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

Vector adjustability
An angulation mechanism allows easy intraoperative selection of the distraction vector. Extensive adaptations to the footplates of the device can be avoided.

The distractors can be angled up to 52° toward the buccal and 32° toward the lingual side.

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

Three distraction lengths
Three implant sizes allow 8 mm, 12 mm and 16 mm of distraction.

This choice offers the flexibility to fit the distractor to different anatomical conditions.
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
Planning and Approach

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 analogous.

1
Select distractor
Select the distractor length (8 mm, 12 mm, or 16 mm) according to the planned height of newly generated bone.

2
Make incision
Make a vestibular incision. Retract the periosteum to expose the surgical site. Take care to avoid the mental nerve if the exposure involves the premolar region.
Place Distractor

3
Place distractor on bone

Place the distractor on the bone so that the base plate engages the residual bone segment and the transport plate engages the desired transport segment. Consider the following factors when placing the device:
– Interference with occlusion
– Adequate bone for screw placement
– Lip closure
– Soft tissue coverage

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

The angulation mechanism extends beyond the axis of the base plate, therefore 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.

Technique tip: If desired, temporary minimal preactivation of the distractor prior to initial placement can compensate for the bone volume that will be lost by the osteotomy. Once the distractor is reattached after the osteotomy, counter-activation permits minimization of the osteotomy gap.
Adapt Base Plate

4
Adapt base plate

Instruments

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>347.964</td>
<td>Combination Bending Pliers</td>
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<tr>
<td>391.965</td>
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</tr>
<tr>
<td>391.98</td>
<td>Plate Cutter</td>
</tr>
</tbody>
</table>

Cut off any undesired screw holes using the combination bending/cutting pliers. 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.

**Note:** The screw holes directly next to the hub of the base plate can be trimmed using the plate cutter.

Bend the base plate to the desired shape, using the combination bending/cutting pliers together with the combination bending pliers.

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

Repeated bending can weaken the footplates.
5
Determine distraction vector

**Instruments**

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>311.005</td>
<td>Screwdriver Handle</td>
</tr>
<tr>
<td>314.004</td>
<td>Angular Adjustment Instrument</td>
</tr>
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</table>

Attach the angular adjustment instrument to the handle. Turn the green fixation screw on the distractor body counterclockwise to release the angulation mechanism.

Adjust the barrel’s angulation to achieve the proper distraction vector.

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.

**Warning:** Care should be taken to not overtighten the green fixation screw, as this may damage the distractor.

**Technique tip:** The distractor barrel may protrude posterior to 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.
Adapt Transport Plate

6
Adapt transport plate

Instruments

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<td>391.965</td>
<td>Combination Bending/Cutting Pliers</td>
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</table>

Cut off any undesired screw holes using the combination bending/cutting pliers. A minimum of two screws 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.

Bend the transport plate to the bone using the combination bending/cutting pliers together with the combination bending pliers.

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

Repeated bending can weaken the footplates.

Technique tip: 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 distractor location**

**Instruments**

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<tr>
<td>313.253</td>
<td>1.5 mm/2.0 mm Screwdriver Blade, PlusDrive</td>
</tr>
<tr>
<td>317.14</td>
<td>1.1 mm Drill Bit, 4 mm stop</td>
</tr>
<tr>
<td>317.16</td>
<td>1.1 mm Drill Bit, 6 mm stop</td>
</tr>
<tr>
<td>317.18</td>
<td>1.1 mm Drill Bit, 8 mm stop</td>
</tr>
<tr>
<td>317.235</td>
<td>1.1 mm Drill Bit, without stop</td>
</tr>
</tbody>
</table>

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 before performing the osteotomy.

8

**Perform osteotomy**

Mark the osteotomy site, allowing 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.
Perform Osteotomy continued

8
Perform osteotomy continued

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

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

Ensure that the transport segment is mobile on all sides. Vertical osteotomy cuts converging toward the lingual or buccal aspect may obstruct subsequent angulation of the distractor. (Distractors shown for reference only).
Reattach Distractor

9
Reattach distractor

Instruments

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<td>317.235</td>
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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 in the desired locations. Fully tighten all screws.

**Reminders:**

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.

If the distractor was preactivated during initial placement it can now be counter-activated to compensate for the bone volume lost by the osteotomy.
Confirm Activation

Confirm device activation

<table>
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<tbody>
<tr>
<td>311.005 Screwdriver Handle</td>
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<tr>
<td>314.001 Activation Instrument</td>
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<tr>
<td>314.003 Activation Instrument, with joint</td>
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<tr>
<td>314.004 Angular Adjustment Instrument</td>
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</table>

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 to its original, undistracted position.

Close all incisions.
Postoperative Considerations

1  
**Suggested distraction protocol**

**Instruments**

- 314.001  Activation Instrument
- 314.003  Activation Instrument, with joint

Distraction should begin 3–5 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. 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 helps to monitor the progress of distraction.

