SURGICAL TECHNIQUE FOR INTRA ORAL DISTRACTION OF MANDIBLE

PLATE AND DISTRACTOR CHARACTERISTICS

- Double-bar design for increased stability
- Optimized bar geometry and plate holes in areas subject to severe stress
- Variety of options for different distraction lengths 10mm to 25mm
- Adaption plates made from semi-rigid stainless steel 316L
- Compact distraction activators –rigid and hinged also available

INDICATIONS

The Ortho Max distraction osteogenesis system is designed for use in unilateral or bilateral underdevelopment (hypoplasia or dysgnathia) or malformations of the ramus, corpus or whole mandible. This includes congenital and acquired deformities such as:

- Congenital malocclusions or malformations:
  - Marked sagittal malformation of the mandible (mandibular retrognathism)
  - Hemifacial microsomia (Pruzansky-Omens classification)
  - Syndromes involving mandibular hypoplasia, microglossia or micrognathia (Hall classification),
  - Transverse mandibular underdevelopment
- Acquired hypoplasia:

- Abnormalities affecting the growth of the ascending ramus as a result of TMJ defects due to:
  - Ankylosis
  - Rheumatic lesions
  - Segmental loss of bone substance after treatment of benign or malignant tumors with healing of bone defects

CONTRAINDICATIONS

- Acute or chronic infections or necrosis of the jaw at or near the implant site (dental infections, osteomyelitis, osteoradionecrosis, bisphosphonate-associated osteo necrosis of the jaw)
- Known allergies and/or hypersensitivity to foreign bodies
- Inadequate bone volume or insufficient bone quality to securely anchor the implant
- Patients who are incapacitated and/or uncooperative during the treatment phase
- The treatment of at risk groups (particularly with bone metabolism disorders) is inadvisable

SURGICAL STEPS

Step 1: Gingival crevicular incision with releasing incision from the alveolar crest towards vestibule.

Step 2: Reflection of Mucoperisteal flap to achieve proper access.

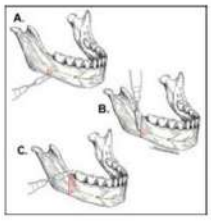
Step 3: Selection of size depends of desired length of distraction to be achieved ranges from 10mm,15mm,20mm,25mm . Ensure good placement of Intra Oral Mandible Distractor (Left or Right) in desired position.

Step 4: Bend the foot plate with three holes to adapt on desired position with screws fixation.

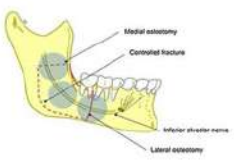
Step 5: Fixation of first monocortical mini bone screw on either side of the planned osteotomy cut. Mini Bone screws of 2mmx 7mm length recommended. Use 1.5mm Drill bit to drill the hole and tighten the screw and take mark of osteotomy line.

Step 6: Then remove the Device and screws

Step 7: Do the osteotomy of the buccal cortex as well as the upper & lower borders between the earlier marked screws position.



Step 8 : Make a green stick fracture of the lingual cortex with an osteotome or periosteal elevator.



Step 9: Place the device again for final fixation. Repeat same procedure of screw fixation with 1.5mm drill hole.
Fix three screws of 2mmx7mm on each side footplate.

Step 10: Checking of distraction function is very important part of this technique. A hinged or fixed activator can be used to check distraction function of the device. Markings of each turn and distraction achieved by one full turn of 360 degree is given on activator handle. The distractor is activated to ensure that it is working properly and is then deactivated (returned to starting position). One should ensure engaging activator at Nno.1 position of handle. Hinged activator shall not be rotated at more than 30 degree angle. _

Step 11: Mucoperiosteal flap suturing can be completed once checking of distraction is found in order. It shall be ensured that the activation square part of device is not sutured and kept open for further distraction.

Distraction Protocol:

1. Latency Period : 7 to 10 days once stabilization of osteotomy is achieved without distraction
2. Activation : Start on 8th or 11 Day
3. Frequency : 1mm distraction per day i.e. two full turn of the activator in a day.
4. Stability of Distraction Device: ideally two months immobilization period after full

activation is recommended

5. Device removal after desired advancement is achieved with complete consolidation

Warning:

This surgical technique is not sufficient for immediate use of the Intra oral Distraction Device system. Training, Instructions and supervision by a surgeon well experienced in handling this Distraction system is highly recommended. We do not take responsibility of wrong or mishandling of any implants or instruments and its consequences. Intended for use on Mandible body distraction only.

