

# Maxillary Distractor

A modular system for distraction of the maxilla

## 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.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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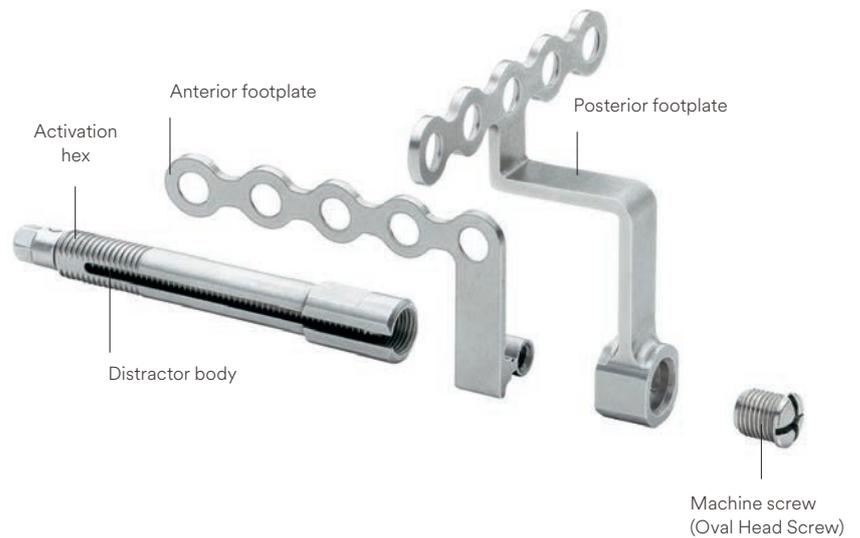
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# Maxillary Distractor

Distraction of the maxilla is accomplished bilaterally using a left and a right assembly.

## Overview

- Four distractor lengths allow up to 10 mm, 15 mm, 20 mm, or 25 mm of advancement
- Three anterior footplate heights for both left and right configurations
- Three posterior footplate heights with two offsets to accommodate pediatric and adult populations
- Distractors may be attached to either the maxilla or a dental splint
- Made from 316L stainless steel, for use with 2.0 or 2.4 mm stainless steel cortex screws



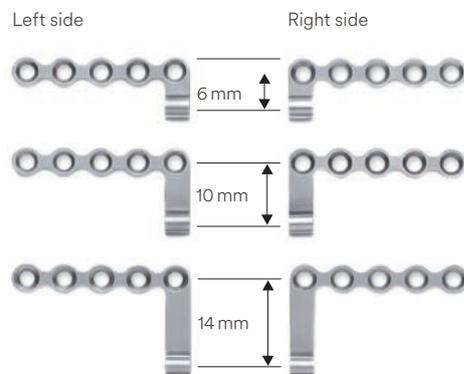
## Distractor body

Distractor bodies are available in 10 mm, 15 mm, 20 mm, or 25 mm lengths.



## Anterior footplate

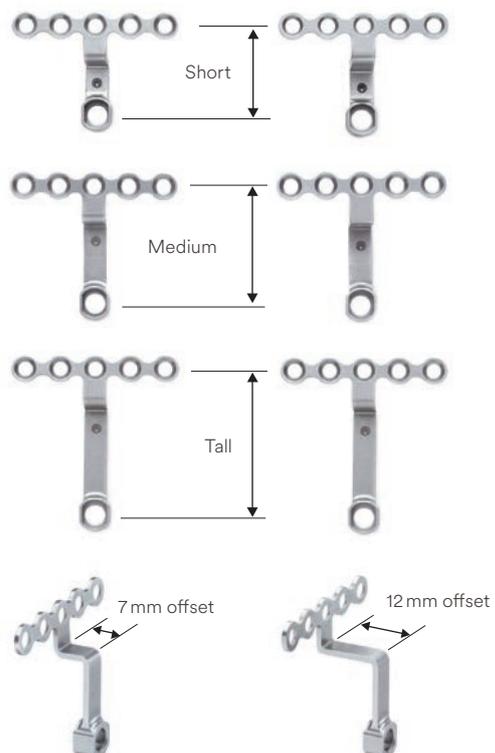
Anterior footplates are available in left and right configurations in 6 mm, 10 mm, or 14 mm heights.



## Posterior footplate

Posterior footplates are available in six sizes:

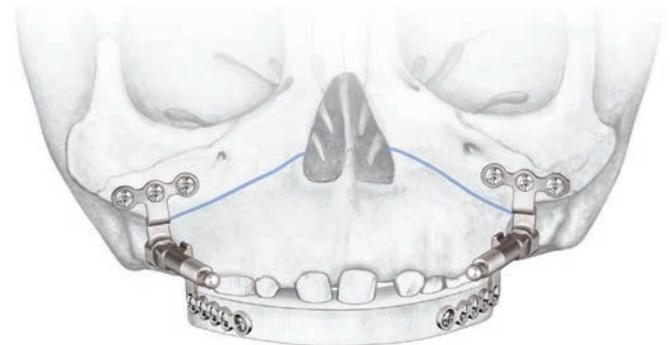
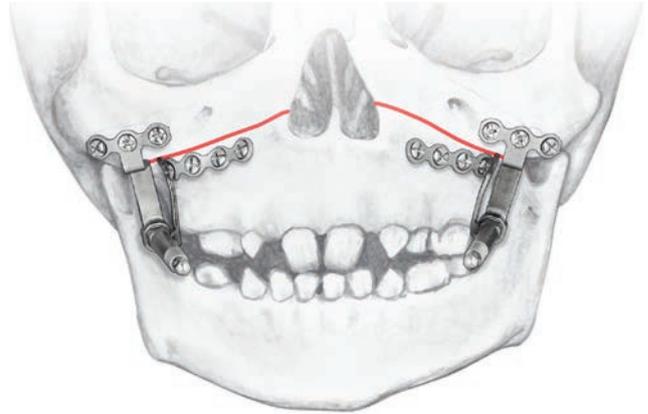
- Short, with 7 mm or 12 mm offset
- Medium, with 7 mm or 12 mm offset
- Tall, with 7 mm or 12 mm offset



# Warnings, General Adverse Events and Device Specific Adverse Events

## ▲ WARNINGS:

- These devices can break during use (when subjected to excessive forces or used 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



Please refer to the corresponding Instructions for Use for specific information on Intended use, Indications, Contraindications, Warnings and Precautions, Potential Adverse Events, Undesirable Side Effect and Residual Risks.

Instruction for Use are available at [www.e-ifu.com](http://www.e-ifu.com) and/or [www.depuysynthes.com/ifu](http://www.depuysynthes.com/ifu)

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

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## 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, dental injuries, neurological impairments, etc.), thrombosis, embolism, infection, nerve and/or tooth root damage 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 hypersensitivity reactions, 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.

