

TPD – All-In-One

ENGLISH

ALL OF THESE INSTRUCTIONS FOR USE MUST BE

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READ CAREFULLY PRIOR TO CLINICAL USE

General

Surgically assisted rapid palatal expansion (SA-RPE) is an established technique to correct maxillary constriction, buccal cross-bite (unilateral or bilateral), anterior crowding and buccal corridors in adult patients.

Using a TPD All-in-One distraction device in the maxilla is tissue-friendly, since it is entirely made of titanium.

Material information

Surgi-Tec TPD All-in-One abutment plates are made of Titanium Grade 2 – Astm F-65, ISO 5832-2.

Surgi-Tec TPD All-in-One distraction modules, osteosynthesis screws and blocking screw are made of Titanium Grade 5 – TiAl6V4 (ELI) Astm F 136, ISO 5832-3. Both materials are biocompatible, corrosion-resistant and non-toxic in the biological environment, and produce negligible artifacts by X ray, CT and MRI.

Indications

Often a too narrow upper jaw creates problems such as tooth crowding, a cross-bite and mouth-breathing. Tooth extractions can make place for the remaining teeth, but may lead to a dish-in, prematurely aged face. A smile showing a wide dental arch, with little space between the cheek and the teeth, is more attractive. "Trans Palatal Distraction" is a 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. Due to this bone born technique the maxilla regains its initial strength after the widening. In this way, the cross-bite is corrected and the space that is created between the central incisors is used to align other teeth. It is recommended to inform the patient that a space between the incisors will occur. (Between 4mm and 10mm). After bone regeneration, due to distraction Osteogenesis, all teeth will be gently aligned by orthodontic treatment.

General contra indications

If the space between the right and left palatal crests is less than 15,5 mm, it is impossible to place a TPD All-In-One device. Patients who suffer from periodontal diseases need to be treated before treatment with bone-borne appliances. Do not use a TPD All-In-One device if the patient has a history of immune deficiency, steroid therapy, problems with blood clotting, uncontrolled endocrinological disease, rheumatic disease, and bone disease, cirrhosis of the liver or any other systemic or acute disease. A TPD All-In-One device must not be used if the patient has an active infection, a metal allergy, foreign body sensitivity, limited blood supply or insufficient quality of bone, unstable physical and/or if the patient has mental or neurological conditions, is severely non-compliant, and is unwilling or incapable of following postoperative care instructions. Treatment is not recommended if the patient suffers from psychological problems such as depressions or other types of psychopathologies.

Local contra-indications

A TPD All-in-One device must not be used if the patient suffers from osteomyelitis, receives radiotherapy of the head, has gingival or periodontal disease, diabetic problems or unsatisfactory oral hygiene. Furthermore, a TPD All-In-One device must not be used if there is insufficient bone structure or possible bone defects in the area in which the device has to be inserted.

Possible system adverse effects

- In many cases, adverse results may be clinical related other than implant related.
- Bone necrosis, osteoporosis, inhibited revascularization, bone resorption, and poor bone formation can cause premature loss of the osteosynthesis screws (ref.70-707S) in the TPD All-in-One abutment plates.
- Loosening of the TPD All-in-One abutment plates in healthy bone environment can be due to insecure tightening of the Osteosynthesis screws (ref. 70-707S).
- Metal sensitivities or allergic reaction.
- Nerve damage due to surgical trauma.
- Early or late infection, both deep and/or superficial.

Warnings and precautions

Responsibility for proper selection of patients, adequate training, experience in the choice and placement of the TPD All-in-One device and the decision to leave or remove the device postoperatively, rests with the clinician.

- TPD All-in-One devices are designed for single use only.
- TPD All-in-One devices may only be placed by oral, maxillo facial and facial surgeons.

The user (surgeon) must ensure to have read and understood the instructions for use supplied with the product.

Only original TPD All-in-One devices and components may be used according to the instructions for use.

Each patient must be examined and informed about the TPD All-in-One devices before use.

Once applied, the product may never be re-used. Although it may appear undamaged, previous stresses may have created imperfections, which reduce its function. The screw-tread of the internal rod (in the TPD All-in-One distraction module), could be damaged by the blocking screw (ref. 99-100S).

Operation warnings and precautions

- Responsibility for proper selection of patients, adequate training, experience in the choice and in the placement of the TPD All-in-One device.
- Choose carefully, before the intervention, the maximum or widest insertable TPD All-in-One device by using the TPD dummies, in order not to lose widening distance.
- Pay attention on the mucosa thickness by measuring the broad of the palatal with TPD dummies.
- Choose an adequate technique to perform the osteotomies.
- Inform the patient clearly that a diasteme between the incisors will occur (4 to 10mm). This will later be corrected by the orthodontic treatment.

- Do not start to expand any TPD All-in-One distraction module before placement.
- The surgeon should discuss the expectations of surgery inherent in the use of the product with the patient. Particular attention should be given to a discussion on post-operative soft diet and the necessity for periodical follow-up.
- The performance for the SA-RPE belongs to the attended surgeon in the decision of lateral or unilateral widening.
- The correct selection of the TPD All-in-One device is important. The TPD All-in-One should be placed in the correct anatomic location, with precautions to avoid root damaging by inserting the osteosynthesis screws in the abutment plates.
- Do not perform drilling; the packing contains 2 self drilling Osteosynthesis (ref. 70-707S) screws and one blocking screw (ref.99-100S).
- The patient should be advised to report any unusual changes in the palatal region to the surgeon. The patient should be closely monitored if an asymmetric change occurs.
- Respect the latency period of 5 to 7 days before starting distraction.
- Avoid over expanding by activating more than 2 colour codes daily.

TPD All-In-One NON- STERILE Packing

A TPD All-In-One package contains one TPD All-in-One device, two self drilling osteosynthesis screws and one blocking screw. TPD All-in-one devices are delivered in non-sterile double see through pack and have to be sterilized before use. Before using the product, be sure to check the packaging for integrity.

Cleaning and Sterilization

Sterilization must be carried out according to a validated steam sterilization process. The responsibility for proper cleaning, disinfection and sterilization of implant components lies with the operator or productuser. Be sure to observe all local regulations (including potential restrictions).

Removal of the TPD All-in-one

- Apply local anesthesia
- Clean carefully the insert hole in the blocking screw, before inserting the small screwdriver (Ref. 99-101A) and unscrew the blocking screw (Ref. 99-100S)
- Unscrew a few turns, the osteosynthesis screws (Ref 70-707S) in the abutment plates of the TPD All-in-one device. De-activate the distraction module of the TPD All-in-one with the patient key (Ref 03-950S), revolve the key upwards – from caudally to cranial -, revolve three full turns upwards
- Remove the osteosynthesis screws (Ref 70-707S) and revolve the distraction module to complete removal
- In case distraction rod is damaged by the blocking screw, the rod need to be cut

Implant / Device Removal

Dispose the removed device with medical waste only. Dispose of the used implant / device in a special container, in accordance with all local guidelines and/or your institution 's safety program.

Explanation of symbols



Please observe instructions for use



Do Not Re-use



Reference number



Lot number



Manufacturer



Not sterile product



Do not use if package is damaged

DECLARATION OF CONFORMITY



Medical device Class II.b

We, SURGI-TEC, hereby declare that the medical device "TPD All-in-one" is complying with the European Directive 93/42/EEC concerning medical devices.

SNCH, notified body N° 0499, issued the full quality assurance system approval certificate N° L9942577-XX.

MANUFACTURED BY

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