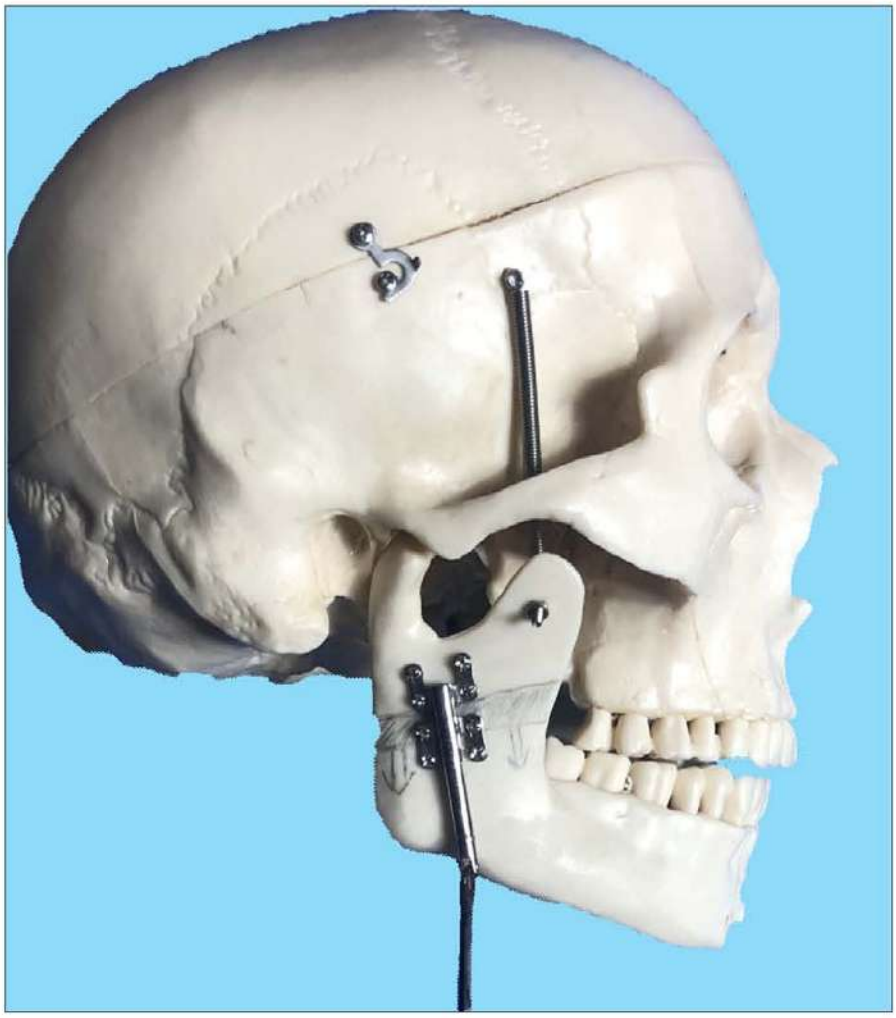
Ortho Max
Mfg. Co. Pvt. Ltd.

RAMUS DISTRACTOR FOR MANDIBLE DISTRACTION OSTEOGENESIS - SURGICAL TECHNIQUE



- **Indications**

- For mandibular bone lengthening where gradual bone distraction is required, including conditions such as congenital mandibular deficiencies or post-traumatic defects.
- **Contraindications:**

- Acute or chronic infections or necrosis of the jaw at or near the implant site (dental infections, osteomyelitis, osteoradionecrosis, bisphosphonate associated osteonecrosis 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

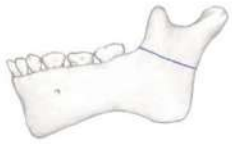
Preoperative Planning

Determine the distractor length to be used depending on the radiographic image from sizes 15mm to 25mm

RAMUS DISTRACTOR FOR MANDIBLE DISTRACTION OSTEOGENESIS - SURGICAL TECHNIQUE

1. Expose surgical site

Expose the surgical site using an intraoral or extraoral incision.

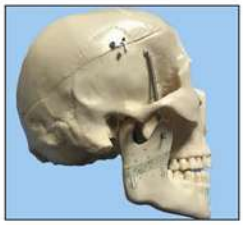


2. Plan the osteotomy site

Mark the appropriate site of the osteotomy on the bone.

