft-tissue portal must remain clean
10. Excessive torque on the distraction rod may cause the wire to break.
11. Failure to follow Planning instructions may contribute to patient harm.
12. Failure to follow Implantation instructions may cause patient harm or device damage.
13. Failure to follow Distraction instructions may cause patient harm or device damage.
14. Failure to follow Distractor removal instructions may cause patient harm.
15. The devices can break or be damaged due to excessive activity or trauma. This could lead to failure of the distractor, spacer and/or screws which could require additional surgery and device removal.
16. It is recommended to remove any fractured implants from patients during surgery. If unable to remove, notify patient/guardian.
17. The *OSTEOMED Oracle Cranial Distraction 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.
18. 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.

Precautions

1. The patient/guardian is to be warned that the device can break or loosen as a result of stress, excessive activity or inappropriate diet.
2. The patient/guardian is to be made aware of the surgical risks and possible adverse effects prior to surgery, and warned that failure to follow postoperative care instructions can cause failure of the implant and the treatment.
3. Surgeon should limit patient activity while device is implanted.

Maintaining Device Effectiveness

1. The surgeon should have specific training, experience, and thorough familiarity with the use of cranial distraction products and techniques.
2. The surgeon must exercise reasonable judgment when deciding which plate and screw type to use for specific indications.
3. The *OSTEOMED Oracle Cranial Distraction System* is not intended to endure excessive abnormal functional stresses.
4. The *OSTEOMED Oracle Cranial Distraction System* is intended for temporary fixation once intended distraction is achieved and osteogenesis occurs.
5. All OsteoMed implants 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.
8. Care must be taken not to damage threads on the distractor during implantation.
9. Drill using the appropriate pilot drill. Note: Speed and torque parameters must be in accordance to the power system instructions for use. Use irrigation when pilot drilling.

Instructions for Use, Auto-Drive™ screws

The Auto-Drive™ screws are self-drilling and can be inserted in one step. Insert the screw in a TaperLock™ screwdriver and drive into the bone at a 90° angle using moderate pressure until the head is flush with the surface of the plate. Higher torque may be required to fully engage the threads than when using a normal screw with a pilot drill.
Note: In high density bone, pilot drilling may be necessary.

Instructions for Placing the Cranial Distractor:

Attention: OsteoMed recommends that prior to performing a cranial distraction using the *OSTEOMED Oracle Cranial Distraction System* device, that pre-op planning is done by matching the device to a 3D Model (preferred) or x-rays/CT scans of the patient.

Planning

The *OSTEOMED Oracle Cranial Distraction System* offers straight designs which can distract up to 25mm. The distractor is chosen based on the desired cranial movement. During pre-op planning x-rays/CT scans taken of the distraction site are needed in order to select the appropriate distractor and plan the necessary distraction. When selecting the appropriate length of distraction, it is important to consider the following:

- Location of osteotomy
- Amount and direction of distraction (Note: distractor fully closed is at zero length and fully open is at the size indicated distraction length).
- Correct length of device selected based on planned distraction and length between fixation point and access point.

Implantation (placing distractor)

Note: *OSTEOMED Oracle Cranial Distraction System* Surgical Technique Guide can be used for further guidance 030-1753.

1. Expose the cranial bone.
2. Make a coronal incision and bring down the scalp to expose the cranial bone.
3. Outline a cranial bone flap as indicated per the particular case.
4. Prepare the distractor. Ensure that both parts of the distractor are working by advancing the distractor rod all the way forward and return the distractor to the starting position.Cut off the excess plate holes (if necessary). Note: If cutting plate holes, ensure no sharp edges remain on the distractor.
5. Use bending forceps to adjust the fixation plates to the anatomy.
6. Use spacers below the cranial distractor feet to ensure distraction will occur in the planned trajectory.
7. Provisionally place 2 distractors one on each side of the cranium. A third distractor may be used if necessary and placed near the midline. Mark the placement of the distractors.
   Note: It is important that the axis of these distractors lie parallel to one another and that their vectors coincide with the direction of the desired expansion.
8. Using a craniotome, cut the bone previously marked in Step 3 leaving the bone attached to the dura.
9. Secure the distractors to the cranial bone using 1.2 mm diameter Auto-Drive Screws or Standard Screws.
10. When fixating the stationary plate of the distractor, place one screw in each mesh plate arm. Then place screws in remaining plate holes.
11. At a minimum, three screws should be placed in each mesh plate arm. Fixate the distractor with no gap between the foot plates surrounding the osteotomy, if gap between plates is necessary subtract the gap from the desired length of the distraction.
    Note: not adding 3screw in each arm may cause pressure in the subcutaneous plate during removal of the distraction rod.
12. Care must be taken not to damage distractor rod threads during implantation of device.
13. Using the distractor tool, rotate the distractor hex nut to advance the distractor to assure adequate mobilization of the bone flap.
14. Place the scalp flap back over the cranial bone covering the distractors. The distractor arm is brought through punctures in the scalp unless the arm is near an incision line, in which case it is allowed to exit through the incision.
15. Suture the incision line closed. Meticulous hemostasis and wound closure are necessary to minimize hemotoma and infection.
16. Wound care should be routinely done where the distractor rod exits the skin.

