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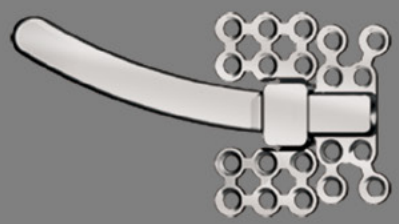
# LOGIC JR.™

## SURGICAL TECHNIQUE GUIDE

Pediatric Distraction System



# LOGIC™ JR.
Pediatric Distraction System

## SURGICAL TECHNIQUE GUIDE

## Indications

The OSTEOMED Logic Jr.™ Pediatric Mandibular Distraction System is indicated as a bone stabilizer and lengthening (and/or transport) device when correction of congenital deficiencies or post traumatic defects of the mandible (including ramus, body, alveolar ridge, symphisis), require gradual distraction. This system is intended for use in pediatric population for children under 4 years of age including infants and neonates. The OsteoMed Logic Jr.™ Pediatric Mandibular Distraction System is intended for single patient use only.

## Contraindications

Use of the OSTEOMED Logic Jr.™ Pediatric Mandibular Distraction System is contraindicated in cases of active or suspected infection, in patients previously sensitized to nickel, titanium or silicone; in patients with certain metabolic diseases, or patients who are immune compromised. The OSTEOMED Logic Jr.™ Pediatric Mandibular Distraction System is also contraindicated in those cases where there is an inadequate volume or quality of bone to place the distractor securely and where the patient/guardian cooperation cannot be guaranteed.

**WARNING** **WARNING indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.**

**CAUTION** **CAUTION used without the safety alert symbol indicates a potentially hazardous situation which, if not avoided, may result in property damage.**

## Latency Period

The latency period is the time period between the initial surgery when the distraction device is placed and when the distraction begins. The duration of the latency period is to be determined by the surgeon.

## Distraction Period

The distraction period is the time period during which the distraction is taking place. The duration of the distraction period is to be determined by the surgeon.

## Consolidation Period

The consolidation period is the period of time that commences when distraction has ceased. The device remains fixated for the consolidation period to allow for the healing and solidification of the newly formed bone. The duration of the consolidation period is to be determined by the surgeon.

## CAUTION General Cautions

Read all information in this manual before implanting the device. Before clinical use, the surgeon should be familiar with all aspects of the Pediatric Mandibular Distraction System, its instrumentation, indications and contraindications. Accepted surgical practice should be followed in postoperative care.

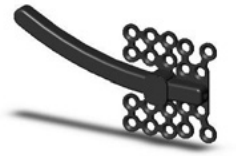
- The guardian is to be warned that the device can break or loosen as a result of stress, excessive activity or inappropriate diet.
- The guardian is to be made aware of the surgical risks and possible adverse effects prior to surgery, and warned that failure to follow postoperative care instructions can cause failure of the implant and the treatment.
- Surgeon should limit patient activity while device is implanted.
- Surgeon should limit patient to a soft diet for the duration of the distraction period.
- Precautions should be taken to avoid damage to the inferior alveolar nerve and tooth buds.

## WARNING General Warnings

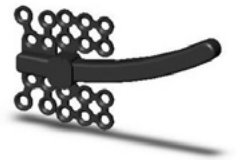
This device is intended for single patient use only and should be removed once the prescribed distraction has been achieved and the consolidation period has been concluded. (Note: Consolidation Period is determined by the surgeon). The devices can break or be damaged due to excessive activity or trauma. This could lead to failure of the distractor and/or screws which could require additional surgery and device removal.

