stryker

Pediatric Mandibular Distractor

with anti-reverse mechanism

Operative Technique

Device Description

The Pediatric Mandibular Distractor with anti-reverse mechanism includes the following components: distractor, flexible and rigid removable activation rods, bone screws, small activation handle, activation key and deactivation instrument. The Pediatric Mandibular Distractor is supplied sterile.

Important Information

The materials contained in this booklet have been provided for general education information purposes only. The information contained in this booklet cannot and should not replace the independent medical judgement of the treating physician.

As a manufacturer, Stryker does not provide medical advice or services and does not recommend specific technique or instruction. It is always the responsibility of the treating physician to determine the appropriate treatment and technique, based on the physician's medical knowledge and the individual circumstances of the particular case. It is also the treating phsyician's sole responsibility to inform the patient about potential risks, complications, and benefits of certain products and procedures.

Surgical Procedure

Step 1 Select and unpack the Pediatric Mandibular Distractor

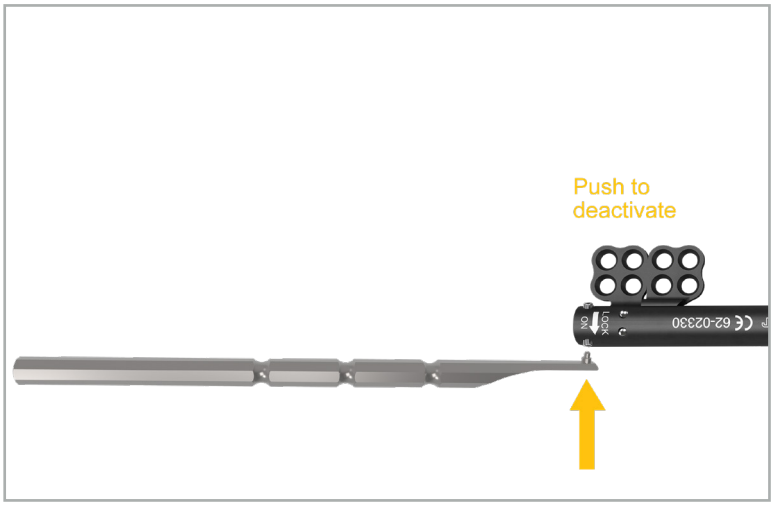
- Select the appropriate distractor/footplate configurations.
- Check the packaging for damage prior to use/surgery.
- Peel back the outer blister lid.
- Remove the blister inlay and transfer the distraction device to the sterile field.
- Open the sterile blister inlay by lifting the middle tab.
- Remove the distraction device from the blister inlay.
- Check the distraction device for damage prior to use/surgery.
- Check for proper functionality of the anti-reverse feature.
  See **a** "How to activate and deactivate the anti-reverse feature" and **b** "Proper activation of the anti-reverse feature".

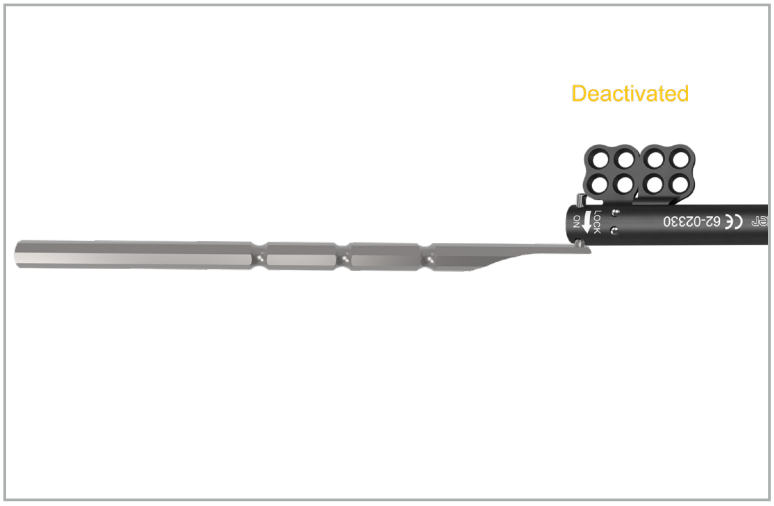
a How to activate and deactivate the anti-reverse feature

- Push in the anti-reverse bar to activate this feature.
  - Distractor should now be unidirectional and can move clockwise only.

- Deactivate the anti-reverse bar by using only the deactivation instrument.
  - Distractor should now be bidirectional and can move both clockwise and counterclockwise.

