ENGLISH	THESE INSTRUCTIONS FOR USE MUST BE READ CAREFULLY PRIOR TO CLINICAL USE	***ENGLISH***

Intended use
Surgically assisted rapid palatal expansion (SA-RPE) with a transpalatal distraction device is an established technique by which the upper jaw is surgically weakened at the buttress areas and widened by an expansion device that is fixed in the palate.
The maxilla regains its initial strength in the consolidation period after the distraction phase.
Surgi-Tec recommends to:

- use a TPD All-in-one if the distraction module can cover the required distraction distance;
- use a TPD Classic if the distraction module needs to be changed during the treatment;
- use a TPD Neo if a slim shape is appropriate.

Intended users

- Implantation is performed by suitably trained and qualified oral and maxillofacial surgeons
- Initial distraction activation is performed by the surgeon
- Ongoing distraction activation is performed by the patient

Intended patient population

- Patients needing transpalatal distraction from ages 14 years onwards who are undergoing surgically assisted rapid palatal expansion (SA-RPE)
- Patient can vary in age as the use of distraction devices are determined by the maxillofacial surgeon. For patients of less than 14 years, distraction can be achieved without SA-RPE.
- Surgi-Tec do not recommend the use of distraction devices in Pregnant or lactating women. The devices itself do not harm Pregnant or lactating women but the surgical procedure requires the use of anaesthetic agent - anaesthesia may have an adverse effect on Pregnant or lactating patients.

Intended environment

- The intended environment for the use of TPDs is Hospitals and Clinics.

Performance characteristics
TPD all in one and TPD classic can cover following distraction distances:

- TPD All in one - Module 1 22 mm distraction
- TPD All in one - Module 2 30 mm distraction
- TPD All in one - Module 2,5 39 mm distraction
- TPD All in one - Module 3 47 mm distraction
- TPD All in one - Module 4 58 mm distraction

TPD Neo can cover following distraction distances:

- TPD Neo - Module 1 24 mm distraction
- TPD Neo - Module 2 32 mm distraction
- TPD Neo - Module 2,5 43 mm distraction
- TPD Neo - Module 3 52 mm distraction

Material information
Surgi-Tec TPD abutment plates are made of Titanium Grade 2 – ASTM F-65, ISO 5832-2.
Surgi-Tec TPD distraction modules, and related osteosynthesis screws and locking screw are made of Titanium Grade 5 – TiAl6V4 (ELI) ASTM F 136, ISO 5832-3.

Composition of Titanium grade 2 (EN - Ti2) :

Carbon	Iron	Oxygen	Nitrogen	Hydrogen	Titanium
Max 0,08 %	Max 0,30%	Max 0,25%	Max 0,03%	Max 0,0125%	Balance

Composition of Titanium grade 5 (EN- TiAl6V4):

Carbon	Iron	Oxygen	Nitrogen	Hydrogen	Aluminium	Vanadium	Yttrium	Titanium
Max 0,08 %	Max 0,25%	Max 0,13%	Max 0,05%	Max 0,012%	5,50-5,60 %	3,50-4,50 %	Max 0,005%	Balance

Indications
Transpalatal distractors are indicated when transpalatal distraction is needed to facilitate treatment of:

- Maxillary constriction;
- Dental malocclusions;
- Dental crowding;
- Mouth breathing;
- Smile aesthetics.

Contraindications

- Pre-existing or suspected infection at or near the implantation site.
- Known allergies and/or hypersensitivity to implant materials.
- Limited blood supply and inferior or insufficient bone quality to attach the abutment plates.
- Patients who are incapacitated and/or uncooperative during the treatment phase.
- Patients suffering from unsatisfactory oral hygiene.
- 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.
- A TPD must not be used if the patient receives radiotherapy of the head.
- TPD Classic and TPD All-in-one: patients that have difficulties to distinguish the colour marks on the device (e.g. colour vision deficiency).
- Patients with gingival and periodontal diseases.
- If the space between the right and left palatal crests is less than 15.5 mm, no TPD can be placed.

Possible adverse effects

- Loosening of the implant from loosening of screws or screw failure.
- Hypersensitivity to metal or allergic reactions.
- Oral hygiene problems.
- Asymmetric expansion.
- Difficult removal due to bone overgrowth.
- Teeth damage.
- Phonetic problems
- Maxilla drop during treatment.
- Possible dentoalveolar changes.
- Morbidities related to orthognathic surgery:
  - Soft tissue irritation, nerve damage or root penetration through surgical trauma.
  - Early or late infection, both superficial and deep.
  - Elevated fibrotic tissue reaction around the surgical area.
  - Postsurgical swelling.
  - Nasal bleeding.
  - Prolonged fatigue or pain postoperatively.
  - False aneurysms.
  - Arteriovenous fistulas.
  - Obstruction of lacrimal canal after maxillary osteotomy.
  - Temporomandibular Joint (TMJ) problems.
  - Frequent maxillary sinusitis,
  - Instable maxilla.

Warnings and precautions

- Read all available documents before first use.
- Check the packaging for integrity, do not use if package is damaged.
  Never use products that have been damaged by transport or improper handling.
- Products labelled as ‘sterile’ are gamma irradiated and delivered in sterile see-through pouches. They are ready to be used unless the original packaging has been damaged. If the package is damaged please notify the manufacturer immediately. Do not use the medical device after the use by date indicated on the Labels. Store the sterile device in a dry and dust-free environment.
- TPD’s may only be used by medical personnel who hold the correct professional qualifications and are familiarized with the procedure. Consult step by step procedures for detailed procedure instructions.
- Follow appropriate procedures for patients who are on anticoagulant, antiplatelet or aspirin therapy.
- Treatment group: adults and children with confirmed skeletal maturity, but a surgeon must always rely on his/her clinical judgement when deciding whether to use a particular product when treating a particular patient.
- Do not bend the abutment plates during placement of the TPD to adapt it to the patient’s palate.
- Advice the patient not to apply excessive forces or tamper with the device after implantation.

