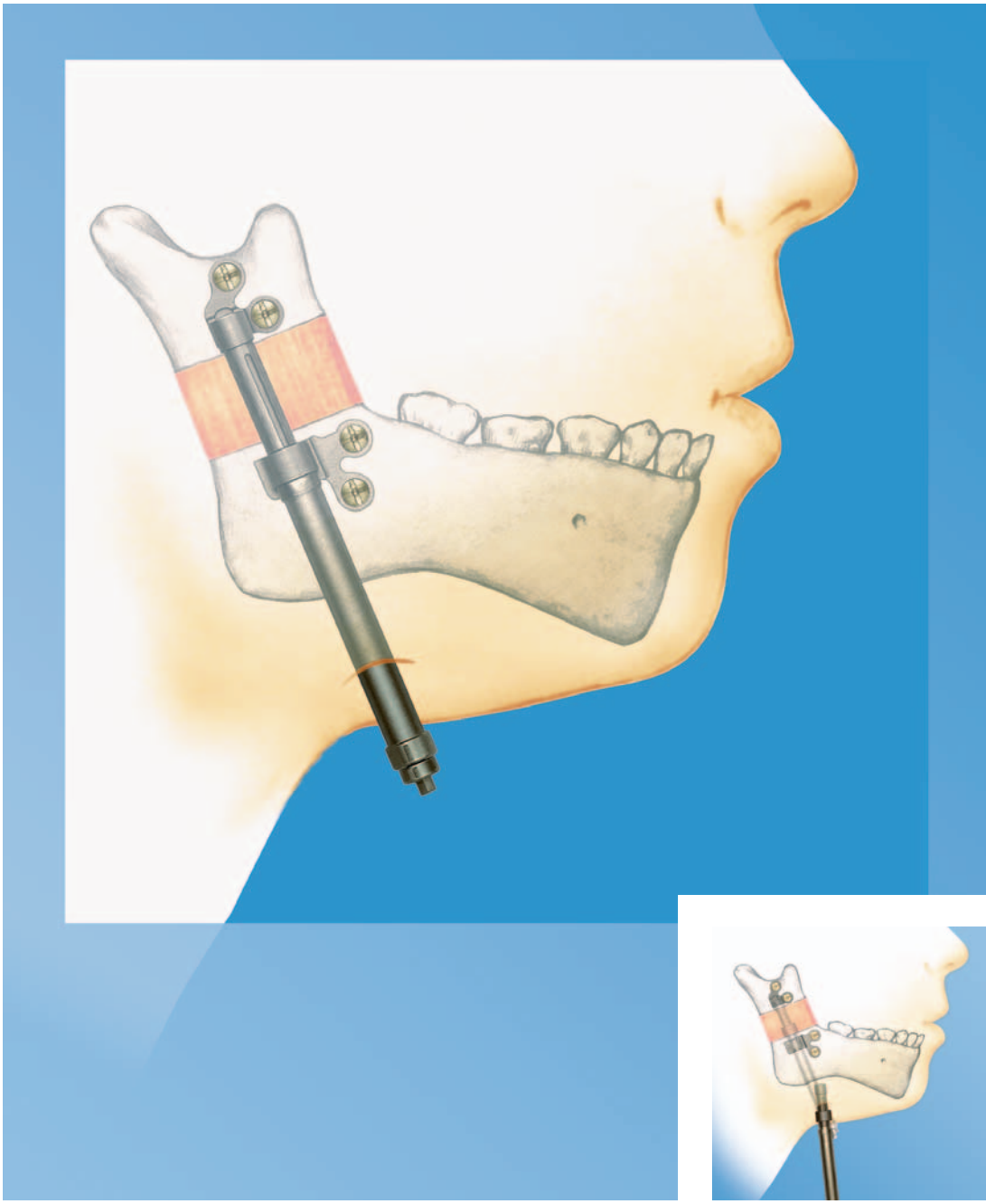
The Titanium Single Vector Distractor. For mandibular bone lengthening.

