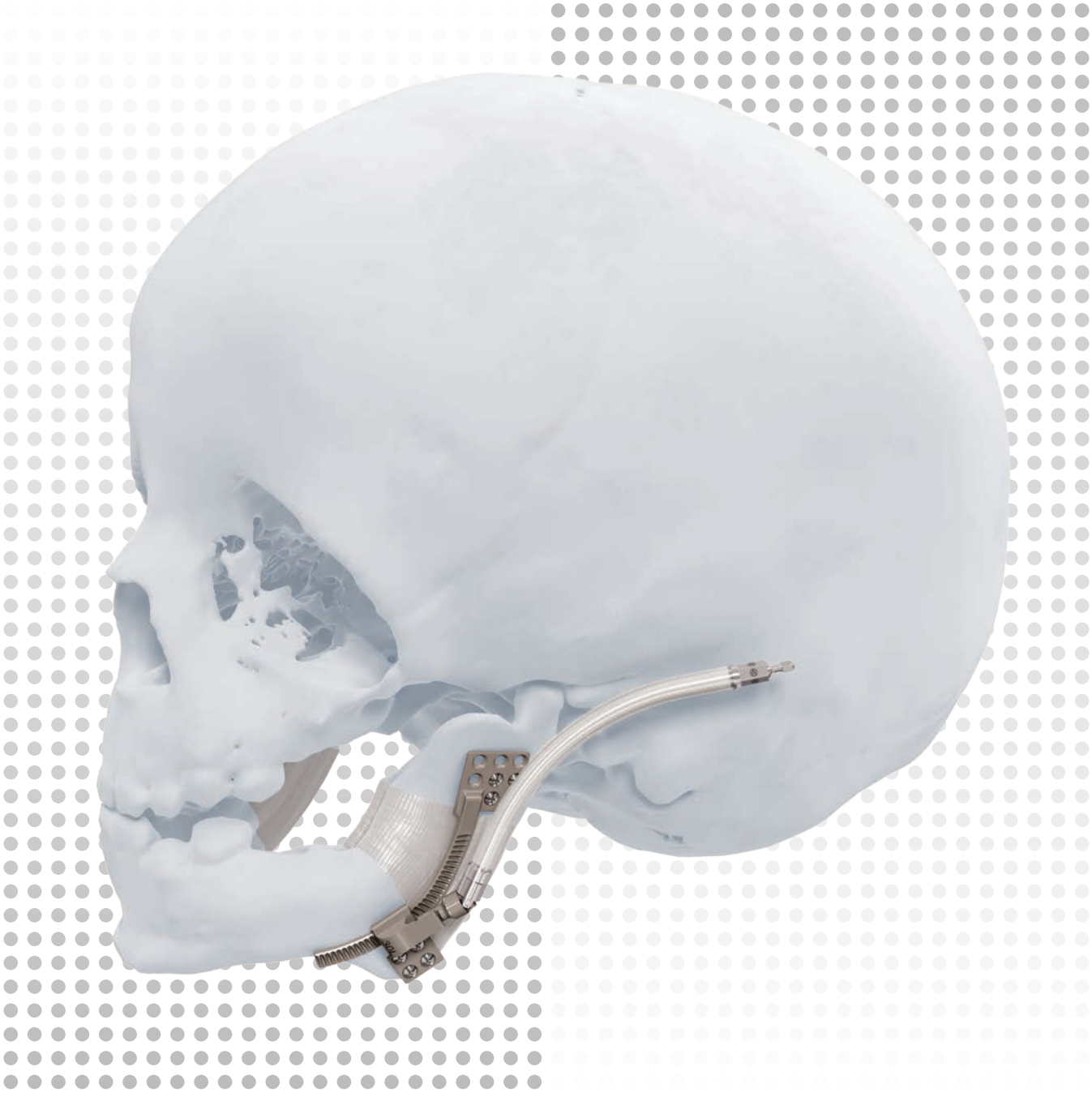
Curvilinear Distraction System

Internal distraction devices that advance the mandible along a curved path

Surgical Technique



approved by AO Technical Commission

DePuy Synthes
THE ORTHOPAEDICS COMPANY OF Johnson & Johnson

Image intensifier control

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

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

Table of Contents

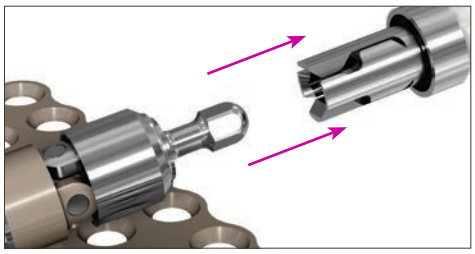
■ **Notes**
▲ **Precautions**
▲ **WARNINGS**

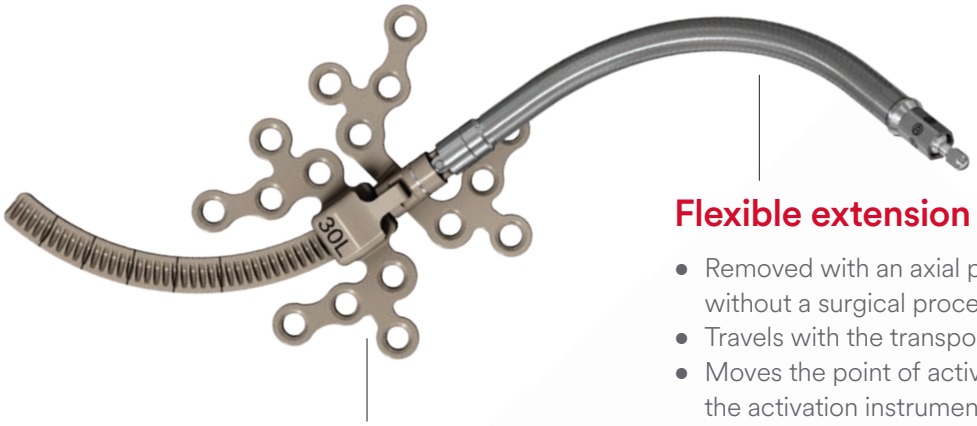
Curvilinear Distraction System

Internal distraction devices that advance the mandible along a curved path

Curvilinear Distractors

- Advance along a curved track for bone growth along both horizontal and vertical vectors
- Available in various radii of curvature (also available in a straight version)
- Capable of 35 mm of advancement





Flexible extension arm

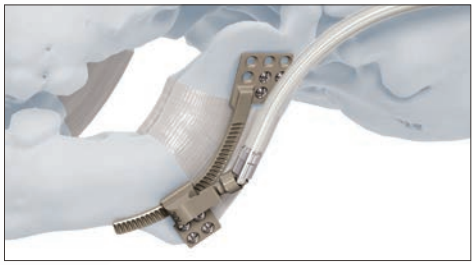
- Removed with an axial pull at the start of consolidation without a surgical procedure
- Travels with the transport footplate
- Moves the point of activation to an area accessible by the activation instrument
- Available in 30 mm, 40 mm and 60 mm lengths
- Includes a protective silicone covering

Curvilinear Distractor 2.0

- Threaded holes accept ∅ 2.0 mm locking screws for added stability (Also accept nonlocking screws)
- Intended for use in adult and pediatric patients more than 1 year old

Curvilinear Distractor 1.3

- Mesh footplates facilitate screw placement in a small area of bone
- Accepts ∅ 1.3 mm screws
- Intended for use in pediatric patients 4 years of age and younger



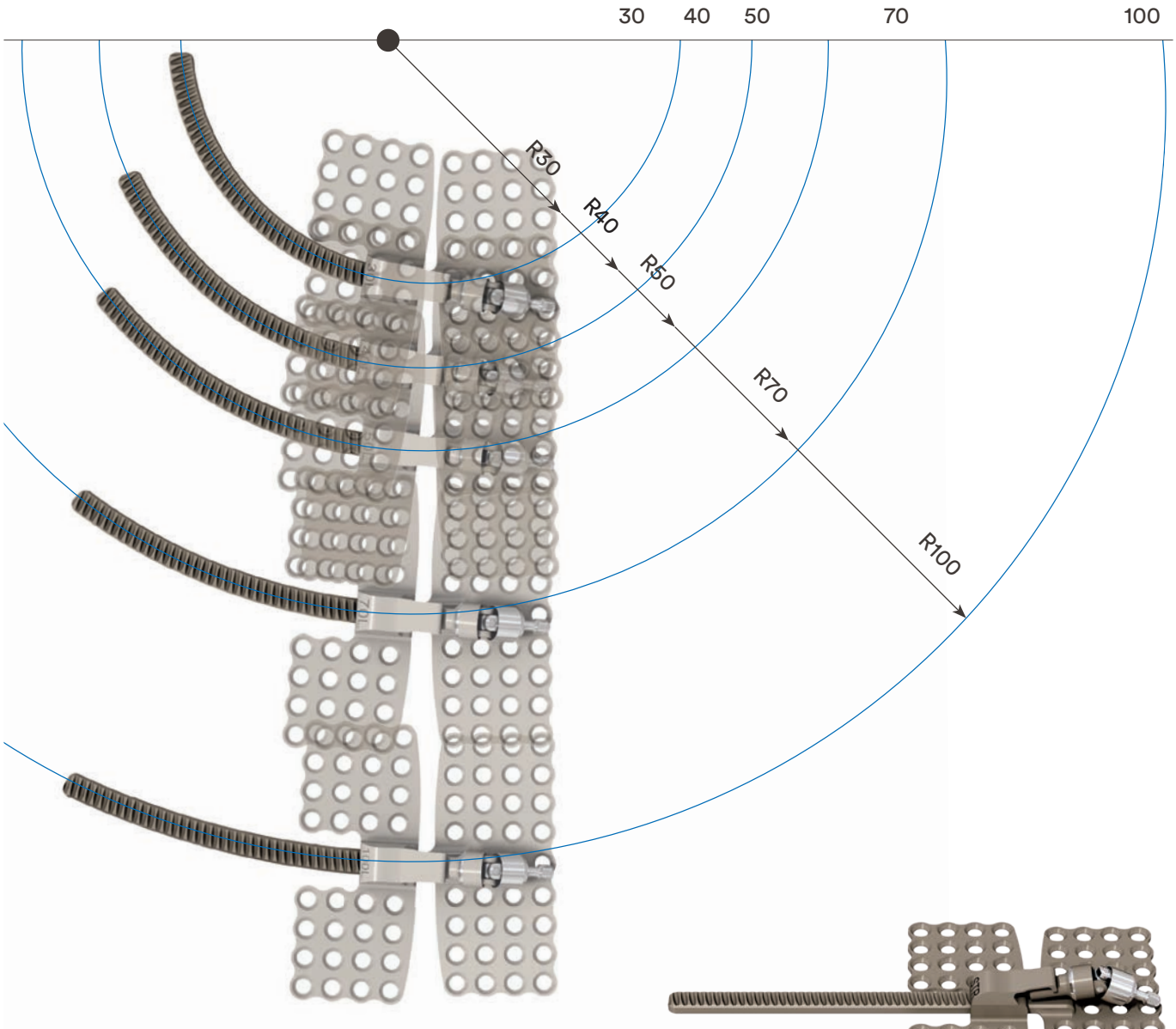
Bone advances in two planes simultaneously: horizontal and vertical

■ Note:

For patients 1–4 years old either size distractor can be used. Selection should be based on the size of the mandible.

Distraction radius

The distraction radius (i.e. R30) corresponds to the distance in millimeters from the center of a circle to the centerline curvature of distractor. A smaller radius results in a tighter curvature of distraction whereas a larger radius is closer to a straight path.



