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LogicTM

SURGICAL TECHNIQUE GUIDE

Mandibular Distraction System





SURGICAL TECHNIQUE GUIDE

INDICATIONS

The OSTEOMED LOGIC™ Mandibular Distractor system is indicated for use as a mandibular bone lengthener for patients diagnosed with conditions where treatment includes mandibular distraction osteogenesis. These conditions may include diagnoses such as mandibular micrognathia or hemi facial microsomia. The device is designed to provide distraction along a curvilinear or straight path approximating the natural growth of the mandible.

CONTRAINDICATIONS

Use of the OSTEOMED LOGIC™ Mandibular Distractor 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 in 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 LOGIC™ mandibular distractor system is also contraindicated in those cases where there is inadequate volume or quantity of bone to place the distractor securely.



WARNING indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury and may result in property damage.

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 OSTEOMED LOGIC™ Mandibular Distractor, its instrumentation, indications and contraindications. Accepted surgical practice should be followed in postoperative care.

- The patient/guardian is to be warned that the device can break or loosen as a result of stress, excessive activity or inappropriate diet.
- The patient/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.



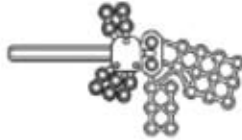
GENERAL WARNINGS

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

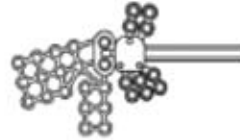
- Plates, screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
- Multiple bending may weaken the device and could result in implant fracture and failure.
- Do not remove activation wire before the consolidation period has been completed.
- Distractor 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 as indicated on the handle of the distraction tool.
- Patient's activities must be governed according to the limitations of the device.
- 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.
- During distraction and consolidation period, the soft-tissue portal 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.
- 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 Distractor removal instructions may cause patient harm.
- 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.
- It is recommended to remove any fractured implants from patients during surgery. If unable to remove, notify patient/guardian.
- Use of screws in high dense bone may lead to implant fracture or failure upon insertion.

DISTRACTORS

Straight Right
216-0119



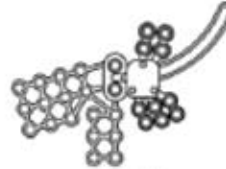
Straight Left
216-0118



24mm Right
216-0115



24mm Left
216-0114



36mm Right
216-0113



36mm Left
216-0112



52mm Right
216-0111



52mm Left
216-0110



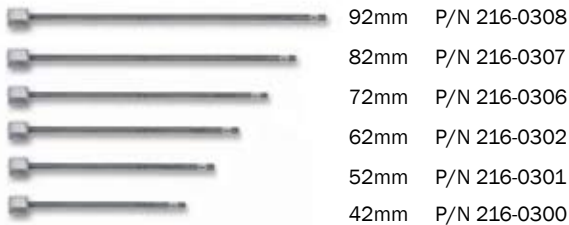
DISTRACTION TOOL

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



92mm P/N 216-0308
82mm P/N 216-0307
72mm P/N 216-0306
62mm P/N 216-0302
52mm P/N 216-0301
42mm P/N 216-0300

SILICONE TUBING

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



P/N 216-0305

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

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

SURGICAL PRE-PLANNING

Placement Planning and Choosing the Curve:

The patient or patient's guardian should receive the "Patient's Progress Chart" to insure proper instruction and tracking of distraction.

The OSTEOMED LOGIC™ Mandibular Distractor System offers three different curved designs and one straight design which approximate natural jaw growth. The curve 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. The lateral headfilm is used for planning, the frontal headfilm is used for determining asymmetry, and the panorex is used to determine position of the teeth.

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 curve and plan the necessary distraction. The planning template features two logarithmic spirals, the Moss Spiral and the Golden Spiral. The Moss Spiral will be used for the majority of patients and the Golden Spiral is indicated for use with brachiocephalic patients where the jaw tends to be more square.

