OBA
ORTHODONTIC BONE ANCHORS (OBA Surgi-Tec and OBA Mommaerts)

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

Intended use
Orthodontic bone anchors are implanted in the anterior or posterior region of the upper and/or lower jaw to serve as a temporary intramucosal skeletal anchor for orthodontic treatment.
OBA's consists of a base-plate fixed with monocortical mini screws, a neck piercing the gingiva or mucous membrane and a coronal part with at the end round bars, hooks, tubes or brackets as fixation unit to exercise traction by means of orthodontic conventional orthodontic tools, such as elastic bands and chains, tension and compression springs and orthodontic arch wires.
Different models accommodate specific anatomical conditions.
Known biomechanical principles apply, OBAs are an alternative for extraoral anchorage

Indications
Skeletal anchor point used in orthodontic procedure to correct:
- Molar distalization
- Dental malocclusions, open bite
- Dental crowding without extracting teeth
- Tilted molars (up righting)
- Dental Intrusion, protrusion, diastema closure
- Maxillary protraction

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 mandibular or maxillar bone quality to attach the anchor
- Patients with a history of immune deficiency, steroid therapy, problems with blood clotting, uncontrolled endocrinological disease, rheumatic disease, bone disease, diabetic problems or any other systemic or acute disease
- Patients with gingival or periodontal disease
- Patients who are incapacitated and/or uncooperative during the treatment phase
- Patients suffering from unsatisfactory oral hygiene
- The OBA must not be used if the patient receives radiotherapy of the head

Possible adverse effects
- Loosening of the orthodontic bone anchors from loosening of screws or screw failure
- Hypersensitivity to metal or allergic reactions
- 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
- Difficult removal due to bone overgrowth
- Postsurgical swelling
- Morbidities related to orthognathic surgery: postoperative haemmorhage, 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
- Orthodontic bone anchors 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 treatment protocols for patients who are on anticoagulant, antiplatelet or aspirin therapy
- Treatment group: adults and children, but a surgeon must always rely on his/her clinical judgement when deciding whether to use a particular product when treating a particular patient
- Inform the patient regarding the possible adverse effects. Stress the importance of oral hygiene
- Surgi-Tec does not recommend a specific surgical procedure for a specific patient
  The operating surgeon is responsible for choosing the appropriate orthodontic bone anchors for each specific case.
- Surgi-Tec advises to use only suitable Surgi-Tec screws and related Surgi-Tec instruments
  Repeatedly bending the anchor in opposite directions may cause the anchor to break during surgery or during orthodontic treatment.

- Orthodontic bone anchors 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 bone anchors 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

- OBA's are made of Titanium Grade 2 – DIN 3.7035
- The orthodontic bone anchors 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
Orthodontic Bone Anchors - Maxilla

ATTENTION

- Preoperative planning and choice of the accurate bone anchor is advised in full cooperation with the surgeon and the orthodontist

STEP 1
A U-shaped incision is made in the maxilla. A vertical incision is made ± 1 cm mesial from and parallel to the infra-zygomatic crest, a horizontal incision 2 mm below the muco-gingival border, and vertical incision upwards ± 1 cm to the infra-zygomatic crest (Fig. 1)

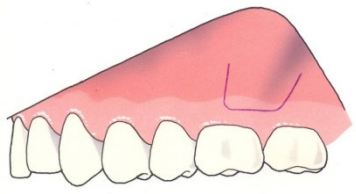

Fig. 1

STEP 2
A superior based muco-periostial flap is made for bone exposure (Fig. 2)

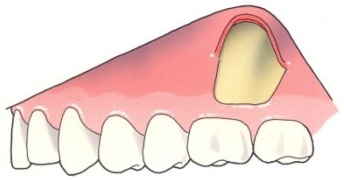

Fig. 2

STEP 3
The bone anchor is positioned on the zygomatic buttress, the neck of the anchor penetrates the soft tissues exactly in the lower incision (2 mm below the muco-gingival border)
Caution
The lowest part of the outcoming orthodontic bone anchor can be ± 1 mm above the bracket in place

STEP 4
The anchor plate may be pre-bent carefully to obtain an optimal contact between the plate and the cortical bone. The bending is limited between the upper and lower hole. Insert the first selfdrilling screw (Surgi-Tec recommends 5 mm length, Ø 2.0 mm, ref. 70-505S) in the middle hole, but do not tighten this first screw completely in order to allow some rotation of the anchor. Insert the second selfdrilling screw in the upper hole (Surgi-Tec recommends 7 mm length, Ø 2.0 mm, ref. 70-507S). Insert the third selfdrilling screw in the lower hole (Surgi-Tec recommends 5 mm length, Ø 2.0 mm, ref. 70-505S) (Fig.3).