Check the functionality of the anti-reverse feature prior to implantation of the device.

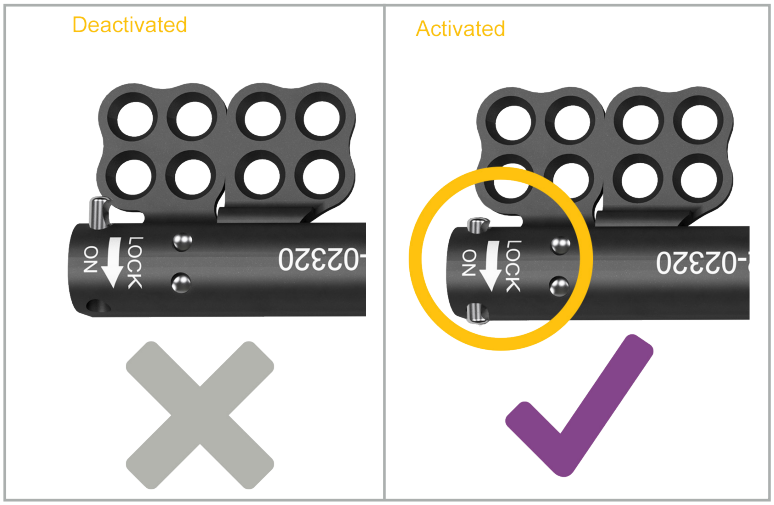




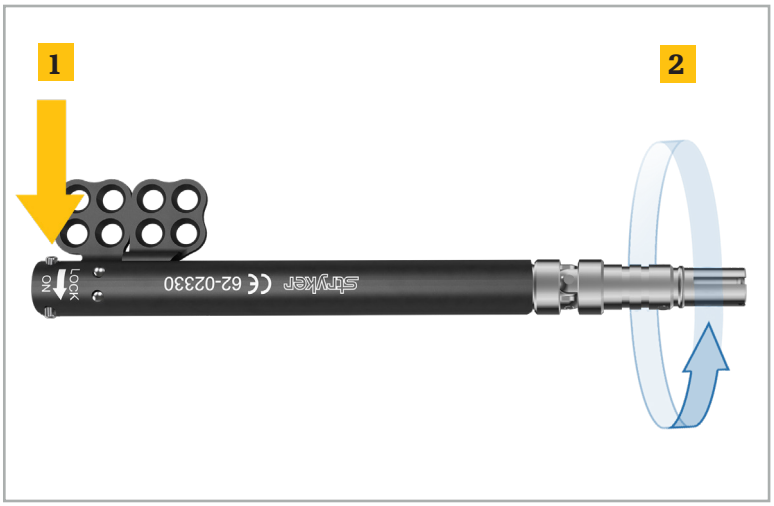
b How to make sure that the anti-reverse feature is properly activated

- Turn the activation rod a minimum of one turn in the clockwise direction and ensure visibly that the bar is properly sliding left and right inside the housing.

If the sliding bar is not properly inside the housing and visibly moving left and right, the anti-reverse feature may not be properly activated.



- Activate the anti-reverse feature (push the bar into the housing 1) and turn the distractor coupling end/activation rod clockwise 2 at the same time.
- If after performing the above step the sliding bar continues to malfunction, discard and use a new device.



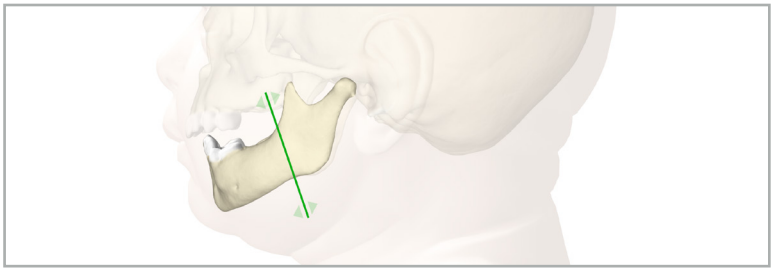
- Verify that the anti-reverse feature prevents backwards movement by turning the activation rod in the opposite or counterclockwise direction. You should feel resistance and not be able to turn counterclockwise.

If resistance is not noticed, the anti-reverse feature may not be properly activated and may lead to device malfunction.

