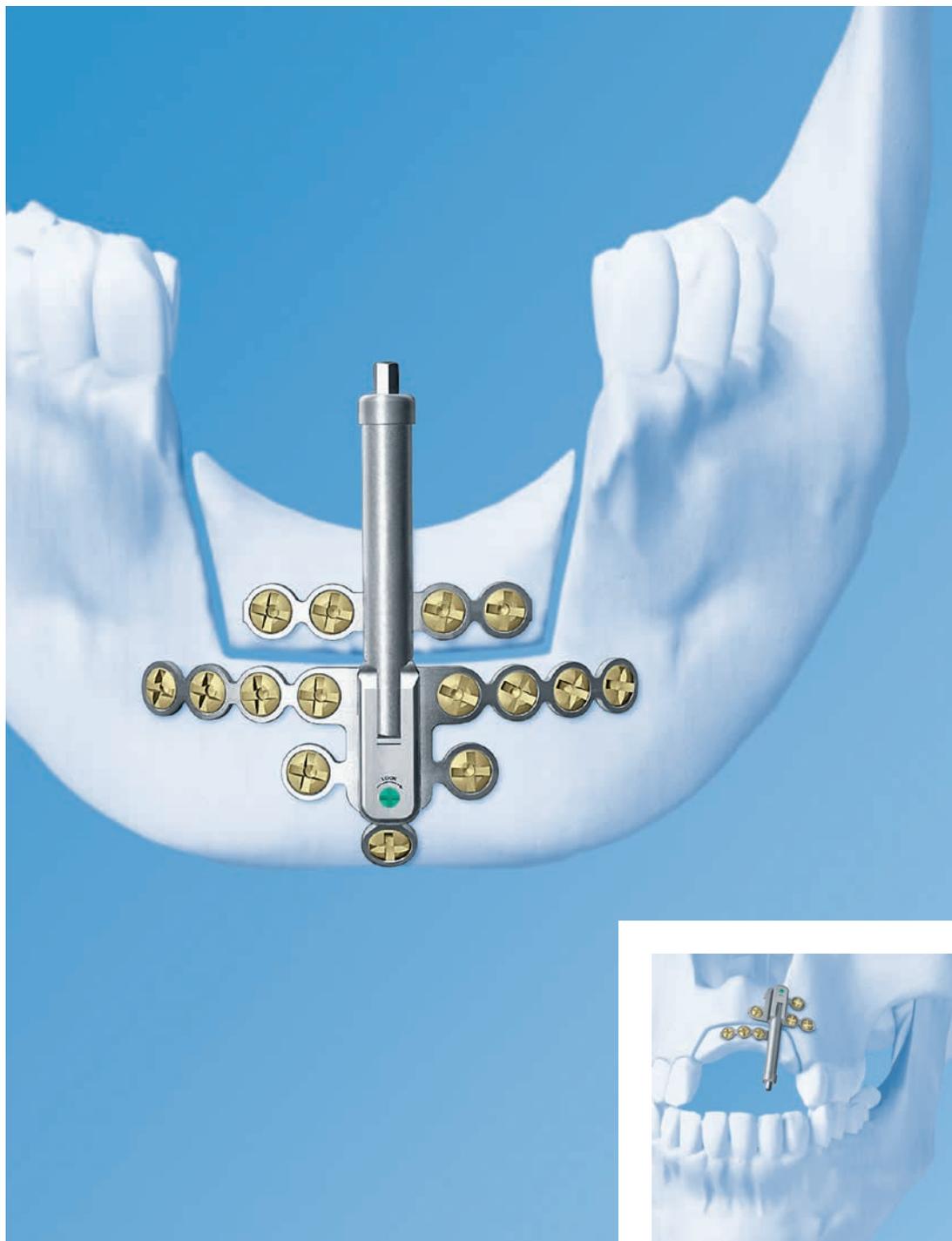


Alveolar Distractor.

Vertical bone lengthening of the alveolar ridge in the mandible and the maxilla.

