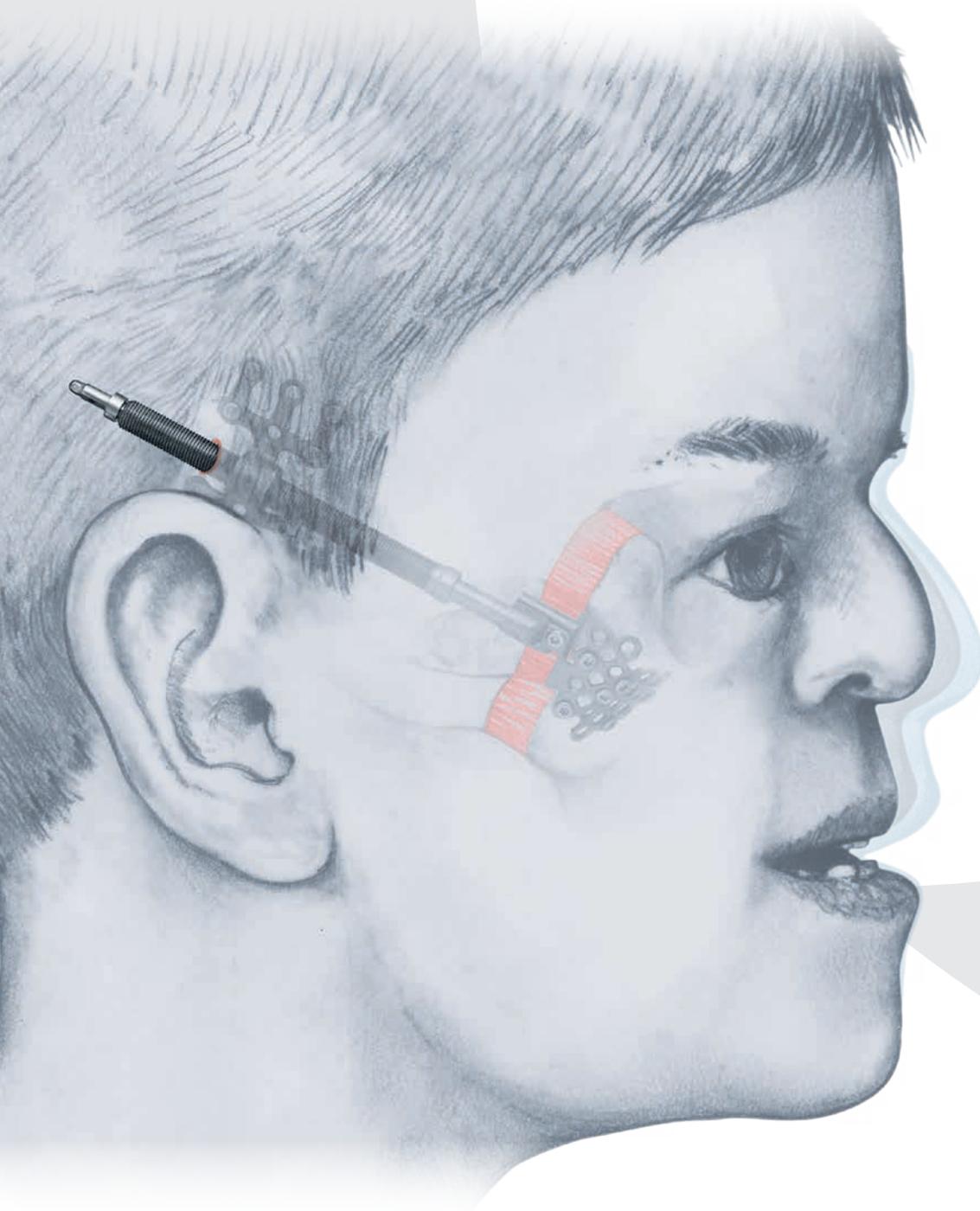


# Internal Midface Distractor

## Surgical Technique



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 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.depuyshes.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.depuyshes.com/hcp/reprocessing-care-maintenance>

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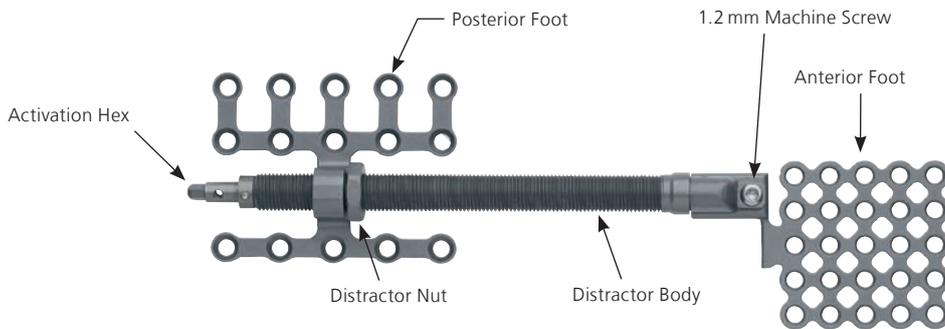
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# Overview

