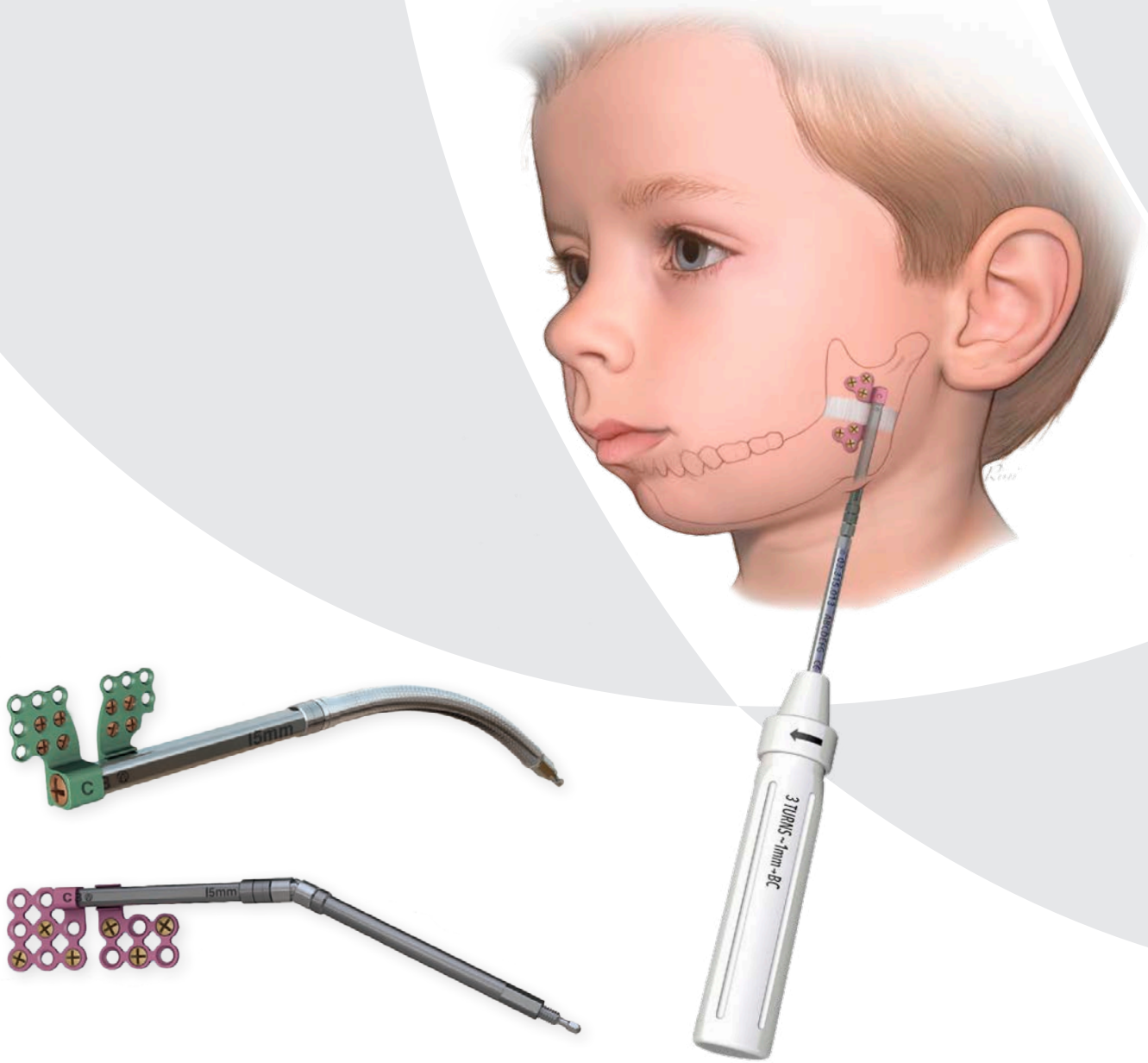
A Modular Family of Internal Distraction Devices
to Lengthen the Mandibular Body, Ramus, and Cranium

Craniomaxillofacial (CMF) Distraction System

Surgical Technique



DePuy Synthes
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

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 Synthes reusable devices, instrument trays and cases, as well as processing of Synthes non-sterile implants, please consult the Important Information leaflet (SE_023827) or refer to:
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance

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Indications and Contraindications

Intended Use

The DePuy Synthes CMF Distraction System is intended for use as a bone stabilizer and lengthening (and/or transport) device.

Indications

The DePuy Synthes CMF Distraction System is indicated for correction of congenital deficiencies or post-traumatic defects of the mandibular body, mandibular ramus, and cranium where gradual bone distraction is required in adults and pediatric patients. DePuy Synthes CMF Distraction System is intended for single use only.

Mandible

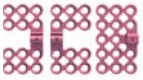
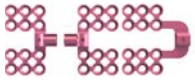
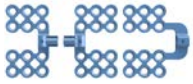
- The 1.0 mm footplates and screws are intended for neonates and infants under the age of 12 months.
- The 1.3 mm footplates and screws are intended for neonates, infants, and children 4 years of age and younger.
- The 1.5 mm and 2.0 mm footplates and screws are intended for infants, children, adolescents, and adults 1 year of age and older.

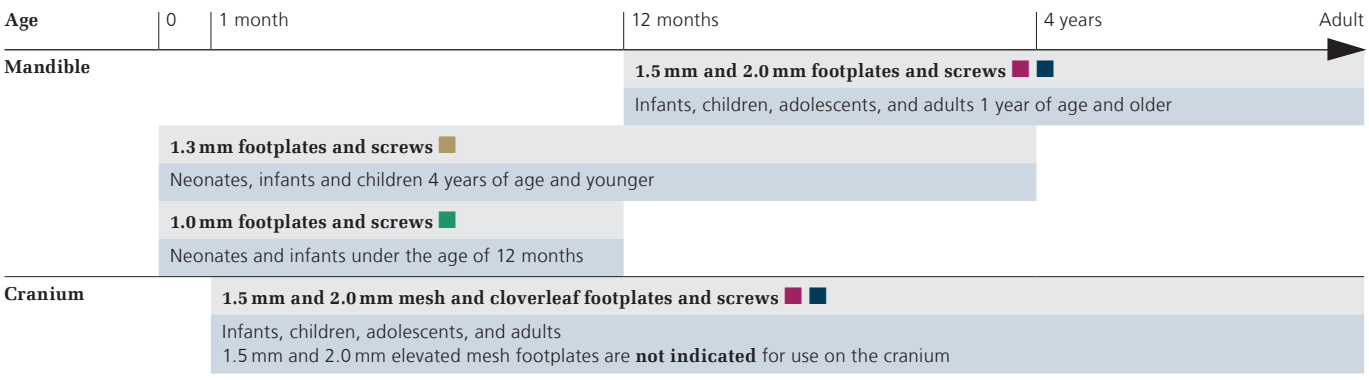
Cranium

- The 1.5 mm and 2.0 mm mesh and cloverleaf footplates and screws are intended for infants, children, adolescents, and adults.

Contraindications

Use of the DePuy Synthes CMF Distraction System is contraindicated in patients previously sensitized to Nickel, Cobalt Chromium, Silicone, or Molybdenum.

	Mandible	Cranium				
1.0 mm mesh footplates and screws	intended for neonates and infants under the age of 12 months	–			 1.0 mm mesh footplates	
1.3 mm cloverleaf and mesh footplates and screws	intended for neonates, infants, and children 4 years of age and younger	–		 1.3 mm cloverleaf footplates	 1.3 mm mesh footplates	
1.5 mm and 2.0 mm cloverleaf and mesh footplates and screws	intended for infants, children, adolescents, and adults 1 year of age and older	intended for infants, children, adolescents, and adults	 1.5 mm cloverleaf footplates	 1.5 mm mesh footplates	 2.0 mm cloverleaf footplates	 2.0 mm mesh footplates
1.5 mm and 2.0 mm elevated mesh plates and screws	intended for infants, children, adolescents, and adults 1 year of age and older	–	 1.5 mm elevated mesh footplates		 2.0 mm elevated mesh footplates	



General 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 cranial distraction, the surgeon should take into account any pre-existing conditions such as non-syndromic craniosynostosis that would not be treated as a result of this procedure.**
- **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.**
- **Instruments should be inspected after processing and worn devices should not be used.**
- **The manufacturer is not responsible for any complication arising from incorrect diagnosis, choice of incorrect implant, incorrectly combined implant components and/or operating techniques, the limitations of treatment method, or inadequate asepsis. The implant components applied (name, article number, lot number) must be documented in each patient's record.**
- **These devices can break during use (when subjected to excessive forces or outside the recommended technique). While the surgeon must make the final decision on removal of the broken part based on associated risk in doing so, it is recommended that whenever possible and practical for the patient, the broken part should be removed.**
- **Take care to remove all device fragments that are not fixated during surgery.**
- **In cases of mandibular distraction when the distractor is placed and/or removed intraorally, use of a hospital-approved throat pack is required to prevent a choking hazard in case of device fragments generated during the surgery.**
- **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 joint mechanics, ankylosis, malunion or non-union, 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.**

Precautions

- **Surgical implants must never be reused. An explanted metal implant must never be reimplanted. Even though the explanted device appears undamaged, it may have small defects and internal stress patterns which could lead to breakage.**
- **Instruments, distractors, 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 or removal is complete, the surgical area should be irrigated and suction should be applied for removal of debris potentially generated during the procedure.**
- **All cut footplates should be deburred as needed by rubbing sharp corners and/or edges with the file on the cutter or with the file instrument included in the set.**

Possible adverse events

As with all major surgical procedures, risks, side effects, and adverse events can occur. While many possible reactions may occur, some of the most common include: problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, dental injuries, neurological impairments, etc.), thrombosis, embolism, infection, cerebrospinal fluid leak, nerve and/or tooth root damage, injury of critical structures including the brain, dura mater, venous sinuses and other blood vessels, Temporomandibular Joint (TMJ) ankylosis and degeneration, excessive bleeding, damage to soft tissues including swelling, perioperative morbidity, abnormal scar formation, wound dehiscence, skin necrosis, functional impairment of the musculoskeletal system, pain, discomfort or abnormal sensation due to the presence of the device,

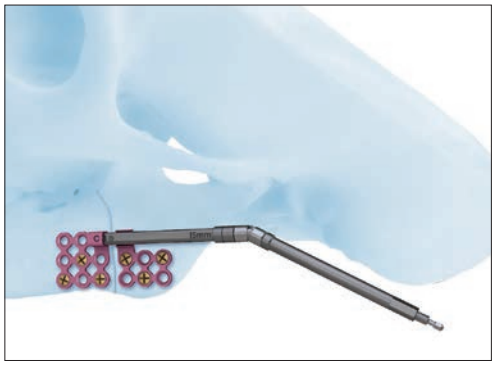
allergy or hypersensitivity reactions, side effects associated with hardware prominence, loosening, bending, or breakage of the device, mal-union, non-union, or delayed union, which may lead to breakage of the implant, reoperation, impairment while eating or feeding.

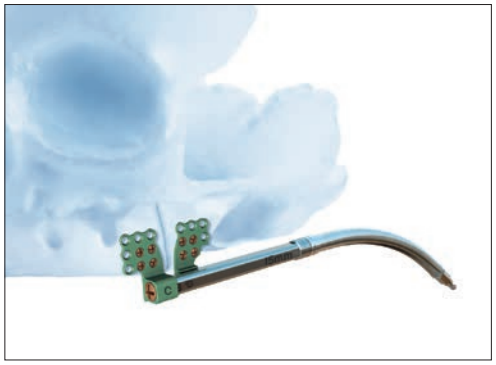
Magnetic Resonance (MR) information
Magnetic Resonance Environment Torque, Displacement and Image Artifacts according to ASTM F 2213-17, ASTM F 2052-15 and ASTM F2119-07
Non-clinical testing of worst case scenario in a 3 T MRI system did not reveal any relevant torque or displacement of the construct for an experimentally measured local spatial gradient of the magnetic field of 70.1 T/m. The largest image artifact extended approximately 55 mm from the construct when scanned using the Gradient Echo (GE). Testing was conducted on a single Siemens Prisma 3 T MRI system.

Radio-Frequency-(RF-)induced heating according to ASTM F2182-11a
Non-clinical electromagnetic and thermal simulations of worst case scenario lead to temperature rises of 9.9 °C (1.5 T) and 4.9 °C (3 T) under MRI conditions using RF Coils (whole body averaged specific absorption rate [SAR] of 1 W/kg for 15 minutes).

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

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



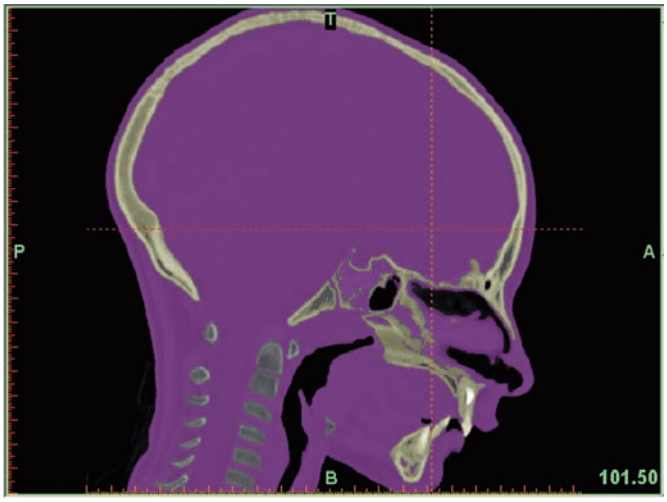


Preoperative Planning

Mandible and Cranial

Preoperative planning
Determine the post-distraction anatomic goal by conducting an evaluation of the craniofacial pathology and asymmetry through clinical exam, Computerized Tomography (CT) scan, cephalogram and/or panoramic x-ray. Anatomical models may be beneficial in severe cases for selecting appropriate distractor components, determining the location of the osteotomy and placement of the devices, and for pre-bending the footplates.

Explain to the patient and/or caregiver before surgery the time needed for the whole treatment (e.g. distraction and consolidation times).



Mandible

Precautions:
When placing the distractors, consider and verify:
- **Occlusal plane**
- **Tooth buds and roots**
- **Planned vector of distraction**
- **Planned length of advancement (consider relapse and overcorrection)**
- **Adequate bone quality and quantity for screw placement. A minimum of three screws (minimum of two screws for mandibular bone transport) is required on each side of the osteotomy. The distractor may be fixated with more than three screws (two screws for mandibular bone transport) per footplate. If large bone advancement is desired, the distractor with mesh footplate can be used to enable the use of more than three screws per footplate. If the 1.0 mm system is selected, at least 4 screws must be used to secure each footplate in poor quality bone to prevent screw pull-out during treatment. Of these 4 screws, at least two screws of a minimum of 6 mm length must be used in the row of screw holes closest to the distractor body.**
- **Location of mental nerve and inferior alveolar nerve**
- **Lip closure**
- **Soft tissue coverage**
- **Location of activation hex of distractor or extension arm**
- **Patient pain due to distractor interference with soft tissue**
- **Access to the screws based on approach:**
  - **For intraoral/transbuccal approach, it is recommended to use screw holes superior to the distractor body because it is difficult to see and access the screw holes in the inferior footplate**
  - **For external approach, screws can be placed inferior or superior to the distractor body**
- **Placement of condyle in the glenoid fossa. Ensure that the distraction plan will not create a significant condylar dislocation. During the course of mandibular treatment, monitor the patient's condyles in the glenoid fossa for symptoms of TMJ displacement (pain, clicking or locking).**
- **Distractor or extension arm does not interfere with mastication.**
- **Devices should be placed as parallel as possible to diminish the possibility of temporomandibular joint displacement. While parallel placement of the distractors is ideal, this may be difficult to accomplish considering the patient's soft tissue coverage, and could potentially lead to patient discomfort.**

Cranial

Precautions:
When placing the distractors, consider and verify:
- **Planned vector of distraction**
- **Planned length of advancement (consider relapse and overcorrection)**
- **Adequate bone quality and quantity for screw placement. A minimum of three screws is required on each side of the osteotomy. The distractor may be fixed with more than three screws per footplate. If large bone advancement is desired, the distractor with mesh footplate can be used to enable the use of more than three screws per footplate.**
- **Dura mater**
- **Venous sinuses and other blood vessels**
- **Number of distractors to be used during treatment**
- **Location of activation hex of distractor or extension arm**
- **Patient pain due to distractor interference with soft tissue and hair**
- **Type of coronal incision**
- **During cranial distraction, parallel placement is necessary to facilitate proper head lengthening and ultimate symmetrical anatomy. Take great care in aligning the distractors used in a parallel position while fitting to ensure proper distraction. If parallel placement is difficult to accomplish when considering the patient's soft tissue coverage and potential patient discomfort, a slight convergence is acceptable if the point of convergence is sufficiently far from the patient.**
- **Soft tissue coverage**

As part of the TRUMATCH CMF Personalized Solutions, DePuy Synthes offers PROPLAN CMF® Online Planning Services for preoperative planning.

Virtual surgical planning may be beneficial in complex cases for selecting appropriate distractor components, determining the location of the osteotomy and placement of the devices, and for pre-bending the footplates.

DePuy Synthes offers following options:

1. Planning Services*

DePuy Synthes PROPLAN CMF Planning Services allows:
- Live interactive planning session with a knowledgeable team of clinical engineers
- The surgeon to make critical clinical decisions preoperatively
- 2D and 3D visualization of preoperative patient anatomy and condition
- Cephalometric analysis
- Simulation of skeletal osteotomies
- Visualization of movement of osteotomized bone structures (bone movement to desired postoperative position)
- Identification of potential bone interferences
- Virtual placement of the distractor on the mandible to determine the proper distractor size and placement
- Visualization of the clinical plan to validate the planned, clinical result
- Soft tissue simulation and (3D) photomapping

2. Anatomic Models* and Surgical Guides*

In addition to virtual case planning, DePuy Synthes PROPLAN CMF Products and Services include anatomic models, surgical guides, and DePuy Synthes PROPLAN CMF Online.
- Anatomic models are useful for bending distractor footplates preoperatively
- Surgical guides function as cutting and drilling guides to accurately transfer the plan to the operating room
- PROPLAN CMF Online is a web-based interface that allows case creation, data exchange, tracking, and visualization of surgical plans, tools, and implants

Steps for planning a case with PROPLAN CMF Virtual Surgical Planning Services
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

* powered by Materialise

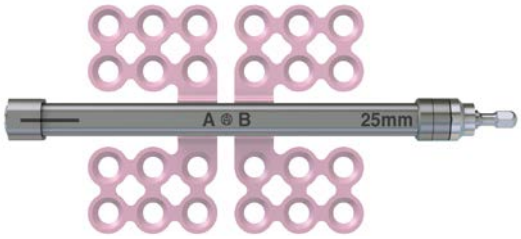
Distractor Assembly

1. Select distractor body

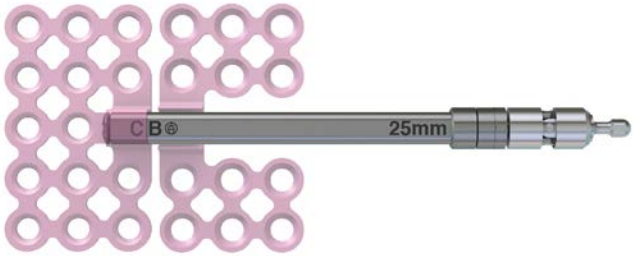
Select the appropriate design and length distractor body according to the treatment plan. The design type and maximum length of the distractor is etched onto the laterally facing side of the distractor body. For details on distractor bodies, refer to implant descriptions on page 77.

Precaution: **To ensure that the soft tissue does not obstruct the activation hex during distraction, the next longer size distractor body and/or extension arm may need to be used.**

Warning: **Ensure all steps of the provided technique are followed. It presents a choking hazard if components of the distractor (e.g. bone screw, machine screw, distractor collar, universal joint, extension arm and silicone tube of flexible extension arm) become loose, disengage from the distractor, or break.**



Center-translating (AB distractor body shown with 1.5 mm mesh footplates)



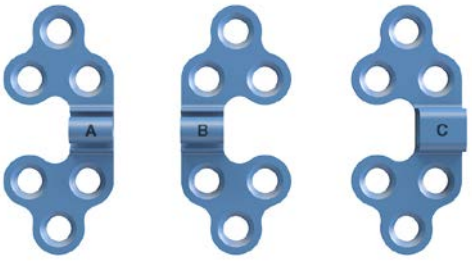
End-translating (BC distractor body shown with universal joint and 1.5 mm mesh footplates)

2. Select footplates

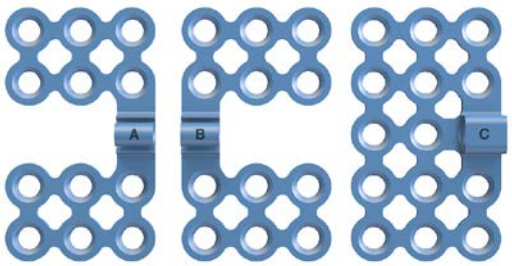
Select two footplates (either A-style and B-style or B-style and C-style) according to the treatment plan and selected distractor body, giving special consideration to the patient's anatomy.