- Distractor is indicated for children under 4 years of age including infants and neonates.
- Failure to follow Planning instructions may contribute to patient harm.
- Failure to follow Implantation instructions may cause patient harm or device damage.
- Failure to follow Distraction instructions may cause patient harm or device damage.
- Failure to follow Activation Wire Removal instructions may cause patient harm or device damage.
- Failure to follow Distractor Removal instructions may cause patient harm.
- 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.
- Do not remove activation wire before the consolidation period has been completed.
- Distractor must be fixated with a minimum of 2 screws on each side of the osteotomy and the screws should be placed in multiple plate arms.
- The activation wire must be turned in the direction of the arrow indicated on the handle of the distraction tool.
- During distraction and consolidation period, the activation wire exit site must remain clean.
- Minimal MRI scattering is possible due to nickel present in the activation wire.
- The silicone tubing is indicated for a maximum implant period of 29 days.
- Excessive torque on the activation wire may cause the wire to break.
- The devices can break or be damaged due to excessive activity or trauma. This could lead to failure of the distractor and/or screws which could require additional surgery and device removal.
- Use of screws in high dense bone may lead to implant fracture or failure upon insertion.
- It is recommended to remove any fractured implants from patients during surgery. If unable to remove, notify patient's guardian.

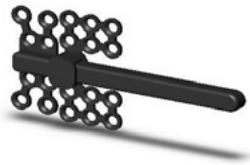
## System Components



216-1000 Logic Jr. Distractor, Left 52mm
(25mm of Distractoin)

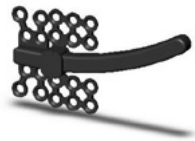


216-1001 Logic Jr. Distractor, Right 52mm
(25mm of Distractoin)



216-1002 Logic Jr. Distractor, Straight
(25mm of Distractoin)

216-1003 Logic Jr. Distractor, Left 52mm Short
(15mm of Distractoin)



216-1004 Logic Jr. Distractor, Left 52mm Short
(15mm of Distractoin)

## Distraction Tool


P/N 216-0102

Three rotations = 1mm distraction.
The patient or patient guardian should be thoroughly instructed on use of the distraction tool and receive a copy of the “Patient Progress Chart.”

## Activation Wires

| | |
|---|---|
| 82mm | P/N 216-0307 |
| 72mm | P/N 216-0306 |
| 62mm | P/N 216-0302 |
| 52mm | P/N 216-0301 |

## Silicone Tubing

(indicated to remain in the body a maximum of 29 days)

P/N 216-0305

## Screws

| P/N | Description |
|---|---|
| 204-1202 | 1.2mm x 2mm Screw |
| 204-1203 | 1.2mm x 3mm Screw |
| 204-1204 | 1.2mm x 4mm Screw |
| 204-1206 | 1.2mm x 6mm Screw |
| 204-1208 | 1.2mm x 8mm Screw |
| 211-1203 | 1.2mm x 3mm Auto-Drive™ Screw |
| 211-1204 | 1.2mm x 4mm Auto-Drive™ Screw |
| 211-1205 | 1.2mm x 5mm Auto-Drive™ Screw |

