OSTEOMED®

A TRADITION OF QUALITY AND INNOVATION

ENVISIONXD™

External Mandibular Distractor

SURGICAL TECHNIQUE GUIDE

EnVisionXD™

External Mandibular Distractor

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.

Description

The **OSTEOMED** EnVisionXD External Mandibular Distractor is an external distraction osteogenesis device for bone elongation for the correction of congenital deficiencies, mandibular hypoplasia or post traumatic defects of the mandible that require gradual distraction. Bone lengthening is achieved by gradually activating the device in a linear fashion. Interchangeable distraction rods that connect to a posterior and anterior pin clamp are provided. The anterior pin clamp can accommodate variations in pin placement. The pin clamps will accept 1.8mm x 9 inches and 2.0mm x 9 inches pins and lock to the pins via screws. The interchangeable distraction rods are available in various lengths for distraction up to 70mm. The distraction rods are activated by a hex driver.

Material

The Distractor assembly is made from Stainless Steel (ASTM F-138) and Titanium Alloy (ASTM-F-136). The pins are made from Stainless Steel (ASTM-F-138). The instrumentation is made from various grades of stainless steel, anodized aluminum, and/or medical grade plastic.

Indications

The **OSTEOMED** EnVisionXD External Mandibular Distractor is an external distraction osteogenesis device for bone elongation for the correction of congenital deficiencies, mandibular hypoplasia or post traumatic defects of the mandible that require gradual distraction.

The **OSTEOMED** EnVisionXD External Mandibular Distractor is intended for use in either adults or pediatric patients.

The **OSTEOMED** EnVisionXD External Mandibular Distractor is intended for single patient use only.

Contraindications

The use of the **OSTEOMED** EnVisionXD External Mandibular Distractor is contraindicated in the setting of active or suspected infection, in patients previously sensitized to nickel or titanium, in patients with conditions which may adversely affect successful distraction osteogenesis or patients who are immune compromised.

It is further contraindicated in patients where adequate supervision or management of the distraction device may be compromised. It is also contraindicated in patients where there is inadequate bone stock to permit secure placement and fixation of the devices.

WARNING Warnings

1. Failure to follow Planning instructions may contribute to patient harm.
2. Failure to follow Implantation instructions may cause patient harm or device damage.
3. Failure to follow Distraction instructions may cause patient harm or device damage.
4. Failure to follow Distractor Removal instructions may cause patient harm.
5. The Distraction Rod must be turned in the direction of the arrow indicated on the handle of the activation tool.
6. During distraction and consolidation periods, the pin exit sites must remain clean.
7. Excessive torque on the distraction rod may cause device failure.
8. The devices can break or be damaged due to excessive activity or trauma. This could lead to failure of the distractor and/or pins which could require additional surgery and device removal.
9. Slower distraction rates (< 1mm/day) may cause premature consolidation of the osteotomies, leading to premature hardware failure, patient discomfort or failure to achieve distraction goals and necessitating a secondary procedure to reosteotomize the callus.

CAUTION Cautions

1. The guardian/patient is to be warned that the device can break or loosen as a result of stress, excessive activity or inappropriate diet.
2. The guardian/patient 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.
4. Surgeon should limit patient to a soft diet for the duration of the distraction period.
5. Precautions should be taken to avoid damage to the inferior alveolar nerve and tooth buds.
6. Avoid dissection near condyle to minimize tendency for ankylosis.

Maintaining Device Effectiveness

1. The surgeon should not use this device if not familiar with the pertinent anatomy, techniques of mandibular osteotomies and the appropriate treatment for potential morbidity or complications which could arise from the use of this device.
2. The surgeon should have specific training, experience, and thorough familiarity with the use of external distraction products and techniques.
3. The surgeon must exercise reasonable judgment when deciding which distractor length to use for specific indications.
4. The **OSTEOMED** EnVisionXD External Mandibular Distractor is not intended to endure excessive abnormal functional stresses.
5. The **OSTEOMED** EnVisionXD External Mandibular Distractor is intended for temporary fixation once intended distraction is achieved and mandibular distraction osteogenesis occurs.
6. 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.
7. Carefully inspect the **OSTEOMED** implants prior to use. Inspect the instruments before and after each procedure to assure they are in proper operating conditions. Instruments which are faulty, damaged or suspect should not be used. They should be replaced or sent to **OSTEOMED** for disposition.
8. **OSTEOMED** recommends the use of **OSTEOMED** products in a sterile environment.

Preoperative Planning:

1 Determine the anatomical goal by evaluation of the pathology through clinical exam, lateral cephalogram and/or three-dimensional CT and Cine-MRI.

a. *Technique Tip: Performing a cross-table lateral cephalogram at 71" from the film plane results in an approximate life size image.*

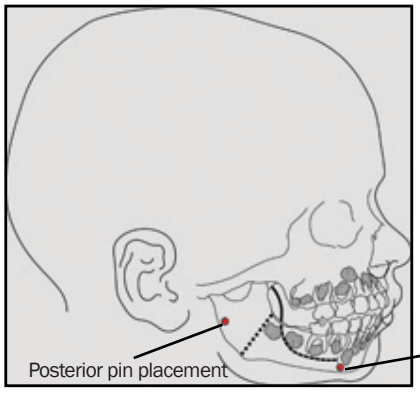
2 Determine required length of distraction and choose appropriate length Distraction Rod.

a. *Note: In a completely collapsed position, the available distraction length will be 17mm, less than the total length of the distraction rod, as outlined in the chart below.*

Note: Average minimum distance between pins is based on pin placement per the following technique in an infant deficient mandible.