Technique Guide



SYNTHES®

Instruments and implants
approved by the AO Foundation

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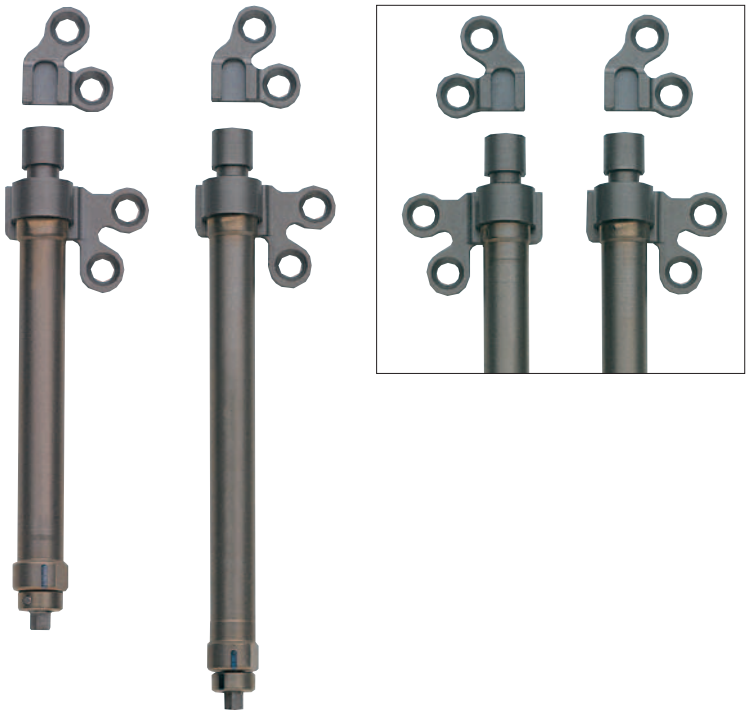
Image intensifier control

Warning
This description alone does not provide sufficient background for direct use of the product. Instruction by a surgeon experienced in handling this product is highly recommended.

Reprocessing, Care and Maintenance of Synthes Instruments
For general guidelines, function control and dismantling of multi-part instruments, please refer to: www.synthes.com/reprocessing

Features and Benefits

Features
- Detachable feet allow less invasive removal
- Subcutaneous placement reduces scarring
- Rigid fixation minimizes micromovement during distraction
- Enclosed distraction mechanism protects soft tissue
- External activator allows easy access for activation
- Titanium alloy for biocompatibility
- Foot plate position may be adjusted up to 5 mm from fully closed position for screw placement, as required by patient anatomy
- Available in 20 mm and 30 mm lengths to accommodate distraction requirements
- Right and left versions available



Activation Screwdriver
An autoclavable screwdriver is used to activate distractor.

Marking on activation screwdriver indicates correct turning direction for lengthening.

Indications

For mandibular bone lengthening where gradual bone distraction is required, including conditions such as congenital mandibular deficiencies or post-traumatic defects.

Left: Preoperative X-ray of a nine-year-old male with Treacher Collins Syndrome, prior to distraction.

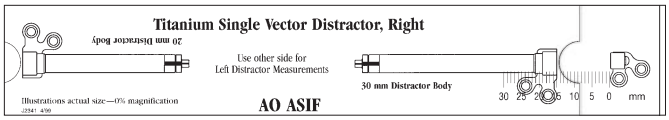
Center: Same patient, eight days postoperative, at initial distraction.

Right: Same patient, 12 weeks postoperative, during consolidation. A total of 20 mm of lengthening was achieved.

Preoperative Planning

Preoperative planning

Determine distractor length, vector, and foot placement using the Single Vector preoperative planner and a radiographic image.