Straight distractor

Intended Use, Indications and Contraindications can be found in the corresponding system Instructions for Use. MRI Information on Torque, Displacement, Image Artifacts and Radio Frequency (RF) – induced heating can be found in the corresponding System Instructions for Use.

General Adverse Event and Device Specific Adverse Events

General Adverse Events

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

Device Specific Adverse Events

Device specific adverse events include but are not limited to: The adverse events for both the 1.3 and 2.0 Curvilinear Distractors could be classified in 3 major groups: choking hazard, re-operation and additional medical treatment.

Preoperative Planning

Determine the postdistraction anatomic goal by conducting an evaluation of the craniofacial pathology and symmetry through clinical exam, CT scan, cephalogram and/or panoramic x-ray.

▲ WARNINGS:

- When selecting patients for treatment with mandibular distraction, the surgeon should take into account any pre-existing conditions such as central apnea, multi-level airway obstruction, severe reflux or other etiologies of airway obstruction that are not tongue based and would not respond to advancement of the mandible. Patients with these conditions may require a tracheostomy.
- When selecting patients for treatment with distraction, the surgeon should take into account any pre-existing conditions such as metal allergy and foreign body sensitivity.

Select the appropriate distractor size based on patient age and anatomy. The Curvilinear Distractor 1.3 is intended for use in pediatric patients 4 years of age and younger. The Curvilinear Distractor 2.0 is intended for use in adult and pediatric patients more than 1 year old. For patients 1–4 years old either size distractor can be used. Selection should be based on the size of the mandible. The distractor is used 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.

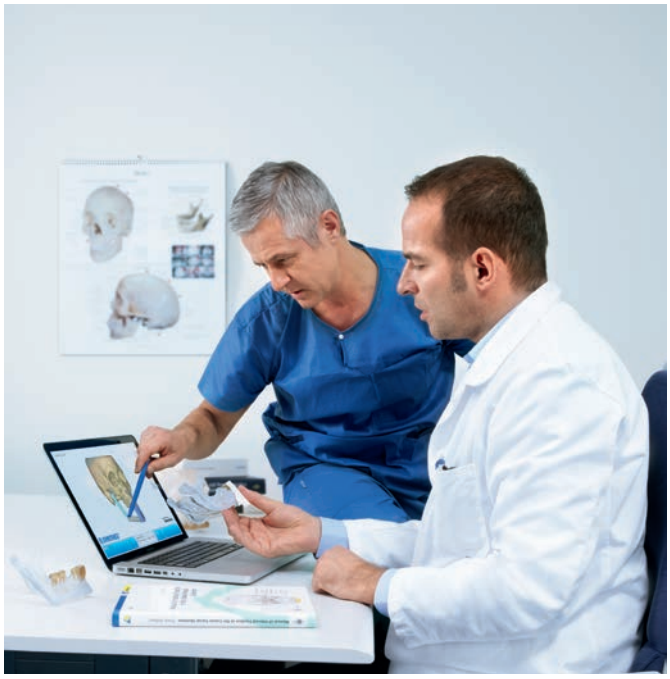
▲ WARNING:

If the extension arm is placed partially in the intraoral cavity, it presents a choking hazard if it disengages from the distractor or breaks.

Correct placement and orientation of osteotomies and distraction devices is critical to successful treatment with curvilinear distraction.

▲ WARNING:

When selecting patients for treatment, ensure there is adequate bone for distractor placement in the desired location. Poor distractor placement or distractor placement on poor quality bone can cause surgical delay, device loosening, poor resulting joint mechanics, ankylosis, malunion or nonunion, soft tissue irritation or damage, damage to surrounding organs and structures, and bone damage, as well as possible distraction relapse or over-correction. In the neonatal patient, it is at the surgeon's discretion to assess the quality of the bone.



DePuy Synthes Companies offer two options for pre-operative planning: computer-aided planning service and templates for bone model surgery.

▲ WARNINGS:

- These devices can break during use (when subjected to excessive forces or outside the recommended surgical technique). While the surgeon must make the final decision on removal of the broken part based on associated risk in doing so, we recommend that whenever possible and practical for the individual patient, the broken part should be removed.
- Metallic internal fixation devices cannot withstand activity levels and/or loads equal to those placed on normal healthy bone as these devices are not designed to withstand the unsupported stress of full weight-bearing or load-bearing.
- Medical devices containing stainless steel may elicit an allergic reaction in patients with hypersensitivity to nickel.
- Be aware that implants are not as strong as native bone.

Option 1:
Depuy Synthes ProPlan CMF

ProPlan CMF is a computer-aided surgical planning service for preoperative case visualization, which includes patient specific surgical guides to transfer the plan to the operating room.

ProPlan CMF planning service allows:

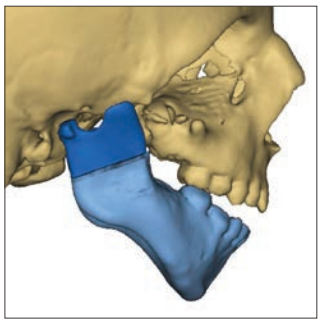
- Live interactive planning session with a knowledgeable support team
- The surgeon to make critical clinical decisions preoperatively
- 2D and 3D visualization of preoperative patient anatomy and condition (to avoid inserting screws into nerves and tooth buds and roots)
- Cephalometric analysis
- Simulation of skeletal osteotomies
- Visualization of movement of osteotomized bone structures (mandibular movement to desired postoperative position)
- Identification of potential bone interferences
- Virtual placement of the distractor on the mandible to determine the proper distractor size, radius and placement
- Visualization of the clinical plan to validate the planned, clinical result
- Soft tissue simulation and (3D) photomapping

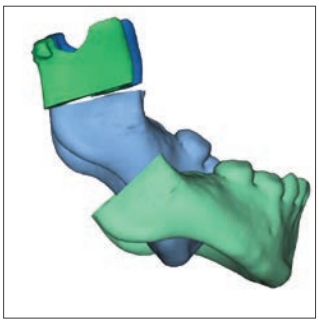
▲ Precautions:

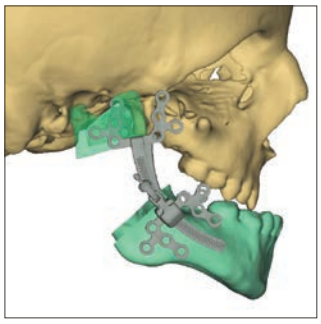
- The distractors must be placed as parallel as possible to each other and to the sagittal plane to prevent binding or not turning freely during actual use.
- Take care to avoid nerves, tooth buds and roots when drilling and/or placing screws.
- Verify for adequate bone volume and quantity for screw placement.
- A minimum of four ∅ 1.3 mm screws (for the Curvilinear Distractor 1.3) and a minimum of two ∅ 2.0 mm screws (for the Curvilinear Distractor 2.0) are required on each side of the osteotomy.

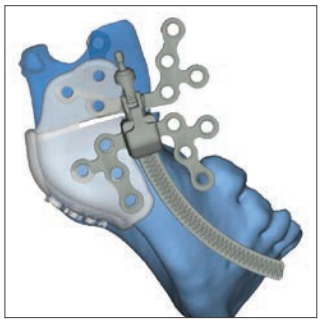
In addition to virtual case planning, Synthes ProPlan CMF products and services include anatomic bone models, surgical guides and ProPlan CMF Connect.

- Bone models are useful for bending distractor footplates preoperatively









- Surgical guides function as cutting and drilling guides to accurately transfer the plan to the OR
- ProPlan CMF Connect is a web-based interface to manage and track ProPlan CMF cases

Steps for planning a case with ProPlan CMF

1. Scan the patient and submit the request for service form and CT scan data
2. Plan the case during an interactive web based planning session
3. Approve the surgical plan
4. Receive the surgical guides and anatomic models
5. Perform the surgery

Getting started

There are several options for getting more information or initiating a case:

- Contact your local DePuy Synthes CMF sales representative.
- Website: www.trumatchcmf.com
- Email: RA-DPYCH-psi@ITS.JNJ.com
- Phone: +41 61 965 61 66

Option 2: Bending templates for bone model surgery

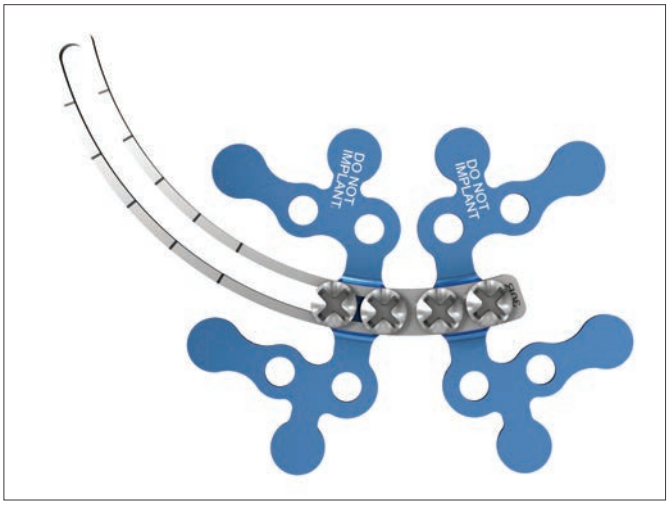
Bending templates are available in the set and they should be used prior to the surgery date for case planning and model surgery. They are available for the 2.0 Curvilinear Distractor only. They are not available for the 1.3 Curvilinear Distractor.

The bending templates translate along the curved track. They are available in each radius of distraction (left and right) and are helpful for:

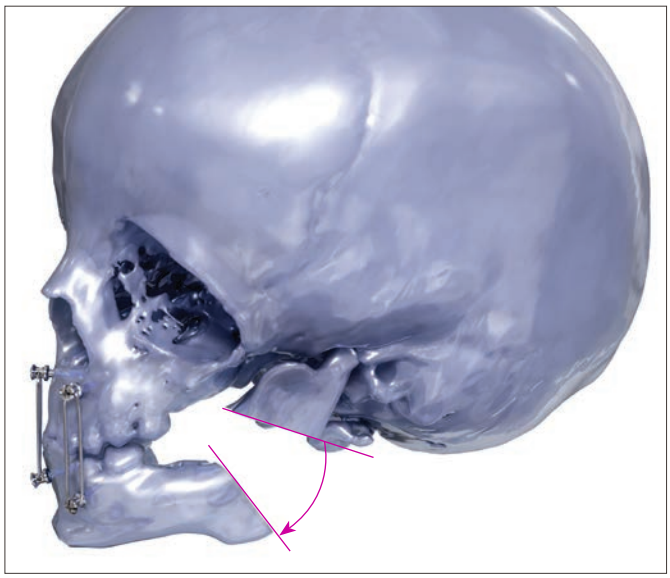
- Selecting the appropriate radius of distraction for an individual patient.
- Determining the location of the osteotomy and placement of the device and bone screws.
- Determining the amount of advancement necessary.
- Pre-bending the footplates and cutting the distractor track to the appropriate length.

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.

A patient specific anatomic bone model including orbits, with the mandible attached, is required for bone model surgery with the bending templates.



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



■ Note:

The proximal segment needs to be attached to the skull base.

2. Move the distal segment of the mandible to the desired postdistraction position and secure it to the maxilla with wire and IMF screws.
3. Select the bending template that most closely approximates the centerline curvature of the missing bone segment. Select the right/left bending template for the right/left side of the mandible.
4. Align the screw holes of the stationary footplate to the desired position on the proximal segment of the mandible and mark the location.