**Note:** The patient should be advised on maintaining good oral hygiene during all phases of treatment.
**Consolidation Phase and Device Removal**

**Consolidation phase**

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

**Device removal**

**Instruments**

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<td>1.5 mm/2.0 mm Screwdriver Blade, PlusDrive</td>
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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.
Implants

Distractors

488.074  Titanium Alveolar Distractor, with straight plate, 8 mm

488.075  Titanium Alveolar Distractor, with straight plate, 12 mm

488.076  Titanium Alveolar Distractor, with straight plate, 16 mm

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

The distractors can be angled up to 52° toward the buccal and 32° toward the lingual side. For angulation, the angulation mechanism must be released by loosening the green fixation screw. After adjusting the distraction vector, the angulation mechanism must be relocked by tightening the green fixation screw.

Screws

400.054–  1.5 mm Titanium Cortex Screws, self-drilling, with PlusDrive Recess, 4 mm–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 and 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.

Angular Adjustment Instrument

314.004 Angular Adjustment Instrument, for Alveolar Distractor, with hexagonal coupling
This instrument is used in combination with:

311.005 Screwdriver Handle, with hexagonal coupling, small
The Angular Adjustment Instrument is used to adjust the distraction vector. It engages the green fixation screw to unlock the angulation mechanism.
<table>
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<tr>
<td>313.253</td>
<td>1.5 mm/2.0 mm Screwdriver Blade, self-retaining, PlusDrive, hex coupling</td>
</tr>
<tr>
<td>314.651</td>
<td>1.5 mm Cruciform Screwdriver Blade with Spring Holding Sleeve, hex coupling</td>
</tr>
<tr>
<td>317.14-317.18</td>
<td>1.1 mm Drill Bit, Stryker J-latch, 4 mm–8 mm stop</td>
</tr>
<tr>
<td>317.235</td>
<td>1.1 mm Drill Bit, Stryker J-latch (without stop)</td>
</tr>
<tr>
<td>347.964</td>
<td>Combination Bending Pliers, for 1.0 mm–2.0 mm plates</td>
</tr>
<tr>
<td>391.965</td>
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<tr>
<td>391.98</td>
<td>Plate Cutter, for 1.0 mm–2.0 mm plates</td>
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</table>
Alveolar Distractor Set (01.500.804)

Module and Instrument Trays
685.000 Module for Alveolar Ridge Distractor
304.686 Instrument Tray, Universal
304.687 Instrument Tray Lid, Universal

Screw Length Markers, for self-drilling screws
304.104W 4 mm
304.106W 6 mm
304.108W 8 mm

Instruments
311.005 Screwdriver Handle with hex coupling, small, 2 ea.
313.253 1.5 mm/2.0 mm Screwdriver Blade, self-retaining, PlusDrive, hex coupling, 76 mm
314.001 Activation Instrument, for Alveolar Distractor, 2 ea.
314.003 Activation Instrument, with joint, for Alveolar Distractor, 2 ea.
314.004 Angular Adjustment Instrument, for Alveolar Distractor, hex coupling, 2 ea.
314.651 1.5 mm Cruciform Screwdriver Blade with Spring Holding Sleeve, hex coupling
317.14 1.1 mm Drill Bit, Stryker J-latch, 4 mm stop, 2 ea.
317.16 1.1 mm Drill Bit, Stryker J-latch, 6 mm stop, 2 ea.
317.18 1.1 mm Drill Bit, Stryker J-latch, 8 mm stop, 2 ea.
317.235 1.1 mm Drill Bit, Stryker J-latch (without stop), 2 ea.
347.964 Combination Bending Pliers, for 1.0 mm–2.0 mm plates, 2 ea.
391.965 Combination Bending/Cutting Pliers, for 1.0 mm–2.0 mm plates
391.98 Plate Cutter, for 1.0 mm–2.0 mm plates

Note: For additional information, please refer to package insert.

For detailed cleaning and sterilization instructions, please refer to http://www.synthes.com/sites/NA/MedicalCommunity/Pages/Cleaning_and_Sterilization.aspx or to the below listed inserts which will be included in the shipping container:
—Processing Synthes Reusable Medical Devices—Instruments, Instrument Trays and Graphic Cases—DJ1305
—Processing Non-sterile Synthes Implants—DJ1304
Distractors*

488.074  Titanium Alveolar Distractor,
        with straight plate, 8 mm, 2 ea.
488.075  Titanium Alveolar Distractor,
        with straight plate, 12 mm, 2 ea.
488.076  Titanium Alveolar Distractor,
        with straight plate, 16 mm, 2 ea.

Screws** (5/pkg.)

400.054  1.5 mm Titanium Cortex Screw, self-drilling,
         with PlusDrive recess, 4 mm, 4 pkgs.
400.056  1.5 mm Titanium Cortex Screw, self-drilling,
         with PlusDrive recess, 6 mm, 4 pkgs.
400.058  1.5 mm Titanium Cortex Screw, self-drilling,
         with PlusDrive recess, 8 mm, 4 pkgs.
400.274  2.0 mm Titanium Emergency Screw,
         with PlusDrive recess, 4 mm, 2 pkgs.
400.276  2.0 mm Titanium Emergency Screw,
         with PlusDrive recess, 6 mm, 2 pkgs.
400.278  2.0 mm Titanium Emergency Screw,
         with PlusDrive recess, 8 mm, 2 pkgs.

* Made of commercially pure titanium and titanium alloy, Ti-6Al-7Nb
**Made of titanium alloy, Ti-6Al-7Nb