Art. No. 018.000.409

1

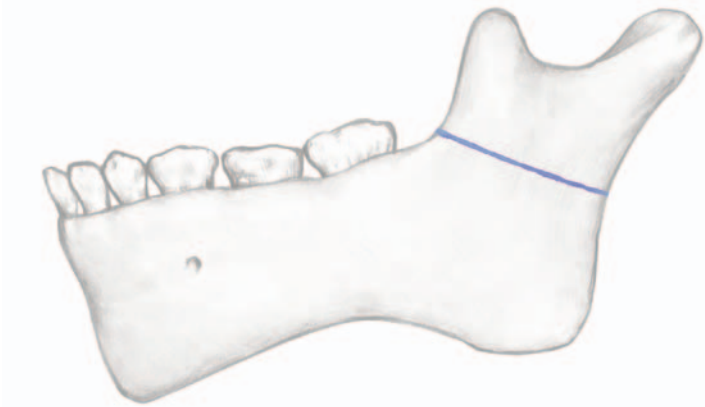
Expose surgical site

Expose the surgical site using an intraoral or extraoral incision.

2

Plan the osteotomy site

Mark the appropriate site of the osteotomy on the bone.



3

Secure the footplates together

Instrument	
314.402	Activation Screwdriver

Insert the wedge of the distractor body into the proximal foot.

Important: It is critically important that the distractor body wedge is fully inserted into the proximal footplate slot.

Using the activation screwdriver, activate the distractor 1 to 2 complete rotations. This will position the screw holes at a suitable distance from the osteotomy site.

Tie a 4.0 Vicryl suture around the footplates in a figure-eight pattern. Do not place the suture through the screw holes. Tie the suture loosely to allow for up to 1 mm of activation once the distractor is attached to the bone.

Note: The suture will help prevent the distractor from prematurely disengaging from the proximal footplate before active distraction.

4

Determine approximate distractor position on the bone

Place the distractor body into the intraoral cavity to fit the device to the mandible.

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.

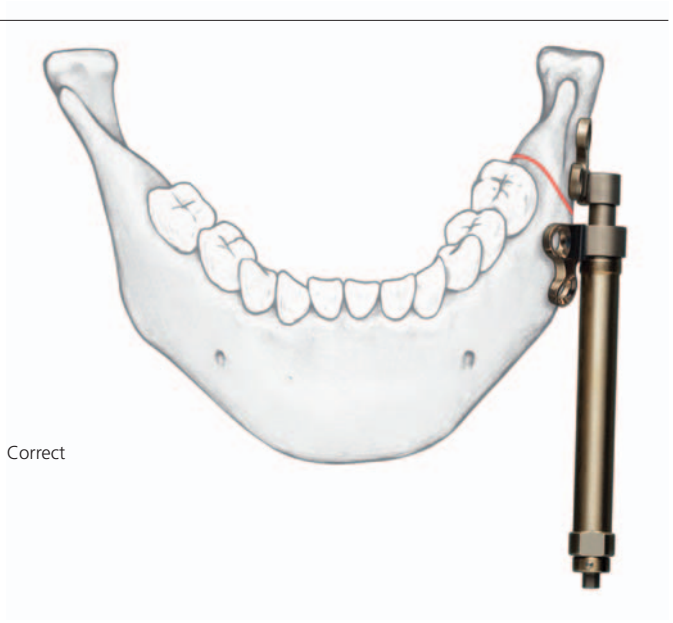
Place silastic tubing over the activation end of the distractor to ease the insertion through the skin.

Pass the silastic tube through the percutaneous activation port and pull the activation end of the distractor out of the intraoral cavity.