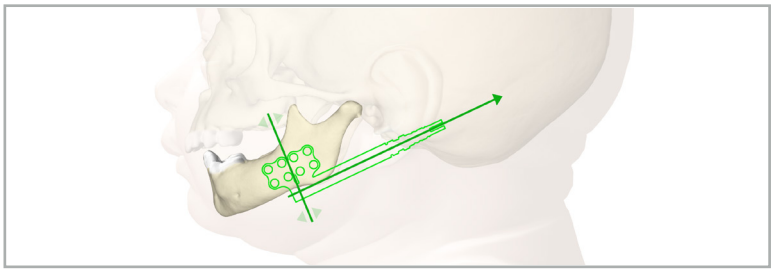
- Activate the anti-reverse feature (push the bar into the housing 1) and turn the distractor coupling end/activation rod clockwise 2 at the same time.
- If after performing the above step the sliding bar continues malfunctioning, discard and use a new device.

Step 2 Plan the osteotomy site

- Plan the approximate site of the osteotomy.

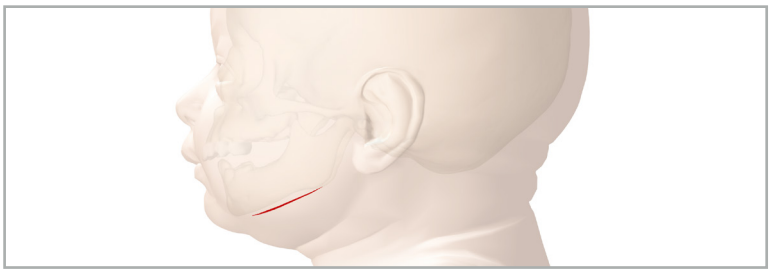


- Determine the desired orientation of the distractor.



Step 3 Make an incision and expose the site

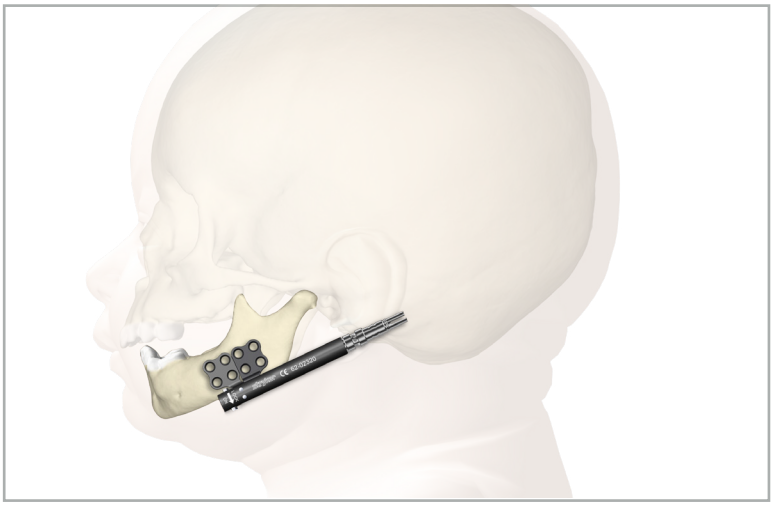
- Make an appropriate incision.



- Elevate the periosteum to obtain access.

Step 4 Modify the distractor

- Place the distractor in the intended area to assess the patient's anatomy and determine the approximate location of the distractor.



- Cut, bend and manipulate the footplates, as needed.

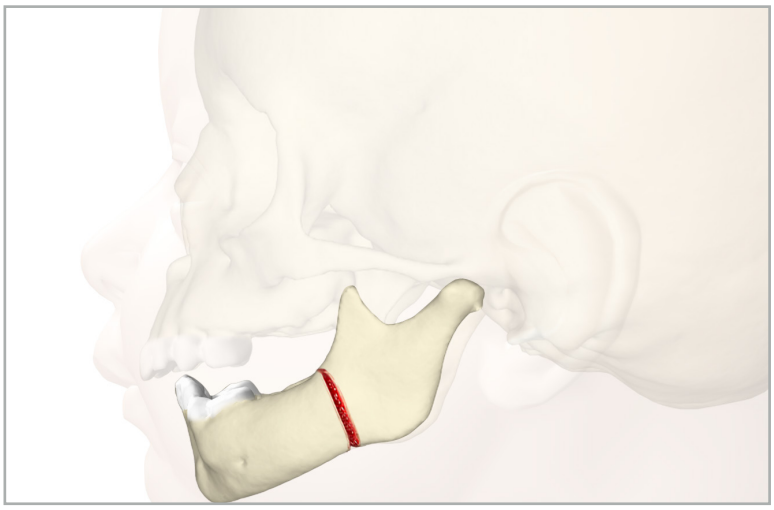
- Test the distractor by running it out to full extension before implantation.

