TPD NEO

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 NEO distraction device in the maxilla is tissue-friendly, since it is entirely made of titanium.

Material information

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

If the space between the right and left palatal crests is less then 15,5 mm, it is impossible to place a TPD NEO device. Patients who suffer from periodontal diseases need to be treated before treatment with bone-borne appliances. Do not use a TPD NEO 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 NEO 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 NEO 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 NEO 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 NEO abutment plates.
- Loosening of the TPD NEO abutment plates in healthy bone environment can by 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 NEO device and the decision to leave or remove the device postoperatively, rests with the clinician.

- TPD NEO devices are designed for single use only.
- TPD NEO 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 NEO devices and components may be used according to the instructions for use.
Each patient must be examined and informed about the TPD NEO 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.

Operation warnings and precautions

- Responsibility for proper selection of patients, adequate training, experience in the choice and in the placement of the TPD NEO device.
- Choose carefully, before the intervention, the maximum or widest insert able TPD NEO device by using the TPD dummies, in order not to loose 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 NEO 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 NEO device is important. The TPD NEO 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
- 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 markings daily.

TPD NEO NON- STERILE Packing

A TPD NEO package contains one TPD NEO device and two self drilling osteosynthesis screws. TPD NEO 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 product-user. Be sure to observe all local regulations (including potential restrictions).

Removal of the TPD NEO

- Apply local anesthesia
- Unscrew the integrated blocking nut of the TPD NEO.
- Unscrew a few turns, the osteosynthesis screws (Ref 70-707S) in the abutment plates of the TPD NEO device. De-activate the distraction module of the TPD NEO with the patient key (Ref 03-750S), 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

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 NEO” 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

“SURGI-TEC”
Poortakkerstraat 43
9051 SINT-DENIJS-WESTERM – BELGIUM
www.surgi-tec.com