Transpalatal Distractor. A bone-borne modular distraction device for surgically assisted, rapid, palatal expansion.

Surgical Technique
Warning
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.depuyssynthes.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.depuyssynthes.com/hcp/reprocessing-care-maintenance

Processing of Transpalatal Distractor Bodies
(04.509.005, 04.509.006, 04.509.007)
Processing instructions for Transpalatal Distractor Bodies (04.509.005, 04.509.006, 04.509.007) deviate from the general processing instructions for non-sterile implants. Specific instructions for the processing of these part numbers are found in the Instructions for Use SE_508221.
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Transpalatal Distractor. A bone-borne modular distraction device for surgically assisted, rapid, palatal expansion.

Transpalatal Distractor

The Transpalatal Distractor is a modular, intraoral distraction system available in three widths.
Features and Benefits

Transpalatal distractor body
- Central body with two telescopic threaded pins
- Available in three widths
- Titanium alloy

<table>
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<tr>
<th>Transpalatal Distractor Body</th>
<th>Length in Closed Position (mm)</th>
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<th>Total Distractor Expansion (mm)</th>
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<td>04.509.007</td>
<td>24</td>
<td>48</td>
<td>24</td>
</tr>
</tbody>
</table>

Closed position

Three “L” markings indicate the left side of the palate.

Three threaded holes for blocking screw. The blocking screw prevents distractor rotation and turns the distractor from an expander into a retainer during latency and consolidation periods.

Open position

Central ring for central placement and retention of activation instrument.

The numbers 1, 2, 3 control/monitor the distractor expansion. Arrows indicate the direction of rotation for distractor expansion (cranial to caudal direction).
Transpalatal Distractor. A bone-borne modular distraction device for surgically assisted, rapid, palatal expansion.

**Threaded pins**
- Left, gold
- Right, blue
- Contains \( \varnothing 0.6 \text{ mm} \) hole for the \( \varnothing 0.4 \text{ mm} \) titanium safety wire

**Footplates**
- Left, gold footplate to be assembled with the gold threaded pin
- Right, blue footplate to be assembled with the blue threaded pin
- Allows horizontal placement of the distractor body: angled socket
- Easy-entry opening facilitates engagement with the threaded pin
- Tapered edges minimize soft tissue damage and facilitate footplate slippage under the palatal mucosa
- Large external contact surface facilitates handling with instruments
- 2 bone screw holes \( \varnothing 2.1 \text{ mm}, 8 \text{ mm} \) apart
- 4 spikes located underneath footplate improve bone grip
- Etched “L” on the left, gold footplate and “R” on the right, blue footplate for correct placement in the patient’s mouth
- Pure titanium
**Blocking screw**
- Blocks the left, gold threaded pin
- Prevents unintentional distractor rotation
- Titanium alloy

**Titanium safety wires**
- Ø 0.4 mm safety wires anchor the distractor to the teeth during the treatment period
- Length 140 mm
- Pure titanium
In 1958, the AO formulated four basic principles, which have become the guidelines for internal fixation.\(^1\)

**Anatomic reduction**
Fracture reduction and fixation to restore anatomical relationships.

**Stable fixation**
Fracture fixation providing absolute or relative stability, as required by the “personality” of the fracture, the patient, and the injury.

**Preservation of blood supply**
Preservation of the blood supply to soft tissues and bone by gentle reduction techniques and careful handling.

**Early, active mobilization**
Early and safe mobilization and rehabilitation of the injured part and the patient as a whole.

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**General Adverse Events**
As with all major surgical procedures, risks, side effects and adverse events can occur. While many possible reactions may occur, some of the most common include:

Problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, dental injuries, neurological impairments, etc.), thrombosis, embolism, infection, nerve and/or tooth root damage or injury of other critical structures including blood vessels, excessive bleeding, damage to soft tissues includ. swelling, abnormal scar formation, 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.

**Device Specific Adverse Events**
Morbidity related to the osteotomies for transpalatal osteodistraction may necessitate medical treatment of the patient for rhinorrhea, nasal bleeding, periostitis, dermatitis, infraorbital ecchymosis, excessive postoperative edema, prolonged cheek hyperesthesia, necrosis of the palatal tissue in the area of a palatal torus, prolonged V2 branch nerve hypoesthesia, hematoma, fractures of the skull base, aneurysms, arterio-cavernous fistulas, injuries involving the cranial nerves. Failure to follow postoperative care and treatment instructions can cause failure of the implant and the treatment.