Notes:

- **Footplates must mate with the selected distractor body. If an AB distractor body is selected, one A-style and one B-style footplate must be used. If a BC distractor body is selected, one B-style and one C-style footplate must be used.**
- **Each footplate type/color is associated with one screw size:**
  - **Green footplate must be used with 1.0 mm screws**
  - **Yellow footplate must be used with 1.3 mm screws**
  - **Red footplate must be used with 1.5 mm screws**
  - **Blue footplate must be used with 2.0 mm screws**
- **If use of locking screws is desired, 2.0 mm footplate must be used**
- **Footplates are able to be cut and contoured to patient anatomy.**



A-style footplate | B-style footplate | C-style footplate



Surgeon activation instruments

Instruments	
03.315.001	Surgeon Activation Instrument, 1.7 mm, for CMF Distractor
03.315.005	Surgeon Activation Instrument, 1.7 mm with U-Joint, for CMF Distractor

Surgeon activation instrument

Surgeon activation instrument, with U-Joint

Proper use of the surgeon activation instruments
The surgeon activation instruments are used throughout distractor assembly and procedure to assemble and activate the distractor. To use either surgeon activation instrument to advance the distractor, engage the instrument with the activation hex and rotate counterclockwise (in the direction of the arrow marked on the instrument). To reverse the distractor, rotate the activation instrument in the clockwise direction (opposite the direction of the arrow marked on the instrument).

Either surgeon activation instrument can be disassembled into a smaller size if desired or required during assembly and activation (Figure 1). This is accomplished by unscrewing the small blue machine screw on the side of the instruments using the 1.5 mm/2.0 mm PlusDrive screwdriver blade. Once the back end of the instrument has been removed, the machine screw can be reinserted into the back end of the instrument and the back end can be placed on the instrument tray for safe keeping.

Figure 1

Technique tip: **The distractor is equipped with a mechanism (detent clip) to prevent unintended device reversal. This increases the force required to activate it. It is recommended to use the surgeon activation instrument instead of fingers to apply the turning force.**

There are different steps for attaching the footplates to the AB and BC distractor bodies.

3a. Assemble footplates – AB distractor

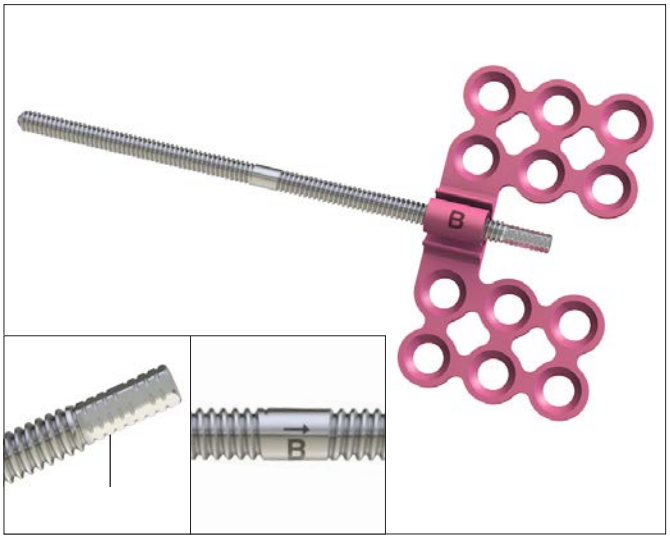
Instruments	
311.005	Screwdriver Handle with Hex Coupling, small
311.006	Screwdriver Handle with Hex Coupling, medium
313.252	1.5 mm/2.0 mm Screwdriver Blade, self-retaining, PlusDrive, 96 mm
313.253	1.5 mm/2.0 mm Screwdriver Blade, self-retaining, PlusDrive, 76 mm

Use the 1.5 mm/2.0 mm PlusDrive screwdriver blade to remove the machine screw and collar from the distractor body.

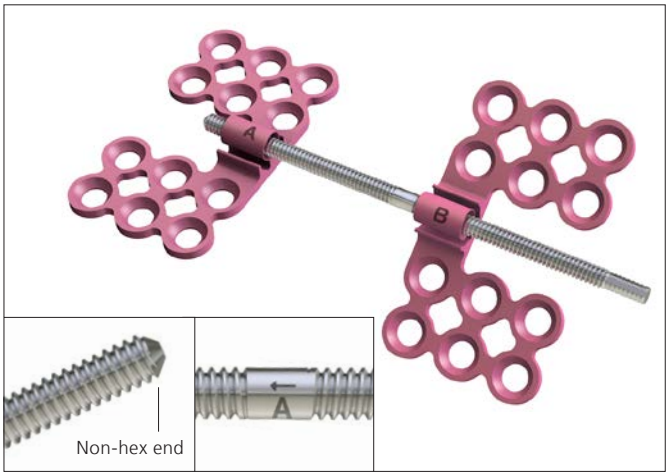
Set these aside for later reassembly.

Remove the lead screw by sliding it out of the distractor body.

Thread the B-style footplate onto the hex end of the lead screw and rotate the footplate counterclockwise until it reaches the center of the lead screw. An etched "B" along with an arrow on the center of the lead screw indicates proper placement of the B-style footplate. (as shown to the right)



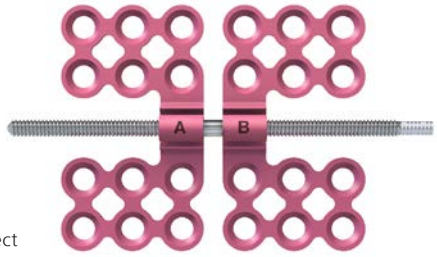
Thread the A-style footplate onto the opposite end of the lead screw and rotate the footplate clockwise until it reaches the center of the lead screw. An "A" and an arrow are etched on the center of the lead screw to assist in assembling the footplate.



Assemble footplates–AB distractor

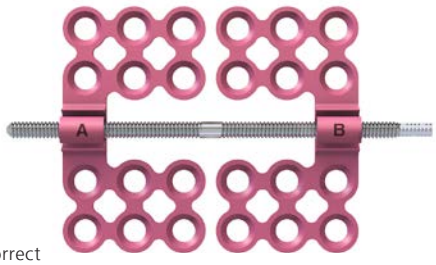
Notes:

- **Footplates should be aligned parallel to each other at the center of the lead screw.**
- **Footplates should be positioned so that the screw holes point away from one another, as shown to the right.**

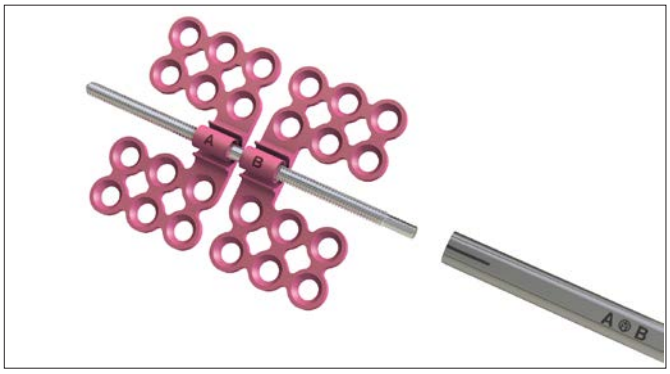


Correct

Insert the hex end of the lead screw (the end with the B-style footplate) back into the distractor body.



Incorrect



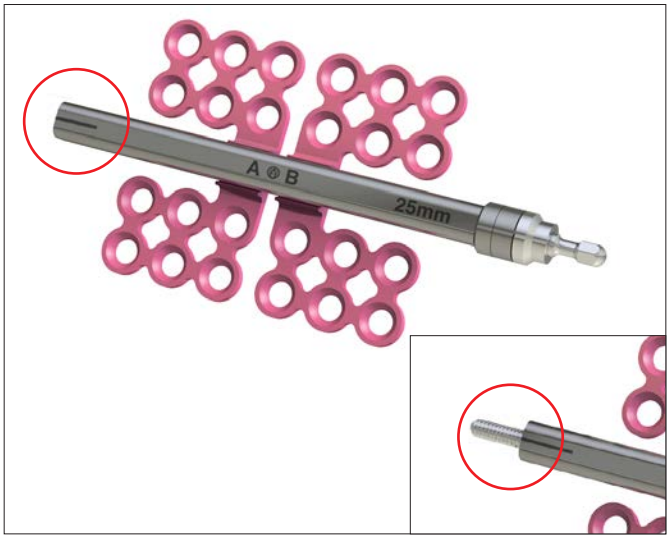
Slide the lead screw all the way into the distractor until it seats in the activation hex.

Retrieve the previously disassembled machine screw and collar.

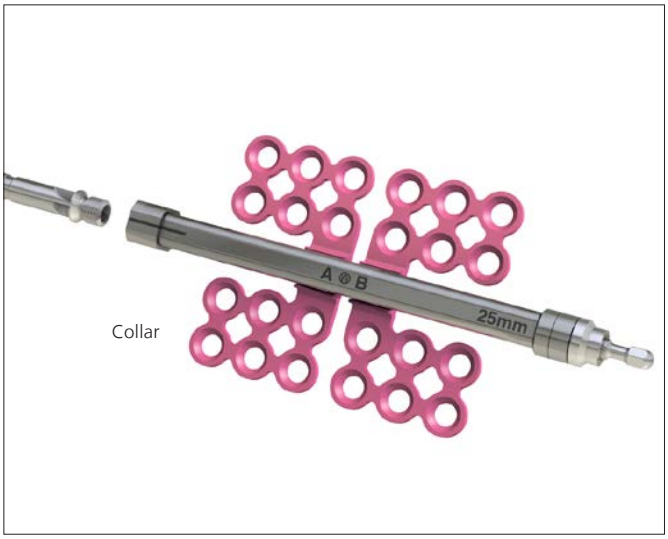
Place the collar onto the distractor body. The etched lines on the collar and distractor body aid in realignment.

Use the 1.5 mm/2.0 mm PlusDrive screwdriver blade to properly align and re-insert the machine screw into the collar and distractor body and fully tighten, locking the construct together.

Warning: **Fully tighten the machine screw to the distractor body using a two-finger tightening technique after it is assembled with the footplates, however, it is important not to overtighten as the machine screw threads may strip leading to a choking hazard.**



Correct Incorrect



Warning: **To ensure proper function of the instrument and help prevent unintended reversing of the distractor by the patient and/or caregiver after implantation, use the surgeon activation instrument to activate the distractor for the full length of distraction prior to implantation.**

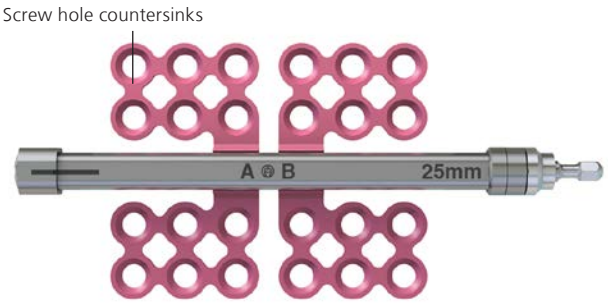
Once the distractor is fully assembled, using surgeon activation instrument, rotate the activation hex counterclockwise so that the footplates translate the entire length of the distractor body to ensure the proper function of the distractor for the entire length of distraction.

Return the footplates to the original position by turning the activation hex clockwise until the footplates reach the center of the distractor body.

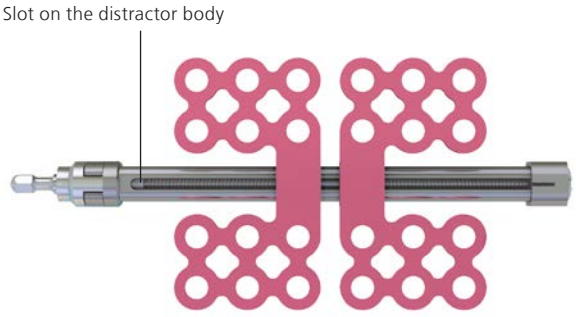
When the distractor is fully assembled, the slot on the distractor body will face medially and the screw hole countersinks will face laterally.

Warning: **If the end of the AB distractor is not assembled with the collar, there is a potential for the distractor to disassemble at the end of distraction and cause a choking hazard.**

Technique tip: **The distractor is equipped with a mechanism (detent clip) to prevent unintended device reversal. This increases the force required to activate it. It is recommended to use the surgeon activation instrument instead of fingers to apply the turning force.**



Final AB distractor assembly with footplates in the home position



Underside of the final AB distractor assembly

3b. Assemble footplates–BC distractor

Instruments	
311.005	Screwdriver Handle with Hex Coupling, small
311.006	Screwdriver Handle with Hex Coupling, medium
313.252	1.5 mm/2.0 mm Screwdriver Blade, self-retaining, PlusDrive, 96 mm
313.253	1.5 mm/2.0 mm Screwdriver Blade, self-retaining, PlusDrive, 76 mm

Use the 1.5 mm/2.0 mm PlusDrive screwdriver blade to remove the machine screw from the distractor body.

Insert the B-style footplate into the open end of the distractor body in the correct orientation, as shown to the right.

Precaution: **The screw holes on the B-style footplate should be positioned so that they point toward the activation hex and not the open end of the distractor. Assembling the device incorrectly will reduce the distraction distance possible.**

Correct

Incorrect

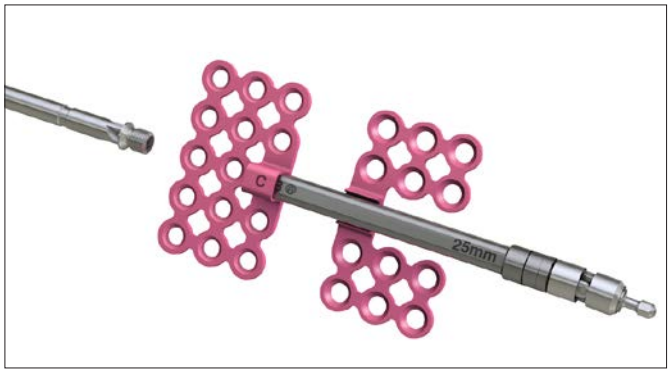
Turn the activation hex counterclockwise to engage the B-style footplate with the lead screw. Rotate the activation hex at least 16 rotations to allow room for the C-style footplate.

Technique tip: **The distractor is equipped with a mechanism (detent clip) to prevent unintended device reversal. This increases the force required to activate it. It is recommended to use the surgeon activation instrument instead of fingers to apply the turning force.**

Attach the C-style footplate by fitting it over the open end of the distractor body.

Use the 1.5 mm/2.0 mm PlusDrive screwdriver blade to properly align and re-insert the machine screw into the C-style footplate and distractor body and fully tighten, locking the construct together.

Warning: **Fully tighten the machine screw to the distractor body using a two-finger tightening technique after it is assembled with the footplates, however, it is important not to overtighten as the machine screw threads may strip leading to a choking hazard.**

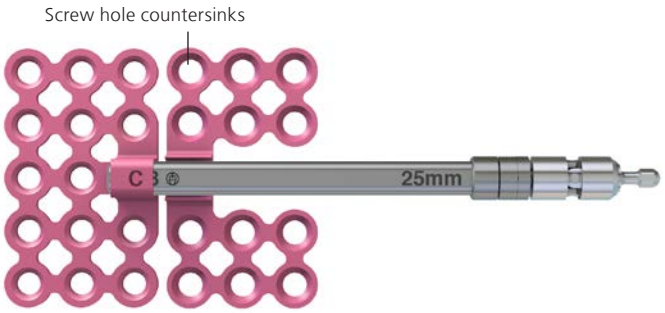


Warning: **To ensure proper function of the instrument and help prevent unintended reversing of the distractor by the patient and/or caregiver after implantation, use the surgeon activation instrument to activate the distractor for the full length of distraction prior to implantation.**

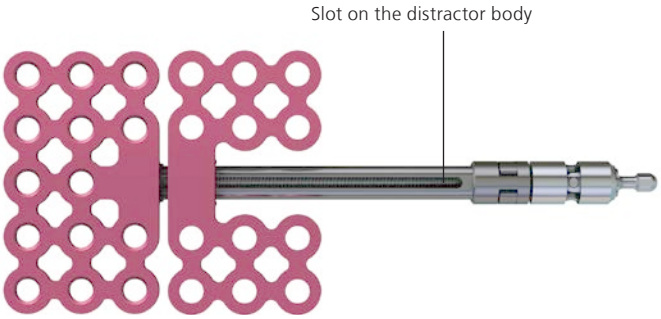
Once the distractor is fully assembled, using surgeon activation instrument, rotate the activation hex counterclockwise so that the B-type footplate translates the entire length of the distractor body to ensure the proper function of the distractor for the entire length of distraction.

Return the footplates to the original position by turning the activation hex clockwise until the B-style footplate reaches the C-style footplate on the end of the distractor body. When the distractor is fully assembled, the slot on the distractor body will face medially and the screw hole countersinks will face laterally.

Technique tip: **The distractor is equipped with a mechanism (detent clip) to prevent unintended device reversal. This increases the force required to activate it. It is recommended to use the surgeon activation instrument instead of fingers to apply the turning force.**



Final BC distractor assembly with footplates in the home position



Underside of the final BC distractor assembly

4. Attach extension arm (optional)

Instrument	
03.315.004	Removal Instrument for Extension Arms

Determine if an extension arm will be needed to place the activation hex in an area easily accessible with the surgeon activation instrument.

Note: **The length of the flexible or rigid extension arm is laser etched on the end of the arm that engages with the distractor body.**

Precaution: **To ensure that the soft tissue does not obstruct the activation hex during distraction, the next longer size distractor body and/or extension arm may need to be used.**

There are two versions of extension arms: flexible and rigid. They each attach to the distractor differently. If the flexible extension arm is used, it attaches to the distractor with spring fingers (Figures 1-2). If rigid extension arm is used, it attaches to the distractor with a hex pocket (Figures 3-4). The instructions for use below provide details for both versions of the extension arm.

Engage the removal instrument with the hex on the extension arm (Figure 5).

Rotate the removal instrument collar counterclockwise at least 16 full turns until the spring fingers (Figure 2) or the hex pocket (Figure 4) of the extension arm is exposed.

Precautions:

- **Do not allow the removal instrument to rotate in your hand; doing so will prevent the extension arm from opening.**
- **Do not grip the flexible extension arm while rotating it with the removal instrument. Gripping the extension arm with your fingers will make it difficult to rotate and cause the silicone sleeve to twist and possibly tear.**
- **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.**

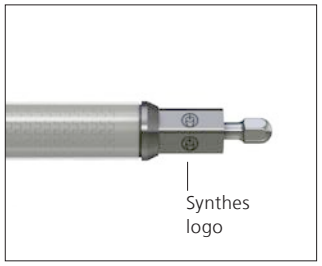


Figure 1

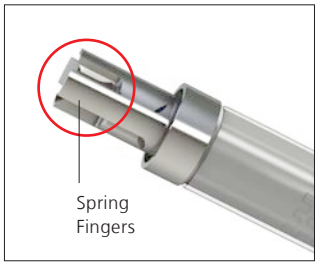


Figure 2

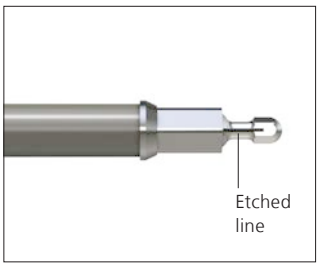


Figure 3

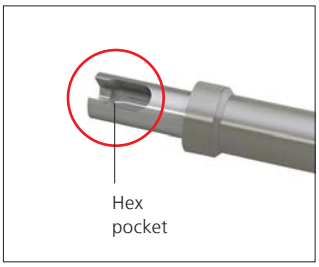


Figure 4

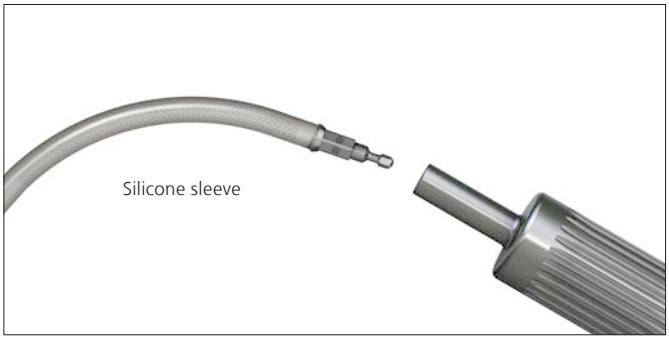


Figure 5

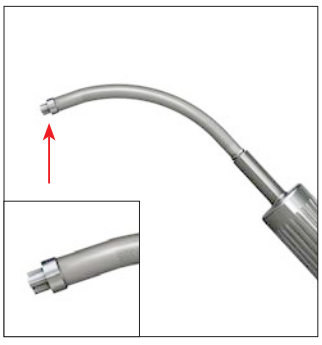


Figure 6


Figure 7

Technique tips

- **Extension arms are provided fully tightened to prevent unintentional separation. When opening an 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 spring fingers or the hex pocket (Figure 6). Alternatively, the extension arm can be held in the removal instrument without any support (Figure 7).**
- **The extension arm is composed of two sleeves (Figure 8). 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.**
- **Extension arms can be detached from the distractor at the start of the consolidation phase without the need for a surgical procedure (see page 71 for instructions).**

For the flexible extension arm, slide the extension arm over the distractor body activation hex so that the spring fingers engage the activation hex. 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 (Figure 9).

