

## Precautions

### Preoperative Planning – 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).

### Perform Osteotomies

- 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 performing 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\* (see drawing next page: Lateral and anterior release) is necessary to safely perform an interdental osteotomy.

### Safety wires 04.509.010.02

If the palatal mucosa is very thick and covers the safety wire holes of the distractor, place the safety wires in the distractor before the distractor body is placed in the footplates.

### Distractor placement

- Place gauze in the mouth to retain any distractor part in the event it is dropped in the mouth and prevent ingestion in the event the blocking screw drops from the screwdriver blade.
- 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.
- Do not place the distractor in a location where it interferes with the lower teeth in occlusion.
- Make sure that there is sufficient space for placement of footplates and for movement of the activation instrument during the activation period.
- Place the distractor body so that the hole for the safety wire is in a horizontally accessible position.

### Distractor expansion

- It is recommended to begin distraction 5–7 days after distractor placement.
- Symmetrically expand both threaded pins to keep the central body in the center/midline.

### Bone screw placement

- Confirm that plate positioning allows for adequate clearance of the tooth roots and other critical structures while drilling or inserting the bone screws.
- Select the appropriate screw length and drill bit in order to avoid damage of the critical structures.
- Confirm the screw length before using it.
- Drill rate should never exceed 1800 rpm. Higher rates may result in thermal generated necrosis of the bone, and an oversized hole to be drilled.
- Irrigate adequately to prevent overheating of the drill bit or the bone.
- Always use two screws in each footplate to ensure adequate distractor stability.

### Footplates 04.509.001-2

- Do not touch the spikes underneath the footplates.
- Handle the footplates with the forceps included in the set.
- Do not bend the footplates.

### Blocking screw 04.509.008

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.

### Forceps 03.509.005

- Hold the central body with the front tip of the forceps to avoid any harm to the palatal mucosa.

### Distraction protocol

- 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 activation 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 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.

### Exchange of the distractor body

- Press plate holder against the footplate while removing the threaded pin from the footplate socket to prevent extrusion of the bone screws.

### Consolidation

- 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.
- The timing for distractor removal should be determined by clinical evaluation and radiographic or CT evidence of bone healing.

### Patient Care

- 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 period.
  - 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 calendar.

### General Precautions

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

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**Synthes Transpalatal Distractor.** A bone-borne modular distraction device for surgically assisted rapid palatal expansion (SARPE).



# Intended Use, Indications, Contraindications, Precautions, Warnings, Adverse Events

## 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.

- For patients to which the distractor can not be anchored to the teeth with the safety wires.
- For patients with palatal crest width (at the distractor location) smaller than 18.6 mm.
- For patients with flat and/or scarred cleft palates.
- For patients who suffer from gingival or periodontal diseases.
- For patients with unsatisfactory oral hygiene.
- 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.
- For patients who suffer from osteomyelitis or have an active infection.
- For patients with metal allergy and foreign body sensitivity.
- For patients previously treated with radiotherapy of the head.
- 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.
- 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.

- For patients who suffer from psychological problems such as depressions or other types of psychopathologies.

## 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.

## 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 incl. swelling, abnormal scar formation, functional impairment of the musculoskeletal system, pain, discomfort or abnormal sensation due to the presence of the device, allergy or 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,

# Distractor Placement

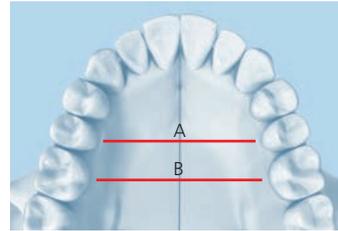
aneurysms, arteriocavernous fistulas, injuries involving the cranial nerves. Failure to follow postoperative care and treatment instructions can cause failure of the implant and the treatment.

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.

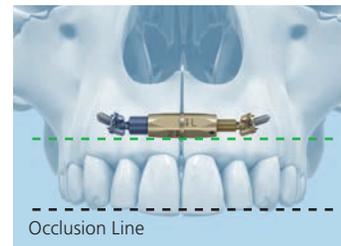
## Distractor placement relative to the teeth

Place the footplates facing each other and parallel with the teeth. Use Ø 1.5 mm/1.85 mm MatrixMIDFACE/ORTHOGNATHIC screws.

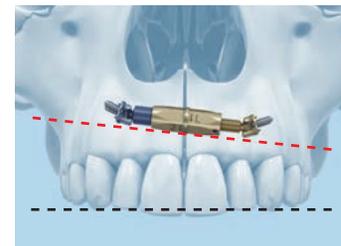


## Distractor orientation relative to the occlusion line

Place distractor parallel with the occlusion line. Wrong position may lead to sinus perforation and/or asymmetric expansion. The tooth roots behind the footplates reinforce the palatal bone.



Correct

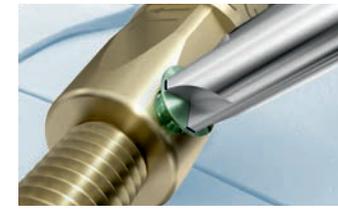


Incorrect

## Distractor secured with safety wires

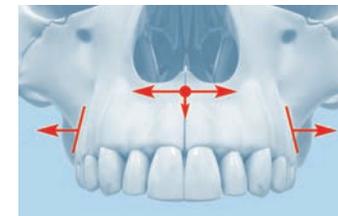
Evaluate the patient teeth to ensure that the distractor can be secured on both sides with safety wires.

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



## Distractor blocked with blocking screw

Place the blocking screw in the distractor for latency and consolidation periods to prevent inadvertent movement of the distractor.



## Bone movement

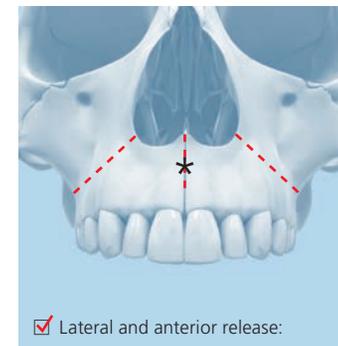
Possible palatal expansion during treatment.

## Warnings:

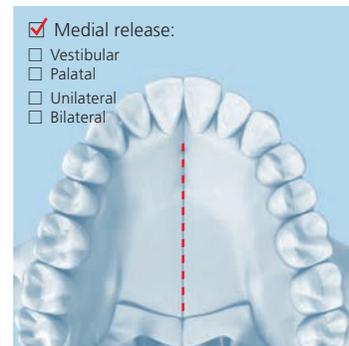
- Do not activate the distractor before the osteotomies are made.
- Do not expand the maxilla to its maximum width intraoperatively.

# Osteotomies

This description alone does not provide sufficient instructions for direct use of the product. Detailed instructions for handling this distractor are available in the Synthes Transpalatal Distractor Surgical Technique (036.001.125).



Lateral and anterior release:

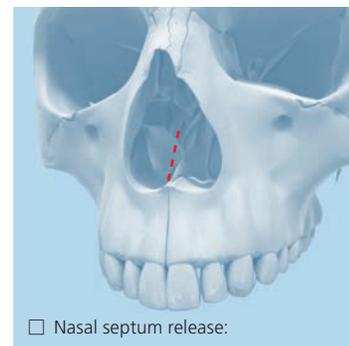


Medial release:

- Vestibular
- Palatal
- Unilateral
- Bilateral



Posterior release:



Nasal septum release: