EXTERNAL MIDFACE DISTRACTOR SYSTEM

Multiple pre-, intra- and postoperative adjustments for vertical, horizontal, sagittal and occlusal vector control

Surgical Technique

AO approved by AO Technical Commission

DePuy Synthes
THE ORTHOPAEDICS COMPANY OF Johnson & Johnson

Image intensifier control

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

Processing, Reprocessing, Care and Maintenance
For general guidelines, function control and dismantling of multi-part instruments, as well as processing guidelines for implants, please contact your local sales representative or refer to:
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance
For general information about reprocessing, care and maintenance of DePuy Synthes reusable devices, instrument trays and cases, as well as processing of DePuy Synthes non-sterile implants, please consult the Important Information leaflet (SE_023827) or refer to:
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance

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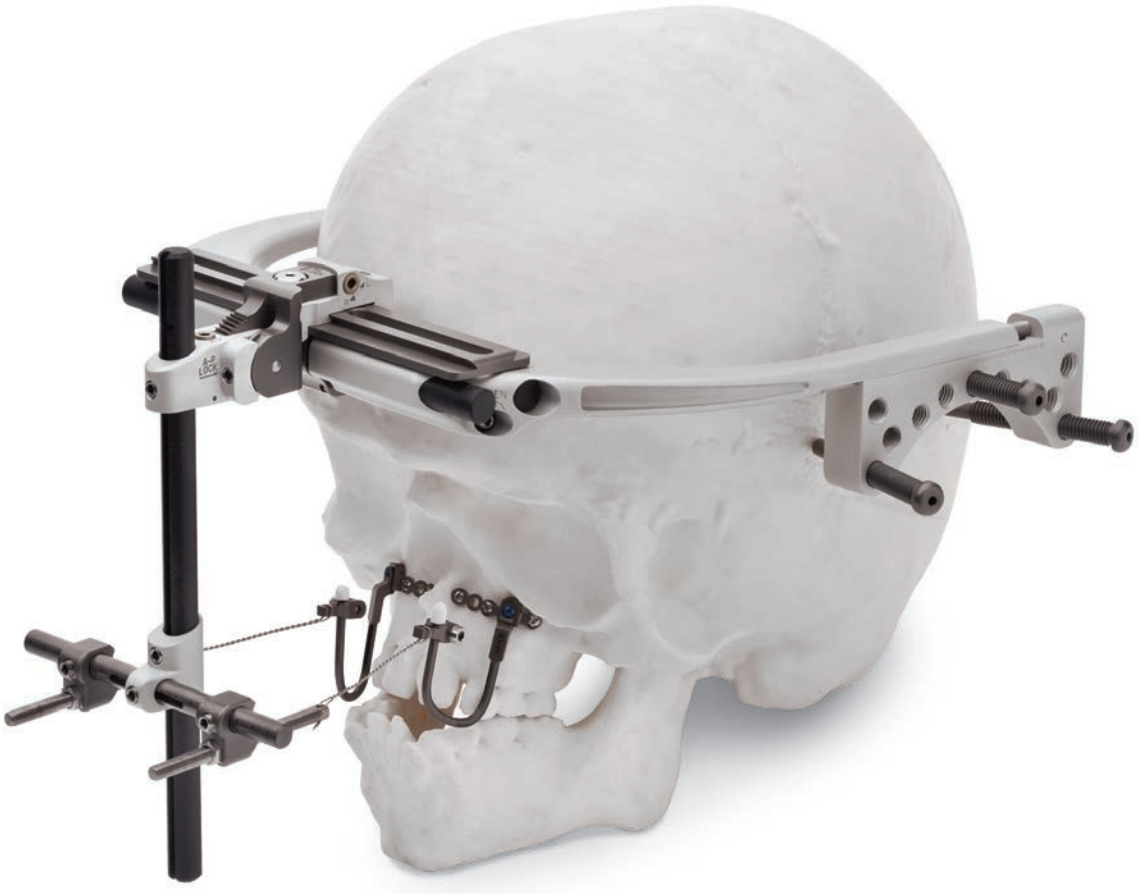
External Midface Distractor System

Overview

- Preassembled components are available
- Internal hardware options for tooth-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 bone engagement
- Multiple pre-, intra- and postoperative adjustments for vertical, horizontal, sagittal and occlusal vector control
- Available in aluminum, titanium, and carbon fiber components



The AO Principles of Fracture Management

Mission

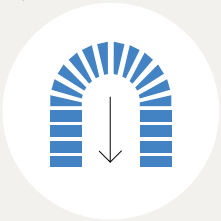
The AO's mission is promoting excellence in patient care and outcomes in trauma and musculoskeletal disorders.

AO Principles[1,2]

1.

Fracture reduction and fixation to restore anatomical relationships.

2.



Fracture fixation providing absolute or relative stability, as required by the "personality" of the fracture, the patient, and the injury.

3.

Preservation of the blood supply to soft-tissues and bone by gentle reduction techniques and careful handling.

4.

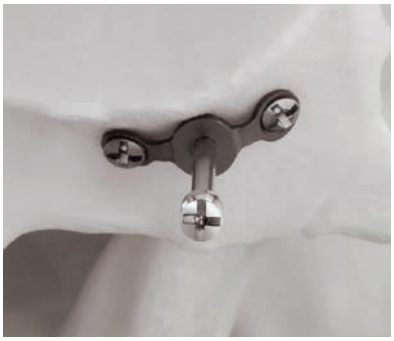
Early and safe mobilization and rehabilitation of the injured part and the patient as a whole.

[1] Müller ME, M Allgöwer, R Schneider, H Willenegger. Manual of Internal Fixation. 3rd ed. Berlin, Heidelberg, New York: Springer. 1991
[2] Buckley RE, Moran CG, Apivatthakakul T. AO Principles of Fracture Management: 3rd ed. Vol. 1: Principles, Vol. 2: Specific fractures. Thieme; 2017.

System Components

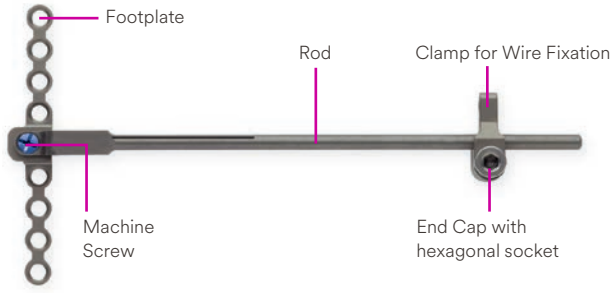
Zygomatic Footplate and Wire Fixation Screw

- 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.



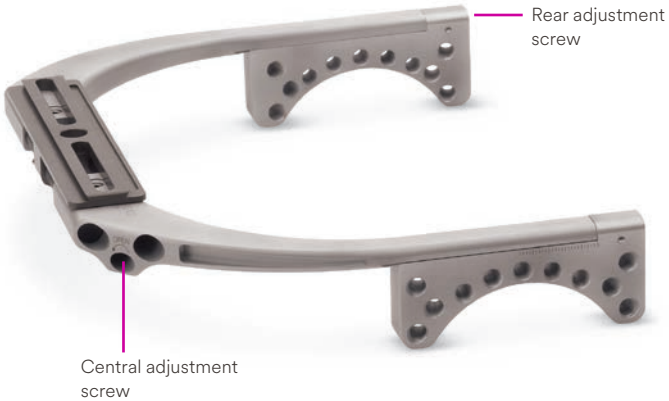
Maxillary Footplate Assembly

- The maxillary footplate assembly consists of a maxillaryfootplate, 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.
- 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 adjustements of the preassembled headframe are possible by rotating the rear adjustment screw.
- ML adjustements 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.

Positioning Pin

Fixation Screw with tip

Fixation Screw with threaded tip

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 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.

Angle adjustment

Right/Left

Anterior/Posterior

Vertical Rod Assembly options

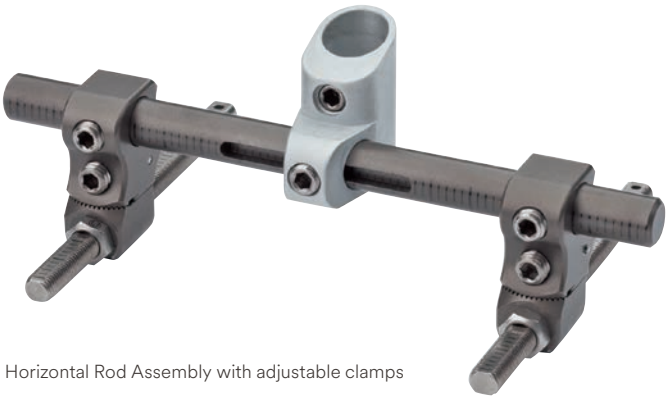
Non-angulating

Angulating

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.

Horizontal Rod Assembly with clamps



Horizontal Rod Assembly with adjustable clamps

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.