## Other Tools


Taperlock™ Screwdriver body
P/N 220-0019

Plate Bending Forceps
P/N 220-0049

Cheek Retractor, Blade, M4/Dist
P/N 220-0564

Plate Cutter
P/N 220-0028

Cannula Trocar
P/N 220-0056

Cannula Drill Guide
P/N 220-0140

Small Grasping Forceps
P/N 220-0027

Cannula
P/N 220-0055



Activation Wire Removal Tool
P/N 216-0103

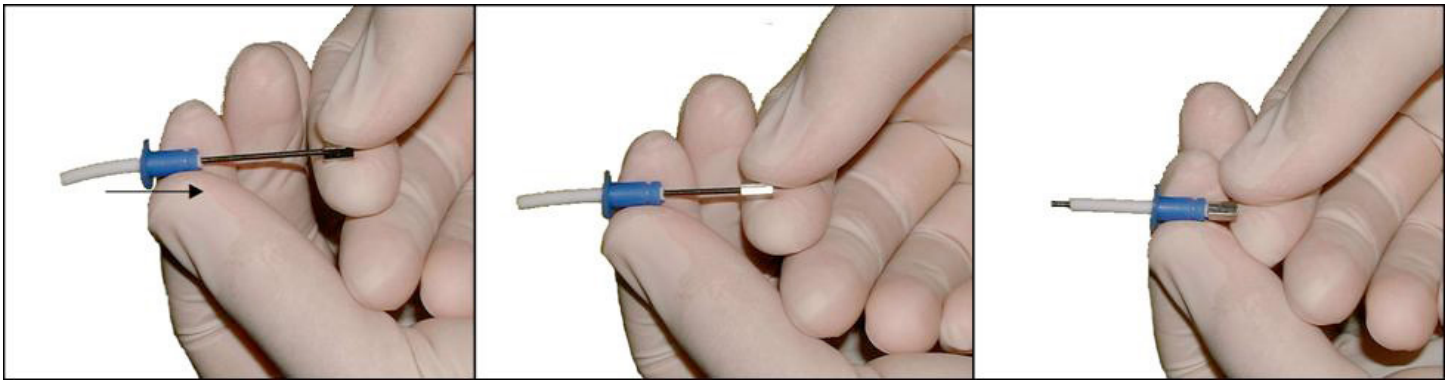
## Surgical Pre-Planning

The OSTEOMED Logic Jr.™ Pediatric Mandibular Distractor offers curved and straight designs which approximate natural jaw growth. The distractor is chosen based on the desired mandibular movement in the horizontal and vertical directions. It should be based on the projection tracing using a lateral cephalometric radiograph. During pre-op planning, the template (P/N 216-0310) should be used with x-rays taken of the distraction site in order to select the appropriate distractor and plan the necessary distraction. When selecting the appropriate length of activation wire, it is important to consider the following:

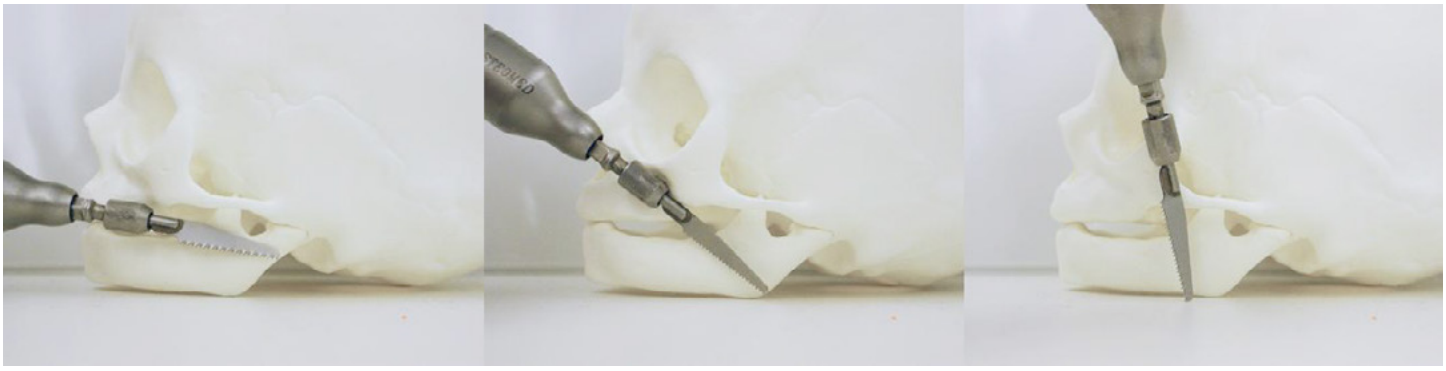
- Amount of mandibular bone present
- Location of osteotomy
- Amount and direction of distraction
- Correct length of activation wire based on planned distraction and length between fixation point and access point

## Implanting Distractor

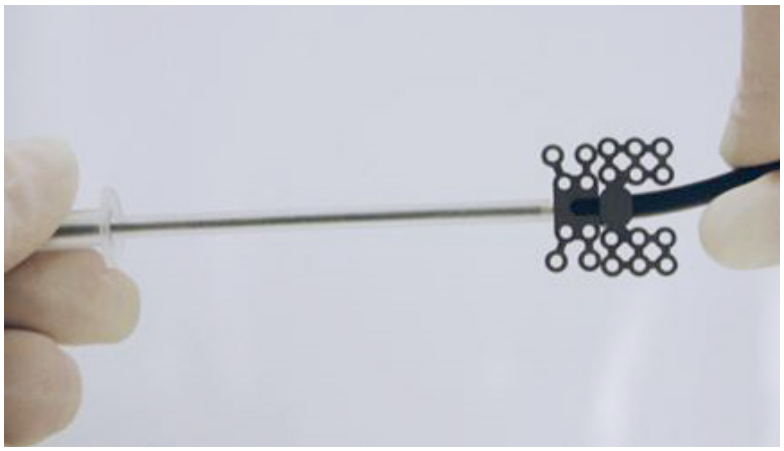
1. Make Risdan incision well below mandibular body approximately 2cm long.
2. Spread to periosteum and retract.
3. Elevate the periosteum over the ramus.
4. Prepare the distractor. Cut off the excess plate holes (if necessary). Check device to ensure free articulation between the two moving plates.
5. Use bending pliers to adjust the fixation plates to the anatomy (this may be done pre-op if a medical model is made).