For the rigid extension arm, place the distractor body activation hex into the hex pocket of the extension arm (Figure 10).

Rotate the removal instrument collar clockwise until the extension arm fully closes over the activation hex of the distractor, and fully tighten. Visually verify that the flange of the extension arm covers the collar of the distractor (Figure 11).

Figure 8

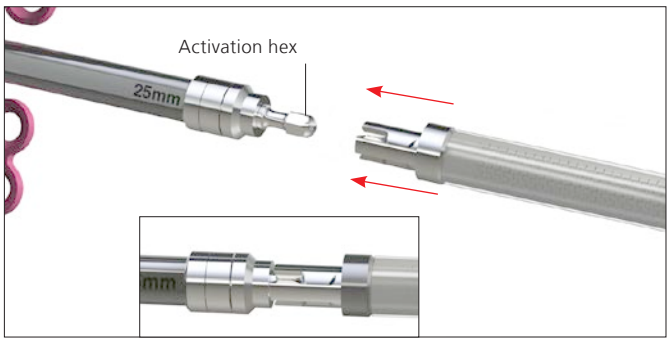


Figure 9

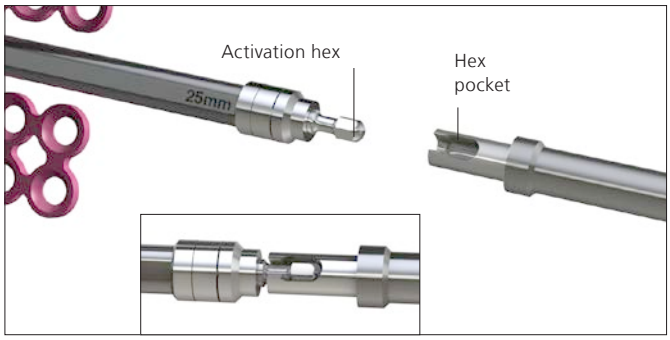


Figure 10

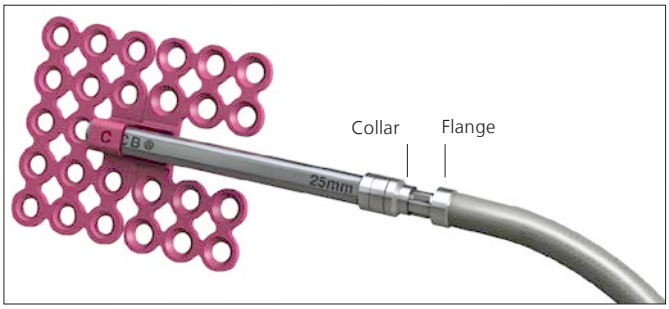


Figure 11

Warnings:

- **Do not cross-thread or overtighten the extension arm when closing it over the activation hex of the distractor or it will not be possible to remove the extension arm at the end of distraction. Overtightening may also cause the threads to strip, leading to a choking hazard.**
- **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 extension arms during sleep can damage and/or break the extension arms which may lead to a choking hazard. It is advised to secure the extension arms to the patient's skin, without affecting the arms' ability to rotate. Options include suture or tape.**
- **During the course of treatment, infection can occur at the extension arm/skin interface. Monitor the patient for symptoms of infection and inform the patient to seek medical care if area becomes painful or sees any redness or drainage from skin.**

Distractor assembly with removable extension arm attached.

5. Assemble second distractor

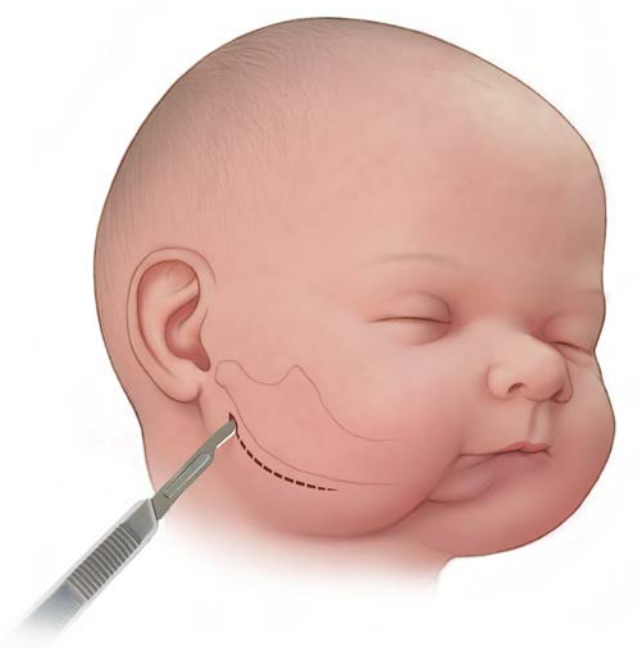
For bilateral procedures, repeat Steps 1 through 4 to assemble a distractor for the contralateral side.

Mandibular Body Distraction

The following surgical technique is an example of a submandibular approach with a distractor placed on the posterior mandibular body region. A similar technique can be used for placing the distractor in an anterior orientation using an intraoral approach.

1. Make incision

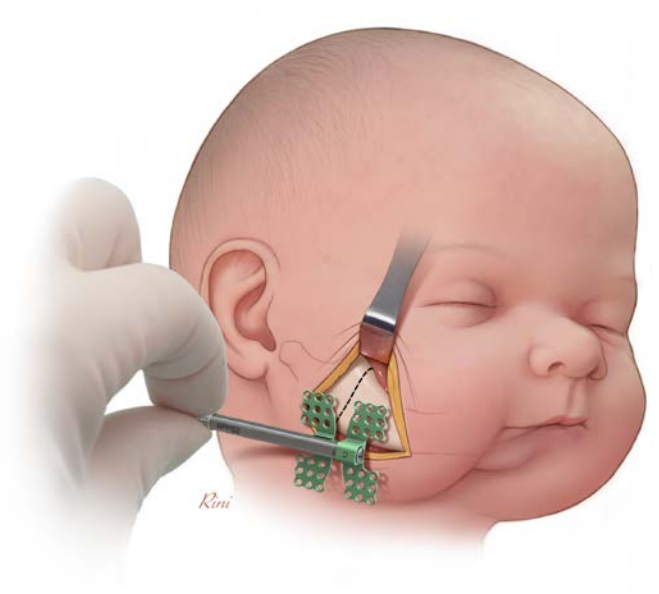
Make a mandibular vestibular or a submandibular incision. Elevate the periosteum to expose the mandible.



2. Mark osteotomy

Mark the approximate site of the osteotomy based on the planned placement of the distractor.

3. Fit distractor



Place a fully assembled distractor in the intended area to assess the patient's anatomy and determine the approximate location of the footplates, bone screws, and/or extension arm.
Factors to consider include:

- Occlusal plane
- Tooth buds and roots
- Planned vector of distraction
- Proper alignment of the condyles in the glenoid fossa
- Adequate bone quality and quantity for screw placement
- Location of mental nerve and inferior alveolar nerve
- Lip closure
- Soft tissue (mucosa) coverage
- Location of activation hex of distractor or extension arm
- Parallel placement

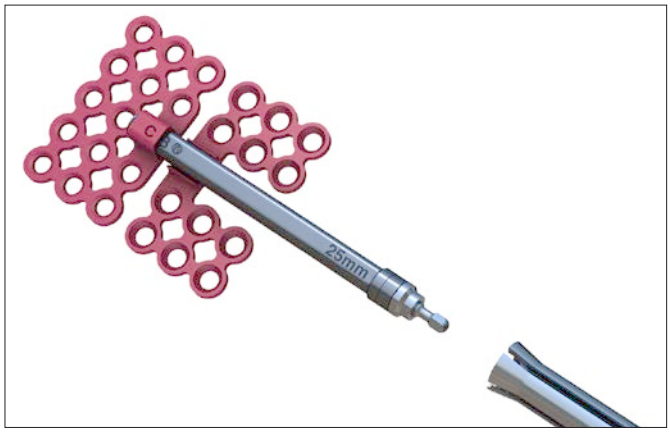
Technique Tip: **Separate the footplates minimum 2 mm to allow enough space for osteotomy and ensure adequate distance between the pilot holes and the osteotomy.**

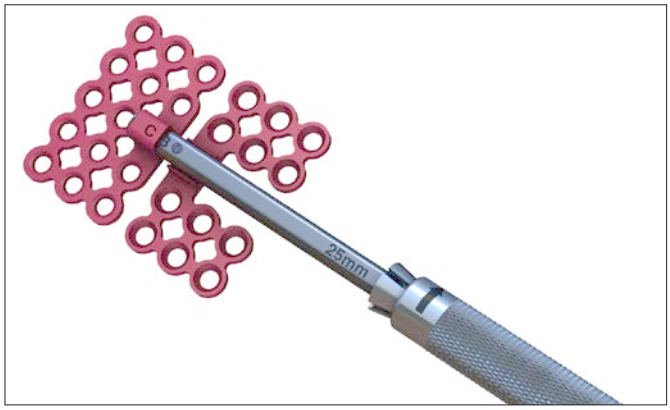
Precautions:

- **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.**
- **Location of activation port should be chosen such that the maximum curvature of the extension arm is not exceeded, as this may cause the arm to break. The extension arm should be placed in-line with the distractor body as much as possible to prevent pressure from being placed on the device and patient's bone which may cause loosening of the device from the bone (especially for patients with poor bone quality).**
- **Location of the activation port should include consideration of important structures that may lie in the path between the distractor and the skin exit site. The main trunk or branches of the facial nerve, as well as other structures, may be injured when creating this port.**
- **To ensure that the soft tissue does not obstruct the activation hex during distraction, the next longer size distractor body and/or extension arm may need to be used.**
- **When inserting the flexible extension arm into the operative site, take care to protect silicone sleeve to prevent soft tissue interference during distraction.**
- **Devices should be placed as parallel as possible to diminish the possibility of temporomandibular joint displacement. While parallel placement of the distractors is ideal, this may be difficult to accomplish considering the patient's soft tissue coverage and could potentially lead to patient discomfort.**

3b. Optional technique (alignment rods)

Instrument	
03.315.003	Alignment Rod, for CMF Distractor





Alignment rods can be used throughout the course of surgery to:

- Aid in parallel placement of the devices
- Indicate the vectors of advancement
- Hold the distractors during screw fixation and device placement

To use the alignment rods, place the open end of the alignment rod over the distractor body or extension arm as shown in the figure to the right.

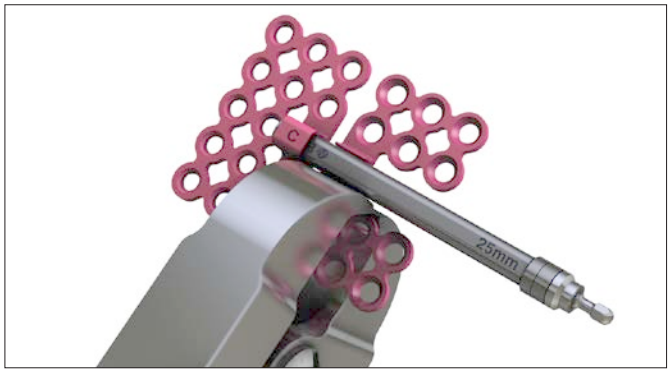
Slide the alignment rod sleeve forward until it meets the threaded portion of the rod and rotate clockwise until the rod tightens onto the distractor.

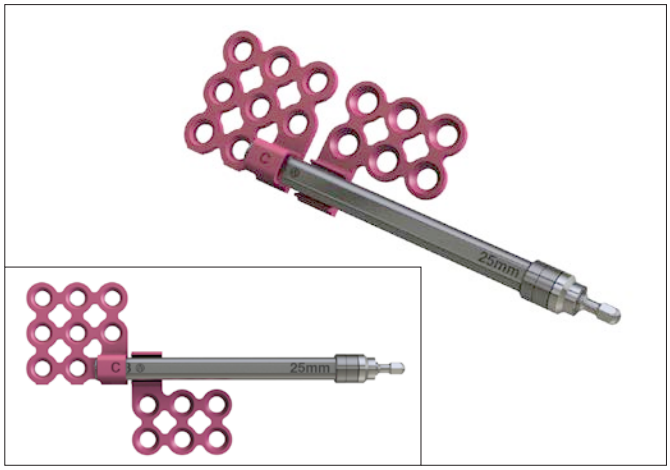
Precaution: **The alignment rods should not be used as leverage for bending or contouring of the footplates as this may cause damage to the distractor bodies.**

Devices should be placed as parallel as possible to diminish the possibility of temporomandibular joint displacement. While parallel placement of the distractors is ideal, this may be difficult to accomplish considering the patient's soft tissue coverage, and could potentially lead to patient discomfort.

4. Cut and contour footplates

Instruments	
03.500.014	Cutting Instrument
03.500.020	File with Hex Coupling
03.503.039	Plate Cutter
311.005	Screwdriver Handle with Hex Coupling, small
or 311.006	Screwdriver Handle with Hex Coupling, medium
347.964	Combination Bending Pliers, for 1.0 mm and 2.0 mm plates
391.965	Combination Bending/Cutting Pliers, for 1.0 mm and 2.0 mm plates





Cut the footplates to remove any unnecessary screw holes.

Technique tips

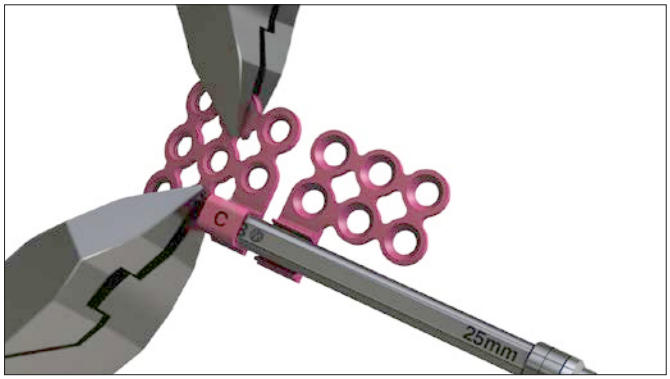
- **Activate the distractor to separate the footplates to allow room for cutting instrumentation.**
- **Deburr the cut portion of the footplate as needed by rubbing sharp corners/edges with the file on the cutter or with the file instrument.**
- **When removing one side of the footplate, cut the footplates so the cut edges are flush with the distractor body.**
- **Screws can be placed in the holes superior to the distractor body in the posterior footplate and in the holes inferior to the distractor body in the anterior footplate for added stability.**

Precautions:

- **A minimum of three screws should be used in each footplate to ensure adequate stability. If the 1.0 mm system is selected, at least 4 screws must be used to secure each footplate in poor quality bone to prevent screw pull-out during treatment. Of these 4 screws, at least two screws of a minimum of 6 mm length must be used in the row of screw holes closest to the distractor body.**
- **Ensure screws will have purchase in good quality bone; footplates may shift during treatment if they are not properly secured.**

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

Firmly press the bending pliers on the footplates. Avoid handling the bending pliers with high forces that could produce surface defects and/or concentrate stress in the core of the implants. This in turn may eventually cause the product to fail.
Do not bend the plate beyond what is required by the anatomy as this may lead to damage of the footplates.*



Precautions:

- **Contour each footplate individually while holding that footplate with the bending pliers. Avoid bending one footplate while holding either the distractor body or the other footplate.**
- **Footplates should be cut and deburred so that the integrity of the screw hole is not compromised and tissue irritation is minimized.**
- **Take care to avoid nerves, tooth buds, tooth roots, or other critical structures when drilling and/or placing screws.**

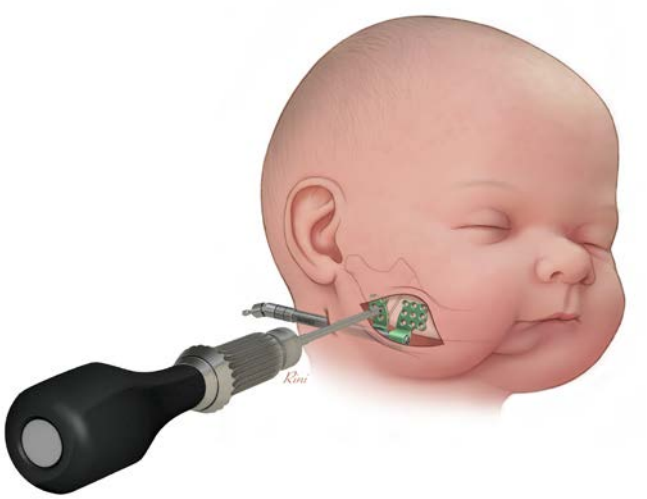
Warnings:

- **Repeat and/or reverse and sharp bending may weaken the plate and lead to premature implant failure.**
- **Do not bend the plate beyond what is required by the anatomy as this may lead to damage of the footplates.**
- **Do not implant a distractor if the footplates have been damaged by over-bending.**

* Bending the footplates past 19 degrees may cause footplate breakage.

5. Mark distractor location

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



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.

Precaution: **It is recommended to separate the footplates by a minimum of 2 mm prior to drilling and/or inserting screws to ensure adequate distance between the pilot holes and the osteotomy.**

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

Note: **Pre-drilling may not be necessary in neonates.**

Use the appropriate drill bit and screwdriver blade for the footplate size selected.

For insertion of screws with PlusDrive screwdriver blades:

Footplate/ Screw type	Drill bit size	PlusDrive screwdriver blade	Screwdriver color band
1.0 mm	0.76 mm	1.0 mm	green
1.3 mm	1.0 mm	1.3 mm	yellow
1.5 mm	1.1 mm	1.5 mm or 1.5 mm/2.0 mm	red or red/blue
2.0 mm	1.5 mm	2.0 mm/1.5 mm or 2.0 mm	blue or red/blue

For insertion of screws with Raised Head screwdriver blades:

Footplate/ Screw type	Drill bit size	Raised Head screwdriver blade	Screwdriver color band
1.0 mm	0.76 mm	1.0 mm/1.3 mm	green/yellow
1.3 mm	1.0 mm	1.0 mm/1.3 mm	green/yellow
1.5 mm	1.1 mm	1.5 mm/2.0 mm	red/blue
2.0 mm	1.5 mm	1.5 mm/2.0 mm	red/blue

See pages 86, 88 and 89 for drill bit and screwdriver blade 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.**

Precaution: **If the 1.0 mm system is selected, at least 4 screws must be used to secure each footplate in poor quality bone to prevent screw pull-out during treatment. Of these 4 screws, at least two screws of a minimum of 6 mm length must be used in the row of screw holes closest to the distractor body.**

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.

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 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 prevent screw pullout after insertion due to retention forces between the Raised Head Screws and Raised Head screwdriver blades.**

Do not fully tighten the screws before completing the osteotomy.

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.

Warnings:
- **When the distractor is placed and/or removed intraorally, use of a hospital-approved throat pack is required to prevent a choking hazard in case of device fragments generated during the surgery.**
- **Take care to remove all device 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 1800 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 screw 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 three screws should be inserted through each distractor footplate to ensure adequate stability. It is recommended to use screw holes closest to the distractor body. If the 1.0 mm system is selected, at least 4 screws must be used to secure each footplate in poor quality bone to prevent screw pull-out during treatment. Of these 4 screws, at least two screws of a minimum of 6 mm length must be used in the row of screw holes closest to the distractor body.**

- **The distractor may be fixated with more than three screws per footplate. If longer bone advancement is desired, the distractor with mesh footplate could be used.**
- **To increase distractor stability in thin bone, insert screws bicortically. In addition, more screws can be used.**
- **Always irrigate adequately during drilling to prevent overheating of the drill bit and bone.**
- **Take care to avoid nerves, tooth buds, tooth roots, or other critical structures when drilling and/or placing screws.**
- **Take care while drilling as not to 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.**
- **Do not fully tighten the screws before completing the osteotomy.**
- **Before making osteotomy irrigate and apply suction for removal of debris potentially generated during implantation or removal.**
- **Use appropriate screw length to avoid distractor loosening or damage of critical/lingual structures.**
- **If locking screws are used, screw holes must be drilled at a right angle to 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.**

Universal Trocar System for 1.5 mm and 2.0 mm screws/footplates

Optional Instruments	
397.211	Universal Trocar Handle
397.213	2.0 mm Cannula and Obturator
397.232	Malleable C-Retractor
397.42	2.0 mm Cheek Retractor Blade
397.43	2.0 mm Cheek Retractor Ring

Optional technique – using universal trocar

- Pass the cannula with obturator carefully through the soft tissue, then remove the obturator.
- Insert or thread (for locking screws) drill guide into the plate through the cannula. Select the appropriate drill bit with stop and drill.
- Remove drill guide.
- Select the appropriate length screw and insert it into the cannula and through the plate.