- Multiple anterior footplate designs are available
- Posterior footplate allows variable positioning in the temporal region
- Optional activation arm extensions are additionally available
- System allows up to 40 mm of distraction
- Distractor bodies and footplates are made of Ti-6Al-7Nb
- For use with 1.5 mm titanium screws

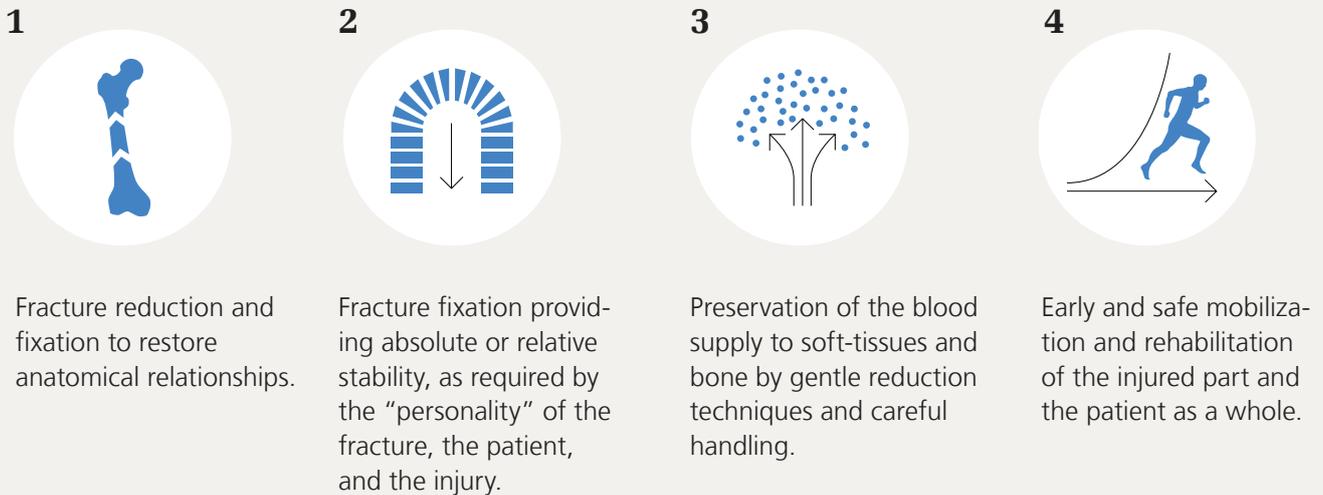


# The AO Principles of Fracture Management

## Mission

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

## AO Principles<sup>1,2</sup>



<sup>1</sup> Müller ME, M Allgöwer, R Schneider, H Willenegger. Manual of Internal Fixation. 3<sup>rd</sup> ed. Berlin, Heidelberg, New York: Springer. 1991

<sup>2</sup> Buckley RE, Moran CG, Apivatthakakul T. AO Principles of Fracture Management: 3<sup>rd</sup> ed. Vol. 1: Principles, Vol. 2: Specific fractures. Thieme; 2017.

# Warnings, General Adverse Events, MRI Information

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## 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.**
- **Instruments and screws may have sharp edges or moving joints that may pinch or tear user's glove or skin.**

## 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 including 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.

## Magnetic Resonance Environment Torque, Displacement and Image Artifacts according to ASTM F 2213-06, ASTM F 2052-14 and ASTM F 2119-07

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

## Radio-Frequency-(RF)-induced heating according to ASTM F 2182-11a

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

**Precautions:** The above mentioned test relies on non-clinical testing. The actual temperature rise in the patient will depend on a variety of factors beyond the SAR and time of RF application. Thus, it is recommended to pay particular attention to the following points:

- **It is recommended to thoroughly monitor patients undergoing MR scanning for perceived temperature and/or pain sensations.**
- **Patients with impaired thermoregulation or temperature sensation should be excluded from MR scanning procedures.**
- **Generally, it is recommended to use an MRI system with low field strength in the presence of conductive implants. The employed specific absorption rate (SAR) should be reduced as far as possible.**
- **Using the ventilation system may further contribute to reduce temperature increase in the body.**

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

# Preoperative Planning

## Planning

- Determine the post-distraction anatomic goal by conducting an evaluation of the craniofacial pathology, the bone quality and volume, and asymmetry through clinical exam, CT scan, cephalogram and/or panoramic x-ray.
- Correct placement and orientation of osteotomies and distraction devices is critical to successful treatment.

