Multiple Pre-, Intra-, and Postoperative Adjustments for Vertical, Horizontal, Sagittal, and Occlusal Vector Control

External Midface Distractor System

Surgical Technique
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**MR Information**
The External Midface Distractor System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration or image artifact in the MR environment. The safety of the External Midface Distractor System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.
Features and Benefits

- Preassembled components for quick device assembly in the OR
- Internal hardware options for bone-borne fixation
- Headframe design for incremental medial/lateral (ML) and anterior/posterior (AP) adjustments
- Cranial pin location options for stability of headframe placement
- Self-drilling or conical-tipped titanium cranial pins for secure bone engagement
- Multiple pre-, intra-, and postoperative adjustments for vertical, horizontal, sagittal and occlusal vector control
- Lightweight aluminum, titanium, and carbon fiber components for patient comfort
**System Components**

**Zygomatic footplate and wire fixation screw**
- The zygomatic footplate and wire fixation screw (available in several lengths) are used for fixation to either the infraorbital or supraorbital rim.
- The wire fixation screw can be removed percutaneously after the consolidation phase, avoiding the need for a second surgery.

**Maxillary footplate assembly**
- The maxillary footplate assembly consists of a maxillary footplate, a machine screw, a wire fixation clamp, a maxillary rod, and a hex socket head cap screw.
- Several maxillary rod styles are available for customization to the patient’s anatomy.
- The maxillary footplate assembly is intended for use where tooth-borne fixation with an orthodontic splint is not desirable or possible.
- A second surgical procedure under local anesthesia is required to remove the maxillary footplate assembly.

**Headframe assembly**
- The headframe assembly attaches to the cranium, parallel to the level of the Frankfort horizontal plane.*
- AP adjustments of the headframe assembly are possible by rotating the rear adjustment screw.
- ML adjustments of the headframe assembly are possible by rotating the central adjustment screw.

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* A reference plane passing through the tragus (projection of cartilage in front of the ear) and the infraorbital rim.
System Components

Cranial pins
- Positioning pins are used for initial placement of the headframe assembly on the skull.
- Conical-tipped mounting pins, available in two lengths, provide rigid fixation of the headframe assembly to the skull.
- Self-drilling mounting pins, available in two lengths, engage the skull by threading into the bone.

Vertical rod assembly
- The vertical rod assembly is available in non-angulating and angulating configurations.
- The vertical rod assembly can be placed anywhere along the central hub of the headframe to precisely align the vertical rod with the patient's midline.
- The angulating vertical rod assembly allows postoperative adjustments to achieve three-dimensional control of the mobile segment.
- A shorter length carbon fiber rod is available to customize the vertical rod assembly to the patient's anatomy.
**Horizontal rod assembly**
- The horizontal rod assembly is available with rigid clamps or swivel clamps.
- Swivel clamps allow postoperative adjustments to achieve three-dimensional control of the mobile segment.
- 40 mm distraction arms attach the horizontal rod assembly to the midface segment using stainless steel surgical wire.
- Alternative connecting bars are available to customize the horizontal rod assembly to the patient’s anatomy.

**Headframe adjustment instruments**
- Headframe adjustment instruments are available in two lengths.
- The headframe adjustment instruments can be used interchangeably based on surgeon preference.
The Synthes External Midface Distractor is intended for use in craniofacial surgery, reconstructive procedures, and selective orthognathic surgery of the maxilla. Specifically, it is intended for distraction of the maxilla utilizing a LeFort I osteotomy, the midface utilizing a LeFort II or III osteotomy, and/or the cranium utilizing a monobloc osteotomy in adult and pediatric populations where gradual bone distraction is required.

**Indications**

- LeFort III and Monobloc Advancements
- LeFort I and LeFort II Advancements
- LeFort III and Monobloc Advancements

**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.
- Medical devices containing stainless steel may elicit an allergic reaction in patients with hypersensitivity to nickel.
Distractor Construct—LeFort I and LeFort II Advancements

1. Headframe Assembly (390.100) (use 1)
2. Vertical Rod Assemblies (choose 1)
   – Non-angulating (390.102)
   – Angulating (390.104)
3. Horizontal Rod Assemblies (choose 1)
   – Rigid clamps (390.106)
   – Swivel clamps (390.108)
4. Wire Fixation Clamp (03.307.001) (use 2)
5. Titanium Maxillary Rods (choose 2)
   – 80 mm (04.307.008)
   – 80 mm, tall offset (04.307.108)
   – 110 mm (04.500.000)
   – 110 mm, tall offset (04.307.111)
6. 1.5 mm Titanium Cortex Screws, self-drilling, with PLUSDRIVE® Screw recess (use a minimum of 6, 3 per footplate)
   – 5 mm (400.055)
   – 6 mm (400.056)
   – 8 mm (400.058)
7. Titanium Machine Screw (04.500.001) (use 2)
8. Titanium Maxillary Footplate (04.307.001) (use 2)
9. Titanium Mounting Pins
   (use a minimum of 6, 3 per side)
   – 40 mm (390.122)
   – 50 mm (390.124)
   – 40 mm, self-drilling (390.126)
   – 50 mm, self-drilling (390.128)
   – Titanium Positioning Pin, 40 mm (390.120) (use 2)*
   – 2.0 mm Titanium Emergency Screws, with PLUSDRIVE Screw recess*
   – 5 mm (400.275)
   – 6 mm (400.276)
   – 8 mm (400.278)