Pediatric Trocar System for 1.0 mm and 1.3 mm screws/footplates

Optional Instruments	
03.315.007	Pediatric Drill Guide
03.315.008	Obturator for Pediatric Drill Guide
03.315.009	Cheek Retractor for Pediatric Drill Guide

Optional technique – using the pediatric trocar

- Make a stab incision through the buccal soft tissue by sliding the obturator through the drill guide cannula and piercing the soft tissue (Figure 1). Remove the obturator from the drill guide.
- Grasp the cheek retractor with forceps (Figure 2). There are holes in the outer surface of the cheek retractor that are designed to facilitate a secure hold with forceps.

Figure 1

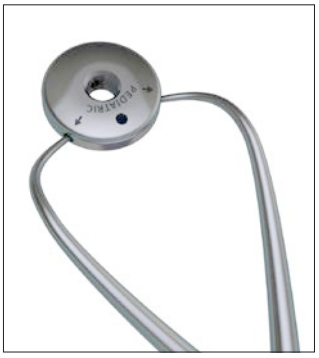


Figure 2

Figure 3

Figure 4

- Insert the drill guide through the buccal soft tissue and introduce the cheek retractor into the intraoral cavity. Place the drill guide through the hole in the center of the cheek retractor (Figure 3).
- Rotate the knurled collar on the drill guide to move the cheek retractor ring up the drill guide (Figure 4). Disengage the forceps from the cheek retractor. Retract the soft tissue as needed.

Technique tips

- **For the pediatric trocar, maintain pressure on the drill guide during drilling and screw insertion to ensure the drill guide remains aligned over the screw holes in the footplate.**
- **It may be helpful to have a DePuy Synthes CMF 90° Screwdriver Set (01.505.002) available for intraoral approaches.**
- **Use 75 mm length 0.76 mm and 1.0 mm drill bits with the pediatric trocar.**

6. 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 segment during reattachment of the distractor.

7. Reattach distractor

Re-insert the distractor into the operative site, and pass the activation end of the distractor body through the percutaneous port created earlier. 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 5 (pages 24–28) for guidance on screw insertion, and associated Precautions, Warnings, Notes, Technique Tips, and part numbers.

Depending on patient anatomy and placement of the distractor, the extension arm can either remain in the intraoral cavity or project through a small percutaneous activation port. If the extension arm remains in the intraoral cavity, care should be taken to ensure that the extension arm does not interfere with the patient's ability to eat or breathe.

If the extension arm is projecting outside the body, an abnormal scar may form at the site of the small percutaneous activation port after treatment.

Extension arms can be secured below the dentition with a loop of wire attached to orthodontic brackets or to the teeth. The loop should restrict the vertical movement of the extension arm without affecting the arms' ability to rotate. This will ensure that the extension arm does not interfere with mastication.

Precautions associated with distractor placement:

- **Applying too much torque to the screws may cause implant and/or instrument breakage, deformation, or bone stripping.**
- **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.**

8. Complete osteotomy

Complete the osteotomy on the lingual aspect of the mandible using an osteotome and gently break the inner cortex. Take care to avoid transection of the inferior alveolar nerve.

Warning: **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.**

9. Confirm device activation

Instruments	
03.315.001	Surgeon Activation Instrument, 1.7 mm
03.315.005	Surgeon Activation Instrument, 1.7 mm with U-Joint

Use a surgeon activation instrument to engage the activation hex of the distractor or extension arm. Activate 2 mm in a counterclockwise direction, as marked on the handle, to confirm device stability and verify movement of the mandible. Return the distractor to its original position.

Technique tip: **The distractor is equipped with a mechanism (detent clip) to prevent unintended device reversal. This increases the force required to activate it. It is recommended to use the surgeon activation instrument instead of fingers to apply the turning force.**

10. Repeat steps for bilateral procedures

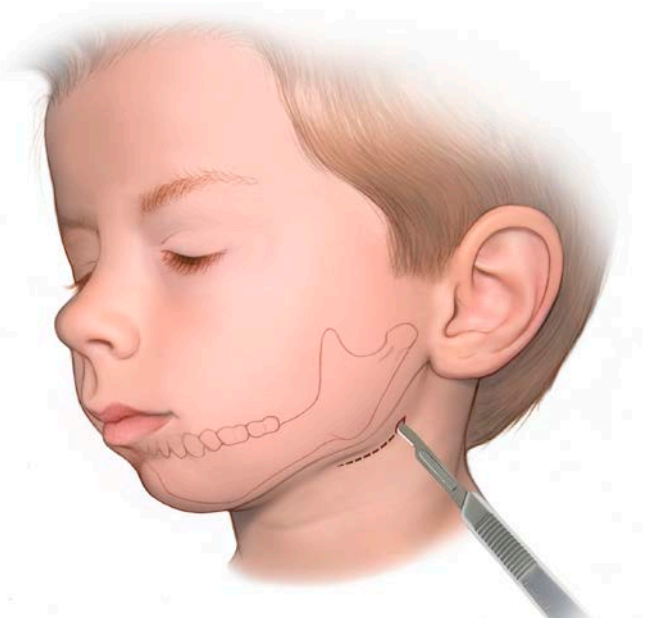
Repeat Steps 1 through 9 on the contralateral side. Close all incisions.

Mandibular Ramus Distraction

The following surgical technique is an example of a submandibular incision with a distractor placed on the mandibular ramus. A similar technique can be used to place the distractor intraorally.

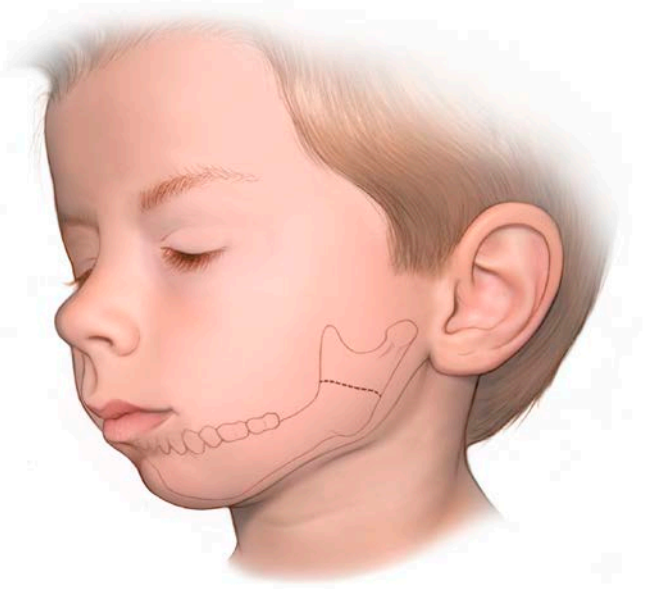
1. Make incision

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



2. Mark osteotomy

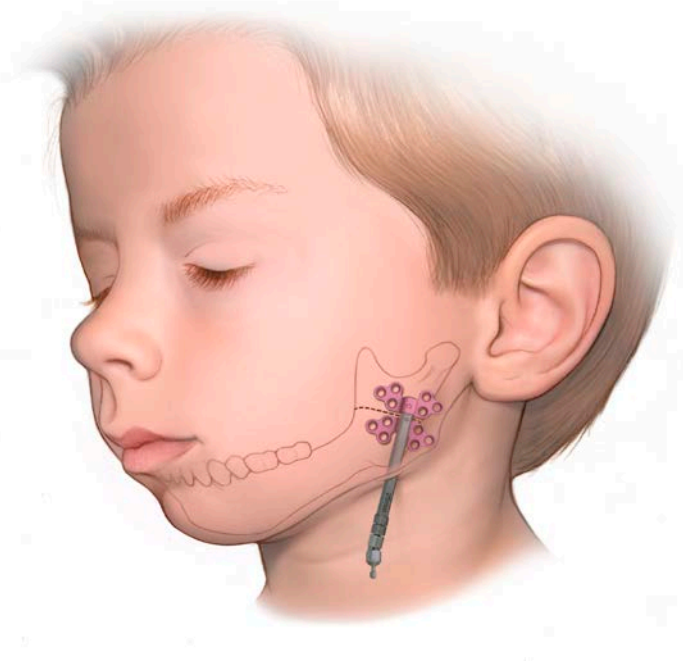
Mark the approximate site of the osteotomy based on the planned placement of the distractor.



3. Fit distractor

Place a fully assembled distractor in the intended area to fit the distractor to the ramus and determine the approximate location of the footplates, bone screws, and/or extension arm.
Factors to consider include:

- Occlusal plane
- Tooth buds and roots
- Planned vector of distraction
- Proper alignment of the condyles in the glenoid fossa
- Adequate bone quality and quantity for screw placement
- Location of mental nerve and inferior alveolar nerve
- Lip closure
- Soft tissue (mucosa) coverage
- Location of activation hex of distractor or extension arm
- Parallel placement



Technique tips:

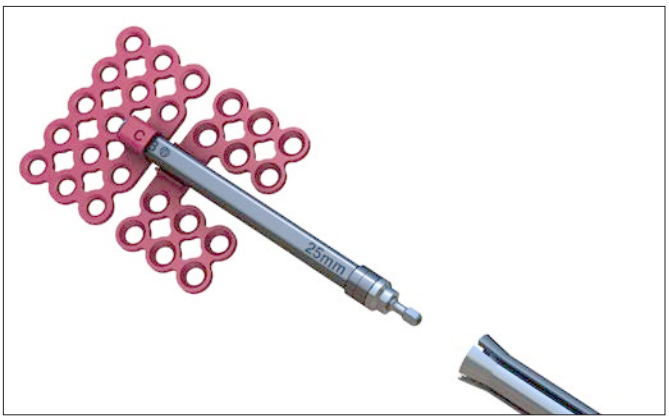
- **Separate the footplates minimum 2 mm to allow enough space for osteotomy and ensure adequate distance between the pilot holes and the osteotomy.**
- **Tent the skin to determine the percutaneous activation port position. Create the percutaneous activation port by making a stab incision through the skin, followed by blunt dissection.**

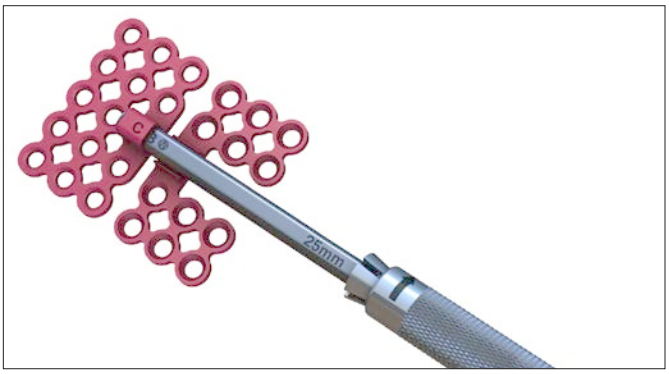
Precautions:

- **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.**
- **Location of activation port should be chosen such that the maximum curvature of the extension arm is not exceeded as this may cause the arm to break. The extension arm should be placed in-line with the distractor body as much as possible to prevent pressure from being placed on the device and patient's bone which may cause loosening of the device from the bone (especially for patients with poor bone quality).**
- **Location of the activation port should include consideration of important structures that may lie in the path between the distractor and the skin exit site. The main trunk or branches of the facial nerve, as well as other structures, may be injured when creating this port.**
- **To ensure that the soft tissue does not obstruct the activation hex during distraction, the next longer size distractor body and/or extension arm may need to be used.**
- **When inserting the flexible extension arm into the operative site, take care to protect silicone sleeve to prevent soft tissue interference during distraction.**
- **Devices should be placed as parallel as possible to diminish the possibility of temporomandibular joint displacement. While parallel placement of the distractors is ideal, this may be difficult to accomplish considering the patient's soft tissue coverage, and could potentially lead to patient discomfort.**

3b. Optional technique (alignment rods)

Instrument	
03.315.003	Alignment Rod, for CMF Distractor





Alignment rods can be used throughout the course of surgery to:
- Aid in parallel placement of the devices
- Indicate the vectors of advancement
- Hold the distractors during screw fixation and device placement

To use the alignment rods, place the open end of the alignment rod over the distractor body or extension arm as shown in the figure to the right.

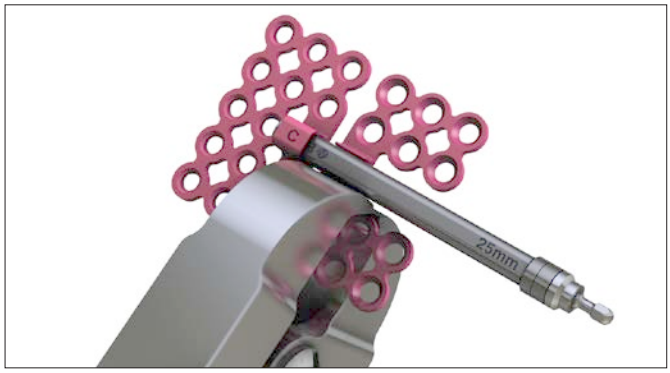
Slide the alignment rod sleeve forward until it meets the threaded portion of the rod and rotate clockwise until the rod tightens onto the distractor.

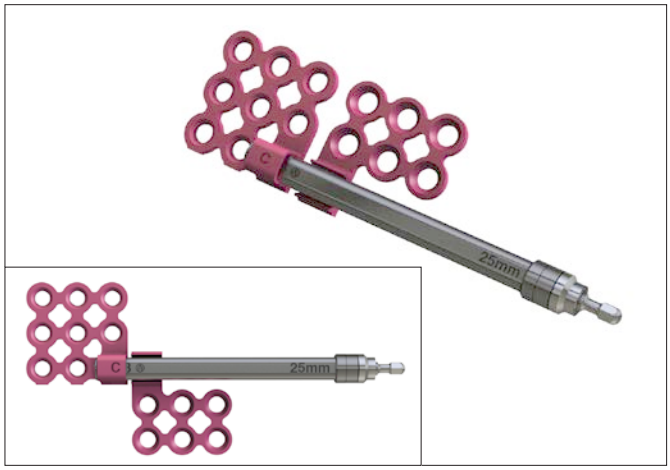
Precaution: **The alignment rods should not be used as leverage for bending or contouring the footplates as this may cause damage to the distractor bodies.**

Devices should be placed as parallel as possible to diminish the possibility of temporomandibular joint displacement. While parallel placement of the distractors is ideal, this may be difficult to accomplish considering the patient's soft tissue coverage, and could potentially lead to patient discomfort.

4. Cut and contour footplates

Instruments	
03.500.014	Cutting Instrument
03.500.020	File with Hex Coupling
03.503.039	Plate Cutter
311.005	Screwdriver Handle with Hex Coupling, small
or 311.006	Screwdriver Handle with Hex Coupling, medium
347.964	Combination Bending Pliers, for 1.0 mm and 2.0 mm plates
391.965	Combination Bending/Cutting Pliers, for 1.0 mm and 2.0 mm plates





Cut the footplates to remove any unnecessary screw holes.

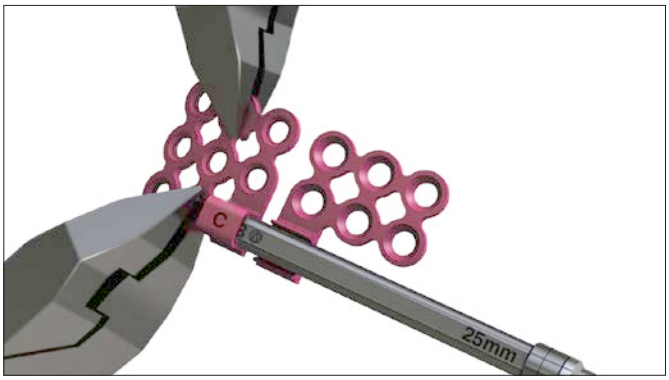
Technique tips:

- **Activate the distractor to separate the footplates to allow room for cutting instrumentation.**
- **Deburr the cut portion of the footplate as needed by rubbing sharp corners/edges with the file on the cutter or with the file instrument.**
- **When removing one side of the footplate, cut the footplates so the cut edges are flush with the distractor body.**
- **Screws can be placed in the holes superior to the distractor body in the posterior footplate and in the holes inferior to the distractor body in the anterior footplate for added stability.**

Precautions:

- **A minimum of three screws should be used in each footplate to ensure adequate stability. If the 1.0 mm system is selected, at least 4 screws must be used to secure each footplate in poor quality bone to prevent screw pull-out during treatment. Of these 4 screws, at least two screws of a minimum of 6 mm length must be used in the row of screw holes closest to the distractor body.**
- **Ensure screws will have purchase in good quality bone; footplates may shift during treatment if they are not properly secured.**

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



Firmly press the bending pliers on the footplates. Avoid handling the bending pliers with high forces that could produce surface defects and/or concentrate stress in the core of the implants. This in turn may eventually cause the product to fail.
Do not bend the plate beyond what is required by the anatomy as this may lead to damage of the footplates.*

Precautions:

- **Contour each footplate individually while holding that footplate with the bending pliers. Avoid bending one footplate while holding either the distractor body or the other footplate.**
- **Footplates should be cut and deburred so that the integrity of the screw hole is not compromised and tissue irritation is minimized.**
- **Take care to avoid nerves, tooth buds, tooth roots, or other critical structures when drilling and/or placing screws.**

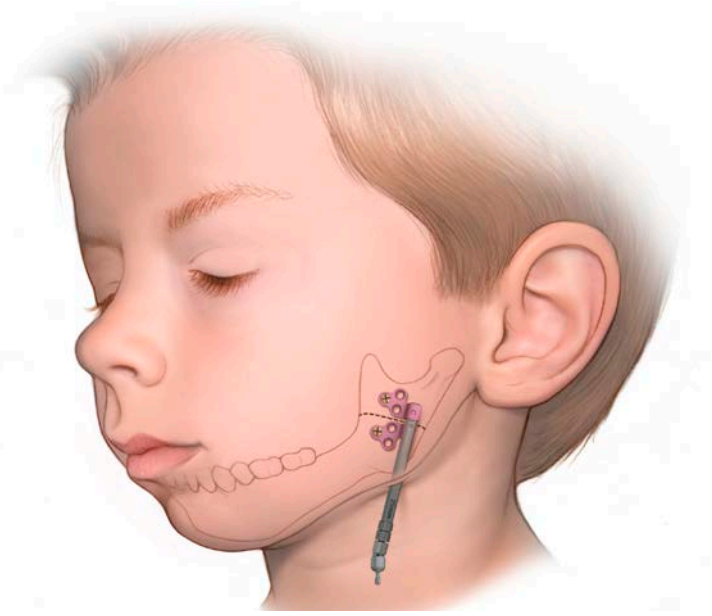
Warnings:

- **Repeat and/or reverse and sharp bending may weaken the plate and lead to premature implant failure.**
- **Do not bend the plate beyond what is required by the anatomy as this may lead to damage of the footplates.**
- **Do not implant a distractor if the footplates have been damaged by over-bending.**

* Bending the footplates past 19 degrees may cause footplate breakage.

5. Mark distractor location

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



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.

Precaution: **It is recommended to separate the footplates by a minimum of 2 mm to drilling and/or inserting screws to ensure adequate distance between the pilot holes and the osteotomy.**

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

Note: **Pre-drilling may not be necessary in neonates.**

Use the appropriate drill bit and screwdriver blade for the footplate size selected.

For insertion of screws with PlusDrive screwdriver blades:

Footplate/ Screw type	Drill bit size	PlusDrive screwdriver blade	Screwdriver color band
1.0 mm	0.76 mm	1.0 mm	green
1.3 mm	1.0 mm	1.3 mm	yellow
1.5 mm	1.1 mm	1.5 mm or 1.5 mm/2.0 mm	red or red/blue
2.0 mm	1.5 mm	2.0 mm/1.5 mm or 2.0 mm	blue or red/blue

For insertion of screws with Raised Head screwdriver blades:

Footplate/ Screw type	Drill bit size	Raised Head screwdriver blade	Screwdriver color band
1.0 mm	0.76 mm	1.0 mm/1.3 mm	green/yellow
1.3 mm	1.0 mm	1.0 mm/1.3 mm	green/yellow
1.5 mm	1.1 mm	1.5 mm/2.0 mm	red/blue
2.0 mm	1.5 mm	1.5 mm/2.0 mm	red/blue

See pages 86, 88 and 89 for drill bit and screwdriver blade 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.**

Precaution: **If the 1.0 mm system is selected, at least 4 screws must be used to secure each footplate in poor quality bone to prevent screw pull-out during treatment. Of these 4 screws, at least two screws of a minimum of 6 mm length must be used in the row of screw holes closest to the distractor body.**

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.

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 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 prevent screw pullout after insertion due to retention forces between the Raised Head Screws and Raised Head screwdriver blades.**

Do not fully tighten the screws before completing the osteotomy.

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.

