External Midface Distractor System.
Multiple pre-, intra- and postoperative adjustments for vertical, horizontal, sagittal and occlusal vector control.
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**Warning**

This description alone does not provide sufficient background for direct use of the product. Instruction by a surgeon experienced in handling this product is highly recommended.

**Reprocessing, Care and Maintenance of Synthes Instruments**

For general guidelines, function control and dismantling of multi-part instruments, please refer to: www.synthes.com/reprocessing
Features and Benefits

- Preassembled components for quick device assembly in the OR
- Internal hardware options for toothborne 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 Titanium Zygomatic Foot Plate (447.007) and Titanium Wire Fixation Screw (available in 15 mm (400.996), 21 mm (400.997), and 27 mm (04.500.002) 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 an end cap with hexagonal socket.
- 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 Preassembled Headframe (390.100) attaches to the cranium, parallel to the level of the Frankfort horizontal plane.
- AP adjustments of the preassembled headframe are possible by rotating the rear adjustment screw.
- ML adjustments of the preassembled headframe are possible by rotating the central adjustment screw.

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

- Titanium Positioning Pins (390.120) are used for initial stabilization of the Headframe Assembly on the skull.
- Fixation Screws with tip (390.122, 390.124) are available in various lengths and provide rigid fixation of the Headframe Assembly to the skull.
- Self-drilling Fixation Screws with threaded tip (390.126, 390.128) are available in various lengths and engage the skull by threading into the bone.

Vertical Rod Assembly

- The Vertical Rod Assembly is available in non-angulating (390.102) and angulating (390.104) 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.
- Alternative carbon fiber rod lengths are available for customization to the patient’s anatomy.
**Horizontal Rod Assembly**

- The Horizontal Rod Assembly is available with clamps (390.106) or adjustable clamps (390.108).
- Adjustable 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.
- Different length Connecting Bars are available for customization of the Horizontal Rod Assembly to the patient’s anatomy.

**Headframe Adjustment Instruments**

- Headframe Adjustment Instruments are available in two lengths, 72 mm (314.407) and 209 mm (314.408).
- 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, distraction of the midface utilizing a LeFort II or III osteotomy, and/or distraction of the cranium utilizing a monobloc osteotomy, where gradual bone distraction is required in adult and pediatric populations.

**Indications**

LeFort I and LeFort II advancements

LeFort III and Monobloc advancements
System Overview – LeFort I and LeFort II Advancements

1 Headframe, preassembled (390.100) (use 1)
2 Vertical Rod Assemblies (choose 1)
   – Non-angulating (390.102)
   – Angulating (390.104)
3 Horizontal Rod Assemblies (choose 1)
   – With clamps (390.106)
   – With Adjustable Clamps (390.108)
4 Clamp for Wire Fixation (03.307.001) (use 2)
5 Maxillary Rods, Titanium Alloy (TAN) (choose 2)
   – 80 mm (04.307.008)
   – Large, 80 mm, with Offset (04.307.108)
   – 110 mm (04.500.000)
6 Cortex Screws PlusDrive Ø 1.5 mm, self-drilling, Titanium Alloy (TAN) (use a minimum of 6, 3 per footplate)
   – 5 mm (400.055)
   – 6 mm (400.056)
   – 8 mm (400.058)
7 Machine Screw for External Midface Distractor, Titanium Alloy (TAN) (04.500.001) (use 2)
8 Maxillary Foot Plate, length 40 mm, Titanium Alloy (TAN) (04.307.001) (use 2)
9 Fixation Screws (use a minimum of 6, 3 per side)
   – With tip 40 mm (390.122)
   – With tip 50 mm (390.124)
   – With threaded tip 40 mm, self-drilling (390.126)
   – With threaded tip 50 mm, self-drilling (390.128)
   – Positioning Pin, 40 mm (390.120) (use 2)*
   – Emergency Screws PlusDrive Ø 2.0 mm, self-tapping, Titanium Alloy (TAN)*
     – 5 mm (400.275)
     – 6 mm (400.276)
     – 8 mm (400.278)

* Not shown above
Application of Internal Hardware for LeFort I and LeFort II Procedures

1  
**Make an intraoral incision**

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

2  
**Mark the osteotomy**

Mark the approximate site of the osteotomy.