* Not shown above
1

Make intraoral incision

Make a maxillary vestibular incision. Elevate the periosteum to expose the maxilla.

Precaution: Factors to be considered and verified:
– Occlusal plane
– Planned length of advancement (consider relapse and overcorrection)
– Lip closure
– Soft tissue coverage
– Patient pain due to distractor interference with soft tissue
– Access to the screws based on approach

2

Mark osteotomy

Mark the approximate site of the osteotomy.

3

Fit maxillary footplate assemblies

Instrument

<table>
<thead>
<tr>
<th>Instrument Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>347.964</td>
<td>Combination Bending Pliers</td>
</tr>
<tr>
<td>391.990</td>
<td>Plate and Rod Cutter</td>
</tr>
</tbody>
</table>

Build two maxillary footplate assemblies. Each assembly includes a maxillary footplate, a maxillary rod, a wire fixation clamp, a machine screw, and a socket head cap screw. (See page 7 for options.)

Contour the maxillary footplates to the maxilla using the combination bending pliers.

If necessary, remove excess screw holes using the plate and rod cutter to allow proper positioning on the maxilla.

Notes:
– The maxillary footplate is symmetrical for use on both sides of the patient’s face.
– Footplates should be placed in areas of maxillary alveoli of adequate bone thickness and above tooth buds and roots.
Contour maxillary rods

Instrument

329.18 Bending Pliers

Contour the maxillary rods using the bending pliers so that the rods protrude medial to the lip commissures and in a position that does not irritate the lips.

Notes:
- Etched lines provide a visual guide to simplify the bending process. Bend the rods along the corresponding etched line to enable them to protrude through the lips parallel to the sagittal plane.
- A torsional bend may be necessary to achieve the proper position.
- Position the wire fixation clamps on the maxillary rods so that both screwheads are facing laterally.

Precaution: Bending beyond anatomic requirements, reverse bending, and repetitive bending may increase the risk of implant breakage.
5

Mark positions of maxillary footplates

Instrument

<table>
<thead>
<tr>
<th>Code</th>
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</thead>
<tbody>
<tr>
<td>311.005</td>
<td>Screwdriver Handle with Hex Coupling, small</td>
</tr>
<tr>
<td>313.253</td>
<td>1.5 mm/2.0 mm Screwdriver Blade</td>
</tr>
</tbody>
</table>

Mark the positions of the maxillary footplates before making the osteotomy by inserting two appropriate length screws through each footplate using the 1.5 mm/2.0 mm screwdriver blade. Do not fully tighten the screws.

Precautions:
- Firmly press the screwdriver blade into the screw recess to ensure retention of the screw on the screwdriver blade.
- Take care to avoid nerves, tooth buds and roots, or other critical structures when drilling and/or placing screws.
- Use the appropriate screw length to avoid distractor loosening or damage of critical/lingual structures.
- Drill speed rate should never exceed 1,800 rpm, particularly in dense, hard bone. Higher drill speed rates can result in:
  - thermal necrosis of the bone,
  - soft tissue burns,
  - an oversized hole, which can lead to reduced pullout force, increased ease of the screws stripping in bone, suboptimal fixation, and/or the need for emergency screws.
- Avoid damaging the plate threads with the drill.
- Always irrigate during drilling to avoid thermal damage to the bone.
- Do not fully tighten the screws before making the osteotomy.
- Irrigate and apply suction for removal of debris potentially generated during implantation or removal.

6

Perform osteotomy

Unscrew and remove the maxillary footplate assemblies. Perform the LeFort I or LeFort II osteotomy and ensure that the maxilla is completely mobilized.

Precaution: The osteotomy must be complete and the bone must be mobile. The distractor is not designed or intended to break bone and/or complete the osteotomy.
Reattach maxillary footplate assemblies

Reattach the maxillary footplates to the bone using the proper length screws.

Precautions:
- Firmly press the screwdriver blade into the screw recess to ensure retention of the screw on the screwdriver blade.
- Use the appropriate screw length to avoid distractor loosening or damage of critical or lingual structures.
- At least three screws should be inserted through each footplate to ensure adequate stability.
- For maximum stability, screws should be inserted into the screw holes closest to the maxillary rod.
- To increase distractor stability in thin bone, insert screws bicortically. In addition, more screws can be used.
- Drill and insert screws closest to the osteotomy first.

