Maxillary Distractor System. A modular system for gradual advancement of the maxilla utilizing a LeFort I osteotomy.
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The maxillary distractor can be customized to meet the anatomical needs of pediatric and adult patients, based on preoperative treatment planning. Distraction of the maxilla is accomplished bilaterally using a left and a right assembly.

**Features**
- 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 mm stainless steel 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
Indications

The Maxillary Distractor System is intended for use in craniofacial surgery, reconstructive procedures, and selective orthognathic surgery of the maxilla. Specifically, it is intended for distraction of the maxilla utilizing a LeFort I osteotomy in adult and pediatric populations.
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).

**Precaution:** 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.
Distractor Assembly for Maxillary Fixation

1

Choose distractor body

Choose the proper length distractor body 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.
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

Instrument

313.925 2.4 mm Screwdriver, self-retaining

Using the 2.4 mm screwdriver, insert the 3.5 mm machine screw through the posterior footplate and into the distractor body, locking the construct together. Verify that the machine 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.
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. Consider the following factors when placing the device:
- Occlusal plane
- Tooth roots
- Planned vector of distraction
- Adequate bone for screw placement
- Lip closure
- Soft tissue (mucosa) coverage

Technique tip: 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 |

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.

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

**Technique tips:** 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.
Contour footplates

**Instruments**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>347.964</td>
<td>Combination Bending Pliers, for 1.0 mm–2.0 mm plates</td>
</tr>
<tr>
<td>391.990</td>
<td>Plate and Rod Cutter</td>
</tr>
</tbody>
</table>

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).
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).

Notes: Be sure to grasp the distractor where the anterior footplate and distractor meet (Figure 13).

Repeated bending can lead to decreased strength of the footplates.

Contouring the footplates to a 3-D anatomical model prior to surgery reduces operating time and difficulty.

At least three screws must be used in each footplate to ensure adequate stability. Undesired screw holes can be removed using the plate and rod cutter (Figure 14).
4  
**Mark distractor location**

**Instrument**

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>311.03</td>
<td>Handle, with mini quick coupling</td>
</tr>
<tr>
<td>314.67</td>
<td>1.5 mm/2.0 mm Cruciform Screwdriver Blade, with holding sleeve, short</td>
</tr>
<tr>
<td>317.72</td>
<td>1.5 mm Drill Bit, Stryker J-latch, with 12 mm stop</td>
</tr>
</tbody>
</table>

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.

**Note:** These screws should not be fully tightened, as they will be removed prior to performing the osteotomy.

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.

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.

**Important:** The maxilla must be completely mobile as the distractors are not intended to complete the osteotomy.
Reattach distractors

<table>
<thead>
<tr>
<th>Instrument</th>
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<tbody>
<tr>
<td>311.03</td>
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</table>

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.

**Note:** 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.

**Technique tip:** Once the distractors are attached, use the alignment rods to verify that the vectors of advancement have not changed.
### 8

**Confirm device stability and activation**

<table>
<thead>
<tr>
<th>Instrument</th>
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<tbody>
<tr>
<td>314.404  Activation Instrument, 2.8 mm hex</td>
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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 each device to its original position.

**Technique tip:** Silicone tip guards can be inserted over the activation end of the distractor body to help prevent soft tissue irritation. The tip guards need to be removed in order for the distractor to be activated and can be reinserted after activation.
Considerations for Dental Splint Fixation

**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 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.
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

Instrument

| 313.925 | 2.4 mm Screwdriver, self-retaining |

Using the 2.4 mm screwdriver, insert the 3.5 mm machine screw through the posterior footplate and into the distractor body, locking the construct together. Verify that the machine 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.
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. Consider the following factors when placing the device:
- Occlusal plane
- Placement of the dental splint
- Adequate bone for screw placement
- Planned vector of distraction
- Lip closure
- Soft tissue (mucosa) coverage

Technique tips: 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

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.

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

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

**Notes:** Be sure to grasp the distractor where the anterior footplate and distractor meet (Figure 11).

Repeated bending can lead to decreased strength of the footplates.

Contouring the footplates to a 3-D anatomical model prior to surgery reduces operating time and difficulty.