▲ Precautions:

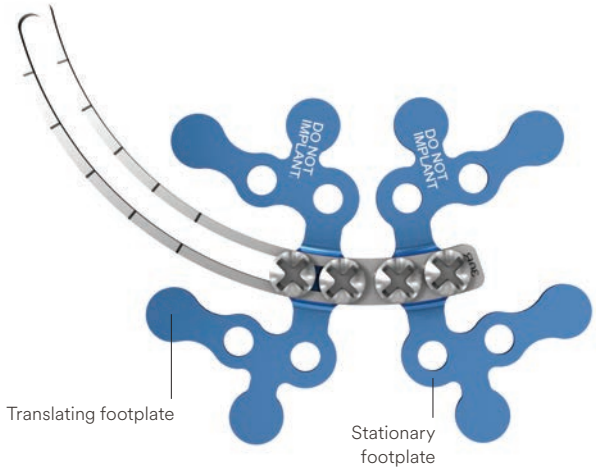
Factors to be considered and verified:

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

a. For an intraoral/transbuccal approach, it is recommended to use screw holes superior to the track because it is difficult to see and access the screw holes in the inferior footplate.

b. For an external approach, it is recommended to use screw holes inferior to the track.

- Placement of condyle in the glenoid fossa.
- A minimum of four ∅ 1.3 mm screws (for the Curvilinear Distractor 1.3) and a minimum of two ∅ 2.0 mm screws (for the Curvilinear Distractor 2.0) are required on each side of the osteotomy.



▲ WARNING:

If the extension arm is placed partially in the intraoral cavity, it presents a choking hazard, if it disengages from the distractor or breaks.

5. Loosen the two machine screws in the translating footplate with a 1.5 mm / 2.0 mm screwdriver blade. Slide the translating footplate along the track to the desired position on the distal segment of the mandible and mark the location. Again, consider the factors in Step 4.
6. Assess if the radius of the 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 another bending template and repeat Steps 3–6.
7. Contour the bending template footplates to the bone model.

▲ Precaution:

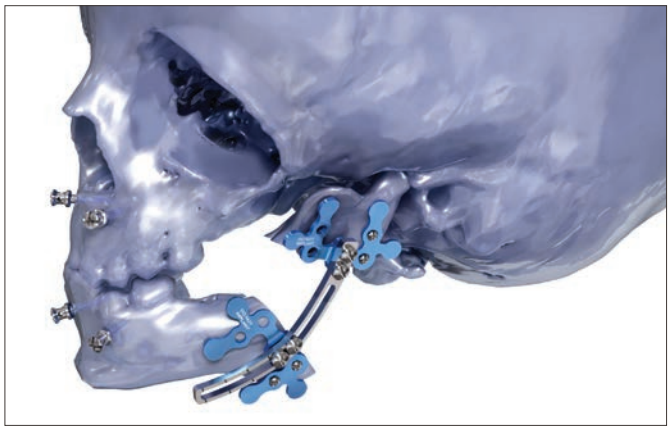
Do not contour the bending template track. The bending template and distractor will not function properly if the track is bent.

8. Attach the bending template to the bone model by drilling and/or inserting two ∅ 2.0 mm screws in each footplate.
9. Repeat Steps 3 through 8 on the contralateral side.

▲ Precautions:

- The distractors must be placed as parallel as possible to each other and to the sagittal plane to prevent binding or not turning freely during actual use.
- Take care to avoid nerves, tooth buds and roots when drilling and/or placing screws.

10. Cut the wire to release the mandible from the maxilla.
11. Translate the distal segment of the mandible along the track from the predistracted to the postdistracted position or in the opposite way. Confirm that the distal segment moves to the desired location.
    a. If the movement is as desired, use the distractor that corresponds to the radius of the bending template.
    b. If the movement is not as desired, select a different bending template and repeat Steps 2 to 11.
    c. If it is difficult to translate the distal segment along the track, further loosen the machine screws.



12. Select the appropriate distractor radius based on the bending template radius that was used. Bend the distractor footplates to match the bending template footplates.

▲ WARNINGS:

- Bending templates should not be used as drill guides for implanting the actual distractor on the patient. Doing so may release nonbiocompatible aluminum fragments into the wound site.
- Discard the bone screws after the bending templates are removed from the bone model.

Distractor Implantation

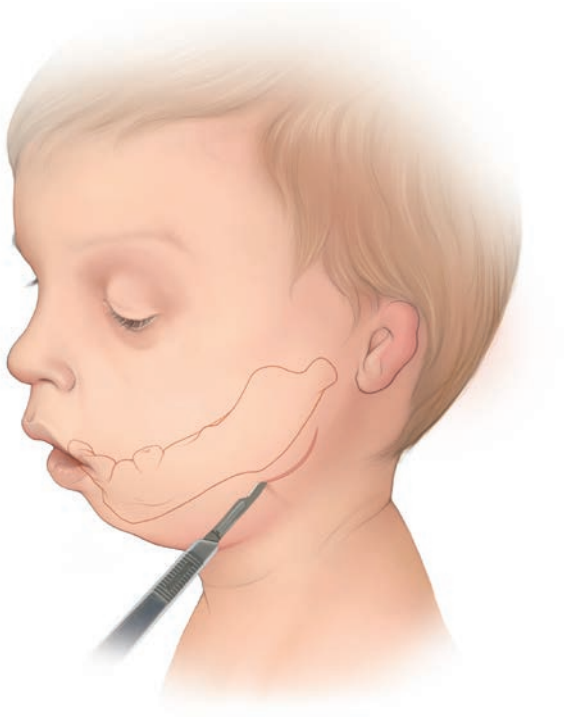
The following surgical technique is an example of an external approach with the distractor positioned so that the extension arm exits through a percutaneous activation port.

1. Make incision submandibular

Make a submandibular incision. Elevate the periosteum to expose the mandible.

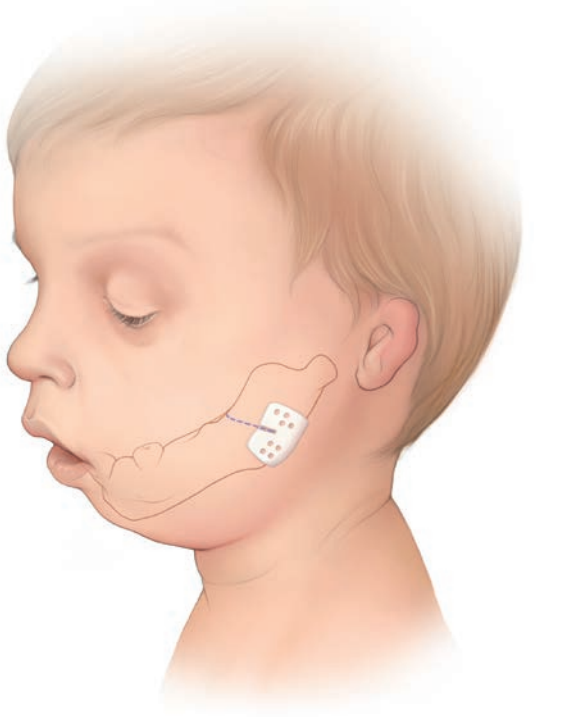
■ Note:

The technique is similar for an intraoral approach using trocar instrumentation.



2. Mark osteotomy

Mark the approximate site of the osteotomy.



3. Fit distractor

If the distractor was not contoured preoperatively it must be fitted to the mandible intraoperatively.

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.

▲ WARNING:

Select the right/left distractor for the right/left side of the mandible in order to limit the intraoral placement of the extension arm.

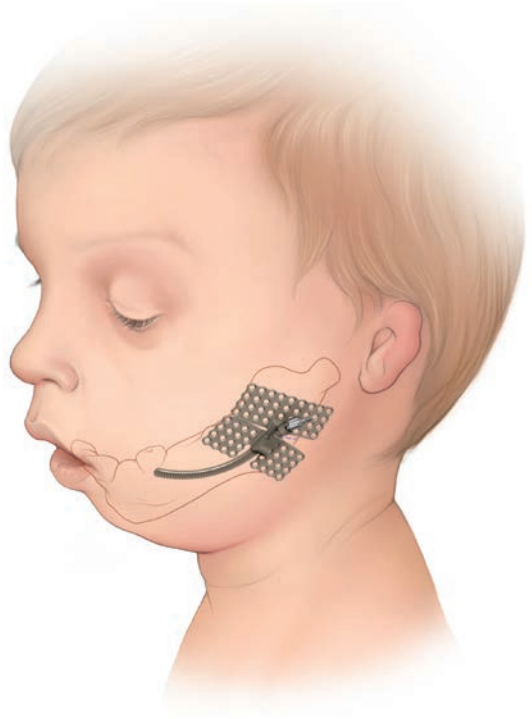
▲ Precautions:

Factors to be considered and verified:

- Occlusal plane.
- Tooth buds and roots.
- Planned vector of distraction.
- Planned length of advancement (consider relapse and overcorrection).
- Adequate bone volume and quantity for screw placement.
- Location of inferior alveolar nerve.
- Lip closure.
- Soft tissue coverage.
- Location of extension arm.
- Patient pain due to distractor interference with soft tissue.
- Access to the screws based on approach.
  a. For an intraoral/transbuccal approach, it is recommended to use screw holes superior to the track because it is difficult to see and access the screw holes in the inferior footplate.
  b. For an external approach, it is recommended to use screw holes inferior to the track.
- Placement of condyle in the glenoid fossa.

▲ WARNING:

f the extension arm is placed partially in the intraoral cavity, it presents a choking hazard, if it disengages from the distractor or breaks.



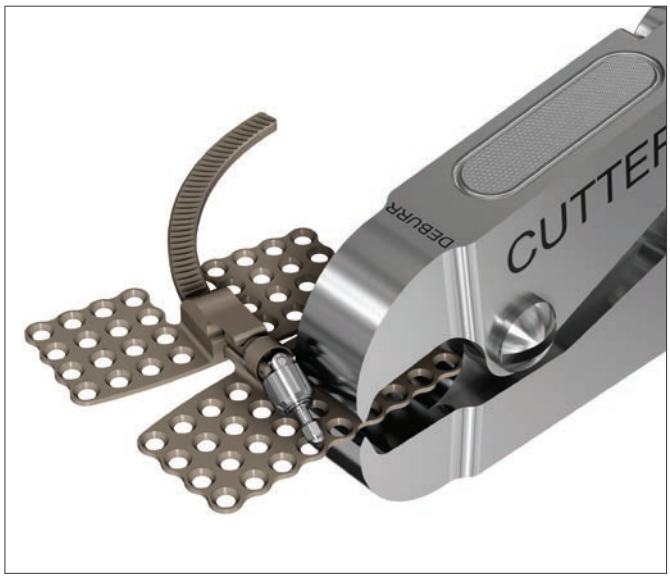
▲ Precautions:

- The distractors must be placed as parallel as possible to each other and to the sagittal plane to prevent binding or not turning freely.
- A minimum of four ∅ 1.3 mm screws (for the Curvilinear Distractor 1.3) and a minimum of two ∅ 2.0 mm screws (for the Curvilinear Distractor 2.0) are required on each side of the osteotomy.

Distractor shown in illustration is smaller than actual device.

4. Cut and contour footplates

Instruments	
03.500.014	Cutter for Distractor Footplates
03.500.020	File, with Hexagonal Coupling
311.005	Handle, small, with Hexagonal Coupling
311.006	Handle, medium, with Hexagonal Coupling
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



Cut the footplates using the cutter to remove any unnecessary screw holes.

Screw holes above and below the distractor track provide flexibility in screw placement. It is not necessary to place screws in all four footplates.

▲ Precaution:

A minimum of four ∅ 1.3 mm screws are required on each side of the osteotomy for the 1.3 distractor. For the 2.0 distractor, a minimum of two ∅ 2.0 mm screws are required on each side of the osteotomy.

Take care to avoid placing screws in the tooth buds and roots.