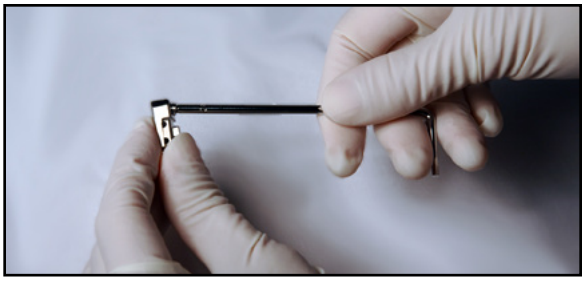
Part Number	Distraction Rod Lengths	Average Minimum Distance Between Pins	Available Distraction Distance
216-2020	58mm	40mm	20mm
216-2030	68mm	40mm	30mm
216-2040	78mm	40mm	40mm
216-2050	88mm	40mm	50mm
216-2060	98mm	40mm	60mm
216-2070	108mm	40mm	70mm

3 Determine planned pin placement based on the trajectory of the inferior alveolar nerve with the lingual and mental foramen, the teeth and tooth buds, the subcondylar bone stock and intermaxillary relationship.



Single Vector Distractor Assembly

1 Remove the Distraction Rod Locking Screw from the Posterior Pin Clamp with the hex driver.

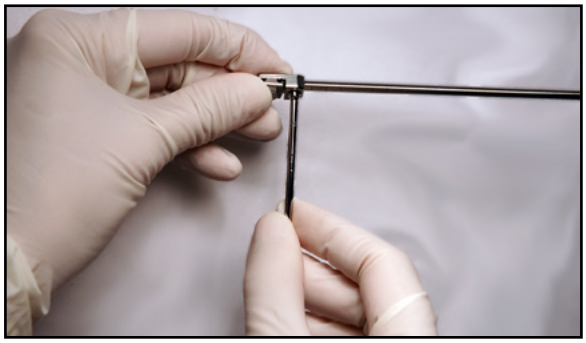


Single Vector Distractor Assembly (Cont.)

2 Insert the Distraction Rod into the Posterior Pin Clamp.

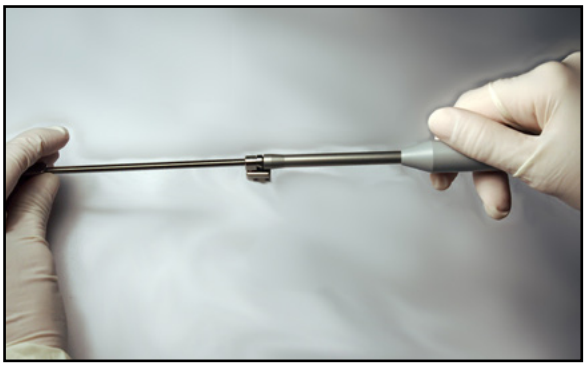
3 Replace the Distraction Rod Locking Screw using the hex driver and tighten, effectively capturing the Distraction Rod.

a. Note: Ensure the rod is captured in the Posterior Pin Clamp



4 Mount the External Distraction Nut onto the Anterior Clamp and thread this assembly onto the distraction rod using the activation tool.

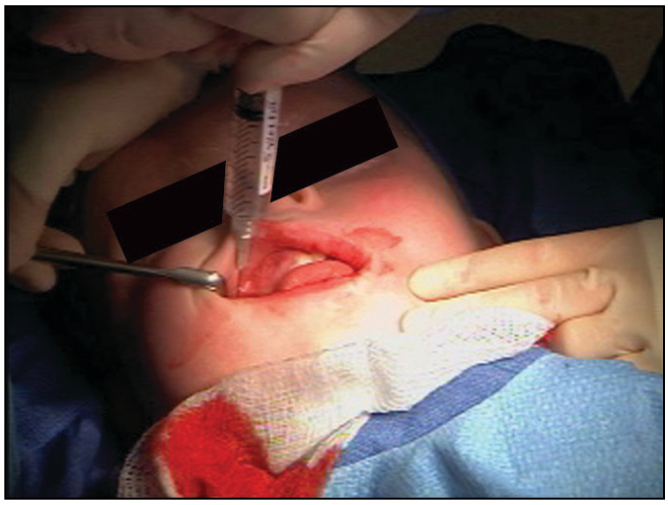
a. Note: Ensure the Anterior Pin Clamp Assembly threads the length of the Distraction Rod.



PLACING THE DISTRACTOR *Photos courtesy of Dr. Gordon, Children's Hospital Medical Center, Cincinnati, Ohio*

1 Nasal intubation is preferred, but if an endotracheal tube is necessary, fix in the midline and secure with suture or wire to the anterior mandible to prevent dislodgement.