## Preoperative Planning Precautions:

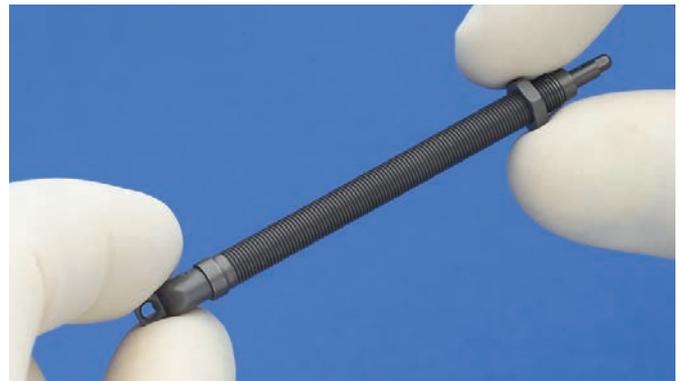
When placing the distractors consider and verify:

- Planned length of advancement (consider relapse and overcorrection)
- Adequate bone quality for screw placement
- Location of nerves
- Soft tissue coverage
- Patient pain due to distractor interference with soft tissue
- Access to the screws based on approach

# Distractor Assembly

## 1. Assemble the distractor nut

Thread the distractor nut onto the distractor body.

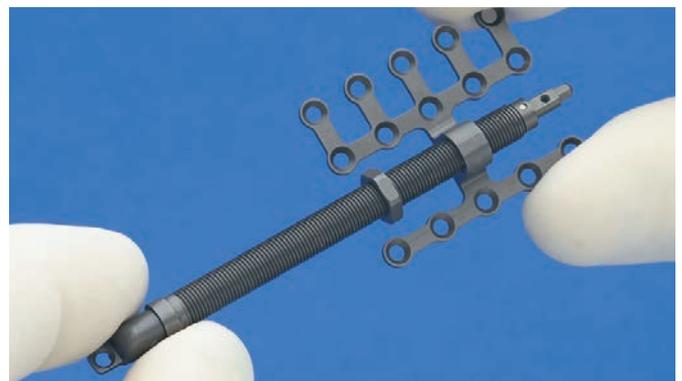


## 2. Assemble the posterior footplate

Thread the posterior footplate onto the distractor body. The posterior footplate can be adjusted in 0.5 mm increments along the distractor body to fit the patient's anatomy.

### Notes:

- **Once the posterior footplate location is determined, finger-tighten the distractor nut against the posterior footplate for stabilization.**
- **A second posterior footplate can be threaded onto the distractor body.**



Assembly shown is for patient's left side

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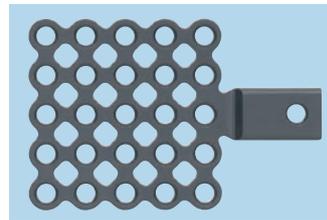
### 3. Choose the anterior footplate

Choose the anterior footplate that suits both the anatomy of the patient and the treatment plan.

Refer to optional footplate configurations section of this Surgical Technique.

#### **Anterior footplate overview:**

- The plates with buttress can be used to push the bone segment forward, thus sharing the load of distraction with the screws.
- Symmetrical Anterior Foot Plates (487.986, 487.987) permit the distractor to be angled for a downward distraction vector.
- Elevated Anterior Foot Plates (487.984, 487.985) permit the distractor to be placed on a vector parallel with the occlusion for a horizontal distraction vector. The buttress on these footplates should sit flush against the bone.



**Precaution:** Screws must be placed in the holes closest to the footplate for adequate device stability.

---

## 4. Attach the anterior footplate

Engage the distractor body into the “slip-fit” of the anterior footplate. Insert the 1.2 mm machine screw to affix the anterior footplate to the distractor body.

**Note:** If the 1.2 mm machine screw is not used, the distractor body may be removed after consolidation, without a coronal incision. (This will leave the anterior footplates on the zygoma.)

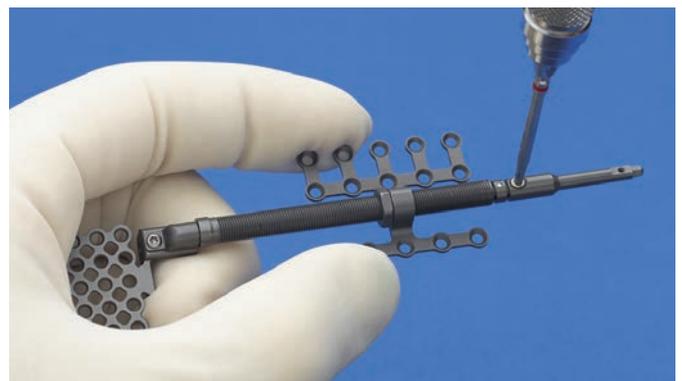
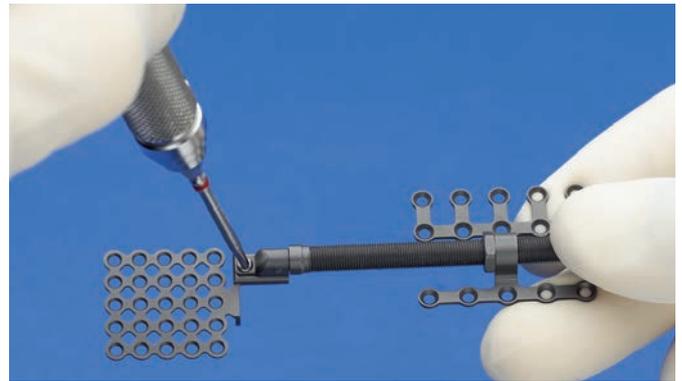
**Warning:** If the 1.2 mm machine screw is not used, extra care should be taken to not reverse the distractor during distraction, as it can inadvertently disengage from the anterior footplate.