Alternative technique for an intraoral/ transbuccal approach

For an intraoral/transbuccal approach, it is recommended to use the footplates superior to the distractor track because it is difficult to see and access the screws in the inferior footplates. For an external approach, it is recommended to use footplates inferior to the track.

To access all areas of the footplates with the cutter, it is helpful to advance the distractor at least 5 full turns and flip the distractor upside down so the U-joint does not interfere with the cutter. Return the distractor to the undistracted position after cutting.

Cut the footplates so the cut edges are flush with the distractor.

▲ Precautions:

- Footplates should be cut so that the integrity of the screw hole is not compromised.
- Use the file or the rasp on the cutter to deburr any sharp edges.

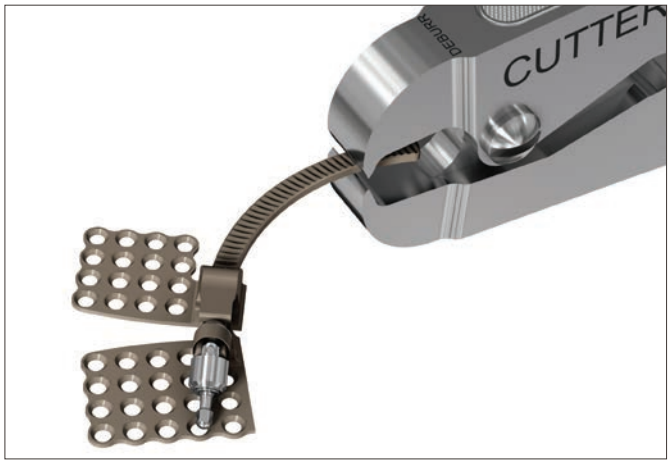
Contour the footplates to the mandible using the combined pliers.

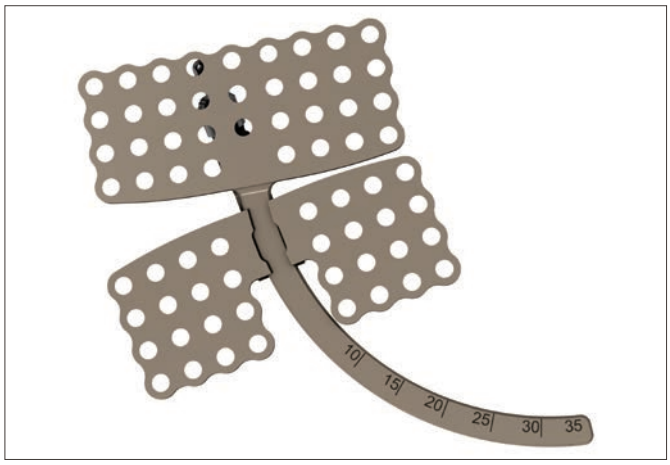
▲ WARNINGS:

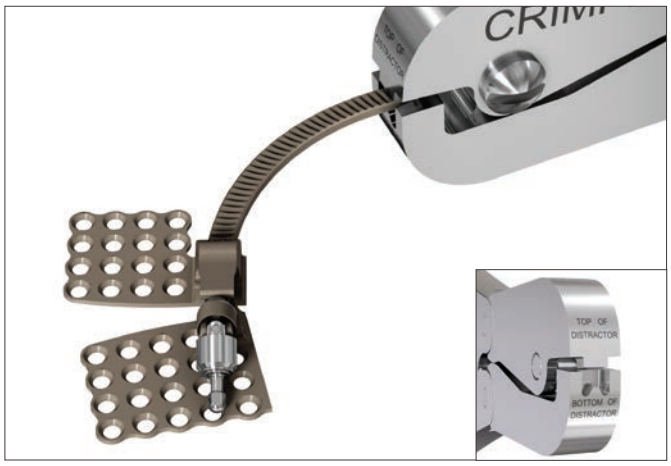
- Do not implant a distractor if the footplates have been damaged by excessive bending.
- Instruments and screws may have sharp edges or moving joints that may pinch or tear users' glove or skin.

5. Cut and crimp distractor track

Instruments	
03.500.014	Cutter for Distractor Footplates
03.500.015	Crimping Instrument for Curvilinear Distractor
03.500.020	File, with Hexagonal Coupling
311.005	Handle, small, with Hexagonal Coupling
311.006	Handle, medium, with Hexagonal Coupling







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. These marks take into account the 2 mm length of the crimp.

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.

■ Note:

To ensure that a complete crimp was achieved, advance the distractor to the end of the track and confirm that it does not separate. Return the footplate back in the starting position.

▲ WARNING:

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

▲ Precautions:

- Failure to crimp the track after cutting it may result in separation of the distractor assembly.
- Use the file or the rasp on the cutter to deburr any sharp edges.
- Consider relapse/overcorrection before cutting the track to the desired length.
- After implant placement is complete, discard any fragments or modified parts in an approved sharps container.

6. Attach extension arm

Instrument

03.315.004	Removal Instrument for Extension Arms

Select the appropriate length extension arm (flexible or rigid) based on the planned amount of distraction and the desired location of the activation hex. The activation hex is the part of the device that engages the activation instrument (Figure 1).

▲ Precautions:

- During the distraction process, the distractor transport footplate and extension arm will advance with the mandible and be pulled into the soft tissue. Choose an adequate length extension arm to ensure that the soft tissue does not obstruct the activation hex during distraction (Figure 1).
- Extension arm should be assembled with the distractor before the distractor is attached to the bone. It is difficult to attach the extension arm after the distractor is screwed to the bone.

There are two versions of flexible extension arms and they attach differently to the distractor. If the extension arm is etched with the Synthes logo on the outer sleeve, it attaches to the distractor with spring fingers (Figures 2–3). If the flexible extension arm is etched with a line on the activation hex, it attaches to the distractor with a hex pocket (Figures 4–5). The instructions for use below provide details for both versions of flexible extension arm.

Engage the removal instrument with the hex on the flexible extension arm (Figure 6).

Rotate the removal instrument collar counterclockwise at least 16 full turns until the spring fingers (Figure 3) or the hex pocket (Figure 5) on the opposite end of the extension arm are exposed.

▲ Precaution:

When attaching the extension arm, 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 will prevent the extension arm from opening.

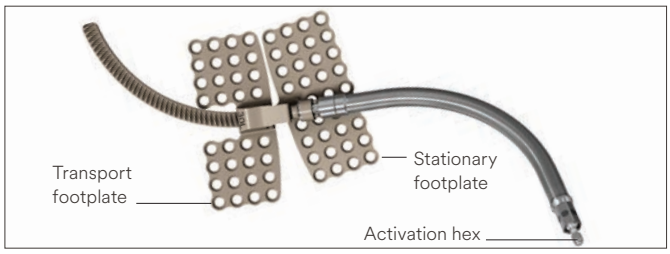


Figure 1

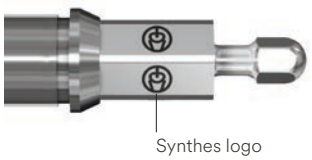


Figure 2

Figure 3

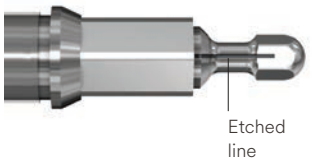


Figure 4

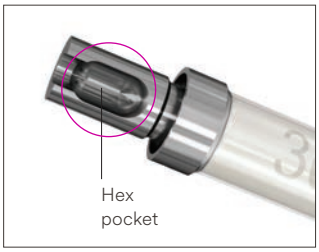


Figure 5

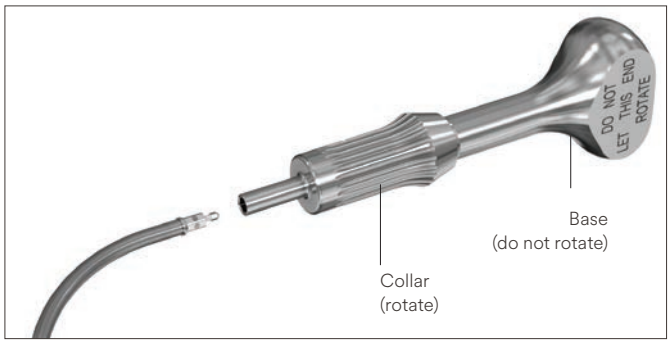


Figure 6

■ Note:

Extension arms (flexible and rigid) are provided fully tightened to prevent unintentional separation. When opening the extension arm for the first time, there will be significant resistance. Rotate the removal instrument collar counterclockwise, in the direction “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 spring fingers or the hex pocket (Figure 7). Alternatively, the extension arm can be held in the removal instrument without any support (Figure 8). Gripping the extension arm with your fingers will make it difficult to open and cause the silicone sleeve to twist and possibly tear. 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. Re-assemble the extension arm by inserting the inner sleeve into the outer sleeve and rotating the outer sleeve clockwise until it fully closes (Figure 9).

For the spring finger extension arm, slide the extension arm over the distractor body activation hex so that the spring fingers engage the activation hex (Figure 10). If the spring fingers do not slide over the activation hex, slightly rotate the extension arm clockwise while pushing toward the distractor to fully engage.

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

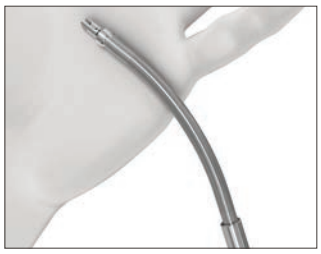


Figure 7

Figure 8

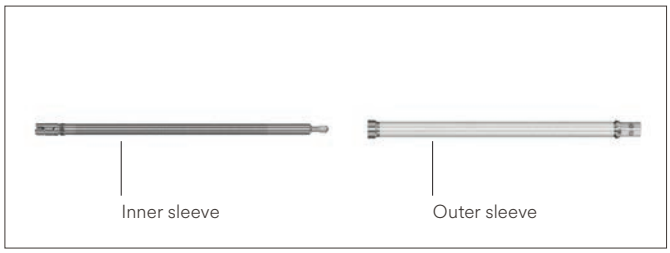


Figure 9

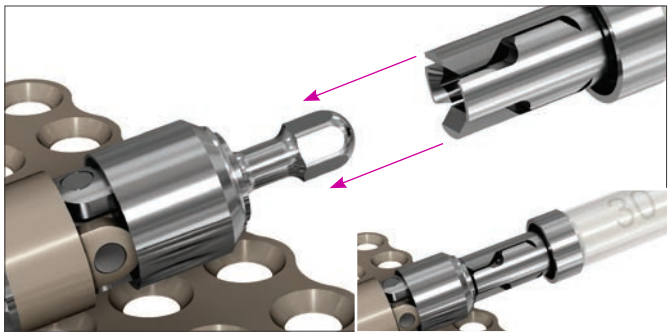


Figure 10

For the hex pocket extension arm, place the distractor body activation hex into the hex pocket of the extension arm (Figure 11).

Rotate the removal instrument collar clockwise until the extension arm closes over the activation hex on the distractor and fully tighten. Visually verify that the flange of the extension arm is contacting the collar of the U-joint (Figure 12).

Rigid extension arms are also available and they attach to the distractor with the hex pocket coupling (Figure 13).

▲ WARNINGS:

- During the course of treatment, care should be taken to protect the extension arms and prevent damage or breakage. Lateral forces from a patient rolling on the flexible extension arms during sleep can damage and/or break the extension arms. It is advised to secure the flexible arms to the patient's skin, without affecting the arm's ability to rotate. As an alternative, rigid extension arms are available.
- The removal instrument must be used to fully tighten the extension arm to the distractor. If the removal instrument is not used, the extension arm may separate from the distractor unintentionally.