Close incisions

Refer to page 19 for application of the external hardware.
Distractor Construct—LeFort III and Monobloc Advancements

1. Headframe Assembly (390.100) (use 1)
2. Vertical Rod Assemblies (choose 1)
   – Non-angulating (390.102)
   – Angulating (390.104)
3. Horizontal Rod Assemblies (choose 2)
   – Rigid clamps (390.106)
   – Swivel clamps (390.108)
4. Titanium Wire Fixation Screws, self-drilling (choose 2)
   – 15 mm (400.996)
   – 21 mm (400.997)
   – 27 mm (04.500.002)
5. Wire Fixation Clamp (03.307.001) (use 2)
6. Titanium Maxillary Rods (choose 2)
   – 80 mm (04.307.008)
   – 80 mm, tall offset (04.307.108)
   – 110 mm (04.500.000)
   – 110 mm, tall offset (04.307.111)
7. Titanium Maxillary Footplate (04.307.001) (use 2)
8. Titanium Machine Screw (04.500.001) (use 2)
9. Titanium Zygomatic Footplate (447.007) (use 2)
10. 1.5 mm Titanium Cortex Screws, self-drilling, with PLUSDRIVE Screw recess (use a minimum of 10, 3 per maxillary footplate and 2 per zygomatic footplate)
   – 5 mm (400.055)
   – 6 mm (400.056)
   – 8 mm (400.058)
11. Titanium Mounting Pins (use a minimum of 6, 3 per side)
   – 40 mm (390.122)
   – 50 mm (390.124)
   – 40 mm, self-drilling (390.126)
   – 50 mm, self-drilling (390.128)
   – Titanium Positioning Pin, 40 mm (390.120) (use 2)*
   – 2.0 mm Titanium Emergency Screws, with PLUSDRIVE Screw recess*
     – 5 mm (400.275)
     – 6 mm (400.276)
     – 8 mm (400.278)

* Not shown above
1
Make incisions
Make incisions and elevate the periosteum to expose the maxilla and the midface.

Precaution: Factors to be considered and verified:
- Occlusal plane
- Planned length of advancement (consider relapse and overcorrection)
- Lip closure
- Soft tissue coverage
- Patient pain due to distractor interference with soft tissue
- Access to the screws based on approach

2
Mark osteotomy
Mark the approximate site of the osteotomy.

3
Fit maxillary footplate assemblies

Instruments

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</table>

Build two maxillary footplate assemblies. Each assembly includes a maxillary footplate, a maxillary rod, a wire fixation clamp, a machine screw, and a socket head cap screw. (See page 12 for options.)

Contour the maxillary footplates to the maxilla using the combination bending pliers.

If necessary, remove excess screw holes using the plate and rod cutter to allow proper positioning on the maxilla.

Notes:
- The maxillary footplate is symmetrical for use on both sides of the patient's face.
- Footplates should be placed in areas of maxillary alveoli of adequate bone thickness and above tooth buds and roots.

Precautions:
- Instrument tips may be sharp—handle with care.
- Take care to avoid nerves, tooth buds and roots, or other critical structures when drilling and/or placing screws.
- Consider and verify adequate bone volume and quantity for screw placement.
- Screws can loosen during the course of treatment if placed in poor quality bone.
- Footplates should be cut so that the integrity of the screw hole is not compromised.
- Bending beyond anatomic requirements, reverse bending, and repetitive bending may increase the risk of implant breakage.
- After implant placement is complete, discard any fragments or modified parts in an approved sharps container.
Contour maxillary rods

Instrument

| 329.18 | Bending Pliers |

Contour the maxillary rods using the bending pliers so that the rods protrude medial to the lip commissures and in a position that does not irritate the lips.

**Notes:**
- Etched lines provide a visual guide to simplify the bending process. Bend the rods along the corresponding etched line to enable them to protrude through the lips parallel to the sagittal plane.
- A torsional bend may be necessary to achieve the proper position.
- Position the wire fixation clamps on the maxillary rods so that both screwheads are facing laterally.

**Precaution:** Bending beyond anatomic requirements, reverse bending, and repetitive bending may increase the risk of implant breakage.

Final position of the maxillary rods
Mark positions of maxillary footplates

Instrument

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<td>1.5 mm/2.0 mm Screwdriver Blade</td>
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</table>

Mark the positions of the maxillary footplates before making the osteotomy by inserting two appropriate length screws through each footplate, using the 1.5 mm/2.0 mm screwdriver blade. Do not fully tighten the screws.