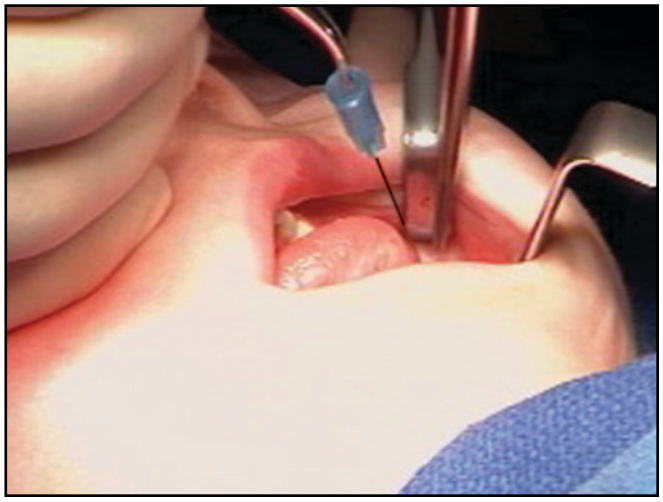
2 Inject diluted local anesthetic in the areas of planned dissection to minimize perioperative hemorrhage.



3 Confirm position of the retromolar body, ramus and condylar portions of the mandible.

a. ***Technique Tip:*** *Use a 25 gauge needle as a sound to ballot the boney structures intraorally.*

b. ***Technique Tip:*** *In severely micrognathic patients, the ramus rapidly diverges from the dental arch and will require a more oblique and lateral incision than in less severe cases.*



4 Make an incision in the oral buccal sulcus inferior to the course of the parotid duct and papilla, along the retromolar zone and superiorly to permit exposure of the coronoid and superior ramus, avoiding further dissection near the condyle.

a. ***Technique Tip:*** *It is advantageous to carefully follow the bony contour to avoid penetrating the buccal fat pad, which can interfere with visualization of the osteotomy site.*

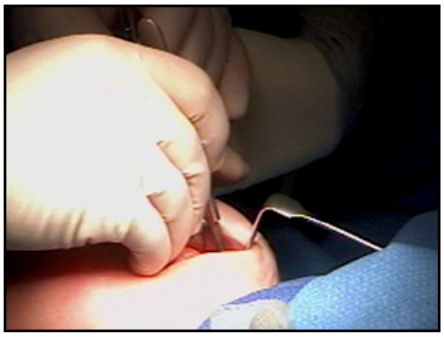
5 Dissect until the retromolar mandible is visualized. The periosteum is then incised with a scalpel and a small periosteal elevator is used to deglove the buccal aspect of the distal body and ramus in the subperiosteal plane.

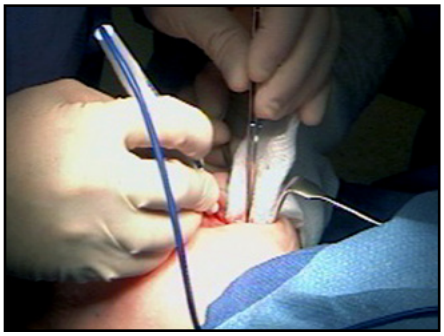
6 Dissect mesially and medially from the subcondylar zone until the inferior alveolar neurovascular bundle is visualized.

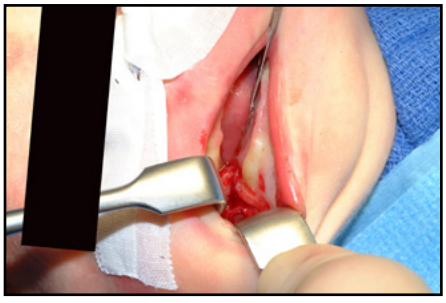
a. ***Note:*** *In young patients the* alveolar neurovascular *is adjacent to the molar tooth bud.*

b. ***Technique Tip:*** *Multiple narrow malleable retractors afford adequate exposure.*

c. ***Note:*** *Confirm that a reciprocating saw blade will enter the surgical site without impinging on the inferior alveolar neurovascular bundle.*



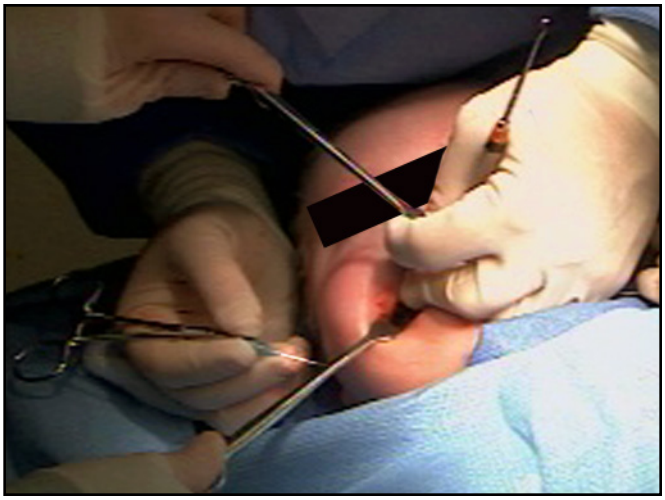




PLACING THE DISTRACTOR *Photos courtesy of Dr. Gordon, Children's Hospital Medical Center , Cincinnati, Ohio*

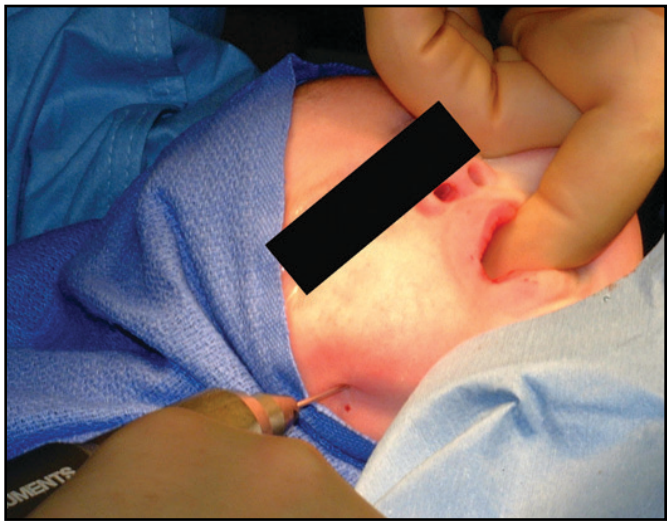
7 Identify planned site for the posterior pin placement through the cheek.

