OSTEOMED®

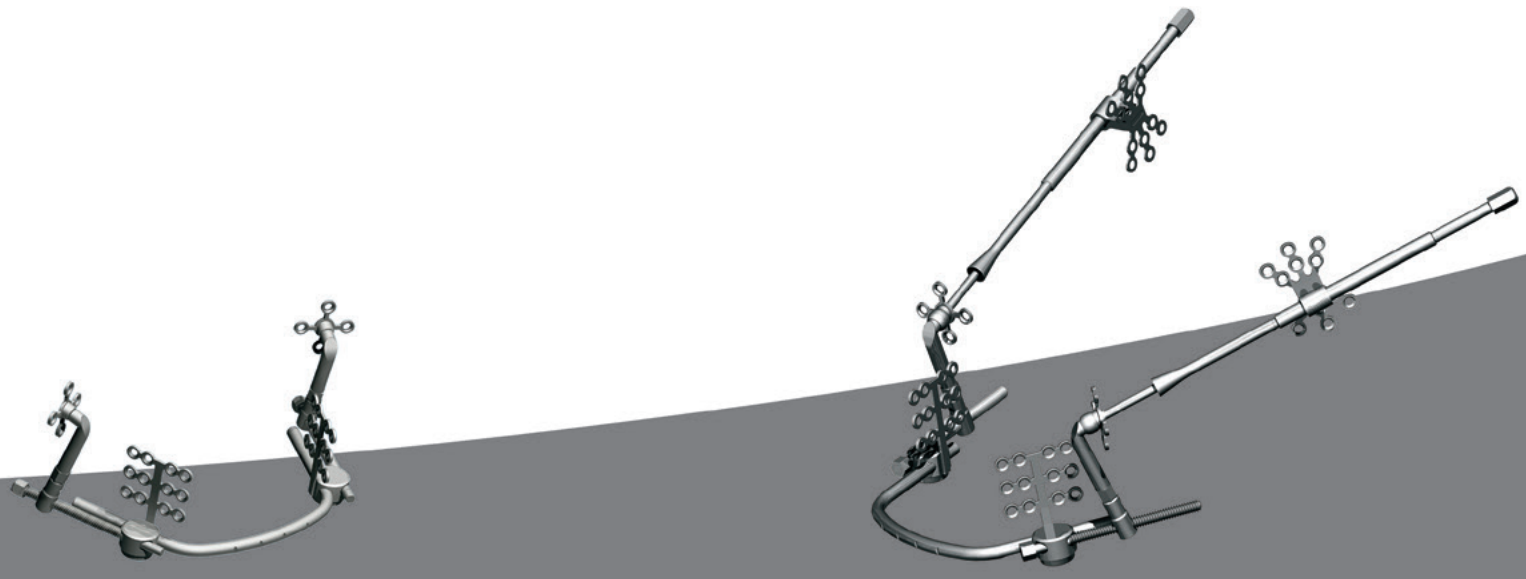
A TRADITION OF QUALITY AND INNOVATION

SPECTRUM™

Mid-face Distraction System

SURGICAL TECHNIQUE GUIDE

LEFORT I AND LEFORT III



SPECTRUM™
Mid-Face Distraction 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** Spectrum™ Mid-face Distraction System is indicated for use in the treatment of cranial or mid-face conditions for which reconstructive osteotomy and segment advancement are indicated. This includes conditions such as, syndromic craniosynostosis, mid-facial retrusion, hemifacial microsomia, and micrognathia. The **OSTEOMED** Spectrum™ Mid-face 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.

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™ Mid-face Distraction System is also contraindicated in those cases where there is an inadequate volume or quality of bone to place the distractor securely.

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 in tended 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.

CAUTIONS

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.

WARNINGS

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

Multiple bending may weaken the device and could result in implant fracture and failure.

SPECTRUM

LEFORT I MIDFACE DISTRACTION

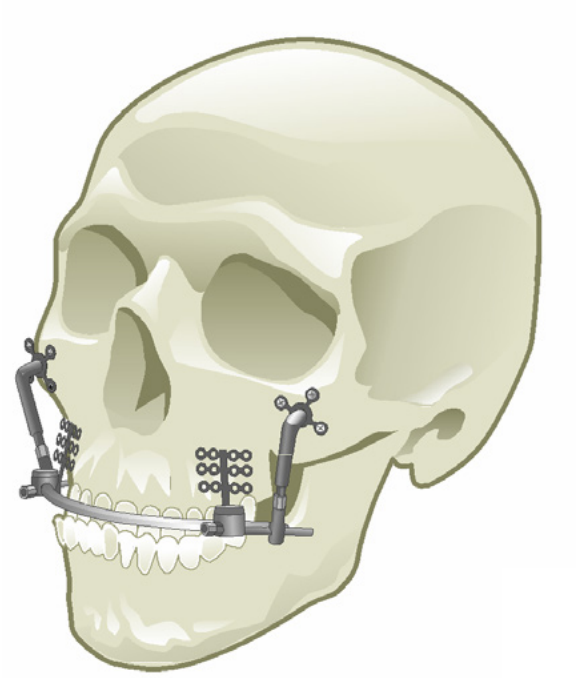
LeFort I Instructions for Use

Part Number	Description
217-0055	Spectrum™ Distraction Tool, Horizontal Adjustment
217-0057	Spectrum™ Distraction Wrench, Vertical Adjustment
217-0060	Spectrum™ Short Malar Anchor Assembly
217-0061	Spectrum™ Long Malar Anchor Assembly
217-0071	Spectrum™ Short Left Maxillary Plate Assembly
217-0062	Spectrum™ Left Maxillary Plate Assembly
217-0072	Spectrum™ Short Right Maxillary Plate Assembly
217-0063	Spectrum™ Right Maxillary Plate Assembly
217-0064	Spectrum™ Small Horizontal Bow
217-0065	Spectrum™ Large Horizontal Bow
217-0068	Spectrum™ Small Straight Horizontal Bow
217-0069	Spectrum™ Large Straight Horizontal Bow
217-0066	Spectrum™ Set Screw
217-0067	Spectrum™ Distraction Rod Cap

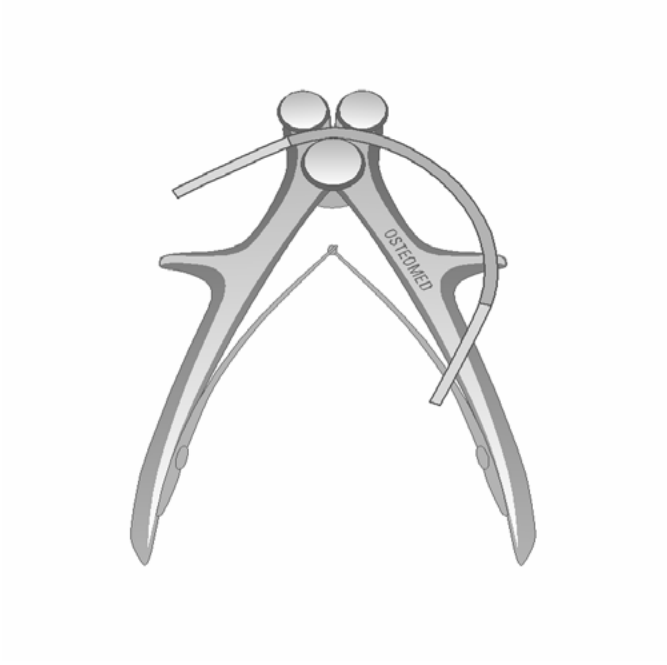
LEFORT I DISTRACTION: DEVICE ASSEMBLY

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.