Precautions:
- Firmly press the screwdriver blade into the screw recess to ensure retention of the screw on the screwdriver blade.
- Take care to avoid nerves, tooth buds and roots, or other critical structures when drilling and/or placing screws.
- Use the appropriate screw length to avoid distractor loosening or damage of critical/lingual structures.
- Drill speed rate should never exceed 1,800 rpm, particularly in dense, hard bone. Higher drill speed rates can result in:
  - thermal necrosis of the bone,
  - soft tissue burns,
  - an oversized hole, which can lead to reduced pullout force, increased ease of the screws stripping in bone, suboptimal fixation, and/or the need for emergency screws.
- Avoid damaging the plate threads with the drill.
- Always irrigate during drilling to avoid thermal damage to the bone.
- Do not fully tighten the screws before making the osteotomy.
- Irrigate and apply suction for removal of debris potentially generated during implantation or removal.

Remove maxillary footplate assemblies

Unscrew and remove the maxillary footplate assemblies.
Perform osteotomy

Perform the LeFort III or monobloc osteotomy and ensure that the midface is completely mobilized.

**Precaution:** The osteotomy must be complete and the bone must be mobile. The distractor is not designed or intended to break bone and/or complete the osteotomy.

**Note:** The zygomatic footplates do not need to be removed to perform the LeFort III or monobloc osteotomy.

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**7**

**Fit and attach zygomatic footplates**

**Instruments**

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<tr>
<th>Item</th>
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</tr>
<tr>
<td>347.964</td>
<td>Combination Bending Pliers</td>
</tr>
</tbody>
</table>

Contour the zygomatic footplates to sit flush on the bone using the combination bending pliers. The footplates can be adapted to the infraorbital rims for LeFort III advancements or to the supraorbital rims for monobloc advancements.

**Precaution:** Bending beyond anatomic requirements, reverse bending, and repetitive bending may increase the risk of implant breakage.

Insert the proper length screws in the two lateral holes of each footplate. The center hole should remain empty at this time.

**Note:** The zygomatic footplate is symmetrical for use on both sides of the patient’s face.

**Precautions:**
- Firmly press the screwdriver blade into the screw recess to ensure retention of the screw on the screwdriver blade.
- Take care to avoid nerves, tooth buds and roots, or other critical structures when drilling and/or placing screws.
- Use the appropriate screw length to avoid distractor loosening or damage of critical/lingual structures.
- Consider and verify for adequate bone volume and quantity for screw placement.
- Screws can loosen during the course of treatment if placed in poor quality bone.

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**8**

**Perform osteotomy**

Perform the LeFort III or monobloc osteotomy and ensure that the midface is completely mobilized.

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DePuy Synthes  
External Midface Distractor System  
Surgical Technique
Reattach maxillary footplate assemblies

Reattach the maxillary footplates to the bone using the proper length screws.

**Precautions:**
- Firmly press the screwdriver blade into the screw recess to ensure retention of the screw on the screwdriver blade.
- Use the appropriate screw length to avoid distractor loosening or damage of critical or lingual structures.
- At least three screws should be inserted through each footplate to ensure adequate stability.
- For maximum stability, screws should be inserted into the screw holes closest to the maxillary rod.
- To increase distractor stability in thin bone, insert screws bicortically. In addition, more screws can be used.
- Drill and insert screws closest to the osteotomy first.

Insert wire fixation screws

**Instruments**

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<tr>
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<tbody>
<tr>
<td>314.651</td>
<td>1.5 mm Cruciform Screwdriver Blade with Spring Holding Sleeve, short, hex coupling</td>
</tr>
</tbody>
</table>

Tent the skin and insert the wire fixation screws through small stab incisions in the soft tissue.

Engage each wire fixation screw with the threaded screw hole in the center of the zygomatic footplate.

**Note:** The wire fixation screw will thread into the footplate and the bone.

Close all incisions

Refer to page 19 for application of the external hardware.
In order to apply traction to the maxilla through the dentition, a rigid intraoral splint can be created to fit the patient.

1. Fit orthodontic bands with .05 inch headgear tubes to the patient's second primary molars (under 6 years of age), or first primary molars (over 6 years of age).

2. Make an impression of the patient's maxillary arch.

3. Fabricate a splint on a working model.

4. If the patient does not have orthodontic brackets, bend the labial and palatal wires so they are in close contact with most of the maxillary teeth.
   or
If the patient has orthodontic brackets, bend the labial wire outward to clear the appliances.

5. Place the rigid splint in the patient's mouth to ensure an adequate fit and mark the labial wire medial to the lip commissure.

6. Remove the splint from the patient's mouth and solder two .06 inch rigid stainless steel orthodontic wires perpendicular to the labial wire. These vertical wires will serve as the external traction hooks.

7. Bend the ends of the vertical wire in a circle to form eyelets that will serve as the location to attach the splint to the distraction arms. Position the eyelets level with the floor of the nose or any other desired position to control rotational movements of the maxilla.

