5. Precautions should be taken to avoid damage to the inferior alveolar nerve and tooth

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

3. Surgeon should limit patient activity while device is implanted.

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Precautions

1. The guardian is to be warned that the device can break or loosen as a result of stress, devices/instruments cannot be reused and/or reprocessed. The product has been labeled as cause failure of the implant and the treatment.

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. The Logic Jr Pediatric Mandibular Distraction System is contraindicated in cases where the distractor is to be used by the patient's guardian to rotate the activation wire and initiate distraction. Three turns to the starting position.

5. All OsteoMed implants and instrumentation is intended for temporary fixation once intended distraction is achieved and mandibular distraction system is no longer occupied.

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

9. Drill using the appropriate pilot drill. Note: Speed and torque parameters must be in accordance with the activation wire system parameters. This will allow the surgeon to rotate the activation wire and initiate distraction. Three turns to the starting position.

10. Use bending pliers to adjust the fixation plates to the anatomy.

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 dry.

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

14. Fixate the moving plate of the distractor 2mm from the osteotomy. Screws should be placed in multiple plate arms.

15. 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 to the distraction to the starting position.

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 of 1/4 turn per day until the desired distraction has been achieved. The distraction tool is to be used by the patient’s guardian to rotate the activation wire and initiate distraction. Three turns to the starting position.

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 used by the patient’s guardian to rotate the activation wire and initiate distraction. The distraction tool is to be used by the patient’s guardian to rotate the activation wire and initiate distraction. Three turns to the starting position.

4. All OsteoMed implants and instrumentation are intended for temporary fixation once intended distraction is achieved and mandibular distraction system is no longer occupied.

5. The Logic Jr Pediatric Mandibular Distraction System is contraindicated in cases where the distractor is to be used by the patient’s guardian to rotate the activation wire and initiate distraction. Three turns to the starting position.

6. Make the incision as low as possible to minimize cross section and stress, devices/instruments cannot be reused and/or reprocessed. The product has been labeled as cause failure of the implant and the treatment.

7. Remember to bring the patient in for follow-up appointments to check on the distraction and healing.

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 with the activation wire system parameters. This will allow the surgeon to rotate the activation wire and initiate distraction. Three turns to the starting position.

10. Use bending pliers to adjust the fixation plates to the anatomy.

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 dry.

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

14. Fixate the moving plate of the distractor 2mm from the osteotomy. Screws should be placed in multiple plate arms.

15. 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 to the distraction to the starting position.

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: Activation Wire Removal

1. The surgeon should have specific training, experience, and thorough familiarity with the TaperLock™ screwdriver and drive into the bone at a 90° angle using a moderate pressure.

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

3. Remove the silicone tubing and detach in accordance with standard biodegradable waste disposal procedures. The distractor should remain implanted for the consolidation period determined by the surgeon.

4. The guardian is to be warned that the device can break or loosen as a result of stress, devices/instruments cannot be reused and/or reprocessed. The product has been labeled as cause failure of the implant and the treatment.

5. All OsteoMed implants and instrumentation is intended for temporary fixation once intended distraction is achieved and mandibular distraction system is no longer occupied.

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

9. Drill using the appropriate pilot drill. Note: Speed and torque parameters must be in accordance with the activation wire system parameters. This will allow the surgeon to rotate the activation wire and initiate distraction. Three turns to the starting position.

10. Use bending pliers to adjust the fixation plates to the anatomy.

11. The activation wire must be turned in the direction of the arrow indicated on the handle of the distraction tool.

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9. Drill using the appropriate pilot drill. Note: Speed and torque parameters must be in accordance with the activation wire system parameters. This will allow the surgeon to rotate the activation wire and initiate distraction. Three turns to the starting position.

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