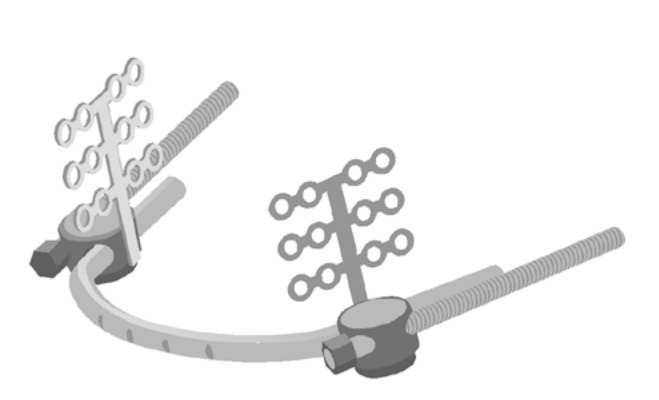
Note: A simultaneous LeFort I and LeFort III distraction can be performed



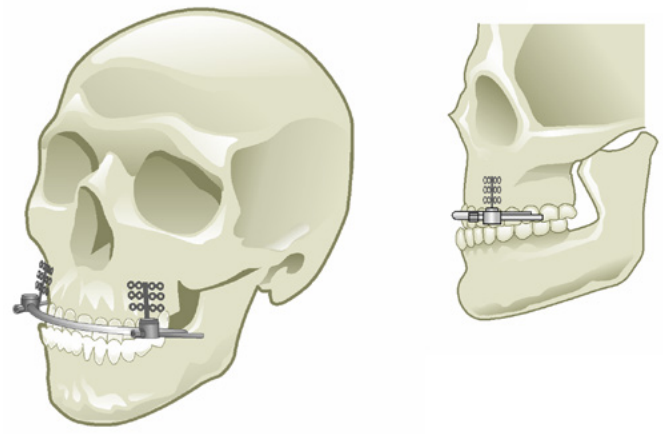
1 Select the appropriately sized horizontal bow and shape to fit the patient's anatomy by using a roller type bender.



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 holes face downward. The hex-nut of the distraction rod should be oriented towards the curve of the distraction bow (anterior).

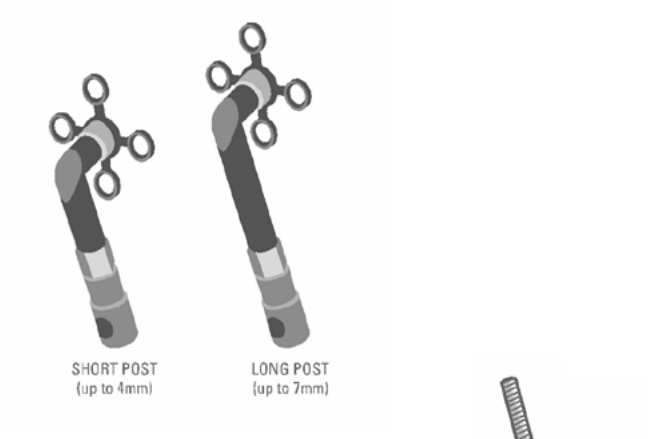


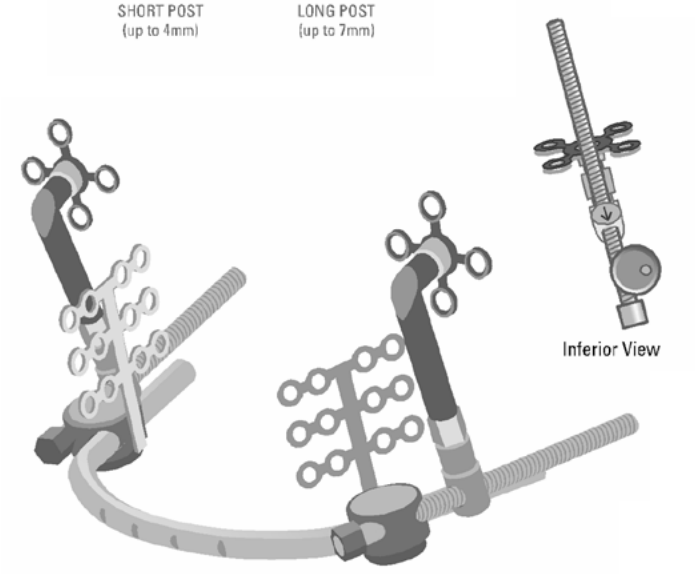
3 Contour the maxillary plates to fit the patient's anatomy. Excess plate holes may be cut and removed if required.



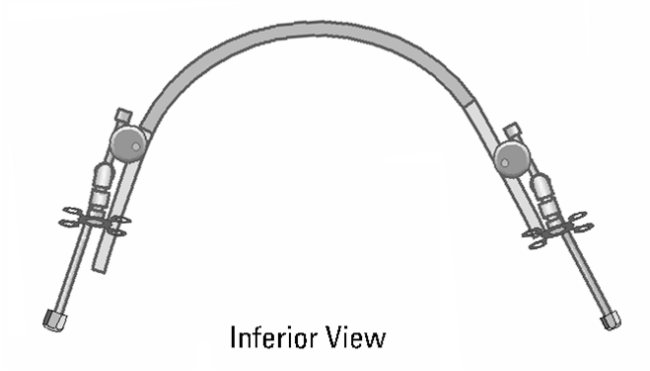
LEFORT I DISTRACTION: DEVICE ASSEMBLY

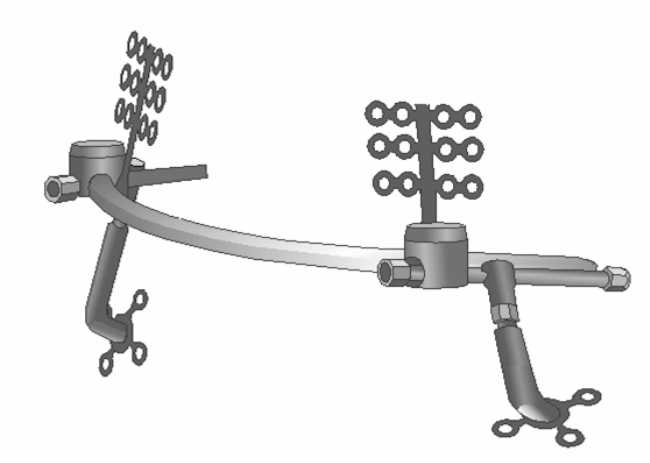
4 Select the appropriate length vertical post (short post allows up to 4mm of vertical distraction, standard post allows up to 7mm of vertical distraction). Thread each vertical support post onto the horizontal distraction rod of the maxillary anchor. The vertical support posts should be in the most 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.