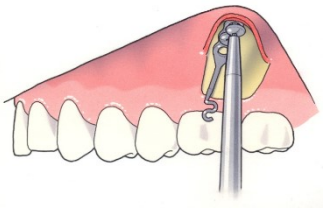

Fig. 3

STEP 5
Tighten all screws. The position of the anchor and the screws with respect to the dental root is shown in Fig. 4.

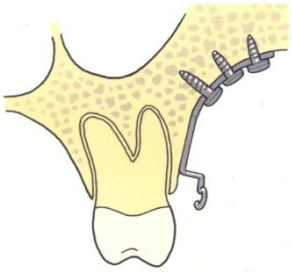

Fig. 4

STEP 6
The final result is shown in Fig. 5, the anchor hook penetrates through the gingiva and is ready for the orthodontic treatment.

STEP 7
Remove the Orthodontic Bone Anchor when no longer needed for orthodontic treatment.

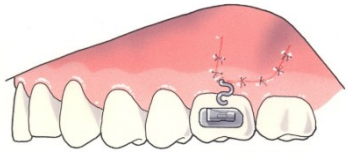

Fig. 5

Step-by-step procedure

Orthodontic Bone Anchors - Mandible

ATTENTION

- Preoperative planning and choice of the accurate bone anchor is advised in full cooperation with the surgeon and the orthodontist

STEP 1
In the mandible a horizontal incision is made into the attached gingiva (2 mm above the mucogingival border) with downwards extensions in the mucosa mesial and distal (Fig. 1)

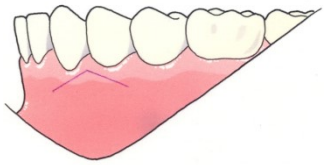

Fig. 1

STEP 2
An inferior based flap is made for bone exposure (Fig. 2)

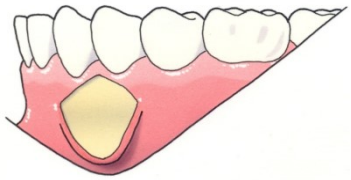

Fig. 2

STEP 3
The bone anchor is positioned between the roots of 2 adjacent teeth. The neck of the anchor should penetrate the soft tissues exactly at the horizontal incision and 2 mm above the muco-gingival border throughout the attached gingiva

Caution
The highest part of the outcoming orthodontic bone anchor can be ± 1 mm below the bracket in place.

STEP 4
The anchor plate may be pre-bent carefully to obtain an optimal contact between the plate and the cortical bone. The bending is limited between the upper and lower hole. Insert the first selfdrilling screw (Surgi-Tec recommends 5 mm length, Ø 2.0 mm, ref. 70-505S) into the upper hole of the anchor but do not completely tighten to allow some rotation of the anchor. The second selfdrilling screw is inserted (Surgi-Tec recommends 5 or 7 mm length, Ø 2.0 mm, ref. 70-505S or 70-507S) (Fig. 3)

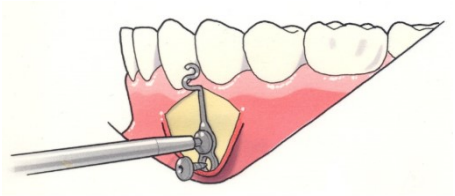

Fig. 3

STEP 5
Tighten all screws.

STEP 6
The final result is shown in Fig. 4, the anchor hook penetrates through the gingiva and is ready for the orthodontic treatment

STEP 7
Remove the Orthodontic Bone Anchor when no longer needed for orthodontic treatment.

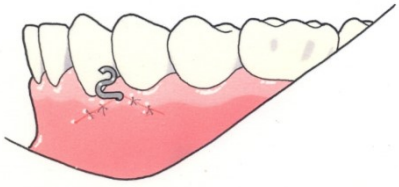

Fig. 4

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: 540700775OBAEN

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