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 subperiostal and transmucosal or transgingival skeletal anchor for orthodontic treatment.
OBA's consists of a base-plate fixed with monocortical screws, a neck piercing the gingiva or mucous membrane and a coronal part with at the end round bars or hooks, 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.
Knowing the biomechanical principles, OBAs are an alternative for extraoral anchorage.

Intended users :
- Suitably trained and qualified oral and maxillo-facial surgeons and orthodontists.
- Implantation is performed by suitably trained and qualified oral and maxillofacial surgeons.
- Anchoring is performed by the trained orthodontists.
- The selection of the OBA device/Model for the correction of indication shall be the responsibility of the Clinician.

Intended patient population
- Patients suffering from imperfections in teeth alignment.
- Patients requiring the correction of orthodontic anomalies such as dental malocclusions, open bite, dental crowding without extracting teeth and tilted molars.

Intended environment
- The intended environment for the use of Surgi-Tec's Orthodontic Bone Anchors is Hospitals and Clinics.

Performance characteristics
- OBA Maxilla is a fixed bone anchor in maxillary bone performant for orthodontic correction of dental malocclusion, open bite, dental crowding and tilted molars.
- OBA Mandible is a fixed bone anchor in mandible bone performant for orthodontic correction of dental malocclusion, open bite, dental crowding and tilted molars.
- OBA SLA is a fixed bone anchor in maxillary or mandibular bone performant for orthodontic correction of dental malocclusion, open bite, dental crowding and tilted molars.
- Surgi-Tec OBAs provide skeletal anchorage and can be used to modify the growth of the jaws.
- In class III children with a prominent chin, Surgi-Tec OBAs can be inserted in the posterior part of the upper and in the anterior part of the lower jaw.
- Continuous traction is applied through elastics fixed between the OBA maxilla and mandible. This results in a restriction of the growth of the lower jaw and a stimulation of the growth of the upper jaw. These growth changes reduce the prominence of the chin.

Material information
Surgi-OBAs are made of Titanium Grade 2 – ASTM F-65, ISO 5832-2.

Composition of Titanium grade 2 (EN - Ti2) :

Carbon	Iron	Oxygen	Nitrogen	Hydrogen	Titanium
Max 0,08 %	Max 0,30%	Max 0,25%	Max 0,03%	Max 0,0125%	Balance

Indications
Orthodontic bone anchors are used in orthodontic procedures to correct the following anomalies
- Dental malocclusions, open bite
- Dental crowding without extracting teeth
- Tilted molars (uprighting)

To obtain:
- Dental Intrusion, protrusion, diastema closure
- Maxillary protraction
- Molar distalization

Contraindications
- 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
- Difficult removal due to bone overgrowth
- Mechanical failure (breakage)
- Morbidities related to orthodontic surgery:
  - 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
  - Postsurgical swelling
  - Postoperative haemmorhage,
  - Frequent maxillary sinusitis
  - Condylar resorption
  - TMJ problems
  - Instable maxilla
  - Tight intraoral scar
  - Phonetic problems
  - Nasal bleeding,
  - Prolonged fatigue or pain postoperatively
  - False aneurysms
  - Arteriovenous fistulas
  - Gingival recession
  - Teeth tipping

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 labelled as ‘sterile’ are gamma irradiated and delivered in sterile see-through pouches. They are ready to be used unless the original packaging has been damaged. If the package is damaged please notify the manufacturer immediately. Do not use the medical device after the use by date indicated on the Labels. Store the sterile device in a dry and dust-free environment
- 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.
  Insertion of 70-200 series of screws at sharp angles could cause soft tissue irritation or pain.
  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
- Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of your EU member state.

