TMD
TRANSMANDIBULAR DISTRACTORS

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

Intended use
"Trans Mandibular Distraction" is a technique by which the lower jaw is surgically splitted in the midline area and widened by an expansion device that is fixed on the chin bone. It is exposed between the lower lip and the front teeth. The jaw regains its initial strength after consolidation of the widened segment. The space that is created between the incisors is used to correct the transversal deficiency and to achieve the teeth alignment.
"Trans Mandibular distraction" is most frequently accompanied by "Trans Palatal Distraction".

Indications
Transmandibular distraction needed for:
- The correction of transversal deficiency
- Achieving teeth alignment

Contra indications
- 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 TMD
- 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 TMD must not be used if the patient receives radiotherapy of the head
- Patients with gingival and periodontal diseases

Possible adverse effects
- Loosening of the implant from loosening of the screws or screw failure.
- Hypersensitivity to metal or allergic reactions.
- Soft tissue irritation and/or nerve damage through surgical trauma.
- Early or late infection, both superficial and deep.
- Elevated fibrotic tissue reaction around the surgical area.
- Postsurgical swelling.
- Oral hygiene problems.
- Difficult removal due to bone overgrowth
- Asymmetric expansion, teeth damage.
- Morbidities related to orthognathic surgery: postoperative haemorrhage frequent maxillary sinusitis, condylar resorption, TMJ problems, instable maxilla, tight intraoral scar, phonetic problems, obstruction of lacrimal canal after maxillary osteotomy, nasal bleeding, prolonged fatigue or pain postoperatively, false aneurysms and arteriovenous fistulas

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 are already cleaned and delivered in non-sterile see-through pouches. They only have to be sterilized in their original packaging before use.
- TMD's may only be used by medical personnel who hold the correct professional qualifications and are familiarised 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
- Respect the latency period of 5 to 7 days before starting distraction
- 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 diasteme 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 TMD-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 TMD for each specific case.
- Surgi-Tec advises to use only suitable Surgi-Tec screws and related Surgi-Tec instruments

- TMD'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 TMD's 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

Sterilization

- Surgi-Tec TMD fixation plates are made of Titanium Grade 2 – DIN 3.7035, the TMD distraction screws are made of Titanium Grade 5 – DIN 3.7165..
- TMD's are appropriately medically cleaned by Surgi-Tec according to a validated procedure and are delivered in non-sterile see-through pouches ready to be steam sterilized in the hospital. The devices do not have to be unpacked and cleaned. They can be sterilised in their original packaging. The labels were printed for this purpose using appropriate ink. In this way, traceability can always be guaranteed.
- The steam autoclaves must be in accordance with EN285 respectively EN13060 regarding validation, servicing, maintenance and control
- Surgi-Tec recommends that sterilization is performed in accordance with following EN ISO 17665 validated process parameters
  -Cycle: Pre-Vacuum (Dynamic air removal)
  -Temperature: 134°C - 137°C
  -Exposure time: minimum 3 minutes
  -Drying time: 30 minutes (in autoclave chamber)
- 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

These IFU and additional information can be found on the internet at www.surgi-tec.com

Step-by-step procedure
Trans Mandibular Distractor - TMD

STEP 1
A horizontal labial sulcus incision of 15 mm width exposes the symphysial surface (Fig. 1). Subperiostial dissection is performed in the midline, between the mentalis muscles.
The mentalis muscles are not transsected (Fig 2)

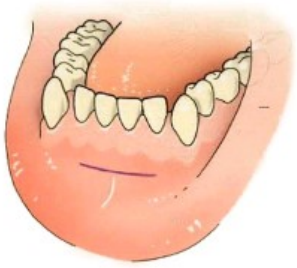

Fig 1

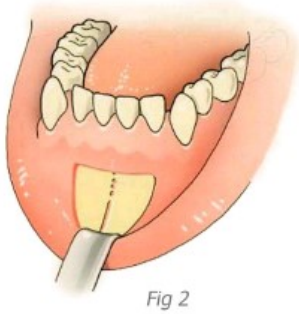

Fig 2

STEP 2
The Trans Mandibular Distractor with the fixing plate is adjusted on the exposed area and positioned close to the fixed gingiva but not to touch it

Attention:
Do not remove the TMD fixation plate attaching the holes 1 and 4 (Fig 3).
Start first to drill bi-cortical through the middle hole 5 of the base plate and insert the 9 mm screw and tighten sufficiently. Adjust correct the device on a level with the occlusion (Fig 4).
Perform drilling bi-cortical through the holes 2, 3 and 6 of the base plate. Remove the 9mm screw, and take away the Trans Mandibular Distraction device

Attention:
While drilling, the hand piece should be directed perpendicular to the beveled surface of the base plate