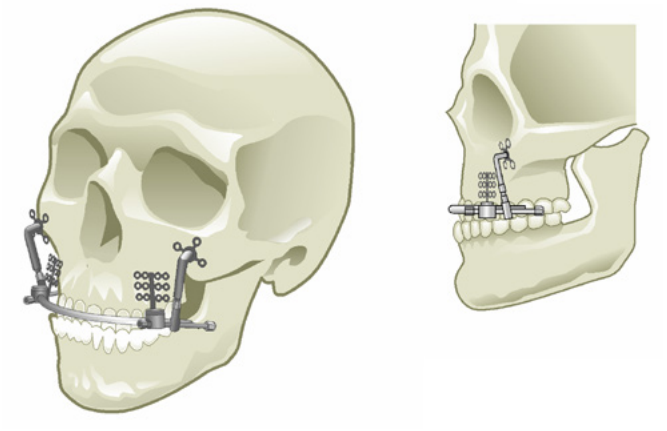




LEFORT I DISTRACTION: INSTRUCTION FOR USE

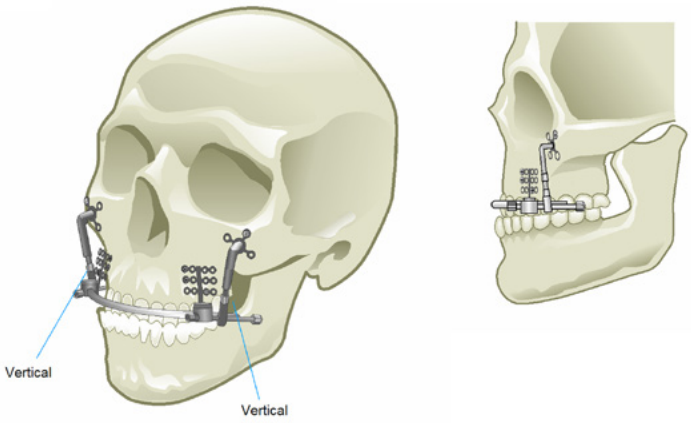
1 Create a maxillary vestibular incision and dissection typical for a Le Fort I osteotomy. It is not necessary to fully strip the nasal mucosa. However, the malar eminences will have to be fully dissected.

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.

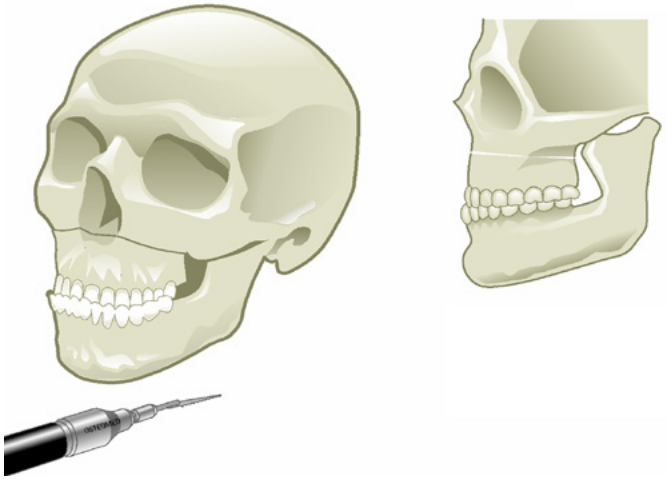


3 Vertical adjustments of the arms can be done at this time with the vertical wrench if needed. It is suggested that the surgeon temporarily place 1-2 screws per each malar anchor and each maxillary plate to mark the desired final position of the device.

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.

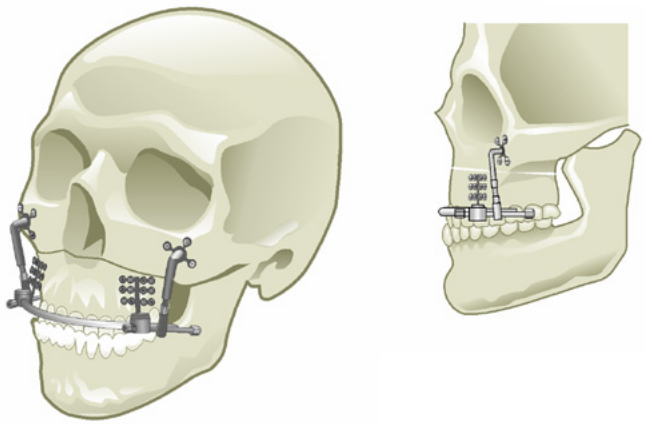


4 Remove the device, create a LeFort I osteotomy and partially mobilize.



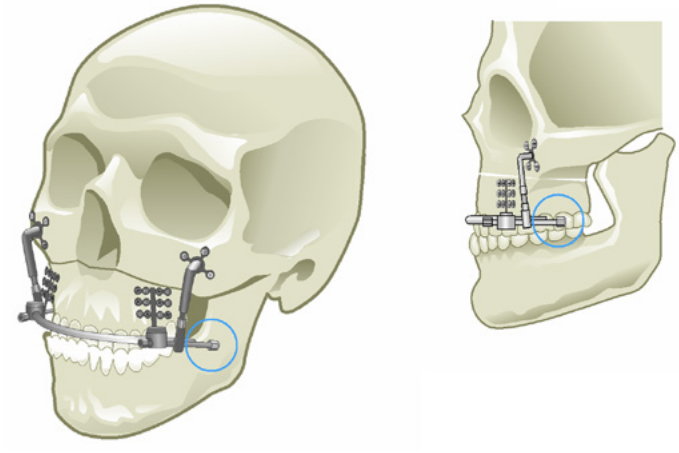
LEFORT I DISTRACTION: INSTRUCTION FOR USE

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.

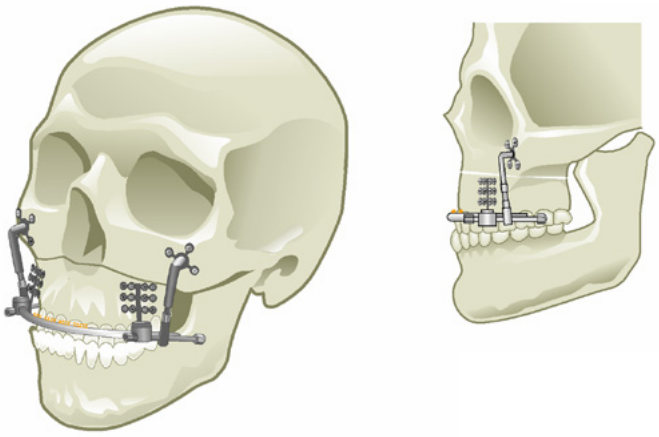


6 The horizontal distraction rod may impinge on the soft tissue of the ramus. This is generally not a problem and can be relieved with subsequent distraction.

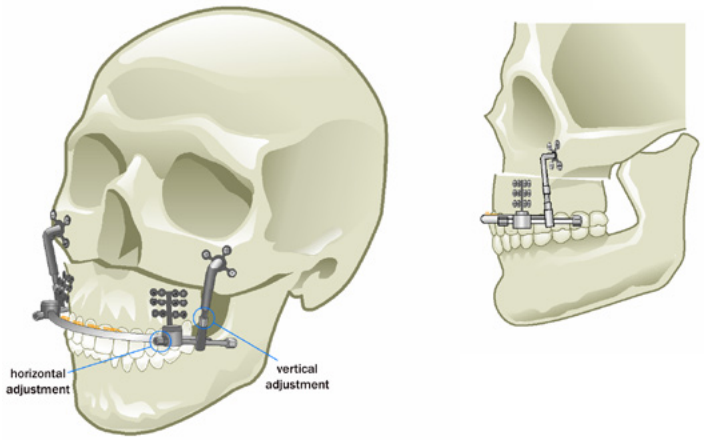
CAUTION Cutting the distraction rod may cause damage to the threads and impede the ability to distract the device.