Surgical Technique



This publication is not intended for distribution in the USA.

Instruments and implants approved by the AO Foundation.

 Image intensifier control

Warning

This description alone does not provide sufficient background for direct use of DePuy Synthes products. Instruction by a surgeon experienced in handling these products is highly recommended.

Processing, Reprocessing, Care and Maintenance

For general guidelines, function control and dismantling of multi-part instruments, as well as processing guidelines for implants, please contact your local sales representative or refer to:

<http://emea.depuyssynthes.com/hcp/reprocessing-care-maintenance>

For general information about reprocessing, care and maintenance of Synthes reusable devices, instrument trays and cases, as well as processing of Synthes non-sterile implants, please consult the Important Information leaflet (SE_023827) or refer to:

<http://emea.depuyssynthes.com/hcp/reprocessing-care-maintenance>

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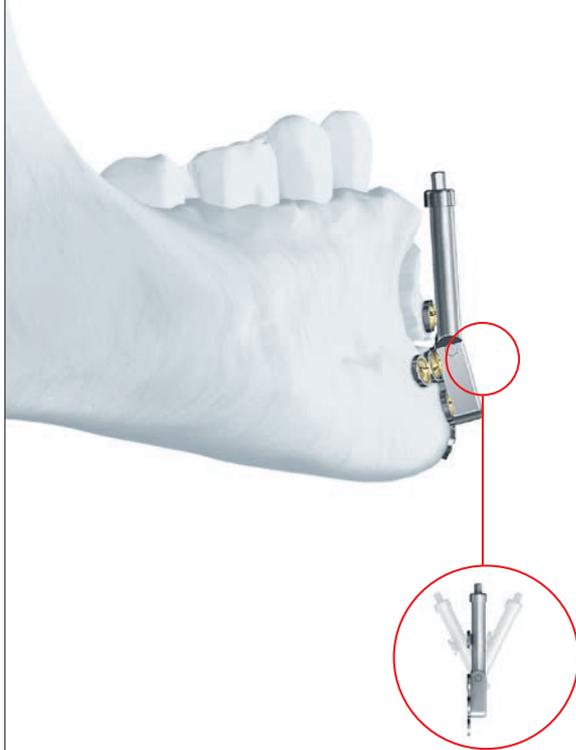
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Alveolar Distractor. Vertical bone lengthening of the alveolar ridge in the mandible and the maxilla.

Vector adjustability

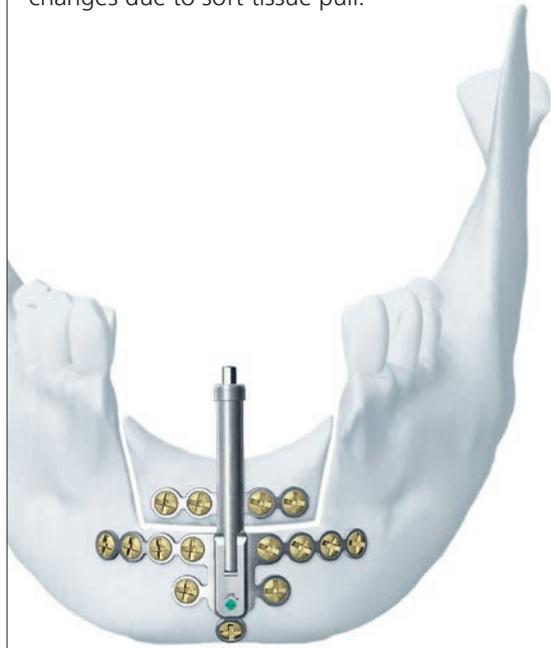
An angulation mechanism allows easy intra-operative installation of the desired distraction vector. Therefore extensive adaptations to the footplates of the device can be avoided.

The distractors can be angulated up to 48° towards the buccal and 36° towards the lingual side.