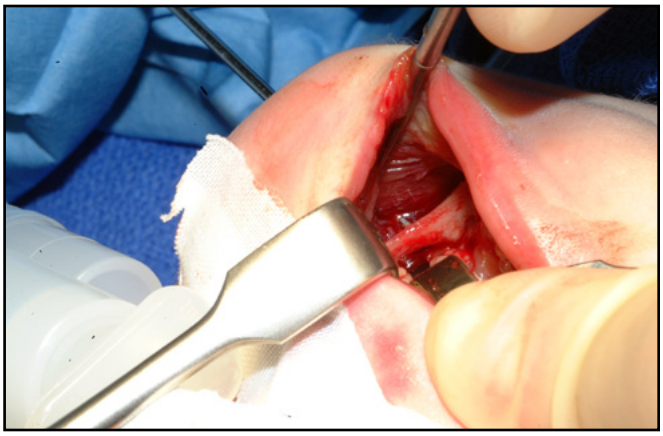
*a. **Technique Tip:** Use a 25 gauge needle to identify the subcondylar area through the cheek to percutaneously sound out the planned sites for posterior pin placement.*

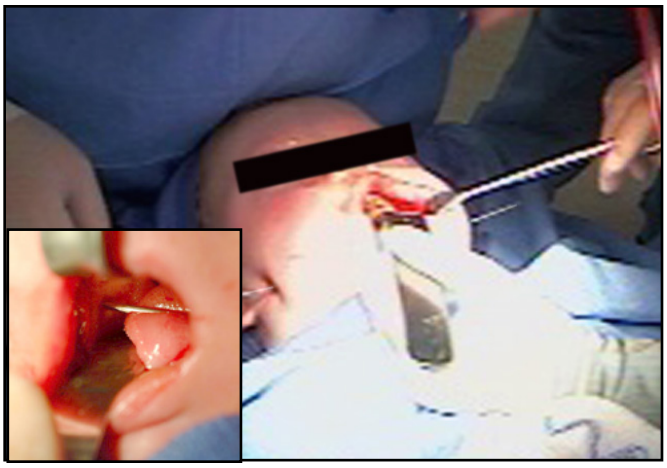


8 If desired, the buccal mandibular cortex may be scored using a reciprocating saw and irrigation.

9 The posterior pin is passed percutaneously through both sides of the mandible. Adequate position of the posterior pin is confirmed visually. The mandible is then ranged to confirm that the pin does not impinge on the maxilla or pterygoid bones, in which case the pin should be repositioned.

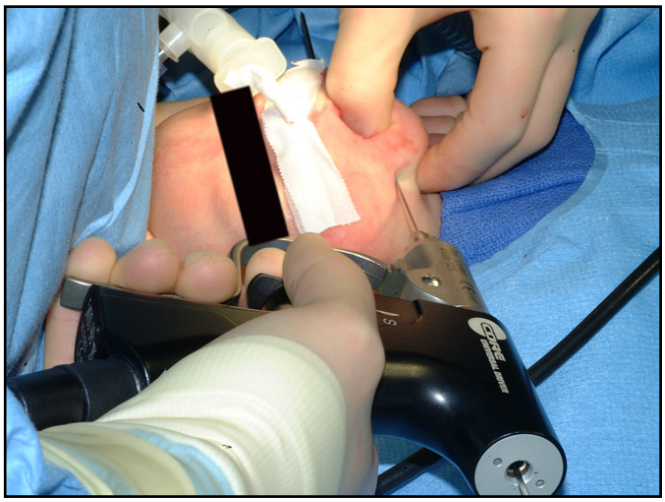






10 Identify planned site for the anterior pin placement.

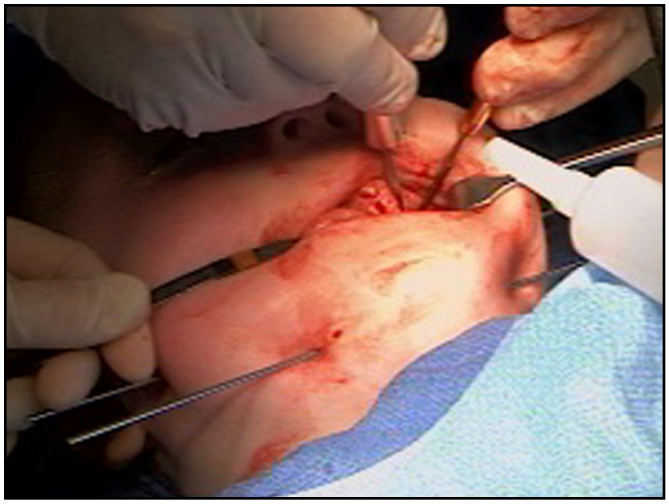
*a. **Technique Tip:** Examine lateral cephalogram to determine the safest position for anterior pin placement.*



PLACING THE DISTRACTOR *Photos courtesy of Dr. Gordon, Children's Hospital Medical Center, Cincinnati, Ohio*

11 The anterior pin is passed percutaneously through both sides of the mandible. Adequate position of the anterior pin is confirmed visually.