6. Before engaging the activation wire, place the silicone tubing over the wire.
7. Determine where posterior (near the ear) the activation wire will exit, and make an incision.
8. Elevate tissue on lingual aspect of ramus and place a small malleable for protection.
9. Position of the cut should be determined based on desired movement. It should be made more horizontal for vertical distraction and more vertical for horizontal distraction. Using the saw, score the buccal mandibular cortex, then cut through both the buccal and lingual cortices at the inferior border and at the superior border. Make certain the osteotomy is made above or in front of the inferior alveolar nerve.



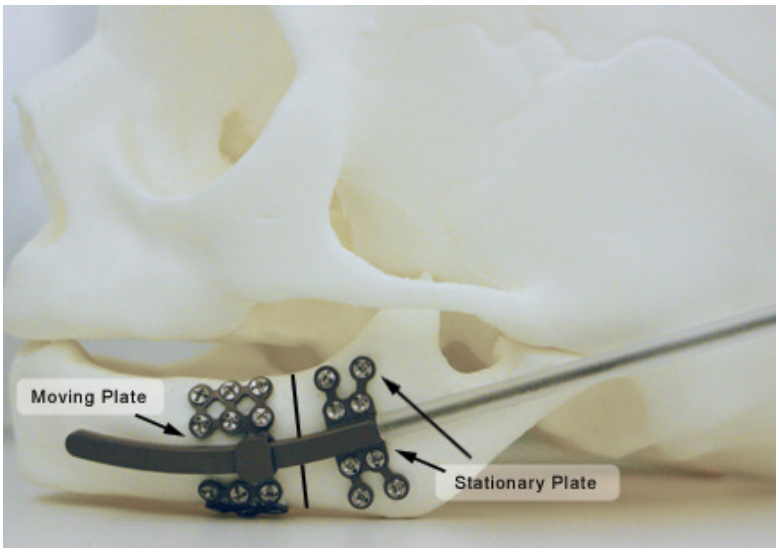
10. Thread activation wire using fingers or distraction tool into both the moving and stationary segments of the distractor. Ensure that the wire is fully engaged by continuing to thread it, and observe that the activation wire is pushing the moving segment along the stationary segment. Engage activation wire before fixating the distractor.



11. Ensure that the activation wire has engaged both parts of the distractor and is working by advancing wire NO more than 2-3mm. Advancing the distractor too far will result in excessive torque and possible damage when attempting to return the distractor to the starting position.

12. Place distractor through Risdon incision; fixate with 1.2mm screws. (Pilot drilling may be necessary, depending on the use of standard or self drilling screws.) There are two areas of the distractor that must be fixated to the mandible: 1) the stationary curve plate 2) the moving plate.

13. When fixating the stationary plate of the distractor, place one screw in each mesh plate. Then place screws in remaining plate holes.




14. Fixate the moving plate of the distractor 2mm from the osteotomy. Screws should be placed in multiple plate arms, and a minimum of 2 screws should be placed in each arm to ensure adequate fixation.

15. After the distractor has been securely fixated, complete the osteotomy using an osteotome, taking care to avoid the inferior alveolar nerve.

16. Suture the wound closed. Meticulous hemostasis and wound closure are necessary to minimize hemotoma and infection.

17. Wound care should be routinely done where the activation wire exits the skin.

## CAUTION DISTRACTION

1. Distraction is recommended to begin at the conclusion of the latency period and continue at a rate as determined by the surgeon until the desired distraction is achieved. The distraction tool is used by the patient's guardian to rotate the activation wire and initiate distraction. Three turns to the distraction tool will approximate 1mm of distraction.