8. Cement the splint in the patient's mouth either in the clinical setting or at the time of surgery.

**Warning:** Tooth movement may affect treatment outcomes and should be carefully considered when using an intraoral splint.
1

**Insert positioning pins**

Thread one positioning pin through the mounting plate on the headframe assembly until the thread of the pin begins to show on the medial side of the headframe.

 Repeat on contralateral side.

2

**Unlock headframe assembly for adjustment**

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<tbody>
<tr>
<td>314.407</td>
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<tr>
<td>Headframe Adjustment Instrument, 72 mm</td>
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<tr>
<td>314.408</td>
</tr>
<tr>
<td>Headframe Adjustment Instrument, 209 mm</td>
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</table>

 Loosen the two headframe lock screws using a headframe adjustment instrument.
### 3
**Place headframe on skull**

**Instruments**

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<td>Headframe Adjustment Instrument, 209 mm</td>
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</tbody>
</table>

Place the headframe assembly with positioning pins in the mounting plates over the patient’s head.

Insert a headframe adjustment instrument into either side of the headframe assembly to engage the central adjustment screw. Rotate the instrument in the opposite direction of the arrow marked “OPEN” on the side of the headframe to close the headframe and positioning pins against the skull.

**Precaution:** The headframe should be placed at a position that is parallel to the Frankfort horizontal plane and at a vertical distance 2 cm above each ear.

If necessary, rotate the rear adjustment screw, using a headframe adjustment instrument, until there is a gap of approximately 2 cm between the forehead and the headframe.

**Precaution:** A gap of approximately 2 cm between the scalp and the headframe assembly is recommended on all sides for easy access for cleaning. Once this is achieved, the device is appropriately sized for the patient.

**Precaution:** Factors to be considered and verified:
- Occlusal plane
- Planned length of advancement (consider relapse and overcorrection)
- Lip closure
- Soft tissue coverage
- Patient pain due to distractor interference with soft tissue
- Access to the screws based on approach

### 4
**Tighten headframe lock screws**

Once the proper position has been attained, tighten the headframe lock screws.
Insert titanium mounting pins

Thread at least three mounting pins through each mounting plate on the headframe assembly. Insert each mounting pin until it contacts the bone, but do not fully tighten. Remove positioning pins after inserting at least two mounting pins on each side, as positioning pins are not designed for permanent fixation. Tighten the mounting pins using a headframe adjustment instrument in a symmetrical manner and at regular intervals until they are finger-tight.

Notes:
- Mounting pins can be inserted in the mounting plates in a radial or a linear pattern.
- There are multiple mounting pin types and sizes available.

Warnings:
- Mounting pins should be inserted in areas with hard cortical bone at least 4 mm thick.
- Mounting pins should be placed at least 2 cm above the ear.
- Overtightening the mounting pins or placement of pins in thin bone may cause bone fractures or dural penetration.
- At least three mounting pins should be placed in each mounting plate before tightening the pins, to ensure equal force distribution.
Attach vertical rod assembly

**Instruments**

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<td>314.408</td>
<td>Headframe Adjustment Instrument, 209 mm</td>
</tr>
</tbody>
</table>

Select either the angulating or non-angulating vertical rod assembly depending on the need for AP and/or transverse adjustments.

Use a headframe adjustment instrument to loosen the set screw on the vertical rod assembly until it is flush with the underside. Slide the vertical rod assembly along the dovetail of the central hub on the headframe assembly.

Align the vertical carbon fiber rod with the patient’s midline and fully tighten the set screw.
7

Adjust vertical rod

Raise the carbon fiber rod by loosening the appropriate set screw to provide access to the patient’s mouth for eating and drinking.

**Note:** The carbon fiber rod can be replaced with a shorter length rod for smaller patients.
Adjust vertical rod continued

For angulating vertical rod assembly
Use a headframe adjustment instrument to adjust the angulating vertical rod assembly.

AP adjustments
To make AP adjustments, unlock the A-P lock screw.

Adjust the gold-colored screw that is etched “A-P” on the top of the angulating vertical rod assembly.

The angulating vertical rod assembly can be angled 50° anteriorly and 30° posteriorly. One full rotation equals 7.2° of AP movement. Fully tighten the A-P lock screw after completing the adjustments.
Transverse adjustments
To make transverse adjustments, unlock the R-L lock screw.

Adjust the gold-colored screw that is etched “R-L” on the side of the angulating vertical rod assembly.

The device can be angled up to 30° in either direction. One full rotation equals 7.2° of transverse movement. Fully tighten the R-L lock screw after completing adjustments.
8

Attach horizontal rod assembly

Instruments

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<tr>
<td>314.408</td>
<td>Headframe Adjustment Instrument, 209 mm</td>
</tr>
</tbody>
</table>

Depending on the necessary vectors of advancement, select the horizontal rod assembly with swivel clamps or rigid clamps. Use one horizontal rod assembly for LeFort I and LeFort II procedures, or two horizontal rod assemblies for LeFort III and monobloc procedures.