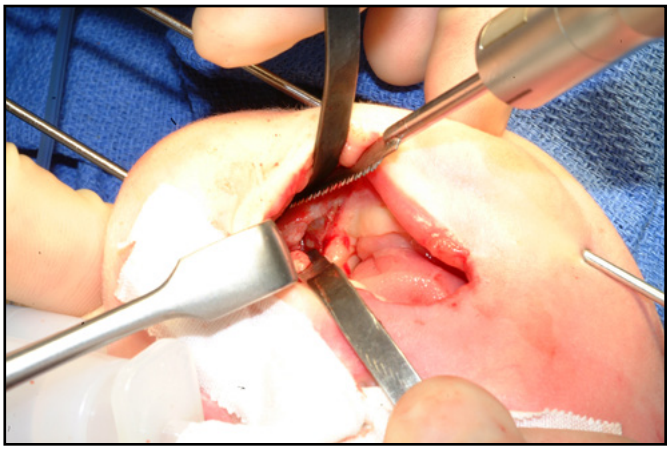
a. Technique Tip: The pin should transverse the anterior mandible distal to the canine tooth bud, inferior to the course of the alveolar nerve, and along the inferior border of the mandible.



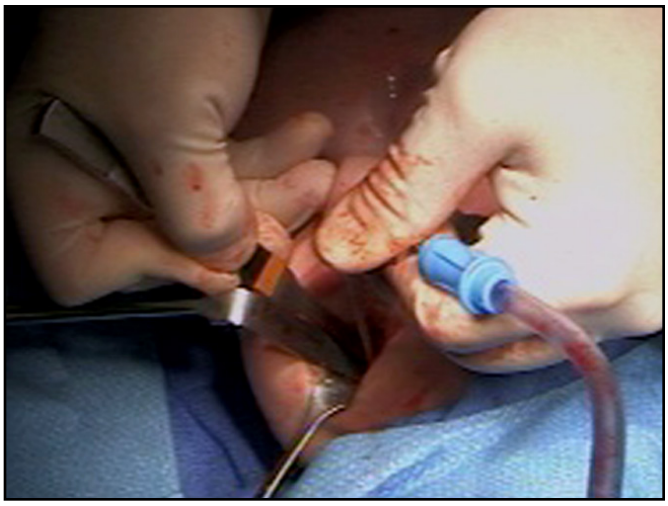
12 The osteotomies are then performed using a reciprocating saw.

a. Technique Tip: It is preferable to make an oblique or slightly sagittal osteotomy to maximize cortex-to-cortex contact for callus generation. In older patients a more sagittal osteotomy may be required based on the location of the alveolar nerve.

b. Technique Tip: Typically, a reciprocating saw is used. Ensure that the osteotomy is not contiguous with the superior pin, or the mandible may fracture at the pin site. It is important to use the saw to finish the osteotomy to avoid this complication, which can also occur when an osteotome is used to finish the cut.

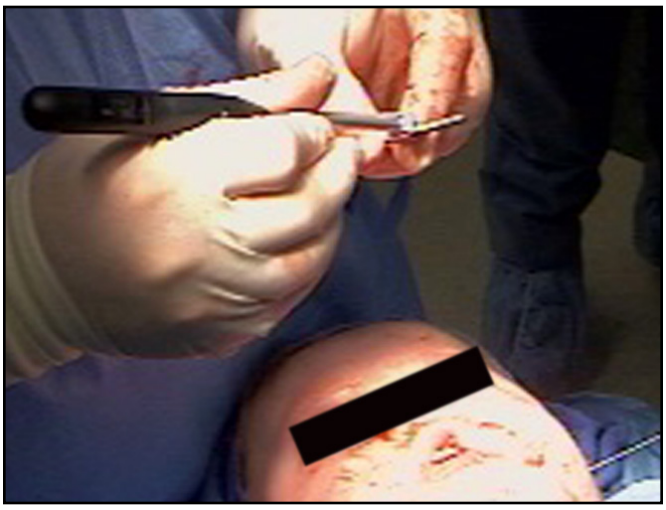


13 An osteotome may be used to confirm completion of osteotomies.



14 The contralateral osteotomy is performed in a similar fashion.

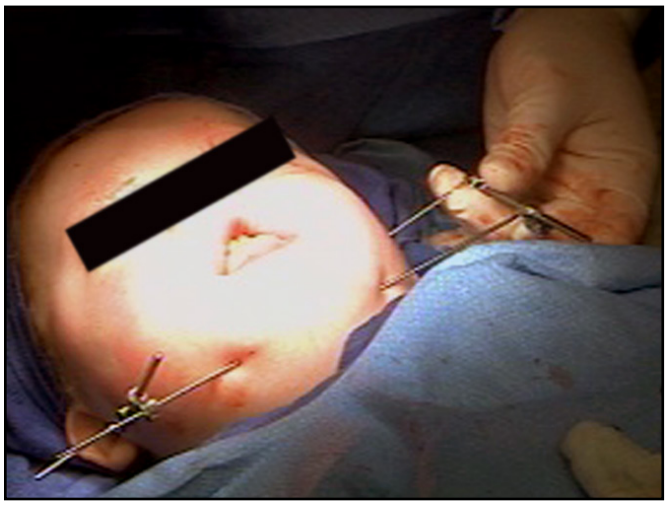
15 Adjust the distance between the posterior and anterior pin clamps using the Activation Tool so that the clamps line up with the anterior and posterior pins.