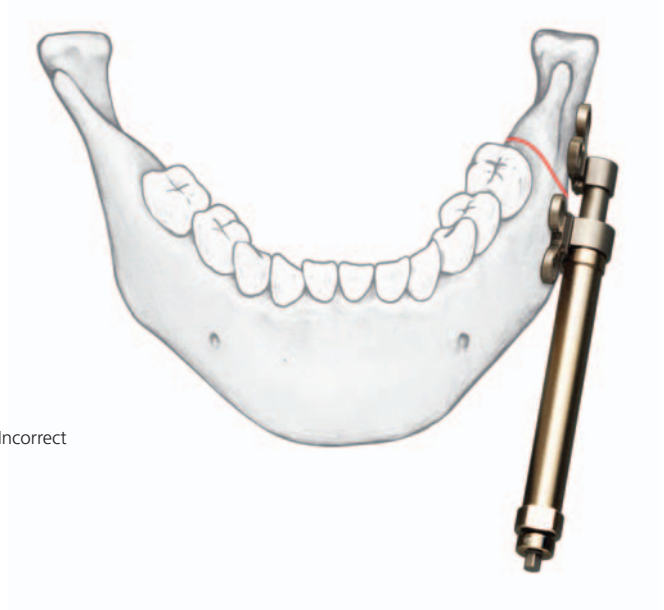
Mark the position of the distractor on the bone.

Technique Tip: When fitting the distractor, it may be helpful to place the distractor body on the skin overlying the mandible to aid in device positioning relative to the soft tissue. Place the patient's head in a neutral position for an accurate evaluation of the exit port and to ensure that the device is placed in a comfortable and accessible position for the patient.

Technique Tip: The distractor should be placed parallel to the ramus.



Correct



Incorrect

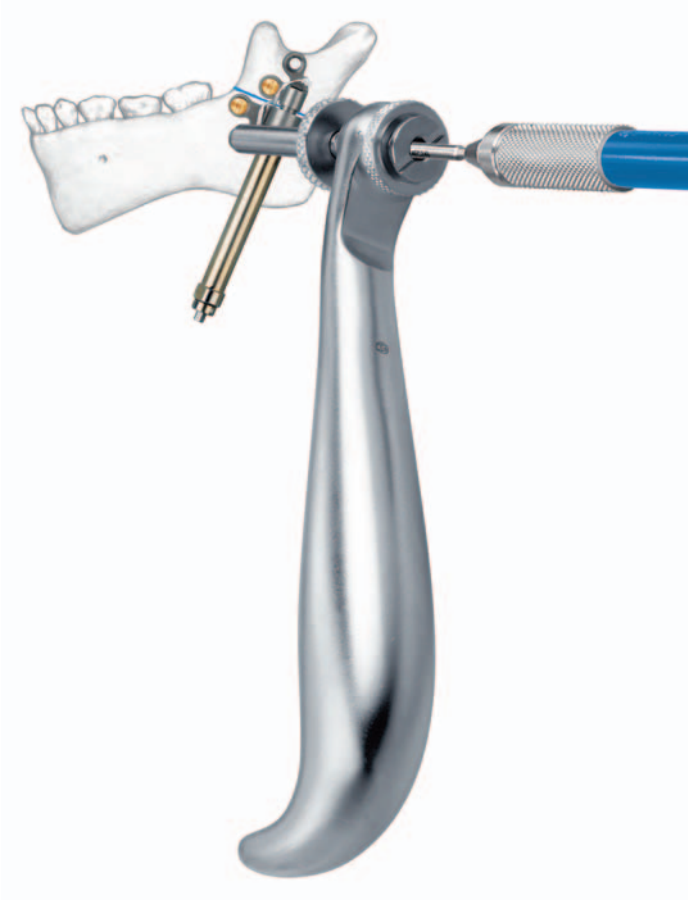
5
Perform the buccal corticotomy

Remove the distractor.

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

6
Attach the distractor

Instruments	
311.011	Handle, small, with Mini Quick Coupling
314.442	Screwdriver Shaft 1.5/2.0
316.520	Drill Bit ∅ 1.5
397.422	Transbuccal Guide 2.0/2.4/3.0
397.433	Drill Sleeve 1.5, for No. 397.422



Reinsert the distractor onto the mandible, passing the activation end of the distractor back through the percutaneous port created earlier.

Using the transbuccal guide, drill screw holes with the 1.5 mm drill bit in the proximal and distal footplates. Insert appropriate length 2.0 mm self-tapping titanium bone screws. Drill and insert screws closest to the osteotomy first.