Warnings:

- **When the distractor is placed and/or removed intraorally, use of a hospital-approved throat pack is required to prevent a choking hazard in case of device fragments generated during the surgery.**
- **Take care to remove all device 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 1800 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 screw 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 three screws should be inserted through each distractor footplate to ensure adequate stability. It is recommended to use screw holes closest to the distractor body. If the 1.0 mm system is selected, at least 4 screws must be used to secure each footplate in poor quality bone to prevent screw pull-out during treatment. Of these 4 screws, at least two screws of a minimum of 6 mm length must be used in the row of screw holes closest to the distractor body.**
- **The distractor may be fixated with more than three screws per footplate. If longer bone advancement is desired, the distractor with mesh footplate could be used.**
- **To increase distractor stability in thin bone, insert screws bicortically. In addition, more screws can be used.**
- **Always irrigate adequately during drilling to prevent overheating of the drill bit and bone.**
- **Take care to avoid nerves, tooth buds, tooth roots, or other critical structures when drilling and/or placing screws.**
- **Take care while drilling as not to 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.**
- **Do not fully tighten the screws before completing the osteotomy.**
- **Before making osteotomy irrigate and apply suction for removal of debris potentially generated during implantation or removal.**
- **Use appropriate screw length to avoid distractor loosening or damage of critical/lingual structures.**
- **If locking screws are used, screw holes must be drilled at a right angle to 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.**

Universal Trocar System for 1.5 mm and 2.0 mm screws/footplates

Optional Instruments	
397.211	Universal Trocar Handle
397.213	2.0 mm Cannula and Obturator
397.232	Malleable C-Retractor
397.42	2.0 mm Cheek Retractor Blade
397.43	2.0 mm Cheek Retractor Ring

Optional technique – using universal trocar

- Pass the cannula with obturator carefully through the soft tissue, then remove the obturator.
- Insert or thread (for locking screws) drill guide into the plate through the cannula. Select the appropriate drill bit with stop and drill.
- Remove drill guide.
- Select the appropriate length screw and insert it into the cannula and through the plate.

Pediatric Trocar System for 1.0 mm and 1.3 mm screws/footplates

Optional Instruments	
03.315.007	Pediatric Drill Guide
03.315.008	Obturator for Pediatric Drill Guide
03.315.009	Cheek Retractor for Pediatric Drill Guide

Optional technique–using the pediatric trocar

- Make a stab incision through the buccal soft tissue by sliding the obturator through the drill guide cannula and piercing the soft tissue (Figure 1). Remove the obturator from the drill guide.
- Grasp the cheek retractor with forceps (Figure 2). There are holes in the outer surface of the cheek retractor that are designed to facilitate a secure hold with forceps.

Figure 1

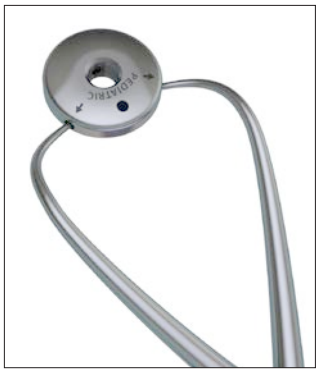


Figure 2

Figure 3

Figure 4

- Insert the drill guide through the buccal soft tissue and introduce the cheek retractor into the intraoral cavity. Place the drill guide through the hole in the center of the cheek retractor (Figure 3).
- Rotate the knurled collar on the drill guide to move the cheek retractor ring up the drill guide (Figure 4). Disengage the forceps from the cheek retractor. Retract the soft tissue as needed.

Technique tips:

- **For the pediatric trocar, maintain pressure on the drill guide during drilling and screw insertion to ensure the drill guide remains aligned over the screw holes in the footplate.**
- **It may be helpful to have a DePuy Synthes CMF 90° Screwdriver Set (01.505.002) available for intraoral approaches.**
- **Use 75 mm length 0.76 mm and 1.0 mm drill bits with the pediatric trocar.**

6. Perform buccal corticotomy

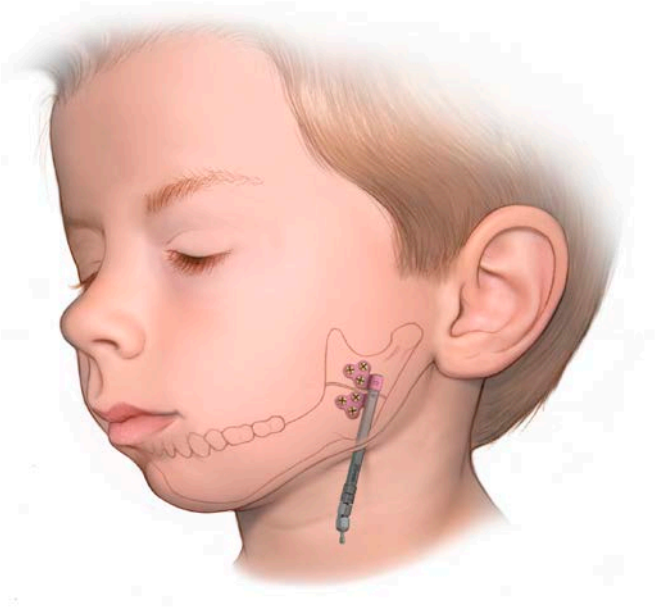
Unscrew and remove the distractor.

Perform the buccal corticotomy on the buccal side of the ramus, extended into the anterior and posterior borders. This allows stability of the bone segment during placement of the distractor.

7. Reattach distractor

Re-insert the distractor into the operative site, and pass the activation end of the distractor body through the percutaneous port created earlier. 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 5 (pages 37–41) for guidance on screw insertion, and associated Precautions, Warnings, Notes, Technique Tips, and part numbers.



Depending on patient anatomy and placement of the distractor, the extension arm can either remain in the intraoral cavity or project through a small percutaneous activation port. If the extension arm remains in the intraoral cavity, care should be taken to ensure that the extension arm does not interfere with the patient's ability to eat or breathe.

If the extension arm is projecting outside the body, an abnormal scar may form at the site of the small percutaneous activation port after treatment.
Extension arms can be secured below the dentition with a loop of wire attached to orthodontic brackets or to the teeth. The loop should restrict the vertical movement of the extension arm without affecting the arms' ability to rotate. This will ensure that the extension arm does not interfere with mastication.

Precautions associated with distractor placement:

- **Applying too much torque to the screws may cause implant and/or instrument breakage, deformation, or bone stripping.**
- **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.**

8. Complete osteotomy

Complete the osteotomy on the lingual aspect of the ramus using an osteotome. Take care to avoid damaging of the inferior alveolar nerve.

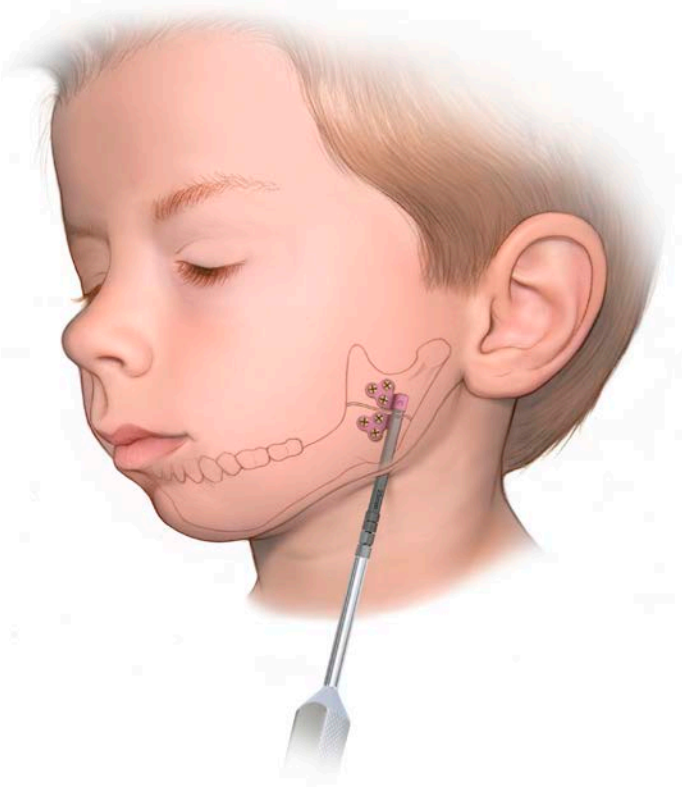
Warning: **The osteotomy must be complete and the bone must be mobile. The distractor is not designed or intended to break bone and/or complete the osteotomy.**

9. Confirm device activation

Instruments	
03.315.001	Surgeon Activation Instrument, 1.7 mm
03.315.005	Surgeon Activation Instrument, 1.7 mm with U-Joint

Use a surgeon activation instrument to engage the activation hex of the distractor or extension arm. Activate 2 mm in a counterclockwise direction, as marked on the handle, to confirm device stability and verify movement of the ramus. Return the distractor to its original position.

Technique tip: **The distractor is equipped with a mechanism (detent clip) to prevent unintended device reversal. This increases the force required to activate it. It is recommended to use the surgeon activation instrument instead of fingers to apply the turning force.**



10. If necessary, repeat steps for bilateral procedures

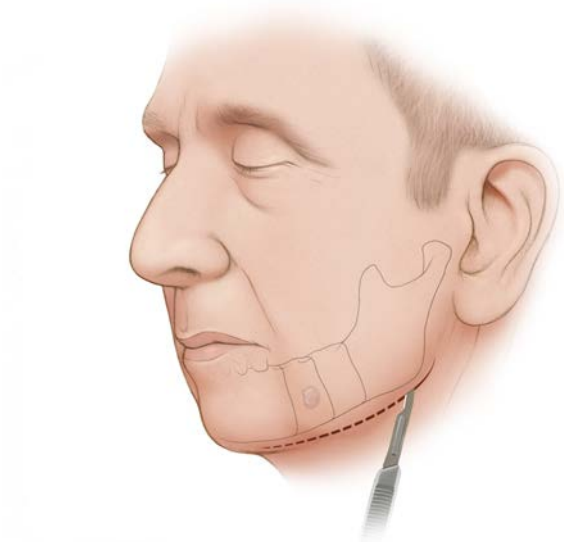
Repeat Steps 1 through 9 on the contralateral side. Close all incisions.

Mandibular Bone Transport

The following surgical technique is an example of a submandibular approach with a locking reconstruction plate and a distractor placed to perform mandible resection and transport. For the information regarding the plating refer to MatrixMANDIBLE Plating System surgical technique.

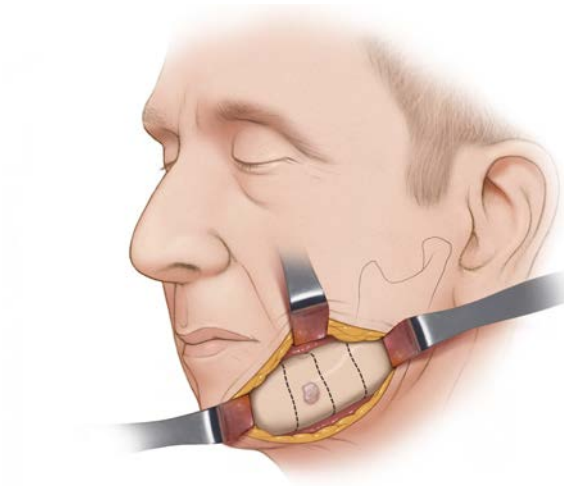
1. Make incision

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



2. Mark osteotomy

Mark the approximate site of the osteotomies to be completed based on the portion of the mandible to be resected.

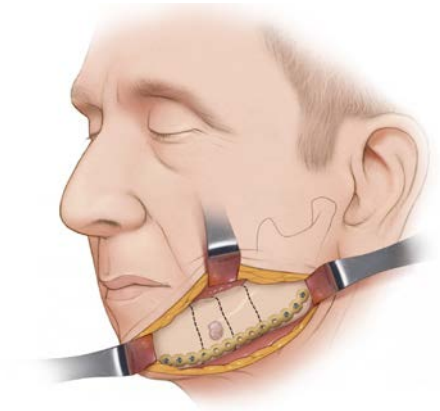


3. Cut, contour, and fit

Cut, contour, and fit an appropriate locking reconstruction plate to the inferior border according to the defined technique for that plating system.

4. Mark plate location

Mark the locking reconstruction plate location by placing all appropriate length screws on each side of the intended osteotomy sites. A minimum of 3 screws should be used in the locking reconstruction plate on both sides of the defect to ensure adequate stability. Screws should not be placed in the section of bone that will serve as the transport disk.

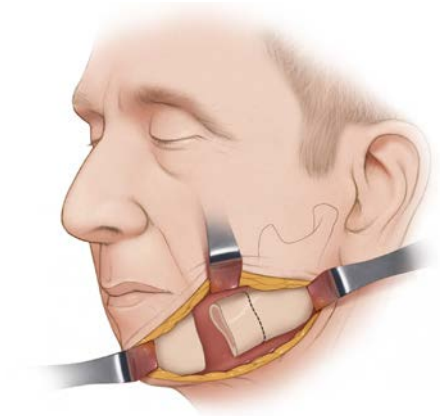


5. Remove plate

Unscrew and remove the locking reconstruction plate.

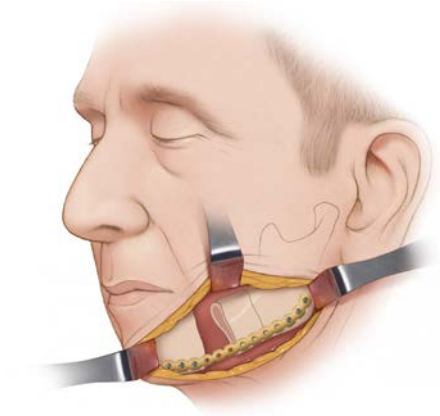
6. Resect the mandible

Resect the mandible.

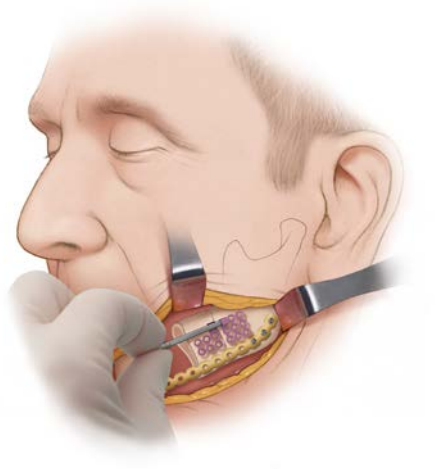


7. Reattach plate

Reattach the locking reconstruction plate to the mandible in its original position. Re-insert each predetermined screw. Check all screws to ensure a secure fit in the plate.



8. Fit distractor



Determine the placement of the CMF distractor keeping in mind the patient anatomy, desired bone movement, and potential interferences of the transport segment with the locking reconstruction plate. Screws should be placed superior to the locking reconstruction plate in the transport disk and in one of the sides of the mandible affixed to the locking reconstruction plate.

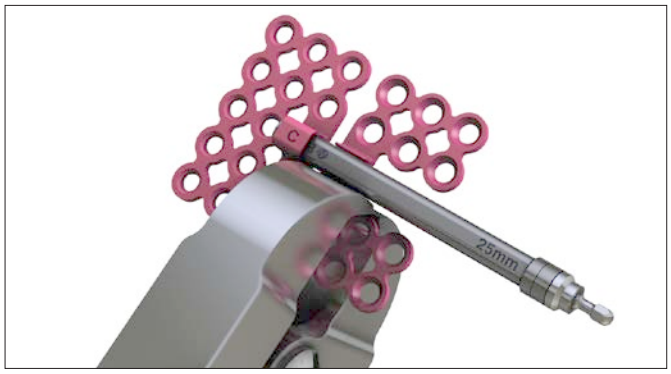
Factors to consider include:
- Occlusal plane
- Planned vector of distraction
- Adequate bone quality and quantity for screw placement
- Soft tissue (mucosa) coverage
- Location of activation hex of distractor or extension arm

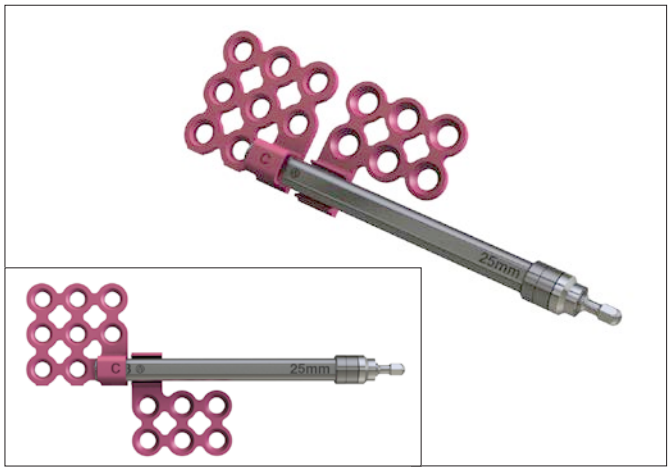
Technique tip: **Separate the footplates minimum 2 mm to allow enough space for osteotomy and ensure adequate distance between the pilot holes and the osteotomy.**

Precautions:
- **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.**
- **Location of the activation port should include consideration of important structures that may lie in the path between the distractor and the skin exit site. The main trunk or branches of the facial nerve, as well as other structures, may be injured when creating this port.**
- **Location of activation port should be chosen such that the maximum curvature of the extension arm is not exceeded as this may cause the arm to break. The extension arm should be placed in-line with the distractor body as much as possible to prevent pressure from being placed on the device and patient's bone which may cause loosening of the device from the bone (especially for patients with poor bone quality).**
- **To ensure that the soft tissue does not obstruct the activation hex during distraction, the next longer size distractor body and/or extension arm may need to be used.**
- **When inserting the flexible extension arm into the operative site, take care to protect silicone sleeve to prevent soft tissue interference during distraction.**

9. Cut and contour footplates

Instruments	
03.500.014	Cutting Instrument
03.500.020	File with Hex Coupling
03.503.039	Plate Cutter
311.005	Screwdriver Handle with Hex Coupling, small
or 311.006	Screwdriver Handle with Hex Coupling, medium
347.964	Combination Bending Pliers, for 1.0 mm and 2.0 mm plates
391.965	Combination Bending/Cutting Pliers, for 1.0 mm and 2.0 mm plates





Cut the footplates to remove any unnecessary screw holes.

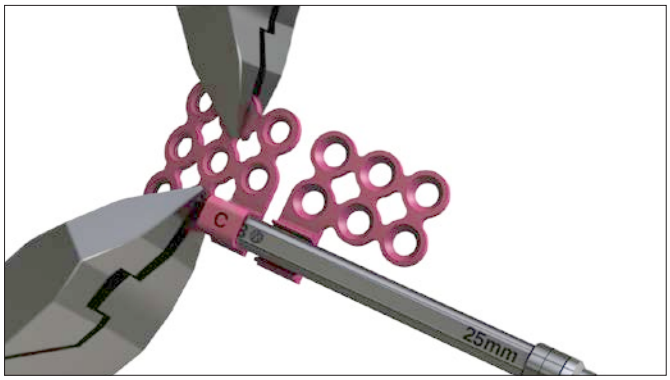
Technique tips:

- **Activate the distractor to separate the footplates to allow room for cutting instrumentation.**
- **Deburr the cut portion of the footplate as needed by rubbing sharp corners/edges with the file on the cutter or with the file instrument.**
- **When removing one side of the footplate, cut the footplates so the cut edges are flush with the distractor body.**
- **Screws can be placed in the holes superior to the distractor body in the posterior footplate and in the holes inferior to the distractor body in the anterior footplate for added stability.**

Precautions:

- **A minimum of two screws should be used in each footplate to ensure adequate stability in bone transport.**
- **Ensure screws will have purchase in good quality bone; footplates may shift during treatment if they are not properly secured.**

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



Firmly press the bending pliers on the footplates. Avoid handling the bending pliers with high forces that could produce surface defects and/or concentrate stress in the core of the implants. This in turn may eventually cause the product to fail.
Do not bend the plate beyond what is required by the anatomy as this may lead to damage of the footplates.*

Precautions:

- **Contour each footplate individually while holding that footplate with the bending pliers. Avoid bending one footplate while holding either the distractor body or the other footplate.**
- **Footplates should be cut and deburred so that the integrity of the screw hole is not compromised and tissue irritation is minimized.**
- **Take care to avoid nerves, tooth buds, tooth roots, or other critical structures when drilling and/or placing screws.**

Warnings:

- **Repeat and/or reverse and sharp bending may weaken the plate and lead to premature implant failure.**
- **Do not bend the plate beyond what is required by the anatomy as this may lead to damage of the footplates.**
- **Do not implant a distractor if the footplates have been damaged by over-bending.**

* Bending the footplates past 19 degrees may cause footplate breakage.

10. Mark distractor location

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

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.

Precaution: **It is recommended to separate the footplates by a minimum of 2 mm prior to drilling and/or inserting screws to ensure adequate distance between the pilot holes and the osteotomy.**

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

Use the appropriate drill bit and screwdriver blade for the footplate size selected.

For insertion of screws with PlusDrive screwdriver blades:

Footplate/ Screw size	Drill bit size	PlusDrive screwdriver blade	Screwdriver color band
1.5 mm	1.1 mm	1.5 mm or 1.5 mm/2.0 mm	red or red/blue
2.0 mm	1.5 mm	2.0 mm or 1.5 mm/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
1.5 mm	1.1 mm	1.5 mm/2.0 mm	red/blue
2.0 mm	1.5 mm	1.5 mm/2.0 mm	red/blue

See pages 86, 88 and 89 for drill bit and screwdriver blade 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.

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 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 prevent 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.