Placing the Distractor

Photos courtesy of Dr. Gordon, Children's Hospital Medical Center , Cincinnati, Ohio

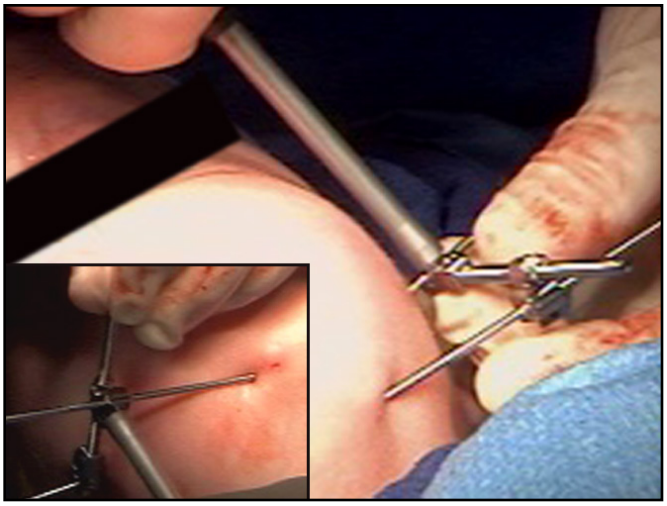
16 Slide the Anterior and Posterior Pin Clamps over the anterior and posterior pins.



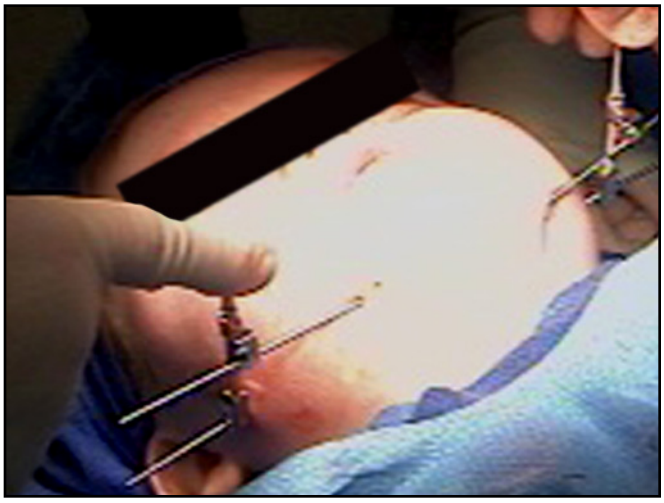
17 Affix the External Distractor to the pins using the Activation Tool, ensuring that the pin clamp screws are adequately tightened to engage the pins rigidly. Ensure that the set screws are accessible during distraction, in the event of loosening. The set screws are checked for tightness. The Distraction Rod is then adjusted for tension, to introduce a gentle, finger-tight tension to the device at the completion of the procedure.

a. ***Technique Tip:*** *Ensure that the distraction rod projects superiorly to the anterior pin to minimize interference with a tracheostomy site or irritation to the chest wall at the limits of the distraction period.*

b. ***Technique Tip:*** *Distract the device 2-3mm to ensure completeness of the osteotomies and functionality of the distractor. Return the device to its original position.*



18 Once the device placement is complete, stability and alignment are confirmed. The incisions are irrigated, hemostasis is confirmed, and the incisions are closed, taking care to preserve the periosteal and mucosal integrity in the area of the osteotomy.