7 Ligate the horizontal bow to the teeth or orthodontic appliances if desired.



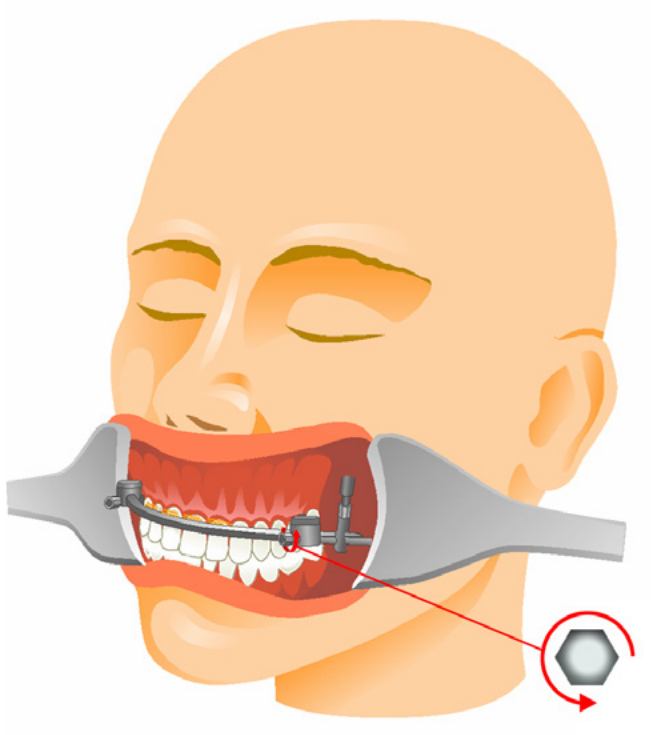
8 Distract the device up to **3mm** horizontally to ascertain the completeness of the osteotomies and proper distraction vectors. Final adjustment of the vertical malar post may also be accomplished at this time to assure intended initial overall distraction vector.



LEFORT I DISTRACTION: INSTRUCTION FOR USE

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.



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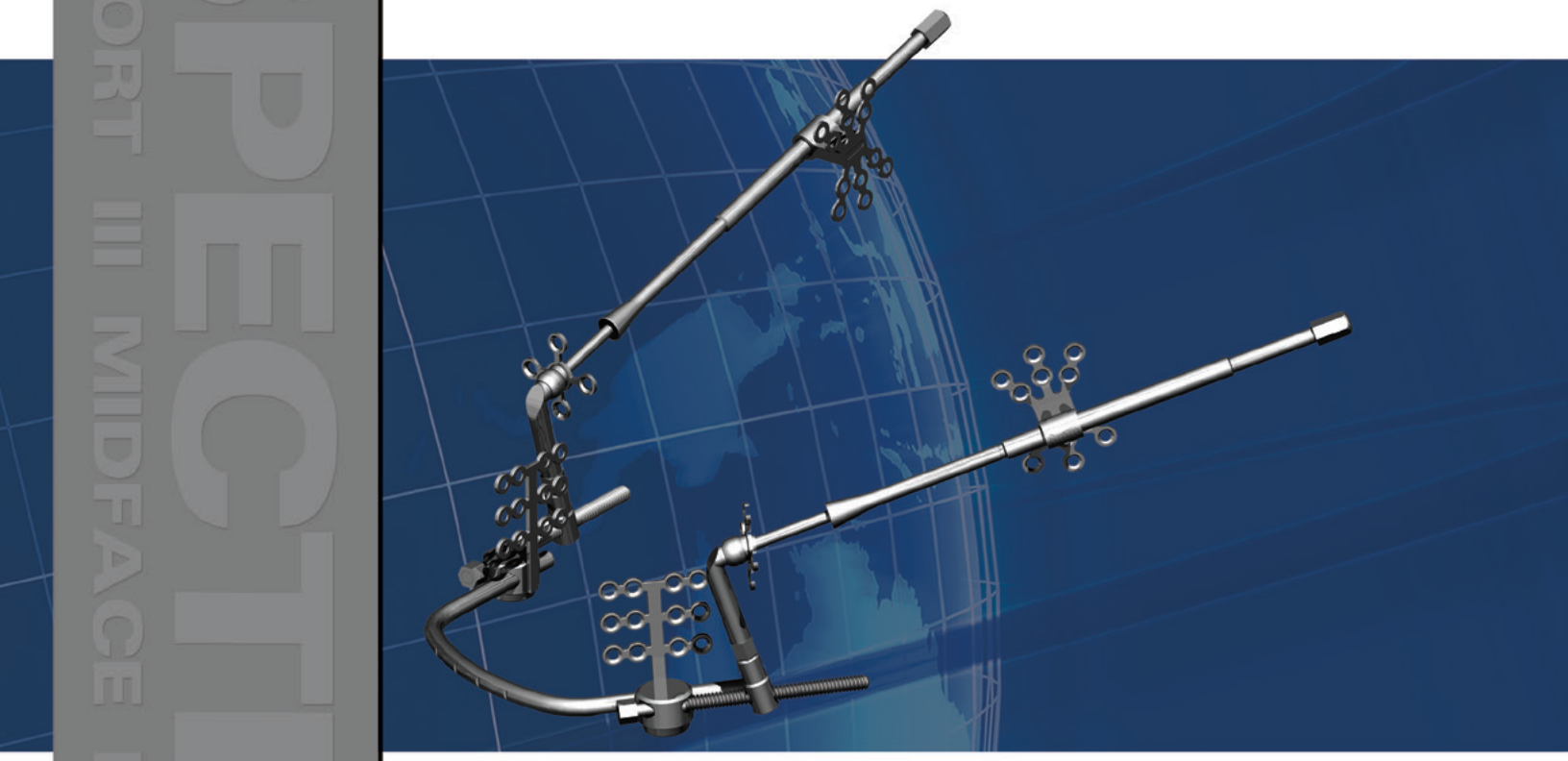
LEFORT III MIDFACE DISTRACTION

LeFort III Instructions for Use



Part Number	Description
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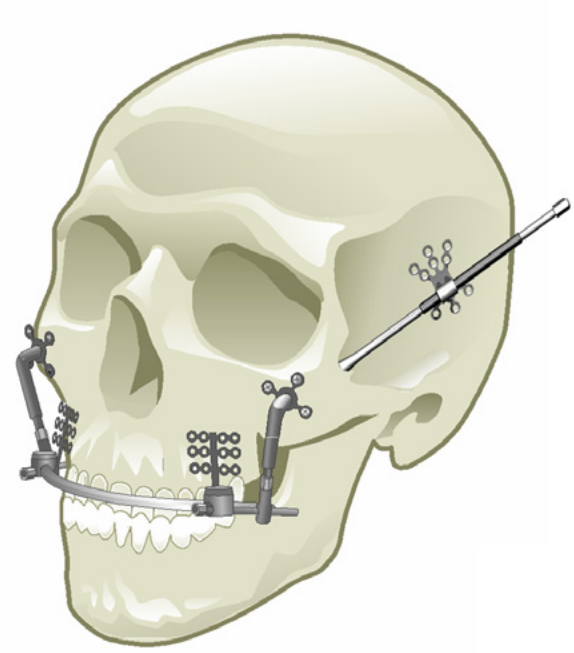
217-0069	Spectrum™ Large Straight Horizontal Bow
217-0066	Spectrum™ Set Screw
217-0067	Spectrum™ Distraction Rod Cap
217 0081	Spectrum™ LeFort III, Anchor Plate Assembly, 3mm
217 0082	Spectrum™ LeFort III, Anchor Plate Assembly, 5mm
217 0083	Spectrum™ LeFort III, Anchor Plate Assembly, 8mm
217 0084	Spectrum™ LeFort III, Malar Pin
217 0085	Spectrum™ LeFort III, Short Activation Rod
217 0086	Spectrum™ LeFort III, Medium Activation Rod
217 0087	Spectrum™ LeFort III, Long Activation Rod
217 0088	Spectrum™ LeFort III, Cap Nut