When selecting the appropriate curve, it is important to consider the following:

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



Use of the Template:

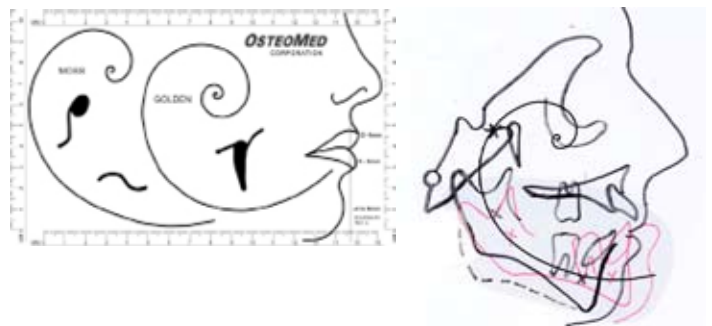
1. Place tracing paper over lateral headfilm and trace all hard and soft tissue landmarks.
2. Use the template to trace teeth onto tracing paper.
3. Determine location of the mental foramen, the inferior alveolar foramen, the pterygoid raphe and therefore the foramen ovale.
4. Once landmarks are established a Surgical Treatment Objective should be made:

- Surgical Treatment Objective (STO) determines the desired final position of teeth and chin. Check to insure that the soft tissue chin is close to the ideal relationship. A drawing of the ideal relationship can be found on the template.
 - Using the landmarks in conjunction with either the Moss Spiral or the Golden Spiral determines which distractor should be used. The foramen ovale, inferior alveolar foramen and mental foramen positions determined by STO should fall on this curve.
5. Position the chosen spiral over the foramen ovale, inferior alveolar foramen and the mental foramen as determined by the STO. Trace the logarithmic curve onto the tracing paper in this position.



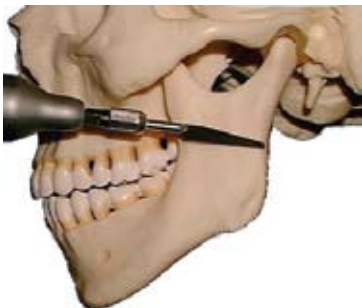
6. Place drawings of devices on top of the curve and determine which curve best fits the spiral, taking into consideration the position of the osteotomy. The cut placement should be based on the nerve location, location of tooth buds, bone stock, and access. Special attention should be given to the rotational orientation of the distractor. Positioning the distractor more vertical or horizontal favors that direction and should be based on the x-rays.

7. Trace curve of the appropriate distractor, screw hole positions and the osteotomy onto the tracing

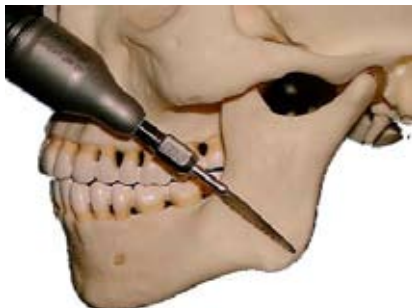


PREPARATION OF DISTRACTION SITE

1. Make an intraoral incision from mid-ramus height to lateral to the second mandibular molar.
2. Perform a subperiosteal dissection to expose the lateral ramus.
3. Position of the cut should be determined based on desired mandibular movement. It should be more horizontal for vertical distraction and more vertical for horizontal distraction. Using the saw, score the lateral mandible, then cut through both buccal and lingual cortices at the posterior or inferior border and at the anterior border. Make certain the osteotomy is made above or in front of the inferior alveolar nerve.



More horizontal osteotomy for vertical distraction



Osteotomy at the angle of the mandible for distraction in both horizontal and vertical vectors