- Respect the latency period of 5 to 7 days before starting distraction. Preferably activate the distractor one marking per day, and a maximum two markings per day, to avoid over expanding.
- Inform the patient regarding the possible adverse effects. Stress the importance of oral hygiene and the necessity for periodical follow-up.
- Inform the patient clearly that a diastema between the incisors will occur; (between 4 and 10mm), this will later be corrected by the orthodontic treatment after the distraction is achieved.
  Discuss the expectations of TPD-surgery with the patient.
  The patient should be advised to report any unusual changes in the midface and/or mandible region to the surgeon and should be closely monitored if an asymmetric change occurs.
- Surgi-Tec does not recommend a specific surgical procedure for a specific patient.
  The operating surgeon is responsible for choosing the appropriate transpalatal distractor for each specific case.
- Surgi-Tec advises to use only suitable Surgi-Tec screws and related Surgi-Tec instruments.
- TPD's are intended for single use and may not be reused.
  Re-use may compromise the structural integrity of the device and may create a risk of contamination due to the transmission of infectious material between patients. This could result in injury to the patient or user.
- The TPD shall be removed when no longer needed for orthodontic treatment.
  Implants that were used in a patient and removed, have to be disposed as medical waste in a dedicated container, in accordance with all local guidelines and/or your institution 's safety program.
- Asymmetric expansion of the TPD could result in corrective orthognathic surgery.
- Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of your EU member state.

Cleaning and Disinfection of Products labelled as 'non-sterile'

- All implants in the Surgi-Tec Transpalatal distractors that are delivered **'non-sterile'** must be cleaned, disinfected and sterilized before use. This also applies to the first use after delivery. All packaging must be removed before preparation.
- Thorough cleaning and disinfection are essential for effective sterilization.
- All implant components are intended for one single application in a single patient.
- It is your responsibility to ensure that the implants are completely sterile when used, to use device- and product-specific procedures for cleaning/disinfection and sterilization that are sufficiently validated, to regularly service and inspect the employed devices (disinfector, sterilizer), and to ensure that the validated and/or manufacturer's recommended parameters are maintained for each cycle.
- The statutory regulations applicable in your country and the hospital's hygiene requirements must also be observed. This applies in particular to the various instructions for effectively deactivating prions.
- Surgi-Tec has used "Neodisher MediClean forte" for the validation process of the automated cleaning and disinfection and has followed the instructions of the manufacturer (instruction Dr. Weigert). The validation was carried out according to table below.
- For the remainder of this document, please use the following definitions regarding water temperature:
  Cold water: T < 40°C
  Warm water: T > 40°C
- When selecting the disinfector, make sure that the cleaning process includes the following phases in accordance with EN ISO 15883:
- The following precleaning steps will be performed: Rinsing the test items under cold running tap water for 5 minutes; NOTE: the test items should NOT be disassembled and screwable parts should NOT be moved

Phase	Temperature	Duration	Action
Pre-rinsing	Not applicable	Soaking time *>120 sec / 2 min*	*Cold tap water* (temperature <40°C)
Cleaning cycle	Cleaning temperature - *45°C*	Soaking time > *300 sec / 5 min*	*Warm tap water* (temperature >40°C) Recommended Detergent - *Neodisher Mediclean Forte* Concentration - *0.6% (v/v)*
Cleaning cycle	Cleaning temperature - *55°C*	Soaking time > *300 sec / 5 min*	*Warm tap water* (temperature >40°C) Recommended Detergent - *Neodisher Mediclean Forte* Concentration - *0.6% (v/v)*

Post-rinsing 1	Rinsing temperature *>40°C*	Rinsing time *> 60 sec/ 1 min*	*Warm tap water* (temperature >40°C)
Post-rinsing 2	Rinsing temperature *<40°C*	Rinsing time *> 60 sec/ 1 min*	*Cold tap water* (temperature <40°C)
Thermal disinfection (A_0 value > 600)* (A_0 value > 3000)	Disinfection temperature *≥ 90°C (194°F)*	Soaking time *> 60 sec/ 1 min (A_0 value > 600)* *> 300 sec / 5 min (A_0 value > 3000)*	*With demineralized (DI water) and/or purified water; do not add additional detergent*
Drying	Drying temperature > 110°C	Drying time *> 1500 sec / 25 min**	*Drying process*
(*) Corresponds to worst case item validated			

- The information provided is based on the use of "Neodisher MediClean forte" by Dr. Weigert; validation was performed with a concentration of 0.60 % v/v at 55°C; if a different detergent is used, exposure times, concentrations and temperatures may vary; the relevant manufacturer's instructions must be observed.
- The products must be completely dried directly afterwards. It is recommended to dry the products using medical compressed air; this is especially gentle and effective. Otherwise lint-free disposable wipes (e.g. Perform classic from Schülke & Mayr) can be used. If applicable, the products have to be stored in a clean environment until they are completely dry.

Inspection

- In general sufficient cleanliness is the basic requirement for a successful sterilization. Before the products are packaged for sterilization they have to be inspected visually. (Recommendation: use working place light fixtures ideally with magnifiers).
- Check the Transpalatal distractors and accessories for after cleaning and disinfection for damages and contamination.
- For TPD modules see if all moving parts are functional by opening and closing the module.