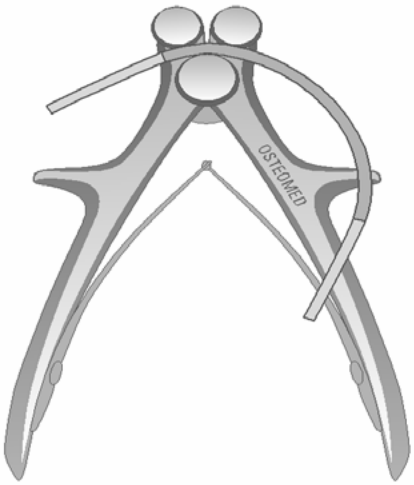
LEFORT III DISTRACTION: DEVICE ASSEMBLY

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.

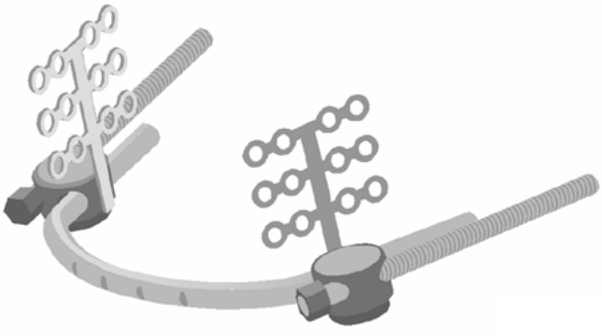
Note: A simultaneous LeFort I and LeFort III distraction can be performed

1 Select the appropriately sized horizontal bow and shape to fit the patient's anatomy by using a roller type bender.

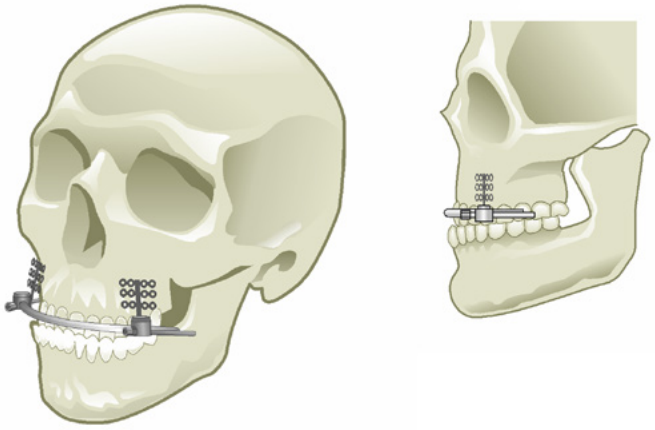




2 Slide each end of the horizontal bow (knurled side facing down) into the mating holes of the distraction assembly. Make sure that the maxillary plates are inside the horizontal bow, and the set screw holes face downward. The hex-nut of the distraction rod should be oriented towards the curve of the distraction bow (anterior).