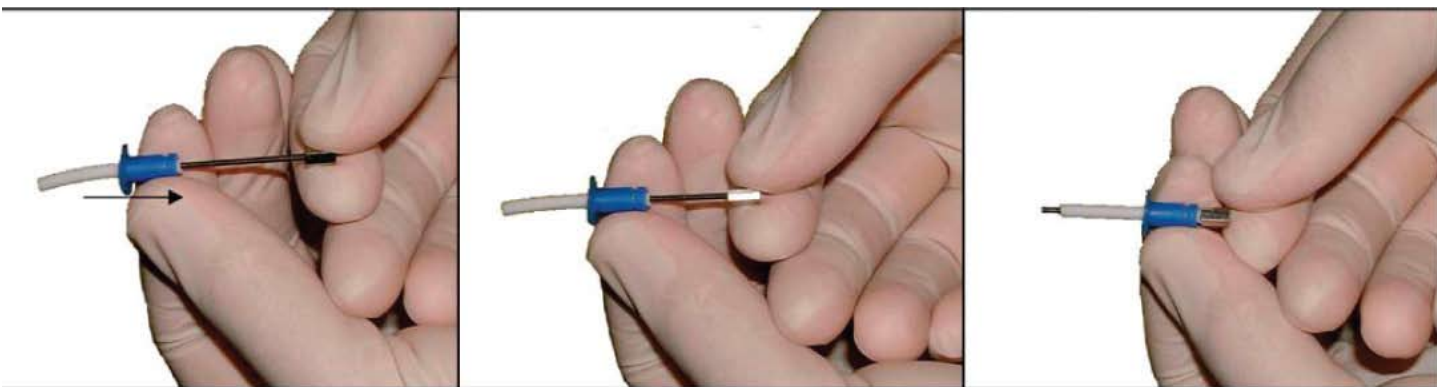


More vertical osteotomy for horizontal distraction

CAUTION Repeated bending of the device by the surgeon may cause the device to weaken or fracture.

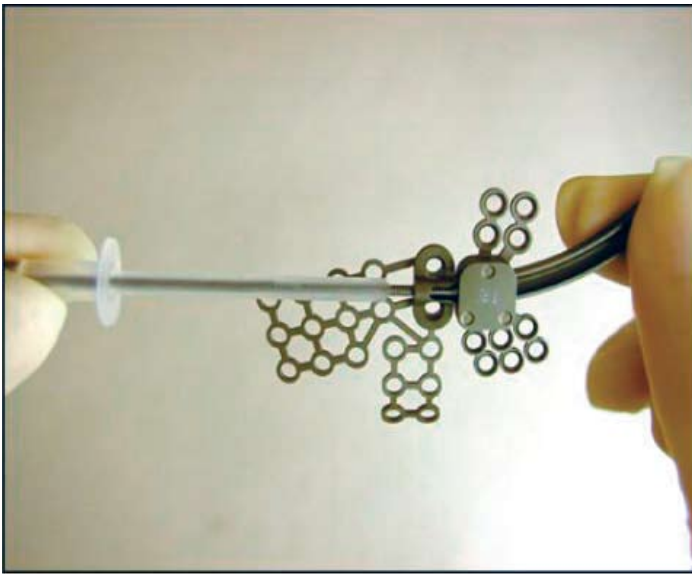
PLACEMENT OF DISTRACTOR

1. Before engaging the activation wire place the silicone tubing over the wire.
2. Check device to ensure free articulation between the two moving plates. They should slide freely.
3. Using bending pliers, adjust the fixation plates of the distractor to accommodate the natural curve of the mandible.



4. Determine if the activation wire will exit through the cheek or if it will remain intraoral. If the activation wire will exit through the cheek, an incision in the cheek must be made. Engage the activation wire into the distractor before fixating.

CAUTION The silicone tubing is indicated for a maximum implant period of 29 days.



5. 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.

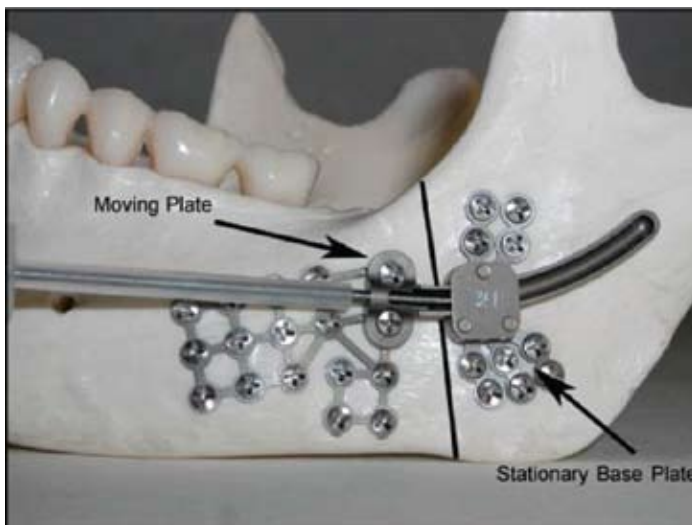
6. Fixate the distractor to the mandible using 1.6mm screws or 2.0mm screws.