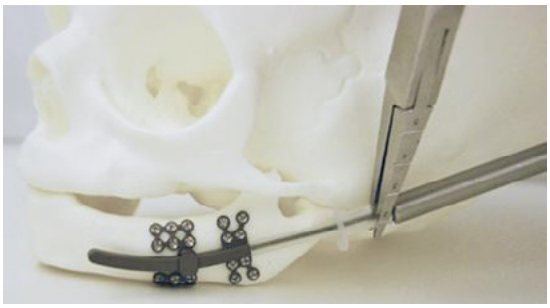
2. If excessive resistance is felt, STOP distracting and contact the surgeon.


3. After the desired distraction has been achieved, the portion of the activation wire protruding through the mucosa may be removed (see Instructions below) and discarded, along with the silicone tubing, according to standard bio-hazard disposal procedures. The distractor should remain implanted for the consolidation period determined by the surgeon.

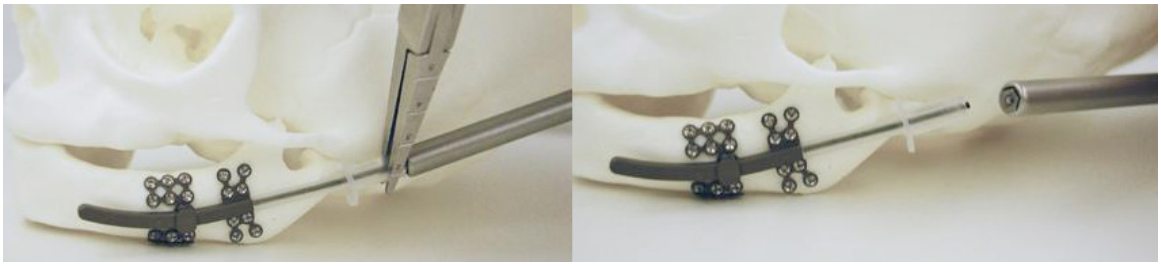
**CAUTION** The patient guardian should make sure that the turns are made in the direction of the arrow indicated on the flat of the distraction tool. Make sure the patient guardian has read and understands the perforated pages (7-9) before returning home after surgery. Please instruct patient's guardian on appropriate diet, activity level and proper techniques for routine wound care.

## ACTIVATION WIRE REMOVAL

1. Hold the activation wire with grasping forceps near the hex nut.



2. Slide the distraction tool (P/N 218-0102) over the hex nut of the activation wire as shown below. Move the distraction tool 40-60 degrees in one direction. Then move the distraction tool back to its original position. The hex nut shall come off at this point. If not, continue moving the distraction tool until the hex nut snaps off. Optionally, use the the plate cutter (P/N 220-0028) to cut the wire just under the hex nut base.



3. Remove the silicone tubing and discard in accordance with standard biohazardous waste disposal procedure.

4. Slide the activation wire removal tool (P/N 216-0103) over the activation wire until it is flush with the moving plate.

5. Using a quick lateral force, snap the activation wire where it enters the moving plate. Discard the activation wire and activation wire removal tool in accordance with standard biohazardous waste disposal procedures. The remainder of the activation wire \ will remain, supporting the distractor in the expanded position.

**CAUTION** **DISTRACTOR REMOVAL**

1. Make the intraoral incision from midramus height to lateral to the second mandibular molar and expose the distractor.

2. Remove the screws fixating the distractor to the mandible.

3. Remove the distractor and discard according to standard biohazard disposal procedures.

4. Suture the distraction site closed.

**CAUTION** It is recommended that the distractor remain implanted for the consolidation period after desired distraction has been achieved as determined by the surgeon.

# Pediatric Mandibular Distractor Patient's Guardian Instructions for Use and Patient Progress Chart

Patient Name: _____

Physician Name: _____

Physician Phone: _____

First Distraction Date: _____

Last Distraction Date: _____

Distraction Plan

Turns AM: _____

Turns Noon: _____

Turns PM: _____

The patient's guardian should track the patient progress from the beginning of distraction to the end as instructed by the physician.