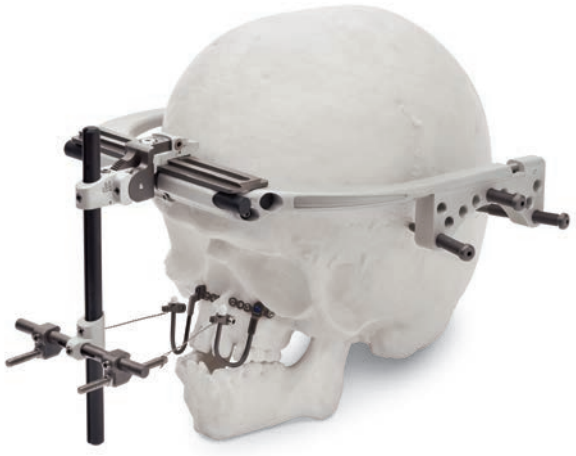
Headframe Adjustment Instrument 72 mm

Headframe Adjustment Instrument 209 mm

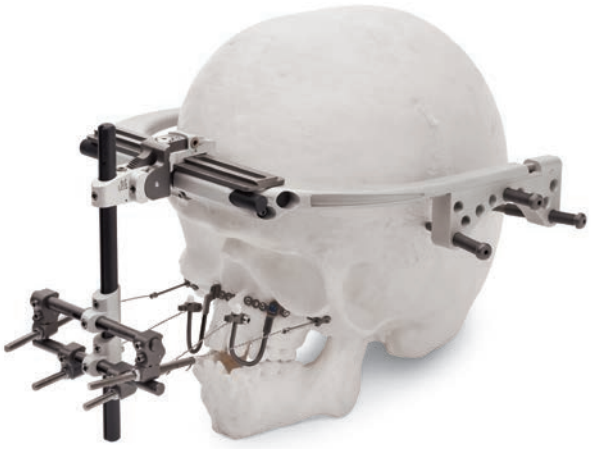
General Adverse Events, Device Specific Adverse Events and Warnings

General Adverse Events

As with all major surgical procedures, risks, side effects and adverse events can occur. While many possible reactions may occur, some of the most common include: Problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, neurological impairments, etc.), thrombosis, embolism, infection or injury of other critical structures including blood vessels, excessive bleeding, damage to soft tissues incl. swelling, abnormal scar formation, functional impairment of the musculoskeletal system, pain, discomfort or abnormal sensation due to the presence of the device, allergy or hyperreactions, side effects associated with hardware prominence, loosening, bending, or breakage of the device, mal-union, non-union or delayed union which may lead to breakage of the implant, reoperation.



LeFort I and LeFort II advancements



LeFort III and Monobloc advancements

Device Specific Adverse Events

Device specific adverse events include but are not limited to:

- Neurologic damage or CSF leak, leading to death, due to cranial pins penetration.
- Re-operation:
  - due to relapse.
  - because the distractor system breaks or disengages due to patient excessive activities.
  - because the footplate breaks after implantation surgery, during treatment due to decreased strength as a result of excessive bending of the footplate during implantation.
  - because the footplate breaks postoperatively prior to bone consolidation process is completed due to an excessive strain by the patient.
  - due to the screw migration in thin bone.
  - to correct the regenerate bone due to the distractor being positioned along incorrect vectors as a result of incorrect vector planning or difficulties transferring the treatment plan to surgical placement.
  - to replace the device due to device disturbance by traumatic patient injury not related to procedure or treatment.
  - due to infection at the distractor site.
  - due to device malfunction.
  - due to inadequate device length selected.
  - due to device backup.
  - due to loose distractor footplate.
  - due to bone fracture under load.

  - due to the pin migration into the bone.
  - due to incomplete osteotomies.
  - Non-union or fibrous union leading to re-operation (worst case) because the number of screws used with the footplates is not sufficient.
  - Premature bone consolidation requiring reoperation due to the distractor being activated in the wrong direction after being activated in the proper direction.
  - Restricted/impaired bone growth requiring further surgery because the distractor is not removed after healing is accomplished.
  - Restricted/impaired bone growth requiring further surgery, because the distractor is not removed after healing of the regenerate is accomplished.
- Additional medical treatment for:
  - Soft tissue erosion due to the distractor components pressure on the soft tissue.
  - Patient pain due to end of distractor protruding into soft tissue.
  - Nerve damage requiring subsequent medical treatment.
  - Injury of the patient due to extended OR time, because the screws/distractors cannot be removed.
  - The healing process may be altered for patients with certain metabolic diseases, with active infection or who are immune compromised.
  - Cellulitis.
  - Discomfort of the patient due to long treatment duration.
  - Scar requiring revision.
  - Pain at bony generate site.
  - Cyst caused by pins.
  - Parotid gland injury.
  - Infection at the pins site.
  - Wound dehiscence.
  - Treatment termination due to the patient incompliance.
  - Mild anterior open bite.
  - Dietary problems, weight loss.

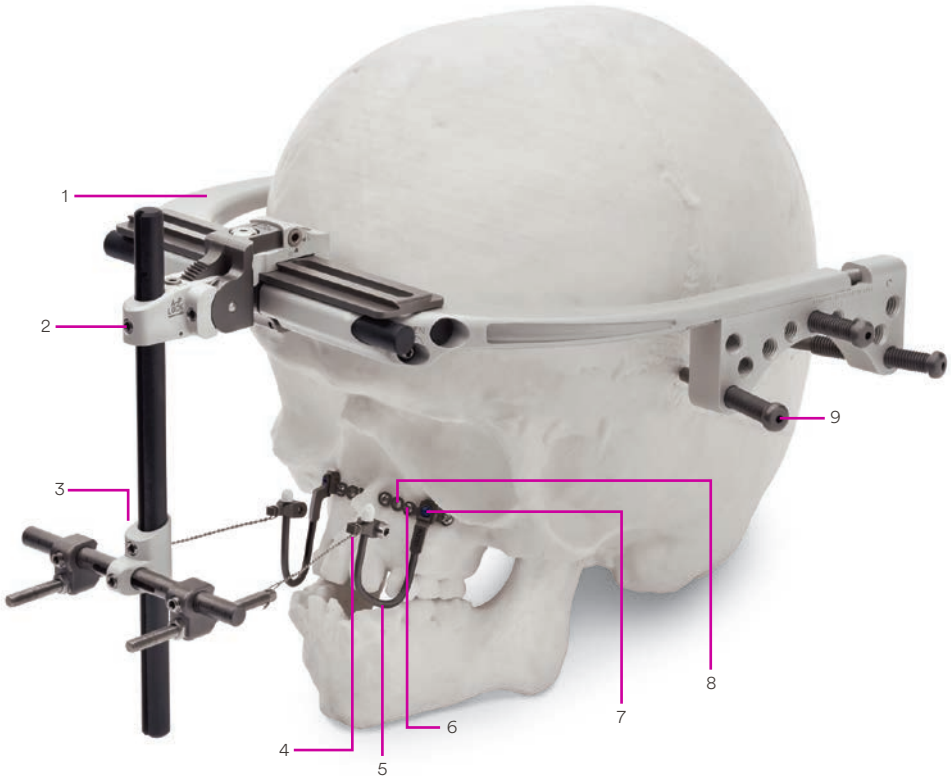
▲ WARNINGS:

- 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.

Intended Use, Indications and Contraindications can be found in the corresponding system Instructions for Use.

MRI Information on Torque, Displacement, Image Artifacts and Radio-Frequency-(RF-)induced heating can be found in the corresponding System Instructions for use.

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® ∅ 1.5 mm, self-drilling, Titanium Alloy (TAN) (use a minimum of 3 per footplate)
- 5 mm (400.055)
- 6 mm (400.056)
- 8 mm (400.058)

The emergency screws are used to replace the cortex screws, if bone stripping occured during initial insertion. Emergency Screws PlusDrive ∅ 2.0 mm, self-tapping, Titanium Alloy (TAN)*
- 5 mm (400.275)
- 6 mm (400.276)
- 8 mm (400.278)

7 Machine Screw for External Midface Distractor, Titanium Alloy (TAN) (04.500.001) (use 2)
8 Maxillary Foot Plate, length 40 mm, Pure Titanium (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)*

* 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.

▲ Precaution:

Factors to be considered and verified:

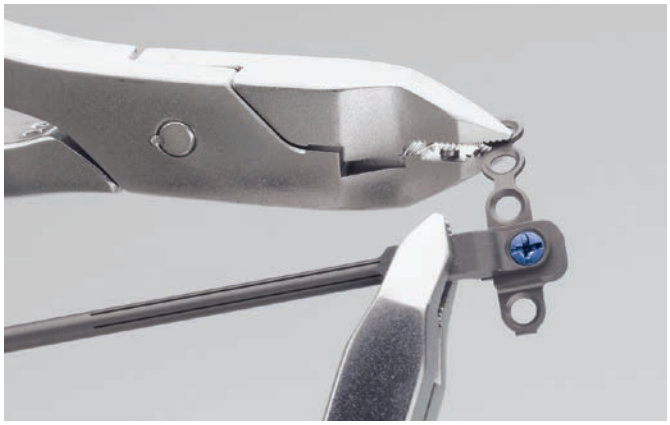
- Occlusal plane
- Planned length of advancement (consider relapse and overcorrection)
- Lip closure
- Soft tissue coverage
- Patient pain due to distractor interference with soft tissue
- Access to the screws based on approach

2. Mark the osteotomy

Mark the approximate site of the osteotomy.

3. Fit the maxillary footplate assemblies

Instruments	
347.964	Bending Pliers 3D, left, for Plates 1.0 to 2.0, with contour-bending function
391.990	Cutting Pliers for Plates and Rods



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 system components section 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.

The maxillary footplate is symmetrical for use on both sides of the patient's face.

▲ 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.

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.

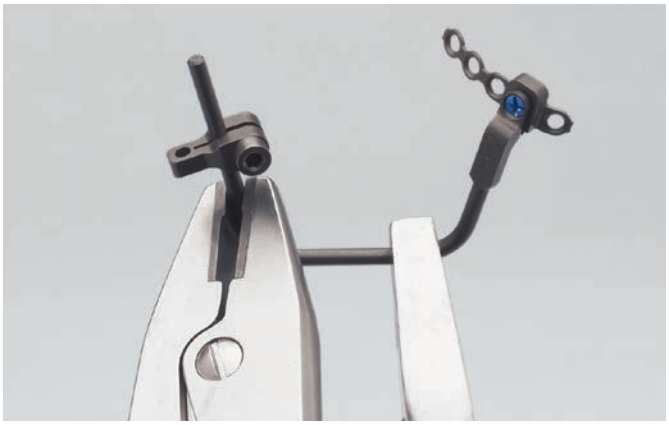
Etched lines provide a visual guide for the bending process. Bend the rods along the corresponding etched line to enable them to protrude through the lips parallel to the sagittal plane.

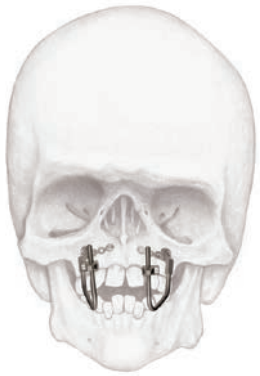
A torsional bend may be necessary to achieve the proper position.

Position the wire fixation clamps on the maxillary rods so that both screw heads are facing laterally.

▲ Precaution:

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





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 Hexagon 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 Screwdriver Shaft.

▲ 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 the osteotomy

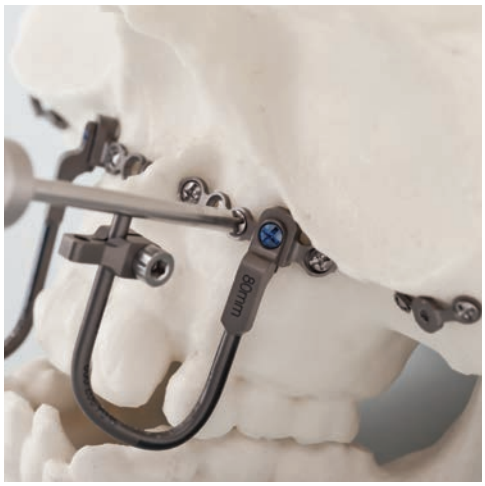
Unscrew and remove the maxillary footplate assemblies. Perform the LeFort I or LeFort II osteotomy and ensure that the maxilla is a mobilized.

▲ 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.

7. Reattach the maxillary footplate assemblies

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



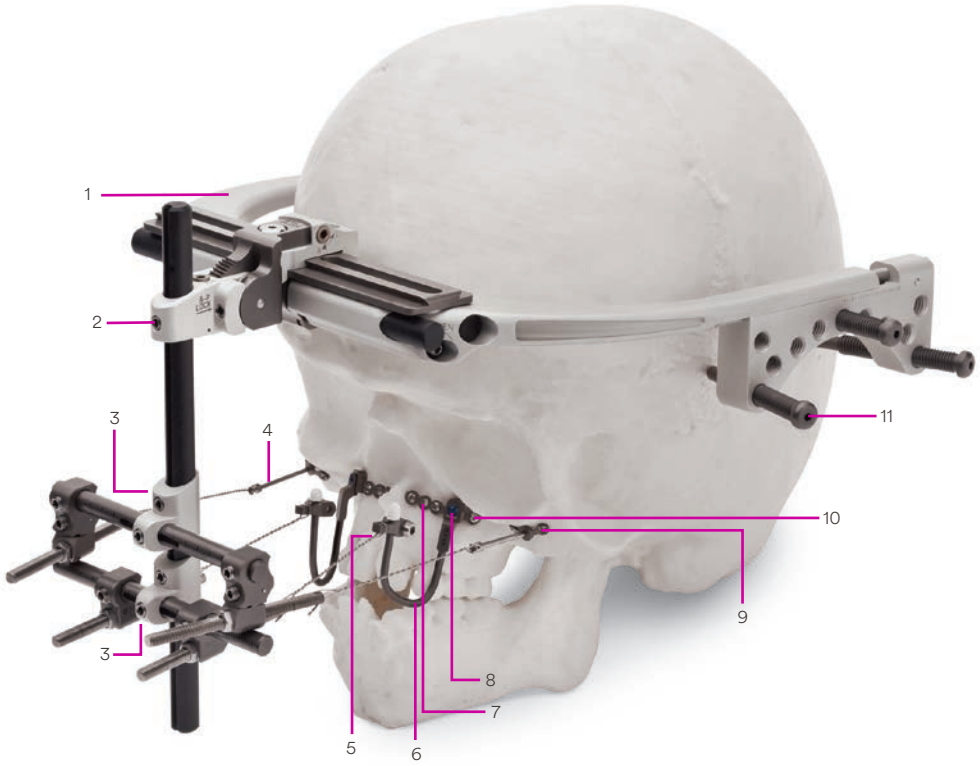
▲ Precautions:

- 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.
- Use a minimum of 3 screws per maxillary footplate.
- Screws must be placed in the holes closest to the maxillary rod for adequate device stability.
- 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.

8. Close incisions

Refer to device placement section to continue with device placement.

System Overview –
LeFort III and Monobloc 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 Wire Fixation Screw, self-drilling, Titanium Alloy (TAN) (use 2)
- 15 mm (400.996)
- 21 mm (400.997)
- 27 mm (04.500.002)

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6 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)

7 Maxillary Foot Plate, length 40 mm, Pure Titanium (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 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)
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11 Fixation Screws (use a minimum of 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

Application of Internal Hardware for LeFort III and Monobloc Procedures

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 the osteotomy

Mark the approximate site of the osteotomy.

3. Fit the maxillary footplate assemblies

Instruments	
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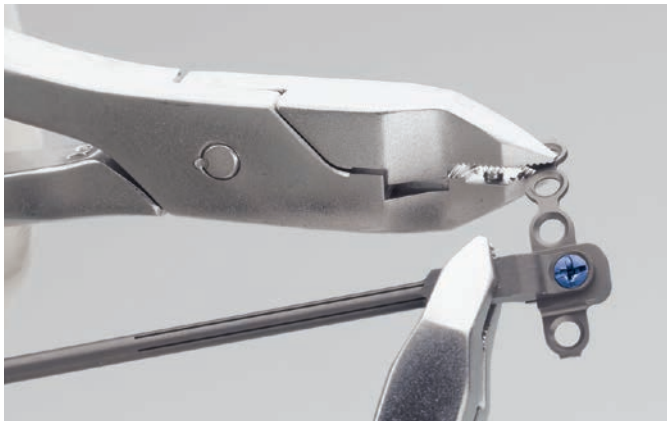
391.990	Cutting Pliers for Plates and Rods



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 system components section 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.

The maxillary footplate is symmetrical for use on both sides of the patient's face.

▲ 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.
- After implant placement is complete, discard any fragments or modified parts in an approved sharps container.
- Bending beyond anatomic requirements, reverse bending, and repetitive bending may increase the risk of implant breakage.

4. Contour the maxillary rods

Instrument	
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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.

Etched lines provide a visual guide for 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.

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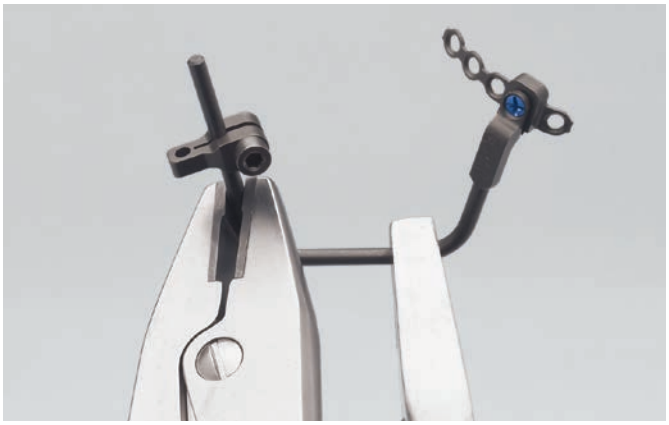

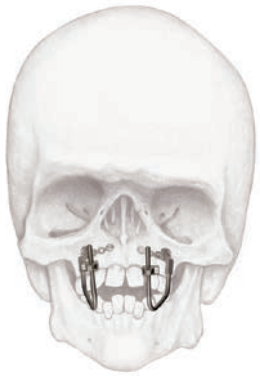

Final position of the maxillary rods

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 Screwdriver Shaft.