## Device Specific Adverse Events

### Re-operation:

1. Re-operation due to relapse.
2. Re-operation because the distractor system breaks or disengages due to patient excessive activities.
3. Re-operation because the footplate breaks after implantation surgery, during treatment due to decreased strength as a result of excessive bending of the footplate during implantation.
4. Re-operation because the footplate breaks postoperatively prior to bone consolidation process is completed due to an excessive strain by the patient.
5. Non-union or fibrous union leading to re-operation (worst case) because the number of screws used with the footplates is not sufficient.
6. Re-operation due to the screw migration in thin bone.
7. Premature bone consolidation requiring re-operation due to the distractor being activated in the wrong direction after being activated in the proper direction.
8. Re-operation 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.

9. Re-operation to replace the device due to device disturbance by traumatic patient injury not related to procedure or treatment.
10. Restricted/impaired bone growth requiring further surgery because the distractor is not removed after healing is accomplished.
11. Re-operation due to infection at the distractor site.
12. Re-operation due to device malfunction.
13. Re-operation due to inadequate device length selected.
14. Re-operation due to device backup.
15. Re-operation due to loose distractor footplate.
16. Re-operation due to bone fracture under load.
17. Re-operation due to incomplete osteotomies.

**Additional Medical Treatment:**

1. Soft tissue erosion due to the distractor components pressure on the soft tissue.
2. Patient pain due to end of distractor protruding into soft tissue.
3. Nerve damage requiring subsequent medical treatment.
4. Infection requiring treatment.
5. Injury of the patient due to extended OR time, because the screws/distractors can not be removed.
6. The healing process may be altered for patients with certain metabolic diseases, with active infection or who are immune compromised.
7. Cellulitis
8. Discomfort of the patient due to long treatment duration.
9. Scar requiring revision.
10. Pain at bony generate site.
11. Wound dehiscence.
12. Treatment termination due to the patient non-compliance.
13. Mild anterior open bite.
14. Dietary problems, weight loss.

# The AO Principles of Fracture Management

## Mission

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

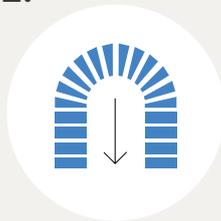
### AO Principles<sup>1,2</sup>

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.

<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.

# Preoperative Planning

Several preoperative investigations are useful in the planning of distractor position and alignment. CT scans, cephalometric tracings, dental models, and 3-D anatomical models are beneficial in determining the location of the osteotomy and placement of the devices. Footplates can either be attached to the zygoma and maxilla or the zygoma and a dental splint.

CT scans and clinical assessments identify the nature of the craniofacial anomaly. If done using a specific scanning technique, a 3-D anatomical model can be developed (Figure 1).

Cephalometric tracings assist in identifying the extent of the deformity, and aid in planning the position of the distraction device to obtain the proper vector of advancement (Figure 2).

Dental models in conjunction with the clinical exam and cephalometric tracings, aid in the determination of the vector and the extent of movement required to correct the deformity (Figure 3).

3-D anatomical models have been used as successful hands-on tools for contouring the footplates, aligning the distractors, and making the osteotomy prior to surgery. They also aid in documenting the preoperative condition of the patient. If a 3-D model is not attainable, bending of the footplates can be achieved intraoperatively (Figure 4).

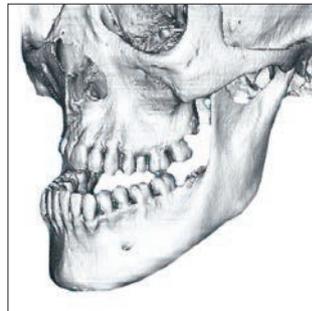


Figure 1

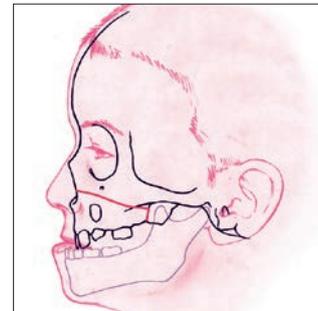


Figure 2

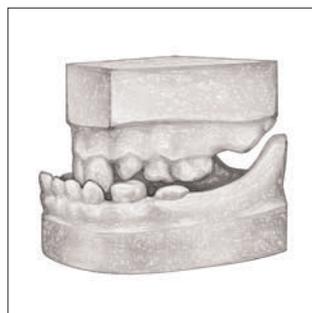


Figure 3



Figure 4

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**▲ Precautions:**

- Do not activate the distractors during model surgery, as the distractors are designed for a single activation cycle only. Activation beyond one cycle could cause the distractors to bind.
- When placing the distractors, consider and verify:
  - Occlusal plane
  - Tooth buds and roots
  - Planned vector of distraction
  - Planned length of advancement  
(consider relapse and overcorrection)
  - Adequate bone quality for screw placement
  - Location of nerves
  - Lip closure
  - Soft tissue coverage
  - Patient pain due to distractor interference with soft tissue
  - Access to the screws based on approach

# Distractor Assembly for Maxillary Fixation

## 1. Choose distractor body

Choose the proper length distractor body (10 mm, 15 mm, 20 mm, or 25 mm) according to the planned amount of distraction.

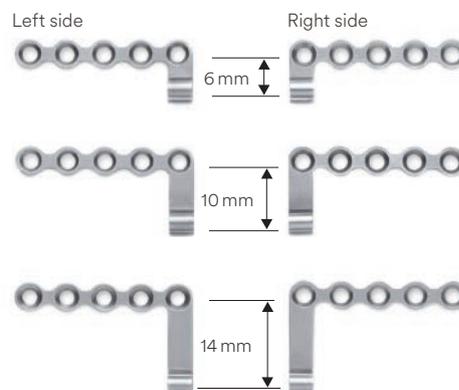
### ■ Note:

During the distraction process, the distractor body will remain in a fixed position while the soft tissue advances with the maxilla toward the front of the distractor body. To ensure the soft tissue does not obstruct the engagement of the activation screwdriver and the activation hex, the next longer size distractor body may be used.



## 2. Choose anterior footplate

Choose the anterior footplate size according to the treatment plan, giving specific consideration to the patient's anatomy and screw placement.