Packaging

- Surgi-Tec recommends Single sterilization wrapping (single or double wrapping) and/or other sterilization containers can be used.

Sterilization of Products labelled as 'non sterile'

- Surgi-Tec TPD abutment plates are made of Titanium Grade 2 – DIN 3.7035
  The TPD distraction modules, osteosynthesis screws and locking screw are made of Titanium Grade 5 – DIN 3.7165
- For the sterilization process the instructions of the appropriate sterilizers have to be followed.
- All NON-STERILE products can be sterilized in an autoclave. The autoclaves must be in accordance with EN285 respectively EN13060 regarding validation, servicing, maintenance and controlling.
- Steam sterilization should be performed after the recommended cleaning, disinfection, inspection and packaging.
- Surgi-Tec recommends that sterilization is performed in accordance with following EN ISO 17665 validated process parameters
- For both initial and subsequent sterilization, the following parameters were validated by Surgi-Tec in accordance with the requirements of the current sterilization standards, EN ISO 17665 and ANSI/AAMI ST79.
- **Cycle: Pre-Vacuum (Dynamic air removal)**

Procedure	Fractionated and dynamic pre-vacuum process
Exposure time	≥ 5 minutes *(Minimum 5 minutes at 134°C)*
Temperature	Temperature ≥ 134°C
Drying time	≥ 20 minutes - 30 minutes (in autoclave chamber)

- Surgi-Tec recommends that sterilization is performed in accordance with the above validated processes. If the user utilizes other processes (e.g. flash sterilization), these must be validated by the user. The ultimate responsibility for validation of sterilization techniques and equipment lies with the user.
- The responsibility for the maintenance and qualification of the sterilization equipment used and the validation of user specific sterilization process lies with the user.
- After sterilization, the products must be stored in a dry and dust-free environment.

The maximum storage time is dependent on different factors such as the sterile barrier employed, storage manner, environmental conditions and handling.

- The user should define a maximal storage time for sterile products until use. Within this defined time the products have to be used or reprocessed again.
- Do not use hot-air sterilization, radiation sterilization, formaldehyde sterilization, ethylene oxide sterilization or substitute procedures for sterilizing thermolabile products such as plasma or peroxide sterilization for Surgi-Tec products.

These IFU and additional information can be found on the internet at www.surgi-tec.com/instructions.
The summary of safety and performance can be found in EUDAMED public website:
https://ec.europa.eu/tools/eudamed

Information related to filling of Implant card supplied with Transpalatal Distractors

- Surgi-Tec supplies Implant cards with Transpalatal distractors.
- The back side of implant card is pre-labelled with the information such as information allowing the identification of the device, including the device name, serial number, lot number, the UDI, the device model, as well as the name, address and the website of the manufacturer.
- The hospital / health Institution and healthcare professional needs to fill in the following information in the provided implant card: (Indicated by pictogram and text in the front side of Implant card)
    - Patient name
    - Date of Implantation
    - Name of Health Institution
    - Name of Healthcare professional
- The hospital / health Institution and healthcare professional must remember to provide the implant card to the end patient after the Implantation is performed.

Step-by-step procedure

Trans Palatal Distractor - TPD Neo

ATTENTION

- Preoperative planning is advised in full cooperation with the surgeon and the orthodontist.
- The accurate device can be chosen by the use of the TPD Dummies.
- Each dummy is an exact copy of its corresponding TPD. (Abutment plates and distraction module).
- Take care when presenting the dummies into the palate, to assess the mucosa thickness.

STEP 1

Corticotomies are performed as usual for surgically assisted rapid palatal expansion (SA-RPE), with transection of the median, anterior and lateral support (Fig la-d). The median support is split by a median buccal approach. Septal release is performed. Bleeding from a small artery within the osseous triangle forming the lateral nasal wall and lateral maxillary walls frequently occurs and must be treated adequately to avoid postoperative bleeding problems. The transsection can be performed with a round bur (preferably 33 mm to allow drainage into the sinus) for the lateral support, a small Lindemann bur or a smaller round bur for the anterior support, as well as with a small straight sharp osteotome for the median support. Mobilisation of the segments is done by prying motions with the osteotome (Fig ld). Control by hand if both segments show equal.

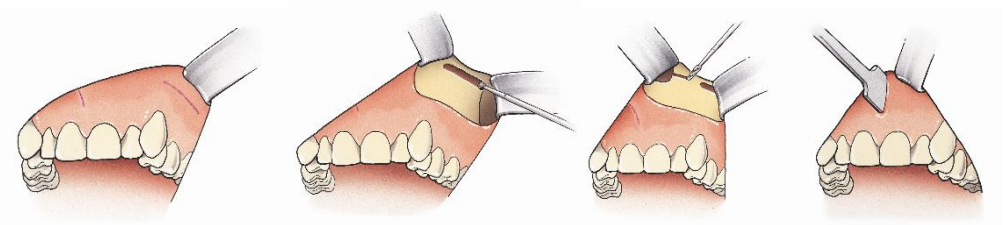

Fig 1a *Fig 1b* *Fig 1c* *Fig 1d*

STEP 2

After application of local anaesthesia with a vasoconstrictor, two incisions of 1 cm long are made in the palatal gingiva over the roots of the second premolars (3/2 expansion canine/first molar) or the first molars (parallel expansion when the pterygo-maxillary junction is also released) (Fig 2). A small relieving incision is made perpendicular to end in the middle of the first incision.