Optional: Attach activation arm extensions

If necessary, attach an activation arm extension to the distractor body to allow the activation hex to protrude through the soft tissue for remote activation. Choose the activation arm extension that suits the patient and engage it with the distractor body by slipping it over the activation hex.\*

Secure the activation arm extension to the distractor body with the 1.2 mm machine screw. Be sure to fully tighten the screw.

**Note:** For smaller patients, the distractor body length may be used for percutaneous activation.



Assembly shown is for patient's left side.

---

## 5. Repeat steps 1–4 for the opposite side

\* See section for activation arm selections in the back of the Surgical Technique.

# Device Placement

The footplates must be contoured to the patient's anatomy, on a 3-D anatomical model prior to surgery, or on the patient intraoperatively. If contouring the footplates intraoperatively, follow the surgical technique below.



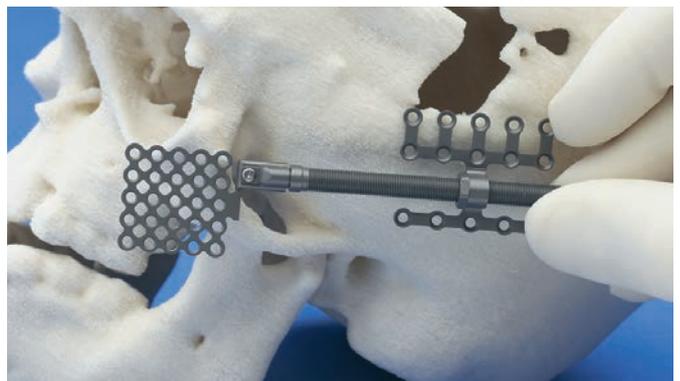
## 1. Fit the distractor

Place a fully assembled distractor in the intended placement area to assess the bony anatomy and to determine approximate anterior and posterior footplate location.

### Precautions:

- Determine if the activation arm extension(s) are necessary for the activation hex to exit through the soft tissue for remote activation.
- Choose an adequate length extension arm to ensure that the soft tissue does not obstruct the activation hex during distraction.
- Extension arm should be assembled with the distractor before the distractor is attached to the bone. It is difficult to attach the extension arm after the distractor is screwed to the bone.
- During the course of treatment, care should be taken to protect the extension arms and prevent damage or breakage. Lateral forces from a patient rolling on the flexible extension arms during sleep can damage and/or break the extension arms. It is advised to secure the flexible arms to the patient's skin, without affecting the arm's ability to rotate. As an alternative, rigid extension arms are available.

**Note:** It is recommended to place the distractor under the temporalis muscle when determining final placement.



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## 2. Contour the footplates

Contour the anterior and posterior footplates using the Bending Pliers. Undesired screw holes may be removed using the Cutter for Strut Plates and Mesh Plates or the Cutting Pliers for Plates and Rods.

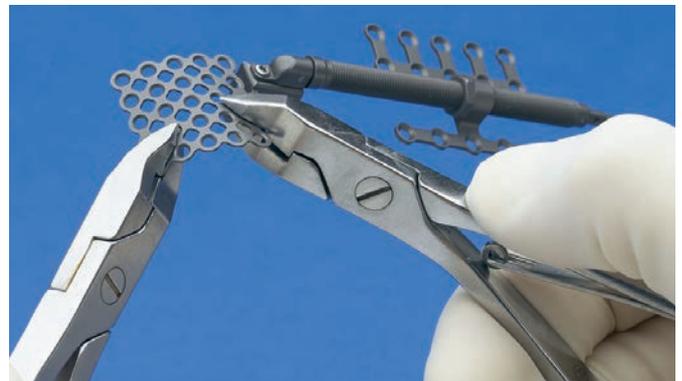
### Precautions:

- Footplates should be cut so that the integrity of the screw hole is not compromised.
- Cut the implant immediately adjacent to the screw holes.
- Take care to protect soft tissue from trimmed edges.
- Each footplate should contain a minimum of four screws for adequate stability.

### Notes:

- Be sure to not overbend the footplates.
- The anterior footplates should span the zygomaticomaxillary sutures to ensure the maxilla advances with the rest of the midface.
- Placement of the footplates determines the advancement vector of distraction and should be aligned with advancement vectors determined during preoperative planning.