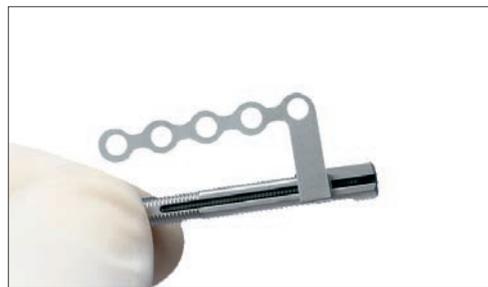
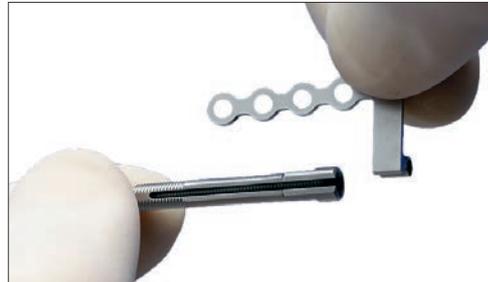


### 3. Insert anterior footplate

Insert the anterior footplate into the back of the distractor body. Ensure that the screw holes are superior to the distractor body for attachment to the maxilla. Turn the activation hex counterclockwise to engage the anterior footplate. (Right assembly shown.)

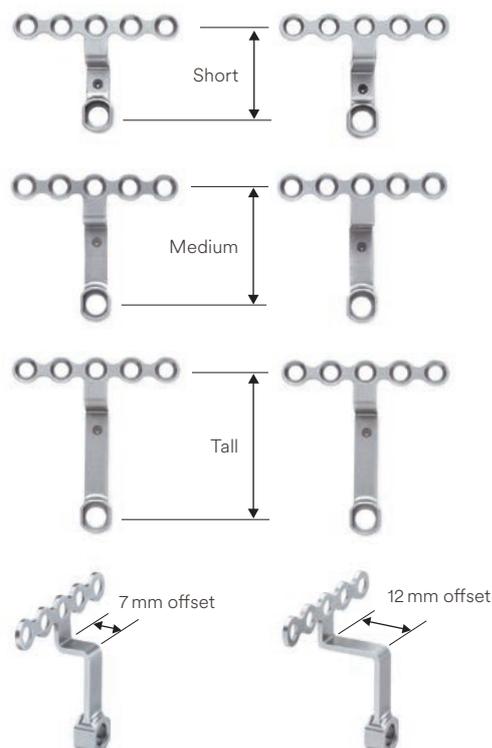
■ **Note:**

When the distractor is fully assembled, the slot on the distractor body must face medially while the countersinks of the screw holes on the anterior footplate must face laterally.



### 4. Choose posterior footplate

Choose the posterior footplate size according to the treatment plan, giving specific consideration to the patient's anatomy and screw placement.



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## 5. Attach posterior footplate

Attach the posterior footplate by engaging the distractor body into the posterior footplate.

■ **Note:**

When the distractor is fully assembled, the countersinks of the screw holes on the posterior footplate should face anteriorly.



## 6. Insert machine screw (Oval Head Screw)

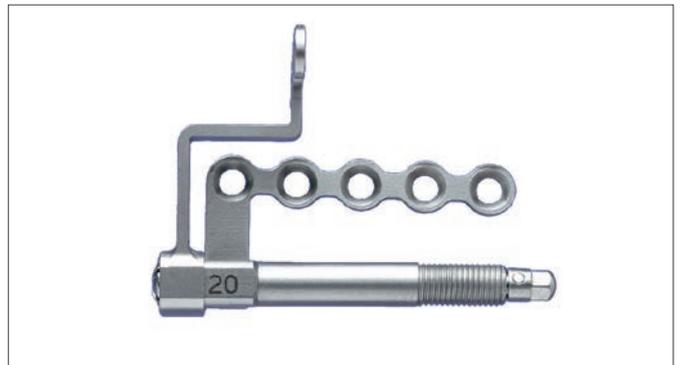
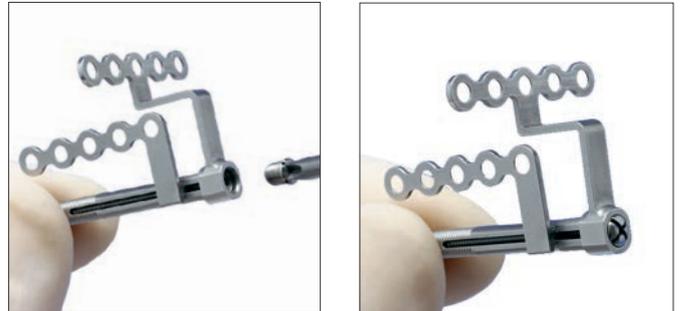
### Instrument

314.441	Screwdriver Shaft 1.5/2.0, cruciform, self-holding, length 66 mm
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Using the Screwdriver Shaft 1.5/2.0, insert the 3.5 mm machine screw (Oval Head Screw) through the posterior footplate and into the distractor body, locking the construct together. Verify that the machine screw (Oval Head Screw) is fully seated in the distractor. (Right assembly shown.)

### ■ Note:

Once the distractor is fully assembled, ensure that the anterior footplate is in the “home” position by turning the activation hex clockwise until the anterior footplate meets the posterior footplate.



## 7. Repeat steps 1 through 6 for the left assembly.

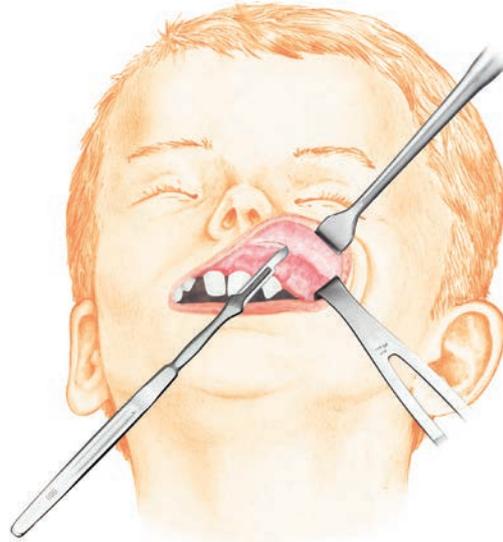
# Surgical Technique for Maxillary Fixation

## 1. Make intraoral incision

Make a maxillary vestibular incision. Elevate the periosteum to expose the maxilla and zygoma. Repeat on the contralateral side.

### ■ Note:

In bilateral cleft patients, it may be preferred to leave the labial soft tissue pedicle attached to the anterior maxilla to preserve the blood supply to this area.



## 2. Fit distractor

The assembly should be placed with the distractor body set just above the level of the occlusion.

### ▲ Precaution:

When placing the distractors consider and verify:

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

### ■ Note:

It may be necessary to slightly reduce the anterior-inferior zygoma at the buttress to allow proper adaptation of the distraction device.