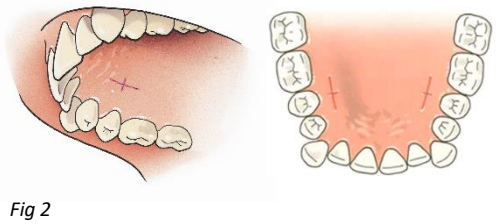

Fig 2

STEP 3

While placing the device, a suitable forceps can be used to keep the distractor in a correct position to insert a screw.
The abutment plate of the TPD Neo, marked with the character "L" (left), is placed subperiosteally, on the bone surface on the left side of the patient (Fig 3).
The abutment plate of the TPD Neo, marked with the character "R" (right), is placed on the right side of the patient.
By this way the distraction module of the TPD Neo is placed with the locking nut on the right side of the patient.

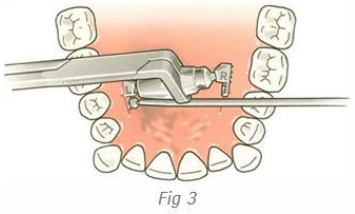

Fig 3

Caution: Both characters L (left) and R (right) need to be clearly visible while looking in the mouth.

STEP 4

Insert the first 7 mm monocortical self drilling screw of 2.0 mm diameter (Ref.70-707S), only halfway depth with the internal pentagon screwdriver insert (Ref. 99-909S) mounted in its handpiece (Ref. 99-901A) (Fig 4).
Insert the second 7mm screw only halfway depth as well.

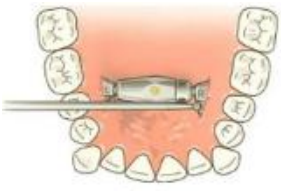

Fig4

STEP 5
Place the TPD Neo hinged key (Ref.03-751A) horizontally into the mouth of the patient and bring the head of the key over the distraction module of the TPD Neo (Fig 5a).
Alternative activation is also possible with the TPD Neo patient key (Ref. 03-750S) (Fig 5 b).
Gently push the handle of the hinged key distally to rotate the module from cranially to caudally (downwards) and activate until light pressure is obtained between the two bone surfaces.

Warning:
While placing the TPD Neo avoid at any time to try activation in opposite direction. If so, the distractor module will be blocked against the abutment plates, and this handling will cause inevitable breakage of the distraction rod.

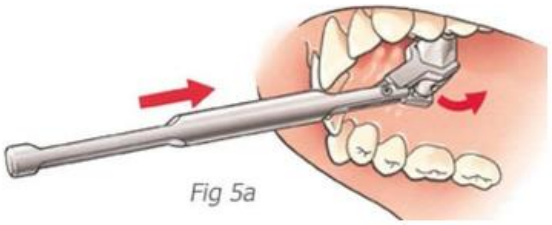
Fig 5a

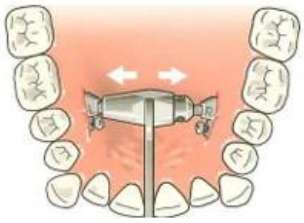
Fig 5b

STEP 6
Once the distraction module is in horizontal position, tighten rigidly
both osteosynthesis screws by using the internal pentagon screwdriver insert
(Ref. 99-909S) mounted in its handpiece (Ref. 99-901A) (Fig 6).
Activate the module until a diasteme occurs of 2 mm between the incisors
to control the opposition force.
Deactivate by means of the TPD Neo patient key (Ref. 03-750S)
in opposite way, until the incisors become on their original place and tension disappear.
One resorbable suture on the posterior incision line is a safe measure
against postoperative bleeding from the palatal branches.

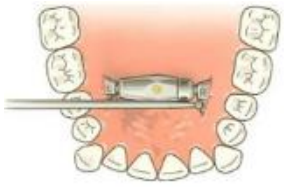
Fig 6

STEP 7
Tighten the locking nut by means of the TPD Neo patient key: (Ref. 03-750S) while holding the module by means of the TPD Neo hinged key (Ref.03-751A) (Fig 7)
Attention
Do not tighten the locking nut hardly to avoid damaging the screw-thread of TPD Neo distraction rod.

Fig 7

STEP 8
After one week latency period loosen the locking nut by means of TPD Neo patient key: (Ref. 03-750S) while holding the module by means of the TPD Neo hinged key (Ref.03-751A) (Fig 7)

STEP 9
Activation
The patient is asked to activate the TPD Neo 1/3 mm (1 colour code) once daily with the TPD Neo patient key (Ref. 03-750S) by rotating it downwards, from cranially to caudally until the next colour code appears. Colour codes are red, yellow and blue (3 colour codes = 1 full turn = 1 mm.).

Attention: use of the TPD patient key
Bring the patient key head over the module, with the handle close to the upper incisors (Fig. 8) and pull downwards until the handle touches the lower teeth.
Remove the key and repeat this procedure, if necessary, until the next color code appears.
In difficult cases (restricted mouth opening) the TPD Hinged key (Ref.03-751A) can be useful (Fig 9).

