Precautions

6. Surgeon should limit patient to a soft diet for the duration of the distraction period.

7. Patient’s activities must be governed according to the limitations of the device.

9. During distraction and consolidation period, the soft-tissue portal must remain clean.

12. Excessive torque on the activation wire may cause the wire to break.

10. Minimal MRI scattering is possible due to nickel present in the activation wire.

20. Use of excessive force during insertion of screws may lead to implant failure.

Use of the OsteoMed Logic Mandibular Distraction System is contraindicated in cases of active or active infection in, or adjacent to, the site of osteotomy. The device is not intended to endure excessive temperatures that may result in exposure to significant heat or fluids, so there is an increased risk of contamination if reused. If the device is placed in an environment where there is a risk of mechanical or biological contamination, the device should not be used. If the device is damaged, should have an equipment malfunction, or show signs of wear and tear, it should not be used.

Instructions for use: Distraction

1. The activation wire should be cut from midline to lateral to the second mandibular molar.

2. Position the distractor with the hex nut to the starting position.

3. Place the distractor on the bone. Engage the activation wire into the distractor before fixating.

4. Slide the Activation Wire Removal Tool (P/N 216-0103) over the activation wire until it is disposed of, thereby enabling the removal of the activation wire.

5. Using a quick lateral force, snap the activation wire where it enters the moving plate.

6. Ensure that the activation wire has engaged both parts of the distractor and is working by ensuring that the activation wire is in place and the distractor is fully engaged.

7. The distractor is to be removed when the desired correction has been achieved.

Instructions for use: Distractor Removal

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

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

3. The removal of the distractor and the fixation of the bone and soft tissue may lead to damage to the activation site.

4. Steam autoclave the following Sterilization Instructions.

5. Clean all instruments thoroughly using mild detergent, soft brush and warm water.

6. Comply with all manufacturers’ user instructions (manual and/or machine cleaning, ultrasound treatment, etc.) and recommendations for chemical detergents.

7. Position the distractor on the bone. Engage the activation wire into the distractor before fixating.

8. Slide the Activation Wire Removal Tool (P/N 216-0103) over the activation wire until it is disposed of, thereby enabling the removal of the activation wire.

9. Using a quick lateral force, snap the activation wire where it enters the moving plate.

10. Ensure that the activation wire has engaged both parts of the distractor and is working by ensuring that the activation wire is in place and the distractor is fully engaged.

11. The distractor is to be removed when the desired correction has been achieved.
Symbols and Definitions

- Single Use Only
- Batch Code (Lot Number)
- Date of Manufacture
- Attention, See User Manual
- Caution, Consult Accompanying Documents
- Keep dry

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