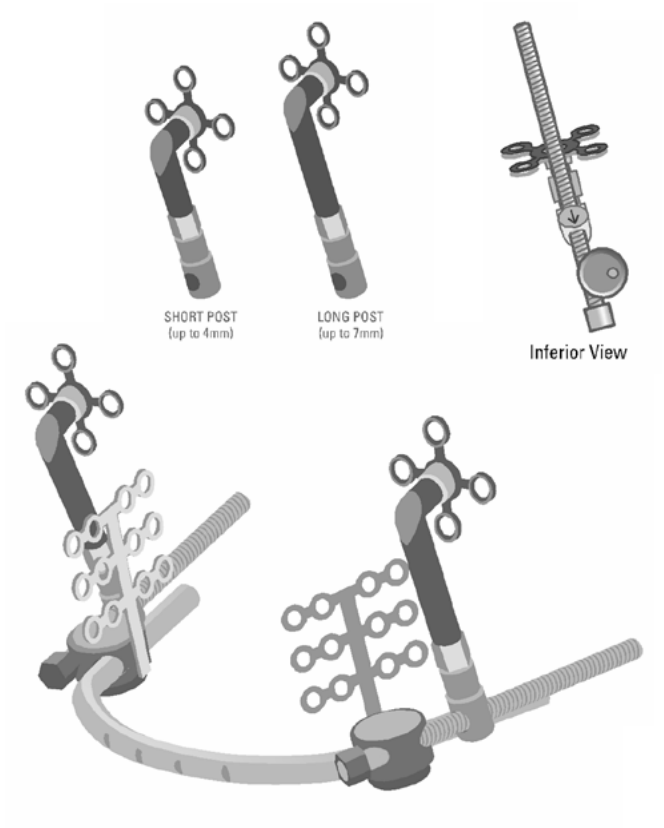


3 Contour the maxillary plates to fit the patient's anatomy. Excess plate holes may be cut and removed if required.

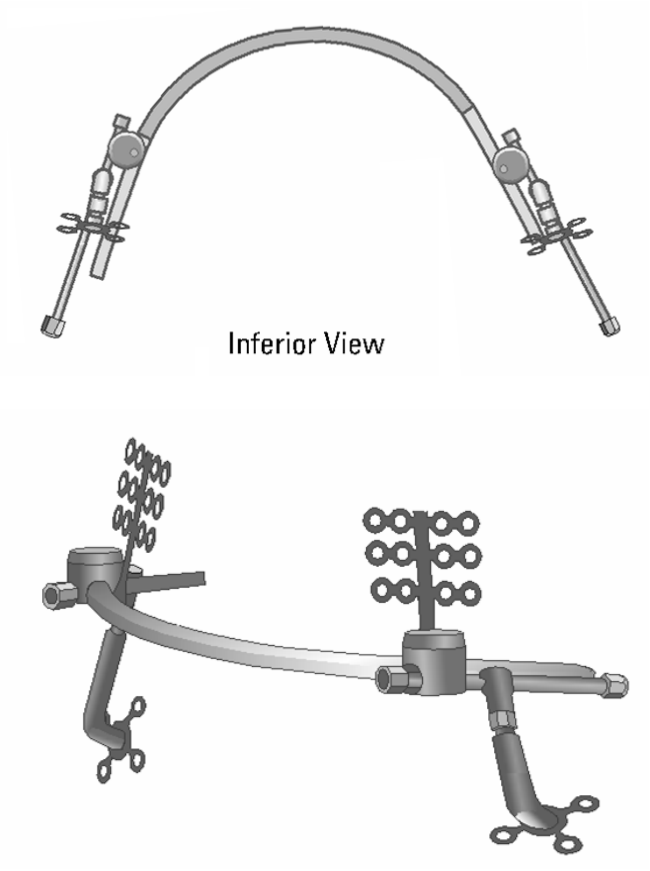


LEFORT III DISTRACTION: DEVICE ASSEMBLY

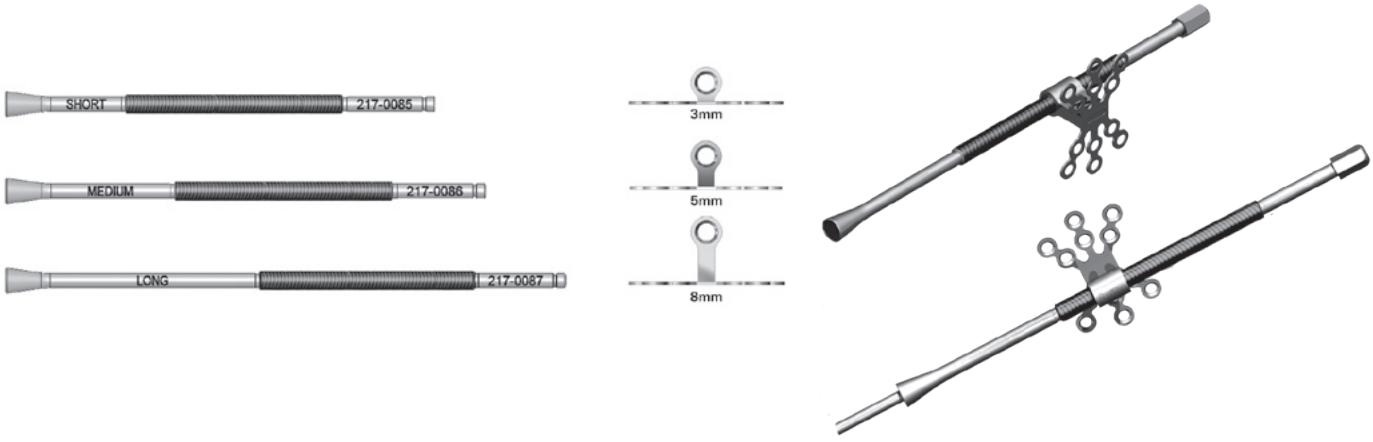
4 Select the appropriate length vertical post (short post allows up to 4mm of vertical distraction, standard post allows up to 7mm of vertical distraction). Thread each vertical post onto the horizontal distraction rod of the maxillary anchor. The vertical support posts should be in the most anterior 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.



6 Select appropriate length rod and anchor plate height. Thread anchor plate onto the distraction rod.

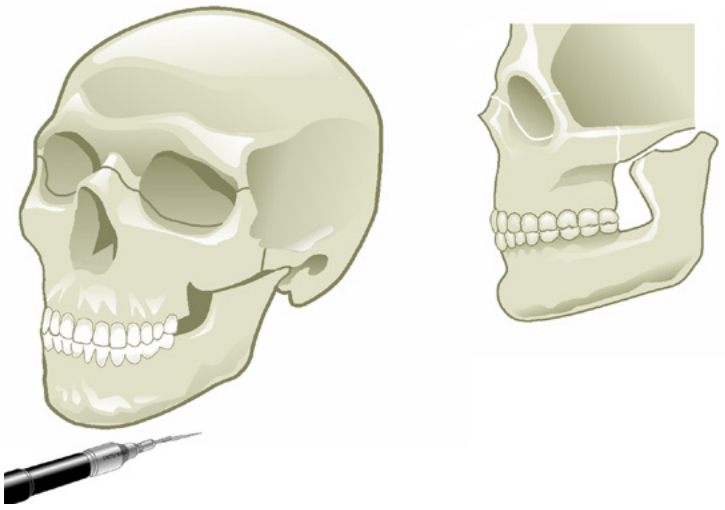


LEFORT III DISTRACTION: INSTRUCTION FOR USE

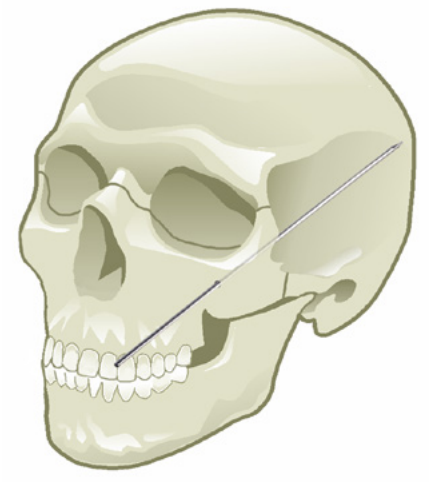
1 Create a maxillary vestibular incision and dissection typical for a LeFort I osteotomy. It is not necessary to fully strip the nasal mucosa. However, the malar eminences will have to be fully dissected. Also, create a coronal incision and dissection typical for a LeFort III osteotomy.

2 Complete all LeFort III osteotomies, dissections, and mobilization.

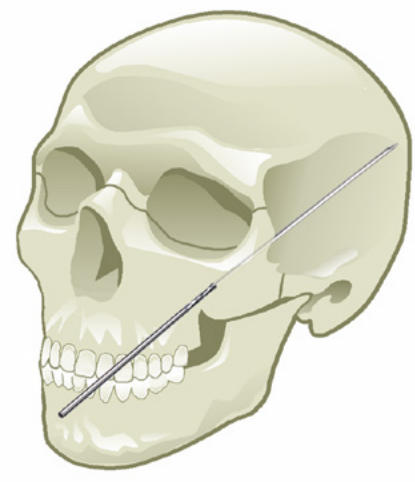
Optional: Surgeon can determine if osteotomy is to be completed and total mobilization attained after the device has been fully placed.



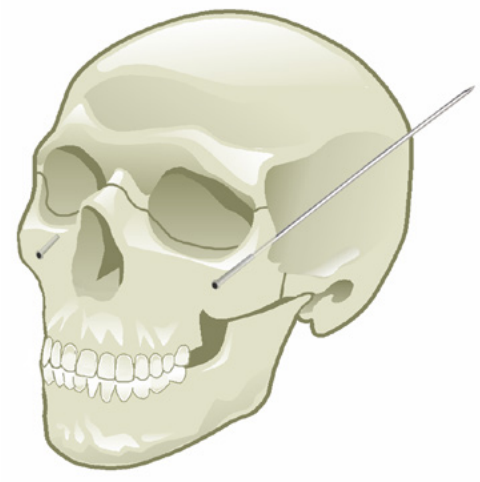
3 K-wire should be driven through each malar bone at the position of malar anchor plate. Attention should be given to place the k-wires as parallel as possible. Drill and place malar pins over the k-wires through the malar bone.