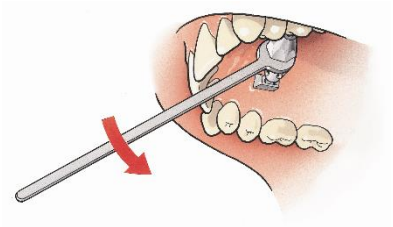

Fig 8

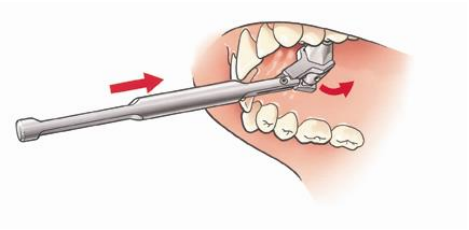

Fig 9

STEP 10 Achieved expansion period
Once the necessary expansion is achieved, the locking nut must be tightened by means of the TPD Neo patient key: (Ref. 03-750S) while holding the module by means of the TPD Neo hinged key (Ref.03-751A) (Fig 7)
Control after the first stabilization if the osteosynthesis screws are still fixed. Retightening is recommended under local anesthesia.

Attention:
Do not tighten the locking nut hardly to avoid damaging the screw-thread of TPD Neo distraction rod.

STEP 11
The consolidation period should be at least 4 months.

STEP 12 Orthodontic treatment
Arch wire appliance is needed to control a perfect dental arch and to avoid a U-shape arch phenomena.
This to control the expansion less or more anterior, or posterior.
Orthodontic treatment can start from four to six weeks after the placement of the distraction device.

STEP 13 Removal of the TPD Neo
- Apply local anesthesia.
- Unscrew the locking nut by means of TPD Neo patient key: (Ref. 03-750S) while holding the module by means of the TPD Neo hinged key (Ref.03-751A) (Fig 7)
- Unscrew a few turns, the osteosynthesis screws in the abutment plates of the TPD Neo.
- De-activate the distraction module of the TPD Neo with the of TPD Neo patient key: (Ref. 03-750S) (revolve the key upwards - from caudally to cranially) - revolve three full turns upwards.
- Remove the osteosynthesis screws and close the distraction module to complete removal.

Step-by-step procedure

Trans Palatal Distractor - TPD All-in-one

ATTENTION

- Preoperative planning is advised in full cooperation with the surgeon and the orthodontist.
- The accurate device can be chosen by the use of the TPD Dummies.
- Each dummy is an exact copy of its corresponding TPD. (Abutment plates and distraction module).
- Take care when presenting the dummies into the palate, to assess the mucosa thickness.

STEP 1

Corticotomies are performed as usual for surgically assisted rapid palatal expansion (SA-RPE), with transection of the median, anterior and lateral support (Fig la-d). The median support is split by a median buccal approach. Septal release is performed. Bleeding from a small artery within the osseous triangle forming the lateral nasal wall and lateral maxillary walls frequently occurs and must be treated adequately to avoid postoperative bleeding problems. The transsection can be performed with a round bur (preferably 33 mm to allow drainage into the sinus) for the lateral support, a small Lindemann bur or a smaller round bur for the anterior support, as well as with a small straight sharp osteotome for the median support. Mobilisation of the segments is done by prying motions with the osteotome (Fig ld). Control by hand if both segments show equal.

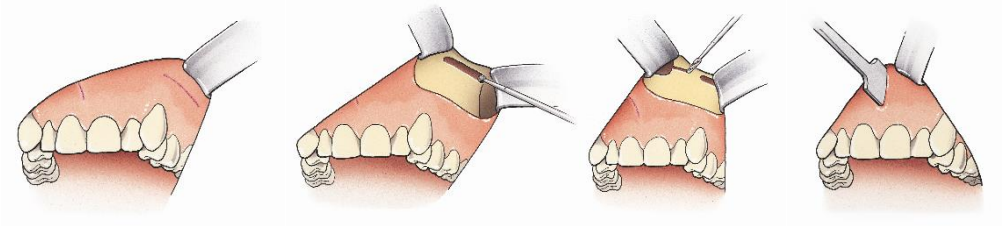

Fig 1a *Fig 1b* *Fig 1c* *Fig 1d*

STEP 2

After application of local anaesthesia with a vasoconstrictor, two incisions of 1 cm long are made in the palatal gingiva over the roots of the second premolars (3/2 expansion canine/first molar) or the first molars (parallel expansion when the pterygo-maxillary junction is also released) (Fig 2). A small relieving incision is made perpendicular to end in the middle of the first incision.

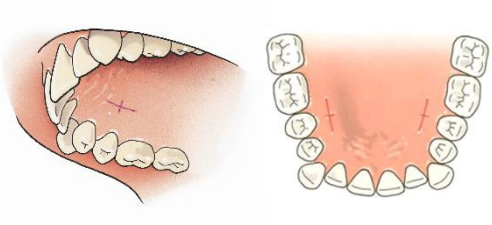

Fig 2

STEP 3

While placing the device, a suitable forceps can be used to keep the distractor in a correct position to insert a screw.
The abutment plate of the TPD All-in-one, marked with the character "L" (left), is placed subperiosteally, on the bone surface on the left side of the patient (Fig 3).
The abutment plate of the TPD All-in-one, marked with the character "R" (right), is placed on the right side of the patient.
By this way the distraction module of the TPD All-in-one is placed with the holes for the locking screw on the right side of the patient.

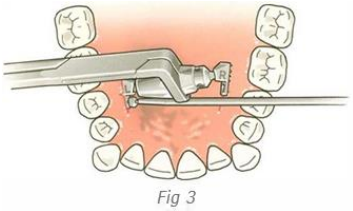

Fig 3

Caution: Both characters L (left) and R (right) need to be clearly visible while looking in the mouth.

STEP 4

Insert the first 7 mm monocortical self drilling screw of 2.0 mm diameter (Ref. 70-707S), only halfway depth with the internal pentagon screwdriver insert (Ref. 99-909S mounted in its handpiece (Ref. 99-901A) (Fig 4).
Insert the second 7mm screw only halfway depth as well.