Figure 11

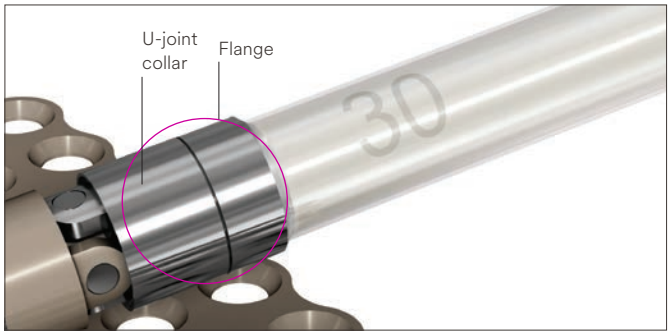


Figure 12

Figure 13

7. Create activation port for extension arm

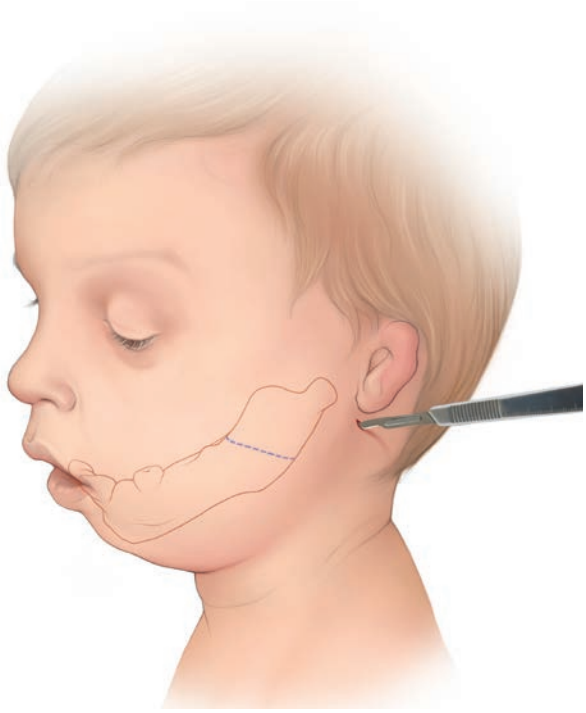
A percutaneous activation port must be created in the soft tissue through which the extension arm will exit.

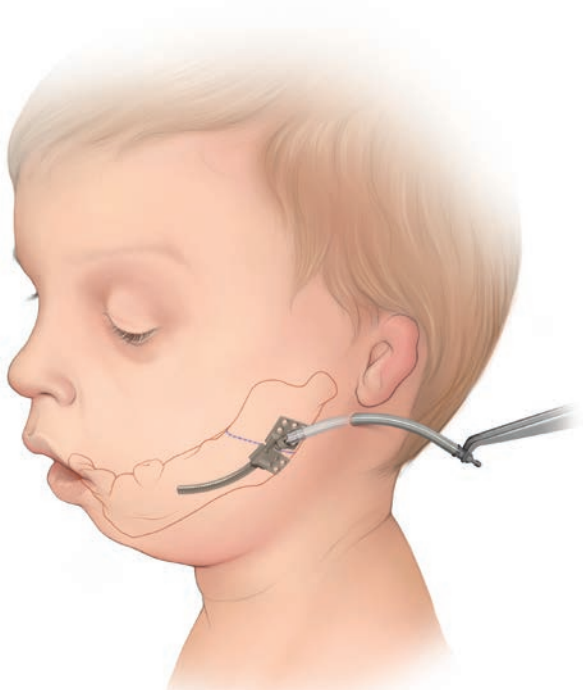
Create the percutaneous activation port by making a stab incision through the skin, followed by blunt dissection.

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

■ Note:

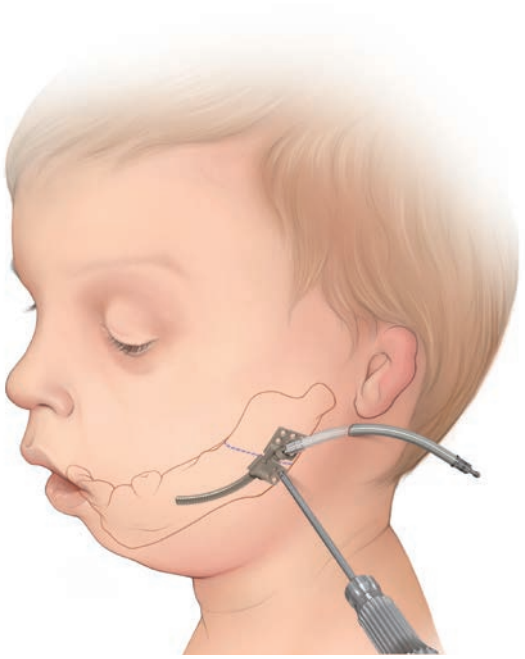
To facilitate insertion of the extension arm through the soft tissue, the tip of the extension arm can be inserted into tubing and pulled through the soft tissue. Remove the tubing once the extension arm is in place.





8. Mark distractor location

Instruments	
311.005	Screwdriver Handle with Hex Coupling, small
311.006	Screwdriver Handle with Hex Coupling, medium
319.520	Depth Gauge, long, for 1.5 mm/2.0 mm screws



Mark the distractor location before making the osteotomy by drilling and/or inserting at least one appropriate length screw at a right angle through each footplate.

▲ WARNING:

Ensure screw insertion at a right angle to the footplate. Off-axis screw insertion may result in improper screw engagement in bone which might lead to a choking hazard.

Use the appropriate drill bit and screwdriver shaft for the distractor size selected.

For insertion of screws with PlusDrive screwdriver blades:

Footplate/ Screw size	Drill bit size	PlusDrive screwdriver blade	Screwdriver color band
1.3 mm	1.0 mm	1.3 mm	Yellow
2.0 mm	1.5 mm	2.0 mm or 1.5/2.0 mm	Blue or Red/Blue

For insertion of screws with Raised Head screwdriver blades:

Footplate/ Screw size	Drill bit size	Raised Head screwdriver blade	Screwdriver color band
1.3 mm	1.0 mm	1.0/1.3 mm	Green/Yellow
2.0 mm	1.5 mm	1.5/2.0 mm	Red/Blue

See Instruments specific for Curvilinear Distractor section for drill bit and screwdriver shaft part numbers.

▲ WARNING:

Use of an inappropriate size screw or drill bit may lead to screw pull out and cause an obstruction or a choking hazard.

Confirm drill bit length prior to drilling.

Confirm screw length prior to implantation. Use a depth gauge or screw length marker in screw module if required.

Optional Instruments

Universal Trocar System for use with 2.0 mm Curvilinear Distractor

397.211	Universal Handle for Drill Sleeves
397.213	Cannula and Obturator 2.0
397.232	Cheek Retractor, for MatrixMANDIBLE, U-shaped, flexible
397.420	Cheek Retractor 2.0, for No. 397.213
397.430	Cheek Retractor Ring 2.0, for No. 397.213

Pediatric Trocar System for use with 1.3 mm Curvilinear Distractor

03.315.007	Pediatric Drill Guide for 1.0 mm/1.3 mm screws
03.315.008	Obturator for Pediatric Drill Guide, 1.0 mm/1.3 mm
03.315.009	Cheek Retractor for Pediatric Drill Guide, 1.0 mm/1.3 mm

Before making the osteotomy, mark the position of the distractor by drilling and/or inserting one appropriate size and length screw through each footplate (for details, see Extension Arms section).

Technique tip:

PlusDrive and Raised Head Screws are color-coded according to type.

Screw type	Screw color
Self-Drilling	Gray
Self-Tapping	Gold
Emergency	Green-Gray

Fully seat the screwdriver blade in the screwdriver handle with hexagonal coupling before use of the screwdriver blade.

PlusDrive Screws are intended to be inserted using PlusDrive screwdriver blades. Raised Head Screws are intended to be inserted using Raised Head screwdriver blades.

Raised Head Screws also engage with the appropriate size PlusDrive screwdriver blade in the same manner as PlusDrive screws.

When using PlusDrive screwdriver blades for insertion, to engage the screw on the blade, align the appropriate size PlusDrive screwdriver blade over the cruciform recess and slowly rotate it counterclockwise until the blade drops into the recess. Firmly press the blade to fully seat it into the screw.

To engage the Raised Head Screws on the Raised Head screwdriver blade, align the internal hexagon of the appropriate size Raised Head screwdriver blade with the hexagonal head of the screws and place the tip of the blade over the head of the screw. Firmly press the blade over the screw to fully engage the screw with the blade.

▲ WARNINGS:

- Do not use the Raised Head screwdriver blade to insert screws in patients with poor bone quality because disengagement of the screws may pull screws out of bone.
- In poor quality bone, it is recommended to use the PlusDrive screwdriver blade when inserting Raised Head Screws with limited retention, to pre-vent screw pullout after insertion due to retention forces between the Raised Head Screws and Raised Head screwdriver blades.

Do not fully tighten the screws.

To disengage the PlusDrive screwdriver blade from the screw, rock the blade off the screw and/or screw module.

To disengage the Raised Head screwdriver blade from the screw, pull the blade away from the screw axially.

▲ Precaution:

Disengaging the Raised Head screwdriver blade from the screw by rocking the blade off the screw in the bone and/or screw module may cause the screw head to break off in the blade.

Remove the distractor and footplates after marking the site.

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

▲ WARNINGS:

- Bending templates (2.0 mm distractor only) should not be used as drill guides for implanting the actual distractor on the patient. Doing so may release nonbiocompatible aluminum fragments into the wound site.
- When the distractor is placed and/or removed intraorally, use of a throat pack is required to prevent a choking hazard in case of implant fragments generated during the surgery.
- Take care to remove all fragments that are not fixated during surgery.
- Instruments should be inspected after processing and worn devices should not be used.
- Ensure appropriate screw length to avoid distractor loosening or damage of other critical/lingual structures.
- Drill rate should never exceed 1,800 rpm. Higher rates can result in thermal necrosis of the bone, soft tissue burns, and an oversized hole to be drilled. The detriments of an oversized hole include reduced construct stability, increased ease of the screws stripping in bone, and/or suboptimal fixation.

▲ Precautions:

- Raised Head Screw geometry does not allow for engagement with the holding sleeve.
- The Raised Head screwdriver blade geometry does not allow for use with the pediatric trocar system. The universal trocar may be used instead.
- A minimum of 4 screws (for the 1.3 mm distractor) and a minimum of 2 screws (for the 2.0 mm distractor) are required on each side of the osteotomy.
- To increase distractor stability in thin bone, insert screws bicortically. In addition, more screws can be used.
- Do not fully tighten the screws before making the osteotomy.
- Always irrigate adequately during drilling to prevent overheating of the drill bit and bone.
- Irrigate and apply suction for removal of debris potentially generated during implantation or removal.
- Avoid damaging the plate threads with the drill.
- Take care to avoid nerves, tooth buds, tooth 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.
- Distractors, instruments, and screws may have sharp edges or moving joints that may pinch or tear user's glove or skin.
- Handle devices with care and dispose of worn bone-cutting instruments in a sharps container.
- After implant placement is complete, discard any fragments or modified parts in an approved sharps container.
- Use appropriate screw length to avoid distractor loosening or damage of critical/lingual structures.
- Activate the distractor counterclockwise a half turn prior to drilling and/or inserting screws to ensure adequate distance between the screw holes and the osteotomy.
- If locking screws are used (2.0 mm distractor only), screw holes must be drilled perpendicular to the plate hole to prevent the screws from becoming cross threaded. A drill guide is provided to facilitate proper placement.
- Ensure there is adequate bone for screw placement in the desired location. Screws can loosen during the course of treatment if placed in poor quality bone because disengagement of the screws may pull screws out of 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.