3  
**Fit the maxillary footplate assemblies**

**Instruments**

<table>
<thead>
<tr>
<th>Code</th>
<th>Instrument</th>
</tr>
</thead>
<tbody>
<tr>
<td>347.964</td>
<td>Bending Pliers 3D, left, for Plates 1.0 to 2.0, with contour-bending function</td>
</tr>
<tr>
<td>391.990</td>
<td>Cutting Pliers for Plates and Rods</td>
</tr>
</tbody>
</table>

Build two maxillary footplate assemblies. Each assembly includes a maxillary footplate, a maxillary rod, a clamp for wire fixation, a machine screw, and an end cap with hexagonal socket. (See page 3 for options.)

Contour the maxillary footplates to the maxilla using the Bending Pliers with contour-bending function.

If necessary, remove excess screw holes using the Cutting Pliers for Plates and Rods 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.
4  Contour the maxillary rods

**Instrument**

| 329.180 | Bending Pliers for Plates 2.4, with Plate Spring |

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 screw heads are facing laterally.
5
Mark the positions of the maxillary footplates

<table>
<thead>
<tr>
<th>Instrument</th>
</tr>
</thead>
<tbody>
<tr>
<td>313.253 Screwdriver Shaft PlusDrive 1.5/2.0, medium, self-holding, for Hexagonal Coupling</td>
</tr>
</tbody>
</table>

Mark the positions of the maxillary footplates prior to making the osteotomy by inserting two appropriate length screws through each footplate using the 1.5 mm/2.0 mm Screwdriver Shaft. Do not fully tighten the screws.

6
Perform the osteotomy

Unscrew and remove the maxillary footplate assemblies. Perform the LeFort I or LeFort II osteotomy and ensure that the maxilla is completely mobilized.
7
Reattach the maxillary footplate assemblies

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

Notes
– 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.

8
Close incisions

Refer to page 19 to continue with device placement.
1 Headframe, preassembled (390.100) (use 1)
2 Vertical Rod Assemblies (choose 1)
   – Non-angulating (390.102)
   – Angulating (390.104)
3 Horizontal Rod Assemblies (choose 1)
   – With clamps (390.106)
   – With Adjustable Clamps (390.108)
4 Wire Fixation Screw, self-drilling, Titanium Alloy (TAN) (choose 2)
   – 15 mm (400.996)
   – 21 mm (400.997)
   – 27 mm (04.500.002)
5 Clamp for Wire Fixation (03.307.001) (use 2)
6 Maxillary Rods, Titanium Alloy (TAN) (choose 2)
   – 80 mm (04.307.008)
   – 80 mm, with Offset (04.307.108)
   – 110 mm (04.500.000)
7 Maxillary Foot Plate, length 40 mm, Titanium Alloy (TAN) (04.307.001) (use 2)
8 Machine Screw, Titanium Alloy (TAN) (04.500.001) (use 2)
9 Zygomatic Foot Plate, 3 holes, Pure Titanium (447.007) (use 2)
10 Cortex Screws PlusDrive ⌀ 1.5 mm, self-drilling, Titanium Alloy (TAN) (use a minimum of 6, 3 per footplate)
   – 5 mm (400.055)
   – 6 mm (400.056)
   – 8 mm (400.058)
   Emergency Screws PlusDrive ⌀ 2.0 mm, self-tapping, Titanium Alloy (TAN)
   – 5 mm (400.275)
   – 6 mm (400.276)
   – 8 mm (400.278)
11 Fixation Screws (use a minimum of 6, 3 per side)
   – With tip 40 mm (390.122)
   – With tip 50 mm (390.124)
   – With threaded tip 40 mm, self-drilling (390.126)
   – With threaded tip 50 mm, self-drilling (390.128)
   – Titanium Positioning Pin, 40 mm (390.120) (use 2)*

* Not shown above
1
Make incisions

Make incisions and elevate the periosteum to expose the maxilla and the midface.

2
Mark the osteotomy

Mark the approximate site of the osteotomy.

