Instructions for Use
Transpalatal Distraction System

This instruction for use is not intended for distribution in the USA.

DePuy Synthes
CMF
COMPANIES OF Johnson&Johnson

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Instructions for Use

Transpalatal Distractor
Please read these instructions for use, the Synthes brochure "Important Information" and the corresponding surgical techniques 0X6.001.125 carefully before use. Ensure that you are familiar with the appropriate surgical technique.
The transpalatal distractor is made up of three components:
– Left footplate
– Right footplate
– ranspalatal Distractor Body, available in 3 widths
– Blocking Screw
– Titanium safety wires
All implant components are provided unsterile and individually packed in a transparent envelop. The titanium safety wires are a pack of two.

Material(s)
Material(s): Standard(s):
Left footplate: TiCp, ISO 5832-02
– Right footplate: TiCp, ISO 5832-02
– Transpalatal Distractor Body: TAN, ISO 5832-11
– Blocking Screw: TAN, ISO 5832-11
– Titanium safety wires: TiCp, ISO 5832-02

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
The transpalatal distractor is contraindicated:

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 in which the transpalatal distractor has to be inserted 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 that suffer from osteomyelitis or have an active infection.
8. For patients with metal allergy and foreign body sensitivity
9. For patients that received 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 patients that are physical unstable 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 that suffer from psychological problems such as depressions or other types of psychopathologies.

Side effects
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.
– Failure to follow postoperative care and treatment instructions can cause failure of the implant and the treatment
– Choking hazard due to the presence of the distractor in the oral cavity

Single-use device


Do not re-use

Products intended for single-use must not be re-used.
Re-use or reprocessing (e.g. cleaning and resterilization) may compromise the structural integrity of the device and / or lead to device failure which may result in patient injury, illness or death.
Furthermore, reuse or reprocessing of single-use devices may create a risk of contamination e.g. due to the transmission of infectious material from one patient to another. This could result in injury or death of the patient or user.

Contaminated implants must not be reprocessed. Any Synthes implant that has been contaminated by blood, tissue, and/or bodily fluids/matter should never be used again and should be handled according to hospital protocol. Even though they may appear undamaged, the implants may have small defects and internal stress patterns that may cause material fatigue.

Precautions
– The hard palate cleft or alveolar cleft is likely to open if the scar is disrupted by the distractor when used in cleft maxillae with steep slopes.
– 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 during progressive expansion.
– Do not touch the spikes underneath the footplates.
Handle the footplates with the plate holder included in the set.
– When possible, use the tooth roots behind the footplates as additional reinforcement of palatal bone.
– 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.
– Do not bend the footplates.
– Irrigate adequately to prevent overheating of the drill bit or the bone.
– Drill rate should never exceed 1800 RPM. Higher rates can result in thermal generated necrosis of the bone, and an oversized hole to be drilled. The detriments of an oversized hole include reduced pullout force, increased ease of screws stripping in bone, and/or suboptimal fixation.
– Always use two screws with each footplate to ensure adequate distractor stability.
– 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 hole for the safety wire is in a horizontally accessible position.
– If the palatal mucosa is very thick and covers
the safety wire holes of the distractor, place the safety wires into the holes before the distractor body is placed into the footplates.
– When inserting the screw, rotate the screwdriver shaft using your fingertips. Note: 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.
– Place gauze in the mouth to prevent ingestion in the event the blocking screw drops from the screwdriver blade.
– 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 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.

– 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.

Patient's precautions:
– Should you have any nose-bleeding, missing or broken safety wires, redness, drainage, undue pain, questions or concerns, contact your physician immediately.
– Please remember to practice good oral hygiene.
– Under instructions from your physician, you need to activate the distractor each day.
– Please follow the steps within the patient care guide.
– Observe arrow direction when operating the distractor
– Follow a soft diet during the entire distraction treatment.
– Maintain daily oral hygiene. Care should be taken not to accidentally activate the distractor with a toothbrush or your tongue during the distraction time.
– Do not tamper the distractor with the toothbrush, tongue, finger or any foreign object.

Warnings
– 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.

The manufacturer is not responsible for any complications arising from incorrect diagnosis, choice of incorrect implant, incorrectly combined implant components and/or operating techniques, the limitations of treatment methods, or inadequate asepsis.
The implant components applied (name, article number, lot number) must be documented in each patient's record.

Magnetic Resonance environment
CAUTION:
Unless stated otherwise, devices have not been evaluated for safety and compatibility within the MR environment. Please note that there are potential hazards which include but are not limited to:
– Heating or migration of the device
– Artifacts on MR images

Treatment before device is used
Synthes products supplied in a non-sterile condition must be cleaned and steam-sterilized prior to surgical use. Prior to cleaning, remove all original packaging. Prior to steam-sterilization, place the product in an approved wrap or container. Follow the cleaning and sterilization instruction given by the Synthes brochure "Important Information".
Device-specific treatment instructions before surgical use:
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 corticotomies and placement of the distractor footplates
Evaluate:
– Desired vector of movement and the magnitude of the desired skeletal correction
– Palatal mucosa thickness
– Anatomic abnormalities of the distraction site (e.g. low maxillary sinuses) and bone quality; especially in young patients, cleft patients and patient's 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)
– Patient cooperation with device activation process and oral hygiene
Explain the treatment process to the patient before surgery, including the corticotomies, the application and functionality of the transpalatal distractor and the time needed for the distraction and consolidation periods..