▲ Precautions:

- Firmly press the screwdriver blade into the screw recess to ensure retention of the screw on the screwdriver blade.
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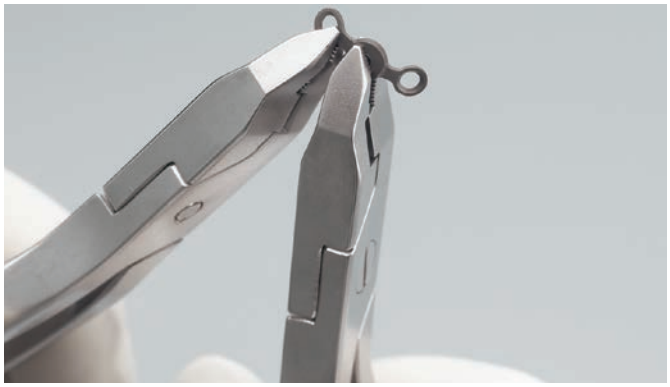
- Use the appropriate screw length to avoid distractor loosening or damage of critical/lingual structures.
- Drill speed rate should never exceed 1,800 rpm, particularly in dense, hard bone. Higher drill speed rates can result in:
  - thermal necrosis of the bone,
  - soft tissue burns,
  - an oversized 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.

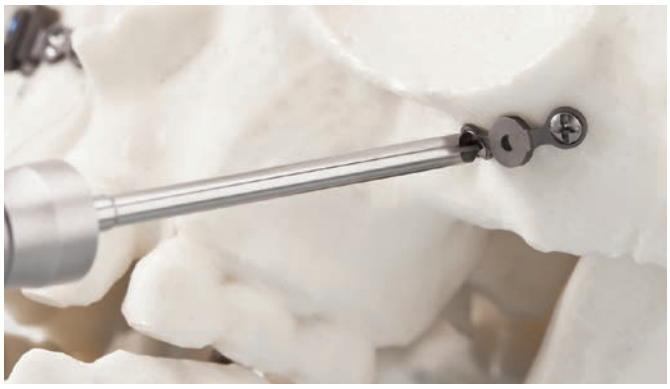
6. Remove the maxillary footplate assemblies

Unscrew and remove the maxillary footplate assemblies at this time.

7. Fit and attach the zygomatic footplates

Instruments	
447.007	Zygomatic Foot Plate, 3 holes, Pure Titanium
347.964	Bending Pliers 3D, left, for Plates 1.0 to 2.0, with contour-bending function





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.

▲ 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.

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.

8. Perform the 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.

9. Reattach the maxillary footplate assemblies

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

▲ Precautions:

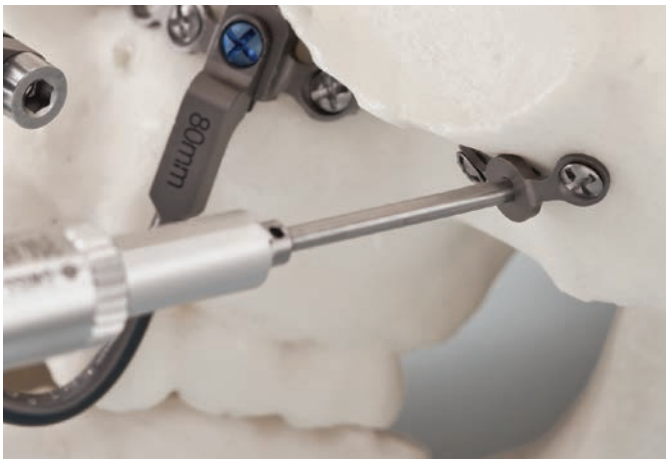
- Firmly press the screwdriver blade into the screw recess to ensure retention of the screw on the screwdriver blade.
- Use the appropriate screw length to avoid distractor loosening or damage of critical or lingual structures.
- Use a minimum of 3 screws per maxillary footplate.
- Screws must be placed in the holes closest to the maxillary rod for adequate device stability.
- 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.

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.

The Wire Fixation Screw will thread into the footplate and the bone.



11. Close all incisions

Refer to device placement section to continue with device placement.

Optional Technique for Intraoral Fixation – Intraoral Splint

In order to apply traction to the maxilla through the dentition, a rigid intraoral splint can be created to fit the patient.

Intraoral splint

1 Fit orthodontic bands with 0,05 inch (1.27 mm) head-gear 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 .06 inch rigid stainless steel orthodontic wires per-pendicular 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

Instrument	
390.120	Positioning Pin, length 40 mm, for External Midface Distractor

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

Instruments	
314.407	Headframe Adjustment Instrument, length 72 mm, for External Midface Distractor
314.408	Headframe Adjustment Instrument, length 209 mm, for External Midface Distractor

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.

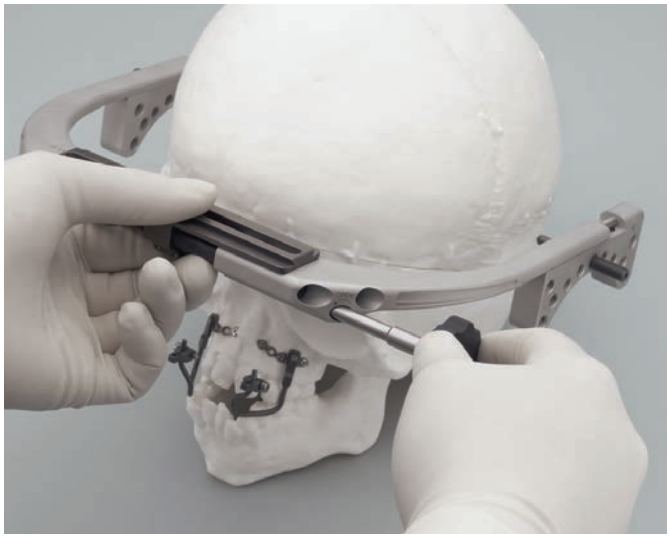
▲ Precaution:

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.

▲ Precautions:

- 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.
- 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 the headframe lock screws

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

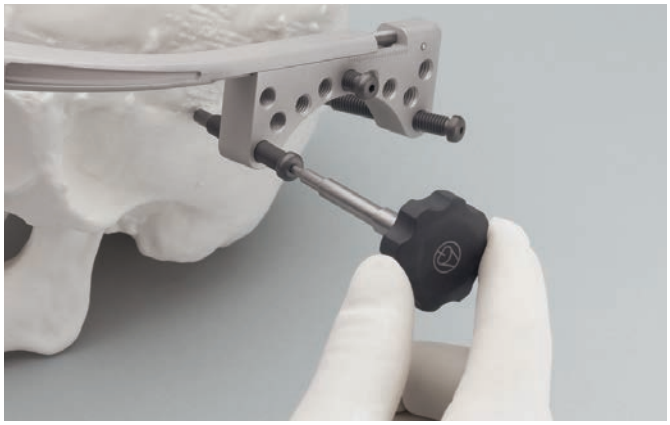
5. Insert the Fixation Screws

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.

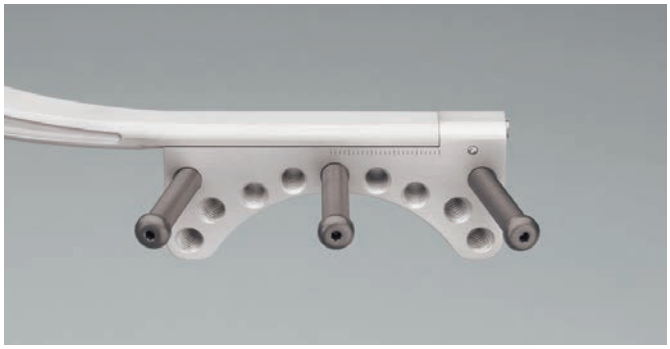
Fixation screws can be inserted in the mounting plates in a radial or a linear pattern. There are multiple fixation screw types and sizes available.

▲ 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, on both sides of the headframe, before tightening the pins, to ensure equal force distribution.
- Fixation screws should be placed at least 2 cm above the ear.



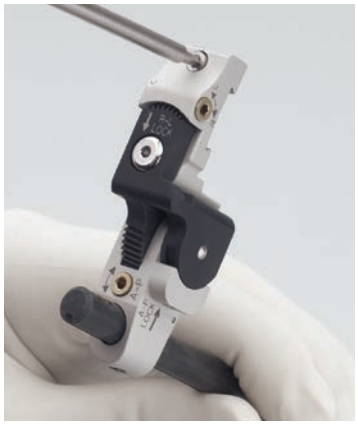
Radial pattern

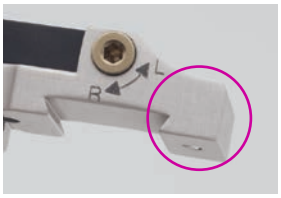


Linear pattern

6. Attach the Vertical Rod Assembly

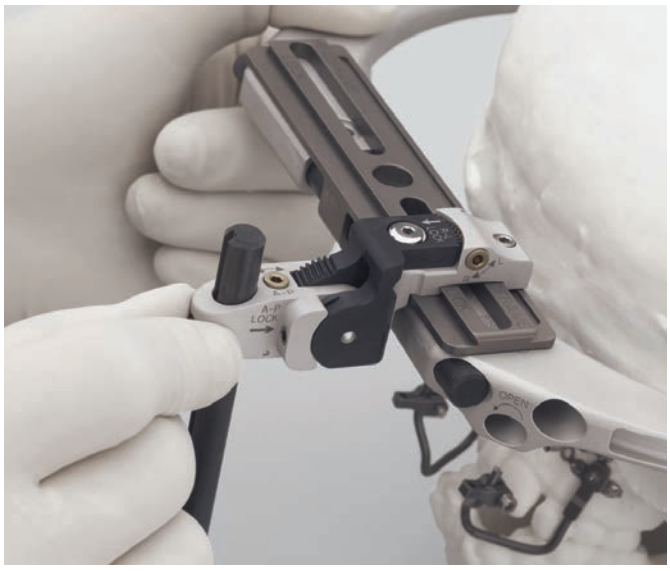
Select either the angulating or non-angulating Vertical Rod Assembly depending on the need for AP and/or transverse adjustments postoperatively.