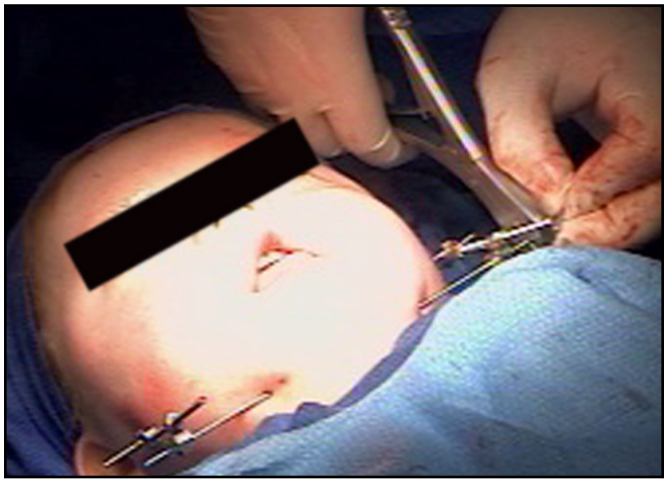


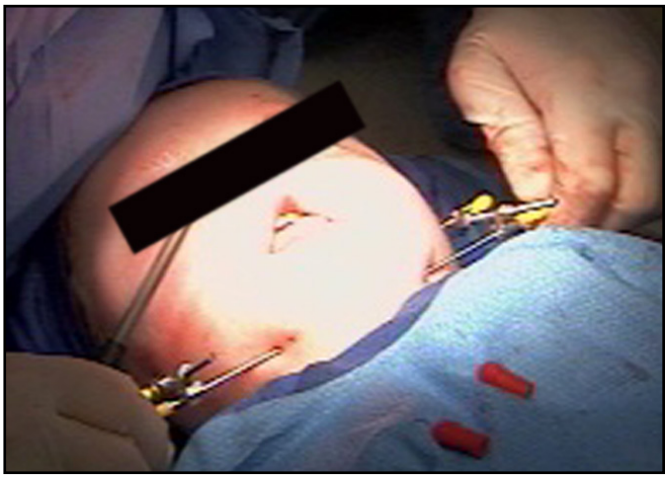
PLACING THE DISTRACTOR

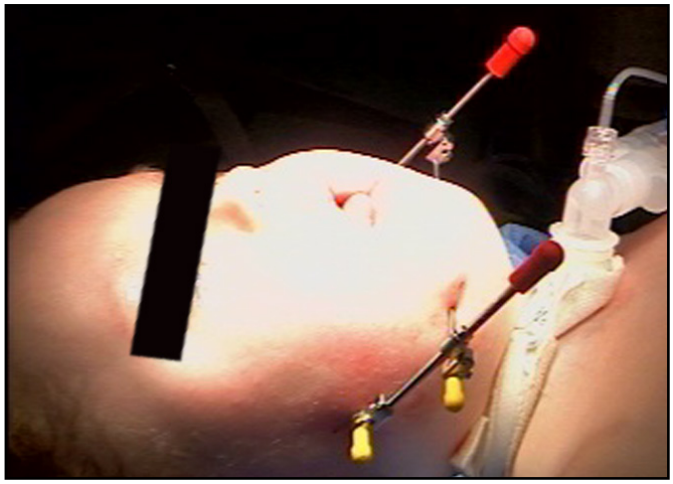
Photos courtesy of Dr. Gordon, Children's Hospital Medical Center , Cincinnati, Ohio

19 The pins are cut to length and capped with the silicone pin caps if desired. Postoperative bupivacaine blocks of the inferior alveolar nerve are performed, if desired, and the throat pack is removed. The patient is then awakened from anesthesia.

a. ***Technique Tip:*** *External medical foam can be cut and shaped to pad the distractor - cheek relationship.*







DISTRACTION PHASE

1 To distract the device, engage the Activation Tool over the external nut and rotate clockwise (in the direction of the arrow marked on the instrument). Each full turn of the device represents 0.5mm of distraction.

a. ***Note:*** *Distraction rates should be 1mm minimum per day or as determined by the surgeon until the desired distraction is achieved. More rapid rates may be determined by surgeon for pediatric patients under 2 years old.*

b. **⚠ CAUTION** *Slower rates may cause premature consolidation of the osteotomies, leading to premature hardware failure, patient discomfort or failure to achieve distraction goals necessitating a secondary procedure to reosteotomize the callus.*

c. ***Note:*** *Minor bending of the pins can be expected through the distraction phase.*

d. ***Note:*** *Avoid sudden loading of the bony pin sites. Gently deliver the distraction force over the course of the day.*

e. **⚠ CAUTION** *If excessive resistance is felt during distraction, the pins suddenly bend over the course of activation or patient discomfort significantly in creases, STOP distraction.*

i. ***Technique Tip:*** *If premature consolidation is recognized early, reosteotomy may be performed through the callus without necessitating replacement of the pins, permitting continuation of the distraction protocol to the determined end point. If not recognized early, replacement of the pins may be required.*

f. ***Note:*** *As Distraction progresses, the bone around the pin tracts will slowly resorb, leading to play in the upper pin assembly, this is not harmful and may be simply realigned manually. Padding of the cheeks may prevent this phenomenon.*

CLEANING AND PIN SITE CARE

Typical pin site care and application of a topical antibacterial ointment is recommended on a daily basis.

CONSOLIDATION PHASE

1 If desired anatomical alignment (occlusion) has been achieved, allow for bony consolidation prior to device removal.

2 If desired alignment has not been achieved, remove the device and follow the technique for Closed Reduction and Postoperative Fixation prior to bony consolidation.

Device Removal

1. The device and pins are scrubbed to avoid introducing foreign or contaminated material into the patient's tissue. The posterior pin is cut adjacent to the cheek on one side. The anterior pin is then cut on the contra-lateral side adjacent to the mention. The posterior pin will typically then be removed with little or no force. A gentle traction with an oscillating motion is used to remove the anterior pin, supporting the mandible during the procedure to avoid compression of the new callus.

    a. ***Technique Tip:*** *It is not recommended to remove the pins with a pin driver or other power devices.*

Closed Reduction and Postoperative Fixation

1. In pediatric patients, under 2 years old, overdistraction followed by callus manipulation with no fixed consolidation period is feasible. The callus is gently compressed by the forces of the muscles of mastication, leading to planned relapse into a stable configuration.

    a. ***Note:*** *In older patients who are unable to suck or chew, or in cases of significant asymmetric distraction, a period of consolidation and or intermaxillary fixation may be desirable. This will be determined by the surgeon.*

2. After device removal, the oropharynx is inspected for any foreign bodies or secretions that could be aspirated and carefully suctioned.

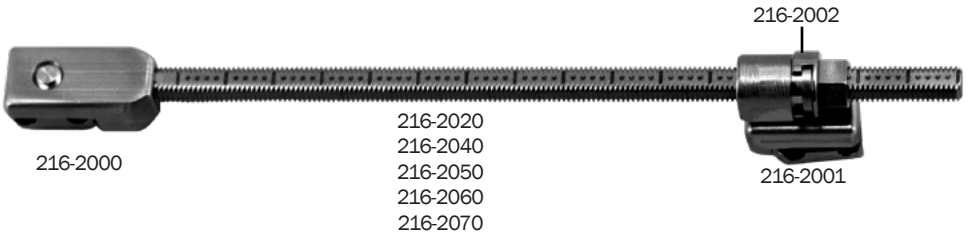
3. Dental rolls or previously fabricated splints are placed in the retromolar area to provide a fulcrum.