At least three screws must be used in each footplate to ensure adequate stability. Undesired screw holes can be removed using the plate and rod cutter (Figure 12).
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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.

**Note:** 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.

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.
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.

Important: The maxilla must be completely mobile as the distractors are not intended to complete the osteotomy.
Reattach distractors

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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.

**Note:** 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.

**Technique tip:** Once the distractors are attached, use the alignment rods to verify that the vectors of advancement have not changed.
Confirm device stability and activation

**Instrument**

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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 each device to its original position.

**Technique tip:** Silicone tip guards can be inserted over the activation end of the distractor body to help prevent soft tissue irritation. The tip guards need to be removed in order for the distractor to be activated and can be reinserted after activation.
Suggested distraction protocol
Distraction should begin four to six days after device placement. 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.

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

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.
Consolidation phase
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.

Note: An optional consolidation technique is to remove the distractors early in the consolidation phase and replace them with Synthes 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.¹

Device removal
The devices can be removed by exposing the anterior and posterior footplates through the same maxillary vestibular incision.

<table>
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<tr>
<th>Code</th>
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<td>Silicone Tip Guard</td>
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<tr>
<td>313.925</td>
<td>2.4 mm Screwdriver, self-retaining</td>
</tr>
<tr>
<td>314.404</td>
<td>Activation Instrument, 2.8 mm hex</td>
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<td>Description</td>
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<td>--------------------------------------------------</td>
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<tr>
<td>391.990</td>
<td>Plate and Rod Cutter</td>
</tr>
<tr>
<td>395.101</td>
<td>Alignment Rod, for Maxillary Distractor</td>
</tr>
</tbody>
</table>
Maxillary Distractor Set (115.628)

Modules and Trays
304.686 Instrument Tray, Universal
304.687 Instrument Tray Lid, Universal
304.753 Maxillary Distractor Module Case

Instruments
03.307.002 Silicone Tip Guard, 2 ea.

Screw Length Markers (10/pkg.)
304.104 4 mm
304.106 6 mm
304.108 8 mm
304.110 10 mm

311.03 Handle, with mini quick coupling, 2 ea.
313.925 2.4 mm Screwdriver, self-retaining
314.404 Activation Instrument, 2.8 mm hex, 2 ea.
314.67 1.5 mm/2.0 mm Cruciform Screwdriver Blade, with holding sleeve, short, 2 ea.
317.72 1.5 mm Drill Bit, Stryker J-latch, with 12 mm stop, 2 ea.
347.964 Combination Bending Pliers, for 1.0 mm–2.0 mm plates, 2 ea.
391.990 Plate and Rod Cutter
395.101 Alignment Rod, for Maxillary Distractor, 4 ea.

Implants
2.0 mm Cortex Screws, self-tapping

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<td>201.810.98</td>
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2.4 mm Cortex Screws, self-tapping, 5 ea.
(For use as emergency screws)

<table>
<thead>
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<td>201.508</td>
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<td>201.510</td>
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Note: For additional information, please refer to package insert.

For detailed cleaning and sterilization instructions, please refer to http://www.synthes.com/sites/NA/MedicalCommunity/Pages/Cleaning_and_Sterilization.aspx or to the below listed inserts which will be included in the shipping container:
—Processing Synthes Reusable Medical Devices—Instruments, Instrument Trays and Graphic Cases—DJ1305
—Processing Non-sterile Synthes Implants—DJ1304
<table>
<thead>
<tr>
<th>Description</th>
<th>Details</th>
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<tbody>
<tr>
<td><strong>Maxillary Distractor Bodies, 4 ea.</strong></td>
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<td>Length (mm)</td>
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<td>288.027</td>
<td>20</td>
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<td>288.028</td>
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<tr>
<td><strong>Anterior Footplates, maxilla right/splint left, 2 ea.</strong></td>
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<td>7 medium</td>
</tr>
<tr>
<td>288.056</td>
<td>12 medium</td>
</tr>
<tr>
<td>288.058</td>
<td>7 tall</td>
</tr>
<tr>
<td>288.059</td>
<td>12 tall</td>
</tr>
<tr>
<td>288.065</td>
<td>3.5 mm Machine Screw, 4 ea.</td>
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