Part No.030-1428
Rev. M

OSTEOMED
Logic Jr Pediatric Mandibular Distraction System
Product Information and Indications For Use

Description
The *OSTEOMED Logic Jr. Pediatric Mandibular Distraction System* is an intraoral bone distractor. It system features curved and straight distractors that are fixed using 1.2mm bone screws. The device is actuated with an activation wire (threaded wire) driven by a hex driver (distraction tool). The device is available in right and left versions and standard and short lengths. The standard device is capable of distraction lengths of up to 25mm. The short device is capable of distraction lenths up to 15mm.

Material
The distractor assembly is made from Titanium (ASTM-F-67). The activation wire is made from Nickel Titanium wire. The screws are made from Titanium Alloy (ASTM-F-136). The instrumentation is made from various grades of stainless steel, anodized aluminum, and/or medical grade plastic.

Clinical 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, symphysis), 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. 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 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 upper airway obstruction, 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 patient/guardian cooperation cannot be guaranteed.

Warnings
1. Distractor is indicated for children under 4 years of age including infants and neonates.
2. Failure to follow Planning instructions may contribute to patient harm.
3. Failure to follow Implantation instructions may cause patient harm or device damage.
4. Failure to follow Distraction instructions may cause patient harm or device damage.
5. Failure to follow Activation Wire Removal instructions may cause patient harm or device damage.
6. Failure to follow Distractor Removal instructions may cause patient harm.
7. Plates, screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
8. Multiple bending may weaken the device and could result in implant fracture and failure.
9. Do not remove activation wire before the consolidation period has been completed.
10. 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.
11. The activation wire must be turned in the direction of the arrow indicated on the handle of the distraction tool.
12. During distraction and consolidation period, the activation wire exit site must remain clean.
13. Minimal MRI scattering is possible due to nickel present in the activation wire.
14. The silicone tubing is indicated for a maximum implant period of 29 days.
15. Excessive torque on the activation wire may cause the wire to break.
16. 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.
17. Use of screws in high density bone may lead to implant fracture or failure upon insertion.
18. It is recommended to remove any fractured implants from patients during surgery. If unable to remove, notify patient's guardian.
19. Use of excessive tor que during insertion of screws may lead to implant failure.
20. The *OSTEOMED Logic Jr. Pediatric 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.
21. 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 guardian is to be warned that the device can break or loosen as a result of stress, excessive activity or inappropriate diet.
2. 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.
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.

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 distractor and screw type to use for specific indications.
3. The *OSTEOMED Logic Jr. Pediatric Mandibular Distraction System* is not intended to endure excessive abnormal functional stresses.
4. The *OSTEOMED Logic Jr. Pediatric 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.

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 a 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)
1. 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 (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 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.

Note Distractor Distraction Limits Per Distractor:

Part No.	Description	Distraction limits
216-1000	Logic Jr. Distractor, Left 52mm	23mm
216-1001	Logic Jr. Distractor, Right 52mm	23mm
216-1002	Logic Jr. Distractor, Straight (Left/Right)	25mm
216-1003	Logic™Jr.52mm,Left Short,Distractor, 15mm Distraction	15mm
216-1004	Logic™Jr. 52mm,Right Short,Distractor,15mm Distraction	15mm

Instructions for Use: Implantation (placing Logic Jr distractor)
Note: Logic Jr Surgical Technique Guide is also available through Customer Service (1-800-456-7779).
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.
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 retractor 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 the activation wire NO more than 2-3mm. Advancing 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 Risdan 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.
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.

Instructions for use: 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 not consumed within the distractor may be removed (see Instructions for Use: Activation Wire Removal) 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.

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
- Product is supplied NON-STERILE.
- Use of the sterilizer shall comply with the manufacturer's user instructions for sterilizers.
- The user facility must clean and disinfect devices prior to sterilization per standard hospital procedures.
- Non-sterile devices are sterilizable by steam sterilization (autoclaving). For sterilization of OsteoMed implant systems, 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 (wrapped with two layers of 1-ply polypropylene (KC600)with a towel placed between the bottom of the tray and wrap)

Aluminum Tray
Pre-Vacuum Steam Sterilization
Temperature: 270°F (132°C)
Cycle Time: 10 minutes
Dry Time: 35minutes
Configuration: Wrapped tray (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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