Device specific adverse events include but are not limited to:
- Choking hazard due to the presence of the distractor in the oral cavity, pain, bleeding, hemorrhage, loosening, inflammatory difficulties, wound dehiscence, tissue damage, teeth damage, orbital damage, infection, lesion of the palatal, buccal displacement, asymmetric expansion, relapse.

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Intended Use
The Synthes Transpalatal Distractor is intended for use as a bone-borne maxillary expander and retainer for surgically assisted, rapid, palatal expansion.

The Synthes Transpalatal Distractor is intended for single use only.

Indications
The Synthes Transpalatal Distractor is indicated in surgically assisted, rapid, palatal expansion (SARPE) for correction of maxillary transverse deficiencies in skeletally mature patients.

Contraindications
Treatment with the Transpalatal Distractor is contraindicated for patients with certain medical conditions.

1. For patients to which the distractor can not be anchored to the teeth with the safety wires.
2. For patients with palatal crest width (at the distractor location) smaller than 18.6 mm.
3. For patients with flat and/or scarred cleft palates.
4. For patients who suffer from gingival or periodontal diseases.
5. For patients with unsatisfactory oral hygiene.
6. For patients with a history of immune deficiency, steroid therapy, problems with blood clotting, uncontrolled endocrinological disease, rheumatic disease, bone disease, diabetic problems or cirrhosis of the liver or any other systemic or acute disease.
7. For patients who suffer from osteomyelitis or have an active infection.
8. For patients with metal allergy and foreign body sensitivity.
9. For patients previously treated with radiotherapy of the head.
10. For patients with limited blood supply and insufficient bone structure (insufficient bone quantity) or possible bone defects (insufficient bone quality) in the area in which the transpalatal distractor has to be inserted.
11. For physically unstable patients and/or if the patients have mental or neurological conditions, are severely non-compliant, and are unwilling or incapable of following postoperative care instructions.
12. For patients who suffer from psychological problems such as depressions or other types of psychopathologies.

General Precautions
Irrigate and apply suction for removal of debris potentially generated during implantation or removal.

General Warnings
These devices can break during use (when subjected to excessive forces or outside the recommended surgical technique). While the surgeon must make the final decision on removal of the broken part based on associated risk in doing so, we recommend that whenever possible and practical for the individual patient, the broken part should be removed. Be aware that implants are not as strong as native bone. Implants subjected to substantial loads may fail.

Medical devices containing stainless steel may elicit an allergic reaction in patients with hypersensitivity to nickel.
MRI Information

Torque, Displacement and Image Artifacts according to ASTM F2213-06, ASTM F2052-06e1 and ASTM F2119-07
Non-clinical testing of a 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 3 T MRI system.

Radio Frequency (RF) – induced heating according to ASTM F2182-11a
Non-clinical electromagnetic and thermal simulations of a worst case scenario lead to temperature rises of 19.5 °C (1.5 T) and 9.78 (3 T) under MRI Conditions using RF Coils (whole body averaged specific absorption rate [SAR] of 2 W/kg for 15 minutes).

Non-clinical testing of worst case scenario in a 1.5 T and 3 T MRI system lead to temperature rises of 12.8 °C (1.5 T) and 11.7 °C (3 T) (whole body averaged specific absorption rate [SAR] of 2 W/kg for 15 minutes). Testing was conducted on a GE CVMR 1.5 T MRI system and a GE MR750 3.0 T MRI system.

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 MR scanning for perceived temperature and/or pain sensations.
- Patients with impaired thermo regulation or temperature sensation should be excluded from MR 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.
Surgical Technique

Preoperative Planning

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<td>03.509.005 Plate Holder, curved</td>
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<tr>
<td>03.509.015 Transpalatal Distractor Sizer, L 16 mm</td>
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<tr>
<td>03.509.016 Transpalatal Distractor Sizer, L 20 mm</td>
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<tr>
<td>03.509.017 Transpalatal Distractor Sizer, L 24 mm</td>
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</tbody>
</table>

Determine the post-distraction anatomical goal by conducting an evaluation of the craniofacial pathology through clinical exams, CT scan, frontal cephalogram and/or x-ray. Dental models are beneficial for selecting the appropriate distractor size, determining the location of the osteotomies and placement of the distractor footplates.

A and B: Two possible placement options for the transpalatal distractor.
Transpalatal distractor sizers are available for preoperative planning in each distractor’s closed position size: 16, 20 and 24 mm.