Remove the Silastic tubing.

7

Complete the osteotomy and screw insertion

Complete the osteotomy on the lingual aspect of the ramus, using an osteotome, taking care to avoid the inferior alveolar nerve. Fully tighten all screws.

8

Activate the distractor

Instrument	
314.402	Activation Screwdriver

Using the activation screwdriver, activate the distractor approximately two full rotations (1 mm) to place tension on the suture. This will help to prevent the distractor from separating from the proximal foot during the latency stage.

Postoperative Distraction

Distraction should begin no later than one week after implantation. To distract, rotate the activation instrument counterclockwise (in the direction of the arrow marked on the activation screwdriver). Each full rotation produces 0.5 mm of distraction.

Note: Marking on distractor determines when one full rotation is complete.

After the desired length of distraction has been achieved, the new bone must be given time to consolidate. The consolidation period is complete when a cortical outline can be visualized in the regenerate on radiographs, or confirmed manually by palpation on the posterior border.

Distractor Body Removal

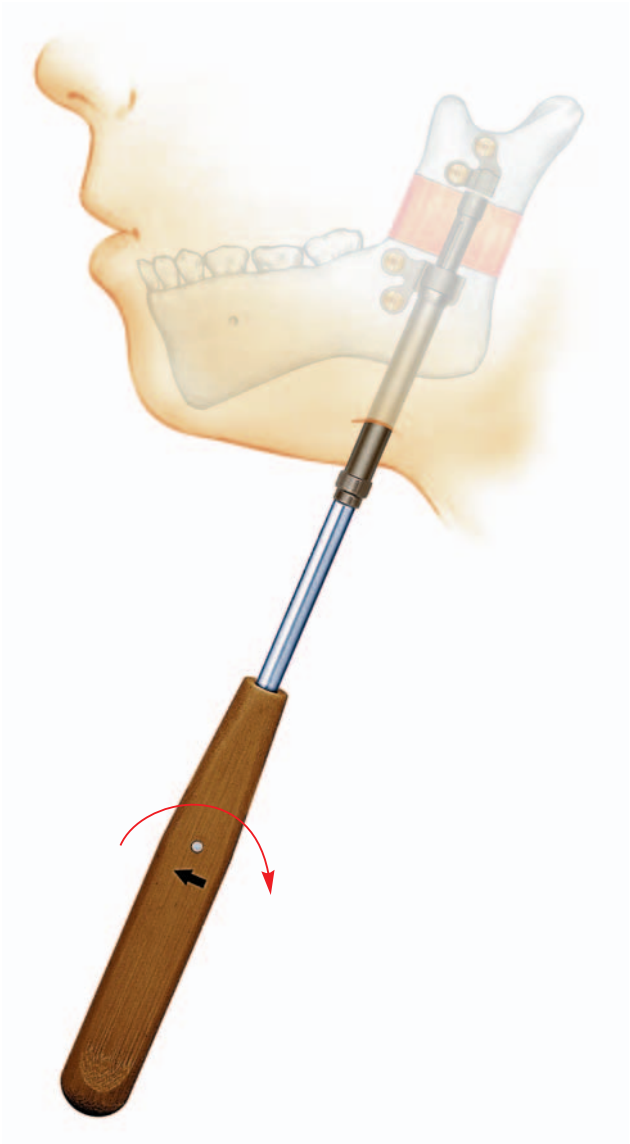
1

Disengage distractor body from proximal foot

Instrument	
314.402	Activation Screwdriver

Loosen the soft tissue surrounding the percutaneous activation port. Using the activation screwdriver, turn the activator 10 clockwise rotations (opposite direction of the arrow on the activation screwdriver) to disengage the body from the proximal foot.