k-wire



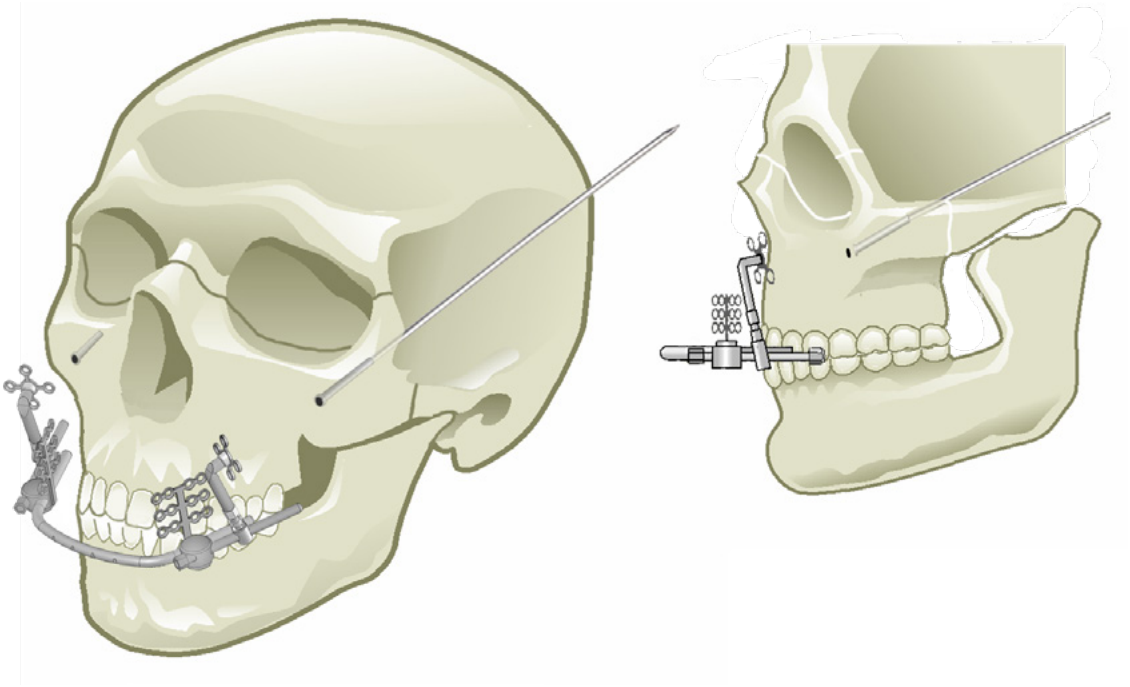
drill



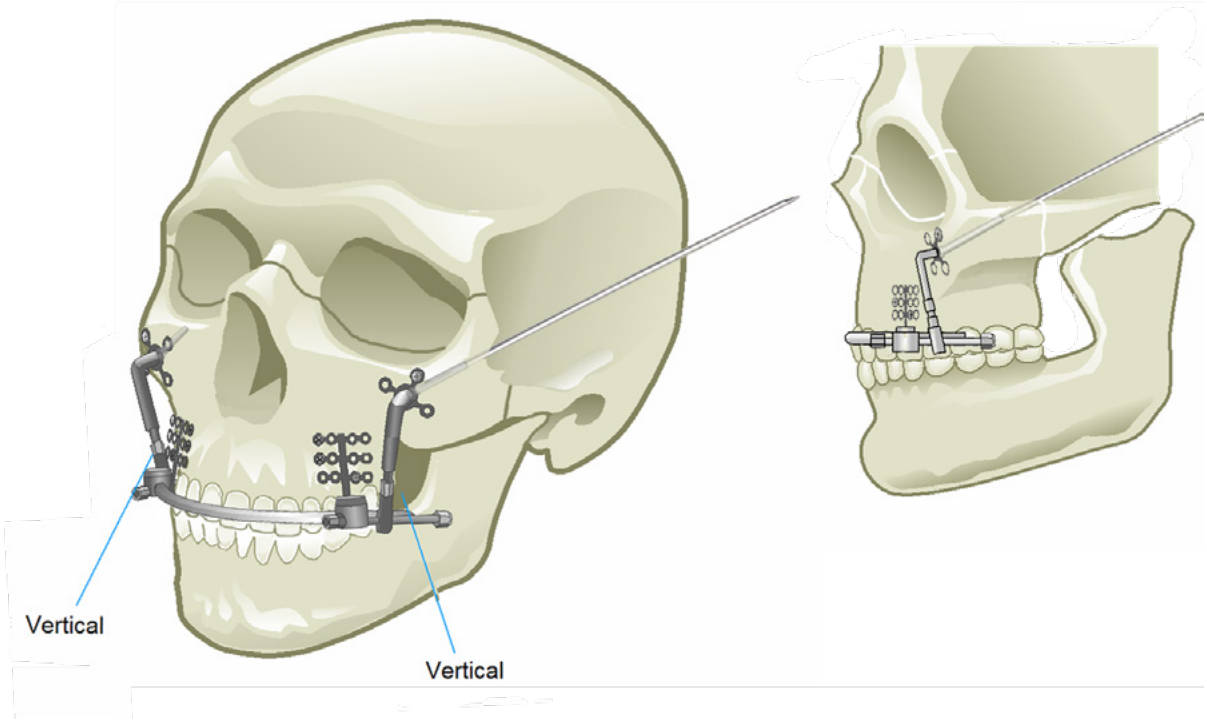
pins

LEFORT III DISTRACTION: INSTRUCTION FOR USE

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.

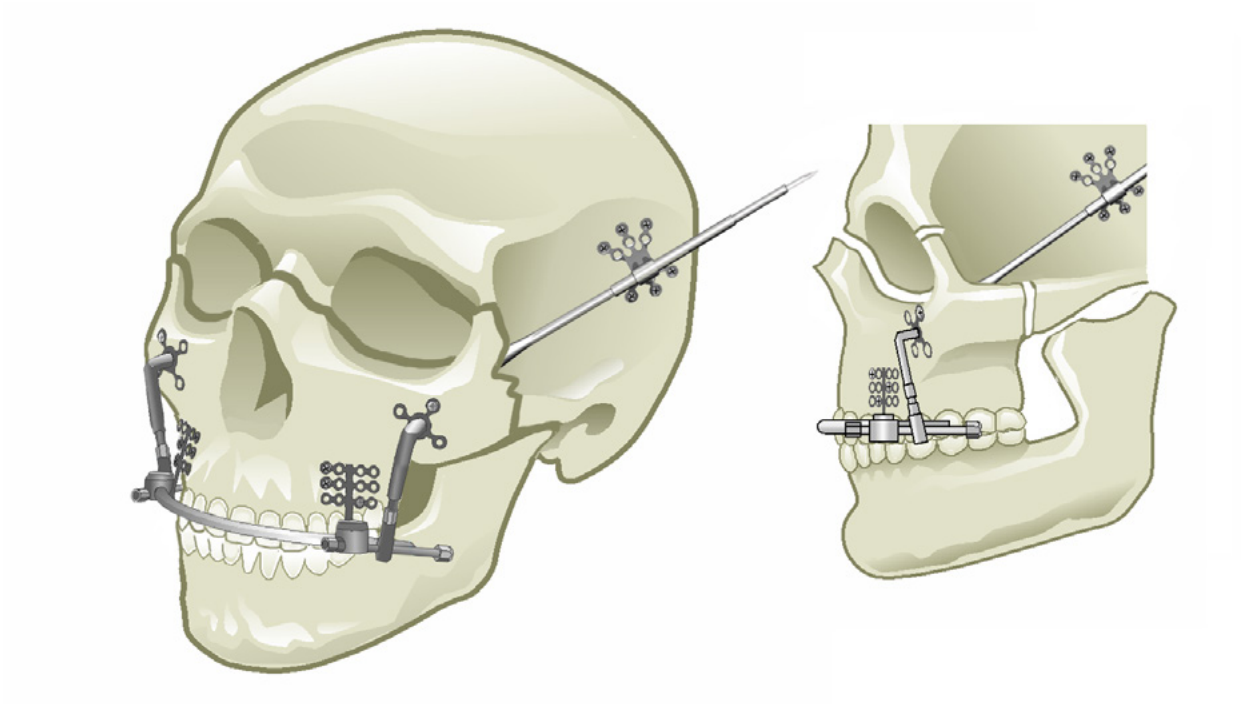


5 Vertical adjustments of the arms can be done at this time with the vertical wrench if needed. The malar anchor plates must be centered over the malar pins. The surgeon can then place appropriate screws into maxillary and malar plates in order to secure device into desired final position.