## Optional technique

### Instrument

395.101	Alignment Rod for Maxillary Distractor, monoaxial
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The alignment rods may be used throughout the course of the surgery to:

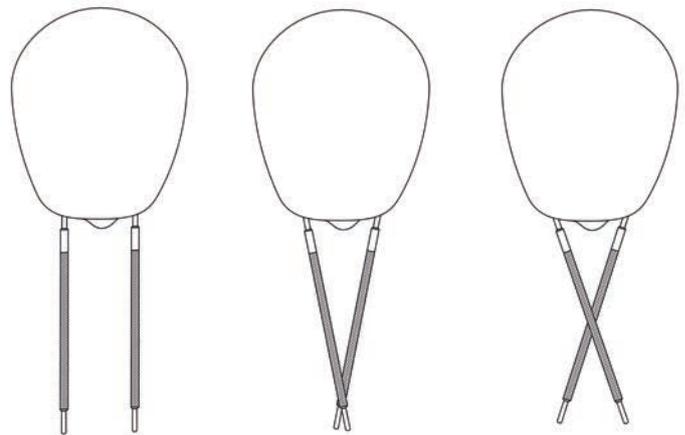
- Aid in the parallel placement of the device;
- Indicate vectors of advancement;
- Hold the distractors during screw placement.

### ▲ WARNING:

The alignment rods should not be used as leverage for bending the footplates as this may cause damage to the distractor bodies.

### ■ Notes:

- While parallel placement of the distractors would be ideal, from a practical standpoint this may traumatize the buccal soft tissue and cause discomfort to the patient. A slight convergence of the distraction vectors is acceptable to ensure patient comfort.
- The point of convergence should be farther from the patient in larger maxillary advancements and can be closer to the patient in smaller maxillary advancements.



Ideal

Acceptable

Not preferable

### 3. Contour footplates

#### Instruments

347.964	Bending Pliers 3D, left, for Plates 1.0 to 2.0, with contour-bending function
391.965	Combined Pliers for Plates 1.0 to 2.0, for Cutting and Bending

Bend the footplates to fit the patient's anatomy, using the combination bending pliers.

#### Contouring recommendations

##### Posterior footplate

- The vertical component of the posterior footplate can be twisted to angle the distractor body closer to the teeth (Figures 1 and 2).
- The vertical and horizontal components of the posterior footplate can be angled to achieve a downward advancement (Figures 3 and 4).
- The medial screw holes of the posterior footplate can be bent anteriorly while the lateral screw holes can be bent posteriorly (S-Bend) (Figures 5 and 6).

##### Anterior footplate

- The vertical component of the anterior footplate can be bent to angle the screw holes toward the maxilla. Be sure to grasp the distractor where the anterior footplate and distractor meet. This will avoid damaging the internal mechanism of the distractor (Figures 7, 8 and 13).

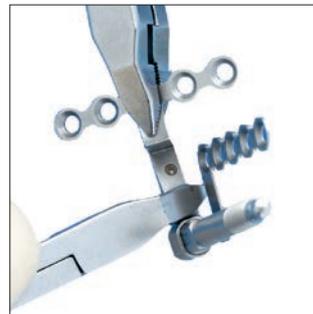


Figure 1



Figure 2



Figure 3



Figure 4



Figure 5



Figure 6



Figure 7



Figure 8

- An in-plane bend on the anterior footplate allows screw holes to be bent upward to avoid the tooth buds or tooth roots in the maxilla (Figures 9 and 10).
- An out-of-plane bend on the anterior footplate allows the screw holes to be contoured around the maxilla (Figures 11 and 12).

**▲ WARNING:**

Excessive and reverse bending or the use of incorrect instrumentation for bending may weaken the footplate and lead to premature footplate failure (e.g. breakage). Do not bend the footplate beyond what is required to match the anatomy.

**■ Notes:**

- Be sure to grasp the distractor where the anterior footplate and distractor meet (Figure 13).
- Contouring the footplates to a 3-D anatomical model prior to surgery potentially reduces operating time.

Undesired screw holes can be removed using the Combined Pliers for Plates for Cutting and Bending.

**▲ Precautions:**

- At least three screws must be used in each footplate to ensure adequate stability.
- Footplate 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.

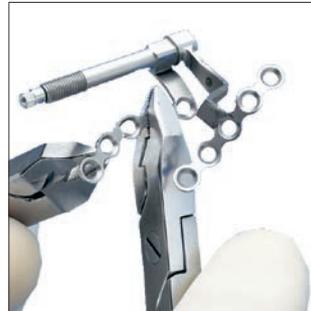


Figure 9



Figure 10



Figure 11



Figure 12



Figure 13

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## 4. Mark distractor location

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### Instruments

311.011	Handle, small, with Mini Quick Coupling
314.441	Screwdriver Shaft 1.5/2.0, cruciform, self-holding, length 66 mm
317.720	Drill Bit $\varnothing$ 1.5 mm with Stop, length 44.5/12 mm, 2-flute, for J-Latch Coupling

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Place the assembly in the predetermined location. Using the 1.5 mm drill bit, drill one hole through the posterior footplate and insert the desired length 2.0 mm screw into the zygoma. Next, drill one hole through the anterior footplate and insert the desired length 2.0 mm screw into the maxilla.



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### ▲ Precautions:

- The screws should not be fully tightened, as they will be removed prior to performing the osteotomy.
- 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/lingual structures.
- Screws can loosen during the course of treatment if placed in poor quality bone.
- 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.
- Use the drill bit size assigned for the system screw.
- Take care to avoid nerves, tooth buds, roots or other critical structures when drilling and/or placing screws.
- Take care while drilling as to not damage, entrap, or tear a patient's soft tissue or damage critical structures. 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.

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## 5. Repeat steps 2 through 4 on the contralateral side

Use the alignment rods to verify the distractors are parallel to the desired vectors of advancement.

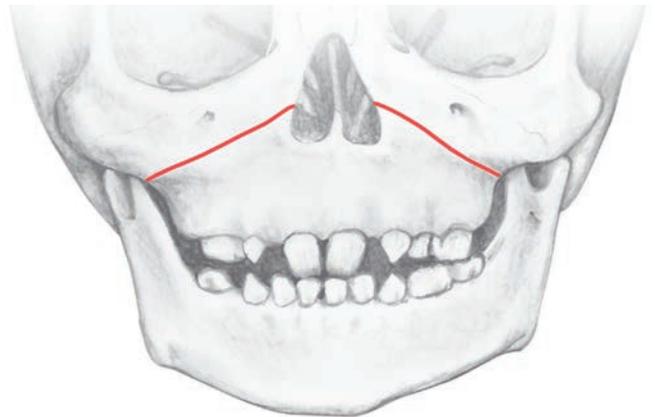
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## 6. Perform LeFort I osteotomy

Mark out the planned osteotomy allowing for clearance of the distractors. Unscrew and remove the distraction devices. Perform the LeFort I osteotomy. Ensure the maxilla is completely mobile and the only holding force is the soft tissue.