High stability

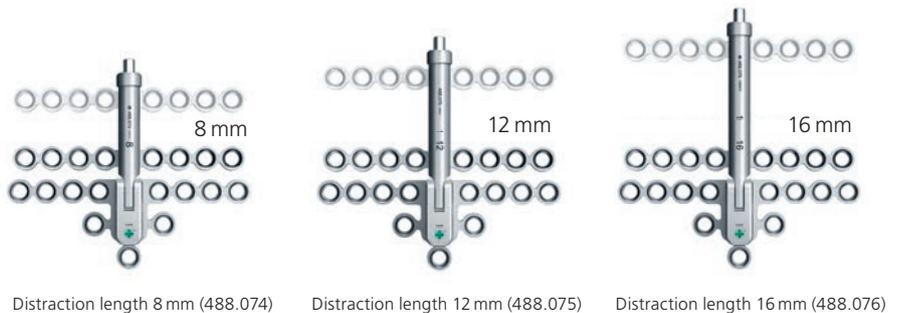
The rigid base plate, with optional screw holes next to the angulation mechanism, allows the anchorage of the distraction device in the residual bone segment. This ensures high rigidity and prevents potential unfavorable distraction vector changes due to soft tissue pull.



Three distraction lengths

Three different implants allow for 8 mm, 12 mm and 16 mm of distraction.

This choice offers the flexibility to accommodate the distractor to different anatomical conditions.



Intended Use, Indications, Contraindications, Warnings, General Adverse Events, Device Specific Adverse Events and MRI Information

Intended use

Bone stabilizer and lengthening device, where gradual bone distraction is required.

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

The Alveolar Distractor has no contraindication.

Warnings

- These devices can break during use (when subjected to excessive forces or outside the recommended surgical technique). While the surgeon must make the final decision on removal of the broken part based on associated risk in doing so, we recommend that whenever possible and practical for the individual patient, the broken part should be removed.
- Be aware that implants are not as strong as native bone. Implants subjected to substantial loads may fail.
- Medical devices containing stainless steel may elicit an allergic reaction in patients with hypersensitivity to nickel.

General Adverse Events

As with all major surgical procedures, risks, side effects and adverse events can occur. While many possible reactions may occur, some of the most common include:

Problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, neurological impairments, etc.), thrombosis, embolism, infection or injury of other critical structures including blood vessels, excessive bleeding, damage to soft tissues incl. swelling, abnormal scar formation, functional impairment of the musculoskeletal system, pain, discomfort or abnormal sensation due to the presence of the device, allergy or hyperreactions, side effects associated with hardware prominence, loosening, bending, or breakage of the device, mal-union, non-union or delayed union which may lead to breakage of the implant, reoperation.

Device Specific Adverse Events

Device specific adverse events include but are not limited to: Bone breakage or bone resorption, inflammatory response, neurological complications (e.g. sensory disturbance, paresthesia).

MRI Information

Torque, Displacement and Image Artifacts according to ASTM F2213-06, ASTM F2052-06e1 and ASTM F2119-07

Non-clinical testing of a worst case scenario in a 3 T MRI system did not reveal any relevant torque or displacement of the construct for an experimentally measured local spatial gradient of the magnetic field of **70.1 T/m**. The largest image artifact extended approximately **55 mm** from the construct when scanned using the Gradient Echo (GE). Testing was conducted on a 3 T MRI system.

Heating according to ASTM F2182-11a

Non-clinical electromagnetic and thermal simulations of a worst case scenario lead to temperature rises of **19.5 °C** (1.5 T) and **9.78 °C** (3 T) under MRI Conditions using RF Coils (whole body averaged specific absorption rate [SAR] of 2 W/kg for 15 minutes).

Precautions: The above mentioned test relies on non-clinical testing. The actual temperature rise in the patient will depend on a variety of factors beyond the SAR and time of RF application. Thus, 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 thermo regulation 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.
-

Implants

Distractors

488.074 Alveolar Distractor, distraction length 8 mm, Titanium



488.075 Alveolar Distractor, distraction length 12 mm, Titanium



488.076 Alveolar Distractor, distraction length 16 mm, Titanium



Three full rotations equal 1.05 mm of distraction (one rotation equals 0.35 mm).