▲ Precautions:

- Do not fully tighten the screws before making the osteotomy.
- Firmly press the screwdriver blade into the screw recess to ensure retention of the screw on the screwdriver blade.
- If locking screws are used (2.0 distractor only), screw holes must be drilled perpendicular to the plate hole to prevent the screws from becoming cross threaded. A drill guide is provided to facilitate proper placement.

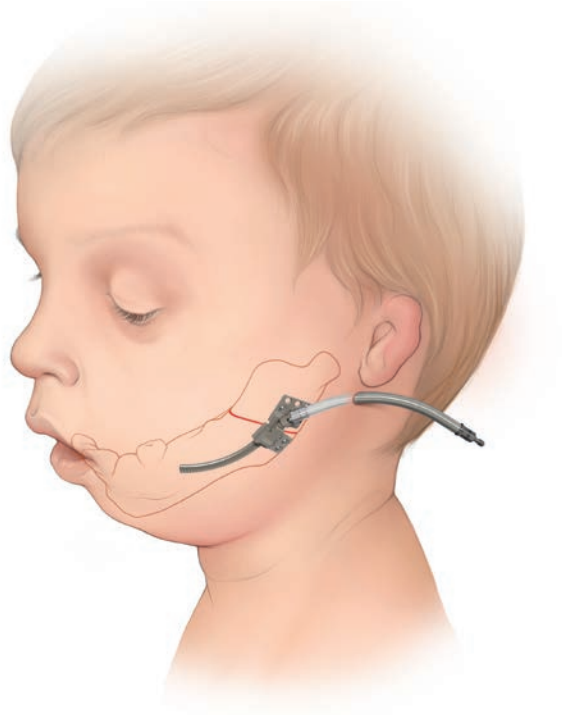
Optional Technique:

It may be desirable to make a complete osteotomy prior to reattaching the distractor as it can be difficult to use an osteotome to complete the osteotomy once the distractor is reattached.

10. Reattach distractor

Reattach the distractor by aligning the footplates with the holes made previously. Drill and/or insert screws at a right angle to the footplate. Fully tighten all screws, but use care not to over-tighten.

Refer to Step 8 (Mark distractor location) for guidance for screw insertion, and associated precautions, warnings, notes, technique tips, and part numbers.



▲ Precautions:

- The extension arm should be assembled with the distractor before the distractor is attached to the bone. It is difficult to attach the extension arm after the distractor is screwed to the bone.
- If the distractor is placed with the extension arm in the intraoral cavity, ensure that the extension arm does not interfere with patient's ability to chew.
- Applying too much torque to the screws may cause implant and/or instrument breakage, deformation, or bone stripping.

■ Note:

To increase distractor stability in thin bone, insert screws bicortically. In addition, more screws can be used.

11. Complete osteotomy

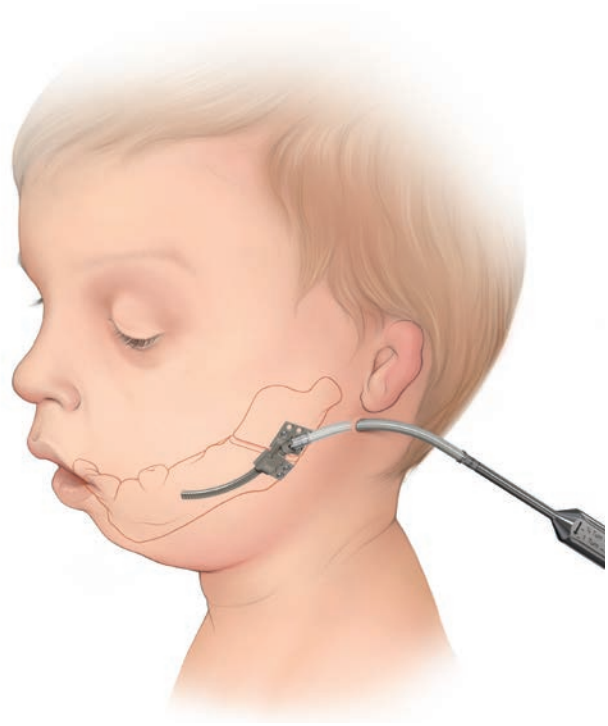
Complete the osteotomy on the lingual aspect of the mandible using an osteotome.

▲ Precautions:

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

12. Confirm device activation

Instrument	
03.500.016	Activation Instrument for Curvilinear Distractor
Optional instrument	
03.307.002	Silicone Tip Guard



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.

Optional technique using the silicone tip:

The silicone tip guard could be used to protect the end of the extension arm.

▲ WARNING:

If the silicone tip guard is used to protect the end of the extension arm, it presents a choking hazard, if it becomes loose and it disengages from the extension arm.

▲ Precaution:

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. Optional technique for bilateral procedures

Repeat Steps 1 through 12 on the contralateral side. Close all incisions.

▲ Precaution:

In case of bilateral procedure, the distractors must be placed as parallel as possible to each other and to the sagittal plane, to prevent binding or not turning freely.

Postoperative Considerations

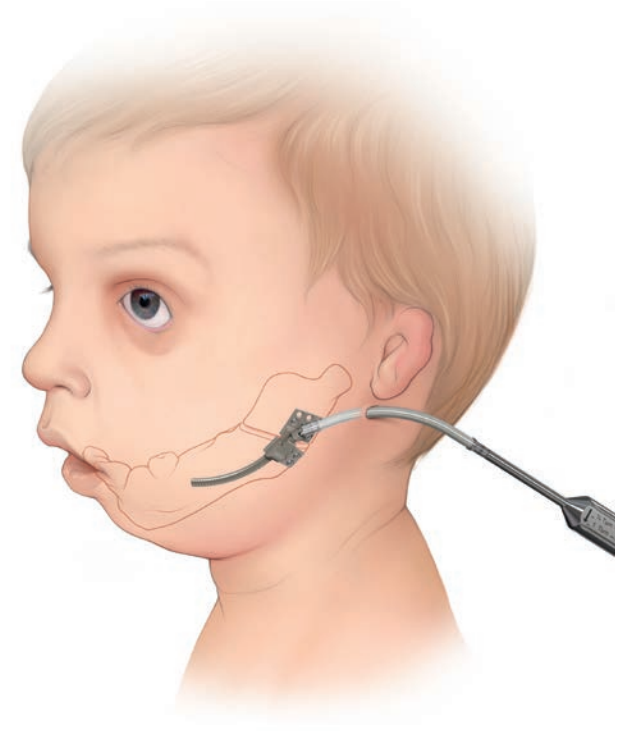
Suggested distraction protocol

Instrument	
03.500.016	Activation Instrument for Curvilinear Distractor

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

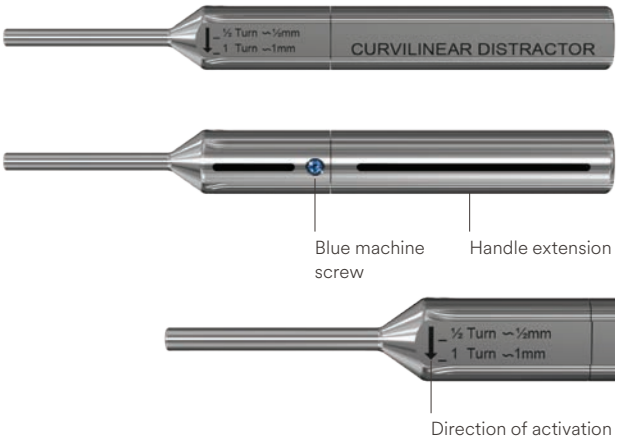
To activate the distractors, engage the activation instrument with the extension arm and rotate counterclockwise in the direction of the arrow marked on the instrument.

A minimum of 1.0 mm of distraction per day (half turn twice daily) is recommended to prevent premature consolidation. In patients one year old and younger, a rate of 1.5 to 2.0 mm per day may be considered.



■ Notes:

- 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.
- The activation instrument can be made smaller for use in young patients by removing the blue machine screw and separating the handle extension.



▲ Precautions:

- It is important to only turn the activation instrument in the direction of the arrow marked on the handle. Turning the activation instrument in the wrong direction (opposite to the arrow) can interfere with the distraction process.
- Do not hold the extension arm while rotating it with the activation instrument. Doing so will make it difficult to rotate the extension arm and may cause the extension arm to separate from the distractor.
- During the course of treatment, monitor the patient's condyles in the glenoid fossae for degenerative changes.

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

▲ Precautions:

- The surgeon must instruct the patient/care giver how to activate and protect the distractor during the treatment.
- It is important that the extension arms be protected from catching on objects that could pull the devices and cause the patient pain or injury.
- Patients should also be advised to not tamper with the distractors and to avoid activities that may interfere with treatment. It is important to instruct patients/care givers to follow the distraction protocol, keep the wound area clean during treatment and contact their surgeon immediately if they lose the activation instrument.

▲ WARNING:

During the course of treatment, care should be taken to protect the extension arms and prevent damage or breakage. Lateral forces from a patient rolling on the flexible extension arms during sleep can damage and/or break the extension arms. It is advised to secure the flexible arms to the patient's skin, without affecting the arm's ability to rotate. As an alternative, rigid extension arms are available.

Consolidation

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

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

Extension Arm Removal

Instrument

03.315.004	Removal Instrument for Extension Arms

There are two versions of extension arms and they are removed from the distractor differently. If the extension arm is etched with the DePuy Synthes logo on the outer sleeve, it is connected to the distractor with spring fingers (Figure 1). If the extension arm is etched with a line on the activation hex, it is connected to the distractor with a hex pocket (Figure 2). The rigid extension arms also connect with hex pocket. The instructions for use below provide details for both versions of extension arm.

Engage the removal instrument with the extension arm. Rotate the removal instrument collar counterclockwise at least 16 full turns in the direction marked “OPEN” in the collar (Figure 3). This will unscrew the outer sleeve of the extension arm and expose the area where the extension arm connects to the distractor (Figures 4–5).

▲ Precaution:

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.

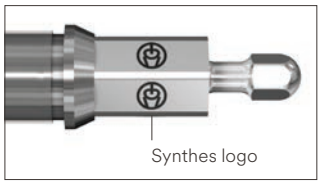


Figure 1

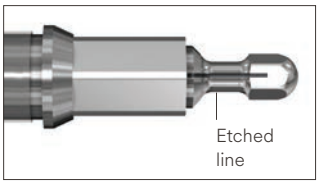


Figure 2

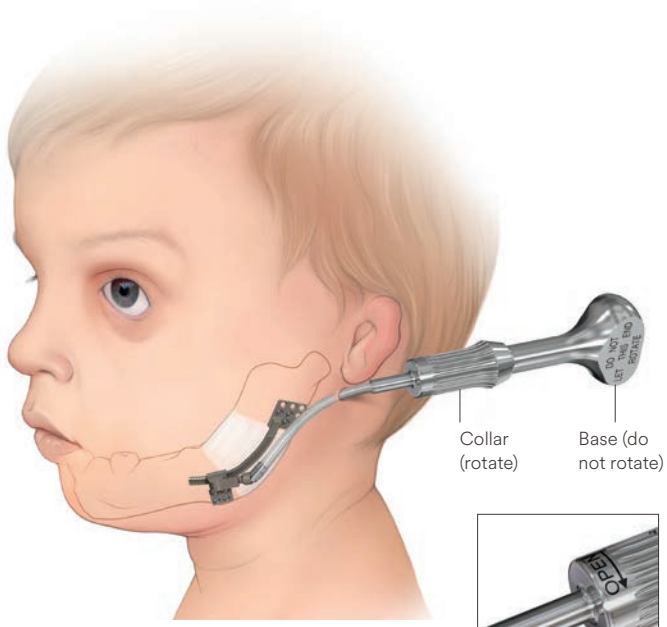


Figure 3

Figure 4

Figure 5

For the spring finger extension arm, disengage the extension arm from the distractor by pulling it axially and remove the extension arm through the percutaneous port (Figure 6).