3. Check approximate distractor position on the bone

Place the distractor into the intraoral cavity to fit the device to the mandible. If bending of footplate is required, do it with two pliers. First hold the base of the footplate with one plier and then bend the footplate gently with other plier to adapt to the Ramus surface.



Tent the skin to determine the percutaneous activation part position. Create the percutaneous activation port by making a stab incision through the skin, followed by blunt dissection.

Place silastic tubing over the activation end of the distractor to ease the insertion through the skin. Pass the silastic tube through the percutaneous activation port and pull the activation end of the distractor out of the intraoral cavity.

Mark the position of the distractor on the bone. The distractor should be placed parallel to the ramus.

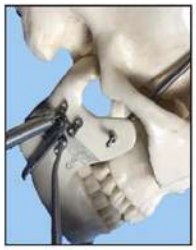
Note : When fitting the distractor, it may be helpful to place the distractor on the skin overlying the mandible to aid in device positioning relative to the soft tissue. Place the patient's head in a neutral position for an accurate evaluation of the exit part and to make sure that the device is placed in a comfortable and accessible position for the patient.

4. Perform the buccal corticotomy

Remove the distractor.
Perform the corticotomy on the buccal side of the ramus, extending into the anterior and posterior borders. This allows stability of the bone segment during placement of the distractor.

5. Attach the distractor

Reinsert the distractor on to the Ramus, passing the Activation end of the distractor back through the percutaneous port created earlier.

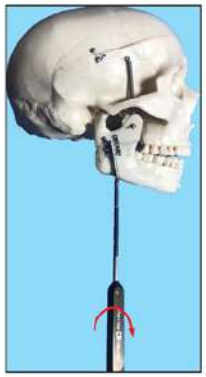


Using the transbuccal device , drill screw holes with the 1.5 mm long drill bit in the proximal and distal footplates. Insert appropriate length 2.0 mm bone screws. Drill and insert screws closest to the osteotomy first then remaining holes

Remove the Silastic tubing.

6. Complete the osteotomy and screw insertion

Complete the osteotomy on the lingual aspect of the ramus, using an osteotome, taking care to avoid the inferior alveolar nerve. Fully tighten all screws.



7. Activate the distractor

Using the rigid activator , activate the distractor approximately two full rotations (1 mm) to place tension on the suture. This will help to prevent the distractor from separating from the proximal foot during the latency stage.

Postoperative Distraction

Note: Distraction should begin no later than one week after implantation.
To distract, rotate the activator counter clock wise (in the direction of the arrow marked on the activator).
Each full rotation produces 0.5 mm of distraction.
Note: Marking on activator determines when one full rotation is completed.
After the desired length of distraction has been achieved, the new bone must be given time to consolidate. The consolidation period is complete when a cortical outline can be visualized in the regenerate on radiographs, or confirmed manually by palpation on the posterior border.

Removal of Distractor

1. Loosen the soft tissue surrounding the percutaneous activation port.
2. Remove the footplates screws using Transbuccal Device approach.In cases where there is soft tissue impingement or excessive scar tissue, an intraoral incision may be necessary to facilitate device removal.
3. Gently push the distractor toward the condyle. Once the device releases,lift the distractor away from the bone and remove it through the percutaneous activation port.

Warning:

This surgical technique is not sufficient for immediate use of the Intra oral Ramus 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 Ramus 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

RAMUS DISTRACTOR FOR MANDIBLE DISTRACTION OSTEOGENESIS - SURGICAL TECHNIQUE

Product Details

INTRAORAL DISTRACTORS

Intraoral Ramus Distractor

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

Reference	Size
502.015	15 mm
502.020	20 mm

Activator For Intraoral Distractor (Rigid)

Reference
516.001

Activator For Intraoral Distractor (Hinged)

Reference
517.001

RAMUS DISTRACTOR FOR MANDIBLE DISTRACTION OSTEOGENESIS - SURGICAL TECHNIQUE

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

Instruments Certified by Self Declaration : CE

MFG. UNIT & REGD. OFFICE
C-1-B/886/4, G.I.D.C. ESTATE
MAKARPURA,
VADODARA – 390 010 GUJ. INDIA

Tel: +91-89800 15555
+91-89800 25555

E-mail: info@orthomaxindia.net
admin@orthomaxindia.net