Warnings:

- **When the distractor is placed and/or removed intraorally, use of a hospital-approved throat pack is required to prevent a choking hazard in case of device fragments generated during the surgery.**
- **Take care to remove all device 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 1800 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 screw stripping in bone, and/or suboptimal fixation.**

Precautions:

- **The Raised Head screwdriver blade geometry does not allow for use with the pediatric trocar system. The universal trocar may be used instead.**
- **To increase distractor stability in thin bone, insert screws bicortically. In addition, more screws can be used.**
- **A minimum of two screws should be inserted through each distractor footplate during bone transport to ensure adequate stability. It is recommended to use screw holes closest to the distractor body.**
- **The distractor may be fixated with more than two screws per footplate. If longer bone advancement is desired, the distractor with mesh footplate could be used.**
- **Always irrigate adequately during drilling to prevent overheating of the drill bit and bone.**
- **Take care to avoid nerves, tooth buds, tooth roots, or other critical structures when drilling and/or placing screws.**
- **Take care while drilling as not to 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.**
- **Do not fully tighten the screws before completing the osteotomy.**
- **Before making osteotomy irrigate and apply suction for removal of debris potentially generated during implantation or removal.**
- **Use appropriate screw length to avoid distractor loosening or damage of critical/lingual structures.**
- **If locking screws are used, screw holes must be drilled at a right angle to 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.**

11. Perform transport disk osteotomy

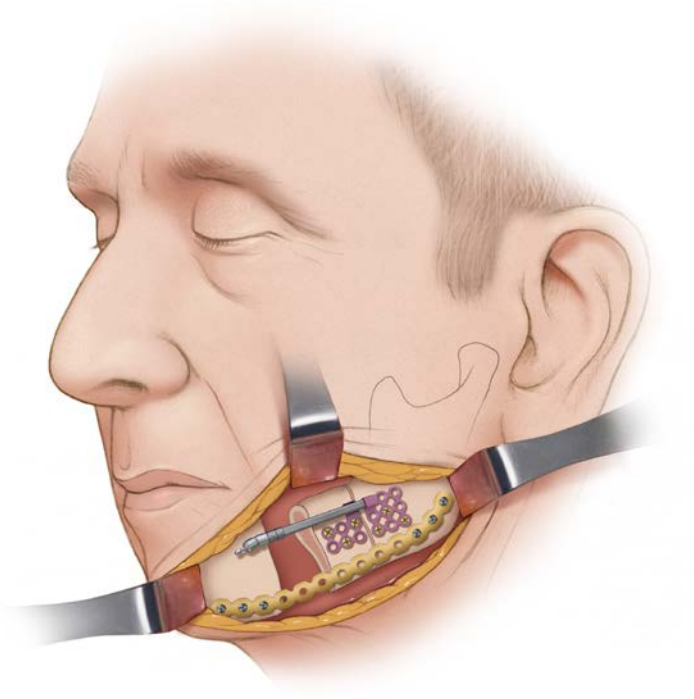
Perform the transport disk osteotomy while preserving the periosteum and taking care to avoid damaging the locking reconstruction plate.

Warning: **The osteotomy must be complete and the transport disk must be mobile. The distractor is not designed or intended to break bone and/or complete the osteotomy.**

12. Reattach distractor

Re-insert the distractor into the operative site, and pass the activation end of the distractor body through the percutaneous port created earlier. 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 10 (pages 50–52) for guidance on screw insertion, and associated Precautions, Warnings, Notes, Technique Tips, and part numbers.



Depending on patient anatomy and placement of the distractor, the extension arm can either remain in the intraoral cavity or project through a small percutaneous activation port. If the extension arm remains in the intraoral cavity, care should be taken to ensure that the extension arm does not interfere with the patient's ability to eat or breathe.

If the extension arm is projecting outside the body, an abnormal scar may form at the site of the small percutaneous activation port after treatment.

Extension arms can be secured below the dentition with a loop of wire attached to orthodontic brackets or to the teeth. The loop should restrict the vertical movement of the extension arm without affecting the arms' ability to rotate. This will ensure that the extension arm does not interfere with mastication.

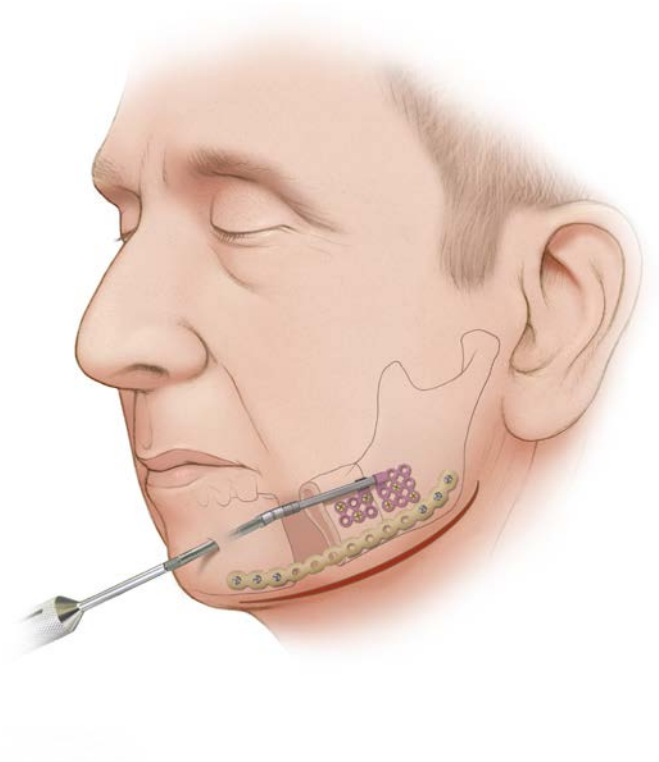
Precautions associated with distractor placement:

- **Applying too much torque to the screws may cause implant and/or instrument breakage, deformation, or bone stripping.**
- **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.**

13. Confirm device activation and mobility of the bone transport segment

Instruments	
03.315.001	Surgeon Activation Instrument, 1.7 mm
03.315.005	Surgeon Activation Instrument, 1.7 mm with U-Joint

Using the surgeon activation instrument, engage the activation hex of the distractor or extension arm. Activate 2 mm in the counterclockwise direction, as marked on handle, to confirm device stability and verify movement of the bone transport segment. Return the distractor to its original position.



Note: **The distraction device can only accomplish 2D movements for bone transport procedures.**

Technique tip:

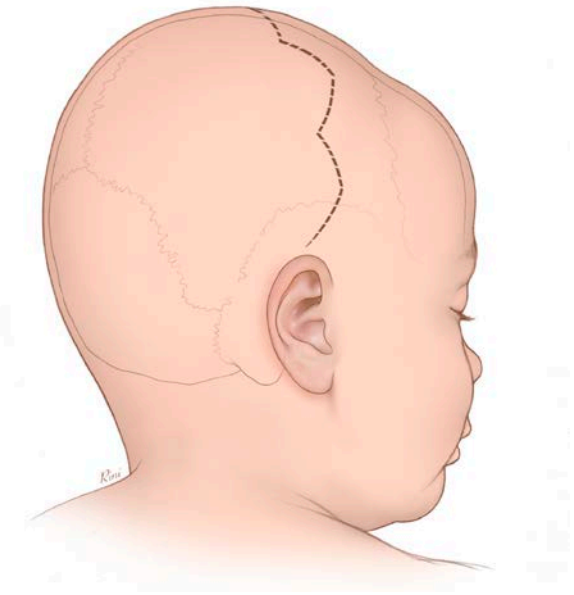
- **Two transport discs could be prepared, as described, for trifocal distraction with two distractors applied on each side of the bone defect.**
- **The distractor is equipped with a mechanism (detent clip) to prevent unintended device reversal. This increases the force required to activate it. It is recommended to use the surgeon activation instrument instead of fingers to apply the turning force.**

Posterior Cranial Vault Distraction

The following surgical technique is an example of a coronal approach with the distractors placed on the cranium with anterior percutaneous activation ports. A similar technique can be used to place the distractors by inverting the distractor so the arm comes out posteriorly versus anteriorly.

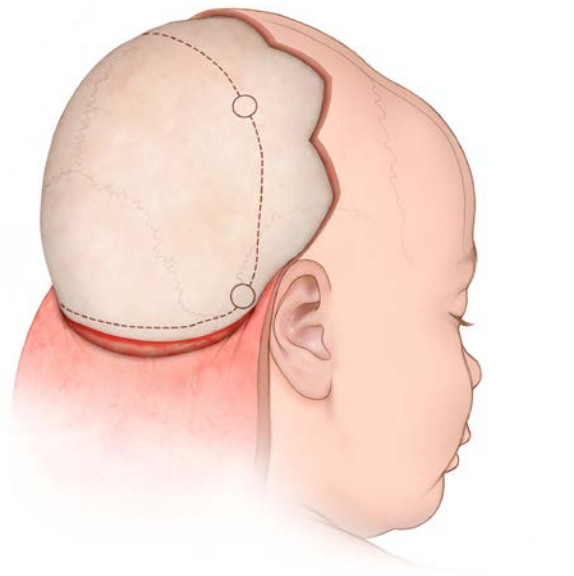
1. Make incision

Make a coronal incision and expose the subgaleal plane.



2. Mark osteotomy

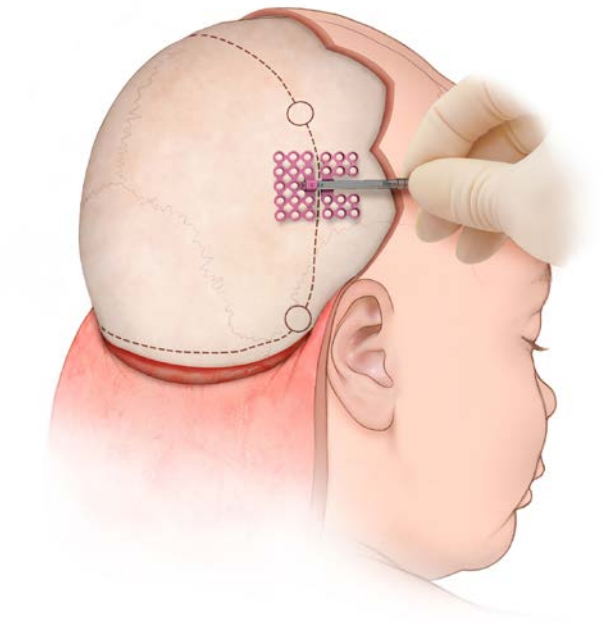
Mark the approximate site of the osteotomy based on the planned placement of the distractor.



3. Fit the distractors

Place a fully assembled distractor in the intended areas to assess the patient's anatomy and determine the approximate location of the footplates and extension arm. Factors to consider:

- Planned vector of distraction (especially in relation to other distractors being used)
- Soft tissue coverage (maximized if placed in a more flat location on the skull)
- Location of activation hex with anterior or posterior exit through the scalp
- Number of distractors being used during treatment
- Adequate bone quality and quantity for screw placement
- Dura mater
- Venous sinuses and other blood vessels
- Patient hairline
- Parallel placement



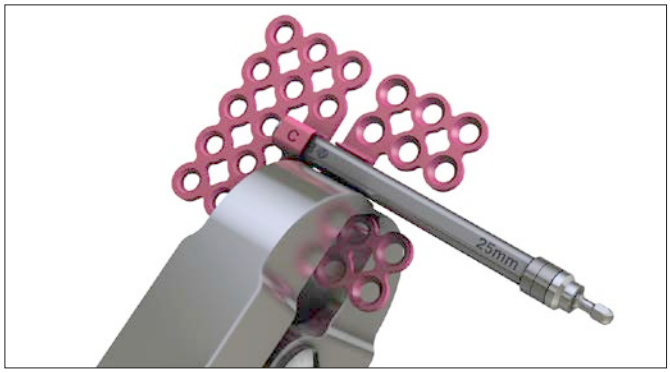
Technique tip: **Separate the footplates minimum 2 mm to allow enough space for osteotomy and ensure adequate distance between the pilot holes and the osteotomy.**

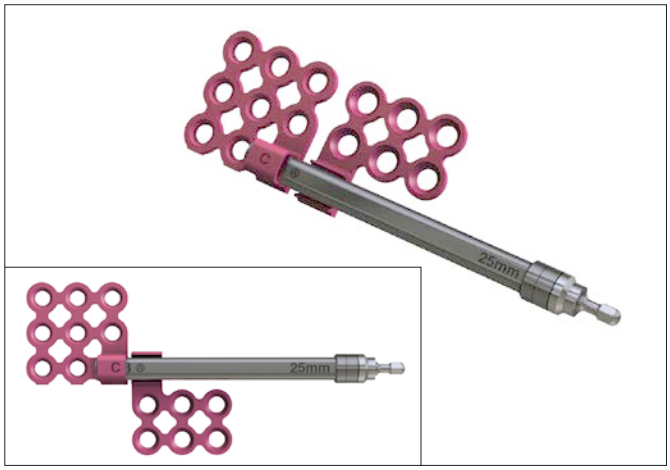
Precautions:

- **During cranial distraction, parallel placement is necessary to facilitate proper head lengthening and ultimate symmetrical anatomy. Take great care in aligning the distractors used in a parallel position while fitting to ensure proper distraction.**
- **If parallel placement is difficult to accomplish when considering the patient's soft tissue coverage and potential patient discomfort, a slight convergence is acceptable if the point of convergence is sufficiently far from the patient.**
- **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.**
- **Location of activation port should be chosen such that the maximum curvature of the extension arm is not exceeded as this may cause the arm to break. The extension arm should be placed in-line with the distractor body as much as possible to prevent pressure from being placed on the device and patient's bone which may cause loosening of the device from the bone (especially for patients with poor bone quality).**
- **Location of the activation port should include consideration of important structures that may lie in the path between the distractor and the skin exit site. The main trunk or nerve branches, as well as other structures, may be injured when creating this port.**
- **To ensure that the soft tissue does not obstruct the activation hex during distraction, the next longer size distractor body and/or extension arm may need to be used.**
- **When inserting the flexible extension arm into the operative site, take care to protect silicone sleeve to prevent soft tissue interference during distraction.**

4. Cut and contour footplates

Instruments	
03.500.014	Cutting Instrument
03.500.020	File with Hex Coupling
03.503.039	Plate Cutter
311.005	Screwdriver Handle with Hex Coupling, small
or 311.006	Screwdriver Handle with Hex Coupling, medium
347.964	Combination Bending Pliers, for 1.0 mm and 2.0 mm plates
391.965	Combination Bending/Cutting Pliers, for 1.0 mm and 2.0 mm plates





Cut the footplates to remove any unnecessary screw holes.

Technique tips:

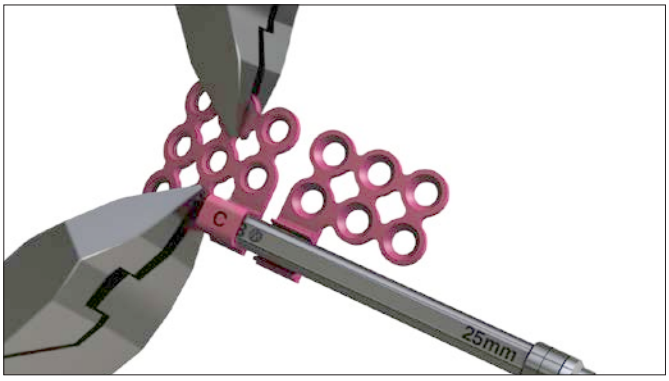
- **Activate the distractors to separate the footplates to allow room for cutting instrumentation.**
- **Deburr the cut portion of the footplate as needed by rubbing sharp corners/edges with the file on the cutter or with the file instrument.**
- **When removing one side of the footplate, cut the footplates so the cut edges are flush with the distractor body.**
- **Screws can be placed in the holes superior to the distractor body in the posterior footplate and in the holes inferior to the distractor body in the anterior footplate for added stability.**

Precautions:

- **A minimum of three screws should be used in each footplate to ensure adequate stability.**
- **Ensure screws will have purchase in good quality bone; footplates may shift during treatment if they are not properly secured.**

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

Firmly press the bending pliers on the footplates. Avoid handling the bending pliers with high forces that could produce surface defects and/or concentrate stress in the core of the implants. This in turn may eventually cause the product to fail.
Do not bend the plate beyond what is required by the anatomy as this may lead to damage of the footplates.*



Precautions:

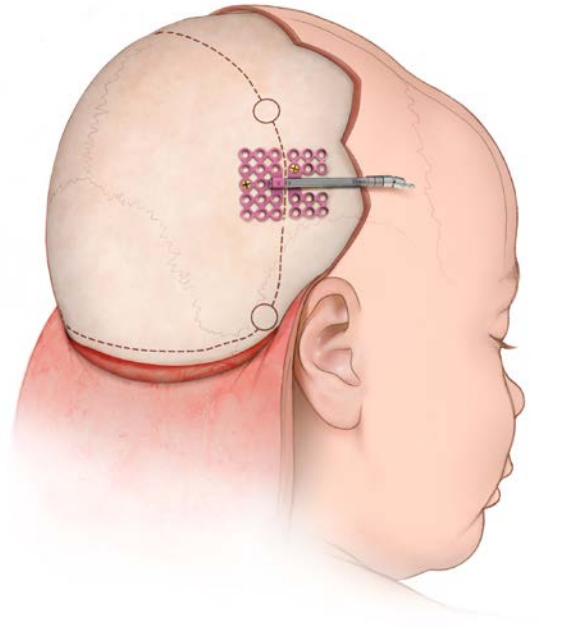
- **Contour each footplate individually while holding that footplate with the bending pliers. Avoid bending one footplate while holding either the distractor body or the other footplate.**
- **Footplates should be cut and deburred so that the integrity of the screw hole is not compromised and tissue irritation is minimized.**
- **Take care to avoid the dura, vascular structures and other critical structures when drilling and/or placing screws.**

Warnings:

- **Repeat and/or reverse and sharp bending may weaken the plate and lead to premature implant failure.**
- **Do not bend the plate beyond what is required by the anatomy as this may lead to damage of the footplates.**
- **Do not implant a distractor if the footplates have been damaged by over-bending.**

* Bending the footplates past 19 degrees may cause footplate breakage.

5. Mark distractor location



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

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.

Precaution: **It is recommended to separate the footplates by a minimum of 2 mm prior to drilling and/or inserting screws to ensure adequate distance between the pilot holes and the osteotomy.**

Warning: **Ensure screw insertion at a right angle to the footplate. Off-axis screw insertion may result in improper screw engagement in bone.**

Use the appropriate drill bit and screwdriver blade for the footplate size selected.

For insertion of screws with PlusDrive screwdriver blades:

Footplate/ Screw size	Drill bit size	PlusDrive screwdriver blade	Screwdriver color band
1.5 mm	1.1 mm	1.5 mm or 1.5 mm/2.0 mm	red or red/blue
2.0 mm	1.5 mm	2.0 mm or 1.5 mm/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
1.5 mm	1.1 mm	1.5 mm/2.0 mm	red/blue
2.0 mm	1.5 mm	1.5 mm/2.0 mm	red/blue

See pages 86, 88 and 89 for drill bit and screwdriver blade part numbers.

Precaution: **4 mm length screws are recommended for use in cranial vault expansion to limit the possibility of dural injury.**

Warning: **Use of an inappropriate size screw or drill bit may lead to screw pull out and cause dural injury.**

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.

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

Warnings:
- **Self-drilling screws have pointed tips which may damage the dura during distraction more easily than self-tapping screws which have rounded tips. Therefore, it is recommended to use self-tapping screws where there is a risk of damage to the dura.**
- **Raised Head Screws in shorter lengths are offered in self-drilling only.**

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 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 prevent 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.

Warnings:
- **Take care to remove all device 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 to the dura or other critical structures.**
- **Drill rate should never exceed 1800 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 screw stripping in bone, and/or suboptimal fixation.**

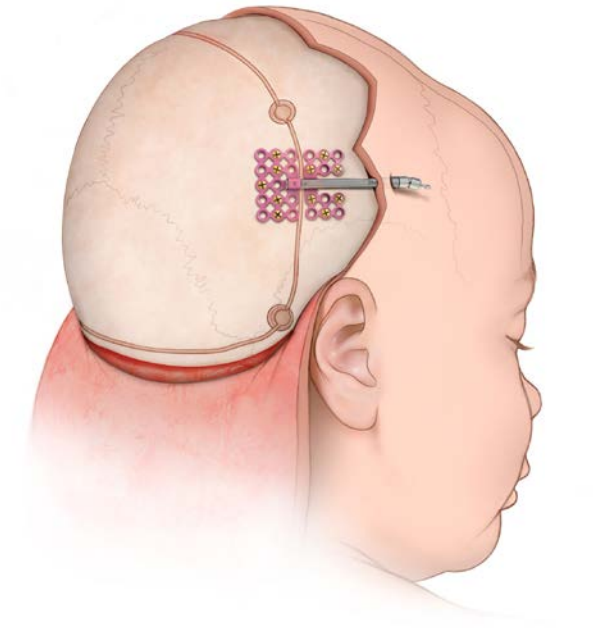
Precautions:
- **Raised Head Screw geometry does not allow for engagement with the holding sleeve.**
- **A minimum of three screws should be inserted through each distractor footplate to ensure adequate stability. It is recommended to use screw holes closest to the distractor body.**
- **The distractor may be fixated with more than three screws per footplate. If longer bone advancement is desired, the distractor with mesh footplate could be used to enable the use of more than three screws per footplate.**
- **To increase distractor stability in thin bone, more screws can be used to enable the use of more than three screws per footplate.**
- **Depending on patient anatomy and placement of the distractor, the extension arm can either exit anterior or posterior. If placed anteriorly, the patient hairline should be considered to cover any potential scarring.**
- **Always irrigate adequately during drilling to prevent overheating of the drill bit and bone.**
- **Take care to avoid the dura, vascular structures and other critical structures when drilling and/or placing screws.**
- **Take care while drilling as not to 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.**
- **Do not fully tighten the screws before completing the osteotomy.**
- **Before making osteotomy irrigate and apply suction for removal of debris potentially generated during implantation or removal.**
- **If locking screws are used, screw holes must be drilled at a right angle to 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.**
- **Use appropriate screw length to avoid distractor loosening or damage of critical structures or dura.**

6. Perform the osteotomy

Perform the osteotomy at the marked site, leaving the dura attached and intact.