Prior to testing, if the anti-reverse feature was activated, please make sure to deactivate the anti-reverse feature.

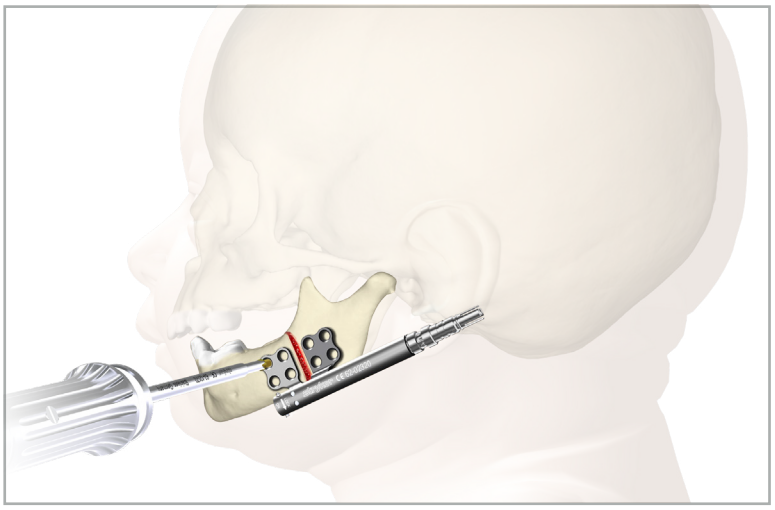
Step 5 Fixate the distractor

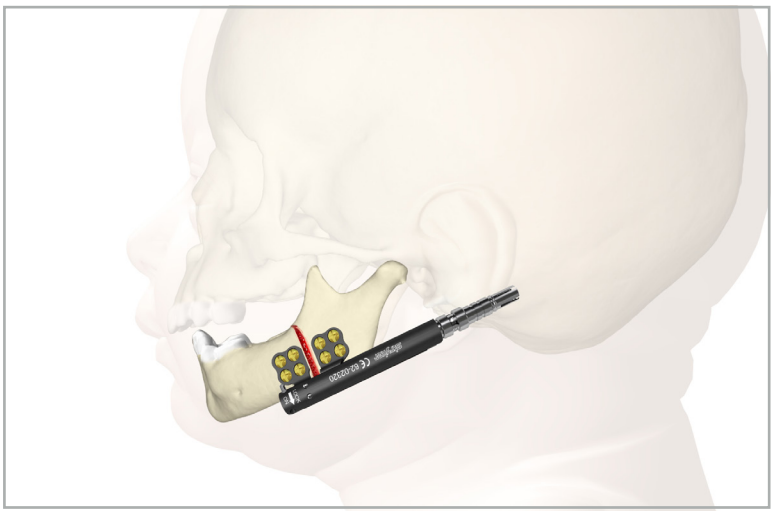
- Create osteotomies or separate the bone through desired techniques.

A full osteotomy has to be performed prior to activating or initiating distraction of the device.



- Attach the distractor to the mandible with 1.7mm self-drilling or self-tapping screws.

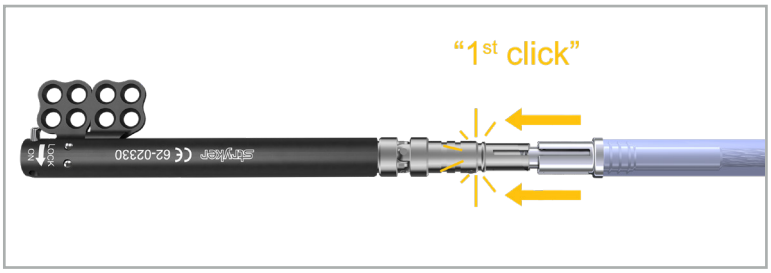




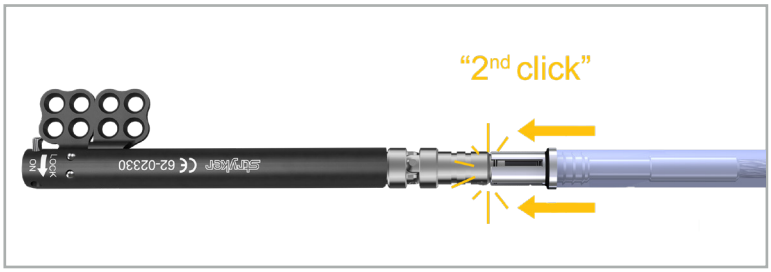
Step 6 Connect the distractor with the activation rod

- Retract locking sleeve and insert activation rod to distractor frame coupling until an audible *click* verifies a first connection.