### ▲ Precaution:

The osteotomy must be complete and the bone must be completely mobile. The distractor is not designed or intended to break bone and/or complete the osteotomy. Take care to avoid nerves.



## 7. Reattach distractors

### Instruments

311.011	Handle, small, with Mini Quick Coupling
314.441	Screwdriver Shaft 1.5/2.0, cruciform, self-holding, length 66 mm
317.720	Drill Bit $\varnothing$ 1.5 mm with Stop, length 44.5/12 mm, 2-flute, for J-Latch Coupling

Once the osteotomy is complete, reattach the distractors on both sides by aligning the footplates with previously drilled holes. Reinsert the screws in the posterior and anterior footplates. Drill and place the remaining screws in the desired locations. Fully tighten all screws.

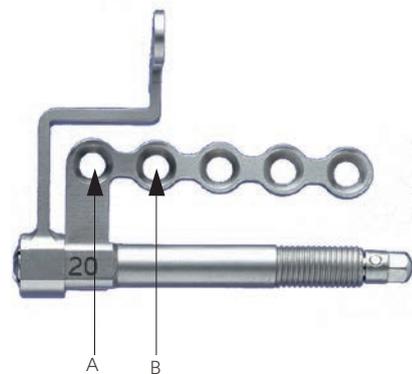
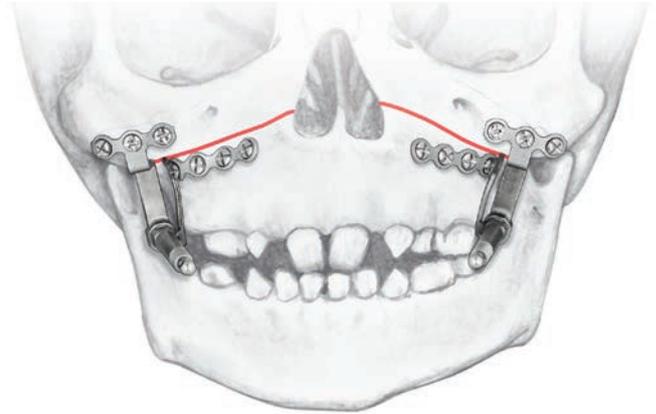
### ▲ Precautions:

- One or both of the holes (A) and (B) on the anterior footplate must contain a screw.
- A minimum of three screws must be placed in each footplate for adequate stability.

### ■ Note:

Once the distractors are attached, use the alignment rods to verify that the vectors of advancement have not changed.

Please refer section 4 for Precautions for Drill Bits.



## 8. Confirm device stability and activation

### Instrument

314.404      Activation Screwdriver, for Maxillary Distractor, monoaxial

Using the activation instrument, turn each distractor in a counterclockwise direction, as marked on the screwdriver's handle, to confirm the stability of the distractor. The maxilla will advance upon activation of the distractors. Before closure, return the distractor to its original position. Close all incisions.



# Considerations for Dental Splint Fixation

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## Preparation of the dental splint before surgery

- The splint can be fabricated on dental models in the laboratory prior to surgery.
- Mix the cold-cured acrylic powder and monomer solution according to the manufacturer's instructions.

## Considerations in splint design

- The occlusal surface, as well as the lateral surfaces of the splint, should be parallel to the vectors of distraction.
- Splint thickness must be a minimum of 5 mm in order to place the fixation screws.
- The lateral surfaces of the splint should have minimal projection (no more than 2 mm), and should allow for placement of screws without contacting teeth.
- The occlusal surface should be smooth to prevent interference with the mandibular teeth during distraction.

# Distractor Assembly for Dental Splint Fixation

## 1. Choose distractor body

Choose the proper length distractor body (10 mm, 15 mm, 20 mm, or 25 mm) according to the planned amount of distraction.

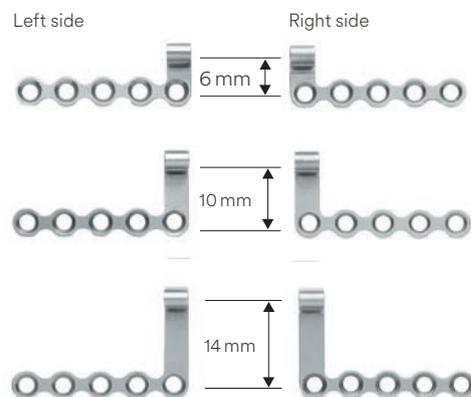
### ■ Note:

During the distraction process, the distractor body will remain in a fixed position while the soft tissue advances with the maxilla toward the front of the distractor body. To ensure the soft tissue does not obstruct the engagement of the activation screwdriver and the activation hex, the next longer size distractor body may be used.



## 2. Choose anterior footplate

Choose the anterior footplate size according to the treatment plan, giving specific consideration to the patient's anatomy and screw placement on the dental splint.



### 3. Insert anterior footplate

Insert the anterior footplate into the back of the distractor body. Ensure that the screw holes are inferior to the distractor body for attachment to the dental splint. Turn the activation hex counterclockwise to engage the anterior footplate. (Right assembly shown.)

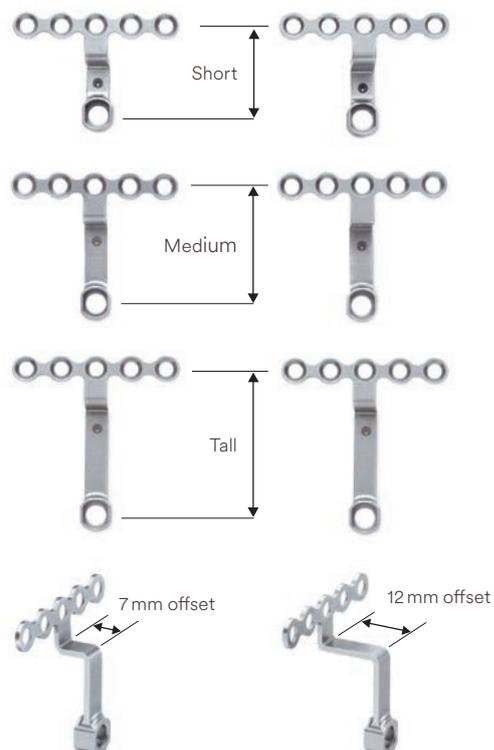
■ **Note:**

When the distractor is fully assembled, the slot on the distractor body must face medially while the countersinks of the screw holes on the anterior footplate must face laterally.



### 4. Choose posterior footplate

Choose the posterior footplate size according to the treatment plan, giving specific consideration to the patient's anatomy and screw placement.



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## 5. Attach posterior footplate

Attach the posterior footplate by engaging the distractor body into the posterior footplate.

■ **Note:**

When the distractor is fully assembled, the countersinks of the screw holes on the posterior footplate should face anteriorly.