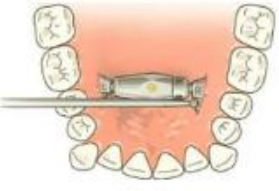

Fig4

STEP 5
Place the TPD All-in-one hinged key (Ref.03-951A) horizontally into the mouth of the patient and bring the head of the key over the distraction module of the TPD All-in-one (Fig 5a).
Alternative activation is also possible with the TPD patient key (Ref. 03-950S) (Fig 5b).
Gently push the handle of the hinged key distally to rotate the module from cranially to caudally (downwards) and activate until light pressure is obtained between the two bone surfaces.

Warning:
While placing the TPD All-In-one avoid at any time to try activation in opposite direction. If so, the distractor module will be blocked against the abutment plates, and this handling will cause inevitable breakage of the distraction rod.

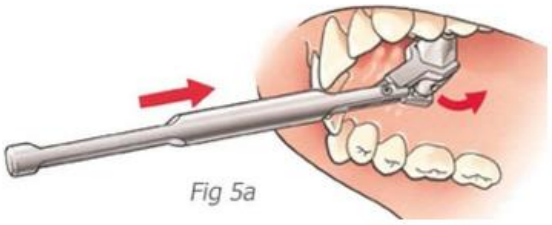
Fig 5a

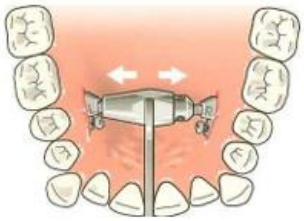
Fig 5b

STEP 6
Once the distraction module is in horizontal position, tighten rigidly both osteosynthesis screws by using the internal pentagon screwdriver insert (Ref. 99-909S) mounted in its handpiece (Ref. 99-901A) (Fig 6).
Activate the module until a diastema occurs of 2 mm between the incisors to control the opposition force.
Deactivate by means of the TPD patient key (Ref. 03-950S) in opposite way, until the incisors return to their original place and tension disappears.
One resorbable suture on the posterior incision line is a safe measure against postoperative bleeding from the palatal branches.

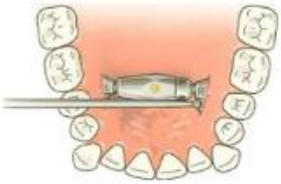
Fig 6

STEP 7
Rotate the module in a position that one of the three screwholes for the locking screw becomes visible.
Insert the locking screw (Ref. 99-100S) in the screwhole with the small screwdriver (Ref. 99-101A) or the screwdriver insert (Ref. 99-909S). Use this screwdriver to avoid damaging the screw-thread in the module (Fig 7).

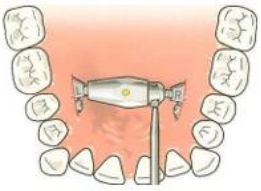
Fig 7

STEP 8
After one week latency period the locking screw (Ref. 99-100S) has to be removed by using the small screwdriver (Ref. 99-101A) or the screwdriver insert (Ref. 99-909S).

STEP 9
Activation
The patient is asked to activate the TPD All-in-one 1/3 mm (1 colour code) once daily with TPD patient key (Ref. 03-950S) by rotating it downwards, from cranially to caudally until the next colour code appears. Colour codes are red, yellow and blue (3 colour codes = 1 full turn = 1 mm.).

Attention: use of the TPD patient key
Bring the patient key head over the module, with the handle close to the upper incisors (Fig. 8) and pull downwards until the handle touches the lower teeth.
Remove the key and repeat this procedure, if necessary, until the next color code appears.
In difficult cases (restricted mouth opening) the TPD Hinged key (Ref.03-951A) can be useful (Fig 9).

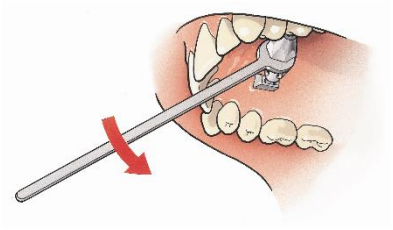

Fig 8

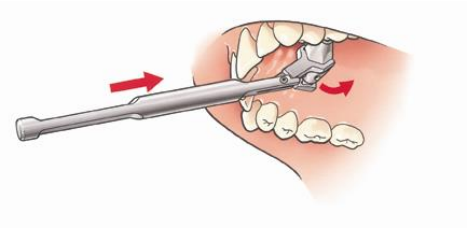

Fig 9

STEP 10 Achieved expansion period
Once the necessary expansion is achieved, the locking screw (Ref. 99-100S) must be inserted in one of the three screwholes of the TPD All-In-one module, by means of the small screwdriver (Ref. 99-101A) or the screwdriver insert (Ref. 99-909S).
Control after the first stabilization if the osteosynthesis screws are still fixed. Retightening is recommended under local anesthesia.

Attention:
Make sure that the module is opened sufficiently so that the screw hole is free for insertion of the locking screw.
Before inserting the locking screw, clean accurate the screw hole.
Do not tighten the locking screw hardly to avoid damaging the screw-thread of the TPD module. Beware to insert the locking screw if some friction occurs. In case of any friction, turn the screwdriver slowly from right to left and back until the correct entrance is found in the thread of the screw hole, and there is no friction feeling while inserting the locking screw.

STEP 11
The consolidation period should be at least 4 months.