**Warning:** Do not implant a distractor if the footplates have been damaged by excessive bending.



### 3. Mark the distractor location

Mark the distractor location prior to the down fracture by inserting two appropriate length screws through the anterior footplate and one appropriate length screw through the posterior footplate. Fully tighten the screws in the anterior footplate.

**Precaution:** Do not tighten the screw in the posterior footplate.

**Notes:**

- Placing screws in the posterior footplate may not be preferable at this time. Instead, mark the location of the footplate with a marking pen.
- Drilling a pilot hole is necessary when using self-tapping screws.

**Precautions:**

- Use the drill bit assigned for the system screw.
- Drill and insert screws closest to the osteotomy first.
- 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.
- Always irrigate during drilling to avoid thermal damage to the bone.
- Irrigate and apply suction for removal of debris potentially generated during implantation or removal.
- Avoid drilling over nerve or tooth roots.
- Take care while drilling as to not damage, entrap, or tear a patient’s soft tissue or damage critical structures.
- Bone screws should be placed in areas of hard cortical bone to provide stable fixation screws can loosen during the course of treatment if placed in poor quality bone.
- Be sure to keep drill clear of loose surgical materials.
- Handle devices with care and dispose worn bone-cutting instruments in an approved sharps container.



- Activate the distractor in open direction a half turn prior to drilling and/or inserting screws to ensure adequate distance between the pilot holes and the osteotomy.
- 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 and other critical structures when drilling and/or placing screws.
- Use the appropriate screw length to avoid distractor loosening or damage of critical/lingual structures.

**Warning:** Instruments and screws may have sharp edges or moving joints that may pinch or tear user’s glove or skin.

---

#### 4. Repeat steps 1–3 on contralateral side

---

#### 5. Remove the distractors

Remove the distractors by unscrewing the 1.2 mm machine screws and the posterior footplate screws. The anterior footplates can stay on the zygomas. This will help realign the devices after the down fracture.

**Note:** If desired, the anterior footplates can be removed with the distractor bodies prior to the down fracture.



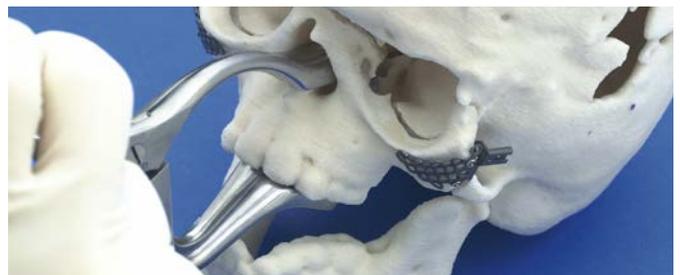
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#### 6. Perform the down fracture

Perform the down fracture and ensure the midface ment is completely mobile.

**Precautions:**

- 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.
- Take care to avoid nerves.



## 7. Reattach the distractors

Once the midface is completely mobile, reattach the distractors by re-engaging the distractor bodies with the “slip-fit” of each anterior footplate. Insert the 1.2 mm machine screws to lock the anterior footplates and distractor bodies together. Reinsert the screws in the posterior footplates, in the previously marked locations. Insert appropriate length screws in the remaining screw holes. Fully tighten all screws.

### Notes:

- If necessary, activation arm extensions can be added to lengthen the distractors for remote activation.
- Drilling a pilot hole is necessary when using self-tapping screws.

### Precautions:

- A minimum of four screws should be placed in each footplate for adequate stability.
- 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 pull-out force, increased ease of the screws stripping in bone, suboptimal fixation, and/or the need for emergency screws.
- Always irrigate during drilling to avoid thermal damage to the bone.
- Irrigate and apply suction for removal of debris potentially generated during implantation or removal.
- Take care while drilling as to not damage, entrap, or tear a patient’s soft tissue or damage critical structures.
- Bone screws should be placed in areas of hard cortical bone to provide stable fixation.
- Be sure to keep drill clear of loose surgical materials.
- Handle devices with care and dispose worn bone-cutting instruments in an approved sharps container.
- To increase distractor stability in thin bone, insert screws bicortically. In addition, more screws can be used.
- Take care to avoid nerves, tooth buds and roots and/or other critical structures when drilling and/or placing screws.
- Use the drill bit size assigned for the system screw.
- Screws can loosen during the course of treatment if placed in poor quality bone.



- Firmly press the screwdriver blade into the screw recess to ensure retention of the screw on the screwdriver blade.
- Extension arm should be assembled with the distractor before the distractor is attached to the bone. It is difficult to attach the extension arm after the distractor is screwed to the bone.
- Use the appropriate screw length to avoid distractor loosening or damage of critical or lingual structures.
- Screws must be placed in the holes closest to the distractor body for adequate device stability.
- Drill and insert screws closest to the osteotomy first.

