Curvilinear Distraction System.
Internal distraction osteogenesis device that advances the mandible along a curved trajectory.
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**Curvilinear Distraction System.** Internal distraction osteogenesis device that advances the mandible along a curved trajectory.

**Distractor**
- Advances along a curved track to promote bone growth along both horizontal and vertical vectors to avoid the creation of, or to close, an anterior open bite.
- Available in various radii of curvature to accommodate individual patient’s needs (Also available in a straight version)
- Capable of 35 mm of advancement

**Flexible extension arm**
- Lies passively in the soft tissue
- Moves the point of activation to an area easily accessible by the activation instrument
- Available in 30 mm, 40 mm and 60 mm lengths
- Includes a protective silicone covering to minimize soft tissue interference
- Removed during the consolidation phase without a surgical procedure

**Footplates**
- Have threaded holes and accept 2.0 mm locking screws for added stability (Also accepts nonlocking screws)
- Designed to withstand repeated bending and contouring*

* Mechanical test data on file at Synthes. Mechanical test results are not necessarily indicative of clinical performance.
**Distraction radius**

The distraction radius corresponds to the distance in millimeters from the center of a circle to the outer circumference. A smaller radius results in a tighter curvature of distraction as opposed to a larger radius which is closer to a straight path.
Indications and Contraindications

**Indications**
The Synthes Curvilinear Distraction System is intended for use as a bone stabilizer and lengthening (and/or transport) device for correction of congenital deficiencies or posttraumatic defects of the mandibular body and ramus where gradual bone distraction is required.

This system is intended for use in either adults or pediatric patients more than 1 year old.

The Synthes Curvilinear Distraction System is intended for single use only.

**Contraindications**
Use of the Synthes Curvilinear Distraction System is contraindicated in patients previously sensitized to nickel.
Preoperative Planning

Determine the postdistraction anatomic goal by conducting an evaluation of the craniofacial pathology 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 with curvilinear distraction.3,4

Options for preoperative planning include computer assisted planning and bone model surgery.

**Computer Assisted Planning**

With computer assisted planning, surgeons may:

– Visualize the patient's anatomy
– Simulate the osteotomies and move the mandible to the desired postoperative position in a virtual environment
– Determine the proper radius of distraction and screw placement to achieve desired outcomes
– Identify potential bone interferences

Synthes Customized Surgical Solutions is a platform that combines ProPlan CMF planning software with a wide variety of planning services and intraoperative guidance systems that accurately transfer the surgical plan to the operating room in the form of anatomic models, osteotomy guides, and drilling guides.

Curvilinear distractor bending templates are also available for preoperative planning. They can be used with anatomic bone models to perform model surgery. The bending templates translate along the curved track. They are available in each radius of distraction and are helpful for:

– Selecting the appropriate radius of distraction for an individual patient
– Determining the location of the osteotomy and placement of the device and bone screws
– Determining the amount of advancement necessary
– Pre-bending the footplates and cutting the distractor track to the appropriate length

The steps on the following pages demonstrate how to use the bending templates with an anatomic bone model to select and confirm the appropriate radius of distraction.

An anatomic bone model including the mandible through the orbits, with the mandible attached, is recommended.
1

**Create osteotomy**
Mark the approximate site of the osteotomy on the bone model. Perform a complete osteotomy. Repeat on the contralateral side.

2

**Secure distal segment in desired location**
Move the distal segment of the mandible to the desired postdistraction position. Secure the mandible to the maxilla using IMF screws and/or wire.
3

Fit bending template

Instruments

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>311.005/</td>
<td>Screwdriver Handle with hex coupling, small or</td>
</tr>
<tr>
<td>311.006</td>
<td>medium</td>
</tr>
<tr>
<td>313.252/</td>
<td>1.5 mm/2.0 mm Screwdriver Blade, self-retaining,</td>
</tr>
<tr>
<td>313.253</td>
<td>PlusDrive, hex coupling, 96 mm or 76 mm</td>
</tr>
</tbody>
</table>

Select the bending template radius that most closely approximates the centerline curvature of the missing bone segment.

Align the screw holes of the stationary footplate to the desired position of the bone screws in the proximal segment of the mandible. Consider the following factors:
- Tooth buds and roots
- Adequate bone for screw placement
- Location of mental nerve
- Access to the screws by an intraoral approach (i.e., superior holes) or an external approach (i.e., inferior holes)

**Technique tip:** Screw holes above and below the distractor track provide flexibility in screw placement. It is not necessary to place screws in all four footplates. A minimum of two screws are required on either side of the osteotomy. Select the appropriate screw holes and cut off excess portions of the footplates, to ensure the best possible fit on the mandible.