**Sizers can be used to:**
- Select the appropriate distractor size for the patient’s anatomy
- Determine the location of the footplate incisions
- Determine the available distractor expansion measurement precautions

**Precautions:**
Evaluate:
- The patient teeth to ensure that the distractor could be secured on both sides with safety wires
- Desired vector of movement and the magnitude of the desired skeletal correction
- Palatal mucosa thickness
- Palatal bone thickness in the area of footplate placement. The bone should provide adequate strength to sustain forces during the treatment. Thin palatal bone in the sinuses areas should be avoided
- Anatomic abnormalities of the distraction site (e.g. low maxillary sinuses) and bone quality; especially in young patients, cleft patients and patients with edentulous maxillae
- Necessary space for distractor placement and movement of the activation instrument during the entire course of treatment
- Surgical access for osteotomy (e.g. proximity of the incisors)

Evaluate patient cooperation with device activation process and oral hygiene.

Explain the treatment process to the patient before surgery, including the osteotomies, the application and functionality of the transpalatal distractor and the time needed for the distraction and consolidation periods. Clearly inform the patient that a diastema between the incisors will occur; this will be corrected later by the orthodontic treatment.
1

**Perform osteotomies**

Perform the planned osteotomies for surgically assisted, rapid, palatal expansion.¹ ² ³ ⁴ ⁵

**Precautions:**

- The distractor is not designed or intended to break bone and/or complete an osteotomy.

- Avoid causing damage to the palatal blood vessels and critical structures while completing an osteotomy.

- Do not compromise periodontal health or tooth vitality while performing osteotomies. A 3 to 5 mm space between the apices of the central teeth* is necessary to safely perform an interdental osteotomy.
2

**Assemble transpalatal distractor**

**Instrument**

<table>
<thead>
<tr>
<th>Instrument Code</th>
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<tr>
<td>03.509.005</td>
<td>Plate Holder, curved</td>
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</table>

Manually adjust the length of the threaded pins to span the palate where the distractor placement is planned. Allow 3 mm on each side for the footplate thickness.

Assemble the distractor body with both footplates. Assemble the blue threaded pin with the blue footplate and gold threaded pin with the gold footplate. Alternatively, match the left side of the main distractor body with the left footplate.

**Precaution:** Do not touch the spikes underneath the footplates. Handle the footplates with the plate holder included in the set.

**Note:** There is a light press fit between the footplate hexagonal hole and the distractor threaded pins to keep the parts together as one construct.
3
Fit transpalatal distractor

Instrument

03.509.005 Plate Holder, curved

Hold the central body with the plate holder.

Place the expanded distractor in the planned location.

**Note:** Expand the distractor symmetrically until the footplate spikes contact the palatal mucosa.

Place the footplates with the easy-entry openings facing anteriorly. Place the left, gold footplate (marked "L") on the left side of the palate and the blue footplate (marked “R”) on the right side of the palate.

**Note:** Actual placement may vary depending on the patient’s clinical situation. Be sure to consider areas where more expansion is required, i.e., parallel or V-shape expansion.
Mark the locations of the footplate holes or of the inferior footplate edge on the palatal mucosa. These markings are used later as reference points for the incision lines.

Remove the distractor from the patient’s mouth.

Precautions:
- When possible, use the tooth roots behind the footplates as additional reinforcement of palatal bone.
- Place the footplates facing each other and parallel to the teeth and occlusion line.
- Be sure to evaluate bone quality and any anatomic abnormalities of the distraction site; especially in young patients, cleft patients, and patients with overdeveloped maxillary sinuses or edentulous maxillae.
- Confirm that plate positioning allows for adequate clearance of the tooth roots and critical structures while drilling or inserting the screws.
- Do not touch the spikes underneath the footplates. Handle the footplates with the plate holder included in the set.
- Do not place the distractor in a location where it interferes with the lower teeth in occlusion.
- Symmetrically expand both threaded pins so that the central body is kept in the center/midline.
- Make sure that there is sufficient space for placement of footplates and for movement of the activation instrument during the activation period.
4

Make incisions for footplate placement

Mark the incision lines on the palatal mucosa using the previous marks as reference points.