**Note:** If present, remove the packaging pin from the central clamp on the horizontal rod assembly by loosening the appropriate set screw.

Loosen the appropriate set screw on the central clamp of the horizontal rod assembly and slide it onto the vertical carbon fiber rod. For LeFort I and LeFort II procedures, bring the horizontal rod assembly to the level of the maxillary footplate.

For LeFort III and monobloc procedures, bring the first horizontal rod assembly to the level of the zygomatic footplates and the second to the level of the maxillary footplates.

Once the assembly/assemblies are in the desired position(s), fully tighten the set screw(s) onto the carbon fiber rod.
Position distraction arms

Adjust each rod clamp by loosening the set screw and sliding the rod clamp along the horizontal rod.

Distraction arms can be angled on the horizontal rod assembly for superior/inferior advancements.

If necessary, the rod clamps can be removed and inverted on the horizontal rod to accommodate the patient’s anatomy.

Once the rod clamp is in the desired position, fully tighten the set screw.

Note: The horizontal rod can be replaced with different length connecting bars to accommodate patient anatomy.

For horizontal rod assembly with swivel clamps

The horizontal rod assembly with swivel clamps allows individual transverse plane adjustments of the distraction arms. Using a headframe adjustment instrument, loosen the appropriate set screw on each swivel clamp to release the vector. Adjust the angle of each distraction arm in the transverse plane. Retighten the set screw to lock the vector.
10
Perform final adjustments, if necessary

Adjust the device to ensure a comfortable fit with easy access to the distraction arms and A-P and R-L lock screws.

Cut the maxillary rods and adjust the position of the wire fixation clamps on the maxillary rods. Protective caps are available to place on the ends of the maxillary rods.

11
Attach wire

Thread prestretched 24 or 26 gauge stainless steel surgical wire through the holes in the internal hardware to the holes in the distraction arms.

**Note:** The position of each wire fixation clamp can be adjusted along the maxillary rod by using a headframe adjustment instrument.

Twist the wire until there is enough tension to stabilize the osteotomized bone.

**Precaution:** Trim any excess wire, taking care not to leave any exposed sharp edges.

**Note:** Wires are manufactured in standard sizes.
### Suggested distraction protocol

#### Instrument

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>314.406</td>
<td>Activation Instrument, 5.5 mm hex</td>
</tr>
</tbody>
</table>

It is recommended to begin active distraction three to five days after device placement. To advance, place the activation instrument over each distraction arm, taking care to engage the linear activation nut, and rotate clockwise (in the direction of the arrow marked on the instrument). Each complete rotation equals 0.5 mm of linear movement.

**Note:** A minimum of 1.0 mm of linear advancement per day (one turn twice daily) is recommended to prevent premature consolidation. In young patients, a rate of 1.5 mm to 2.0 mm per day may be considered (one turn three or four times a day).

**Note:** Distraction arms are capable of 40 mm of distraction. Advancements greater than 40 mm can be achieved by repositioning the distraction arms and shortening the surgical wires.

**Precaution:** It is important to only turn the activation instrument in the direction of the arrow marked on the handle. Turning the activation instrument in the wrong direction (opposite to the arrow) can interfere with the distraction process.

### Document progress

Distraction progress should be observed by documenting the movement of the midface at the appropriate levels. A Patient Care Guide is included with the system to help record and monitor distraction progress.
Postoperative vector adjustments

Instruments

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<td>Headframe Adjustment Instrument, 72 mm</td>
</tr>
<tr>
<td>314.408</td>
<td>Headframe Adjustment Instrument, 209 mm</td>
</tr>
</tbody>
</table>

For horizontal rod assembly

Transverse adjustments of each distraction arm may be performed at any time during the distraction phase, using a headframe adjustment instrument.

Individual vectors can be adjusted by loosening the appropriate set screw on each clamp, and repositioning the distraction arm along the horizontal rod. Retighten the set screw to lock the clamp in position.

If the horizontal rod assembly with swivel clamps was used, loosen the appropriate set screw on each clamp and adjust the angle of each distraction arm in the transverse plane. Retighten the set screw to lock the vector.
For angulating vertical rod assembly
If the angulating vertical rod assembly was used, AP and transverse adjustments may be performed at any time during the distraction phase, using a headframe adjustment instrument.

AP adjustments
To make AP adjustments, unlock the A-P lock screw.

Adjust the gold-colored screw that is etched “A-P” on the top of the angulating vertical rod assembly. The device may be angled 50° anteriorly and 30° posteriorly. One full rotation equals 7.2° of AP movement. Fully tighten the A-P lock screw after completing adjustments.
Postoperative vector adjustments continued

Transverse adjustments
To make transverse adjustments, unlock the R-L lock screw. Adjust the gold-colored screw that is etched “R-L” on the side of the angulating vertical rod assembly. The device can be angled up to 30° in either direction. One full rotation equals 7.2° of transverse movement. Fully tighten the R-L lock screw after completing adjustments.