3
Fit the maxillary footplate assemblies

<table>
<thead>
<tr>
<th>Instruments</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>347.964 Bending Pliers 3D, left,</td>
<td>Bending Pliers 3D, left, for Plates 1.0 to 2.0, with contour-bending function</td>
</tr>
<tr>
<td>391.990 Cutting Pliers for Plates</td>
<td>Cutting Pliers for Plates and Rods</td>
</tr>
<tr>
<td>and Rods</td>
<td></td>
</tr>
</tbody>
</table>

Build two maxillary footplate assemblies. Each assembly includes a maxillary footplate, a maxillary rod, a maxillary footplate, a maxillary rod, a clamp for wire fixation, a machine screw, and an end cap with hexagonal socket. (See page 3 for options.)

Contour the maxillary footplates to the maxilla using the Bending Pliers with contour-bending function.

If necessary, remove excess screw holes using the Cutting Pliers for Plates and Rods 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 the maxillary rods

Instrument

329.180  Bending Pliers for Plates 2.4, with Plate Spring

Contour the maxillary rods using the Bending Pliers so that the rods protrude medial to the 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 screw heads are facing laterally.

Final position of the maxillary rods
5
Mark the positions of the maxillary footplates

Instrument

| 313.253 | Screwdriver Shaft PlusDrive 1.5/2.0, medium, self-holding, for Hexagonal Coupling |

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

6
Remove the maxillary footplate assemblies

Unscrew and remove the maxillary footplate assemblies at this time.
7  
**Fit and attach the zygomatic footplates**

<table>
<thead>
<tr>
<th>Instruments</th>
</tr>
</thead>
<tbody>
<tr>
<td>447.007 Zygomatic Foot Plate, 3 holes, Pure Titanium</td>
</tr>
<tr>
<td>347.964 Bending Pliers 3D, left, for Plates 1.0 to 2.0, with contour-bending function</td>
</tr>
</tbody>
</table>

Contour the Zygomatic Footplates to sit flush on the bone using the Bending Pliers with contour-bending function. The footplates can be adapted to the infraorbital rims for LeFort III advancements or to the supraorbital rims for monobloc advancements.

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.

8  
**Perform the osteotomy**

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

**Note:** The zygomatic footplates do not need to be removed to perform the LeFort III or monobloc osteotomy.
9
Reattach the maxillary footplate assemblies

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

Notes
– 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.

10
Insert the wire fixation screws

Tent the skin and insert the Wire Fixation Screws (400.996, 400.997 or 04.500.002) 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.

11
Close all incisions

Refer to page 19 to continue with device placement.
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 0.05 inch (1.27 mm) headgear tubes to the patient’s second primary molars (under 6 years of age), or first primary molars 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 0.06 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.
## Device Placement

### 1

**Insert positioning pins**

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>390.120</td>
<td>Positioning Pin, length 40 mm, for External Midface Distractor</td>
</tr>
</tbody>
</table>

Thread one Positioning Pin through each mounting plate on the Headframe Assembly until the thread of each pin is just exposed on the medial sides.

### 2

**Unlock the Headframe Assembly for adjustment**

<table>
<thead>
<tr>
<th>Instruments</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>314.407</td>
<td>Headframe Adjustment Instrument, length 72 mm, for External Midface Distractor</td>
</tr>
<tr>
<td>314.408</td>
<td>Headframe Adjustment Instrument, length 209 mm, for External Midface Distractor</td>
</tr>
</tbody>
</table>

Loosen the two headframe lock screws using a Headframe Adjustment Instrument.
3

Place the headframe on the skull

Place the Headframe Assembly with positioning pins 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. 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.

Note: 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 inserting the fixation screws.

4

Tighten the headframe lock screws

Once the proper position has been attained, tighten the headframe lock screws.
5

Insert the Fixation Screws

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

Notes
− Fixation screws can be inserted in the mounting plates in a radial or a linear pattern.
− There are multiple fixation screw types and sizes available.

Warnings
− Fixation screws should be inserted in areas with hard cortical bone at least 4 mm thick.
− Overtightening the fixation screws or placement of pins in thin bone may cause bone fractures or dural penetration.
− At least three fixation screws should be placed in each mounting plate before tightening the pins, to ensure equal force distribution.