Note: Proximal foot disengagement = 10 clockwise rotations



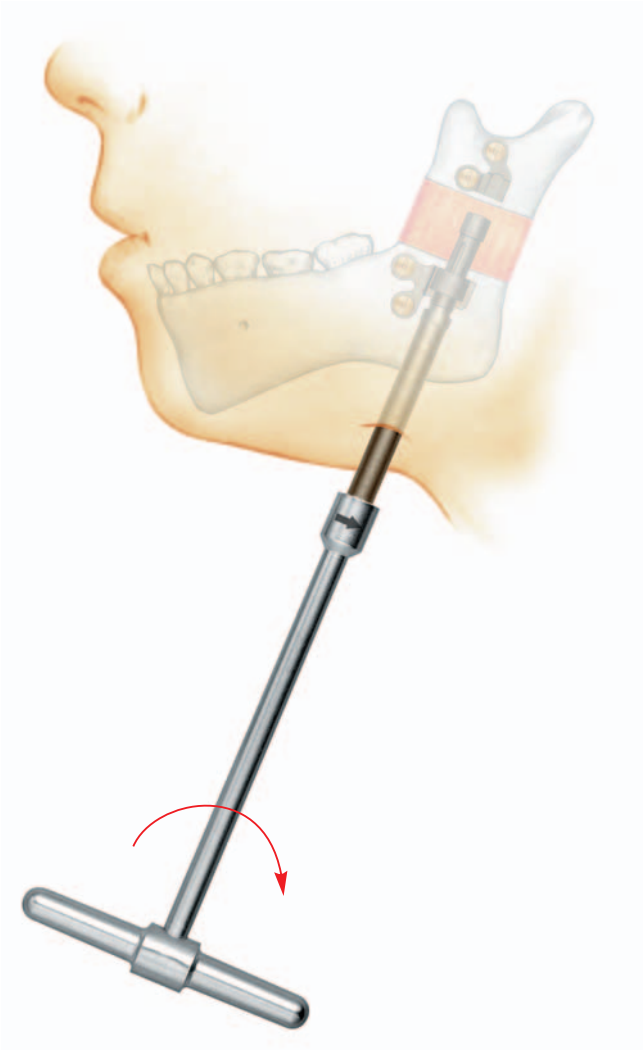
2

Disengage distractor body from distal foot

Instrument	
329.399	Dismantling Instrument

Place the dismantling instrument over the outer shaft of the distractor body. Turn 4 full clockwise rotations to unlock the body from the distal foot.

Warning: Turning the distractor body more than 4 turns at this stage can result in a partial release of the footplate that can prevent proper device release and removal.

