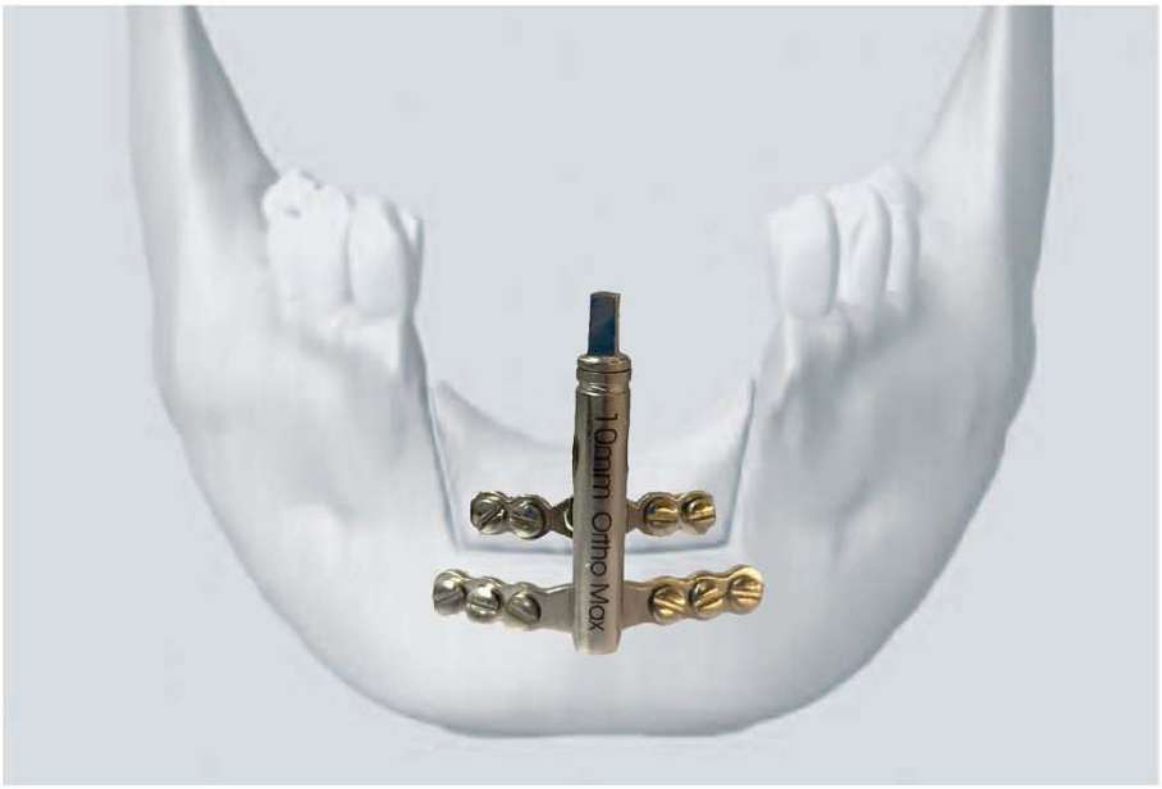

10mm Ortho Max

Distractor Characteristics:

- Double-bar design for increasedstability
- Optimizedbargeometryandplateholesinareassubjectto severestress
- Varietyofoptionsfor different distraction lengths 10mm to 25mm
- Adaptionplatesmadefromsemi-rigidstainless steel 316L
- Compactdistractionactivators –rigid and hinged alsoavailable

INDICATIONS:

The Alveolar Distractor is intended for vertical bone lengthening of the alveolar ridge in the mandible and the maxilla where gradual bone distraction is required, including deficiency in bone height as a result of:

- Trauma
- Resorption after dental extraction
- Periodontal disease
- Tumor resection
- Congenital deformity
-

CONTRAINDICATIONS

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

SURGICAL STEPS:

The following surgical technique is described using the example of an anterior mandible defect. For posterior defects in the mandible or defects in the maxilla, the corresponding surgical technique is applied.

1. Select appropriate size of the distractor

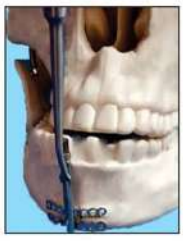
Select the appropriate distractor length (10mm, 15mm or 20mm) according to the planned height of newly generated bone.

2. Make an incision

Make a vestibular incision. Reflect the periosteum to expose the surgical site. Take care to avoid the mental nerve if the exposure involves the premolar region.

