Description

The Logic Mandibular Distraction System is an internal bone distraction. It features various curved and straight bone arms activated with an activation wire (threaded wire) that have slots for fixation to bone 1.6mm or 2.0mm screws. The distraction is adjustable in right and left movements. The activation wire is activated by a key driver and is capable of disturbing movement of up to 25mm.

Materials

The Distactor assembly is made from Titanium Alloy (ASTM-F-136) and Titanium-A6F-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 instruments are made from 420 series stainless steel, anodized aluminum, and/or aluminum oxide powder.

Clinical Indications

The 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 deficiency or with certain cleft lip/palate repairs for patients 12 years of age or older. OsteoMed recommends its use in those cases where there is an adequate volume of bone to place the distractor safely.

Contraindications

The use of the OsteoMed Logic Mandibular Distraction System is contraindicated in cases of active or suspected infection, in patients presenting with impacted teeth, and in those cases where there is not sufficient bone stock to support the distractor. It is also contraindicated in patients who are immobile. It is further contraindicated in patients exhibiting disorders which would cause the patient to ignore the limitations of distraction osteogenesis. This system is also contraindicated in those cases where there is an adequate volume or quality of bone to place the distractor safely.

Warnings

1. Place, sponges, wires, or other appliances of stainless steel should not be used together in or near the implant site.
2. Multiple bending may weaken the arm and could result in fracture and failure.
3. Do not remove activation wire before the consolidation period has been completed.
4. Distactor must be fixed with a minimum of 2 screws on each arm of the moving plate and the stationary plate.
5. The activation wire must be maintained in the direction of the activation wire 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 the key driver to a soft diet for the duration of the distraction period.
8. Precautions should be taken to avoid damage to the inferior alveolar nerve or tooth buds.
9. During distraction and consolidation period, the activation wire must not facilitate the infection by creating an open wound that could lead to significant complications.
10. Minimal MRI scanning is possible due to nickel present in the activation wire.
11. The outcome of the treatment is limited to a maximum implant period of 60 days.
12. Excessive torque on the activation wire may cause wire to break.
13. Failure to follow Post-Implantation instructions may cause patient harm or device damage.
14. Failure to follow Post-Operation instructions may cause patient harm or device damage.
15. Failure to follow Distraction Removal instructions may cause patient harm or device damage.
16. The device arms can break with use.
17. This could lead to failure of the distractor and/or screws which could require additional surgery and device removal.
18. It is recommended to use the distractor in patients during surgery, if available to remove, notify medical personnel immediately.
19. Use of screws in high density bone may lead to fracture or failure due to insertion.
20. Use of bone screws may not be possible.
21. The device should be removed if it is not functioning as intended.
22. The surgeon must exercise reasonable judgment when deciding which plate and screw type to use for specific indications.

Instructions for Use

Distractor Placement

1. The patient/guardian is to be warned that the device can break or loosen as a result of stress, excessive activity or movement of the mandible.
2. The device should not be used for patients with a history of osteomyelitis or osteoporosis.
3. The device should not be used for patients who are immobile. It is further contraindicated in patients exhibiting disorders which would cause the patient to ignore the limitations of distraction osteogenesis. This system is also contraindicated in those cases where there is an inadequate volume or quality of bone to place the distractor safely.

Precautions

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Storage

The Logic Mandibular Distraction System is to be stored at a controlled temperature range between 10ºC to 30ºC (50ºF to 86ºF).

Cautions

1. Federal (United States) law restricts this device to sale by or on the order of a medical practitioner licensed to do so.
2. Legal restrictions may apply to the use of this product.
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Symbols and Definitions

- Single Use Only
- Batch Code (Lot Number)
- MFR (Manufacturer)
- Authorized Representative in the European Community