4. Gentle upward pressure on the submental area will produce a compression of the callus, reestablishing a planned class III malocclusion. Avoid over compression of the callus which can lead to loss of sagittal projection or open bite.

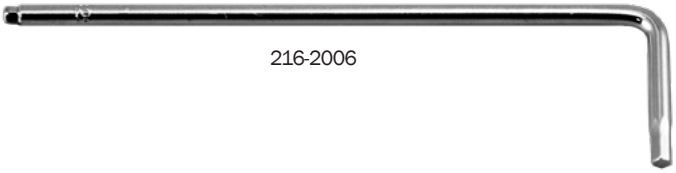
5. At the end of the manipulation, the patient should have a 2-3 mm posterior open bite, which will gradually diminish over days, as the patient masticates or sucks.

6. A gentle elastic wrap or garment can assist with maintaining a closed bite in the early postoperative period. If the patient is not able to masticate or suck or the surgeon suspects that an open bite posture is not improving, there may be an indication for a period of intermaxillary fixation.

Instrumentation

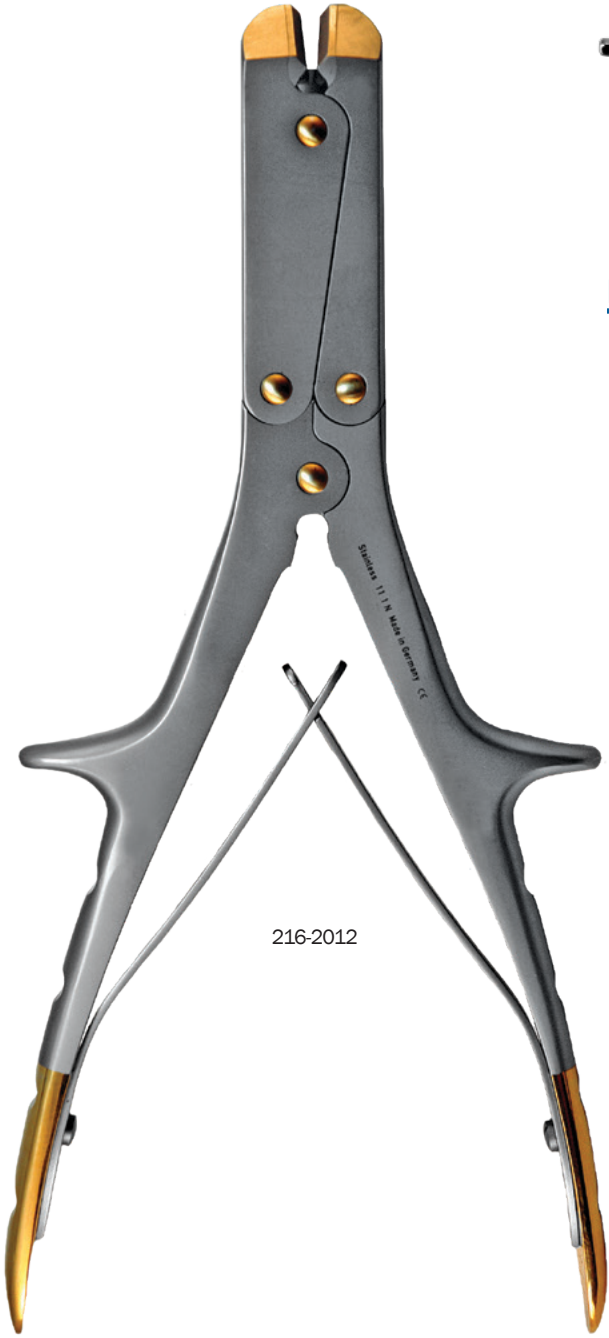


216-2005



216-2006

216-2003
216-2004



216-2012

Part Numbers	Descriptions
216-2000	EnVisionXD™, Posterior Clamp Assembly
216-2001	EnVisionXD™, Anterior Clamp Assembly
216-2002	EnVisionXD™, External Nut
216-2020	EnVisionXD™, 20mm Distraction Rod
216-2030	EnVisionXD™, 30mm Distraction Rod
216-2040	EnVisionXD™, 40mm Distraction Rod
216-2050	EnVisionXD™, 50mm Distraction Rod
216-2060	EnVisionXD™, 60mm Distraction Rod
216-2070	EnVisionXD™, 70mm Distraction Rod
216-2005	EnVisionXD™, Activation Tool
216-2006	EnVisionXD™, Hex Driver
216-2003	EnVisionXD™, 2.0mm x 9in Steiman Pin
216-2004	EnVisionXD™, 1.8mm x 9in K-wire
216-2010	EnVisionXD™, Pin Caps
216-2012	EnVisionXD™, Pin Cutters
216-2014	EnVisionXD™, Block Assembly
216-2015	EnVisionXD™, Autoclave Tray

NOTES

OSTEOMED®

A TRADITION OF QUALITY AND INNOVATION

Customer Service: 800.456.7779

3885 Arapaho Road | Addison, TX 75001 | Phone: 972.677.4600 | Fax: 800.390.2620

A COLSON ASSOCIATE

www.osteomedcorp.com

P/N 030-1531 Rev.A