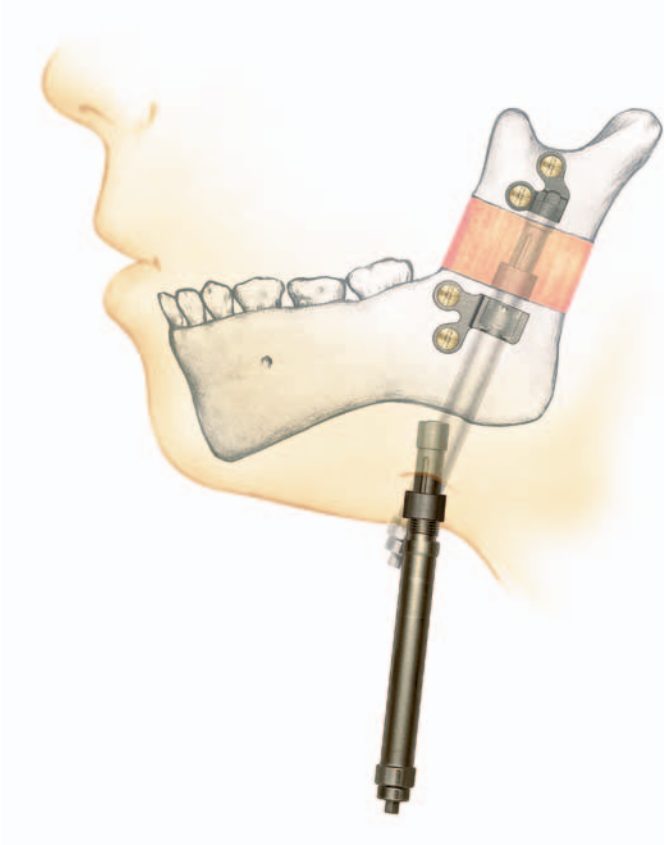


3

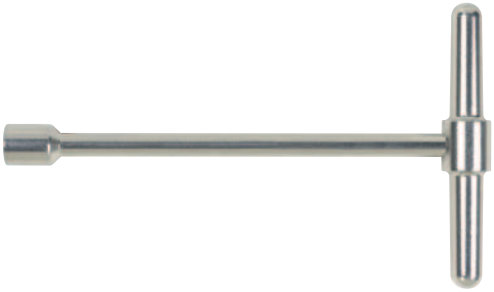
Remove distractor body

Grasp the outer shaft of the distractor body and gently push it toward the condyle. Once the device releases from the distal foot, lift the distractor body away from the bone and remove it through the percutaneous activation port.

Note: In cases where there is soft tissue impingement or excessive scar tissue, an intraoral incision may be necessary to facilitate device removal.



Instruments

311.011	Handle, small, with Mini Quick Coupling	
314.442	Screwdriver Shaft 1.5/2.0, cruciform, self-holding, length 92 mm	
314.402	Activation Screwdriver, for Mandible Distractor, monoaxial	
316.520	Drill Bit ∅ 1.5 mm, length 125 mm, 2-flute, for J-Latch Coupling	
329.399	Dismantling Instrument, for monoaxial Mandible Distractor	

Ordering Information

Set and Module	
184.810	Mandible Distractor, monoaxial (Titanium Alloy)
684.810	Module Mandible Distractor, monoaxial, with Lid, without Contents
Implants	
487.962	Mandible Distractor, monoaxial, right, distraction length 20 mm, Titanium Alloy (TAN)
487.963	Mandible Distractor, monoaxial, left, distraction length 20 mm, Titanium Alloy (TAN)
487.964	Mandible Distractor, monoaxial, right, distraction length 30 mm, Titanium Alloy (TAN)
487.965	Mandible Distractor, monoaxial, left, distraction length 30 mm, Titanium Alloy (TAN)
487.974	Proximal Foot Plate, right, for Mandible Distractor, monoaxial
487.975	Proximal Foot Plate, left, for Mandible Distractor, monoaxial
401.106	MF Cortex Screw ∅ 2.0 mm, self-tapping, length 6 mm, Pure Titanium
401.108	MF Cortex Screw ∅ 2.0 mm, self-tapping, length 8 mm, Pure Titanium
401.110	MF Cortex Screw ∅ 2.0 mm, self-tapping, length 10 mm, Pure Titanium
401.306	Emergency Screw ∅ 2.4 mm, self-tapping, length 6 mm, Pure Titanium, blue
401.308	Emergency Screw Cruciform Recess ∅ 2.4 mm, self-tapping, length 8 mm, Pure Titanium, blue
401.310	Emergency Screw Cruciform Recess ∅ 2.4 mm, self-tapping, length 10 mm, Pure Titanium, blue

Instruments	
311.011	Handle, small, with Mini Quick Coupling
314.442	Screwdriver Shaft 1.5/2.0, cruciform, self-holding, length 92 mm
314.402	Activation Screwdriver, for Mandible Distractor, monoaxial
316.520	Drill Bit ∅ 1.5 mm, length 125 mm, 2-flute, for J-Latch Coupling
329.399	Dismantling Instrument, for monoaxial Mandible Distractor
Additionally available	
397.422	Transbuccal Guide 2.0/2.4/3.0
397.433	Drill Sleeve 1.5, for No. 397.422
397.423	Cheek Retractor, U-shaped, for No. 397.422
397.424	Cheek Retractor Ring, for No. 397.422

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