Part No.030-1373
Rev N

OSTEOMED SPECTRUM™ LeFort I / LeFort III Mid-Face Distraction System

Product Information and Indications for Use

Description

The *OSTEOMED Spectrum Mid-Face Distraction System* is a distraction osteogenesis system consisting of distractor frame, bone plates, threaded rods, and an activation instrument. The plates attach to bone using bone screws and then gradually distract the osteotomized segment via activation of the threaded rod with the activation instrument.

Material

The Distractor assembly is made from Titanium (ASTM-F-67) and Titanium Alloy (ASTM-F-136). The plates are 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 Spectrum Mid-Face Distraction System* is indicated for use in the treatment of cranial or midface conditions for which reconstructive osteotomy and segment advancement are indicated. This includes conditions such as, syndromic craniosynostosis, midfacial retrusion, hemifacial microsomia, and micrognathia. The *OSTEOMED Spectrum Maxillary Distraction* device is intended to provide temporary stabilization and gradual lengthening of the cranial or midfacial bones. This device is intended to be removed after consolidation. The *OSTEOMED Spectrum Mid-Face Distraction 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 Spectrum Mid-Face Distraction System* is contraindicated in cases of active or suspected infection, in patients previously sensitized to titanium or silicone; 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 Spectrum Maxillary 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. Manipulation of maxillofacial bones or tissues can potentially result in cardiac complications such as ectopic beats, atrioventricular block, bradycardia, syncope, vomiting, and asystole. These are known complications during maxillofacial surgery and are not specifically related to any device.
2. Plates, screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
3. Multiple bending may weaken the device and could result in implant fracture and failure.
4. Use of screws in high density bone may lead to implant fracture or failure upon insertion.
5. Use of excessive torque during insertion of screws may lead to implant failure.
6. 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.
7. The *OSTEOMED Spectrum Mid-Face 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.

Maintaining Device Effectiveness

1. The surgeon should have specific training, experience, and thorough familiarity with the use of intraoral 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 Spectrum Mid-Face Distraction System* is not intended to endure excessive abnormal functional stresses.
4. The *OSTEOMED Spectrum Mid-Face Distraction System* is intended for temporary fixation once intended distraction is achieved and 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.

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 bone/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 Maxillary Distractor:

Le Fort I Distraction

Attention: OsteoMed recommends that prior to performing a Le Fort I distraction using the *OSTEOMED Spectrum Mid-Face Distraction* device, that pre-op planning is done by matching a device to a 3D Model (preferred) or dental model of the patient.

Note: A simultaneous LeFort I and LeFort III distraction can be performed

Assembly and Placement of LeFort I Distractor

1. Select the appropriately sized horizontal bow and shape to fit the patient's anatomy by using a roller type bender.
2. Slide each end of the horizontal bow (knurled side facing down) into the mating holes of the distraction assembly. Make sure that the maxillary plates are inside the horizontal bow, and the set screw holds face downward. The hex-nut of the distraction rod should be oriented towards the curve of the distraction bow (anterior).
3. Contour the maxillary plates to fit the patient's anatomy. Excess plate holes may be cut and removed if required.
4. Select the appropriate length vertical post (short post allows up to 4mm of vertical distraction, standard post allows up to 7mm of vertical distraction). Thread each vertical support post onto the horizontal distraction rod of the maxillary anchor. The vertical support posts should be in the most anterior position to ensure maximum horizontal distraction potential (25mm). The inferior face of the vertical posts are marked with an arrow which should be oriented towards the anterior aspect of the device so that once threaded, the vertical posts will lean with anterior direction.
5. Adjust the position of the horizontal distraction rod in relationship to the patient's anatomy and provisionally lock the device by inserting and tightening the set screws. Small caps are provided and should be threaded onto the posterior ends of the horizontal distraction rods to prevent the device from over distracting.

Lefort I Distraction: Instructions for Use

1. Create a maxillary vestibular incision and dissection typical for a Le Fort I osteotomy. It is not necessary to fully strip the nasal mucosa. However, the malar eminences will have to be fully dissected.
2. Rotate the vertical arms up and place fully assembled distractor in the mouth, holding it horizontal. Temporarily ligate the horizontal bow to the teeth or orthodontic appliances to maintain horizontal position and ensure proper device placement.
3. Vertical adjustments of the arms can be done at this time with the vertical wrench if needed. It is suggested that the surgeon temporarily place 1-2 screws per each malar anchor and each maxillary plate to mark the desired final position of the device.
   Note: The malar anchor plates are asymmetric and should be rotated for best fit to the bone. The plates should be somewhat lateral to the vertical assembly to prevent binding.
4. Remove the device, then create a Le Fort I osteotomy and partially mobilize.
5. Place the device into the patient securing the maxillary plates with 1.6mm screws. Complete the down-fracture, then secure the malar anchors using 1.6mm screws.
6. The horizontal distraction rod may impinge on the soft tissue of the ramus. This is generally not a problem and can be relieved with subsequent distraction.
   Caution: Cutting the distraction rod may cause damage to the threads and impede the ability to distract the device.
7. Ligate the horizontal bow to the teeth or orthodontic appliances if desired.
8. Distract the device up to 3mm horizontally to ascertain the completeness of the osteotomies and proper distraction vectors. Final adjustment of the vertical malar post may also be accomplished at this time to assure intended initial overall distraction vector.
9. Close incisions.
10. After the latency period, the device may be distracted 1mm a day using the OsteoMed Horizontal Distraction Tool by turning it 1.5 turns counter-clockwise.