Make the mucoperiosteal incisions. For a cross-shaped incision, use the hole marking; for a T incision, use the footplate edge marking.
Fixate footplates to the bone

Instruments

<table>
<thead>
<tr>
<th>Code</th>
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</tr>
</thead>
<tbody>
<tr>
<td>311.007</td>
<td>Handle, large, with Hexagonal Coupling</td>
</tr>
<tr>
<td>03.503.203</td>
<td>Screwdriver Shaft MatrixMIDFACE, long, self-holding, length 96 mm, with Hexagonal Coupling</td>
</tr>
<tr>
<td>03.509.240</td>
<td>Drill Bit $\varnothing$ 1.1 mm, length 110/16 mm, 2-flute, for J-Latch Coupling</td>
</tr>
<tr>
<td>03.509.005</td>
<td>Plate Holder, curved</td>
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</tbody>
</table>

Disengage the distractor body from the footplate.
- Use the plate holder to grab the footplate.
- Slip the footplate under the mucoperiosteal flap with the easy-entry opening facing the incisors.
- Place the blue footplate marked R on the right side of the palate.
- Press the footplates into the palatal bone using finger pressure to partially insert the spikes into the bone.
Keep the footplate in place with the plate holder and drill through the anterior hole in the footplate hole.

Verify the screw length. The graphic case provides a slot with etched screw length markers to facilitate the confirmation of the correct screw length. Choose a screw for plate fixation. Pick up the screw using the self-holding screwdriver shaft. Place the screw in the slot as shown in the image. Make sure that the bottom of the screw head rests against the bottom of the counterbore at the lower end of the slot. Read the number adjacent to the screw tip.

Insert the screw on the footplate without fully tightening to avoid possible screw extrusion caused by the insertion forces of the second screw.
Drill the posterior hole. The plate holder can be removed to improve visibility.

Tighten the screws in an alternating fashion until they are fully inserted into the bone.
Repeat the above steps to place the gold footplate marked “L+” on the left side of the palate.

**Precautions:**
- Place gauze in the mouth to retain any distractor part in the event it is dropped in the mouth.
- Do not touch the spikes underneath the footplates. Handle the footplates with the plate holder included in the set.
- Do not bend the footplates.
- Select the appropriate drill bits and screw lengths in order to avoid damage to the critical structures.
- Confirm the screw length before using it.
- Confirm that plate positioning allows for adequate clearance of the tooth roots and other critical structures while drilling or inserting the screws.
- Drill rates should never exceed 1800 rpm. Higher rates can result in thermal generated necrosis of the bone and an oversized hole.
- Irrigate adequately to prevent overheating of the drill bit or the bone.
- Always use two screws with each footplate to ensure adequate distractor stability.

**Notes:**
- The distractor can be used alternatively as an all-in-one device. However do not use the distractor as an all-in-one device if the posterior screw is difficult to insert.
- Do not use the distractor as an all-in-one device if the distractor obstructs or if there is no room for the instrument to drill/insert the bone screws. Use the distractor as a three-piece device (footplates separate from the distractor body) if you need more room to handle the instruments in the patient’s mouth.
- Self-drilling and self-tapping screws are available in the set.
- Ø 1.85 mm MatrixORTHOGNATHIC screws could be used as optional screws. See the optional screws and their Ø 1.4 mm drill bits on page 40.
6

Place distractor body

**Instrument**

<table>
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<tr>
<th>Item Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>03.509.005</td>
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</table>

Manually adjust the length of the threaded pins by rotating the threaded pins so that the distractor body bridges the span between the footplate’s easy-entry openings.

Hold the central body with the plate holder and place the threaded pins in the footplates. Assemble the blue threaded pin with the blue footplate and the gold threaded pin with the gold footplate (or match the “L” side of the main distractor body with the “L” footplate).

**Precautions:**
- Hold the central body with the front tip of the plate holder to avoid harm to the palatal mucosa.
- Place the distractor body so that the holes for the titanium safety wire are in a horizontally accessible position.
- Symmetrically expand both threaded pins so that the central body is kept in the center/midline.
- If the palatal mucosa is very thick and covers the titanium safety wire holes of the distractor, place the titanium safety wires in the distractor before the distractor body is placed into the footplates.
Confirm activation of transpalatal distractor

Instruments

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<tr>
<th>Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>03.509.002</td>
<td>Activation Instrument for Transpalatal Distractor</td>
</tr>
<tr>
<td>03.509.003</td>
<td>Patient Instrument for Transpalatal Distractor</td>
</tr>
</tbody>
</table>

Confirm stability of the device by verifying the pins' insertion in the footplates.

Expand the transpalatal distractor slightly to obtain a total widening of 1.5 – 2 mm at the incisors diastema and confirm independent, symmetric expansion and mobility of both sides of the maxilla.

Expansion takes place when the distractor central body is rotated from the cranial to the caudal position, as the arrows on the central body indicate.

The transpalatal distractor should be reset to the starting position.