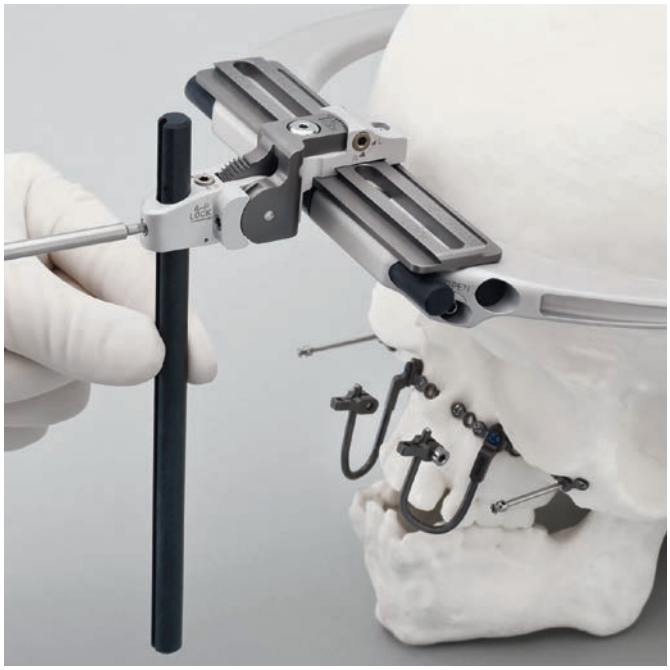
Use a Headframe Adjustment Instrument to loosen the set screw on the Vertical Rod Assembly until it is flush with the underside. Slide the Vertical Rod Assembly along the dovetail of the central hub on the Headframe Assembly.

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



7. 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

Instrument	
390.104	Vertical Rod Assembly, angulating

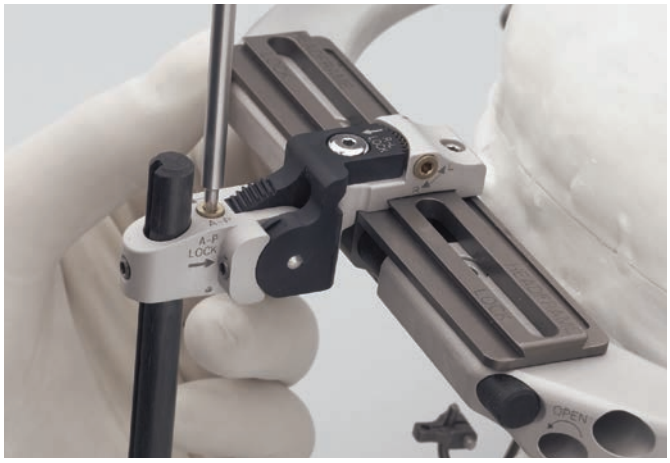
Use a Headframe Adjustment Instrument to adjust the angulating Vertical Rod Assembly.

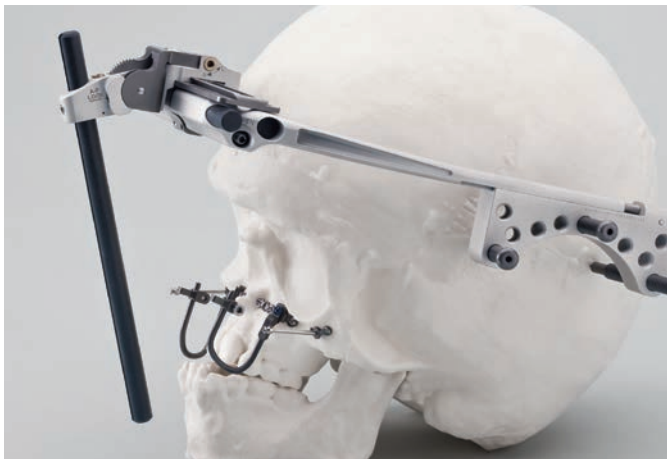
2. AP adjustments

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.

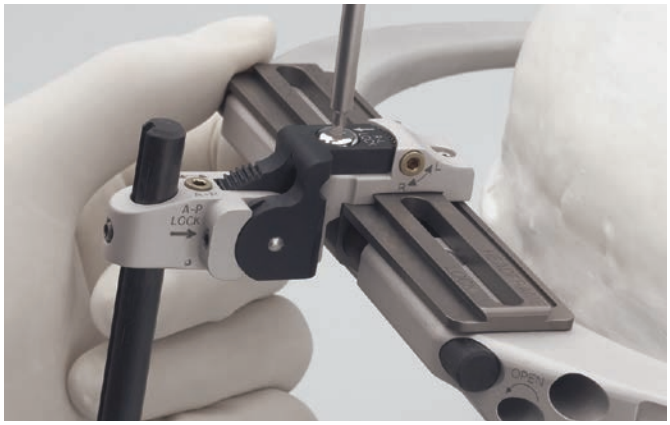
The angulating Vertical Rod Assembly can be angled 50° anteriorly and 30° posteriorly. One full rotation equals 7.2° of AP movement. Fully tighten the A-P lock screw after completing the adjustments.



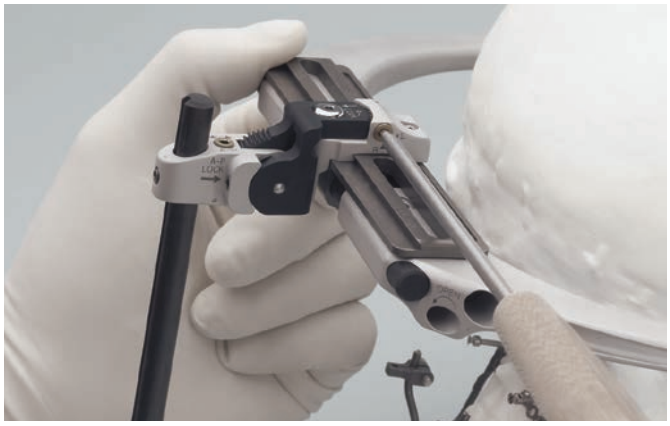


3. Transverse adjustments

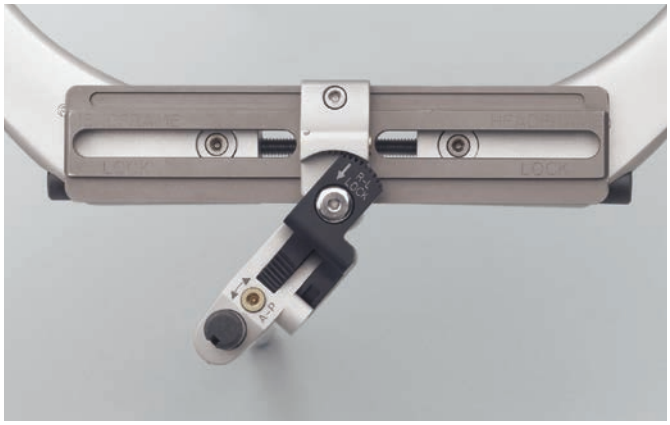
To make transverse adjustments, unlock the R-L lock screw.



Adjust the gold-colored screw that is etched “R-L” on the side of the angulating Vertical Rod Assembly.

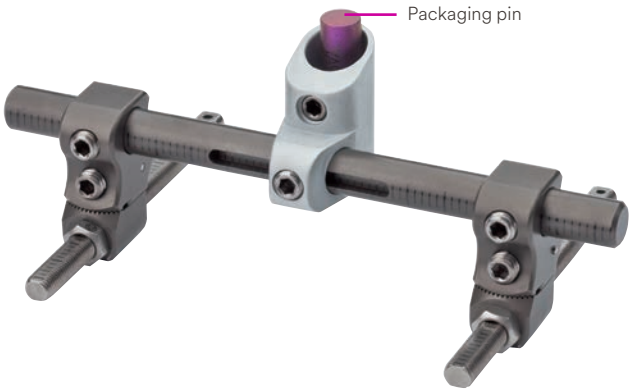


The device can be angled up to 30° in either direction. One full rotation equals 7.2° of transverse movement. Fully tighten the R-L lock screw after completing adjustments.