Notes:
- It is important to tension all wires after changing the vector of advancement. This will ensure that movement of the midface is not disrupted.
- Only small incremental adjustments should be made to the vertical rod assembly, as they will result in pronounced movements of the mobile bone segment.
Postoperative Considerations

Patient care
Cranial pins may need to be tightened 24 hours postoperatively and at regular intervals to maintain headframe stability. Pin sites should be cleaned twice per day with hydrogen peroxide. A normal routine of shampooing the hair and regular scalp hygiene is recommended. It is also recommended that the patient lie on his or her back while sleeping, to prevent discomfort or disruption of the distraction process.

Notes:
- Keeping the hair short during the distraction and consolidation phases will be beneficial and enhance patient comfort.
- It is recommended that surgeons keep one headframe adjustment instrument readily accessible for postoperative adjustments.

Precautions:
- It is important to only turn the activation instrument in the direction of the arrow marked on the handle. Turning the activation instrument in the wrong direction (opposite to the arrow) can interfere with the distraction process.
- The surgeon must instruct the patient/caregiver how to activate and protect the distractor during the treatment.
- Patients should also be advised to not tamper with the distractors and to avoid activities that may interfere with treatment. It is important to instruct patients to follow the distraction protocol, keep the wound area clean during treatment and contact their surgeon immediately if they lose the activation instrument.

Warning: Patients should be advised to avoid high risk activities, as serious injury can occur if the patient falls on the device.

Emergency airway access

Instruments

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</table>

Warning:
In instances where emergency intubation is necessary, the device can be removed quickly using wire cutters and a headframe adjustment instrument.

1

Remove wires
Cut the stainless steel surgical wires which attach the distraction arms to the midface.
Emergency airway access continued

2
Detach vertical carbon fiber rod

Using a headframe adjustment instrument, loosen the appropriate set screw on the vertical rod assembly.

Detach the carbon fiber rod from the headframe assembly by pulling the rod downward.

Consolidation

After the desired advancement has been achieved, the new bone must be given time to consolidate. The consolidation period should be approximately six to eight weeks. This time period may vary in relation to the patient’s age. Adequate bone consolidation can be confirmed by manually verifying midface stability.

Note: An optional consolidation technique is to remove the entire device early in the consolidation phase and place DePuy Synthes orthognathic plates and screws over the distraction gap. At this time, special consideration can be given to the occlusion, and the maxilla or midface can be adjusted to maximize the dental interdigitation with the mandibula teeth.
Device Removal

1  **Remove wires**

Using wire cutters, cut the stainless steel wires that attach the distraction arms to the midface.

2  **Remove headframe assembly**

**Instruments**

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**Precaution:** Loosen each mounting pin individually with a headframe adjustment instrument until the headframe assembly disengages from the skull.

**Note:** If only conical-tipped mounting pins were used, it is possible to remove the headframe assembly without loosening each pin. Instead, unlock the headframe lock screws with a headframe adjustment instrument and turn the central adjustment screw in the direction marked “OPEN” until the device separates from the skull.
3

Remove intraoral/internal fixation

Instrument

<table>
<thead>
<tr>
<th>Part Number</th>
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</tr>
</thead>
<tbody>
<tr>
<td>311.005</td>
<td>Screwdriver Handle with Hex Coupling, small</td>
</tr>
<tr>
<td>313.253</td>
<td>1.5 mm/2.0 mm Screwdriver Blade, self-retaining, PlusDrive, hex coupling, 76 mm</td>
</tr>
<tr>
<td>314.651</td>
<td>1.5 mm Cruciform Screwdriver Blade with Spring Holding Sleeve</td>
</tr>
</tbody>
</table>

If the maxillary footplate assemblies were used, it will be necessary to make a maxillary vestibular incision to remove the bone screws and the footplates.

**Precaution:** To avoid implant migration, the distractor should be removed after treatment.

For LeFort III and monobloc procedures, remove the wire fixation screws using the 1.5 mm cruciform screwdriver blade with spring holding sleeve. It is not necessary to remove the zygomatic footplates.

**Precaution:** Irrigate and apply suction for removal of debris potentially generated during implantation or removal.
Screw Identification

The headframe, vertical rod, and horizontal rod assemblies contain multiple cap screws and set screws. The diagram below indicates the type of screw used in each assembly.

**Note:** Cap screws or set screws may become loose during shipping, and may need to be loosened for sterilization. Extra screws are provided in the module, in the event that replacements are needed.