Reminder: Fixation screws should be placed at least 2 cm above the ear.
6
Attach the Vertical Rod Assembly

Select either the angulating or non-angulating Vertical Rod Assembly depending on the need for AP and/or transverse adjustments postoperatively.

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.
Adjust the 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.

1. For angulating Vertical Rod Assembly

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>390.104</td>
<td>Vertical Rod Assembly, angulating</td>
</tr>
</tbody>
</table>

Use a Headframe Adjustment Instrument to adjust the angulating Vertical Rod Assembly.
2. 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.
3. 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 the Horizontal Rod Assembly

Depending on the necessary advancement vectors, select the Horizontal Rod Assembly with adjustable 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.
9

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 adjustable clamps:

The Horizontal Rod Assembly with adjustable clamps allows individual transverse plane adjustments of the distraction arms. Using a Headframe Adjustment Instrument, loosen the appropriate set screw on each adjustable 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 adjustment 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.

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

**Note:** Wires are manufactured in standard sizes.

<table>
<thead>
<tr>
<th>Imperial Standard Wire Gauge (SWG)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SWG</td>
</tr>
<tr>
<td>Diameter</td>
</tr>
</tbody>
</table>
Suggested Distraction Protocol

**Instrument**

| 314.406 | Activation Screwdriver, ø 5.5 mm, with Hexagonal |

It is recommended to begin active distraction three to five days after device placement. To advance, place the Activation Screwdriver 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).

**Technique Tip:** 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.

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**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.
Distraction Vector Adjustments

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 adjustable 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.
1. 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.
2. 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.
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 the 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.

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

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.
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.

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**Consolidation**

After the desired advancement has been achieved, the new bone must be given time to consolidate. The consolidation period should be at least 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 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 mandibular teeth.
1 Remove wires

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

2 Remove Headframe Assembly

Loosen each fixation screw individually with a Headframe Adjustment Instrument until the Headframe Assembly disengages from the skull.

**Note:** If only fixation screws with tip 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

<table>
<thead>
<tr>
<th>Instrument</th>
</tr>
</thead>
<tbody>
<tr>
<td>314.651 Screwdriver Shaft 1.5, cruciform, length 79 mm, with Holding Sleeve, with Hexagonal Coupling</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.

For LeFort III and monobloc procedures, remove the wire fixation screws using the cruciform 1.5 Screwdriver Shaft with Holding Sleeve. It is not necessary to remove the zygomatic footplates.
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 see Sterilization. Extra screws are provided in the module, in the event that replacements are needed.

1. **End Cap with hexagonal socket** 390.130
2. **Set Screw, flat, with hexagonal socket** 390.131
3. **Set Screw, with cone point, with hexagonal socket** 390.132
4. **Set Screw, with Peg, with hexagonal socket** 390.133
## Instruments

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>311.005</td>
<td>Handle, small, with Hexagonal Coupling</td>
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<td>313.253</td>
<td>Screwdriver Shaft PlusDrive 1.5/2.0, medium, self-holding, for Hexagonal Coupling</td>
</tr>
<tr>
<td>314.406</td>
<td>Activation Screwdriver, $\varnothing$ 5.5 mm, with Hexagonal</td>
</tr>
<tr>
<td>314.407</td>
<td>Headframe Adjustment Instrument, length 72 mm, for External Midface Distractor</td>
</tr>
<tr>
<td>314.408</td>
<td>Headframe Adjustment Instrument, length 209 mm, for External Midface Distractor</td>
</tr>
<tr>
<td>314.651</td>
<td>Screwdriver Shaft 1.5, cruciform, length 79 mm, with Holding Sleeve, with Hexagonal Coupling</td>
</tr>
<tr>
<td>317.180</td>
<td>Drill Bit $\varnothing$ 1.1 mm with Stop, length 44.5/8 mm, 2-flute, for J-Latch Coupling</td>
</tr>
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<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>--------</td>
<td>-------------------------------------------------------</td>
</tr>
<tr>
<td>329.180</td>
<td>Bending Pliers for Plates 2.4, with Plate Spring</td>
</tr>
<tr>
<td>347.964</td>
<td>Bending Pliers 3D, left, for Plates 1.0 to 2.0, with contour-bending function</td>
</tr>
<tr>
<td>391.990</td>
<td>Cutting Pliers for Plates and Rods</td>
</tr>
<tr>
<td>392.180</td>
<td>Protective Cap for Wires Ø 1.8 and 2.0 mm</td>
</tr>
</tbody>
</table>
### Graphic Cases