Instructions for Placing the LeFort III Distractor:

Le Fort III Distraction

Attention: OsteoMed recommends that prior to performing a Le Fort III distraction using the *OSTEOMED Spectrum Mid-Face Distraction* device, that pre-op planning is done by matching a device to a 3D Model of the patient.

Note: A simultaneous LeFort I and LeFort III distraction can be performed

1. Select the appropriately sized horizontal bow and shape to fit the patient's anatomy by using a roller type bender.
2. Slide each end of the horizontal bow (knurled side facing down) into the mating holes of the distraction assembly. Make sure that the maxillary plates are inside the horizontal bow, and the set screw holds face downward. The hex-nut of the distraction rod should be oriented towards the curve of the distraction bow (anterior).
3. Contour the maxillary plates to fit the patient's anatomy. Excess plate holes may be cut and removed if required.
4. Select the appropriate length vertical post (short post allows up to 4mm of vertical distraction, standard post allows up to 7mm of vertical distraction). Thread each vertical post onto the horizontal distraction rod of the maxillary anchor. The vertical posts should be in the most anterior position to ensure maximum horizontal distraction potential (25mm). The inferior face of the vertical posts are marked with an arrow which should be oriented towards the anterior aspect of the device so that once threaded, the vertical posts will lean with anterior direction.
5. Adjust the position of the horizontal distraction rod in relationship to the patient's anatomy and provisionally lock the device by inserting and tightening the set screws. Small caps are provided and should be threaded onto the posterior ends of the horizontal distraction rods to prevent the device from over distracting.
6. Select appropriate length rod and anchor plate height. Thread anchor plate onto the distraction rod.

Lefort III Distraction: Instruction For Use

1. Create a maxillary vestibular incision and dissection typical for a LeFort I osteotomy. It is not necessary to fully strip the nasal mucosa. However, the malar eminences will have to be fully dissected. Also, create a coronal incision and dissection typical for a LeFort III osteotomy.
2. Complete all LeFort III osteotomies, dissections, and mobilization.
   Optional: Surgeon can determine if osteotomy is to be completed and total mobilization attained after the device has been fully place.
3. K-wire should be driven through each malar bone at the postion of malar anchor plate. Attention should be given to place the k-wires as parallel as possible. Drill and place malar pins over the k-wires through the malar bone.
4. Rotate the vertical arms up and place distractor in the mouth, holding it horizontal. Ligate the horizontal bow to the teeth or orthodontic appliances to maintain horizontal position and ensure proper device placement.
5. Vertical adjustments of the arms can be done at this time with the vertical wrench if needed. The malar anchor plates must be centered over the malar pins. The surgeon can then place appropriate screws into maxillary and malar plates in order to secure device into desired final position.
6. Place the distraction rod over the k-wire until it engages the malar-pin. The rod can be under or above the temporalis muscle. Remove the k-wires and adjust the cranial plate to appropriate location by rotating the distraction rod. Secure cranial plate with 1.6mm screws.
7. Thread the LeFort III cap nut on the end of the distraction rod and distract the device up to 3mm horizontally to ascertain the completeness of the osteotomies and proper distraction vectors.
8. Create incision to allow the LeFort III activation rods to exit the scalp posteriorly. Close incisions.
9. After the latency period, the device may be distracted 1mm a day using the OsteoMed Horizontal Distraction Tool by turning it 1.5 turns counter-clockwise.

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.
- OsteoMed recommends the following cleaning and sterilization instructions for Instrumentation:
  1. Clean all instruments thoroughly using mild detergent, soft brush and warm water. Ensure that dried blood, bone chips and other deposits are removed from the instruments and sterilization tray.
  2. Thoroughly rinse all instruments and the sterilization tray with water.
  3. Arrange all the instruments in the sterilization case and ensure that the lid is in place and properly closed.
  4. Steam autoclave per the following Sterilization Instructions.

Sterility

- Product is supplied STERILE (Gamma Sterilized) and NON-STERILE. DO NOT USE IF STERILE PACKAGE IS DAMAGED. DO NOT USE AFTER EXPIRATION DATE.
- NON-STERILE implants and instruments MUST be sterilized prior to use.
- Use of the sterilizer shall comply with the manufacturer's user instructions for sterilizers.
- The user facility must clean and disinfect instruments prior to sterilization per standard hospital procedures.
- Non-sterile devices are sterilizable by steam sterilization (autoclaving). For sterilization of *OSTEOMED Spectrum Maxillary Distraction System*, the following parameters should be used.

Pre-Vacuum Steam Sterilization:
Temperature: 270°F (132°C)
Cycle Time: 15 minutes
Dry Time: 20 Minutes
Configuration: Indivigually wrapped the case 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 warps and the bottom of the case.

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

Note: Biological Indicator of *G. stearothermophilus* was used in sterilization validation

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
	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

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