Part No. 030-1205
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OSTEOMED
Logic Mandibular Distraction System
Product Information and Indications For Use

Description
The *OSTEOMED Logic Mandibular Distraction System* is an intraoral bone distractor. It features various curved and straight bars activated with an activation wire (threaded wire) that has screw holes that are fixed to bone via 1.6mm or 2.0mm bone screws. The distractor is available in right and left versions. The activation wire is activated by a hex driver and is capable of distraction lengths of up to 25mm.

Material
The Distractor assembly is made from Titanium Alloy (ASTM-F-136) and Titanium (ASTM-F-67). The threaded guide wire is made from Nickel Titanium and Titanium Alloy (ASTM-F-136). The screws are made from Titanium Alloy (ASTM-F-136). The instrumentation is made from various grades of stainless steel, anodized aluminum, and/or acetal copolymer plastic.

Clinical Indications
The *OSTEOMED Logic Mandibular Distraction 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 hemifacial microsomia. The *OSTEOMED Logic Mandibular Distraction System* is intended for single patient use only. OsteoMed single use devices/instruments cannot be reused and/or reprocessed. The product has been labeled as single use only for patient safety. The design of the device and the intricacies of the surfaces may not facilitate cleaning and sterilization after contact with body tissues or fluids, so there is an increased risk of contamination if reused. This may lead to potential risks of cross infection/contamination associated with using inadequately cleaned and sterilized devices. For cutting instruments the cutting efficacy may be reduced requiring the surgeon to use increased force that might cause patient harm and/or increase the risk of thermal necrosis. Because these products have not been validated for multiple use, OsteoMed cannot guarantee the safety and effectiveness of the device if it is used on more than one patient.

Contraindications
Use of the *OSTEOMED Logic Mandibular Distraction System* is contraindicated in cases of active or suspected infection, in patients previously sensitized to nickel, titanium, or silicone; in patients with upper airway obstruction withcertain 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 Logic Mandibular Distraction System* is also contraindicated in those cases where there is an inadequate volume or quality of bone to place the distractor securely.

Warnings
1. Plates, screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
2. Multiple bending may weaken the device and could result in implant fracture and failure.
3. Do not remove activation wire before the consolidation period has been completed.
4. Distractor must be fixated with a minimum of 2 screws on each arm of the moving plate and the stationary plate.
5. The activation wire must be turned in the direction of the arrow as indicated on the handle of the distraction tool.
6. Patient's activities must be governed according to the limitations of the device.
7. Surgeon should limit patient to a soft diet for the duration of the distraction period.
8. Precautions should be taken to avoid damage to the inferior alveolar or facial nerves.
9. During distraction and consolidation period, the soft-tissue portal must remain clean.
10. Minimal MRI scattering is possible due to nickel present in the activation wire.
11. The silicone tubing is indicated for a maximum implant period of 29 days.
12. Excessive torque on the activation wire may cause the wire to break.
13. Failure to follow Planning instructions may contribute to patient harm.
14. Failure to follow Implantation instructions may cause patient harm or device damage.
15. Failure to follow Distraction instructions may cause patient harm or device damage.
16. Failure to follow Distractor removal instructions may cause patient harm.
17. 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.
18. It is recommended to remove any fractured implants from patients during surgery. If unable to remove, notify patient/guardian.
19. Use of screws in high density bone may lead to implant fracture or failure upon insertion.
20. Use of excessive force during insertion of screws may lead to implant failure.
21. The *OSTEOMED Logic Mandibular Distraction System* has not been tested for safety and compatibility in the MR environment, nor has it been tested for heating or migration in the MR environment.
22. Evaluation of the safety and compatibility of the device in the MR environment, the following concerns were determined: magnetically induced displacement force and torque, radio frequency (RF) heating and image artifacts.

Precautions
1. The patient/guardian is to be warned that the device can break or loosen as a result of stress, excessive activity or inappropriate diet.
2. 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.
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. During distraction, the activation wire should be kept coaxial (aligned) with the distractor body.

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 Logic Mandibular Distraction System* is not intended to endure excessive abnormal functional stresses.
4. The *OSTEOMED Logic Mandibular Distraction System* is intended for temporary fixation once intended distraction is achieved and mandibular distraction osteogenesis occurs.
5. 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.
6. 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 and repair.
7. Care must be taken not to damage threads on the activation wire during implantation.
8. OsteoMed recommends the use of OsteoMed products in a sterile environment.
9. Drill using the appropriate pilot drill. Note: Speed and torque parameters must be in accordance to the power system instructions for use. Use irrigation when pilot drilling.

Attention: Instructions for Use are in the Surgical Technique Guide (030-1206)

Instructions for Use, Auto-Drive™ screws
The Auto-Drive™ screws are self drilling and can be inserted in one step. Insert the screw in a TaperLock™ screwdriver and drive into the bone at a 90° angle using moderate pressure until the head is flush with the surface of the bone/plate. Higher torque may be required to fully engage the threads than when using a normal screw with a pilot drill.

Note: In high density bone, pilot drilling may be necessary.

Instructions for Use: Planning (template)
Note: Logic Surgical Technique Guide is also available through Customer Service (1-800-456-7770).