---

## 8. Confirm device stability and activation

Tighten the distractor nuts against the posterior footplates using the Combination Wrench. Using the Activation Screwdriver, turn each distractor in a counterclockwise direction, as marked on the screwdriver's handle, to confirm the stability and verify the movement of the midface.

The midface should advance upon activation of the distractors. Before closure, return each distractor to its original position.

**Precaution:** Do not hold the extension arm while rotating it with activation instrument. Doing so will make it difficult to rotate the extension arm and may cause the extension arm to separate.

### Warnings:

- If the 1.2 mm machine screws were not used to lock the anterior footplates to the distractor bodies, ensure the two components are fully engaged when the devices are returned to their original position.
- The screwdriver must be used to fully tighten the extension arm to the distractor. If the screwdriver is not used, the extension arm may separate from the distractor unintentionally.



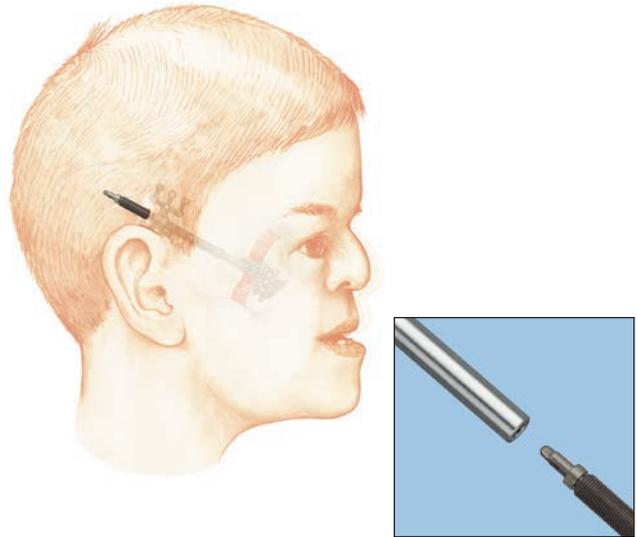
# Postoperative Considerations

## 1. Suggested distraction protocol

Distraction should begin three to five days after device placement. For young patients, active distraction can begin earlier to reduce the risk of premature consolidation. To achieve lengthening, engage the activation hex with the activation screwdriver and rotate counterclockwise (in the direction of the arrow marked on the instrument). A rate of 1.0 mm of distraction per day is recommended to reduce the risk of premature consolidation. Each full rotation equals 0.5 mm of distraction.

### 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.
- Do not hold the extension arm while rotating it with the activation instrument. Doing so will make it difficult to rotate the extension arm and may cause the extension arm to separate from the distractor.
- During the course of treatment, monitor the patient's condyles in the glenoid fossae for degenerative changes.
- The surgeon must instruct the patient/care giver how to activate and protect the distractor during the treatment.
- It is important that the extension arms be protected from catching on objects that could pull the devices and cause the patient pain or injury.
- 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.



### Warnings:

- The devices are capable of 40 mm of distraction (80 counterclockwise rotations). Distraction beyond this limit will cause the devices to separate.
- During the course of treatment, care should be taken to protect the extension arms and prevent damage or breakage. Lateral forces from a patient rolling on the flexible extension arms during sleep can damage and/or break the extension arms. It is advised to secure the flexible arms to the patient's skin, without affecting the arm's ability to rotate. As an alternative, rigid extension arms are available.
- Patients should be advised to avoid high risk activities, as injury can occur if the patient falls on the device.

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## 2. Site care

- To avoid the accretion of dried blood to the device, a regimen of applying antibiotic ointment to the percutaneous port is recommended throughout the course of distraction.
- Upon the first activation, special care should be given to ensure that the activation hex is free from soft tissue adhesion. Similar care should be given on all subsequent activations to provide the most comfort for the patient.
- Keeping the hair short around the activation port can also be beneficial to the patient's comfort during distraction.

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## 3. Document progress

Distraction progress should be observed by documenting the movement of the infraorbital rim and anterior maxillary teeth. A Patient Care Guide is included with the Activation Screwdriver to help record and monitor distraction progress.

# Consolidation

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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.

## Device Removal

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**Warning:** While the surgeon must make the final decision on implant removal, we recommend that whenever possible and practical for the individual patient, fixation devices should be removed once their service as an aid to healing is accomplished. Implant removal should be followed by adequate post-operative management to avoid refracture.

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### 1. If 1.2 mm machine screws were used

If the 1.2 mm machine screws were used to lock the anterior footplates to the distractor bodies, it will be necessary to gain access to the screws in the anterior and posterior footplates for device removal.