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## 6. Insert machine screw (Oval Head Screw)

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### Instrument

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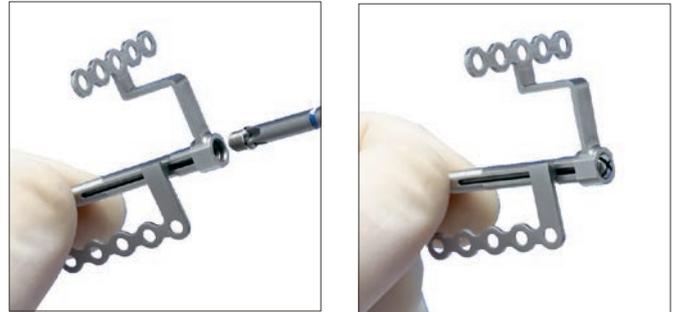
314.441	Screwdriver Shaft 1.5/2.0, cruciform, self-holding, length 66 mm
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Using the 2.4 mm screwdriver, insert the 3.5 mm machine screw (Oval Head Screw) through the posterior footplate and into the distractor body, locking the construct together. Verify that the machine screw (Oval Head Screw) is fully seated in the distractor. (Right assembly shown.)

### ■ Note:

Once the distractor is fully assembled, ensure that the anterior footplate is in the “home” position by turning the activation hex clockwise until the anterior footplate meets the posterior footplate.



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## 7. Repeat steps 1 through 6 for the left assembly.

# Surgical Technique for Dental Splint Fixation

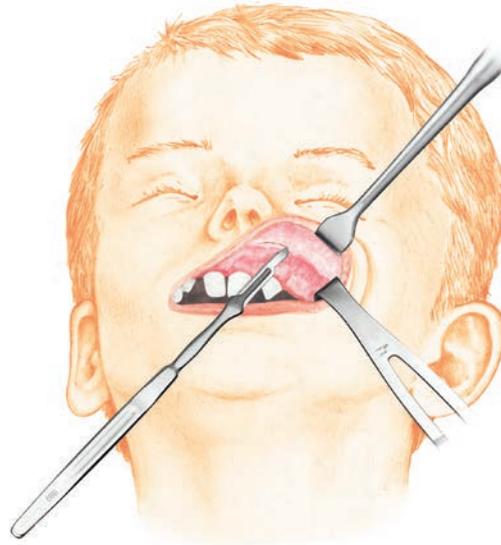
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## 1. Make intraoral incision

Make a maxillary vestibular incision. Elevate the periosteum to expose the maxilla and zygoma. Repeat on the contralateral side.

### ■ Note:

In bilateral cleft patients, it may be preferred to leave the labial soft tissue pedicle attached to the anterior maxilla to preserve the blood supply to this area.



---

## 2. Fit distractor

The assembly should be placed with the distractor body set just above the level of the occlusion.

### ▲ Precaution:

When placing the distractors consider and verify:

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

### ■ Notes:

- It may be necessary to slightly reduce the anterior-inferior zygoma at the buttress to allow proper adaptation of the distraction device.
- The dental splint should not be permanently affixed to the patient's teeth at this point, as it will be removed with the distractors prior to making the osteotomy.



## Optional technique

### Instrument

395.101	Alignment Rod for Maxillary Distractor, monoaxial
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The alignment rods may be used throughout the course of the surgery to:

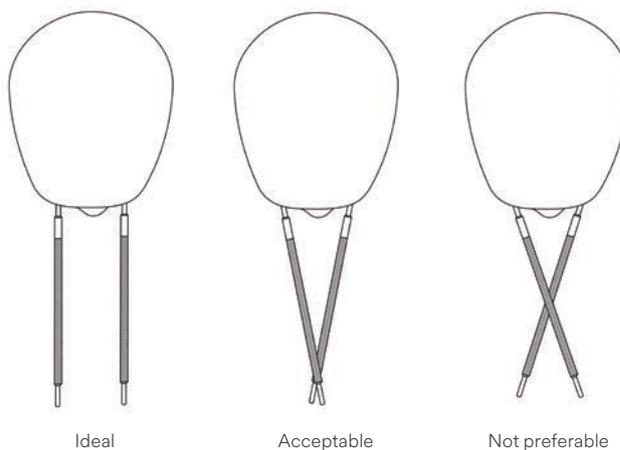
- Aid in the parallel placement of the device;
- Indicate vectors of advancement;
- Hold the distractors during screw placement.

### ▲ WARNING:

The alignment rods should not be used as leverage for bending the footplates as this may cause damage to the distractor bodies.

### ■ Notes:

- While parallel placement of the distractors would be ideal, from a practical standpoint this may traumatize the buccal soft tissue and cause discomfort to the patient. A slight convergence of the distraction vectors is acceptable to ensure patient comfort.
- The point of convergence should be farther from the patient in larger maxillary advancements and can be closer to the patient in smaller maxillary advancements.



### 3. Contour footplates

#### Instruments

347.964	Bending Pliers 3D, left, for Plates 1.0 to 2.0, with contour-bending function
391.965	Combined Pliers for Plates 1.0 to 2.0, for Cutting and Bending

Bend the footplates to fit the patient's anatomy, using the combination bending pliers.

#### Contouring recommendations

##### Posterior footplates

- The vertical component of the posterior footplate can be twisted to angle the distractor body closer to the teeth (Figures 1 and 2).
- The vertical and horizontal components of the posterior footplate can be angled to achieve a downward advancement (Figures 3 and 4).
- The medial screw holes of the posterior footplate can be bent anteriorly while the lateral screw holes can be bent posteriorly (S-Bend) (Figures 5 and 6).

##### Anterior footplate

- The vertical component of the anterior footplate can be bent to angle the screw holes toward the dental splint. Be sure to grasp the distractor where the anterior footplate and distractor meet. This will avoid damaging the internal mechanism of the distractor (Figures 7, 8 and 11).



Figure 1



Figure 2



Figure 3



Figure 4



Figure 5



Figure 6



Figure 7



Figure 8

- An out-of-plane bend on the anterior footplate allows the screw holes to be contoured around the dental splint (Figures 9 and 10).

**▲ WARNING:**

Excessive and reverse bending or the use of incorrect instrumentation for bending may weaken the footplate and lead to premature footplate failure (e.g. breakage). Do not bend the footplate beyond what is required to match the anatomy.

**■ Notes:**

- Be sure to grasp the distractor where the anterior footplate and distractor meet (Figure 11).
- Contouring the footplates to a 3-D anatomical model prior to surgery potentially reduces operating time.

Undesired screw holes can be removed using Combined Pliers for Plates for Cutting and Bending.

**▲ Precautions:**

- At least three screws must be used in each footplate to ensure adequate stability.
- 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.