MRI Information:

It is recommended to pay particular attention to the following points:

– It is recommended to thoroughly monitor patients undergoing MR scanning for perceived temperature and/or pain sensations.

– Patients with impaired thermoregulation or temperature sensation should be excluded from MR scanning procedures.

– Generally, it is recommended to use an MRI system with low field strength in the presence of conductive implants. The employed specific absorption rate (SAR) should be reduced as far as possible.

– Using the ventilation system may further contribute to reduce temperature increase in the body

CAUTION:

Used Implants :

Used implants which appear un-damaged may have internal and/or external defects. It is possible that individual stress analysis of each part fail to reveal the accumulated stress on the metals as a result of use within the body. This may lead ultimately to implant failure after certain point of time due to metal fatigue. Therefore reuse of implants are strictly not recommended.

Disposal of Used Implants:

Every used or removed implant must be discarded after use and must never be re- used. It should be bent or scratched & then disposed off properly so that it becomes unfit for reuse. While disposing it off, it should be ensured that the discarded implant does not

pose any threat to children, stray animals and environment. Dispose off the implants as per applicable medical practices and local, state and country specific regulatory requirement of Bio Medical Waste rules.

PACKAGING MATERIAL DISPOSAL: The packaging material of this device is made of LDPE and therefore if swallowed, may cause choking Hazards. Therefore, it should be disposed of in such a way that keeps out of reach of children and stray animals.

SINGLE BRAND USAGE: Implant components from one manufacture should not be used with those of another. Implants from each manufacture may have metal, dimensions and design differences so that the use in conjunction with different brands of devices may lead to inadequate fixation or adverse performances of the devices.

END OF SURGICAL TECHNIQUE

SURGICAL TECHNIQUE FOR INTRA ORAL DISTRACTION OF MANDIBLE

Product Details:

INTRAORAL DISTRACTORS

Intraoral Mini Distractor For Mandible

Reference	Size
511.10R	10 mm Right
511.10L	10 mm Left
511.15R	15 mm Right
511.15L	15 mm Left
511.20R	20 mm Right
511.20L	20 mm Left
511.25R	25 mm Right
511.25L	25 mm Left

Intended Use : For Distraction Osteogenesis of Mandible Body
Rotation : Clock wise two Full Turns for 1mm distraction - Screw size 2

Activator For Intraoral Distractor (Rigid)

Reference
516.001

Activator For Intraoral Distractor (Hinged)

Reference
517.001

SURGICAL TECHNIQUE FOR INTRA ORAL DISTRACTION OF MANDIBLE

INSTRUMENTS SET

INSTRUMENT SET FOR DISTRACTION OSTEOGENESIS SYSTEM

Instruments Contents:	Qty
Schanz Screws - For Micromotor 2.35mm x 3"	10 Nos
Mini Screws - S.S. 2mm x 8, 10mm - 15 each	30 Nos
Self Holding Screw Driver 2mm	01 No
Ordinary Screw Driver 2mm	01 No
Screw / Plate Holding Forceps	01 No
S.S. Drill Bits for Micromotor 1.5mm	02 Nos
Plier	02 Nos
Intraoral Distractor for Mandible 20mm Right & Left	01 Pair
Intraoral Distractor for Vertical 3+3 Holes	01 No
Intraoral Ramus Distractor - 15mm & 20mm	02 Nos
External Mandibular Distractor - Uni Directional	01 No
External Mandible Distractor - Bi Directional	01 No
Activator For Intraoral Distractor (Fixed)	01 No
Activator For Intraoral Distractor (Hinged)	01 No
Activator for External Distractor (Box Type)	01 No
Screw Driver for External Distractor (Hexagonal)	01 No
Wrench for External Distractor	01 No
Container Box with Screw Tray	01 No

Reference
1030

SURGICAL TECHNIQUE FOR
INTRA ORAL DISTRACTION OF MANDIBLE

Instruments Certified : CE

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