Cleaning and Disinfection of Products labelled as 'non-sterile'

- All products in the Surgi-Tec Orthodontic Bone Anchors family that are delivered **'non-sterile'** must be cleaned, disinfected and sterilized before use. This also applies to the first use after delivery. All packaging must be removed before preparation.
- Thorough cleaning and disinfection are essential for effective sterilization.
- All implant components are intended for one single application in a single patient.
- It is your responsibility to ensure that the implants are completely sterile when used, to use device- and product-specific procedures for cleaning/disinfection and sterilization that are sufficiently validated, to regularly service and inspect the employed devices (disinfector, sterilizer), and to ensure that the validated and/or manufacturer's recommended parameters are maintained for each cycle.
- The statutory regulations applicable in your country and the hospital's hygiene requirements must also be observed. This applies in particular to the various instructions for effectively deactivating prions.
- Surgi-Tec has used "Neodisher MediClean forte" for the validation process of the automated cleaning and disinfection and has followed the instructions of the manufacturer (instruction Dr. Weigert). The validation was carried out according to the table below.
- For the remainder of this document, please use the following definitions regarding water temperature:
  Cold water: T < 40°C
  Warm water: T > 40°C
- When selecting the disinfector, make sure that the cleaning process includes the following phases in accordance with EN ISO 15883:
- The following precleaning steps will be performed: Rinsing the test items under cold running tap water for 5 minutes; NOTE: the test items should NOT be disassembled and screwable parts should NOT be moved

Phase	Temperature	Duration	Action
Pre-rinsing	Not applicable	Soaking time *>120 sec / 2 min*	*Cold tap water* (temperature <40°C)
Cleaning cycle	Cleaning temperature - *45°C*	Soaking time > *300 sec / 5 min*	*Warm tap water* (temperature >40°C) Recommended Detergent - *Neodisher Mediclean Forte* Concentration - *0.6% (v/v)*
Cleaning cycle	Cleaning temperature - *55°C*	Soaking time > *300 sec / 5 min*	*Warm tap water* (temperature >40°C) Recommended Detergent - *Neodisher Mediclean Forte* Concentration - *0.6% (v/v)*
Post-rinsing 1	Rinsing temperature *>40°C*	Rinsing time > *60 sec/ 1 min*	*Warm tap water* (temperature >40°C)
Post-rinsing 2	Rinsing temperature *<40°C*	Rinsing time > *60 sec/ 1 min*	*Cold tap water* (temperature <40°C)
Thermal disinfection (A_0 value > 600)* (A_0 value > 3000)	Disinfection temperature *≥ 90°C (194°F)*	Soaking time *> 60 sec/ 1 min (A_0 value > 600)* *> 300 sec / 5 min (A_0 value > 3000)*	*With demineralized (DI water) and/or purified water; do not add additional detergent*
Drying	Drying temperature > 110°C	Drying time > *1500 sec / 25 min**	*Drying process*
(*) Corresponds to worst-case item validated			

- The information provided is based on the use of "Neodisher MediClean forte" by Dr. Weigert; validation was performed with a concentration of 0.60 % v/v at 55°C; if a different detergent is used, exposure times, concentrations and temperatures may vary; the relevant manufacturer's instructions must be observed.
- The products must be completely dried directly afterwards. It is recommended to dry the products using medical compressed air; this is especially gentle and effective. Otherwise lint-free disposable wipes (e.g. Perform classic from Schülke & Mayr) can be used. If applicable, the products have to be stored in a clean environment until they are completely dry.

Inspection

- In general sufficient cleanliness is the basic requirement for a successful sterilization. Before the products are packaged for sterilization they have to be inspected visually. (Recommendation: use working place light fixtures ideally with magnifiers).
- Check the Orthodontic Bone Anchors and accessories after cleaning and disinfection for damages and contamination.

Packaging

- Surgi-Tec recommends Single sterilization wrapping (single or double wrapping) and/or other sterilization containers can be used.

Sterilization of Products labelled as 'non-sterile'

- OBA's are made of Titanium Grade 2 – DIN 3.7035
- For the sterilization process the instructions of the appropriate sterilizers have to be followed.
- All NON-STERILE products can be sterilized in an autoclave. The autoclaves must be in accordance with EN285 respectively EN13060 regarding validation, servicing, maintenance and controlling.
- Steam sterilization should be performed after the recommended cleaning, disinfection, inspection and packaging.
- Surgi-Tec recommends that sterilization is performed in accordance with following EN ISO 17665 validated process parameters
- For both initial and subsequent sterilization, the following parameters were validated by Surgi-Tec in accordance with the requirements of the current sterilization standards, EN ISO 17665 and ANSI/AAMI ST79.
- **Cycle: Pre-Vacuum (Dynamic air removal)**