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>304.754</td>
<td>Graphic Case for External Midface Distractor</td>
</tr>
<tr>
<td>304.756</td>
<td>Module External Midface Distractor for Implants, in Graphic Case</td>
</tr>
</tbody>
</table>

### External Hardware

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>390.100</td>
<td>Headframe, preassembled, 2 ea.</td>
</tr>
<tr>
<td>390.102</td>
<td>Vertical Rod Assembly</td>
</tr>
<tr>
<td>390.104</td>
<td>Vertical Rod Assembly, angulating</td>
</tr>
<tr>
<td>390.106</td>
<td>Horizontal Rod Assembly, with clamps, 2 ea.</td>
</tr>
<tr>
<td>390.108</td>
<td>Horizontal Rod Assembly, with Adjustable Clamps, 2 ea.</td>
</tr>
</tbody>
</table>

### Cranial Pins

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>390.120</td>
<td>Positioning Pin, 40 mm, 4 ea.</td>
</tr>
<tr>
<td>390.122</td>
<td>Fixation Screw with tip, 40 mm, 8 ea.</td>
</tr>
<tr>
<td>390.124</td>
<td>Fixation Screw with tip, 50 mm, 10 ea.</td>
</tr>
<tr>
<td>390.126</td>
<td>Fixation Screw with threaded tip, self-drilling, 40 mm, 8 ea.</td>
</tr>
<tr>
<td>390.128</td>
<td>Fixation Screw with threaded tip, self-drilling, 50 mm, 10 ea.</td>
</tr>
</tbody>
</table>

### Cap and Set Screws

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>390.130</td>
<td>End Cap Ø 5.0 mm with hexagonal socket, 10 ea.</td>
</tr>
<tr>
<td>390.131</td>
<td>Set Screw, flat, with hexagonal socket, 4 mm, 6 ea.</td>
</tr>
<tr>
<td>390.132</td>
<td>Set Screw, with cone point, with hexagonal socket, 5 mm, 6 ea.</td>
</tr>
<tr>
<td>390.133</td>
<td>Set Screw, with Peg, with hexagonal socket, 6 mm, 6 ea.</td>
</tr>
</tbody>
</table>
### Internal Hardware

<table>
<thead>
<tr>
<th>Item No.</th>
<th>Description</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>03.307.001</td>
<td>Clamp for Wire Fixation, 4 ea.</td>
<td></td>
</tr>
<tr>
<td>400.996</td>
<td>Wire Fixation Screw, self-drilling, Titanium Alloy (TAN)</td>
<td>4 ea.</td>
</tr>
<tr>
<td>400.997</td>
<td>15 mm, 4 ea.</td>
<td></td>
</tr>
<tr>
<td>04.500.002</td>
<td>21 mm, 4 ea.</td>
<td></td>
</tr>
<tr>
<td>04.307.001</td>
<td>Maxillary Foot Plate, 40 mm, Titanium Alloy (TAN), 4 ea.</td>
<td></td>
</tr>
<tr>
<td>04.500.001</td>
<td>Machine Screw, Titanium Alloy (TAN), 8 ea.</td>
<td></td>
</tr>
</tbody>
</table>

### Wire Fixation Screw, self-drilling, Titanium Alloy (TAN)

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<thead>
<tr>
<th>Item No.</th>
<th>Description</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>400.996</td>
<td>15 mm, 4 ea.</td>
<td></td>
</tr>
<tr>
<td>400.997</td>
<td>21 mm, 4 ea.</td>
<td></td>
</tr>
<tr>
<td>04.500.002</td>
<td>27 mm, 4 ea.</td>
<td></td>
</tr>
<tr>
<td>04.307.001</td>
<td>Maxillary Foot Plate, 40 mm, Titanium Alloy (TAN), 4 ea.</td>
<td></td>
</tr>
<tr>
<td>04.500.001</td>
<td>Machine Screw, Titanium Alloy (TAN), 8 ea.</td>
<td></td>
</tr>
<tr>
<td>04.307.108</td>
<td>Large, 80 mm, with Offset, 4 ea.</td>
<td></td>
</tr>
</tbody>
</table>