- Slide the locking sleeve forward until an audible *second click* verifies a secure final connection.



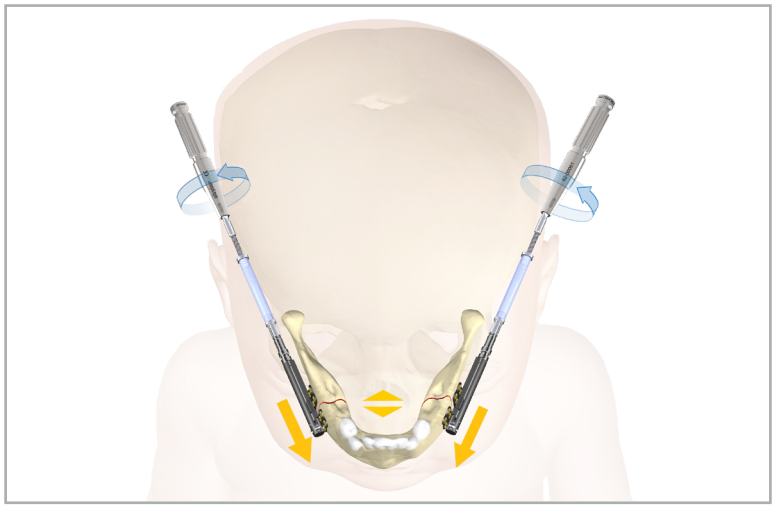
Ensure that you practice sliding the locking sleeve forward before the operation to verify that the connection is correct.



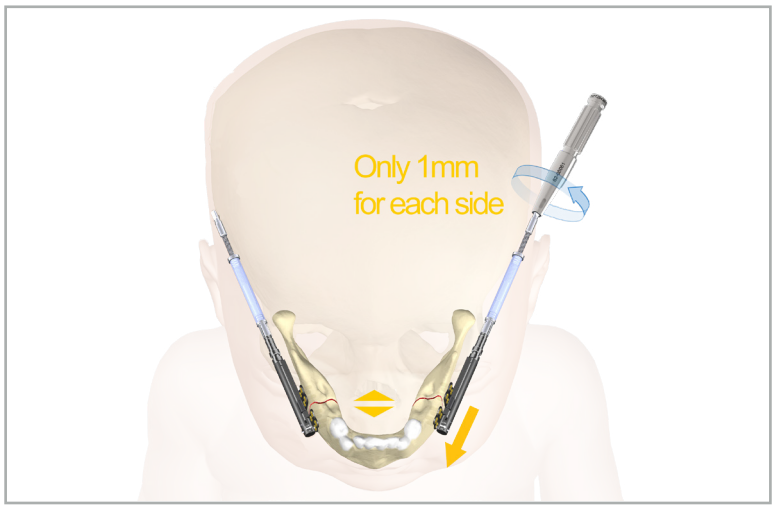
Distraction

Step 1 Inspect the distractor

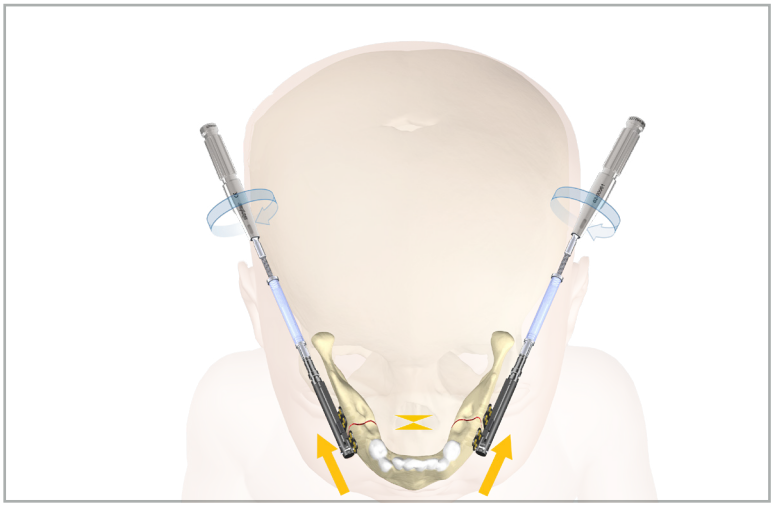
- Inspect the distractor and ensure the bone segment can be properly mobilized by the distractor by turning the activation rod.
- Ensure that the distractor can be fully activated by turning the activation rods.