Procedure	Fractionated and dynamic pre-vacuum process
Exposure time	≥ 5 minutes *(Minimum 5 minutes at 134°C)*
Temperature	Temperature ≥ 134°C
Drying time	≥ 20 minutes - 30 minutes (in autoclave chamber)

- Surgi-Tec recommends that sterilization be performed in accordance with the above-validated processes. If the user utilizes other processes (e.g. flash sterilization), these must be validated by the user. The ultimate responsibility for the validation of sterilization techniques and equipment lies with the user.
- The responsibility for the maintenance and qualification of the sterilization equipment used and the validation of the 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.
- Do not use hot-air sterilization, radiation sterilization, formaldehyde sterilization, ethylene oxide sterilization or substitute procedures for sterilizing thermolabile products such as plasma or peroxide sterilization for Surgi-Tec products.

These IFU and additional information can be found on the internet at www.surgi-tec.com/instructions.
The summary of safety and performance can be found in EUDAMED public website:
https://ec.europa.eu/tools/eudamed

Step-by-step procedure

Orthodontic Bone Anchors – Maxilla and SLA

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)

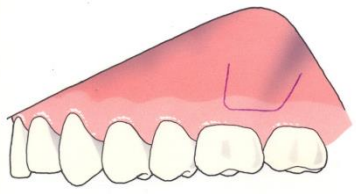


Fig. 1

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

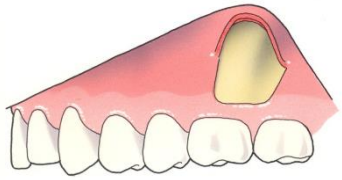


Fig. 2

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).

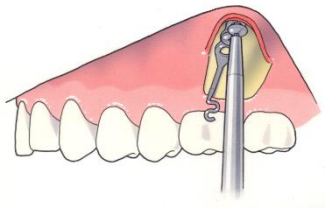


Fig. 3

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

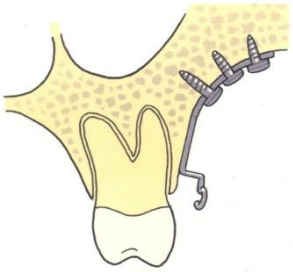


Fig. 4

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.

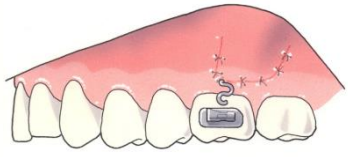


Fig. 5

Step-by-step procedure

Orthodontic Bone Anchors – Mandible and SLA

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)

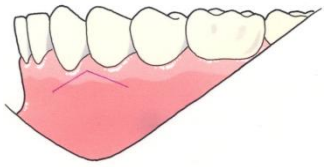


Fig. 1

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

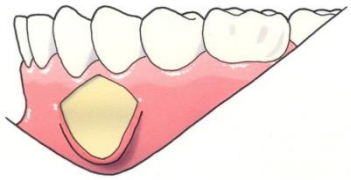


Fig. 2

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)

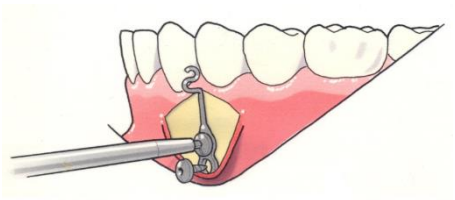


Fig. 3

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.

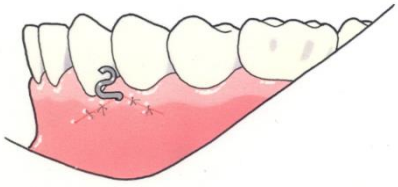
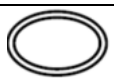


Fig. 4

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

Explanation of symbols:

	Please observe instructions for use
	Caution
	Do Not Re-use
	Reference number
	Lot number
	Manufacturer
	Non sterile product
	Do not use if package is damaged
	Medical device
	Unique device identifier
	Sterilized using irradiation
	Use-by date
	Double sterile barrier system

CE

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Medical device Class II.b

BASIC UDI-DI: 540700775OBAEN

MANUFACTURED BY
"SURGI-TEC"
Poortakkerstraat 43
9051 SINT-DENIJS-WESTREM – BELGIUM
www.surgi-tec.com