### Maxillary Rod, Titanium Alloy (TAN)

<table>
<thead>
<tr>
<th>Item No.</th>
<th>Description</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>04.307.008</td>
<td>80 mm, 4 ea.</td>
<td></td>
</tr>
<tr>
<td>04.500.000</td>
<td>110 mm, 4 ea.</td>
<td></td>
</tr>
<tr>
<td>04.307.108</td>
<td>Large, 80 mm, with Offset, 4 ea.</td>
<td></td>
</tr>
<tr>
<td>447.007</td>
<td>Zygomatic Foot Plate, 3 holes, Pure Titanium, 4 ea.</td>
<td></td>
</tr>
</tbody>
</table>

### Cortex Screws PlusDrive Φ 1.5 mm, self-drilling, Titanium Alloy (TAN)

<table>
<thead>
<tr>
<th>Item No.</th>
<th>Description</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>400.055</td>
<td>Length 5 mm, 15 ea.</td>
<td></td>
</tr>
<tr>
<td>400.056</td>
<td>Length 6 mm, 15 ea.</td>
<td></td>
</tr>
<tr>
<td>400.058</td>
<td>Length 8 mm, 15 ea.</td>
<td></td>
</tr>
</tbody>
</table>

### Emergency Screw PlusDrive Φ 2.0 mm, self-tapping, Titanium Alloy (TAN)

<table>
<thead>
<tr>
<th>Item No.</th>
<th>Description</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>400.275</td>
<td>Length 5 mm, 6 ea.</td>
<td></td>
</tr>
<tr>
<td>400.276</td>
<td>Length 6 mm, 6 ea.</td>
<td></td>
</tr>
<tr>
<td>400.278</td>
<td>Length 8 mm, 6 ea.</td>
<td></td>
</tr>
</tbody>
</table>
## Instruments

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<tbody>
<tr>
<td>314.406</td>
<td>Activation Screwdriver, $\odot$ 5.5 mm, with Hexagonal, 2 ea.</td>
</tr>
<tr>
<td>314.407</td>
<td>Headframe Adjustment Instrument, 72 mm, 2 ea.</td>
</tr>
<tr>
<td>314.408</td>
<td>Headframe Adjustment Instrument, 209 mm, 2 ea.</td>
</tr>
<tr>
<td>317.180</td>
<td>Drill Bit $\odot$ 1.1 mm with Stop, 44.5/8 mm, 2-flute, for J-Latch Coupling, 2 ea.</td>
</tr>
<tr>
<td>311.005</td>
<td>Handle, small, with Hexagonal Coupling, 2 ea.</td>
</tr>
<tr>
<td>313.253</td>
<td>Screwdriver Shaft PlusDrive 1.5/2.0, medium, self-holding, for Hexagonal Coupling, 2 ea.</td>
</tr>
<tr>
<td>314.651</td>
<td>Screwdriver Shaft 1.5, cruciform, 79 mm, with Holding Sleeve, with Hexagonal Coupling</td>
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<td>Protective Cap for Wires $\odot$ 1.8 and 2.0 mm, 1 pkg. of 10</td>
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### Length Marker, for self drilling screws

<table>
<thead>
<tr>
<th>Code</th>
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</tr>
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<tbody>
<tr>
<td>304.105W</td>
<td>White, type 5, 3 ea.</td>
</tr>
<tr>
<td>304.106W</td>
<td>White, type 6, 3 ea.</td>
</tr>
<tr>
<td>304.108W</td>
<td>White, type 8, 3 ea.</td>
</tr>
</tbody>
</table>
### Also available

<table>
<thead>
<tr>
<th>Code</th>
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</tr>
</thead>
<tbody>
<tr>
<td>03.307.010</td>
<td>Carbon Fibre Rod, with Groove, 100 mm</td>
</tr>
<tr>
<td>03.307.105</td>
<td>Connecting Rod, 50 mm</td>
</tr>
<tr>
<td>03.307.112</td>
<td>Connecting Rod, 120 mm</td>
</tr>
</tbody>
</table>