Distraction

1. Distraction is recommended to begin at the conclusion of the latency period and continue at a rate of 1mm per day or as determined by the surgeon until the desired distraction is achieved. The distractor tool is used by the patient's guardian to rotate the distractor rod and initiate distraction. Three turns to the distraction tool equals 1mm of distraction.
2. If excessive resistance is felt, STOP distracting and contact the surgeon.
3. After the desired distraction has been achieved, the portion of the distractor rod not consumed within the distractor may be removed (see Instructions for Use: Distractor Rod Removal) and discarded, according to standard bio-hazard disposal procedures. The distractor should remain implanted for the consolidation period determined by the surgeon.

Distractor Rod Removal

1. Using plate cutters, remove the hex nut.
2. Slide the Distractor Rod Removal Tool (P/N 216-0103) all the way until it reaches the distractor body.
3. Move the wire back and forth parallel to the cranial bone until it breaks off.
4. Remove the portion of Distractor Rod that broke off.
5. Discard the removed Distractor Rod and Distractor Rod Removal tool in accordance with standard biohazard waste disposal procedures. The remainder of the distractor rod will remain inside the distractor, supporting it in its expanded position.
6. The distractor should remain implanted for the consolidation period determined by the surgeon.

Distractor Removal:

1. Make the cranial incision and expose the distractor.
2. Remove the screws fixating the distractor to the cranium.
3. Remove the distractor from the cranium.
4. Remove the spacers from the cranium, if used.
5. Discard all devices according to standard biohazard disposal procedures.
5. Suture the distraction site closed.

Cleaning

- Products must be carefully cleaned prior to sterilization. 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.
- It is the responsibility of the facility/user to qualify any deviations from the recommended method of processing.
- OsteoMed recommends the following cleaning and sterilization instructions for Instrumentation:

1. Rinse the articles to be cleaned under running cool tap water (<40°C) to remove visible soil until visibly clean.
2. Prepare an enzymatic cleaner, Klenzyme®, per manufacturer's recommendations. Fully immerse the articles in the solution and soak for a minimum of 10 minutes. Actuate the articles while immersed in the solution to ensure complete penetration of cleaning solution.
3. Using a soft bristled brush, clean the entire article paying close attention to hard to reach areas until all evidence of soil is removed. A syringe may be used to clean the lumens and other hard to reach areas. Actuate the articles while brushing in order to clean matted surfaces and movable parts.
4. Prepare a mild detergent such as Renu-Klenz™, per manufacturer's recommendations. Fully immerse the articles in the prepared solutions and sonicate the articles for a minimum of 10 minutes. Following sonication, remove the articles and proceed to the rinse step.
5. Rinse the articles under running reverse osmosis/deionized (RO/DI) water until all evidence of detergent is removed.
6. Steam Autoclave per the following Sterilization Instructions.

Sterility

- Implants and Instruments are provided non-sterile and must be sterilized prior to use.
- Use of the sterilizer shall comply with the manufacturer's user instructions for sterilizers.
- Non-sterile devices are sterilizable by steam sterilization (autoclaving). For sterilization of *OSTEOMED Oracle Cranial Distraction System*, the following parameters should be used.

Steam Sterilization:

Pre-Vacuum Steam Sterilization:

Temperature:	270°F (132°C)
Cycle Time:	4 minutes
Dry Time:	20 Minutes
Configuration:	Wrapped Tray

Wrapping Technique: Wrap tray in two layers of 1-ply polypropylene wrap (Kimguard KC600 – 510(k) K082554) using sequential envelope folding techniques with a surgical towel placed between the wraps and the bottom of the tray.

Do not exceed 275°F (135°C), to avoid compromising functions of polymeric instrumentation.

Note: Steam Validation Biological Indicator over kill method. Geobacillus stearothermophilus was the indicator organism.

Caution

- Federal (United States) law restricts this device for sale by or on the order of a medical practitioner licensed to do so.
- Do not 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.

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Symbols and Definitions

	Single Use Only	REF	Catalogue Number
LOT	Batch Code (Lot Number)		Consult Instructions for Use
	Date of Manufacture (MFG DATE)		Manufacturer (MFR)
	Attention, See Instructions for Use	EC REP	Authorized Representative in the European Community
	Caution, Consult Accompanying Documents		
Rx ONLY	Federal Law (U.S.A.) Restricts this device to sale by or on the order of a physician.		

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