Warnings:

- Do not activate the distractor before the osteotomies are made.
- Do not activate the distractor to its maximum width intraoperatively.
Secure transpalatal distractor with titanium safety wires

**Instrument**

| 03.509.005 | Plate Holder, curved |

Using the plate holder, insert a Ø 0.4 mm titanium safety wire in each hole of the threaded pin necks. Anchor each side of the distractor to the teeth with the titanium safety wires.

**Warning:** At any time while the distractor is in the patient’s mouth, both sides of the distractor must be secured to the teeth with the safety wires in order to avoid hazard of swallowing or choking.

**Precaution:** If the palatal mucosa is very thick and covers the titanium safety wire holes of the distractor, place the titanium safety wires into the holes before the distractor body is placed into the footplates.
### 9

**Lock transpalatal distractor**

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<td>03.503.203</td>
<td>Screwdriver Shaft MatrixMIDFACE, long, self-holding, length 96 mm, with Hexagonal Coupling</td>
</tr>
<tr>
<td>311.007</td>
<td>Handle, large, with Hexagonal Coupling</td>
</tr>
</tbody>
</table>

Remove the green blocking screw from the case with the screwdriver blade or the blade with sleeve.

Ensure proper blade engagement with the screw recess.
Tighten the blocking screw in one of the three holes of the central body until it contacts the threaded pin to prevent central body rotation during the latency period.

**Precautions:**
- When inserting the blocking screw, rotate the screwdriver shaft using your fingertips. The screwdriver handle is not attached to the shaft. Once the blocking screw is properly engaged, the screwdriver handle may be mounted to the shaft to further tighten the blocking screw. Do not overtighten the blocking screw.
- Place gauze in the mouth to prevent ingestion in the event the blocking screw drops from the screwdriver blade.
- It is recommended to begin distraction 5–7 days after distractor placement.

**Notes:**
- Maintain a clear view of the hole.
- Place the blocking screw perpendicular to the distractor.
1 Blocking screw removal

Instruments

<table>
<thead>
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<th>Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>03.503.206</td>
<td>Screwdriver Shaft MatrixMIDFACE, long, with Holding Sleeve, length 95 mm, with Hexagonal Coupling</td>
</tr>
<tr>
<td>311.007</td>
<td>Handle, large, with Hexagonal Coupling</td>
</tr>
</tbody>
</table>

Following the latency period, remove the green blocking screw from the central body of the distractor with the screwdriver.

**Precaution:** Place gauze in the mouth to prevent ingestion in the event the blocking screw drops from the screwdriver blade.
2

Suggested distraction protocol

<table>
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<th>Instrument</th>
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<tr>
<td>Activation Instrument for Transpalatal Distractor</td>
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<tr>
<th>Optional instrument</th>
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<tr>
<td>03.509.003</td>
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<tr>
<td>Patient Instrument for Transpalatal Distractor</td>
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</tbody>
</table>

It is recommended to activate the device 0.33 mm per day (2 activation instrument strokes), after the latency period.

To open the distractor 0.33 mm, the central body must be rotated in the direction of the arrows (from the cranial to the caudal position); from one number to the next (e.g. from 1 to 2, from 2 to 3 or from 3 to 1).

Follow the steps below to accomplish 0.33 mm distractor expansion.
Two instrument activations, as described below, are necessary to expand the distractor by 0.33 mm.

A number is visible on the front surface of the distractor central body.

Hold the activation instrument by its handle and push its pivot head forward.

Center and fully engage the tip on top of the distractor central body. The instrument head has a slot that must mate with the central body ring 1.

Push the activation instrument handle forward along a horizontal plan 2 3 until its head comes to a stop 4. The instrument head together with the distractor central body will rotate 60° exposing the next distractor surface 5.

Carefully slide the activation instrument downward off the distractor central body and remove it from the mouth.

After this first activation sequence, a new distractor front surface is visible. This surface is not marked with a number.

Repeat the above steps to rotate the distractor central body and to expose the surface marked with the next number (e.g. from 1 to 2, from 2 to 3 or from 3 to 1).

The next number must be visible on the distractor front surface.
Precautions:
- Carefully plan the rate and frequency of the distraction in order to avoid injuries to important neurovascular structures that may result from forces associated with the maxillary expansion.
- Do not distract with higher rates than 0.33 mm. This could be detrimental to the patient health and treatment outcome.
- Do not force the instrument after it comes to a stop. Its head may slip off the distractor central body causing damage to the soft tissue of the mouth.
- Do not activate the distractor central body in reverse during palatal distraction.
- During the first days of distraction, the distractor might need to be blocked with the blocking screw by the surgeon every day after expansion to prevent it from being activated unintentionally. The blocking screw must be removed each day prior to distraction.

