The LeFort I Distraction System is indicated for use in the treatment of cranial or maxillary deformity for which reconstructive osteotomy and segmental distraction would be desirable. This includes cases such as, synchronous craniosynostosis, midfacial retrusion, hemifacial microsomia, and micrognathia. The Orthopedic Extreme Distraction System is contraindicated in those cases where it is not intended to be removed after consolidation. The device is also contraindicated in those cases where there is inadequate volume or quality of bone to place the distractor securely.

Contraindications

1. Plates, screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
2. Multiple threads 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.

Maintaining Device Effectiveness

1. This device requires 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 screws to use for specific indications.
3. The OrthoMed Spectrum Mid-Face Distraction System is not intended to endure lifelong osteotomy procedures.
4. The OrthoMed Spectrum Mid-Face Distraction System is intended for temporary fixation once intended distraction is achieved and osteogenesis has occurred.
5. All OrthoMed plates, screws, and instrumentation may be required for each procedure. Failure to use dedicated, unique OrthoMed 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 should be removed and replaced. For cutting instruments the cutting efficiency may be reduced requiring the surgeon to use increased force that might cause patient harm and increase the risk of thermal necrosis. Because these products have not been validated for multiple use, OrthoMed cannot guarantee the safety and effectiveness of the device if it is used on more than one patient.

Cleaning

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.
2. Thoroughly rinse all instruments and the sterilization tray with water. Ensure that any bone chips and other deposits are removed from the instruments and tray.
3. Arrange all the instruments in the sterilization case and ensure that the lid is securely sealed.
4. Place the instruments and case in the Sterilizer by turning it 1 1/2 turns clockwise.

Instructions for Placing the Maxillary 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 malar plates are inside the horizontal bow, and the set screw holds face clockwise.
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 posts into the corresponding mating holes 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 in anterior direction.
5. Adjust the position of the horizontal distraction rod in relationship to the patient’s anatomy and partially lock the device by inserting and tightening the appropriate screws.
6. Place the vertical posts over the k-wire until it engages the malar-pin. The rod should be oriented towards the curve of the distraction bow (anterior).
7. Contour the maxillary plates to the bone and attach with bone screws. Small caps are provided and should be threaded onto the posterior ends of the horizontal distraction rods to prevent the device from falling over during distraction.
8. Place the distraction rod over the malar-pin. The rod should be cut and removed if required.
9. After the latency period, the device may be distracted 1mm a day using the OrthoMed Horizontal Distraction Tool by turning it 1.5 turns counter-clockwise.

Instructions for Placing the LeFort III 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 malar plates are inside the horizontal bow, and the set screw holds face clockwise.
3. Contour the maxillary plates to fit the patient’s anatomy. Excess plate holes may be cut and removed if required.
4. Adjust the position of the horizontal distraction rod in relationship to the patient’s anatomy and partially lock the device by inserting and tightening the appropriate screws.
5. Place the vertical posts over the k-wire until it engages the malar-pin. The rod should be oriented towards the anterior aspect of the arrow which should be oriented towards the anterior aspect of the device so that once threaded, the vertical posts will lean in anterior direction.
6. Adjust the position of the horizontal distraction rod in relationship to the patient’s anatomy and partially lock the device by inserting and tightening the appropriate screws.
7. Place the distraction rod over the k-wire until it engages the malar-pin. The rod should be oriented towards the anterior aspect of the device so that once threaded, the vertical posts will lean in anterior direction.
8. After the latency period, the device may be distracted 1mm a day using the OrthoMed Horizontal Distraction Tool by turning it 1.5 turns counter-clockwise.
Cycle Time: 15 minutes
Dry Time: 20 Minutes
Configuration: Wrapped Tray
Wrapping Technique: Individually wrap in 1-ply polypropylene wrap using sequential wrapping techniques. Do not exceed 275°F (135°C), to avoid compromising functions of polymeric instrumentation.

**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
- Use By (Date)
- Batch Code (Lot Number)
- Date of Manufacture
- Attention, See Instructions for Use
- Caution, Consult Accompanying Documents
- Authorized Representative in the European Community
- Sterile, Method of Sterilization Using Irradiation

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