Figure 9



Figure 10



Figure 11

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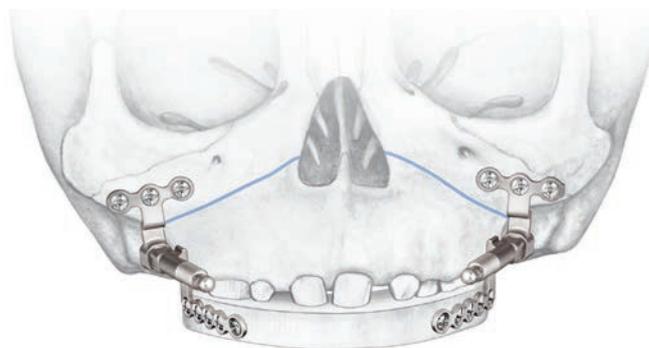
## 4. Mark distractor location

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### Instruments

311.011	Handle, small, with Mini Quick Coupling
314.441	Screwdriver Shaft 1.5/2.0, cruciform, self-holding, length 66 mm
317.720	Drill Bit $\varnothing$ 1.5 mm with Stop, length 44.5/12 mm, 2-flute, for J-Latch Coupling

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Place the assembly in the predetermined location. Using the 1.5 mm drill bit, drill one hole through the posterior footplate and insert the desired length 2.0 mm screw into the zygoma. Next, drill two holes through the anterior footplate and insert the desired length 2.0 mm screws into the dental splint.

**▲ Precautions:**

- The screw in the posterior footplate should not be fully tightened, as it will be removed prior to performing the osteotomy. The two screws in the anterior footplate can be fully tightened.
- 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/lingual structures.
- Screws can loosen during the course of treatment if placed in poor quality bone.
- 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.
- Use the drill bit size assigned for the system screw.
- Take care to avoid nerves, tooth buds, roots or other critical structures when drilling and/or placing screws.
- Take care while drilling as to not damage, entrap, or tear a patient's soft tissue or damage critical structures. 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.

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## 5. Repeat steps 2 through 4 on the contralateral side

Use the alignment rods to verify the distractors are parallel to the desired vectors of advancement.

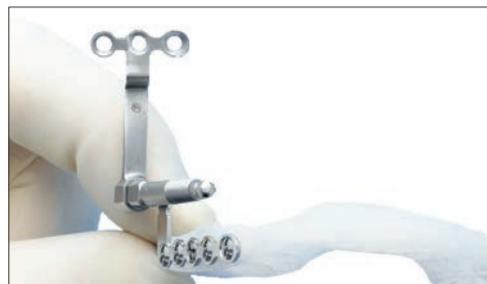
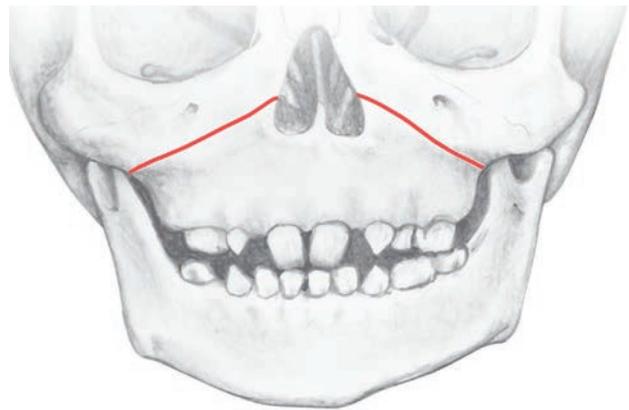
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## 6. Perform LeFort I osteotomy

Mark out the planned osteotomy allowing for clearance of the distractors. Remove the screws in the posterior footplates only. This will allow the distractors and dental splint to be removed in one piece. Perform the LeFort I osteotomy. Ensure the maxilla is completely mobile and the only holding force is the soft tissue.

### ▲ Precaution:

The osteotomy must be complete and the bone must be completely mobile. The distractor is not designed or intended to break bone and/or complete the osteotomy. Take care to avoid nerves.



## 7. Reattach distractors

### Instruments

311.011	Handle, small, with Mini Quick Coupling
314.441	Screwdriver Shaft 1.5/2.0, cruciform, self-holding, length 66 mm
317.720	Drill Bit $\varnothing$ 1.5 mm with Stop, length 44.5/12 mm, 2-flute, for J-Latch Coupling

Once the osteotomy is complete, realign the distractors and dental splint with the previously drilled holes in the zygoma. Affix the dental splint to the patient's teeth with arch bar wiring, interdental wiring, circummaxillary wiring, or wiring to orthodontic brackets. Reinsert the screws in the posterior footplates. Drill and place the remaining screws in the desired locations. Fully tighten all screws.

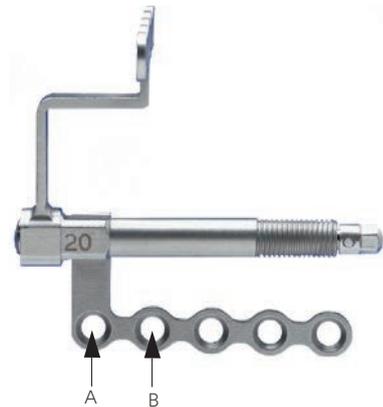
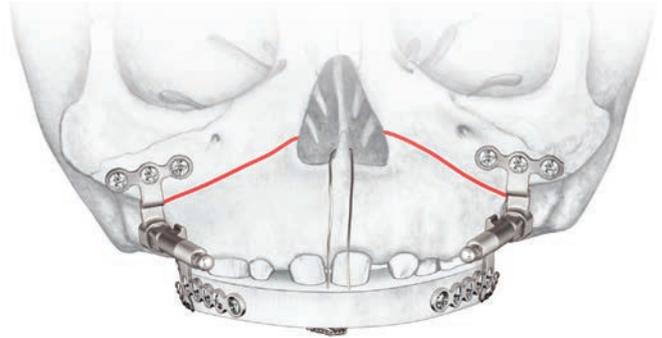
### ▲ Precautions:

- One or both of the holes (A) and (B) on the anterior footplate must contain a screw.
- A minimum of three screws must be placed in each footplate for adequate stability.

### ■ Note:

Once the distractors are attached, use the alignment rods to verify that the vectors of advancement have not changed.

Please refer section 4 for Precautions for Drill Bits.



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## 8. Confirm device stability and activation

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### Instrument

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314.404	Activation Screwdriver, for Maxillary Distractor, monoaxial
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Using the activation instrument, turn each distractor in a counterclockwise direction, as marked on the screwdriver's handle, to confirm the stability of the distractor. The maxilla will advance upon activation of the distractors. Before closure, return the distractor to its original position. Close all incisions.