The distractors can be angulated up to 48° towards the buccal and 36° towards the lingual side. For angulation, the angulation mechanism must be released by loosening the green fixation screw. After installing the desired distraction vector, the angulation mechanism has to be relocked by tightening the green fixation screw.

buccal

lingual



Screws

The distractors use 1.5 mm screws, available in the set in 4, 6 or 8 mm lengths.

Instruments

Activation Instruments

314.001

Activation Instrument for Alveolar Distractor

This Activation Instrument is marked with arrows to indicate the correct activation direction. The ergonomic shape of the head allows the patient to activate the device while looking in a mirror. The head of the instrument has a through hole to which dental floss can be tied. Fixing dental floss to the instrument allows the instrument to be secured to the operator's hand to prevent it from falling into the oral cavity.



314.003

Activation Instrument, with Joint, for Alveolar Distractor

The Activation Instrument with joint allows for easy activation due to its length and its ability to be angled. The handle is marked with arrows indicating the correct activation direction as well as the completion of half and full rotations.



Angulation Instrument

314.004

Angular Adjustment Instrument for Alveolar Distractor, with Hexagonal Coupling

This instrument is used in combination with:

311.005

Handle, small, with Hexagonal Coupling

The Angular Adjustment Instrument is used to adjust the vector of distraction. It engages the green fixation screw to unlock the angulation mechanism.



Surgical Technique

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 surgical technique is applied analogously.

1

Select the distractor

Select the distractor length (8 mm, 12 mm or 16 mm) according to the planned height of newly generated bone.

Precaution: Select a distractor with sufficient distraction length to allow for the planned procedure.

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

Fit the distractor

Fit the distractor to the bone so that the base plate engages the residual bone segment and the transport plate engages the desired transport segment.

Precaution: Consider and verify the following when placing the device:

- Interference with occlusion
- Adequate bone volume and quantity for screw placement
- Lip closure
- Soft tissue coverage
- Patient pain due to distractor interference with soft tissue

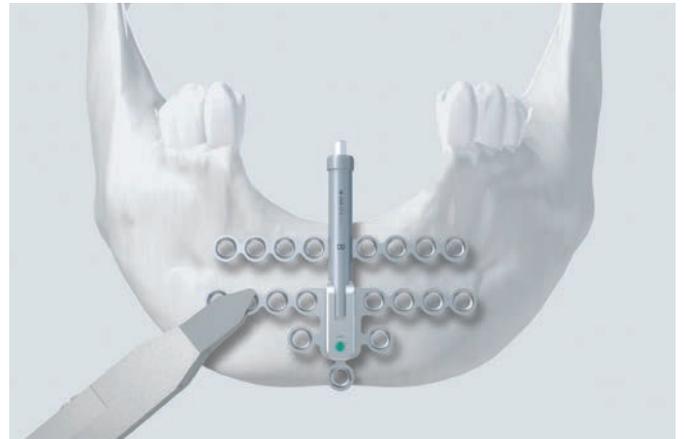
Precautions:

- Avoid nerves, tooth buds, roots or other critical structures when drilling and/or placing screws.
- Verify patient access of the barrel for proper distraction.

Note: Height of the bone segments should be at least 5 mm to ensure secure distractor placement.

Note: As the angulation mechanism continues beyond the axis of the base plate, the inferior portion of the device may protrude below the mandible. In the anterior maxilla, the bone may need to be burred down to avoid interference with the nasal spine.