- Hex Socket Head Cap Screw 390.130
- Hex Socket Set Screw, flat point 390.131
- Hex Socket Set Screw, cone point 390.132
- Hex Socket Set Screw, dog point 390.133
## Instruments

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<td>314.651</td>
<td>1.5 mm Cruciform Screwdriver Blade with Spring Holding Sleeve, short, hex coupling</td>
</tr>
<tr>
<td>317.18</td>
<td>1.1 mm Drill Bit, Stryker J-latch, with 8 mm stop, 44.5 mm</td>
</tr>
</tbody>
</table>
Instruments

329.18 Bending Pliers

347.964 Combination Bending Pliers

391.990 Plate and Rod Cutter

392.18 Protective Caps
External Midface Distractor Set (115.660)

Graphic Cases
304.754 Graphic Case for External Midface Distractor System
304.756 Implant Module

External Hardware
390.100 Headframe Assembly, 2 ea.
390.102 Vertical Rod Assembly, non-angulating
390.104 Vertical Rod Assembly, angulating
390.106 Horizontal Rod Assembly, with rigid clamps, 2 ea.
390.108 Horizontal Rod Assembly, with swivel clamps, 2 ea.

Cranial Pins
390.120 Titanium Positioning Pin, 40 mm, 4 ea.

Titanium Mounting Pins
390.122 40 mm, 8 ea.
390.124 50 mm, 10 ea.
390.126 Self-drilling, 40 mm, 8 ea.
390.128 Self-drilling, 50 mm, 10 ea.

Cap and Set Screws
390.130 Hex Socket Head Cap Screw, 5 mm, 10 ea.

Hex Socket Set Screws, 6 ea.
390.131 Flat point, 4 mm
390.132 Cone point, 5 mm
390.133 Dog point, 6 mm

Internal Hardware
03.307.001 Wire Fixation Clamp, 4 ea.

Titanium Wire Fixation Screws, self-drilling, 4 ea.
400.996 15 mm
400.997 21 mm
04.500.002 27 mm

04.307.001 Titanium Maxillary Footplate, 40 mm, 4 ea.
04.500.001 Titanium Machine Screw, 8 ea.

Titanium Maxillary Rods, 4 ea.
04.307.008 80 mm
04.500.000 110 mm
04.307.108 Tall offset, 80 mm

447.007 Titanium Zygomatic Footplate, 3 holes, 4 ea.

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

For detailed cleaning and sterilization instructions, please refer to www.synthes.com/cleaning-sterilization or sterilization instructions, if provided.
## Internal Hardware continued

<table>
<thead>
<tr>
<th>Code</th>
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</tr>
</thead>
<tbody>
<tr>
<td>400.055</td>
<td>1.5 mm Titanium Cortex Screw, self-drilling, with PLUSDRIVE Screw recess, 5/pkg., 3 pkgs. ea. 5 mm</td>
</tr>
<tr>
<td>400.056</td>
<td>6 mm</td>
</tr>
<tr>
<td>400.058</td>
<td>8 mm</td>
</tr>
<tr>
<td>400.275</td>
<td>2.0 mm Titanium Emergency Screw, with PLUSDRIVE Screw recess, 5/pkg., 1 pkg. ea. 5 mm</td>
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<tr>
<td>400.276</td>
<td>6 mm</td>
</tr>
<tr>
<td>400.278</td>
<td>8 mm</td>
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<tr>
<td>317.18</td>
<td>1.1 mm Drill Bit, Stryker J-latch, with 8 mm stop, 44.5 mm, 2 ea.</td>
</tr>
<tr>
<td>329.18</td>
<td>Bending Pliers, 2 ea.</td>
</tr>
<tr>
<td>347.964</td>
<td>Combination Bending Pliers, 2 ea.</td>
</tr>
<tr>
<td>391.990</td>
<td>Plate and Rod Cutter</td>
</tr>
<tr>
<td>392.18</td>
<td>Protective Caps, 1 pkg. of 10</td>
</tr>
<tr>
<td>304.105W</td>
<td>Screw Length Markers, for self-drilling screws, 3 ea.</td>
</tr>
<tr>
<td>304.106W</td>
<td>5 mm</td>
</tr>
<tr>
<td>304.108W</td>
<td>6 mm</td>
</tr>
<tr>
<td>304.108W</td>
<td>8 mm</td>
</tr>
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## Also Available

<table>
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<tr>
<th>Code</th>
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</tr>
</thead>
<tbody>
<tr>
<td>03.307.010</td>
<td>Carbon Fiber Rod, notched, 100 mm</td>
</tr>
<tr>
<td>03.307.105</td>
<td>Connecting Bar, 50 mm</td>
</tr>
<tr>
<td>03.307.112</td>
<td>Connecting Bar, 120 mm</td>
</tr>
<tr>
<td>04.307.111</td>
<td>Titanium Maxillary Rod, tall offset, 110 mm</td>
</tr>
</tbody>
</table>
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