1. The OsteoMed Logic Mandibular Distractor 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 (see Surgical Technique Guide), 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:
   - 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.
2. Place tracing paper over lateral headfilm and trace all hard and soft tissue landmarks
3. Use the template to trace teeth onto tracing paper.

   Determine location of the mental foramen, the inferior alveolar foramen, the pterygoid raphe and therefore the foramen ovale. 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.
4. 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.
5. 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.
6. Trace curve of the appropriate distractor, screw hole positions and the osteotomy onto the tracing

NOTE DISTRACTOR DISTRACTION LIMITS PER DISTRACTOR:

	Description	Distraction Length Limits
216-0110	LOGIC™ Distractor, Left 52mm	23mm
216-0111	LOGIC™ Distractor, Right 52mm	23mm
216-0112	LOGIC™ Distractor, Left 36mm	17mm
216-0113	LOGIC™ Distractor, Right 36mm	17mm
216-0114	LOGIC™ Distractor, Left 24mm	10mm
216-0115	LOGIC™ Distractor, Right 24mm	10mm
216-0118	LOGIC™ Distractor, Left Straight	25mm
216-0119	LOGIC™ Distractor, Right Straight	25mm

Instructions for Use: Implantation (placing distractor)
1. Make an intraoral incision from midramus 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 made 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.
4. Before engaging the activation wire place the silicone tubing over the wire.
5. Check device to ensure free articulation between the two moving plates. They should slide freely. Using bending pliers, adjust the fixation plates of the distractor to accommodate the natural curve of the mandible.
6. 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.
7. 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.
8. Fixate the distractor to the mandible using 1.6mm screws or 2.0mm screws. There are two areas of the distractor that must be fixated to the mandible: 1) the stationary base plate; 2) the moving plate. Bicortical fixation of the distractor is not always necessary. Screws may be placed using either a transbuccal approach or by using a contra angle drill and screwdriver.
9. When fixating the stationary base plate of the distractor, place one screw in each arm. Then place remaining screws in additional holes.
10. Fixate the moving plate of the distractor placing the screws 5mm away from the osteotomy. At a minimum, two screws should be placed in each arm of the plate.
11. After the distractor has been securely fixated, complete the osteotomy using an osteotome, taking care to avoid damaging the inferior alveolar nerve.
12. 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.

Instructions for use: 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 to the distraction tool will approximate 1mm of distraction.

Instructions for use: Activation Wire Removal
1. Hold the activation wire with grasping forceps near the hex nut.
2. Slide the distraction tool (P/N 216-0102) over the hex nut of the activation wire. Move the distraction tool 40-60 degreese in one direction. Then move the distraction tool back to its original position. The hex nut shall come off at this point. If it does not, continue moving the distraction tool until the hex nut snaps off. Optionally, use 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 biohazard 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 biohazard waste disposal procedures. The remainder of the activation wire will remain, supporting the distractor in the expanded position.

Instructions for use: 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.

Cleaning
- Products must be carefully cleaned prior to sterilization. Trained personnel must perform cleaning and mechanical inspection prior to sterilization.
- Compliance is required with the equipment manufacturer's user instructions (manual and/or machine cleaning, ultrasound treatment, etc.) and recommendations for chemical detergents.
- OsteoMed recommends the following cleaning and sterilization instructions for Instrumentation:
  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 and sterilization tray.
  2. Thoroughly rinse all instruments and the sterilization tray with water.
  3. Arrange all the instruments in the sterilization case and ensure that the lid is in place and properly closed.
  4. Steam Autoclave per the following Sterilization Instructions.

Sterility
- Implants and Instruments are provided non sterile and must be sterilized prior to use.
- Use of the sterilizer shall comply with the manufacturer's user instructions for sterilizers.
- The user facility must clean and disinfect instruments prior to sterilization per standard hospital procedures.
- Non-sterile devices are sterilizable by steam sterilization (autoclaving). For sterilization of *OSTEOMED Logic Mandibular Distraction System*, the following parameters should be used.

Plastic Tray
Pre-Vacuum Steam Sterilization:
Temperature: 270°F (132°C)
Cycle Time: 20 minutes
Dry Time: 35minutes
Configuration: Wrapped tray
Wrapping Techique : Wrapped with two layers of 1-ply polypropylene (KC600) with a towel placed between the bottom of the tray and wrap.
Do not exceed 275°F (135°C), to avoid compromising functions of polymeric instrumentation.

Aluminum Tray
Pre-Vacuum Steam Sterilization
Temperature: 270°F (132°C)
Cycle Time: 10 minutes
Dry Time: 35minutes
Configuration: Wrapped tray
Wrapping Techique : Wrapped with two layers of 1-ply polypropylene (KC600) with a towel placed between the bottom of the tray and wrap.
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	REF	Catalogue Number
LOT	Batch Code (Lot Number)		Consult Instructions for Use
	Date of Manufacture (MFG DATE)		Manufacturer (MFR)
	Attention, See Instructions for Use Caution, Consult Accompanying Documents	EC REP	Authorized Representative in the European Community
Rx ONLY	Federal Law (U.S.A.) Restricts this device to sale by or on the order of a physician.		

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