Notes:
- A full (360°) rotation of the central body will expand the distractor 1 mm (e.g. the central body is rotated from 1 to 1, from 2 to 2 or from 3 to 3).
- The patient activation instrument (wrench design) could also be used in case of unrestricted mouth opening. The head of the wrench is turned upside down after every rotation.

3 Document patient progress

Distraction progress must be observed by documenting the changes in the intended diastema. The Patient Care Guide is included in the system to help the patient record and monitor distractor activation. This Patient Care Guide must be provided to the patient.
4

Patient care

Care should be taken not to accidentally activate the distractor with a toothbrush or the tongue during the distraction time.

The patient should fill in the dates from the beginning of the distraction through completion as instructed and return the patient care schedule once the transpalatal distractions treatment is finished.

The Surgeon should instruct the patient on the transpalatal distraction treatment.

**Precaution:** The patient should be advised to report any unusual changes in the palatal region to the surgeon and be closely monitored if any asymmetric change occurs.

**Patient care precautions:**
Accept the transpalatal distractor as a foreign body in your mouth:
- Do not tamper with, remove or activate the distractor with the tongue, finger, toothbrush or other foreign objects. Do not tamper with the safety wires.
- Observe arrow direction when operating the distractor.
- Follow a soft diet during the entire distraction treatment.
- Consider gentle cleaning of the nose. Avoid aggressive nose blowing.
- Should you have any nose-bleeding, missing or broken safety wires, redness, drainage, undue pain, questions or concerns, contact your physician immediately.
- Maintain daily oral hygiene.
- Comply fully with your doctor’s instructions. Regular follow-up visits are essential for long term clinical success.
- Under instructions from your physician, you need to activate the distractor each day.
- Please follow the distractor activation steps within the patient guide. Mark your progress on the distraction calender.
5 Optional: Exchange distractor body during distraction period

**Instruments**

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</tbody>
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It is possible to exchange the distractor body with the next available size when further expansion of the maxilla is desired.

Remove the green blocking screw from the distractor central body using the screwdriver shaft with holing sleeve and handle.

Select the next size distractor body. Prepare the new safety wires.

Prior to distractor removal, ensure that the gold and blue threaded pins are clean.

Cut the safety wires from around the teeth and remove them from the mouth.

Remove the distractor body from the patient’s mouth.

Rotate the distractor central body in reverse (opposite to the direction of the arrows) with the plate holder or patient instrument from the caudal to the cranial position until the threaded pins disengage from the footplates.

Repeat steps 6–8 of the Transpalatal Distractor Placement on pages 20–22 to place and secure the next size distractor in the patient’s mouth.

Follow the distraction steps according to the next size distraction protocol.

**Warning:** At any time while the distractor is in the patient’s mouth, both sides of the distractor must be secured to the teeth with the safety wires.
**Precautions:**

- Press plate holder against the footplate while removing the threaded pin from the footplate socket to prevent extrusion of the bone screws.
- Hold the central body with the front tip of the plate holder to avoid harm to the palatal mucosa during rotation of the central body.
- Place the distractor body so that the holes for the titanium safety wires are in a horizontally accessible position.
- Symmetrically expand both threaded pins so that the central body is kept in the center/midline.
- If the palatal mucosa is very thick and it covers the titanium safety holes of the distractor, place the titanium safety wires into the holes before the distractor body is placed into the footplates.
Surgical Technique

Consolidation Period

Instruments

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>311.007</td>
<td>Handle, large, with Hexagonal Coupling</td>
</tr>
<tr>
<td>03.503.206</td>
<td>Screwdriver Shaft Matrix MIDFACE, long, with Holding Sleeve, length 95 mm, with Hexagonal Coupling</td>
</tr>
</tbody>
</table>

Once the planned expansion is accomplished, the new bone must be given time to consolidate.

Block the distractor with the green blocking screw using the screwdriver blade with holding sleeve and handle. The blocking screw must contact the threaded pin to prevent central body rotation during the consolidation time.

Precautions:

- Allow the bone to consolidate for 12 weeks. This time period may vary in relation to patient age and to accomplished palatal expansion and should be determined by clinical evaluation and radiographic or CT evidence of bone healing.
- Consolidation time should be lengthened to allow bone to mineralize and become strong enough to resist high forces from skull bones and stretched palatal soft tissue.

