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

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

Intended use
Ortho bone anchors are implanted in the anterior or posterior region of the upper and/or lower jaw to serve as a the 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 ortho bone anchors from insufficient fixation 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 delivered in non-sterile see through pouches and have to be sterilized before use
- Ortho bone anchors may only be used by medical personnel who hold relevant qualifications and are familiarized with the procedure. Consult the step by step procedure.
- 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 ortho 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.
- Ortho 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 of the patient or user.

- The bone anchors shall be removed and eliminated 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 ortho bone anchors are appropriately cleaned and are delivered in non-sterile see through pouches ready to be steam sterilized.
- 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 by the user 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.

Additional information can be found on the internet at www.surgi-tec.com

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

CE
1639

Medical device Class II.b

MANUFACTURED BY
"SURGI-TEC"
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Step-by-step procedure
Ortho 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 (3) ± 1 cm to the infra-zygomatic crest (Fig. 1)

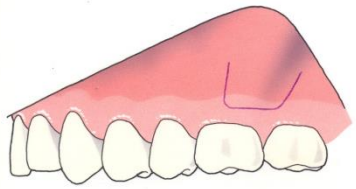


Fig. 1

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

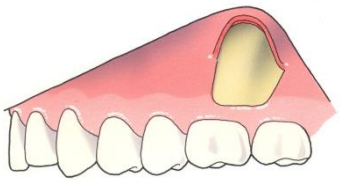


Fig. 2

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). A first hole is drilled with a suitable drill through the middle hole of the anchor (Fig. 3).
Caution
The lowest part of the outcoming orthodontic fixture can be ± 1 mm above the bracket in place

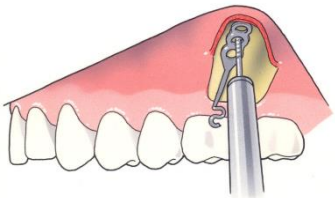


Fig. 3

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 screw (Surgi-Tec recommends 5 mm length, Ø 2.3 mm, eg. 70-105S) in the middle hole, but do not tighten this first screw completely in order to allow some rotation of the anchor. Drill through the upper hole of the anchor and insert the second screw (Surgi-Tec recommends 5 mm length, Ø 2.3 mm, eg. 70-105S). Drill through the lower hole of the anchor and insert the third screw (Surgi-Tec recommends 7 mm length, Ø 2.3 mm, eg. 70-107S) (Fig. 4).

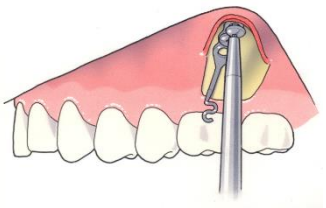


Fig. 4

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

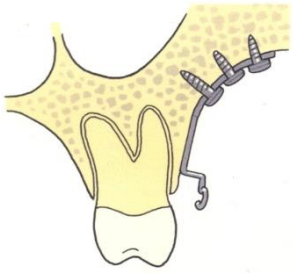


Fig. 5

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

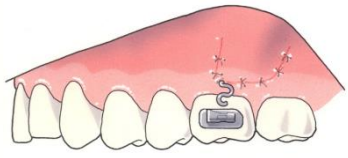


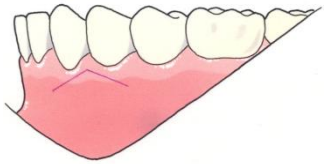
Fig. 6

Step-by-step procedure
Ortho Bone Anchors - Mandibula

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 with downwards extensions in the mucosa mesial and distal (Fig. 1)



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

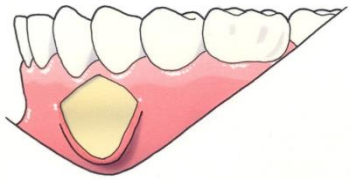


Fig. 6

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. A first hole is drilled in the with a suitable drill through the upper hole of the anchor (Fig. 3).
Caution
The lowest part of the outcoming orthodontic fixture can be ± 1 mm above the bracket in plate

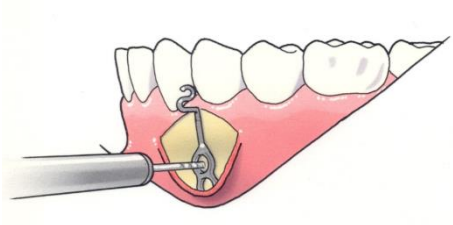


Fig. 7

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 screw into the upper hole of the anchor but do not completely tighten to allow some rotation of the anchor. The second screwhole is drilled through the lower hole after correct positioning of the anchor. The second screw is inserted (Surgi-Tec recommends 5 or 7 mm length, Ø 2.3 mm, eg. 70-105S or 70-107S) (Fig. 4).

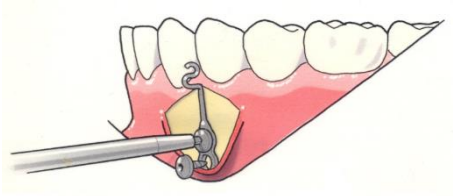


Fig. 8

STEP 5
Tighten all screws.

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

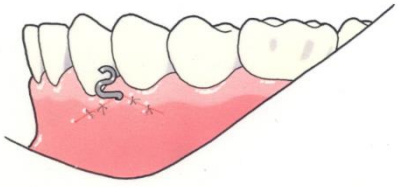


Fig. 5