CAUTION Distractor must be fixated with a minimum of 2 screws on each side of the osteotomy.

There are two areas of the distractor that must be fixated to the mandible:

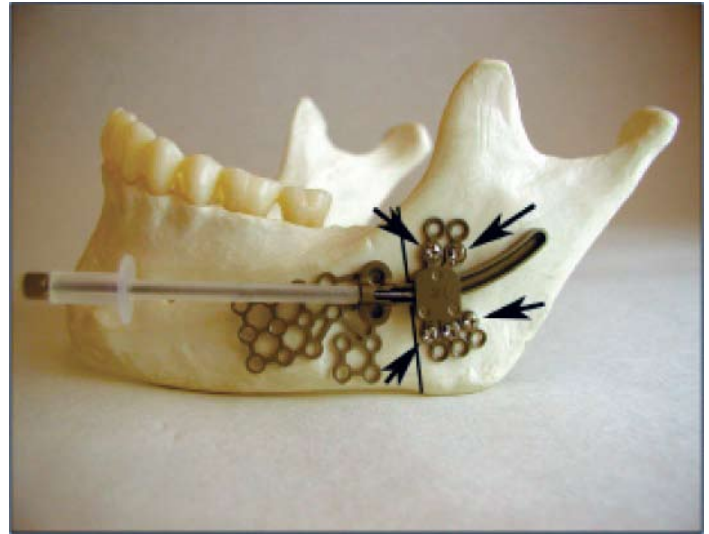
- 1) The stationary base plate
- 2) The moving plate

Bi-cortical fixation of the distractor is not always necessary.

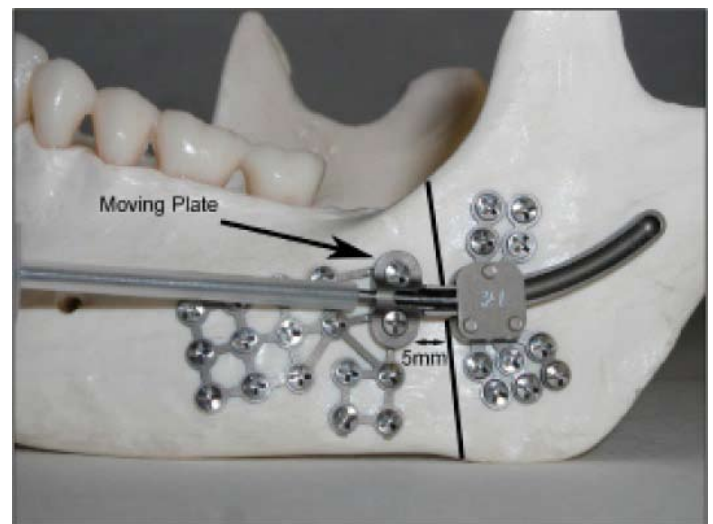


Screws may be placed using either a trans-buccal approach or by using a contra angle drill and screwdriver.

7. When fixating the stationary base plate of the distractor, place one screw in each arm. Then place remaining screws in additional holes.



8. Fixate the moving plate of the distractor placing the screws 5mm away from the osteotomy. Screws should be placed in multiple mesh arms.



CLOSURE OF THE DISTRACTION SITE

1. After the distractor has been securely fixated, complete the osteotomy using an osteotome, taking care to avoid damaging the inferior alveolar nerve.
2. Suture the intraoral wound closed. Meticulous hemostasis and wound closure are necessary to minimize hematoma and infection. If the activation wire exits through the skin, wound care should routinely be done.

DAILY DISTRACTION

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 or patient guardian to rotate the activation wire and initiate distraction.