Note: Active orthodontic treatment may possibly start after six weeks.
Surgical Technique

Transpalatal Distractor Removal

Instruments

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>311.007</td>
<td>Handle, large, with Hexagonal Coupling</td>
</tr>
<tr>
<td>03.503.206</td>
<td>Screwdriver Shaft MatrixMIDFACE, long, with Holding Sleeve, length 95 mm, with Hexagonal Coupling</td>
</tr>
<tr>
<td>03.503.203</td>
<td>Screwdriver Shaft MatrixMIDFACE, long, self-holding, length 96 mm, with Hexagonal Coupling</td>
</tr>
<tr>
<td>03.509.003</td>
<td>Patient Instrument for Transpalatal Distractor</td>
</tr>
<tr>
<td>03.509.002</td>
<td>Activation Instrument for Transpalatal Distractor</td>
</tr>
<tr>
<td>03.509.005</td>
<td>Plate Holder, curved</td>
</tr>
</tbody>
</table>

Clean the gold and blue threaded pins.

Remove the green blocking screw from the distractor central body using the screwdriver shaft with holding sleeve and handle.

Cut the titanium safety wires and remove them from the mouth.

Remove the distractor body. Rotate the central body counterclockwise using the plate holder or the activation/patient instrument until at least one threaded pin disengages from its footplates.

Disengage the distractor from the second footplate and remove it from the mouth.
Remove both footplates by incising the palatal mucosa, exposing the footplates and removing the four bone screws with the self-holding screwdriver shaft with handle.

**Precautions:**
- Hold the central body with the front tip of the plate holder to avoid harm to the palatal mucosa during rotation of the central body.
- The timing for distractor removal should be determined by clinical evaluation and radiographic or CT evidence of bone healing.
### Implants

#### Distractor implants

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>04.509.008</td>
<td>Blocking Screw for Implant, for Transpalatal Distractor</td>
</tr>
<tr>
<td>04.509.001</td>
<td>Foot Plate, right, for Transpalatal Distractor</td>
</tr>
<tr>
<td>04.509.002</td>
<td>Foot Plate, left, for Transpalatal Distractor</td>
</tr>
<tr>
<td>04.509.010.02</td>
<td>Titanium Wire, Ø 0.4 mm, L 140 mm, pack of 2 units</td>
</tr>
<tr>
<td>04.509.005</td>
<td>Transpalatal Distractor Body, 16 – 24 mm</td>
</tr>
<tr>
<td>04.509.006</td>
<td>Transpalatal Distractor Body, 20 – 36 mm</td>
</tr>
<tr>
<td>04.509.007</td>
<td>Transpalatal Distractor Body, 24 – 48 mm</td>
</tr>
</tbody>
</table>
Screws

1.5 mm MatrixMIDFACE Self-Drilling Screw, 4 in clip*

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Length</th>
<th>Image</th>
</tr>
</thead>
<tbody>
<tr>
<td>04.503.225.04C</td>
<td>5 mm</td>
<td><img src="https://via.placeholder.com/150" alt="Image" /></td>
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<tr>
<td>04.503.226.04C</td>
<td>6 mm</td>
<td><img src="https://via.placeholder.com/150" alt="Image" /></td>
</tr>
<tr>
<td>04.503.228.04C</td>
<td>8 mm</td>
<td><img src="https://via.placeholder.com/150" alt="Image" /></td>
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</tbody>
</table>

1.5 mm MatrixMIDFACE Self-Tapping Screw, 4 in clip*

<table>
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<tr>
<th>Part Number</th>
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</thead>
<tbody>
<tr>
<td>04.503.205.04C</td>
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<td><img src="https://via.placeholder.com/150" alt="Image" /></td>
</tr>
<tr>
<td>04.503.206.04C</td>
<td>6 mm</td>
<td><img src="https://via.placeholder.com/150" alt="Image" /></td>
</tr>
<tr>
<td>04.503.208.04C</td>
<td>8 mm</td>
<td><img src="https://via.placeholder.com/150" alt="Image" /></td>
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</tbody>
</table>

1.8 mm MatrixMIDFACE Emergency Screw, 1 in clip

<table>
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<th>Part Number</th>
<th>Length</th>
<th>Image</th>
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</thead>
<tbody>
<tr>
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<tr>
<td>04.503.236.01C</td>
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<td><img src="https://via.placeholder.com/150" alt="Image" /></td>
</tr>
<tr>
<td>04.503.238.01C</td>
<td>8 mm</td>
<td><img src="https://via.placeholder.com/150" alt="Image" /></td>
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</tbody>
</table>

*Screws are also available in packs of 1 screw in clip. Substitute 04C with 01C in the part number to order.
### Instruments