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

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### 2. If 1.2 mm machine screws were not used

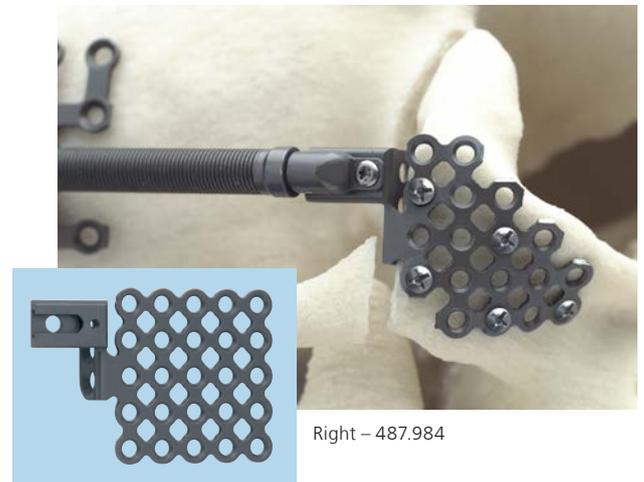
If the 1.2 mm machine screws were not used, it is possible to remove the devices without gaining access to the anterior footplates. Using the Activation Instrument, turn each distractor clockwise at least 20 times to disengage the distractor bodies from the anterior footplates. Make an incision over each posterior footplate to gain access to the screws. Remove all screws in the posterior footplates and lightly pull the distractor bodies through the incisions, leaving the anterior footplates on the zygomas.

# Anterior Footplate Options

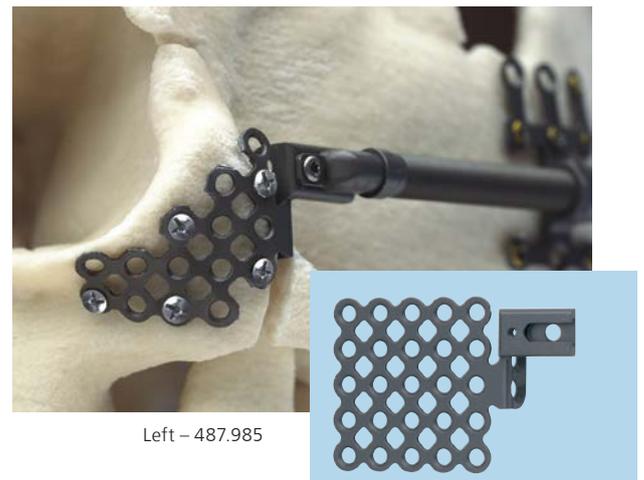
## **Anterior Foot Plate, right (487.984)/left (487.985), elevated**

Screw holes on these footplates are offset from the distractor body. This allows the distractor to be placed more in line with the vector of the occlusion, and to allow the placement of screws lower on the zygoma. The buttress acts as an aid to push the midface segment forward, sharing the load of distraction with the screws.

**Note:** The buttress on these footplates should sit flush against the bone for stability.



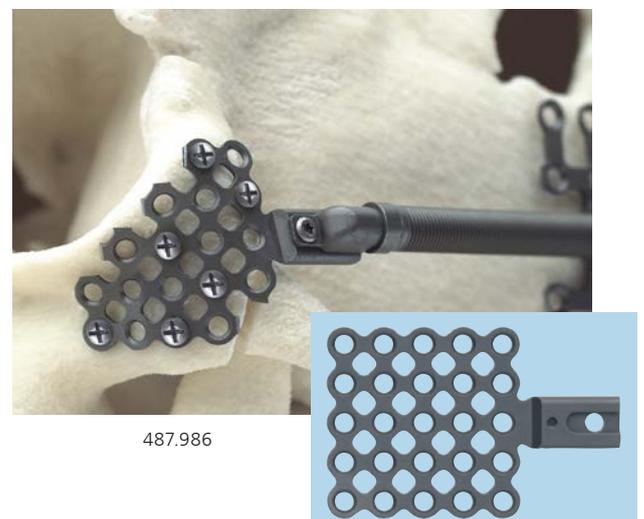
Right – 487.984



Left – 487.985

## **Anterior Foot Plate, symmetrical, low profile (487.986)**

Screw holes on the footplate are symmetrical with the distractor body. This allows the distractor to be placed on an angle to achieve a downward vector of distraction. Engagement of the distractor body and the anterior footplate occurs on the medial side of the anterior footplate, making the distractor assembly lower profile in the lateral orbital region.

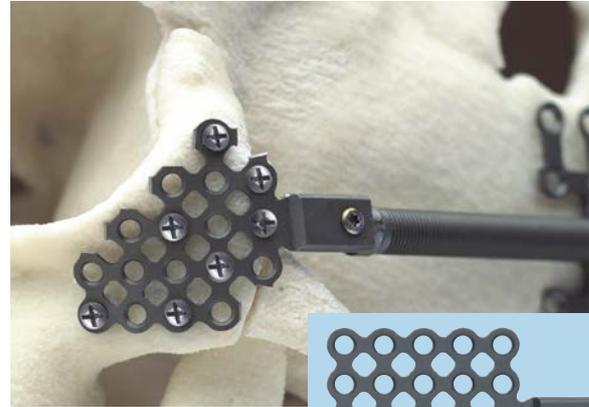


487.986

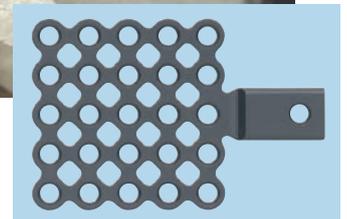
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**Anterior Foot Plate, symmetrical, elevated (487.987)**

Screw holes on the footplate are symmetrical with the distractor body. This allows the distractor to be placed on an angle to achieve a downward vector of distraction.