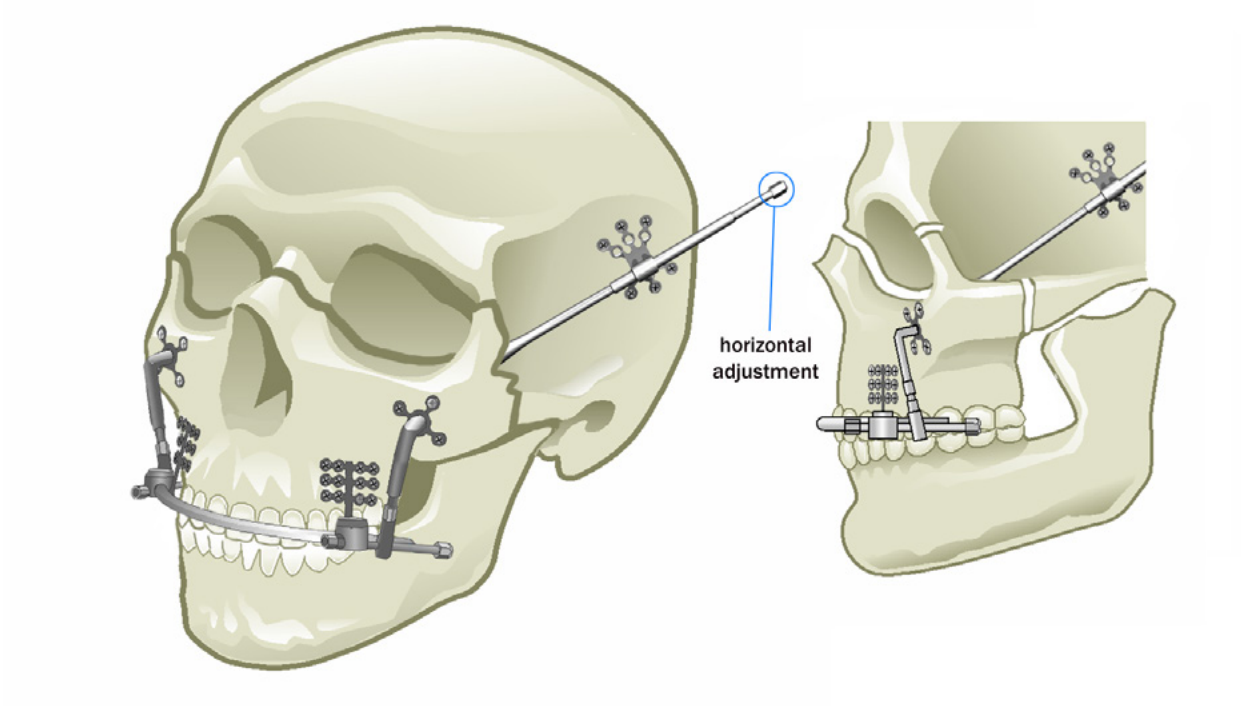


LEFORT III DISTRACTION: INSTRUCTION FOR USE

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.

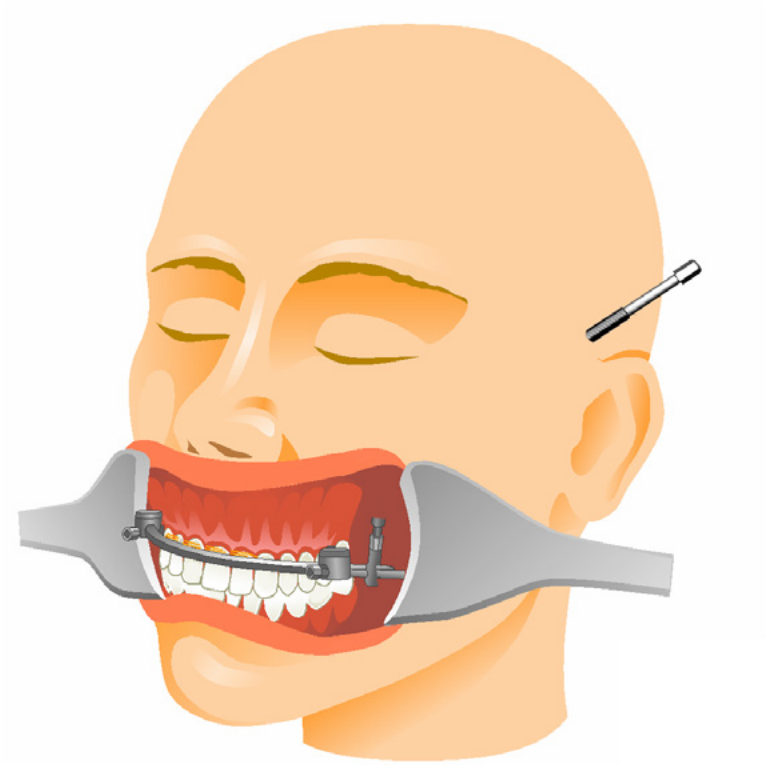


7 Thread the LeFort III cap nut on the end of the distraction rod and distract the device up to 3mm horizontally to ascertain the completeness of the osteotomies and proper distraction vectors.

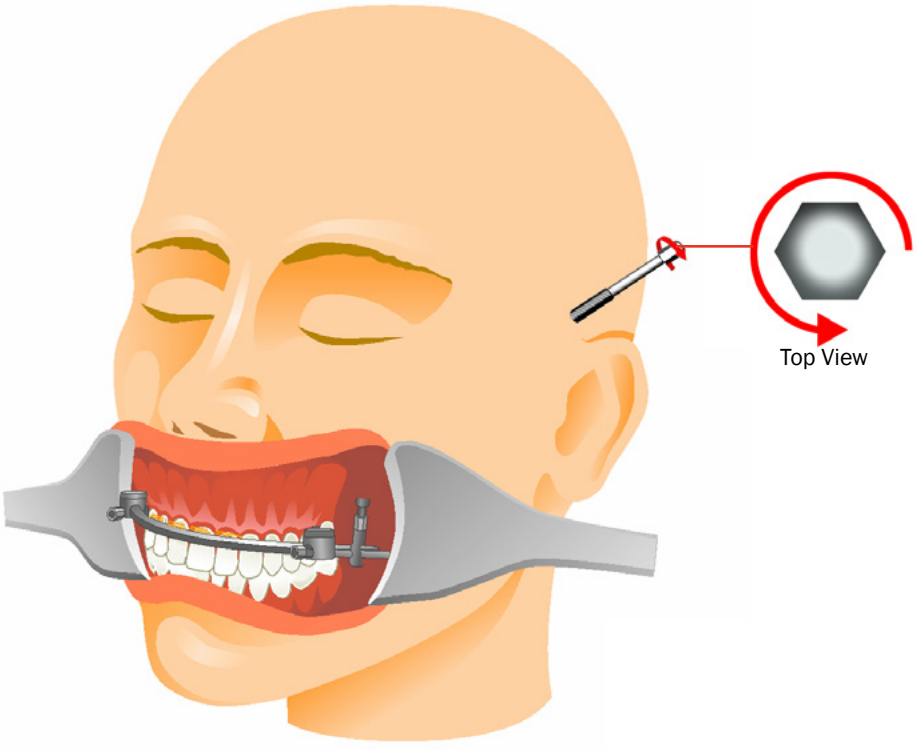


LEFORT III DISTRACTION: INSTRUCTION FOR USE

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 per day using the **OSTEOMED** Horizontal Distraction Tool by turning it 1.5 turns counter-clock wise.



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