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<tr>
<th>Code</th>
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</tr>
</thead>
<tbody>
<tr>
<td>311.007</td>
<td>Handle, large, with Hexagonal Coupling</td>
</tr>
<tr>
<td>03.503.203</td>
<td>Screwdriver Shaft MatrixMIDFACE, long, self-holding, length 96 mm, with Hexagonal Coupling</td>
</tr>
<tr>
<td>03.503.206</td>
<td>Screwdriver Shaft MatrixMIDFACE, long, with Holding Sleeve, length 95 mm, with Hexagonal Coupling</td>
</tr>
<tr>
<td>03.509.002</td>
<td>Activation Instrument for Transpalatal Distractor</td>
</tr>
<tr>
<td>03.509.003</td>
<td>Patient Instrument for Transpalatal Distractor</td>
</tr>
<tr>
<td>03.509.240</td>
<td>Drill Bit ø 1.1 mm, length 110/16 mm, 2-flute, for J-Latch Coupling</td>
</tr>
<tr>
<td>03.509.280</td>
<td>Drill Bit ø 1.1 mm, length 110/16 mm, 2-flute, for Quick Coupling</td>
</tr>
<tr>
<td>03.503.248</td>
<td>Drill Bit ø 1.1 mm with Stop, length 44.5/8 mm, for J-Latch Coupling</td>
</tr>
<tr>
<td>03.503.288</td>
<td>Drill Bit ø 1.1 mm with Stop, length 44.5/8 mm, for Mini Quick Coupling</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>------------</td>
<td>-----------------------------------------------------</td>
</tr>
<tr>
<td>03.509.015</td>
<td>Transpalatal Distractor Sizer, L 16 mm</td>
</tr>
<tr>
<td>03.509.016</td>
<td>Transpalatal Distractor Sizer, L 20 mm</td>
</tr>
<tr>
<td>03.509.017</td>
<td>Transpalatal Distractor Sizer, L 24 mm</td>
</tr>
<tr>
<td>03.509.005</td>
<td>Plate Holder, curved, complete</td>
</tr>
</tbody>
</table>

### Cases

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>68.509.001</td>
<td>Module for Transpalatal Distractor System, (\frac{2}{3}), with Lid, without Contents</td>
</tr>
<tr>
<td>01.509.001</td>
<td>Transpalatal Distractor Set</td>
</tr>
</tbody>
</table>
Additionally Available

Screws

MatrixORTHOGNATHIC Screws, Titanium Alloy (TAN)

**Self-tapping screws ☸ 1.85 mm***

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>04.511.205.04C</td>
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<td>04.511.206.04C</td>
<td>6 mm</td>
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<tr>
<td>04.511.208.04C</td>
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</tbody>
</table>

**Self-drilling screws ☸ 1.85 mm***

<table>
<thead>
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<th>Part Number</th>
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<tbody>
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<td>04.511.225.04C</td>
<td>5 mm</td>
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<tr>
<td>04.511.226.04C</td>
<td>6 mm</td>
</tr>
<tr>
<td>04.511.228.04C</td>
<td>8 mm</td>
</tr>
</tbody>
</table>

**Matrix screws ☸ 2.1 mm, self-tapping**

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Length</th>
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</thead>
<tbody>
<tr>
<td>04.511.235.01C</td>
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</tr>
<tr>
<td>04.511.236.01C</td>
<td>6 mm</td>
</tr>
<tr>
<td>04.511.238.01C</td>
<td>8 mm</td>
</tr>
</tbody>
</table>

*Screws are also available in packs of 1 screw in clip. Substitute 04C with 01C in the part number to order.*
### Drill bits

**Matrix Drill Bits Ø 1.4 mm, for J-Latch Coupling**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>03.511.244</td>
<td>Drill Bit with Stop, length 44.5/4 mm</td>
</tr>
<tr>
<td>03.511.246</td>
<td>Drill Bit with Stop, length 44.5/6 mm</td>
</tr>
<tr>
<td>03.511.248</td>
<td>Drill Bit with Stop, length 44.5/8 mm</td>
</tr>
</tbody>
</table>

**Matrix Drill Bits Ø 1.4 mm, for Mini Quick Coupling**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>03.511.284</td>
<td>Drill Bit with Stop, length 44.5/4 mm</td>
</tr>
<tr>
<td>03.511.286</td>
<td>Drill Bit with Stop, length 44.5/6 mm</td>
</tr>
<tr>
<td>03.511.288</td>
<td>Drill Bit with Stop, length 44.5/8 mm</td>
</tr>
</tbody>
</table>
Bibliography