Three turns of the distraction tool will approximate 1mm of distraction.



CAUTION

The patient or patient guardian should make sure that the turns are made in the direction of the arrow indicated on the flat of the distraction tool.

POST DISTRACTION PERIOD

After the desired distraction has been achieved, the portion of the activation wire protruding through the mucosa may be snapped off and discarded, along with the silicone tubing, according to standard biohazard disposal procedures. The end of the activation wire will then retract beneath the skin and remain there for the duration of the consolidation period. The distractor should remain implanted for the consolidation period determined by the surgeon.

ACTIVATION WIRE REMOVAL

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



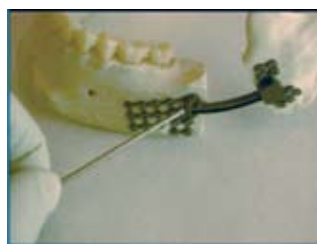
2. Slide the distraction tool (P/N 216-0102) over the hex nut of the activation wire as shown below. In one swift motion snap the hex nut by applying force.



3. Remove the silicone tubing and discard in accordance with standard bio-hazardous waste disposal procedures. Slide the activation wire removal tool (P/N 216-0103) over the activation wire until it is flush with the moving plate as shown below.



4. Using a quick lateral force, snap the activation wire where it enters the moving plate as shown below. Discard the activation wire and distraction tool in accordance with standard bio-hazard waste disposal procedures. The remainder of the activation wire will remain, supporting the distractor in the expanded position.



DISTRATOR REMOVAL

CAUTION

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

1. Make the intraoral incision from mid-ramus 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.

MANDIBULAR DISTRATOR PATIENT/GUARDIAN INSTRUCTIONS FOR USE AND PATIENT PROGRESS CHART

Patient Name: _____ First Distraction Date: _____

Physician Name: _____ Last Distraction Date: _____

Physician Phone: _____ Distraction Plan

Turns AM: _____

Turns Noon: _____

Turns PM: _____

The patient/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.

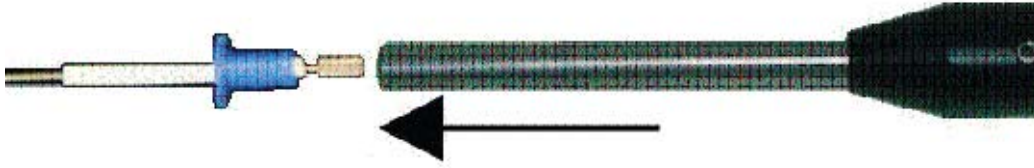
If you have any questions or concerns, please contact your physician.

Day	Date	Rotations		
		AM	Noon	PM
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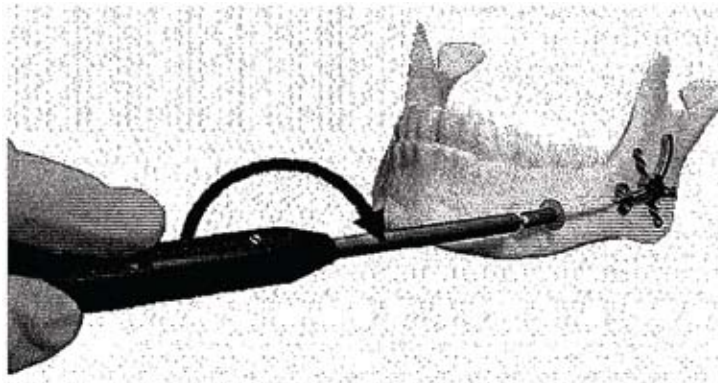
Day	Date	Rotations		
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Daily Instructions

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.



Patient or patient guardian should rotate the activation wire

_____ full rotation(s)

_____ time(s) per day

Precautions to the patient's guardian:

Your doctor has fitted you with a distraction device to aid in the lengthening of your 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.

Notes to the physician:

Please be sure the patient or patient guardian has read and understands this pamphlet before implanting the mandibular distractor.

The patient guardian should track progress on the progress chart.



Customer Service: 800.456.7779



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

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