For the pocket extension arm, disengage the extension arm from the distractor with side-to-side movements of the arm. Remove the extension arm through the percutaneous port (Figure 6).

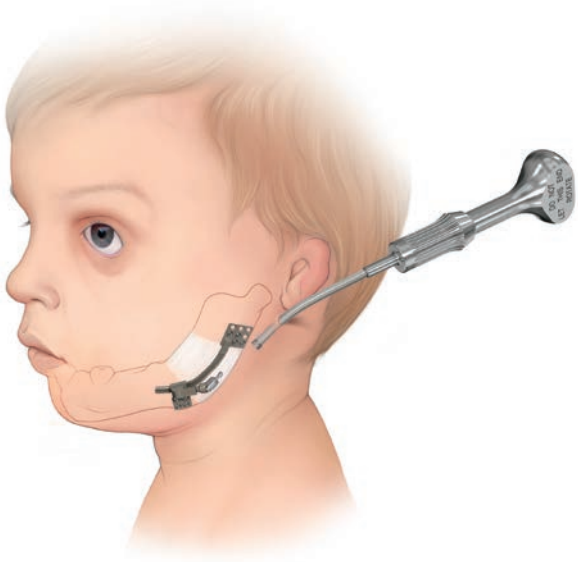


Figure 6

Notes:

- For the pocket extension arm, the line etched on the hex end of the extension arm corresponds to the direction of the hex pocket opening at the opposite end 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.

Optional technique for extension arm removal

Instruments	
03.500.016	Activation Instrument for Curvilinear Distractor
347.964	Bending Pliers 3D, left, for Plates 1.0 to 2.0, with contour-bending function

If the removal instrument is not available, the extension arms can be removed using the activation instrument and bending 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 area where the extension arm connects to the distractor (Figure 7). Disengage the extension arm from the distractor by pulling axially for the spring finger extension arm or with side-to-side movements for the hex pocket extension arm.

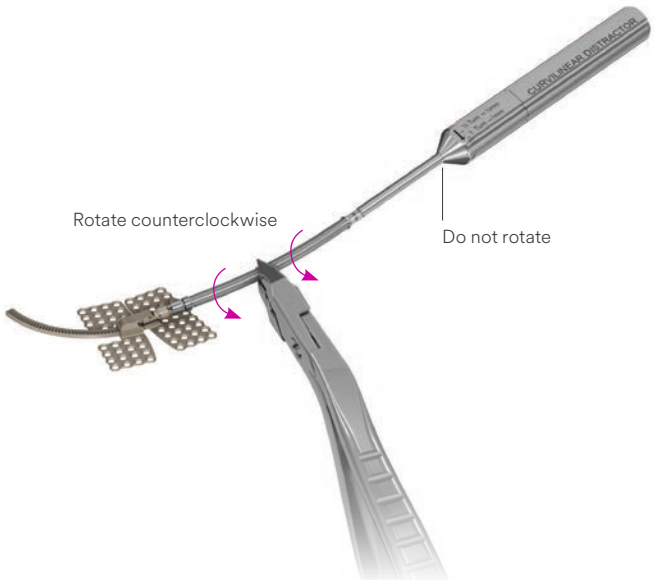


Figure 7

Device Removal

Expose the distractor footplates and bone screws through the same incisions that were used during initial placement surgery.

■ Note:

The extension arms are removed before distractor removal. This will also help keep internal tissue from contacting the externally exposed extension arm.

▲ Precautions:

- Screw heads might become obscured by bone or tissue ingrowth. It may be necessary to remove this ingrowth before screw removal.
- Device/Distractor might have distracted away from the incision site. It may be necessary to extend the existing incision or create a new incision for access to screws for removal.

▲ Warnings:

- Instruments should be inspected after processing and worn devices should not be used.
- When the distractor is placed and/or removed intraorally, use of a throat pack is required to prevent a choking hazard in case of implant fragments generated during the surgery.

Instruments

311.005	Screwdriver Handle with Hex Coupling, small
311.006	Screwdriver Handle with Hex Coupling, medium

For removal of screws with PlusDrive screwdriver blades, use the appropriate screwdriver blade for the footplate size selected.

Footplate/ Screw size	PlusDrive screwdriver blade	Screwdriver color band
1.3 mm	1.3 mm	Yellow
2.0 mm	2.0 mm 1.5/2.0 mm	Blue or Red/Blue

See Screwdriver shafts section for screwdriver blade part numbers.

Fully seat the screwdriver blade in the screwdriver handle with hexagonal coupling before use of the screwdriver blade.

When using PlusDrive screwdriver blades for removal, to engage the screw on the blade, align the appropriate size PlusDrive blade over the cruciform recess and slowly rotate it counterclockwise until the blade drops into the recess.

Firmly press the blade to fully seat it into the screw.

Remove the screw from the distractor footplate.

If Raised Head Screws were used, Raised Head Screwdriver Blades should be used for screw removal.

For removal of screws with Raised Head Screwdriver Blades, use the appropriate screwdriver blade for the footplate size selected.

▲ Precautions:

- The Raised Head Screw geometry does not allow for engagement with the holding sleeve.
- The Raised Head Screwdriver Blade geometry does not allow for use with the pediatric trocar system. The universal trocar may be used instead.

Footplate/ Screw size	Raised Head screwdriver blade	Screwdriver color band
1.3 mm	1.3 mm	Green/Yellow
2.0 mm	2.0 mm	Red/Blue

See Screwdriver shafts section for screwdriver blade part numbers.

Fully seat the screwdriver blade in the screwdriver handle with hexagonal coupling before use of the screwdriver blade.

To engage the Raised Head Screws on the Raised Head Screwdriver Blade, align the internal hexagon of the appropriate size Raised Head Screwdriver blade with the hexagonal head of the screws and place the tip of the blade over the head of the screw.

Firmly press the blade over the screw to fully engage the screw with the blade.

Remove the screw from the distractor footplate.

To disengage the screw from the blade, pull the screw axially using forceps.

▲ Precaution:

Disengaging the Raised Head screwdriver blade from the screw by rocking the blade off the screw in the bone and/ or screw module may cause the screw head to break off in the blade.

Remove all screws from the distractor footplates. Remove the distractor from the treatment site and discard according to standard procedures.

▲ Precautions:

- After implant placement or removal is complete, the surgical area should be irrigated and suction should be applied for removal of debris potentially generated during the procedure.
- To avoid implant migration, the distractor construct should be removed after treatment.
- Distractors, instruments, and screws may have sharp edges or moving joints that may pinch or tear user's glove or skin.
- Handle devices with care and dispose of worn bone-cutting instruments in a sharps container.

▲ WARNING:

Take care to remove all fragments that are not fixated during surgery.

For additional screw removal options, refer to the Universal Screw Removal Set brochure.

Instruments

Instruments for the Curvilinear Distraction System

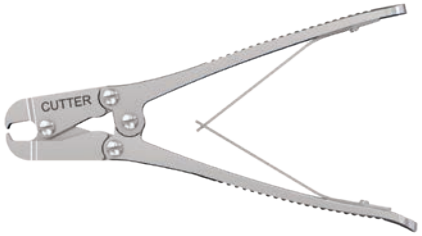
03.500.015	Crimping Instrument for Curvilinear Distractor

03.500.016	Activation Instrument for Curvilinear Distractor

03.500.020	File, with Hexagonal Coupling

03.315.004	Removal Instrument for Extension Arms (for attaching and removing extension arms)

03.500.014	Cutter for Distractor Footplates



311.005	Handle, small, with Hexagonal Coupling	
311.006	Handle, medium, with Hexagonal Coupling	
347.980	Holding Forceps for Plates	
347.964	Bending Pliers 3D, left, for Plates 1.0 to 2.0, with contour-bending function	
03.503.039	Plate Cutter for MatrixMIDFACE	

Instruments specific for Curvilinear Distractor 1.3

03.315.007	Drill Sleeve for Paediatrics for 1.0 mm and 1.3 mm screws	
03.315.008	Obturator for Pediatric Drill Guide	
03.315.009	Cheek Retractor Ring	
03.315.011	Drill Bit ∅ 1.0 mm, with Stop, length 75/12 mm, for J-Latch Coupling	

Drill bits, for use with ∅ 1.3 mm

316.236	Drill Bit ∅ 1.0 mm, length 60/35 mm, for Stryker Coupling	
316.446	Drill Bit ∅ 1.0 mm with Stop, length 44.5/4 mm, 2-flute, for J-LatchCoupling	
316.447	Drill Bit ∅ 1.0 mm with Stop, length 44.5/6 mm, 2-flute, for J-Latch Coupling	
316.448	Drill Bit ∅ 1.0 mm with Stop, length 44.5/8 mm, 2-flute, for J-Latch Coupling	

Screwdriver shafts

313.805	Screwdriver Shaft PlusDrive 1.3, self-holding, for Hexagonal Coupling
313.806	Screwdriver Shaft PlusDrive 1.3, medium, self-holding, for Hexagonal Coupling
03.315.700	Screwdriver Blade for Raised Head Screws, 1.0 mm/1.3 mm, Hex Coupling, 86 mm
314.491	Screwdriver Shaft 1.3, cruciform, length 75 mm, with Holding Sleeve, with Hexagonal Coupling

Instruments specific for Curvilinear Distractor 2.0

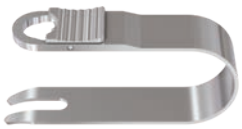
03.500.018	Bending Template for 2.0 Curvilinear Distractor, straight
03.500.030 03.500.101	Bending Template for 2.0 Curvilinear Distractor Radius 30–100, left and right versions

Drill bits, for use with ∅ 2.0 mm screws

316.510	Drill Bit ∅ 1.5 mm, length 80 mm, 2-flute, for J-Latch Coupling
316.520	Drill Bit ∅ 1.5 mm, length 125 mm, 2-flute, for J-Latch Coupling
317.640	Drill Bit ∅ 1.5 mm with Stop, length 44.5/4 mm, 2-flute, for J-Latch Coupling
317.660	Drill Bit ∅ 1.5 mm with Stop, length 44.5/6 mm, 2-flute, for J-Latch Coupling
317.680	Drill Bit ∅ 1.5 mm with Stop, length 44.5/8 mm, 2-flute, for J-Latch Coupling
317.720	Drill Bit ∅ 1.5 mm with Stop, length 44.5/12 mm, 2-flute, for J-Latch Coupling

Screwdriver shafts

313.252	Screwdriver Shaft PlusDrive 1.5/2.0, long, self-holding, for Hexagonal Coupling
313.253	Screwdriver Shaft PlusDrive 1.5/2.0, medium, self-holding, for Hexagonal Coupling
314.675	Screwdriver Shaft 2.0, cruciform, with Holding Sleeve, length 79 mm, with Hexagonal Coupling
03.315.701	Screwdriver Blade for Raised Head Screws, 1.5 mm/2.0 mm, Hex Coupling, 86 mm

312.154	Drill Sleeve 1.5, long, with thread, for LOCK Mandible Plates 2.0	
397.232	Cheek Retractor, for MatrixMANDIBLE, U-shaped, flexible	
397.420	Cheek Retractor 2.0, for No. 397.213	
397.430	Cheek Retractor Ring 2.0, for No. 397.213	
397.211	Universal Handle for Drill Sleeves	
397.213	Cannula and Obturator 2.0	
319.520	Depth Gauge for Screws 1.5–2.0 mm, up to 45 mm	