487.987



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## Activation Arm Extension Options

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**Extension, length 20 mm, Titanium Alloy (TAN) (487.992)**



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**Universal Extension, with Joint, length 20 mm, Titanium Alloy (TAN) (487.993)**



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**Extension, flexible, 40 mm, (487.994)**



L-605 Cobalt chromium alloy cable, with silicone tubing.

# Midface Distractor Set (145.955)

## Implants

487.980	Nut Ø 7.0 mm, Titanium Alloy (TAN), 8 ea.
487.990	Posterior Foot Plate, monoaxial, Titanium Alloy (TAN), 4 ea.
487.982	Midface Distractor, complete, distraction length 40 mm, Titanium Alloy (TAN), 4 ea.
487.992	Extension, length 20 mm, Titanium Alloy (TAN), 4 ea.
487.993	Universal Extension, with Joint, length 20 mm, Titanium Alloy (TAN), 4 ea.
487.994	Extension, flexible, 40 mm, 4 ea.
487.995	Machine Screw Ø 1.2 mm, Titanium Alloy (TAN), 12 ea.

## Titanium Midface Distractor Anterior Feet

487.984	Anterior Foot Plate, right, elevated, Titanium Alloy (TAN), 2 ea.
487.985	Anterior Foot Plate, left, elevated, Titanium Alloy (TAN), 2 ea.
487.986	Anterior Foot Plate, symmetrical, low profile, Titanium Alloy (TAN), 4 ea.
487.987	Anterior Foot Plate, symmetrical, elevated, Titanium Alloy (TAN), 4 ea.

## Cortex Screws PlusDrive Ø 1.5 mm, self-tapping, Titanium Alloy (TAN)\*

400.034	length 4 mm**
400.036	length 6 mm**
400.038	length 8 mm**

## Cortex Screws PlusDrive Ø 1.5 mm, self-drilling, Titanium Alloy (TAN)\*

400.054	length 4 mm**
400.056	length 6 mm**
400.058	length 8 mm**

## Emergency Screws PlusDrive Ø 2.0 mm, self-tapping, Titanium Alloy (TAN)\*

400.274	length 4 mm**
400.276	length 6 mm**
400.278	length 8 mm**

## Instruments

395.350	Combination Wrench Ø 7.0 mm, 2 ea.
314.402	Activation Screwdriver, for Mandible Distractor, monoaxial, 2 ea.
311.005	Handle, Small, with Hexagonal Coupling
313.254	Screwdriver Shaft PlusDrive 1.5/2.0, short, self-holding, for Hexagonal Coupling
313.837	Screwdriver Shaft Stardrive 1.5, short, self-holding, for Hexagonal Coupling
347.964	Bending Pliers 3D, left, for Plates 1.0 to 2.0, with contour-bending function, 2 ea.
391.952	Cutter for Strut Plates and Mesh Plates
391.990	Cutting Pliers for Plates and Rods

\* 1.5 mm Cortex screws are available non sterile (without clip and in clip) or sterile packed (in clip). To order sterile single packed screws, add suffix "S" to the part number; e.g. 400.034S

\*\* 1.5 mm Cortex screws are also available in packs of 4 screws in clip, add suffix ".04C" to the part number for non-sterile article without clip; eg. 400.034.04C. To order sterile 4 packed screws (in clip), add suffix ".04S" of the non-sterile part number without clip, e.g. 400.034.04S.

**Drill Bit  $\varnothing$  1.1 mm with Stop, 2-flute, for J-Latch Coupling, 2 ea.\***

317.140	length 44.5/4 mm, 2-flute
317.160	length 44.5/6 mm, 2-flute
317.180	length 44.5/8 mm, 2-flute

**Length Markers**

304.104	Black, type 4
304.106	Black, type 6
304.108	Black, type 8
304.104W	White, type 4
304.106W	White, type 6
304.108W	White, type 8

**Cases and Lids**

304.686	Instrument Tray
304.687	Lid, for No. 304.686
304.797	Module Midface Distractor

**Also Available**

487.988	Foot Plate for Mesh Plate, Titanium Alloy (TAN), 4 ea.
487.989	Foot Plate for Mesh Plate with buttress, Titanium Alloy (TAN), 4 ea.



\* 1.1 mm Drill Bits are available non sterile or sterile packed.  
To order sterile drill bits, add suffix "S" to the part number; e.g. 317.140S