STEP 12 Orthodontic treatment
Arch wire appliance is needed to control a perfect dental arch and to avoid a U-shape arch phenomena.
This to control the expansion less or more anterior, or posterior.
Orthodontic treatment can start from four to six weeks after the placement of the distraction device.

STEP 13 Removal of the TPD All-In-one

- Apply local anesthesia.
- Clean carefully the insert hole in the locking screw, before inserting the small screwdriver (Ref. 99-101A) or the screwdriver insert (Ref. 99-909S).
- Unscrew the locking screw (Ref. 99-100S)
- Unscrew a few turns, the osteosynthesis screws (Ref. 70-707S) in the abutment plates of the TPD All-in-one.
- Deactivate the distraction module of the TPD All-in-One with the TPD patient key (revolve the key upwards - from caudally to cranial) - revolve three full turns upwards.
- In case distraction rod is damaged by the locking screw, the rod needs to be cut.
- Remove the osteosynthesis screws (Ref. 70-707S) and close the distraction module to complete removal.

Step-by-step procedure

Trans Palatal Distractor - TPD Classic

ATTENTION

- Preoperative planning is advised in full cooperation with the surgeon and the orthodontist.
- The accurate device can be chosen by the use of the TPD Dummies.
- Each dummy is an exact copy of its corresponding TPD. (Abutment plates and distraction module).
- Take care when presenting the dummies into the palate, to assess the mucosa thickness.

STEP 1

Corticotomies are performed as usual for surgically assisted rapid palatal expansion (SA-RPE), with transsection of the median, anterior and lateral support (Fig 1a-d). The median support is split by a median buccal approach. Septal release is only performed in unilateral expansion. Bleeding from a small artery within the osseous triangle forming the lateral nasal wall and lateral maxillary walls frequently occurs and must be treated adequately to avoid postoperative bleeding problems. The transsection can be performed with a round bur (preferably 33 mm to allow drainage into the sinus) for the lateral support, a small Lindemann bur or a smaller round bur for the anterior support, a 1 cm wide sharp osteotome for the median support. Mobilization of the segments is done by prying motions with the 1 cm wide osteotome (Fig 1d). Control by hand if both segments show equal.

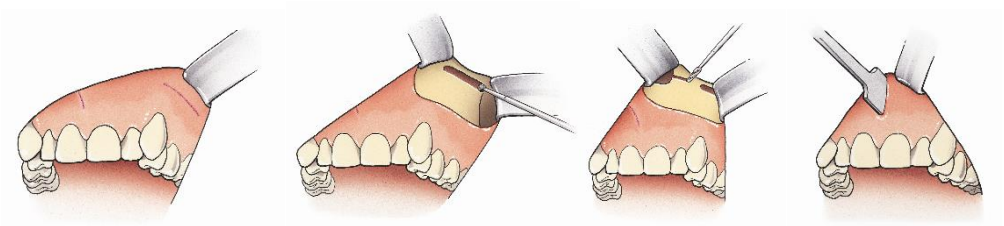

Fig 1a *Fig 1b* *Fig 1c* *Fig 1d*

STEP 2

After application of local anaesthesia with a vasoconstrictor, two incisions of 1 cm long are made in the palatal gingiva over the roots of the second premolars (3/2 expansion canine/first molar) or the first molars (parallel expansion when the pterygo-maxillary junction is also released) (Fig 2). A small relieving incision is made perpendicular to end in the middle of the first incision.

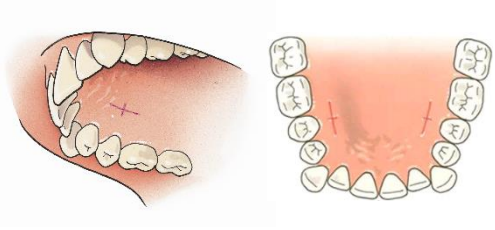

Fig 2

STEP 3

The abutment plates (Ref.03-800A) are placed subperiosteally, on the bone surface (Fig 3). Care should be taken to place the plates high enough, horizontally and opposite to each other. Be aware that the abutment plates are marked left (L) and right (R). The plates are fixed with 7 mm monocortical self-drilling screws of 2,0 mm diameter (Ref.70-707S) (Fig 4).

Caution: Both characters L (left) and R (right) need to be clearly visible while looking in the mouth.

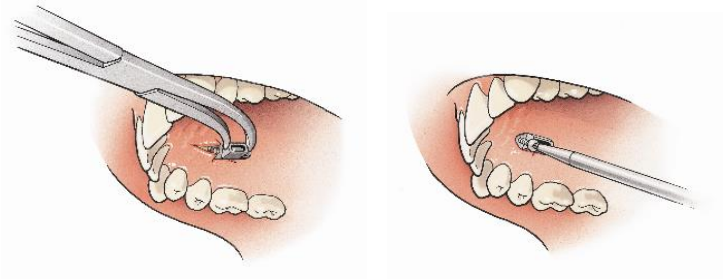

Fig 3 *Fig 4*

STEP 4
One resorbable suture on the posterior incision line is a safe measure against postoperative bleeding from the palatal branches (Fig 5).

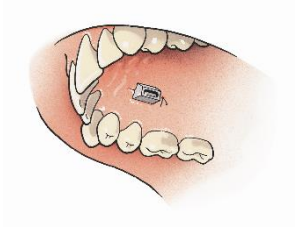

Fig 5

STEP 5
Placement requires some prying of the bone segments and adjusting of the width of the module (Fig. 6). The module should be placed such that expansion will occur when the patient rotates the patient key (Ref. 03-905S) from cranially to caudally. This means with the holes for the locking screw to the right. Insert the locking screw (Ref. 99-100S) in the screwhole with the small screwdriver (Ref. 99-101A) or the screwdriver insert (Ref. 99-909S). Use this screwdriver to avoid damaging the screw-thread in the module (Fig 7).