Mark the location of the screws on the bone model with a marking pen.
3. Fit bending template continued

Loosen the two machine screws in the translating footplate with the 1.5 mm/2.0 mm screwdriver blade.

Reposition the translating footplate by sliding it along the track to the desired position of the bone screws in the distal segment of the mandible. Again, consider the following factors:

– Tooth buds and roots
– Adequate bone for screw placement
– Location of mental nerve
– Access to the screws by an intraoral approach (i.e., superior holes) or an external approach (i.e., inferior holes)

Mark the location of the screws on the bone model with a marking pen.

Assess if the radius of the selected bending template matches the centerline curvature of the missing bone segment, and if the desired position of the bone screws in both segments of the mandible is achieved. If the radius is not appropriate, select a bending template with a different radius and repeat Step 3.
4

**Contour footplates**

Contour the footplates to fit the mandible.

The footplates should be placed parallel to the edge of the osteotomy to ensure the curvature is correct.

Bending templates should be contoured in the footplate regions only. Contouring the bending template track will prevent it from functioning properly.

---

5

**Attach footplates**

**Instruments**

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>311.005/311.006</td>
<td>Screwdriver Handle with hex coupling, small or medium</td>
</tr>
<tr>
<td>313.252/313.253</td>
<td>1.5 mm/2.0 mm Screwdriver Blade, self-retaining, PlusDrive, hex coupling, 96 mm or 76 mm</td>
</tr>
</tbody>
</table>

Attach the bending template to the bone model by drilling and/or inserting two screws in each footplate.
6
Repeat steps
Repeat Steps 3, 4 and 5 on the contralateral side.

**Note:** The distractors must be placed as parallel as possible to each other and to the sagittal plane to prevent binding during actual use.

7
Release mandible
Release the mandible from the maxilla by cutting the wire.
8

Confirm radius
Translate the distal segment of the mandible along the bending template tracks. Move the distal segment to the predistracted position and then back to the postdistracted position. Confirm that the distal segment moves to the desired postdistraction location.

If the movement of the mandible is as desired, use the distractor radius that corresponds to the radius of each bending template.

If the movement of the mandible does not seem appropriate, select a bending template with a different radius and repeat Steps 2 through 8.

If it is difficult to translate the distal segment along the template track, further loosen the machine screws.

**Warning:** Bending templates should not be used as drill guides for implanting the distractor on the patient. Doing so may accidentally release nonbiocompatible aluminum fragments into the woundsite.
The following surgical technique is an example of an intraoral approach with the distractor placed in a posterior orientation with a percutaneous activation port.

1. **Make incision**

Make a mandibular vestibular incision. Elevate the periosteum to expose the mandible.

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**Note:** The technique is similar for an extraoral approach, eliminating the need for the trocar instrumentation.
2

**Mark osteotomy**

Mark the approximate site of the osteotomy.

3

**Fit distractor**

If the distractor was not cut and contoured preoperatively using an anatomic bone model, the device must be fitted to the mandible.

Place a distractor in the intended area to assess the patient’s anatomy and determine the approximate location of the footplates, bone screws and extension arm.

Factors to consider include:

- Occlusal plane
- Tooth buds and roots
- Planned vector of distraction
- Adequate bone for screw placement
- Location of mental nerve
- Lip closure
- Soft tissue (mucosa) coverage
- Location of activation hex

Distractor shown in illustration is smaller than actual device.
4

Cut and contour footplates

<table>
<thead>
<tr>
<th>Instruments</th>
</tr>
</thead>
<tbody>
<tr>
<td>03.500.014 Cutting Instrument, for Distraction Footplates</td>
</tr>
<tr>
<td>347.964 Combination Bending Pliers, for 1.0 mm to 2.0 mm Plates</td>
</tr>
<tr>
<td>391.965 Combination Bending/Cutting Pliers, for 1.0 mm to 2.0 mm Plates</td>
</tr>
</tbody>
</table>

Cut the footplates using the cutting instrument to remove any unnecessary screw holes.

Contour the footplates to the mandible using the combination bending pliers.

**Technique tips:** Cut the footplates so the cut edges are flush with the distractor. Use the rasp on the cutting instrument to deburr any sharp edges.

A minimum of two screws should be used in each footplate to ensure adequate stability. Take care to avoid placing screws in the tooth buds and roots.