- To avoid excessive torque on the contralateral side, either:
  - Turn the rods simultaneously, **or**
  - Distract up to 1mm on each side at a time.



- If bending or malfunction occurs, identify the incision site and correct before closing.
- If the distractor performs properly, return the distractor to the starting position.



If removal of the activation rod at the end of the distraction phase is planned, ensure that the activation rod incision is positioned so that an adequate amount of the outer sleeve is exposed. This is due to less exposure of the activation rod, as distraction occurs and the device moves further into the patient.

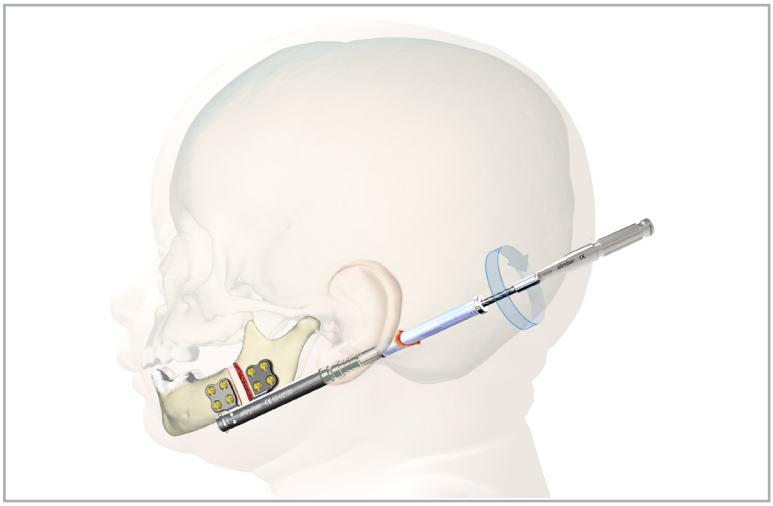
When anti-reverse feature is activated resistance should be noticed in the counterclockwise direction. Do not apply excessive torque/forces when resistance is already noticed.

Either the small activation handle or the activation key can be used with the activation rod to perform distraction.

Step 2 Turn the small activation handle/activation key

- Use professional judgement to determine the appropriate rate and distance of distraction.
  - The rhythm of distraction can vary under certain conditions.

One full turn of the activation key clockwise (360°) achieves 0.5mm of advancement.



Step 3 Activate the anti-reverse feature

- Activate the anti-reverse feature.
- To activate the anti-reverse feature, please follow the instructions in 1 "How to activate and deactivate the anti-reverse feature" and 2 "How to make sure that the anti-reverse feature is properly activated".

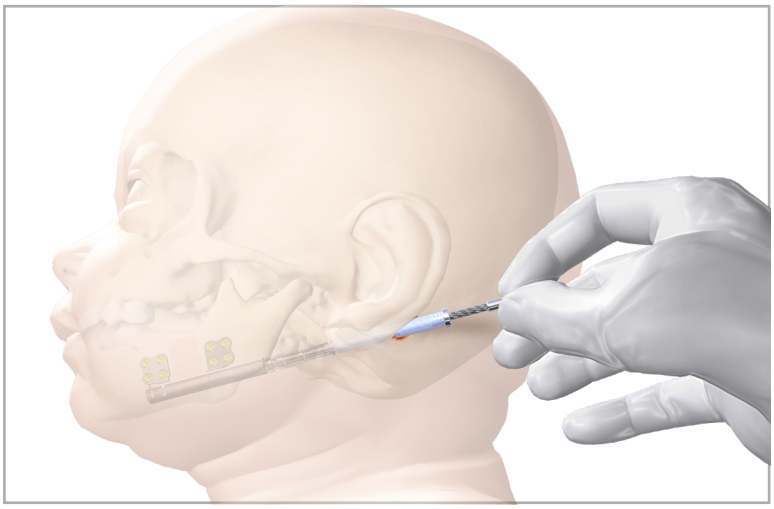
Step 4 Close the site

- Close the incision.