Warning: **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.**

7. Reattach distractor



Make an incision in the scalp tissue for the distraction activation hex or extension arm to protrude through. Alternatively, activation hex can be used to puncture through the skin. This can be done so the activation hex is either anterior or posterior according to the predetermined surgical plan.

Note: **It should be considered to place the activation hex incision within the hairline as an abnormal scar may form at the site of the small incision after treatment is complete.**

Pass the activation end of the distractor body through the percutaneous port. 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 5 (pages 60–62) for guidance on screw insertion, and associated Precautions, Warnings, Notes, Technique Tips, and part numbers.

Precautions associated with distractor placement:

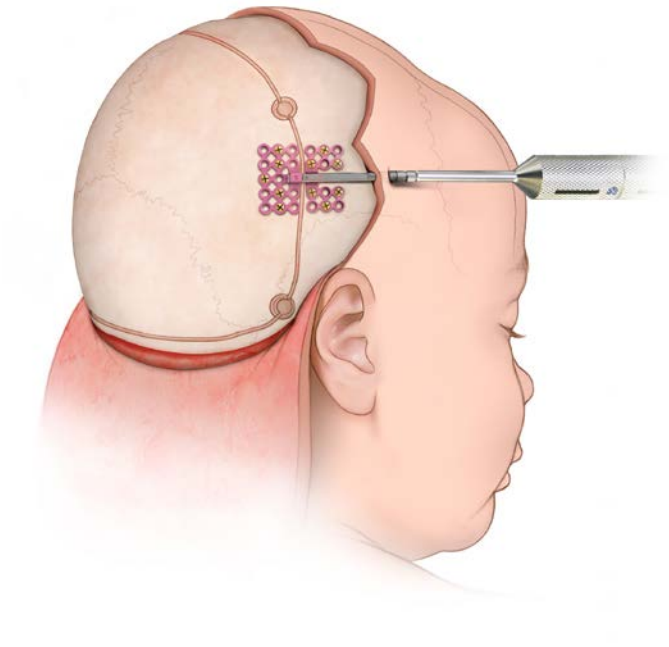
- **Applying too much torque to the screws may cause implant and/or instrument breakage, deformation, or bone stripping.**
- **After implant placement or removal is complete, the surgical area should be irrigated and suction should be applied for removal of debris potentially generated during the procedure.**

8. Confirm device activation

Instruments	
03.315.001	Surgeon Activation Instrument, 1.7 mm
03.315.005	Surgeon Activation Instrument, 1.7 mm with U-Joint

Use a surgeon activation instrument to engage the activation hex of the distractor or extension arm. Activate 2 mm in a counterclockwise direction, as marked on the handle, to confirm device stability and verify movement of the cranium. Return the distractor to its original position.

Technique tip: **The distractor is equipped with a mechanism (detent clip) to prevent unintended device reversal. This increases the force required to activate it. It is recommended to use the surgeon activation instrument instead of fingers to apply the turning force.**



9. Repeat steps for all distractors

Repeat steps 1 through 8 for all distractors being placed.

Closure
Bring the scalp tissue back over the skull and cover the distractors.

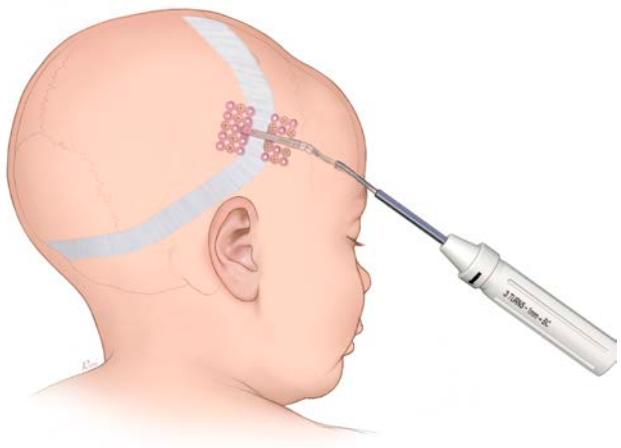
Suture the incision closed.

Postoperative Considerations

Mandible and Cranial

Suggested distraction protocol

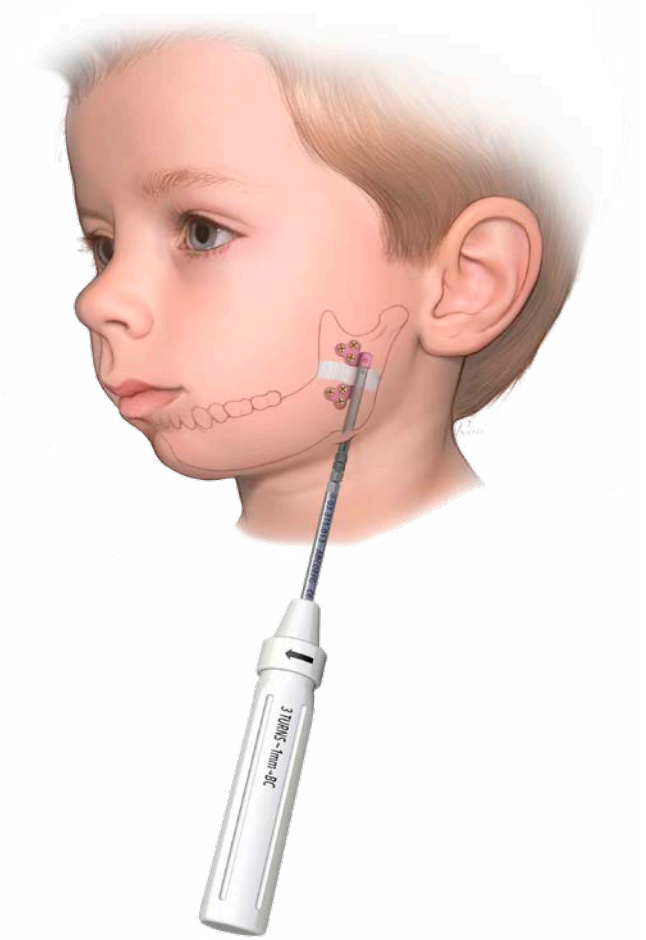
Instruments	
03.315.013	Patient Activation Instrument
304.098	AB Distraction Label for Patient Activation Instrument



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

Note: **If the dura mater or other underlying structures may have been damaged during cranial distraction, an increased latency period may be used for structures to heal before distraction begins.**

Warning: **Activation of the device on poor quality bone should be done with the activation end of the extension in-line with the distractor axis to avoid placing a levering force on the distractor which could cause separation of the device from the bone. In neonates and others with poor quality bone, it is recommended this activation be done by or under the supervision of the physician.**



Using the patient activation instrument
Instructions and guidance are required and should be provided to the patient or caregiver for the use and cleaning of the device. A demonstration to the patient and/or caregiver of the correct and incorrect activation of the distractor with the patient activation instrument is recommended.

Patients/caregivers are given a different activation instrument than is provided to the surgeon. The surgeon activation instrument is able to activate the distractor for advancement and reversal. The patient activation instrument is designed to help reduce the chance of reversing the distractor.

Note: Patient activation instrument is etched with "CMF Distraction System".

BC advancement instructions

Patient activation instrument

Warnings:

- The patient activation instrument has only instruction for BC distractor advancement printed on the device. If an AB distractor was used during surgery, place the AB distraction label on the patient activation device so that the BC distractor advancement instruction is fully covered.
- If the BC distractor advancement instruction is not fully covered, it may result in an increased rate of distraction and/or non-union.
- Be sure to follow the instructions on the back of the AB distraction label for surface preparation of the patient activation instrument prior to applying the label.
- The AB distraction label should be completely affixed to the device. If the AB label is not completely affixed, it may separate from the patient activation instrument and result in an increased rate of distraction and/or non-union. If a BC distractor was used during surgery, please discard the AB distraction label(s) provided with the patient activation device.
- Carefully remove label from label sheet and place on instrument to prevent damage to the label.
- Do not use damaged label. If the label is damaged, use replacement label.

Patient activation instrument with AB Distraction Label

The distractor is equipped with a mechanism (detent clip) to prevent unintended device reversal. This increases the force required to activate it. It is recommended to use the patient activation instrument (Figure 1) instead of fingers to apply the turning force. To activate the distractor, hold the patient activation instrument by the handle (not the shaft), engage the activation hex, and rotate the handle counterclockwise (direction indicated by arrow on instrument). The patient activation instrument should be lined up with the distractor or extension arm end so that a sideways (levering) force is not applied to the end during activation.

Figure 1

To make a full turn, rotate the patient activation instrument in the direction of the arrow until the arrow has reached its original or starting position (Figure 2).

To make a half turn, rotate the patient activation instrument in the direction of the arrow until the dot (•) on the opposite side of the instrument is facing you (Figure 3).

Figure 2


Figure 3

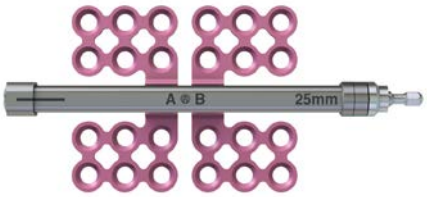
Precautions:

- **The patient activation instrument was designed to help prevent activation of the distractor in the incorrect direction (clockwise–opposite the direction of the arrow); however, there is a possibility that the instrument can reverse the distractor when activated in the clockwise direction. Off-axis engagement of patient activation instrument with activation hex or extension arm further increases the risk of reversing distractor. Therefore, it is important to communicate to the caregiver the correct direction (counterclockwise–the direction of the arrow) and alignment for activation to prevent accidental distractor reversal which may, in severe cases, lead to obstruction of airway or increased intracranial pressure.**
- **Ensure the patient activation instrument is always held by the handle, not the shaft, during activation. Only activation by the handle will provide enough turning force to activate the distractor.**
- **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.**
- **Ensure that the distraction plan will not create a significant condylar dislocation. During the course of mandibular treatment, monitor the patient's condyles in the glenoid fossa for symptoms of TMJ displacement (pain, clicking or locking).**
- **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.**

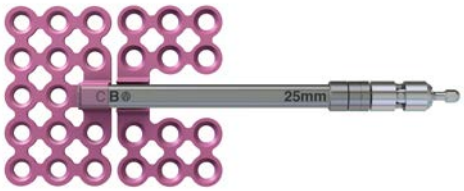
Rate of activation

The rate of activation and distraction protocol should be defined by the physician based on a comprehensive assessment of the medical needs and health condition of that individual patient.
The AB and BC distractors advance at different rates.

AB distractor



BC distractor

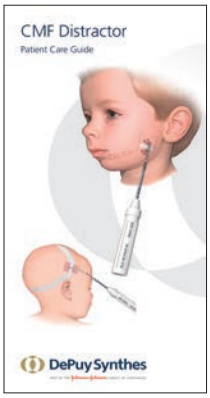


	Recommended rates based on patient age: [1–4]	0.70 mm of linear advancement/1 full rotation	0.35 mm of linear advancement/1 full rotation
Mandible	< 1 year old (up to 1.8 mm/day)	2½ rotations (1.75 mm)/day	5 rotations (1.75 mm)/day
	> 1 year old (1 mm/day)	1½ rotations (1.05 mm)/day	3 rotations (1.05 mm)/day
Cranial	1 mm/day	1½ rotations (1.05 mm)/day	3 rotations (1.05 mm)/day
Bone transport	0.5 mm–1 mm/day	¾ –1½ rotations (0.53–1.05 mm)/day	1½–3 rotations (0.53–1.05 mm)/day

Notes:

- **During one full rotation in the counter-clockwise direction, the detent tab slips over the advancement screw four times. This can be felt by the end user and may be used as an indication that one full rotation has occurred.**
- **It is important to communicate to the caregiver that if the arrow is moving in the backwards direction during activation and/or an audible clicking sound is heard, then the activation is not being completed in the correct direction and should be stopped. It is critical the caregiver know how to properly use the patient activation instrument.**
- **1.0 mm of linear advancement per day is the standard rate of activation and allows for optimal osteogenesis of the regenerate. Distraction of less than 1 mm per day can be considered for cases of compromised bone healing such as heavy smokers, previously radiated patients, and patients on bisphosphonates and in bone transport procedures. Distraction of more than 1 mm per day is recommended to prevent premature consolidation in young children and neonates.**

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
If the distractors are placed with the extension arms in the intraoral cavity during mandibular distraction cases, care must be taken to prevent the arms from interfering with mastication. Extension arms can be secured below the dentition with a loop of wire attached to orthodontic brackets or to the teeth. The loop should restrict the vertical movement of the extension arm without affecting the arm's ability to rotate. This will ensure that the extension arm does not interfere with mastication.

If the distractors are placed with the extension arms exiting through percutaneous ports, 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.

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 extension arms during sleep can damage and/or break the extension arms which may lead to a choking hazard. It is advised to secure the extension arms to the patient's skin, without affecting the arms' ability to rotate. Options include suture or tape.**
- **Ensure all steps of the provided technique are followed. It presents a choking hazard if components of the distractor (e.g., bone screw, machine screw, distractor collar, universal joint, extension arm and silicone tube of flexible extension arm) become loose, disengage from the distractor, or break.**

Precautions:
- **It is important to instruct patients regarding hazards, harms, and proper use of the distractor: to seek Emergency Care immediately if the patient experiences any difficulty in breathing, how to turn the distractor, to follow the distraction protocol, to follow up with appointments, to report loose or broken parts immediately to surgeon, to keep wound area clean during treatment, to maintain good oral hygiene during all phases of treatment, and to contact surgeon immediately if they lose the patient activation instrument or AB distraction label or the distractor is loose or broken and/or when the patient has changes/increased difficulty in eating.**
- **The patient activation instrument was designed to help prevent activation of the distractor in the incorrect direction (clockwise–opposite the direction of the arrow); however, there is a possibility that the instrument can reverse the distractor when activated in the clockwise direction. Therefore, it is important to communicate to the caregiver the correct direction (counterclockwise–the direction of the arrow) for activation to prevent accidental distractor reversal which may, in severe cases, lead to obstruction of airway or increased intracranial pressure.**
- **Advise the patient not to tamper with the distractor(s) or extension arm(s) and to avoid physical activities that may interfere with treatment or device such as those that may include unexpected falls.**

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.[2] This time period may vary in relation to patient age and extent of mandibular advancement. The timing of distractor removal should be determined by clinical evaluation and radiographic or CT evidence of bone healing.

If extension arms were used, they can be removed at the start of the consolidation phase. Doing so allows the distractor body to be embedded in the soft tissue and minimizes the chance of mucosal infection around the extension arms.

Extension Arm Removal

Mandible and Cranial

Extension arm removal

Instrument	
03.315.004	Removal Instrument for Extension Arms

There are two versions of the extension arm: flexible and rigid. They are removed from the distractor differently. If a flexible extension arm was used, it is connected to the distractor with spring fingers. If a rigid extension arm was used, it is connected to the distractor with a hex pocket. The instructions for use below provide details for both versions of the extension arm.

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 area where the extension arm connects to the distractor.

- For the flexible extension arm, disengage the extension arm from the distractor by pulling it axially and remove the extension arm through the percutaneous port or intraoral cavity.
- For the rigid extension arm, disengage the extension arm from the distractor with side-to-side movement of the arm. Remove the extension arm through the percutaneous port or intraoral cavity.

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 result in a change in the distraction distance that has been achieved.**

For rigid extension arm only
The etching on the hex end of the extension arm (Figure 1) 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 will help to disengage it from the distractor.

Precaution: **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.**

If the extension arm cannot be removed, fully tighten the extension arm again by rotating the removal instrument collar clockwise (it closes the extension arm over the activation hex of the distractor).

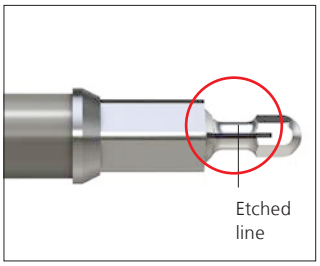
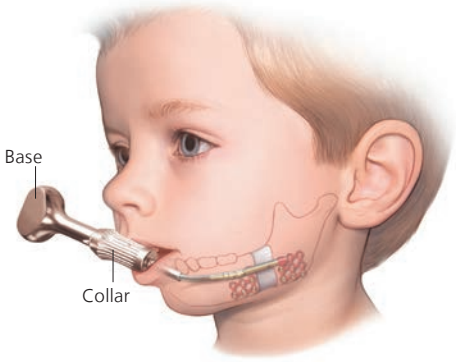
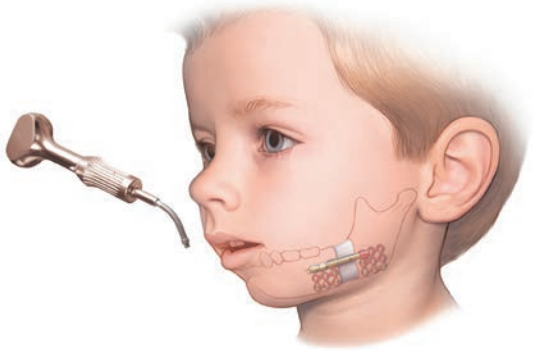


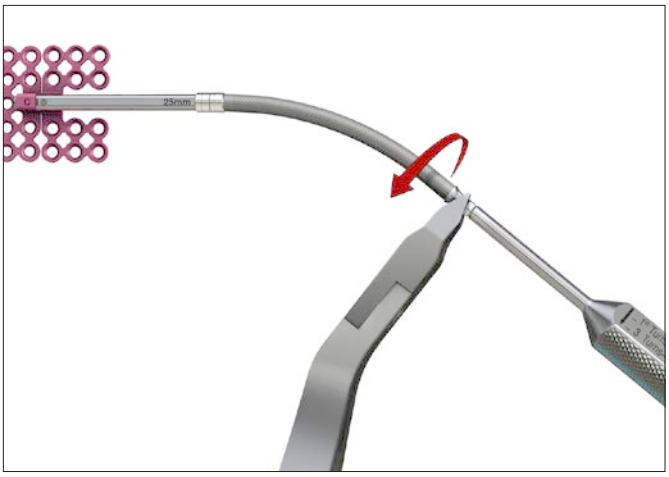
Figure 1





Optional technique

Instruments	
03.315.001	Surgeon Activation Instrument, 1.7 mm
03.315.005	Surgeon Activation Instrument, 1.7 mm with U-Joint
347.964	Combination Bending Pliers, for 1.0 mm and 2.0 mm plates



If the extension arm removal instrument is not available, the extension arms can be removed using a surgeon 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 spring fingers for the flexible extension arm and the hex pocket for the rigid extension arm where the extension arm connects to the distractor. Disengage the extension arm from the distractor by pulling axially for the flexible extension arm or with side-to-side movement for the rigid extension arm.