Screw holes above and below the distractor track provide flexibility in screw placement. It is not necessary to place screws in all four footplates. A minimum of two screws are required on either side of the osteotomy. Select the appropriate screw holes and cut off excess portions of the footplates, to ensure the best possible fit on the mandible.
Cut and crimp distractor track

Instruments

<table>
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<tr>
<th>Code</th>
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<tbody>
<tr>
<td>03.500.014</td>
<td>Cutting Instrument, for Distraction Footplates</td>
</tr>
<tr>
<td>03.500.015</td>
<td>Crimping Instrument, for Curvilinear Distractor</td>
</tr>
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</table>

The distractor track allows for 35 mm of advancement. If less advancement is required, cut the distractor track to the desired length according to the treatment plan. The underside of the distractor track is etched to indicate the cutting location in order to achieve the desired length of advancement. Use the rasp on the cutting instrument to deburr any sharp edges.

If the track is cut, it must be crimped to prevent separation of the distractor assembly. Engage the crimping instrument with the track and follow the orientation instructions etched on the instrument.

Warning: Do not contour the distractor track, as doing so may damage the distractor.

Important: Failure to crimp the track after cutting it may result in separation of the distractor assembly.

Technique tip: To ensure that a complete crimp was achieved, advance the distractor to the end of the track and confirm that it does not separate.
6

Attach extension arm

Instrument

03.315.004  Removal Instrument

Select the appropriate length extension arm based on the planned amount of distraction and the desired location of the activation hex.

**Important:** During the distraction process, the distractor and extension arm will advance with the mandible. To ensure that the soft tissue does not obstruct the activation hex during distraction, the next longer extension arm may be needed.

Engage the removal instrument with the hex on the extension arm (Figure 1).

Rotate the removal instrument collar counterclockwise at least 16 full turns until the hex pocket of the extension arm is exposed (Figure 2).

**Technique tips:** Extension arms are provided fully tightened to prevent unintentional separation. When opening the extension arm for the first time, there will be significant resistance. Rotate counterclockwise, in the direction marked “OPEN”, past the point of resistance.

Lay the extension arm in the palm of your hand when rotating the removal instrument collar to expose the hex pocket (Figure 2). Alternatively, the extension arm can be held in the removal instrument without any support (Figure 3). Gripping the extension arm with your fingers will make it difficult to open and cause the silicone sleeve to twist and possibly tear.
**Technique tips continued**

The extension arm is composed of two sleeves. If the extension arm separates (the outer sleeve separates from the inner sleeve), it is possible to reassemble it. Reassemble the extension arm by inserting the inner sleeve into the outer sleeve and rotating the outer sleeve clockwise until it fully closes (Figure 4).

Extension arms can be detached from the distractor at the start of the consolidation phase without the need for a surgical procedure (see page 24 for instructions).

Place the distractor body activation hex into the hex pocket of the extension arm (Figure 5).

Rotate the removal instrument collar clockwise until the extension arm closes over the activation hex on the distractor and fully tighten (Figure 6).

**Warning:** Care should be taken to protect the extension arms, during the course of treatment, to prevent them from being damaged or broken. 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.
7
Create activation port for extension arm
A percutaneous activation port must be created in the soft tissue through which the extension arm will exit.

Create the percutaneous activation port by making a stab incision through the skin, followed by blunt dissection.

Place the distractor on the mandible and pull the extension arm through the percutaneous activation port using forceps.

**Technique tip:** To ease insertion through the soft tissue, the extension arm can be inserted into a silicone tube and pulled through the soft tissue.
Mark distractor location

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<td>1.5 mm/2.0 mm Screwdriver Blade, self-retaining, PlusDrive, hex coupling, 96 mm or 76 mm</td>
</tr>
<tr>
<td>317.64–1.5 mm Drill Bits, Stryker J-latch, 4–10 mm stops or 317.835</td>
<td>1.5 mm Drill Bit, Stryker J-latch, 110 mm</td>
</tr>
<tr>
<td>397.211</td>
<td>Universal Trocar Handle</td>
</tr>
<tr>
<td>397.213</td>
<td>2.0 mm Cannula and Obturator</td>
</tr>
<tr>
<td>397.232</td>
<td>Malleable C-Retractor</td>
</tr>
<tr>
<td>397.42</td>
<td>2.0 mm Cheek Retractor Blade</td>
</tr>
<tr>
<td>397.43</td>
<td>2.0 mm Cheek Retractor Ring</td>
</tr>
</tbody>
</table>

Before making the osteotomy, mark the position of the distractor by drilling and/or inserting one appropriate length 2.0 mm locking or nonlocking screw through each footplate. Do not fully tighten the screws.