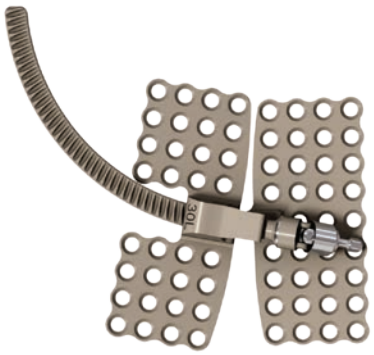
Optional Instruments from the CMF Distraction System for Use with the Curvilinear Distractor

03.307.002	Silicone Tip Guard
347.981	Holding Forceps for Plates 1.0 to 2.4
311.007	Handle, large, with Hexagonal Coupling
347.901	Pliers, flat-nosed, pointed, for Plates 1.0 to 2.4
311.011	Handle, small, with Mini Quick Coupling
311.012	Handle, medium, with Mini Quick Coupling
311.013	Handle, large, with Mini Quick Coupling
312.140	Double Drill Guide 1.5/1.1
312.220	Double Drill Guide 2.0/1.5
313.251	PlusDrive Screwdriver 1.5/2.0, self-holding
397.433	Drill Sleeve 1.5, for No. 397.422
397.422	Transbuccal Guide 2.0/2.4/3.0
397.423	Cheek Retractor, U-shaped, for No. 397.422
397.424	Cheek Retractor Ring, for No. 397.422
397.417	Drill Sleeve 2.0, for No. 397.422
317.740	Drill Bit ∅ 1.5 mm with Stop, length 44.5/4 mm, 2-flute, for Mini Quick Coupling
317.760	Drill Bit ∅ 1.5 mm with Stop, length 44.5/6 mm, 2-flute, for Mini Quick Coupling
317.780	Drill Bit ∅ 1.5 mm with Stop, length 44.5/8 mm, 2-flute, for Mini Quick Coupling
317.820	Drill Bit ∅ 1.5 mm with Stop, length 44.5/12 mm, 2-flute, for Mini Quick Coupling
347.986	Plate Holding Instrument, for Plates 1.0/1.3
347.987	Plate Holding Instrument, for Plates 1.5/2.0
316.521	Drill Bit ∅ 1.5 mm, length 125 mm, 2-flute, for Mini Quick Coupling
316.710	Drill Bit ∅ 1.5 mm, length 80 mm, 2-flute, for Mini Quick Coupling
313.254	Screwdriver Shaft PlusDrive 1.5/2.0, short, self-holding, for Hexagonal Coupling
316.410	Drill Bit ∅ 1.5 mm, length 100/85 mm, 2-flute, for Mini Quick Coupling
316.451	Drill Bit ∅ 1.0 mm with Stop, length 44.5/4 mm, 2-flute, for Mini Quick Coupling
316.452	Drill Bit ∅ 1.0 mm with Stop, length 44.5/6 mm, 2-flute, for Mini Quick Coupling
316.453	Drill Bit ∅ 1.0 mm with Stop, length 44.5/8 mm, 2-flute, for Mini Quick Coupling
313.917	Screwdriver Shaft 1.3, cruciform, self-holding, with Hexagonal Coupling
391.965	Combined Pliers for Plates 1.0 to 2.0, for Cutting and Bending

Implants

Curvilinear Distractors 1.3

Art. no	Radius (mm)	Design
04.500.218	Straight	
04.500.230	30	Right side
04.500.231	30	Left side
04.500.240	40	Right side
04.500.241	40	Left side
04.500.250	50	Right side
04.500.251	50	Left side
04.500.270	70	Right side
04.500.271	70	Left side
04.500.200	100	Right side
04.500.201	100	Left side



Curvilinear Distractors 2.0

Art. no	Radius (mm)	Design
04.500.018	Straight	
04.500.130	30	Right side
04.500.131	30	Left side
04.500.140	40	Right side
04.500.141	40	Left side
04.500.150	50	Right side
04.500.151	50	Left side
04.500.170	70	Right side
04.500.171	70	Left side
04.500.100	100	Right side
04.500.101	100	Left side

Extension Arms

Removable Extension Arms

04.315.104	Extension Arm, removable, rigid, length 20 mm, for CMF Distractor
04.315.108	Extension Arm, removable, rigid, length 40 mm, for CMF Distractor
04.315.112	Extension Arm, removable, rigid, length 60 mm, for CMF Distractor

04.315.125	Extension Arm, removable, flexible, length 30 mm, for CMF Distractor
04.315.127	Extension Arm, removable, flexible, length 40 mm, for CMF Distractor
04.315.132	Extension Arm, removable, flexible, length 60 mm, for CMF Distractor

■ Note:

Distractors with extension arms contain the following materials: Ti-15Mo, Ti-6Al-7Nb and Co-35Ni-20Cr-10Mo/ Silicone

Screws for Curvilinear Distractor 1.3

1.3 mm Titanium Raised Head Screw, self-drilling, PlusDrive, gray

Art. no.	Length (mm)
04.315.744.01C	4
04.315.746.01C	6

1.3 mm Titanium Raised Head Screw, self-tapping, PlusDrive, gold

Art. no.	Length (mm)
04.315.748.01C	8
04.315.750.01C	10
04.315.752.01C	12

1.7 mm Titanium Raised Head Emergency Screw, self-tapping, PlusDrive, green-gray

Art. no.	Length (mm)
04.315.764.01C	4
04.315.766.01C	6
04.315.768.01C	8
04.315.770.01C	10
04.315.772.01C	12

Cortex Screws PlusDrive ∅ 1.3 mm, self-drilling, Titanium Alloy (TAN), pack of 1 unit* in Clip

Art. no.	Length (mm)
400.454.01C	4
400.455.01C	5
400.456.01C	6

Cortex Screws PlusDrive ∅ 1.3 mm, self-tapping, Titanium Alloy (TAN), pack of 1 unit* in Clip

Art. no.	Length (mm)
400.434.01C	4
400.435.01C	5
400.436.01C	6
400.438.01C	8
400.440.01C	10
400.442.01C	12

Emergency Screws PlusDrive ∅ 1.7 mm, self-tapping, Titanium Alloy (TAN), pack of 1 unit* in Clip

Art. no.	Length (mm)
400.484.01C	4
400.485.01C	5
400.486.01C	6
400.488.01C	8
400.490.01C	10
400.492.01C	12

* For pack of 4 units, replace suffix .01C with .04C

Screws for Curvilinear Distractor 2.0

2.0 mm Titanium Raised Head Screw, self-drilling, PlusDrive, gray

Art. no.	Length (mm)
04.315.824.01C	4
04.315.826.01C	6
04.315.828.01C	8

2.0 mm Titanium Raised Head Screw, self-tapping, PlusDrive, gold

Art. no.	Length (mm)
04.315.830.01C	10
04.315.832.01C	12

2.4 mm Titanium Raised Head Emergency Screw, self-tapping, PlusDrive, green-gray

Art. no.	Length (mm)
04.315.845.01C	5
04.315.846.01C	6
04.315.848.01C	8
04.315.850.01C	10
04.315.852.01C	12

Cortex Screws PlusDrive ∅ 2.0 mm, self-drilling, Titanium Alloy (TAN), pack of 1 unit* in Clip

Art. no.	Length (mm)
401.061.01C	4
401.063.01C	6
401.065.01C	8

Cortex Screws PlusDrive ∅ 2.0 mm, self-tapping, Titanium Alloy (TAN), pack of 1 unit* in Clip

Art. no.	Length (mm)
401.041.01C	4
401.043.01C	6
401.044.01C	8
401.045.01C	10
401.046.01C	12

Emergency Screws PlusDrive ∅ 2.4 mm, self-tapping, Titanium Alloy (TAN), pack of 1 unit* in Clip

Art. no.	Length (mm)
401.791.01C	5
401.792.01C	6
401.794.01C	8
401.795.01C	10
401.796.01C	12

Lock Screws PlusDrive ∅ 2.0 mm, self-tapping, Titanium Alloy (TAN), pack of 1 unit* in Clip

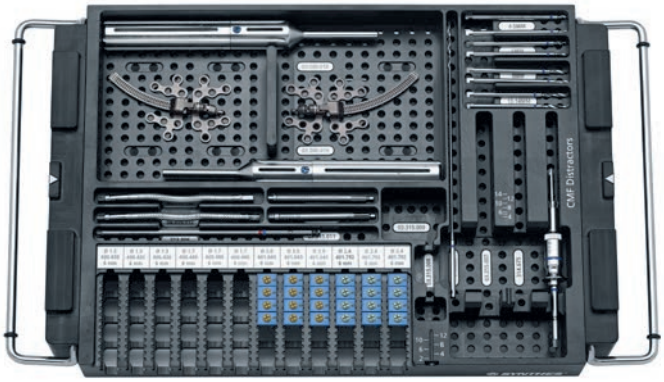
Art. no.	Length (mm)
401.291.01C	5
401.292.01C	6
401.294.01C	8
401.295.01C	10
401.296.01C	12

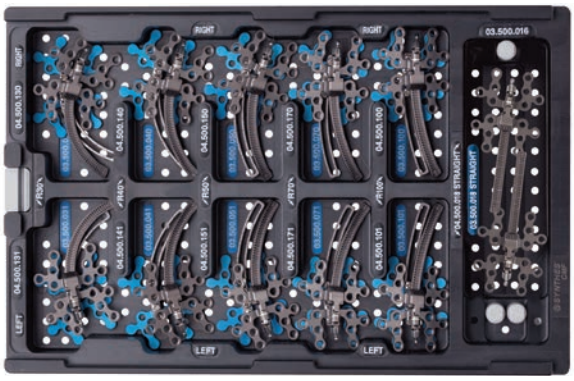
* For pack of 4 units, replace suffix .01C with .04C

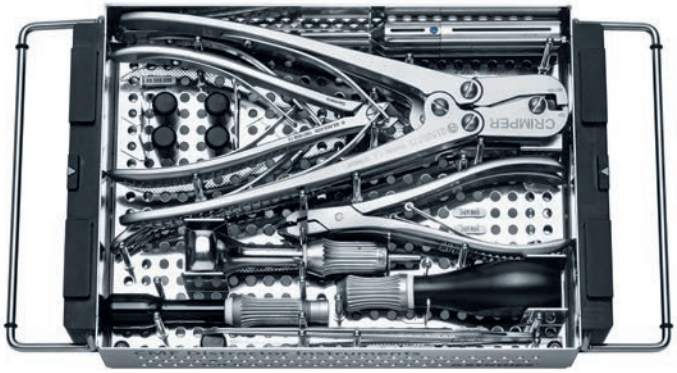
Curvilinear Distraction System Set

Cases

68.500.201	Module for curvilinear Distractor, without Contents, 2/3
304.095	Module for curvilinear Distractor 2.0, with Lid, without Contents
68.315.002	Instrument Tray for CMF Distractor, size 2/3, with Lid, without Contents







Sets

01.500.201	Set for curvilinear Distractor 1.3
01.500.202	Set for curvilinear Distractor 2.0
01.500.203	Instrument and Implant Set for curvilinear Distractor 1.3, 2/3
01.500.204	Instrument and Implant Set for curvilinear Distractor 2.0, 2/3
01.500.205	Set Bending Templates for curvilinear Distractor 2.0
01.500.208	Instrument Set for curvilinear Distractor 1.3 and 2.0, 2/3

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

DePuy Synthes
THE ORTHOPAEDICS COMPANY OF Johnson&Johnson

Synthes GmbH
Eimattstrasse 3
4436 Oberdorf
Switzerland
Tel: +41 61 965 61 11

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