8. Attach the Horizontal Rod Assembly

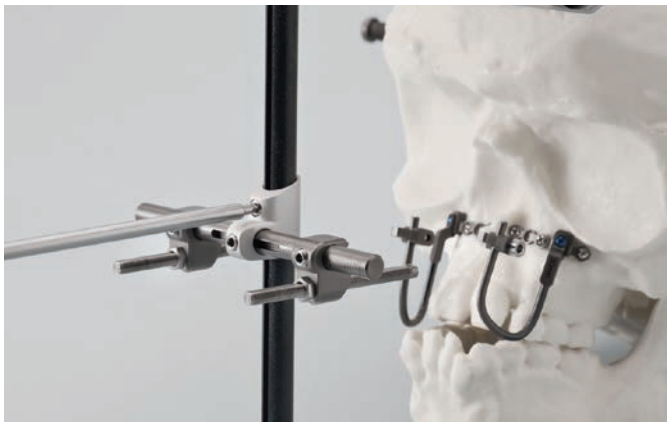
Depending on the necessary advancement vectors, select the Horizontal Rod Assembly with adjustable clamps or rigid clamps. Use one Horizontal Rod Assembly for LeFort I and LeFort II procedures, or two Horizontal Rod Assemblies for LeFort III and monobloc procedures.



■ 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.

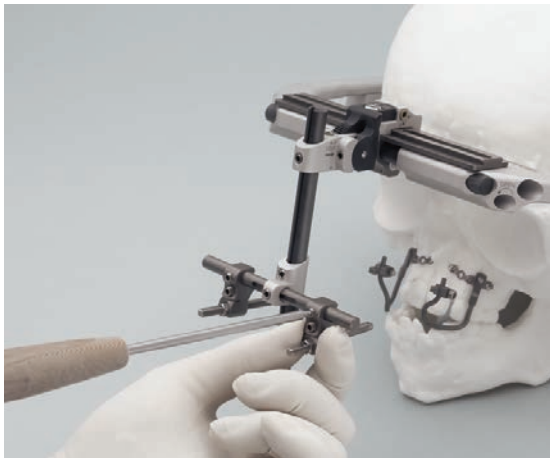
9. Position distraction arms

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.

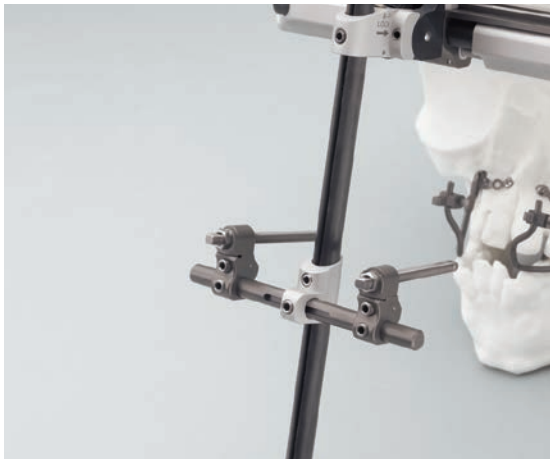
If necessary, the rod clamps can be removed and inverted on the horizontal rod to accommodate the patient's anatomy.

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



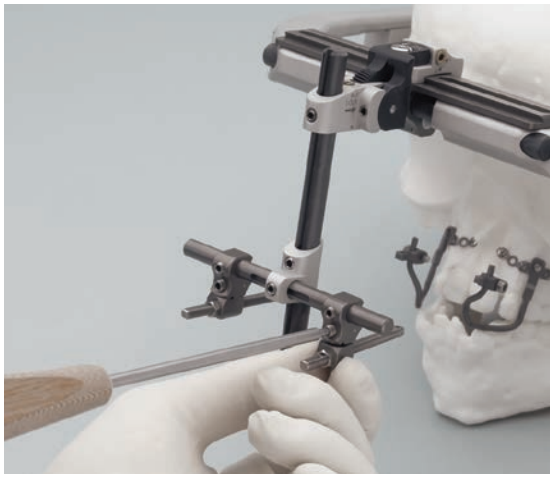
■ Note:

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 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.

▲ Precaution:

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

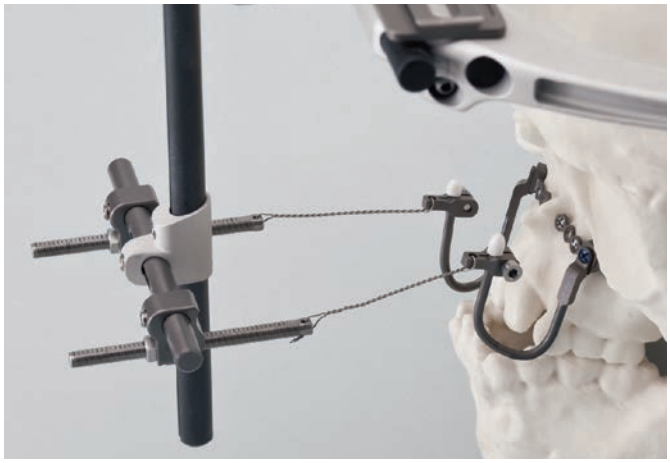
■ Note:

Wires are manufactured in standard sizes.

Imperial Standard Wire Gauge (SWG)

SWG	24	26
Diameter	0.559 mm	0.457 mm

Confirm device stability and verify movement of the bone. Use the activation instrument to engage the hexagonal activation tip of the distractor. Rotate in the direction marked on the instrument handle, to confirm device stability and verify movement of the bone. Return the distractor to its original position.



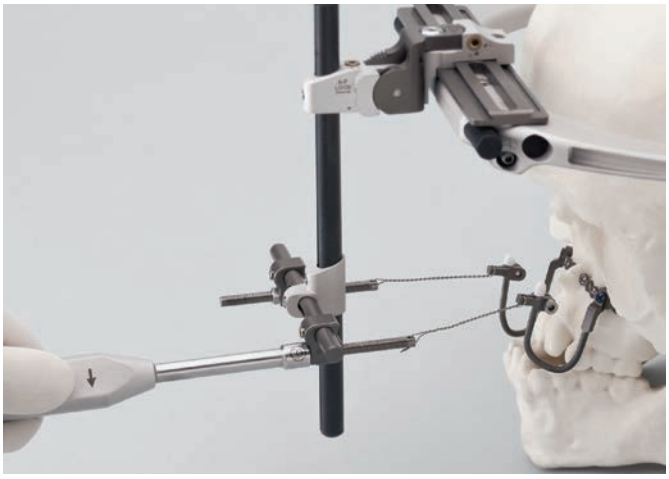
Placement of wire for LeFort I and II

Placement of wire for LeFort III and monobloc

Postoperative Considerations

Suggested Distraction Protocol

Instrument	
314.406	Activation Screwdriver, ∅ 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.

■ Notes:

- 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).
- 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

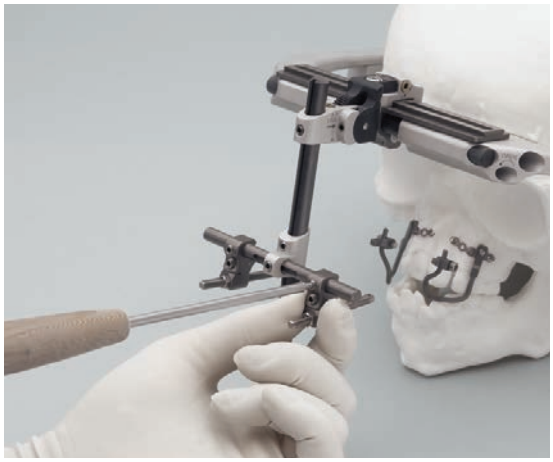
Distraction progress should be observed by documenting the movement of the midface at the appropriate levels. A Patient Care Guide is included with the system to help record and monitor distraction progress.

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.

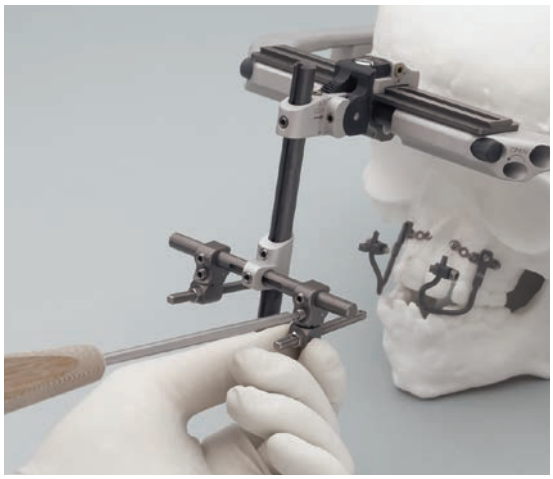
Individual vectors can be adjusted by loosening the appropriate set screw on each clamp, and repositioning the distraction arm along the horizontal rod. Retighten the set screw to lock the clamp in position.



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:

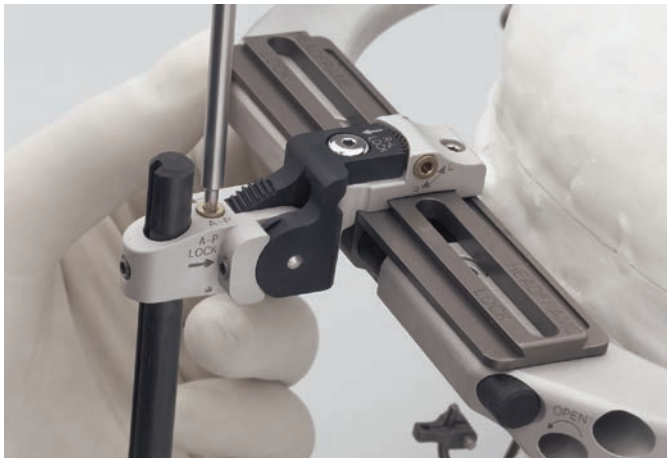
If the angulating Vertical Rod Assembly was used, AP and transverse adjustments may be performed at any time during the distraction phase, using a Headframe Adjustment Instrument.