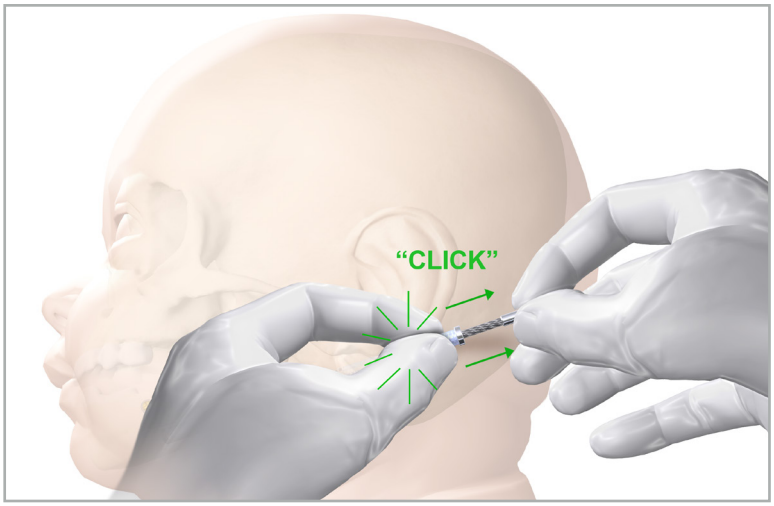
Consolidation

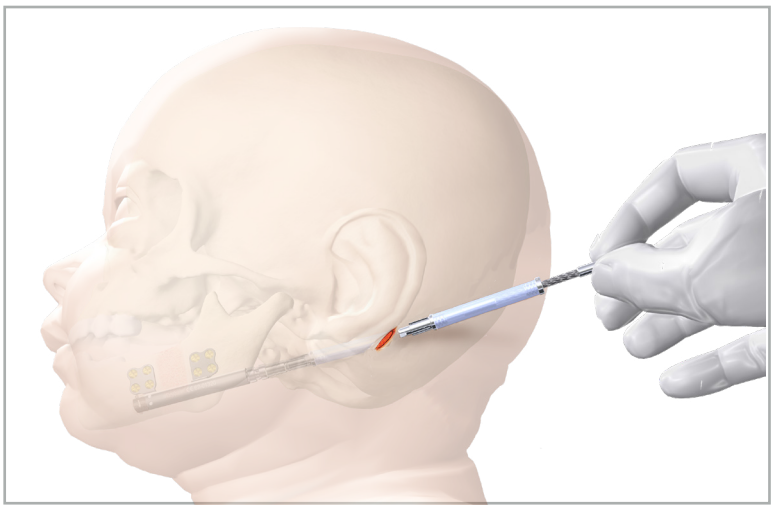
Step 1 Remove the activation rod

- Upon completion of distraction, the surgeon can remove the activation rod.
- For removal secure the end of the activation rod where the small activation handle/activation key attaches and hold it in place.



- While still holding the inner rod in place, grasp the outer plastic tube and pull back.
- An audible click signifies disconnection. The activation rod may now be removed.