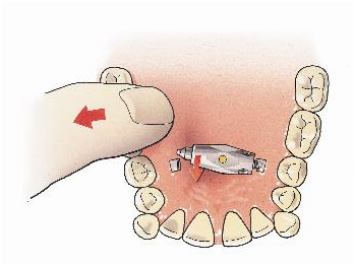

Fig 6

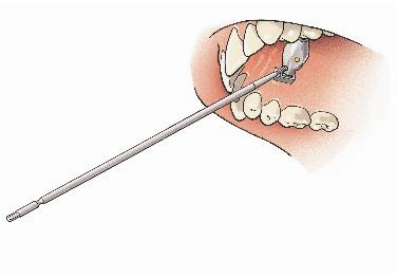

Fig 7

Attention
The module is preferably fixed bilaterally to the bicuspids with a fine titanium ligature for safety reasons. Small holes are for that purpose provided in the distraction rod (Fig 8).

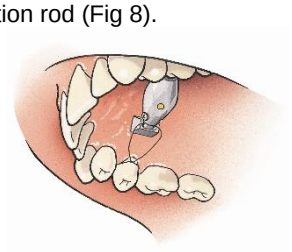

Fig 8

STEP 6
After one week latency period the locking screw (Ref. 99-100S) has to be removed by using the small screwdriver (Ref. 99-101A) or the screwdriver insert (Ref. 99-909S).

STEP 7 Activation
The patient is asked to activate the TPD 1/3 mm (1 colour code) once daily with the TPD patient key (Ref.03-950S) by turning it downwards until the next colour code appears. Colour codes are red, yellow and blue (3 colour codes = 1 full turn = 1 mm).

Attention: use of the TPD patient key
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Remove the key and repeat this procedure, if necessary, until the next color code appears.
In difficult cases (restricted mouth opening) the TPD Hinged key (Ref.03-951A) can be useful (Fig 10).

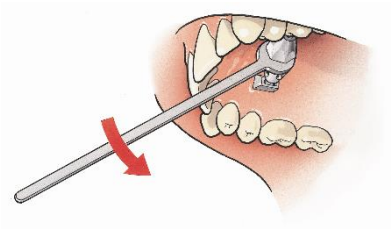


Fig 9

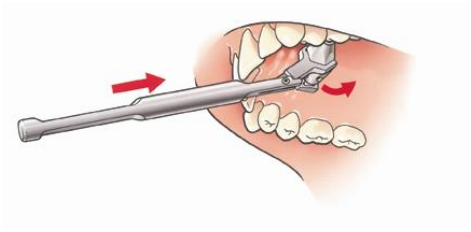


Fig 10

STEP 8
The module can easily be exchanged for a larger model when this seems necessary

STEP 9 Achieved expansion period
Once the necessary expansion is achieved, the locking screw (Ref. 99-100S) must be inserted in one of the three screwholes of the TPD Classic module, by means of the small screwdriver (Ref. 99-101A) or the screwdriver insert (Ref. 99-909S).
Control after the first stabilization if the osteosynthesis screws are still fixed. Retightening is recommended under local anesthesia.

Attention:
Make sure that the module is opened sufficiently so that the screw hole is free for insertion of the locking screw.
Before inserting the locking screw, clean accurate the screw hole.
Do not tighten the locking screw hardly to avoid damaging the screw-thread of TPD module. Beware to insert the locking screw if some friction occurs. In case of any friction, turn the screwdriver slowly from right to left and back until the correct entrance is found in the thread of the screw hole, and there is no friction feeling while inserting the locking screw.

STEP 10
The consolidation period should be at least 4 months.

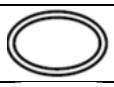
STEP 11 Orthodontic treatment
Arch wire appliance is needed to control a perfect dental arch and to avoid a U-shape arch phenomena.
This to control the expansion less or more anterior, or posterior.
Orthodontic treatment can start from four to six weeks after the placement of the distraction device.

STEP 12 Removal of the TPD:

- Apply local anesthesia.
- Clean carefully the insert hole in the locking screw, before inserting the small screwdriver (Ref. 99-101A) or the screwdriver insert (Ref. 99-909S).
- Unscrew the locking screw (Ref. 99-100S).
- De-activate the distraction module of the TPD Classic with the TPD patient key (Ref.03-950S) and remove the module .
- In case distraction rod is damaged by the locking screw, the rod needs to be cut.
- Unscrew the osteosynthesis screws (Ref.70-707S) and remove the abutment plates (Ref.03-800A).

ENGLISH	THESE INSTRUCTIONS FOR USE MUST BE READ CAREFULLY PRIOR TO CLINICAL USE	***ENGLISH***

Explanation of symbols:

	Please observe instructions for use
	Caution
	Do Not Re-use
	Reference number
	Lot number
	Manufacturer
	Non sterile product
	Do not use if package is damaged
	Medical device
	Unique device identifier
	Sterilized using irradiation
	Use-by date
	Double sterile barrier system
	Patient identification (Patient name)(*)
	Patient information website(*)
	Healthcare centre or doctor(*)
	Date (Date of implantation)(*)

(*) Symbols are part of implant card provided with Transpalatal distractors by manufacturer.

CE
1639

Medical device Class II.b

BASIC UDI-DI : 540700775DISEQ

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