Special operating instructions
– Perform the planned corticotomies for surgically assisted, rapid, palatal expansion
– 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.
– Hold the central body with the plate holder.
– Place the expanded distractor in the planned location.
– 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.
– 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.
– 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.
– 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.
– 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.
– 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).
– 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 into the footplates.
– Confirm stability of the device by verifying the pins' insertion in the footplates.
– Check that 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.
– Confirm symmetrical movement of both palatal halves.
– Using the plate holder, insert a 0.4 mm diameter 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.
– 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.
– Maintain a clear view of the hole.
– Place the blocking screw perpendicular to the distractor.
– Following the latency period, remove the green blocking screw from the central body of the distractor with the screwdriver.
– Activate the device 0.33 mm per day (2 activation instrument strokes), after a 7 day 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).
– Two instrument activations, as described below, arenecessary to expand the distractor by 0.33 mm.
– 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.
– Distraction progress must be observed by documenting thechanges 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.
Patient care
– 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.
– Comply fully with your doctor's instructions. Regular follow-up visits are essential for long term clinical success.
– Observe arrow direction when operating the distractor.
– Follow a soft diet during the entire distraction period.
– Careful oral hygiene is indicated during the entire treatment.
Optional: Exchange distractor body during distraction
Period
– It is possible to exchange the distractor body with the next available size when further expansion of the maxilla is desired.
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Rotate the distractor central body with the plate holder or patient instrument from the caudal to the cranial position until the threaded pins disengage from the footplates.
– Cut the safety wires from around the teeth.
– Remove the distractor body from the patient's mouth.
– Select the next size distractor body.

Repeat steps above to place and secure the distractor in the patient's mouth.
– Follow the distraction steps according to the distraction protocol.
– Once the planned expansion is accomplished, the new bone must be given time to consolidate.
– Insert the green blocking screw using the screwdriver blade with holding sleeve and handle. The blocking screw must contact the threaded pin to prevent rotation during the consolidation time.
– Allow the bone to consolidate for 12 weeks. This time period may vary in relation to patient age and to accomplished palatal expansion.
– Active orthodontic treatment may possibly start after six weeks.

Transpalatal Distractor Removal
– Remove the green blocking screw from the distractor central body using the screwdriver shaft with holding sleeve and handle.
– Cut the titanium safety wires.
– Remove the distractor body. Rotate the central body counterclockwise using the plate holder or the patient instrument until the threaded pins disengage from both footplates.
– Remove both footplates by incising the palatal mucosa, exposing the footplates and removing the four bone screws with the long screwdriver shaft with handle.
– The timing for distractor removal should be determined by clinical evaluation and radiographic or CT evidence of bone healing (minimum 4 months).
– Fill in the dates from the beginning of distraction through completion as instructed by your physician.

Follow the physician's daily instructions and mark your progress on the distraction calendar.
– Follow a soft diet during the entire distraction treatment.
– Maintain daily oral hygiene. Care should be taken not to accidentally activate the distractor with a toothbrush or your tongue during the distraction time.
– Do not tamper the distractor with the toothbrush, tongue, finger or any foreign object.
– Follow up appointments. Regular follow-up visits are essential for long term clinical success.
– Return this schedule to your physician when you have finished distraction.
– You have been fitted with a distractor to gain palatal bone and expand the dental arch. - - Distraction is an ongoing procedure which requires daily activation of the distractor with a special activation instrument.
– Under instructions from your physician, you need to activate the distractor each day.
– Please follow the steps within this guide.
– Should you have any nose-bleeding, missing or broken safety wires, redness, drainage, undue pain, questions or concerns, contact your physician immediately.
– Please remember to practice good oral hygiene.
– To open the distractor 0.33 mm, its central body must be rotated in the direction of the arrow from one number to the next number (e.g. from 1 to 2, or from 2 to 3 or from 3 to 1). Please see the pictures
– on the Patient Care Guide.
– Activation steps-please see pictures in the Patient Care Guide
– Two activation instrument strokes, as described below, are necessary to expand the distractor by 0.33 mm.
– A number is visible on the front surface of the distractor (1, 2 or 3).
– Hold the activation instrument by its handle and push the pivot head forward.
– Center and fully engage the instrument head on top of the central body. The instrument head has a slot that must mate with the central body ring.
– Push the activation instrument handle forward along a horizontal plane until its head comes to a stop. The instrument head together with the distractor central body will rotate exposing the next distractor surface.
– Carefully slide the activation instrument downward off the central body and remove it from the mouth.
– After this first activation stroke, a new distractor front surface is visible. This surface is not marked with a number.
– For the second activation stroke, repeat the above steps to rotate the central body again 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.
– Write down this number on the patient care guide. You have achieved 0.33 mm expansion.
– Repeat these steps as described in the daily instructions, if necessary.
– The patient activation instrument (wrench design) could also be used in case the mouth opening is not restricted. The instrument head is turned upside down after every rotary movement.

Processing/reprocessing of the device

Detailed instructions for processing implants and reprocessing reusable devices, instrument trays and cases are described in the Synthes brochure "Important Information". Assembly and disassembly instructions of instruments "Dismantling multipart instruments" can be downloaded from http://www.synthes.com/reprocessing

Additional device-specific information

REF Reference Number

LOT Lot or batch number

Manufacturer

Manufacturing date

Do not use when packaging is damaged

0123 Notified body

Caution, see instructions for use

CE
0123

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