**Technique tip:** It may be desirable to drill and/or insert all screws before making the osteotomy, to enable easier attachment of the distractor once the bone becomes mobile. Screws should not be fully tightened at this point, to avoid compromising bone integrity.

**Warning:** If bending templates were used for preoperative planning, they should not be used as drill guides on the patient. Doing so may accidentally release nonbiocompatible aluminum fragments into the wound site.

**Caution:** Irrigate adequately while drilling to prevent overheating of the drill bit and thermal generated necrosis of the bone.
9
Perform buccal corticotomy
Unscrew and remove the distractor.

Perform the corticotomy on the buccal side of the mandible, extending into the superior and inferior borders. This allows stability of the bone segments during reattachment of the distractor.

10
Reattach distractor

**Instruments**

<table>
<thead>
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<tr>
<td>317.64 or 317.72 or 317.835</td>
<td>1.5 mm Drill Bits, Stryker J-latch, 4–10 mm stops or 110 mm</td>
</tr>
</tbody>
</table>

Reattach the distractor by aligning the footplates with the holes made previously. Drill and/or insert the remaining screws. Fully tighten all screws.

**Notes:** A minimum of two screws should be inserted through each footplate to ensure adequate stability. The surgeon may decide intraoperatively to insert additional screws, to increase stability. Take care to avoid tooth buds and roots when placing screws.

The distractor is designed for percutaneous activation. However, if it is placed with the extension arm in the intraoral cavity, ensure that the extension arm does not interfere with the patient’s ability to chew.

**Cautions:** Screws can loosen during the course of treatment if placed in poor quality bone.

Irrigate adequately while drilling to prevent overheating of the drill bit and thermal generated necrosis of the bone.

If locking screws are used, screw holes must be drilled at a right angle to the plate hole to prevent the screws from becoming cross threaded. A drill guide is provided to facilitate proper placement.
11
Complete osteomy
Complete the osteotomy on the lingual aspect of the mandible using an osteotome. Take care to avoid the nerve.

Important: 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.

12
Confirm device activation

Instrument

| 03.500.016 | Activation Instrument, for Curvilinear Distractor |

Use the activation instrument to engage the activation hex of the extension arm. Rotate counterclockwise, in the direction marked on the instrument handle, to confirm device stability and verify movement of the mandible. Return the distractor to its original position.

Important: 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.

13
Repeat steps for bilateral procedures
Repeat Steps 1 through 12 on the contralateral side. Close all incisions.

Note: The distractors must be placed as parallel as possible to each other and to the sagittal plane, to prevent binding.
Suggested distraction protocol

Instrument

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>03.500.016</td>
<td>Activation Instrument, for Curvilinear Distractor</td>
</tr>
</tbody>
</table>

It is recommended to begin active distraction three to five days after device placement. For young patients, active distraction can begin earlier, to prevent premature consolidation.

To activate the distractors, engage the activation instrument with the extension arm and rotate counterclockwise in the direction of the arrow marked on the instrument.

One full rotation equals 1.0 mm of distraction.

**Note:** A minimum of 1.0 mm of distraction per day (half turn twice daily) is recommended to prevent premature consolidation. In young patients, a rate of 1.5 to 2.0 mm per day may be considered.

**Important:** To accomplish a half-turn, rotate the activation instrument from the side with the arrow marked on it to the side with the open slot.

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.

The activation instrument can be made smaller for use in young patients by removing the blue machine screw and separating the handle extension.
**Document progress**
Distraction progress should be observed by documenting the changes in the patient's occlusion. A Patient Care Guide is included with the system to help record and monitor device activation.

**Patient care**
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.

**Warning:** Care should be taken to protect the extension arms, during the course of treatment, to prevent them from being damaged or broken. 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.

It is important to instruct the patient to keep the wound area clean during distraction by rinsing.

**Consolidation**
After the desired advancement has been achieved, the new bone must be given time to consolidate. The consolidation period should be approximately six to twelve weeks. This time period may vary in relation to patient age and should be determined by clinical evaluation.

The extension arms can be removed at the start of the consolidation phase.
Extension Arm Removal

Instrument

03.315.004  Removal Instrument

Engage the removal instrument with the extension arm. Rotate the removal instrument collar counterclockwise at least 16 full turns. This will unscrew the outer sleeve of the extension arm and expose the hex pocket where the extension arm connects to the distractor.

Disengage the extension arm from the distractor with side-to-side movements of the arm. Remove the extension arm through the percutaneous port.

Warning: When removing the extension arms, rotate only the collar of the removal instrument. Do not allow the base of the removal instrument to rotate in your hand, as doing so may cause a change in the distraction distance that was achieved.

Notes: The line etched on the hex end of the extension arm corresponds to the direction of the hex pocket opening at the top of the extension arm. Pushing the extension arm in the direction of the line should disengage it from the distractor.

If the connection between the distractor and extension arm is buried under the soft tissue, it may be difficult to remove the extension arm. If this occurs, the extension arm can remain intact for the duration of the consolidation period. Alternatively, the outer sleeve of the extension arm can be removed using the removal instrument. The inner sleeve may detach at a later time.
Optional technique for extension arm removal

Instruments

<table>
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<th>Code</th>
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<tr>
<td>03.500.016</td>
<td>Activation Instrument, for Curvilinear Distractor</td>
</tr>
<tr>
<td>347.964</td>
<td>Combination Bending Pliers, for 1.0 mm to 2.0 mm plates</td>
</tr>
</tbody>
</table>

If the removal instrument is not available, the extension arms can be removed using the activation instrument and pliers. Engage the extension arm with the activation instrument. While holding the activation instrument still, use the pliers to rotate the sleeve on the extension arm counterclockwise at least 16 full turns to expose the hex pocket where the extension arm connects to the distractor. Disengage the extension arm from the distractor with side-to-side movements.

Device Removal

Instruments

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<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>311.005/6</td>
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<td>313.252/3</td>
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</table>

Remove the distractors by exposing the footplates through the same incisions that were used during the initial placement surgery, and removing the titanium bone screws.

Note: The distractors are easier to remove if the extension arms are removed before distractor removal.
**Curvilinear Distractors**

- Distract the mandible along a specific curved trajectory
- Available in left and right assemblies, in a variety of radii

<table>
<thead>
<tr>
<th>Radius (mm)</th>
<th>Right Side</th>
<th>Left Side</th>
</tr>
</thead>
<tbody>
<tr>
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<td>04.500.170</td>
<td>04.500.171</td>
</tr>
<tr>
<td>100</td>
<td>04.500.100</td>
<td>04.500.101</td>
</tr>
</tbody>
</table>

- Straight version available (04.500.018)
- Produce bone growth in both horizontal and vertical vectors to avoid the creation of an anterior open bite
- Allow up to 35 mm of distraction
- Used with flexible or rigid extension arms that can be easily removed during the consolidation phase without the need for a second surgical procedure
- Accept 2.0 mm locking screws for added strength and stability; also accepts nonlocking screws
- Made of titanium alloy to withstand repeated bending of the footplates and the forces of distraction

**Extension Arms**

- Allow the point of activation to be moved away from the distractor for easier access with the activation instrument
- May be removed during the consolidation phase without a surgical procedure
- Rigid arms available in 20 mm, 40 mm, and 60 mm lengths
- Flexible arms available in 30 mm, 40 mm, and 60 mm lengths

**Note:** Distractors contain the following materials: Ti-15Mo, Ti-6Al-7Nb and Co-20Cr-15W-10Ni
Instruments from the Curvilinear Distractor Set (01.500.030)

03.500.016  Activation Instrument, for Curvilinear Distraction

03.500.018  Bending Template for Curvilinear Distractor, straight

03.500.030–  Bending Template for Curvilinear Distractor,  
03.500.101  R30–R100, left and right versions
<table>
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<tr>
<th>Instrument Code</th>
<th>Description</th>
<th>Image</th>
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<td>03.315.004</td>
<td>Removal Instrument, for CMF Distractor (For attaching and removing extension arms)</td>
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<td>03.500.014</td>
<td>Cutting Instrument, for Distraction Footplates</td>
<td><img src="image2.png" alt="Cutting Instrument" /></td>
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<td>03.500.015</td>
<td>Crimping Instrument, for Curvilinear Distractor</td>
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<td>Item</td>
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Curvilinear Distractor Set (01.500.030)

Graphic Case and Accessory
- 304.095 Curvilinear Distractor Module
- 306.758 Label Sheet for Curvilinear Distractor Module

Instruments
- 03.500.016 Activation Instrument, for Curvilinear Distractor, 2 ea.

Bending Templates for Curvilinear Distractor

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<tr>
<td>03.500.070</td>
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<tr>
<td>03.500.071</td>
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<tr>
<td>03.500.101</td>
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Implants
Curvilinear Distractors, 2 ea.

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</tr>
<tr>
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</table>

Required Set*
- 01.315.000 CMF Distraction System Set

* The CMF Distraction System Set contains the extension arms, bone screws and instruments necessary for a curvilinear distractor case.

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