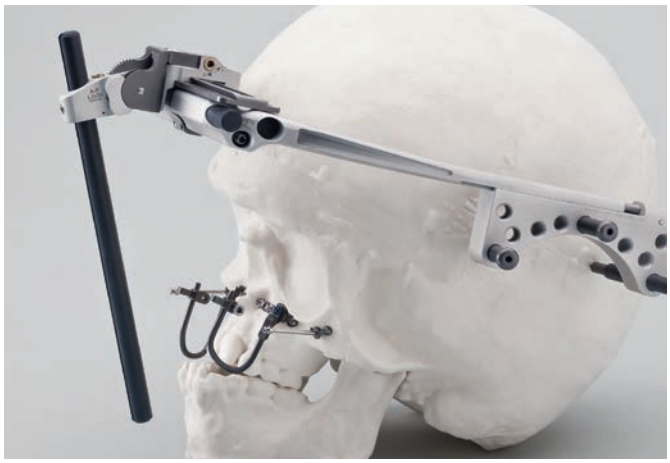


1. AP adjustments

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.



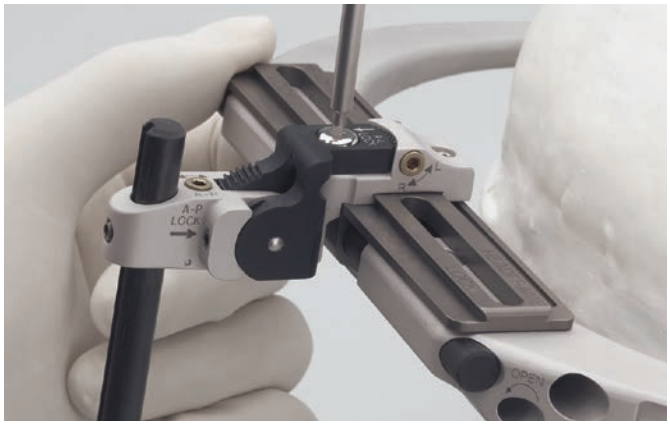


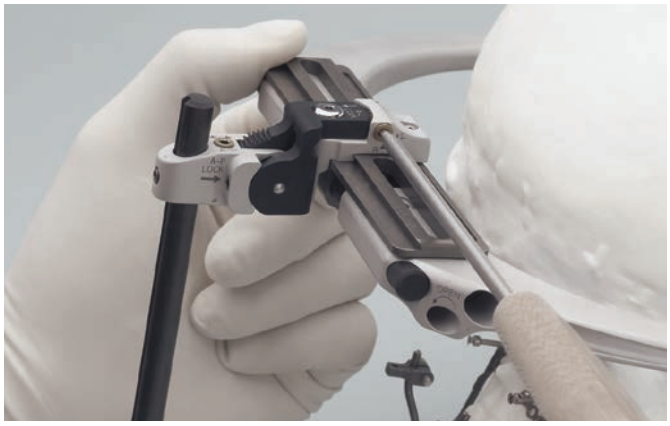
2. Transverse adjustments

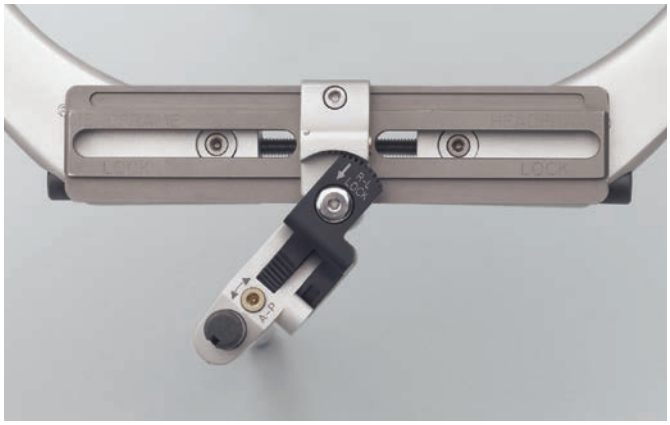
To make transverse adjustments, unlock the R-L lock screw. Adjust the gold-colored screw that is etched “R-L” on the side of the angulating Vertical Rod Assembly. The device can be angled up to 30° in either direction. One full rotation equals 7.2° of transverse movement. Fully tighten the R-L lock screw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

▲ 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/care giver 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

▲ WARNING:

In instances where emergency intubation is necessary, the device can be removed quickly using wire cutters and a Headframe Adjustment Instrument.

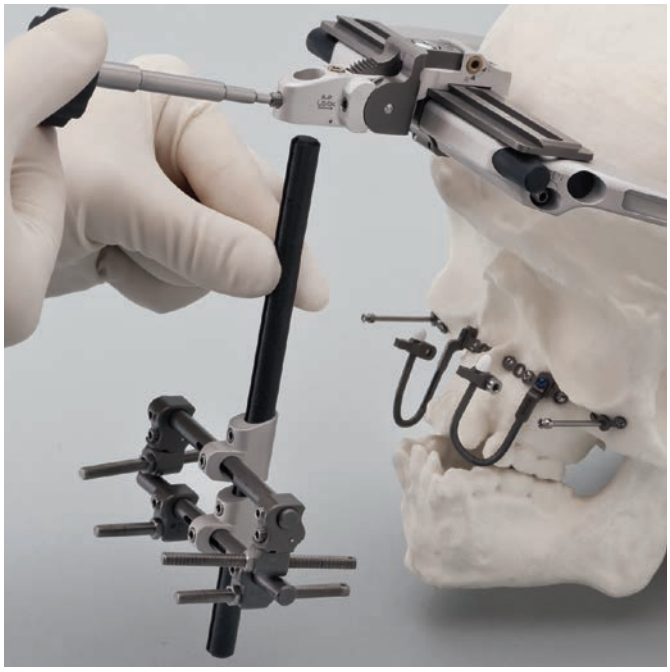
1. Remove wires

Cut the stainless steel surgical wires which attach the distraction arms to the midface.

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. 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 mandibular teeth.

Device Removal

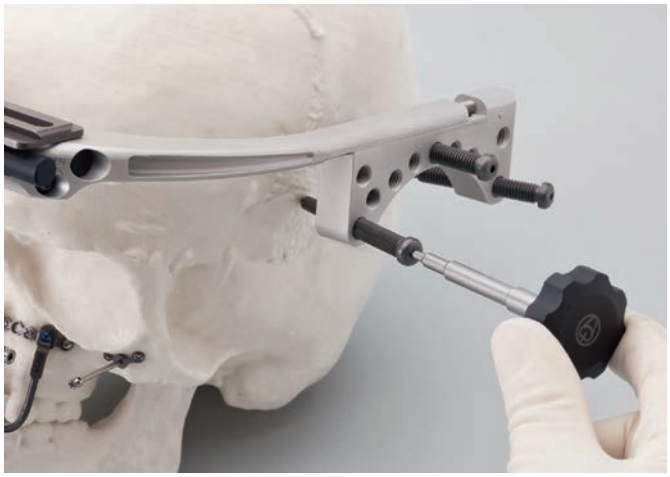
1. Remove wires

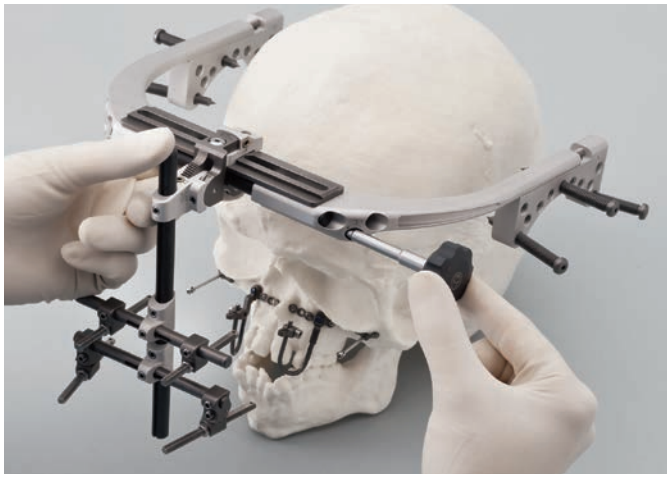
Using wire cutters, cut the stainless steel wires that attach the distraction arms to the midface.

2. Remove Headframe Assembly

▲ Precaution:

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





3. Remove intraoral/internal fixation

Instrument	
314.651	Screwdriver Shaft 1.5, cruciform, length 79 mm, with Holding Sleeve, with Hexagonal Coupling

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.