# Postoperative Considerations

## Suggested distraction protocol

Distraction should begin three to five days after device placement. For young patients, active distraction can begin earlier, to prevent premature consolidation. To achieve lengthening, engage the activation hex with the activation instrument and rotate counterclockwise (in direction of arrow marked on the instrument).

Each complete rotation equals 0.5 mm of distraction. It is recommended to perform one turn twice a day, or alternatively, a half turn four times a day if the patient experiences pain or discomfort.

### ▲ Precaution:

A rate of 1.0 mm of distraction per day is recommended to prevent premature consolidation.



Activation instrument

## Patient Care Document progress

Distraction progress should be observed by documenting the changes in the anterior maxillary and mandibular occlusion. A Patient Care Guide is included with the activation instrument to help record and monitor distraction progress.

### ■ Note:

The patient should be advised on maintaining good oral hygiene during all phases of treatment.

### ▲ 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 and contact their surgeon immediately if they lose the activation instrument.

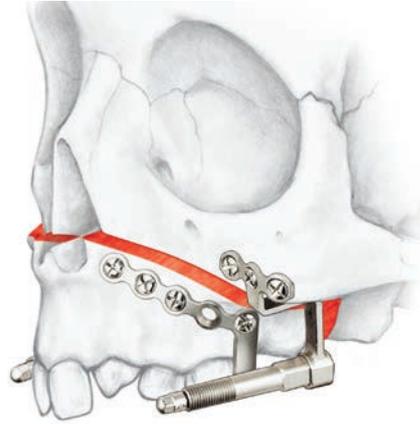
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## Consolidation phase

After the desired advancement has been achieved, the new bone must be given time to consolidate.

### ■ Note:

An optional consolidation technique is to remove the distractors early in the consolidation phase and replace them with DePuy Synthes CMF orthognathic plates and screws. At this time, special consideration can be given to the occlusion, and the maxilla may be adjusted to maximize the dental interdigitation with the mandibular teeth.



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## Device removal

### Instruments

311.011	Handle, small, with Mini Quick Coupling
314.441	Screwdriver Shaft 1.5/2.0, cruciform, self-holding, length 66 mm

After the consolidation period, remove the distractors by exposing the anterior and posterior footplates through the same maxillary vestibular incision, and removing the bone screws.

### ▲ Precaution:

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

# Instruments

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311.011 Handle, small, with Mini Quick Coupling



---

314.404 Activation Screwdriver, for Maxillary Distractor, monoaxial



---

314.441 Screwdriver Shaft 1.5/2.0, cruciform, self-holding, length 66 mm



---

317.720 Drill Bit Ø 1.5 mm with Stop, length 44.5/12 mm, 2-flute, for J-Latch Coupling



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347.964 Bending Pliers 3D, left, for Plates 1.0 to 2.0, with contour-bending function



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391.965 Combined Pliers for Plates 1.0 to 2.0, for Cutting and Bending



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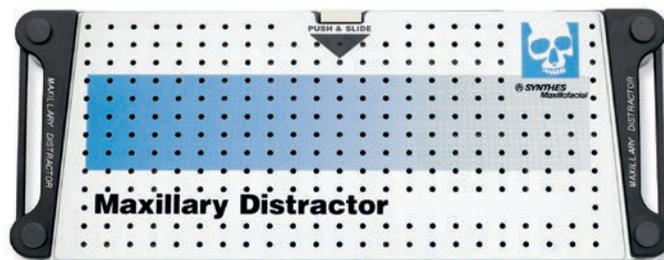
395.101 Alignment Rod for Maxillary Distractor, monoaxial



# Maxillary Distractor Set (115.629)

## Modules and Trays

304.686	Instrument Tray
304.687	Lid, for No. 304.686
304.753	Module for Maxillary Distractor, monoaxial, with Lid, without Contents



## Length Markers, black (10/pkg)

304.104	type 4
304.106	type 6
304.108	type 8
304.110	type 10
311.011	Handle, small, with Mini Quick Coupling, 2 ea
314.404	Activation Screwdriver, for Maxillary Distractor, monoaxial, 2 ea
314.441	Screwdriver Shaft 1.5/2.0, cruciform, self-holding, length 66 mm
317.720*	Drill Bit $\varnothing$ 1.5 mm with Stop, length 44.5/12 mm, 2-flute, for J-Latch Coupling, 2 ea
347.964	Bending Pliers 3D, left, for Plates 1.0 to 2.0, with contour-bending function, 2 ea
391.965	Combined Pliers for Plates 1.0 to 2.0, for Cutting and Bending
395.101	Alignment Rod for Maxillary Distractor, monoaxial, 4 ea

\* Available non-sterile or sterile-packed; for sterile parts, add suffix "S" to the part number; e.g. 317.720S

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## Implants

### Cortex Screws $\varnothing$ 2.0 mm, self-tapping, Stainless Steel

201.804*	length 4 mm
201.806*	length 6 mm
201.808*	length 8 mm
201.810*	length 10 mm
201.812*	length 12 mm
201.814*	length 14 mm

### Cortex Screws $\varnothing$ 2.4 mm, self-tapping, Stainless Steel

201.506*	length 6 mm
201.508*	length 8 mm
201.510*	length 10 mm
201.512	length 12 mm
201.514	length 14 mm

### Maxillary Distractor Main Body, monoaxial, 4 ea.

	Distraction length (mm)
288.025*	10
288.026*	15
288.027*	20
288.028*	25

\* Available non-sterile or sterile-packed; for sterile parts, add suffix "S"  
to the part number; e.g. 317.720S

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**Anterior Foot Plate, right, for Maxillary Distractor,  
monoaxial, 2 ea**

	Height (mm)
288.038*	6
288.039*	10
288.040*	14

**Anterior Foot Plate, left, for Maxillary Distractor,  
monoaxial, 2 ea**

	Height (mm)
288.042*	6
288.043*	10
288.044*	14

**Posterior Foot Plate, for Maxillary Distractor,  
monoaxial, 4 ea**

288.052*	15×7 mm
288.053*	15×12 mm
288.055*	20×7 mm
288.056*	20×12 mm
288.058*	25×7 mm
288.059*	25×12 mm

288.065*	Oval Head Screw (Machine Screw) Ø 3.5 mm, for Maxillary Distractor, monoaxial, 4 ea
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\* Available non-sterile or sterile-packed; for sterile parts, add suffix "S" to the part number; e.g. 288.025S.



Please refer to the corresponding Instructions for Use for specific information on Intended use, Indications, Contraindications, Warnings and Precautions, Potential Adverse Events, Undesirable Side Effect and Residual Risks. Instruction for Use are available at [www.e-ifu.com](http://www.e-ifu.com) and/or [www.depuysynthes.com/ifu](http://www.depuysynthes.com/ifu)

Not all products are currently available in all markets.  
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