Precaution: Perform a temporary 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

Required instrument

391.965	Combined Pliers for Plates 1.0 to 2.0, for Cutting and Bending
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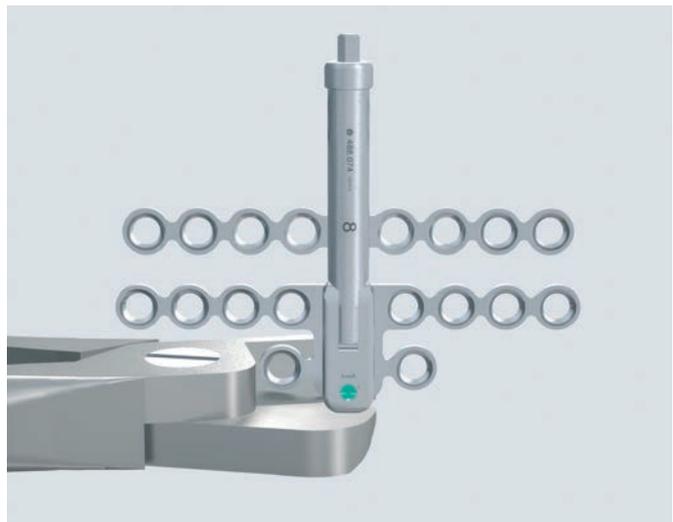
Cut off any undesired screw holes using the Combined Pliers. A minimum of two screws, one on each side, should be placed in the base plate for adequate stability during distraction of narrow bone segments. Wider distraction segments may require more screws in the base plate.

Optional instrument

391.980	Cutter for Resorbable Plates
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The screw holes directly next to the hub of the base plate can be trimmed using the Cutter for Resorbable Plates.

Precaution: Cut any sharp edges.



Required instruments

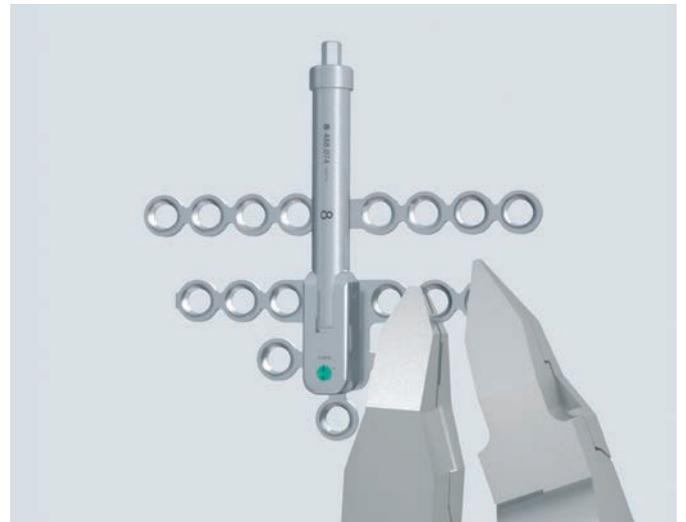
391.965 Combined Pliers for Plates 1.0 to 2.0,
for Cutting and Bending

347.964 Bending Pliers 3D, left, for Plates 1.0 to
2.0, with contour-bending function

Bend the base plate to the desired shape,
using the Combined Pliers together with
the Bending Pliers.

Warning: Pliers should be used to hold the distractor by its
footplates only. Holding the distractor barrel with pliers may
damage the distractor.

Precaution: Avoid excessive and reverse bending as it may
weaken the plate and lead to premature implant failure.



5

Determine distraction vector

Required instruments

314.004	Angular Adjustment Instrument for Alveolar Distractor, with Hexagonal Coupling
311.005	Handle, small, with Hexagonal Coupling

Attach the Angular Adjustment Instrument to the Handle. Turn the green fixation screw on the distractor body counter clockwise to release the angulation mechanism.

Adjust the barrel's angulation to achieve the proper vector of distraction.