Device Removal

Mandible and Cranial

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

Note: The distractors are easier to remove if 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.**
- **In cases of mandibular distraction when the distractor is placed and/or removed intraorally, use of a hospital-approved throat pack is required to prevent a choking hazard in case of device 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**
1.0 mm	1.0 mm	green
1.3 mm	1.3 mm	yellow
1.5 mm	1.5 mm/2.0 mm	red/blue
2.0 mm	1.5 mm/2.0 mm	red/blue

See pages 82, 84 and 85 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 (see page 28 for universal trocar instructions).**

Footplate/ Screw size	Raised Head screwdriver blade	Screwdriver color band
1.0 mm	1.0 mm/1.3 mm	green/yellow
1.3 mm	1.0 mm/1.3 mm	green/yellow
1.5 mm	1.5 mm/2.0 mm	red/blue
2.0 mm	1.5 mm/2.0 mm	red/blue

See pages 82, 84 and 85 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 hospital 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.**

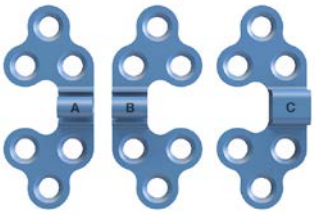
Warning: **Take care to remove all device fragments that are not fixated during surgery.**

For additional screw removal options refer to the Universal Screw Removal Set brochure (036.000.773)

Implants

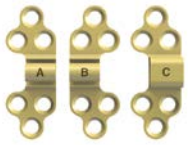
Footplates

- Available in A, B, and C styles to mate with the selected distractor body. Each footplate is etched with a style letter designation
- Available in four types for use in a wide range of patients:
  - 1.0 mm (green, available in mesh design only)
  - 1.3 mm (yellow)
  - 1.5 mm (red)
  - 2.0 mm (blue)
- Footplates are used with corresponding size titanium bone screws
- Available in cloverleaf and mesh designs (1.0 mm plates are available in mesh design only)
- 1.5 mm and 2.0 mm mesh footplates available in elevated designs to facilitate parallel placement of the distractors in the mandible
- Elevated designs available in 5.5 mm offset and 7.5 mm offset
- Material: Commercially pure titanium

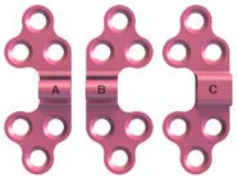


A-style B-style C-style

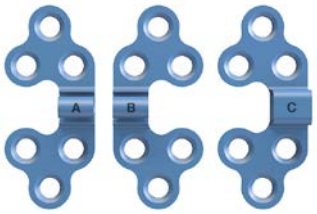
Cloverleaf footplates



1.3 mm

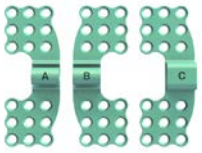


1.5 mm

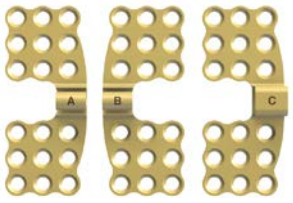


2.0 mm

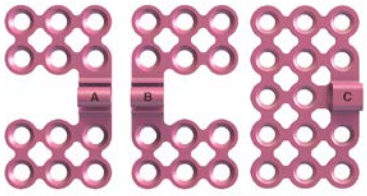
Mesh footplates



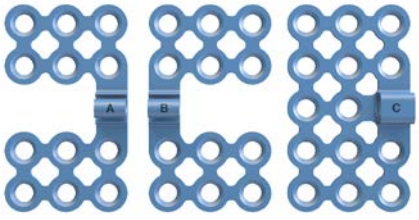
1.0 mm



1.3 mm



1.5 mm



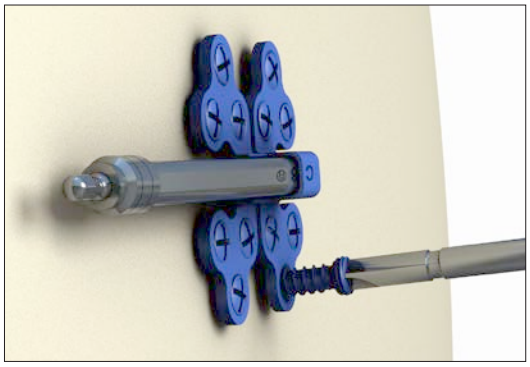
2.0 mm

Elevated mesh footplates

1.5 mm

2.0 mm

- 2.0 mm footplates accept DePuy Synthes 2.0 mm titanium locking screws



2.0 mm locking screw

Distractor bodies

- Offered in center-translating (AB distractor) and end-translating (BC distractor) designs
- Available with or without a universal joint
- Materials:
  - AB distractor body, AB distractor body with universal joint and BC distractor body with universal joint: Cobalt-chromium (Co-20Cr-15W-10Ni), cobalt-chromium-molybdenum alloy (Co-28Cr-6Mo), cobalt-nickel alloy (35Co-35Ni-20Cr-10Mo) and titanium alloy (Ti-6Al-7Nb)
  - BC distractor body: Cobalt-chromium-molybdenum alloy (Co-28Cr-6Mo), cobalt-nickel alloy (35Co-35Ni-20Cr-10Mo) and titanium alloy (Ti-6Al-7Nb)

AB distractor body

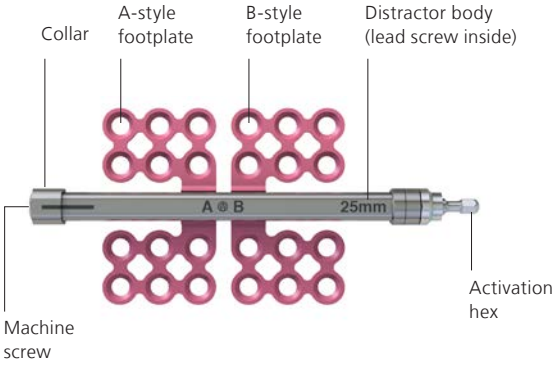
BC distractor body

AB distractor body with universal joint

BC distractor body with universal joint

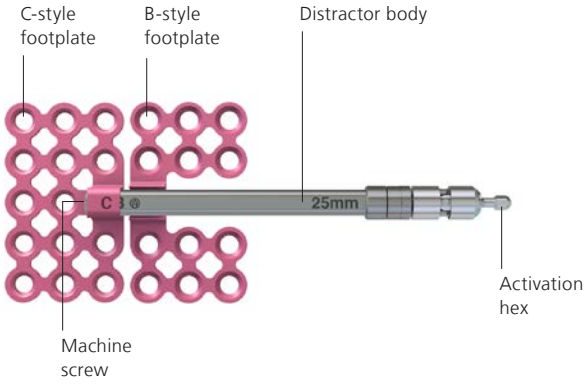
AB distractor bodies

- Center-translating distractor bodies work with A-style and B-style footplates
- Both footplates are positioned in the center of the distractor and move laterally away from one another when the distractor is activated
- Footplates can be placed more anteriorly on the mandible with half of the distractor initially positioned posterior to the osteotomy
- Available in 15 mm, 20 mm, 25 mm, and 30 mm lengths



BC distractor bodies

- End-translating distractor bodies work with B-style and C-style footplates
- Both footplates are positioned at one end of the distractor. When the distractor is activated, the B-style footplate translates down the distractor away from the C-style footplate, which remains stationary
- Footplates can be placed more posteriorly on the mandible with the distractor body initially positioned either anterior or posterior to the osteotomy, depending on the orientation
- Available in 15 mm, 20 mm, 25 mm, 30 mm, 35 mm, and 40 mm lengths



Extension arms

- Allow the point of activation to be moved away from the distractor to convenient access with the activation instrument
- Can be placed intraorally or percutaneously
- May be removed during the consolidation phase without a surgical procedure (see page 71)
- Rigid arms available in 20 mm, 40 mm, and 60 mm lengths, flexible arms available in 30 mm, 40 mm, and 60 mm lengths
- The flexible extension arm is available with a spring finger
- The rigid extension arm has a hex pocket design
- Materials:
  - Flexible extension arm: Cobalt-nickel alloy (Co-35Ni-20Cr-10Mo), and silicone
  - Rigid extension arm: Cobalt-chromium alloy (Co-20Cr-15W-10Ni) and titanium alloy (Ti-6AI-7Nb)

Rigid extension arm

Flexible extension arm with spring finger

Screws
- 2 types of screws available: PlusDrive Screws and Raised Head Screws
- Screw diameter corresponds footplate thickness
- Screw design include: self-drilling (gray), self-tapping (gold) and emergency (green-grey) screws
- PlusDrive and Raised Head Screws are color-coded according to type

Raised Head Screws
- Material: Commercially pure titanium or titanium alloy (Ti-6Al-7Nb)
- Raised Head Screws can be inserted and removed with:
  – PlusDrive screwdriver blades
  – Raised Head screwdriver blades
- Screw length does not include the screw head

Self-drilling Self-tapping Emergency

Raised Head Screws		
Screw ∅ [mm]	**Type**	**Length [mm]**
1.0 mm	Self-tapping	4, 6, 8
1.3 mm	Self-drilling Self-tapping	4, 6 8, 10, 12
1.5 mm	Self-drilling Self-tapping	4, 6, 8 10, 12
2.0 mm	Self-drilling Self-tapping	4, 6, 8 10, 12

Raised Head Emergency Screws		
Screw ∅ [mm]	**Type**	**Length [mm]**
1.2 mm	Self-tapping	4, 6, 8
1.7 mm	Self-tapping	4, 6, 8, 10, 12
2.0 mm	Self-tapping	4, 6, 8, 10, 12
2.4 mm	Self-tapping	5, 6, 8, 10, 12

PlusDrive Screws

- Material: Commercially pure titanium or titanium alloy (Ti-6Al-7Nb)
- Plus Drive Screws can be inserted and removed with PlusDrive screwdriver blades

Self-drilling Self-tapping Emergency

PlusDrive Screws		
Screw ∅ [mm]	**Type**	**Length [mm]**
1.0 mm	Self-tapping	4, 6, 8
1.3 mm	Self-tapping Self-drilling	4, 6, 8, 10, 12 4, 6
1.5 mm	Self-tapping Self-drilling	4, 6, 8, 10, 12 4, 6, 8
2.0 mm	Self-tapping Self-drilling Locking self-tapping	4, 6, 8, 10, 12 4, 6, 8 6, 8, 10, 12

PlusDrive Emergency Screws		
Screw ∅ [mm]	**Type**	**Length [mm]**
1.2 mm	Self-tapping	4, 6, 8
1.7 mm	Self-tapping	4, 6, 8, 10, 12
2.0 mm	Self-tapping	4, 6, 8, 10, 12
2.4 mm	Self-tapping	5, 6, 8, 10, 12

Modules

68.315.001	CMFD Implants and Instruments Module
68.315.002	CMFD Instruments Module

Implants

04.315.000	2.7 mm Titanium Machine Screw, for CMF Distractor
04.315.001	Removable End Cap, for CMF Distractor

AB Distractor Bodies, End Activated, for CMF Distractor

	Length (mm)		Length (mm)
04.315.003	15	04.315.005	25
04.315.004	20	04.315.006	30

BC Distractor Bodies, End Activated, for CMF Distractor

	Length (mm)		Length (mm)
04.315.023	15	04.315.026	30
04.315.024	20	04.315.027	35
04.315.025	25	04.315.028	40

AB Distractor Bodies, End Activated with U-Joint, for CMF Distractor

	Length (mm)		Length (mm)
04.315.053	15	04.315.055	25
04.315.054	20	04.315.056	30

BC Distractor Bodies, End Activated with U-Joint, for CMF Distractor

	Length (mm)		Length (mm)
04.315.063	15	04.315.066	30
04.315.064	20	04.315.067	35
04.315.065	25	04.315.068	40

Removable Extension Arms, rigid

	Length (mm)
04.315.104	20
04.315.108	40
04.315.112	60

Removable Extension Arms, flexible

	Length (mm)
04.315.125	30
04.315.127	40
04.315.132	60

1.0 mm Mesh Footplate, for CMF Distractor

	Style
04.315.201	A-Type
04.315.202	B-Type
04.315.203	C-Type

1.3 mm Mesh Footplate, for CMF Distractor

	Style
04.315.501	A-Type
04.315.502	B-Type
04.315.503	C-Type

1.3 mm Cloverleaf Footplate, for CMF Distractor

	Style
04.315.511	A-Type
04.315.512	B-Type
04.315.513	C-Type

1.5 mm Mesh Footplate, for CMF Distractor

	Style
04.315.301	A-Type
04.315.302	B-Type
04.315.303	C-Type

1.5 mm Cloverleaf Footplate, for CMF Distractor

	Style
04.315.311	A-Type
04.315.312	B-Type
04.315.313	C-Type

1.5 mm Elevated Mesh Footplate

	Style	Offset
04.315.321	B-Type	5.5 mm
04.315.322	B-Type	7.5 mm
04.315.323	C-Type	

2.0 mm Mesh Footplate, for CMF Distractor

	Style
04.315.401	A-Type
04.315.402	B-Type
04.315.403	C-Type

2.0 mm Cloverleaf Footplate, for CMF Distractor

	Style
04.315.411	A-Type
04.315.412	B-Type
04.315.413	C-Type

2.0 mm Elevated Mesh Footplate

	Style	Offset
04.315.421	B-Type	5.5 mm
04.315.422	B-Type	7.5 mm
04.315.423	C-Type	

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

	Length (mm)
04.315.704.01C	4
04.315.706.01C	6
04.315.708.01C	8

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

	Length (mm)
04.315.724.01C	4
04.315.726.01C	6
04.315.728.01C	8

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

	Length (mm)
04.315.744.01C	4
04.315.746.01C	6

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

	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

	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

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

	Length (mm)
04.315.784.01C	4
04.315.786.01C	6
04.315.788.01C	8

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

	Length (mm)
04.315.790.01C	10
04.315.792.01C	12

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

	Length (mm)
04.315.804.01C	4
04.315.806.01C	6
04.315.808.01C	8
04.315.810.01C	10
04.315.812.01C	12

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

	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

	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

	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

1.0 mm Titanium Cortex Screws, self-tapping, with PlusDrive recess, gold*

	Length (mm)
400.404.01C	4
400.406.01C	6
400.408.01C	8

1.2 mm Titanium Emergency Screws, with PlusDrive recess, green-gray

	Length (mm)
400.464.01C	4
400.466.01C	6
400.468.01C	8

1.3 mm Titanium Cortex Screws, self-drilling, with PlusDrive recess*

	Length (mm)		Length (mm)
400.454.01C	4	400.456.01C	6

1.3 mm Titanium Cortex Screws, self-tapping, with PlusDrive recess, gold

	Length (mm)
400.434.01C*	4
400.436.01C*	6
400.438.01C*	8
400.440.01C	10
400.442.01C	12

1.7 mm Titanium Emergency Screws, with PlusDrive recess, green-gray

	Length (mm)
400.484.01C	4
400.486.01C	6
400.488.01C	8
400.490.01C	10
400.492.01C	12

1.5 mm Titanium Cortex Screws, self-drilling, with PlusDrive recess*

	Length (mm)
400.054.01C	4
400.056.01C	6
400.058.01C	8

1.5 mm Titanium Cortex Screws, self-tapping, with PlusDrive recess, gold*

	Length (mm)
400.034.01C	4
400.036.01C	6
400.038.01C	8
400.040.01C	10
400.042.01C	12

* For 4-packs, replace suffix .01C with .04C.
Sterile PlusDrive screws are also available, where applicable.

2.0 mm Titanium Emergency Screws, with PlusDrive recess, green-gray

	Length (mm)
400.274.01C	4
400.276.01C	6
400.278.01C	8
400.280.01C	10
400.282.01C	12

2.4 mm Titanium Emergency Screws, with PlusDrive recess, green-gray

	Length (mm)
401.791.01C	5
401.792.01C	6
401.794.01C	8
401.795.01C	10
401.796.01C	12

2.0 mm Titanium Cortex Screws, self-drilling, with PlusDrive recess*

	Length (mm)
401.061.01C	4
401.063.01C	6
401.065.01C	8

2.0 mm Titanium Cortex Screws, self-tapping, with PlusDrive recess, gold*

	Length (mm)
401.041.01C	4
401.043.01C	6
401.044.01C	8
401.045.01C**	10
401.046.01C**	12

2.0 mm Titanium Locking Screws, self-tapping, with PlusDrive recess, blue*

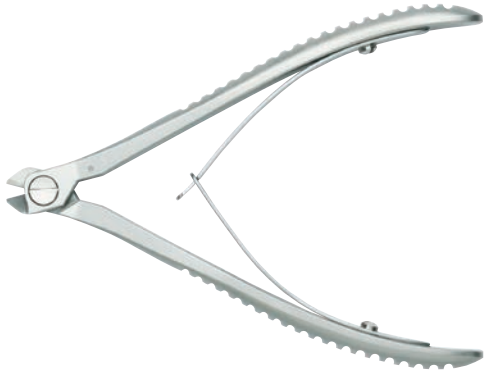
	Length (mm)
401.292.01C	6
401.294.01C	8
401.295.01C	10
401.296.01C	12

* For 4-packs, replace suffix .01C with .04C.
Sterile PlusDrive screws are also available, where applicable.
** Coarse pitch.

Instruments

03.315.001	Surgeon Activation Instrument, 1.7 mm, for CMF Distractor	
03.315.003	Alignment Rod, for CMF Distractor	
03.315.004	Removal Instrument for Extension Arms (For attaching and removing extension arms)	
03.315.005	Surgeon Activation Instrument, 1.7 mm with U-Joint, for CMF Distractor	

03.315.007	Pediatric Drill Guide, for 1.0 mm and 1.3 mm screws	
03.315.008	Obturator for Pediatric Drill Guide	
03.315.009	Cheek Retractor for Pediatric Drill Guide	
03.315.010	0.76 mm Drill Bit, Stryker J-latch, 14 mm stop, 75 mm length	
03.315.011	1.0 mm Drill Bit, Stryker J-latch, 12 mm stop, 75 mm length	
03.315.013	Patient Activation Instrument	
304.098	AB Distraction Label for Patient Activation Instrument	

03.500.014	Cutting Instrument, for Distraction Footplates	
03.500.020	File with hex coupling	
03.503.039	Plate Cutter for Midface Plates	
311.005	Screwdriver Handle with Hex Coupling, small	
311.006	Screwdriver Handle with Hex Coupling, medium	
	Handle with Mini Quick Coupling	
311.011	small	
311.012	medium	
311.013	large	

312.154	1.5 mm Threaded Drill Guide, long, for 2.0 mm plates	
	1.5 mm/2.0 mm Screwdriver Blades, self-retaining, PlusDrive, Hex Coupling	
313.252	96 mm	
313.253	76 mm	
	Screwdriver Blade For Raised Head Screws, Hex Coupling, 86 mm	
03.315.700	1.0 mm/1.3 mm	
03.315.701	1.5 mm/2.0 mm	
	Screwdriver Blades, self-retaining, PlusDrive, Hex Coupling	
313.806	1.3 mm, 76 mm	
314.485	1.0 mm, 75 mm	
	Cruciform Screwdriver Blades with Spring Holding Sleeve, Hex Coupling	
314.482	1.0 mm	
314.491	1.3 mm	
314.651	1.5 mm	
314.675	2.0 mm	
	Screwdriver Shaft, cruciform, with Holding Sleeve, with Mini Quick Coupling	
314.413	1.3 mm, 62 mm	
314.414	1.3 mm, 92 mm	
314.481	1.0 mm, 62 mm	
314.483	1.0 mm, 92 mm	
314.667	1.5 mm, 66 mm	
314.668	1.5 mm, 92 mm	
314.682	1.5 mm, 95 mm	
314.672	2.0 mm, 66 mm	
314.673	2.0 mm, 92 mm	
314.684	2.0 mm, 95 mm	

	0.76 mm Drill Bits, Stryker J-latch, for use with 1.0 mm screws	
316.114	with 14 mm stop, 44.5 mm	
316.150	with 5 mm stop, 44.5 mm	
316.180	with 8 mm stop, 44.5 mm	
	1.0 mm Drill Bits, Stryker J-latch, for use with 1.3 mm screws	
316.236	60 mm	
316.446	with 4 mm stop, 44.5 mm	
316.447	with 6 mm stop, 44.5 mm	
316.448	with 8 mm stop, 44.5 mm	
	1.1 mm Drill Bits, Stryker J-latch, for use with 1.5 mm screws	
317.140	with 4 mm stop, 44.5 mm	
317.160	with 6 mm stop, 44.5 mm	
317.180	with 8 mm stop, 44.5 mm	
317.220	with 12 mm stop, 44.5 mm	
316.500	80 mm	
	1.5 mm Drill Bits, Stryker J-latch, for use with 2.0 mm screws	
317.640	with 4 mm stop, 44.5 mm	
317.660	with 6 mm stop, 44.5 mm	
317.680	with 8 mm stop, 44.5 mm	
317.720	with 12 mm stop, 44.5 mm	
316.510	80 mm	
316.520	125 mm	
319.520	Depth Gauge, long, for 1.5 mm and 2.0 mm screws	
347.964	Combination Bending Pliers, for 1.0 mm and 2.0 mm Plates	

347.980	Plate Holding Forceps, for 1.5 mm, 2.0 mm, and 2.4 mm plates	
	Plate Holding Instruments	
347.986	for 1.0 mm and 1.3 mm plates	
347.987	for 1.5 mm and 2.0 mm plates	
391.952	Mesh Cutter	
391.965	Combination Bending/Cutting Pliers, for 1.0 mm and 2.0 mm plates	

397.211	Universal Trocar Handle	
397.213	2.0 mm Cannula and Obturator	
397.232	Malleable C-Retractor	
397.420	2.0 mm Cheek Retractor Blade	
397.430	2.0 mm Cheek Retractor Ring	

References

1. Izadi K, Yellon R, Mandell DL, et al. Correction of upper airway obstruction in the newborn with internal mandibular distraction osteogenesis. J Craniofac Surg. 2003;14(4):493-499.

2. Mandell DL, Yellon R, Bradley J, et al. Mandibular distraction for micrognathia and severe upper airway obstruction. Arch Otolaryngol Head Neck Surg. 2004;130(3):344-348.

3. Steinbacher D, Kaban L, Troulis M. Mandibular advancement by distraction osteogenesis for tracheostomy-dependent children with severe micrognathia. J Oral Maxillofac Surg. 2005;63(8):1072-1079.

4. Ow A, Cheung L. Meta-analysis of mandibular distraction osteogenesis: clinical applications and functional outcomes. Plast Reconstr Surg. 2008;121(3):54e-69e.

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