Fig 3

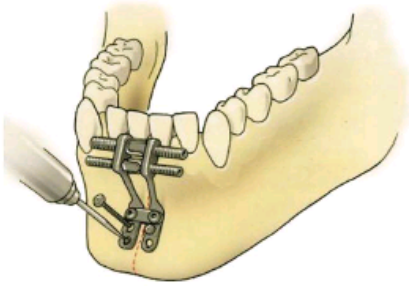

Fig 4

STEP 3
The splitting is then performed with a reciprocating saw in the chin region. (A Piezzo machine is recommended).
In the apical region, cortical perforations are performed with a small round bur (Fig.2).
An osteotome connects them with gentle tapping and is wedged between the roots. The lingual cortex is transected with the reciprocating saw, that can be entered safely now in the interdental osteotomy gap. Care is taken not to tear or even to dissect the fixed gingiva

STEP 4
Once the mandible is splitted, the TMD device is placed faced to the previously drilled holes 2, 3 and 5 still with the TMD fixing plate on place. Insert the 13 mm screws in the middle holes 2 and 5, followed by insertion of 11 mm screws into the lower holes 3 and 6.
Control the correct leveling and tighten firmly the screws. Unscrew 1 and 4, remove the fixation plate on the base plate of the device.
Drill mono-cortically through the holes 1 and 4; insert firmly the 9 mm screws. (Fig. 5)

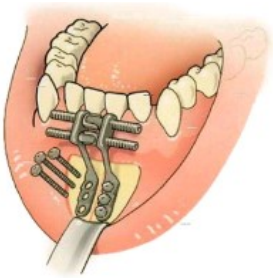

Fig 5

STEP 5
The incision is closed with resorbable sutures (Fig. 6)

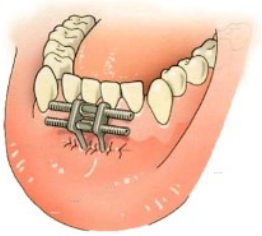

Fig 6

STEP 6
Do not start to activate the TMD before the latency period of one week

STEP 7 Activation
Activation with TMD Patient key (Ref 06-950A) starts by the surgeon one week later and continues daily by the patient himself. By young children, it is recomended to start the activation after 5 days. The recommended rate is only half a turn (0.5 mm) on the upper screw and half a turn on the lower screw each day with the supplied Patient key (1 full turn = 1mm) (Fig 7). The TMD Patient key (Ref 06-950A) can be used at both sides.
Both distraction cardan screws need to be activated in the same direction: counter clockwise if activated on the left side of the patient, and clockwise if activated on the right side of the patient.
Towards the end of the distraction, malocclusion or angulated mandible can be corrected by rotating the lower screw more than the upper one (or vice-versa). This procedure is enabled by the cardan joints in the screws

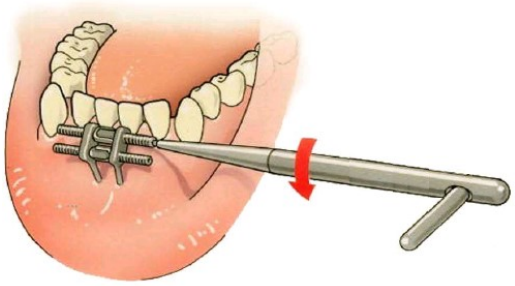

Fig 7

STEP 8 Achieved expansion period
Towards the end of the activation, check carefully the occlusion. The occlusion can be corrected by activating or deactivating the lower cardan screw of the device more than the upper cardan screw. Pay attention by making use of the Trans Mandibular Distractor, that during the widening, there also will occur an advancement of the mandible, ranging from 2 to 3mm

STEP 9
The consolidation period should be at least 4 months

STEP 10 Orthodontic treatment
Placing the brackets before the surgery is recommended, to activate distalisation effect obtaining a diastema of 1 - 2 mm between the central incisors prior to the operation. This will prevent iatrogenic damage to the central teeth or sockets during the splitting of the mandible.
Legating 31 and 32, and also the 41 and the 42 to avoid a drifting phenomena. Orthodontic alignment can start 6 weeks or longer after the end of activation

STEP 11 Removal of the Trans Mandibular Device
- Apply local anesthesia.
- Unscrew a few turns, the osteosynthesis screws in the base plates of the TMD
- Deactivate slightly the cardan screws of the TMD device with the TMD Patient key (Ref 06-950A)
- Remove the osteosynthesis screws and the TMD

Explanation of symbols

 Please observe instructions for use

 Do Not Re-use

 Reference number

 Lot number

 Manufacturer

 Non sterile product

 Do not use if package is damaged

 Medical device

 Unique device identifier

CE
1639

Medical device Class II.b

BASIC UDI-DI : 540700775DISEQ

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