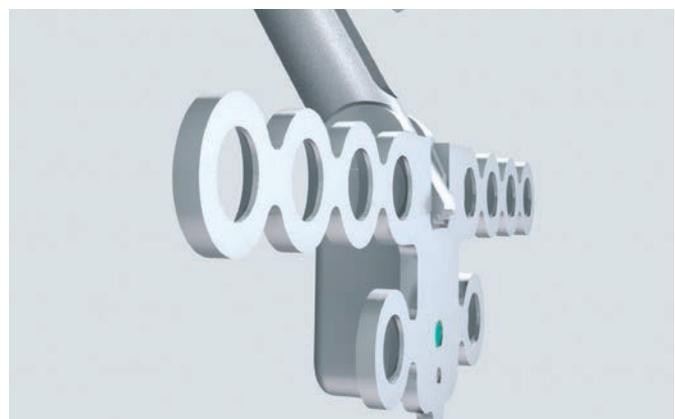
Precaution: Lock the angulation mechanism after determining the vector by firmly tightening the green fixation screw clockwise.

Note: The correct direction (clockwise) to lock the mechanism is marked with an arrow on the distractor.

Precaution: Care should be taken to not overtighten the green fixation screw as it may damage the distractor.



Note: The distractor barrel may protrude below the base plate for large buccal angles. In these instances, it may be necessary to burr down the surface of the bone in this area to allow the distractor to sit flush.



6

Adapt the transport plate

Required instruments

391.965	Combined Pliers for Plates 1.0 to 2.0, for Cutting and Bending
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Cut off any undesired screw holes using the Combined Pliers. A minimum of two screws, one on each side, should be placed in the transport plate for adequate stability during distraction of narrow bone segments. Wider distraction segments may require more screws in the transport plate.

Required instruments

391.965	Combined Pliers for Plates 1.0 to 2.0, for Cutting and Bending
347.964	Bending Pliers 3D, left, for Plates 1.0 to 2.0, with contour-bending function

Bend the transport plate to the bone using the Combined Pliers together with the Bending Pliers.

Warning: Pliers should be used to hold the distractor by its footplates only. Holding the distractor barrel with pliers may damage the distractor.

Precaution: Avoid excessive and reverse bending as it may weaken the plate and lead to premature implant failure.

Note: If the distractor is angulated, it may be necessary to make a double bend in the transport plate to bridge the distance between the distractor barrel and the bone.



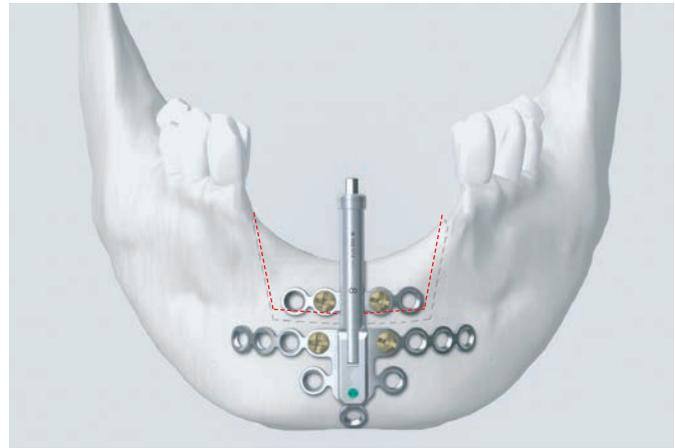
7

Mark the distractor location

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

Precautions:

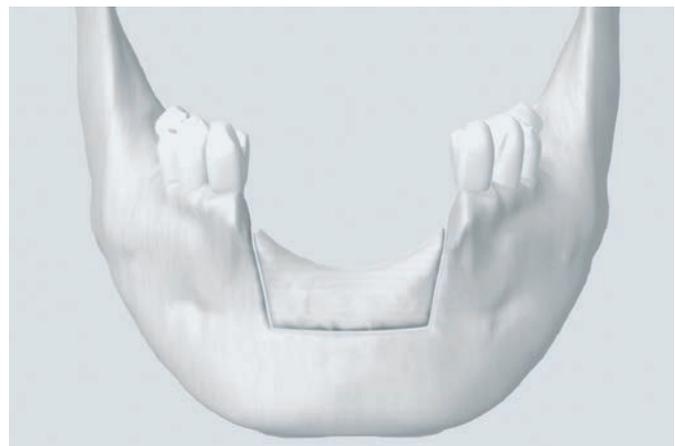
- Avoid nerves, tooth buds, roots or other critical structures when drilling and/or placing screws.
- Use the drill bit size assigned for the screws used to fix the distractor.
- Irrigate during drilling to avoid thermal damage to the bone.
- Drilling speed should never exceed 1800 rpm. Higher speeds can result in thermal necrosis of the bone and increased hole diameter and may lead to unstable fixation.