A copy of this progress report should be given to the physician once the distraction has been completed.

If you have any questions or concerns, please contact your physician.

| *Day* | *Date* | *Rotations* | | |
|---|---|---|---|---|
| | | *AM* | *Noon* | *PM* |
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| *Day* | *Date* | *Rotations* | | |
|---|---|---|---|---|
| | | *AM* | *Noon* | *PM* |
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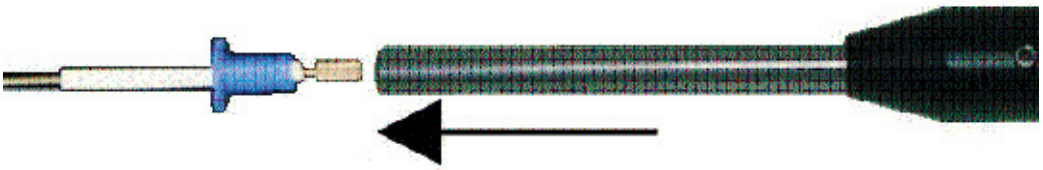
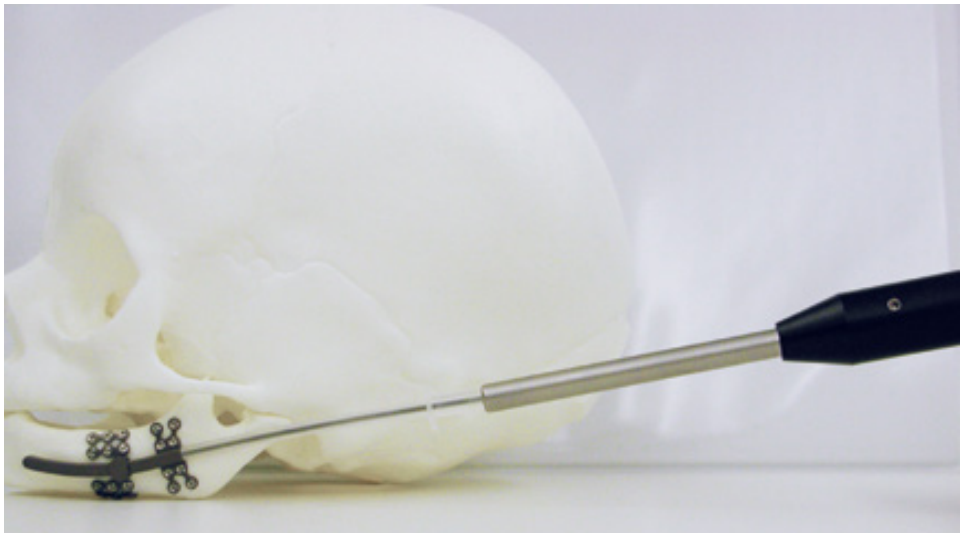
Daily Instructions

1. Engage the hex nut of the activation wire with the internal hex of the distraction tool.



2. Rotate the distraction tool in the direction of the arrow on the distraction tool. Three (3) rotations advances the distractor 1mm.



**CAUTION**

**Precautions to the patient's guardian:**

Your doctor has fitted your child with a distraction device to aid in the lengthening of his/her mandible. This process requires you to be familiar with the instructions for daily use of this distractor. Patient progress should be tracked on the "Patient Progress Chart" inside this pamphlet. Your compliance with your physician's instructions will help ensure positive outcome. If you have any questions or concerns, contact the physician. If excessive resistance is felt, STOP distracting and call physician immediately

**Precautions to the physician:**

Please be sure the patient's guardian has read and understands this pamphlet before patient returns home after surgery. The patient guardian should track progress on the progress chart.

Please instruct patient's guardian on the appropriate diet and activity level for the patient. Please instruct patient's guardian on proper techniques for routine wound care.

NOTES:

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Customer Service: 800.456.7779

3885 Arapaho Road | Addison, TX 75001 | Phone: 972.677.4600 | Fax: 800.390.2620
www.osteomed.com
Colson A COLSON ASSOCIATE

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