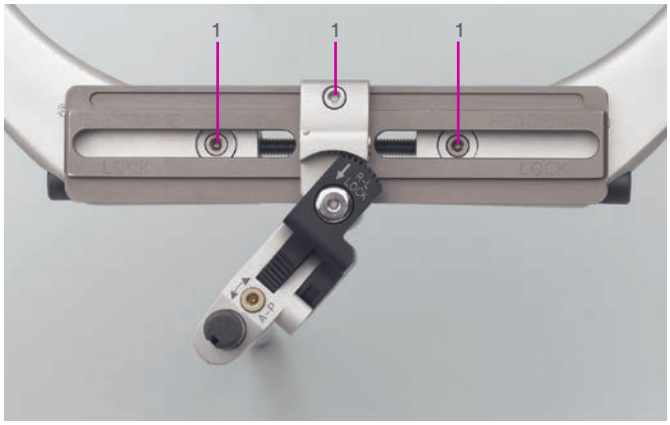
For LeFort III and monobloc procedures, remove the wire fixation screws using the cruciform 1.5 Screwdriver Shaft with Holding Sleeve. It is not necessary to remove the zygomatic footplates.

▲ Precaution:

Irrigate and apply suction for removal of debris potentially generated during implantation or removal.

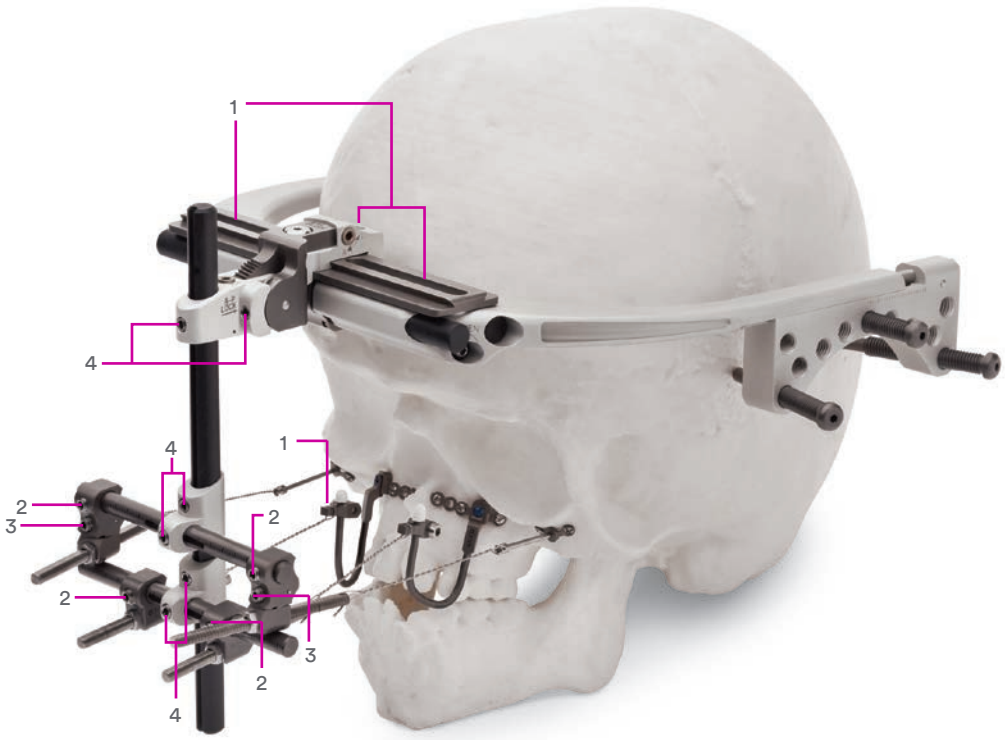
Screw Configuration

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.



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

311.005	Handle, small, with Hexagonal Coupling	
313.253	Screwdriver Shaft PlusDrive 1.5/2.0, medium, self-holding, for Hexagonal Coupling	
314.406	Activation Screwdriver, ∅ 5.5 mm, with Hexagonal	
314.407	Headframe Adjustment Instrument, length 72 mm, for External Midface Distractor	
314.408	Headframe Adjustment Instrument length 209 mm, for External Midface Distractor	
314.651	Screwdriver Shaft 1.5, cruciform, length 79 mm, with Holding Sleeve, with Hexagonal Coupling	
317.180	Drill Bit ∅ 1.1 mm with Stop, length 44.5/8 mm, 2-flute, for J-Latch Coupling	

329.180	Bending Pliers for Plates 2.4, with Plate Spring	
347.964	Bending Pliers 3D, left, for Plates 1.0 to 2.0, with contour-bending function	
391.990	Cutting Pliers for Plates and Rods	
392.180.10	Protective Cap for Wires ∅ 1.8 and 2.0 mm, pack of 10 units	

External Midface Distractor Set (115.660)

Graphic Cases

304.754	Graphic Case for External Midface Distractor
304.756	Module External Midface Distractor for Implants, in Graphic Case

External Hardware

390.100	Headframe, preassembled, 2 ea.
390.102	Vertical Rod Assembly
390.104	Vertical Rod Assembly, angulating
390.106	Horizontal Rod Assembly, with clamps, 2 ea.
390.108	Horizontal Rod Assembly, with Adjustable Clamps, 2 ea.

Cranial Pins

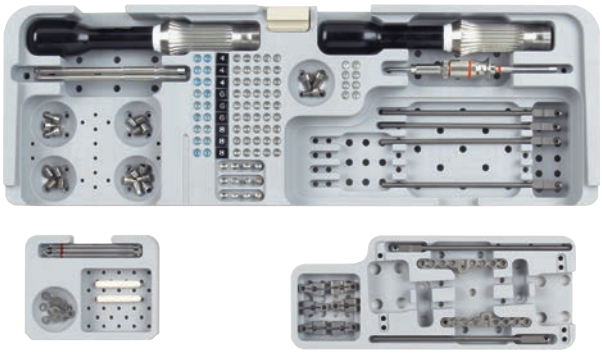
390.120	Positioning Pin, 40 mm, 4 ea.
390.122	Fixation Screw with tip, 40 mm, 8 ea.
390.124	Fixation Screw with tip, 50 mm, 10 ea.
390.126	Fixation Screw with threaded tip, self-drilling, 40 mm, 8 ea.
390.128	Fixation Screw with threaded tip, self-drilling, 50 mm, 10 ea.

Cap and Set Screws

390.130	End Cap ∅ 5.0 mm with hexagonal socket, 10 ea.
390.131	Set Screw, flat, with hexagonal socket, 4 mm, 6 ea.
390.132	Set Screw, with cone point, with hexagonal socket, 5 mm, 6 ea.
390.133	Set Screw, with Peg, with hexagonal socket, 6 mm, 6 ea.

Internal Hardware

03.307.001	Clamp for Wire Fixation, 4 ea.



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

400.996	15 mm, 4 ea.
400.997	21 mm, 4 ea.
04.500.002	27 mm, 4 ea.

Maxillary Rod, Titanium Alloy (TAN)

04.307.008	80 mm, 4 ea.
04.500.000	110 mm, 4 ea.
04.307.108	Large, 80 mm, with Offset, 4 ea.
04.500.001	Machine Screw, 8 ea.

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

400.055	Length 5 mm, 15 ea.
400.056	Length 6 mm, 15 ea.
400.058	Length 8 mm, 15 ea.

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

400.275	Length 5 mm, 6 ea.
400.276	Length 6 mm, 6 ea.
400.278	Length 8 mm, 6 ea.

Footplates

04.307.001	Maxillary Foot Plate, length 40 mm, Pure Titanium, 4 ea.
447.007	Zygomatic Foot Plate, 3 holes, Pure Titanium, 4 ea.

Instruments

314.406	Activation Screwdriver, ∅ 5.5 mm, with Hexagonal, 2 ea.
314.407	Headframe Adjustment Instrument, 72 mm, 2 ea.
314.408	Headframe Adjustment Instrument, 209 mm, 2 ea.
317.180	Drill Bit ∅ 1.1 mm with Stop, 44.5/8 mm, 2-flute, for J-Latch Coupling, 2 ea.
311.005	Handle, small, with Hexagonal Coupling, 2 ea.
313.253	Screwdriver Shaft PlusDrive 1.5/2.0, medium, self-holding, for Hexagonal Coupling, 2 ea.
314.651	Screwdriver Shaft 1.5, cruciform, 79 mm, with Holding Sleeve, with Hexagonal Coupling
329.180	Bending Pliers for Plates 2.4, with Plate Spring, 2 ea.
347.964	Bending Pliers 3D, left, for Plates 1.0 to 2.0, with contour-bending function, 2 ea.
391.990	Cutting Pliers for Plates and Rods
392.180.10	Protective Cap for Wires ∅ 1.8 and 2.0 mm, pack of 10 units

Length Marker, for self drilling screws

304.105W	White, type 5, 3 ea.
304.106W	White, type 6, 3 ea.
304.108W	White, type 8, 3 ea.

Also available

03.307.010	Carbon Fibre Rod, with Groove, 100 mm
03.307.105	Connecting Rod, 50 mm
03.307.112	Connecting Rod, 120 mm

Not all products are currently available in all markets.
This publication is not intended for distribution in the USA.
Intended use, Indications and Contraindications can be found in the corresponding system Instructions for Use.
All Surgical Techniques are available as PDF files at www.depuysynthes.com/ifu

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