3. Place the distractor

Place the distractor to the desired location of the bone so that the footplate engages the residual bone segment and the transport plate engages the desired transport segment. Consider the following factors when placing the distractor :



- Interference with occlusion
- Adequate bone for screw placement
- Lip closure
- Soft tissue coverage

Note: Keep height of the bone segments at least 5mm to ensure secure distractor placement.

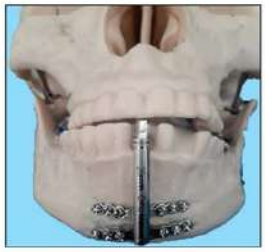
Technique tip: If desired, temporary minimal pre-activation of the distractor prior to initial placement compensates for the bone volume that will be lost by the osteotomy cut. Once the distractor is reattached after the osteotomy, counter-activation permits minimization of the osteotomy gap.

4. Adapt the base plate

Cut off any undesired footplate holes using the Vertical Plate Cutter. A minimum of two screws should be placed in the base plate for adequate stability during distraction of narrow bone segments. Wider distraction segments may require more screws in the base plate.

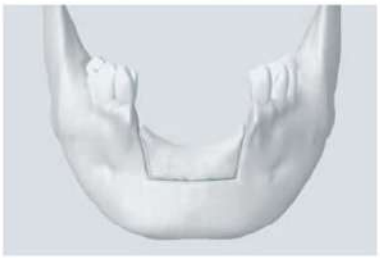
Bend the base plate to the desired shape, using the two Pliers together.
Warning: Pliers should be used to hold the distractor by its footplates only. Holding the distractor barrel with pliers may damage the distraction process.
Warning: Repeated bending can damage the footplates.

5. Mark the distractor location



Mark the distractor location prior to the osteotomy by drilling and inserting at least one screw of 2mm dia. on each side of the foot plate and the transport plate. Do not fully tighten these screws as they will be removed prior to performing the osteotomy.

6. Perform the osteotomy



Mark the osteotomy site allowing for adequate width of the transport segment. Remove the distractor by unscrewing the screws in both footplates. Perform the osteotomy and ensure the transport segment is completely mobile.

Important: Ensure adequate distance remains between the bone edges and the screw hole edges for secure distractor placement.

7. Reattach the distractor

Reattach the distractor by aligning the footplates with the previously drilled holes. Reinsert the screws in the base and transport plates. Drill and insert the remaining screws of 2mm dia. in the desired locations. Fully tighten all screws.

Note: For indications where narrow bone segments are distracted, a minimum of 2 screws must be placed in each footplate for adequate stability. Wider distraction segments may require more screws in both footplates.

Note : If the distractor was pre-activated during initial placement it can now be counter-activated to compensate for the bone volume lost by the osteotomy.

8. Check Distractor activation

Using Activator with hinge for Alveolar Distractor , activate the distractor in the clockwise direction (as marked on the instrument) to confirm the mobility of the bone segment. Verify that the desired vector is correct and does not interfere with the occlusion. After verifying device placement, return the distractor back to its original, undistracted position. Close all incisions

Note: Do not apply reverse force with activator while putting the distractor at a start point

Postoperative Protocol

1. Recommended distraction protocol:

Distraction should begin 3–5 days after implantation. To achieve lengthening, turn the activator with hinge clockwise (in the direction of the arrow marked on the instrument). Do not keep the Activator at a more than 75 degree angle. Each full rotation equals 0.5mm of distraction. A rate of 1mm of distraction per day (one full turn two times a day) is recommended to prevent premature consolidation.

2. Record progress:

Record for the distraction progress should be documented. The Patient Care Guide shall be made to help them monitor the progress of distraction every day.

Note: The patient should be advised on maintaining good oral hygiene during all phases of treatment

3. Consolidation phase:

After a satisfactory gain in alveolar height, the new bone must be given time to consolidate. A consolidation period of at least 10–12 weeks is recommended.

4. Distractor removal:

After confirmation of a bony bridge in the distraction gap during consolidation, the distractor can be removed. To remove, expose the transport and footplates through the same vestibular incision and remove all screws.

WARNING:

This surgical technique is not sufficient for immediate use of the Alveolar 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 of Alveolar Ridge 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

Product Details:

INTRAORAL DISTRACTORS

Intraoral Distractor For Alveolar - Vertical

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

Reference	Size	Bar Length
513.1022	2+2 Holes	10 mm
513.1033	3+3 Holes	10 mm
514.1522	2+2 Holes	15 mm
514.1533	3+3 Holes	15 mm
515.2022	2+2 Holes	20 mm
515.2033	3+3 Holes	20 mm

Activator For Intraoral Distractor (Rigid)

Reference
516.001

Activator For Intraoral Distractor (Hinged)

Reference
517.001

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 : CE

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