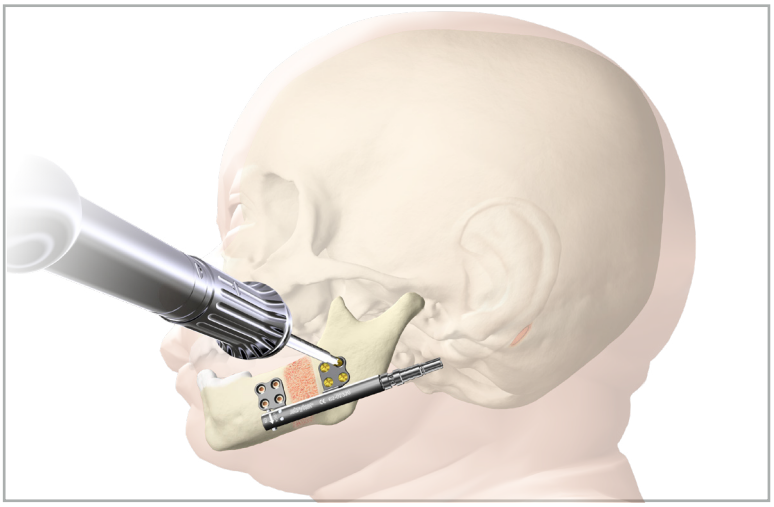


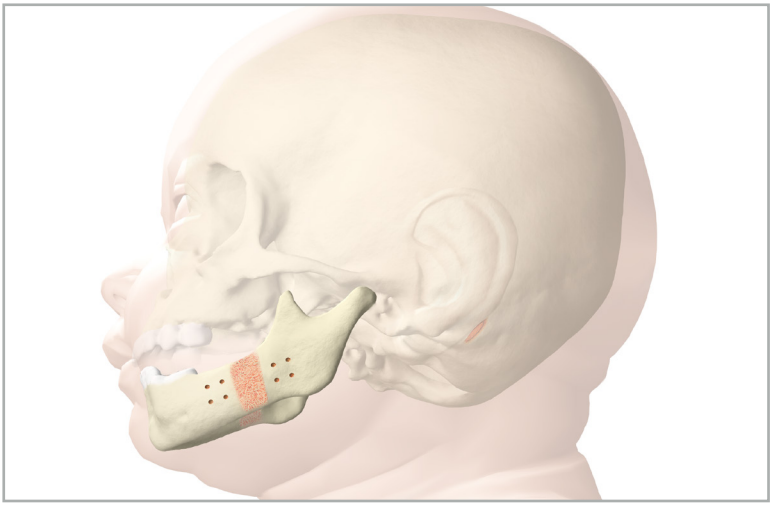


Removal

Step 1 Remove the distractor

- The distractor is a temporary implant. The distractor should be removed when the surgeon determines sufficient bone consolidation.





Ordering Information

Distractor Frame and Components		
	62-02320	Pediatric Mandibular Distractor 2, 2x2, left, 20mm
	62-02321	Pediatric Mandibular Distractor 2, 2x2, right, 20mm
	62-02322	Pediatric Mandibular Distractor 2, 3x3, left, 20mm
	62-02323	Pediatric Mandibular Distractor 2, 3x3, right, 20mm
	62-02330	Pediatric Mandibular Distractor 2, 2x2, left, 30mm
	62-02331	Pediatric Mandibular Distractor 2, 2x2, right, 30mm
	62-02332	Pediatric Mandibular Distractor 2, 3x3, left, 30mm
	62-02333	Pediatric Mandibular Distractor 2, 3x3, right, 30mm
Accessories		
	62-00060	Activation key, rigid
	62-00061	Small activation handle
	62-00080	Activation rod rigid, short
	62-00081	Activation rod flexible, short
	62-00082	Activation rod flexible
	62-02335	Deactivation instrument

Bone screws

Non-sterile; 5 per pack

Self Tapping	
	50-17003 1.7 x 3mm
	50-17004 1.7 x 4mm
	50-17005 1.7 x 5mm
	50-17006 1.7 x 6mm
	50-17007 1.7 x 7mm
	50-17008 1.7 x 8mm
	50-17010 1.7 x 10mm
	50-17012 1.7 x 12mm
Self Drilling	
	50-17903 1.7 x 3mm
	50-17904 1.7 x 4mm
	50-17905 1.7 x 5mm
	50-17906 1.7 x 6mm

Self Tapping (Emergency)		
	50-19003	1.9 x 3mm
	50-19005	1.9 x 5mm
	50-19007	1.9 x 7mm
	50-19009	1.9 x 9mm

Twist Drills	
60-13505	1.35 x 50mm, 5mm WL
60-13506	1.35 x 50mm, 6mm WL
60-14008	1.45 x 54mm, 8mm WL
60-13512	1.40 x 54mm, 12mm WL
Markers	
50-17000	Marker, 1.7mm self-tapping screws
50-17900	Marker, 1.7mm self-drilling screws
52-00003	Screw length marker for 3mm
52-00004	Screw length marker for 4mm
52-00005	Screw length marker for 5mm
52-00006	Screw length marker for 6mm
52-00007	Screw length marker for 7mm
52-00008	Screw length marker for 8mm
52-00009	Screw length marker for 9mm
52-00010	Screw length marker for 10mm
52-00012	Screw length marker for 12mm

Container/ module/ tray	
29-17151	Pediatric Mandibular Distractor 2, module with lid
29-17152	Pediatric Mandibular Distractor 2, inlay
29-13018	Pediatric Mandibular Distractor 2 container lid, quarter-size
29-15031	Universal quarter-size container
29-15036	Universal quarter-size accessory tray
29-15037	Universal quarter-size silicone mat

Instruments	
	62-12170 Screwdriver blade, metal
	62-20285 Screwdriver handle, metal
	01-08110 Plate holding forceps
	36-00726 Plate bending pliers

Stryker Craniomaxillofacial

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