TPD Classic

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

General
Surgically assisted rapid palatal expansion (SA-RPE) is an established technique to correct maxillary constriction, bucal cross-bite (unilateral or bilateral), anterior crowding and bucal 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 Classic abutment plates are made of Titanium Grade 2 – Astm F-65, ISO 5832-2.
Surgi-Tec TPD Classic 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 artefacts 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 dished-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
Patients who suffer from periodontal diseases need to be treated before treatment with bone-borne appliances. If the space between the right and left palatal crests is less then 15,5 mm, it is impossible to place a TPD Classic device. Do not use a TPD Classic 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 Classic 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 Classic 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 Classic device must not be used if there is insufficient bone structure or possible bone defects in the area in which the devise 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 of osteosynthesis screws (ref.70-707S) in the TPD Classic abutment plates.
- Loosening of the TPD Classic abutment plates in healthy bone environment is a result of insecure tightening of the osteosynthesis screws (ref. 70-707S).
- Loosing the TPD Classic distraction module due to non-insertion or incorrect inserting of the blocking screw (ref. 99-100S).
- 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 Classic device and the decision to leave or remove the device postoperatively, rests with the clinician.
- TPD Classic devices are designed for single use only.
- TPD Classic 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 Classic devices and components may be used according to the instructions for use. Each patient must be examined and informed about the TPD Classic 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 Classic distraction module), could be damaged by the blocking screw (ref. 99-100S).Surgi-Tec guarantees the TPD Classic devices in their undamaged, original packaging only.

Operation warnings and precautions
- Responsibility for proper selection of patients, adequate training, experience in the choice and in the placement of the TPD Classic device.
- Choose carefully, before the intervention, the maximum or widest insert able TPD Classic distraction module in order not to loose widening distance.
- 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 Classic 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 systematic follow-up.
- The performance for the SA-RPE belongs to the attended surgeon in the decision of bilateral or unilateral widening.
- The correct selection of the TPD Classic device is important. The TPD Classic device should be placed in the correct anatomic location, with precautions to fix the abutment plates avoiding root damaging by inserting the osteosynthesis screws.
- Do not perform drilling; the packing contains 2 self drilling osteosynthesis screws (ref. 70-707S) and one blocking screw (ref.99-100S).
- Loosing the TPD Classic distraction module due to not using the fine titanium ligature to the bicuspids.
- The patient should be advised to report any unusual changes in the palatal region to the surgeon. The patient should be closely monitored if any 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 Classic NON-STERILE packing

TPD Classic 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 restrisctions).

Removal of the TPD Classic

- Apply local anesthesia
- Clean carefully the insert hole in the blocking screw, before inserting the small screwdriver (Ref. 99-101A)
- Unscrew the blocking scew (Ref. 99-100S)
- De-activate the distraction module of the TPD classic with the patient key (Ref 03-950S) and remove
- Unscrew the osteosynthesis screws (Ref 70-707S) and remove the abutment plates (Ref 03-800A)
- 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

CE 0499

Medical device Class II.b

We, SURGI-TEC, hereby declare that the medical device “TPD Classic” 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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