8

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.



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

Note: The transport segment must be completely mobile as the distractor is not intended to complete the osteotomy.

Note: Ensure that the transport segment is mobile on all sides required. Vertical osteotomy cuts converging toward the lingual or buccal aspect may obstruct subsequent angulation of the distractor.



X = ensure adequate distance



Vertical osteotomy cuts converging towards the lingual aspect

9

Reattach the distractor

Reattach the distractor by aligning the footplates with the previously drilled holes. Reinsert the screws in the base and transport plates, in the holes closest to the distractor body. Drill and insert the remaining screws in the desired locations. Fully tighten all screws. Use an emergency screw if the pre-drilled hole strips the bone.

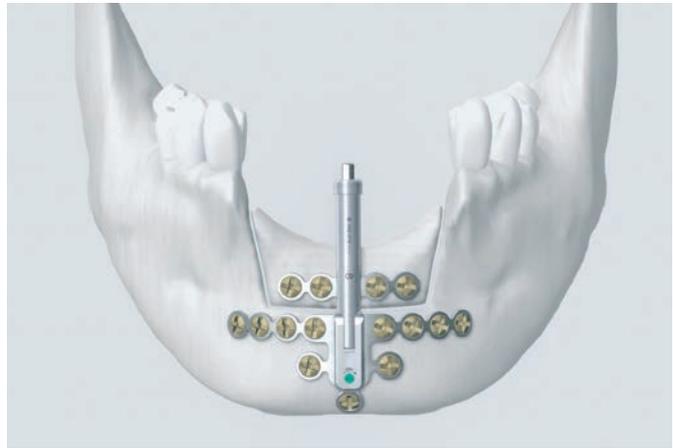
Precaution: Use the appropriate screw length to avoid distractor loosening or damage of critical/lingual structures.

Note: For indications where narrow bone segments are distracted, a minimum of two 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.

Precautions:

- Avoid nerves, tooth buds, roots or other critical structures when drilling and/or placing screws.
- Drill and insert screws closest to the osteotomy first.
- Irrigate during drilling to avoid thermal damage to the bone.
- Drilling speed should never exceed 1800 rpm. Higher speeds can result in thermal necrosis of the bone and increased hole diameter and may lead to unstable fixation.
- Do not apply too much force when tightening the screws.



10

Confirm device activation

Required instruments

314.001	Activation Instrument for Alveolar Distractor
314.003	Activation Instrument, with Joint, for Alveolar Distractor

Using one of the activation instruments, 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. Use the Angular Adjustment Instrument to unlock the angulation mechanism and readjust the vector, if necessary. After verifying device placement, return the distractor back to its original, undistracted position. Close all incisions.

Precautions:

- After implant placement is complete, discard any fragments or modified parts in an approved sharps container.
 - Irrigate and apply suction for removal of debris potentially generated during implantation.
-



Postoperative Considerations

1

Suggested distraction protocol

Distraction should begin three to five days after implantation. To achieve lengthening, turn the activation instrument clockwise (in the direction of the arrow marked on the instrument). Each full rotation equals 0.35 mm of distraction.

Precaution: A rate of 1.05 mm of distraction per day (one turn three times a day) is recommended to prevent premature consolidation.



2

Document progress

The distraction progress should be documented. The Patient Care Guide (036.000.302) helps to monitor the progress of distraction.

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 ten to twelve weeks is recommended.

4

Device removal

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

