General
With the help of intramucosal skeletal anchorage, is the use of the temporary "OBA" Orthodontic Bone Anchor" a remarkable advantage in orthodontic treatment. OBA increase skeletal orthodontic anchorage in the anterior or posterior region of the upper and/or lower jaw. The mini plates consist of 3 holes to use in the maxilla segment and 2 holes for mandible segment. They are fixed by monocortical mini screws from 5 or 7mm. (Consult the step-by-step procedure). The mini plates are geometric plane with a neck of 1,2mm width at the end and penetrate the attached gingiva 2 mm away from de muco-gingival boarder. At the end of the round conical bar a hook or eyelid is the fixation unit to exercise traction by means of orthodontic expedients, such as round guiding bars, elastics or springs fixed to orthodontic appliances.

Material information
The OBA is made of Titanium Grade 2 – ASTM F-65, ISO 5832-2. This material is corrosion resistant and non-toxic in the biological environment, and produce negligible artefacts by X-ray, CT and MRI.

Indications
- Distal movement of the anterior segment in premolar extraction cases.
- Distalisation of molars, premolars, canines and processes alveolaris by class II malocclusions.
- Mesial movement of posterior teeth.
- Up righting of tilted molars.
- Orthopedic intermaxillary tractions, correction light class III.
- Intrusion

General contra indications
Increased risk of failure or infection if the patient has a history of immune deficiency, steroid therapy, problems with blood clotting, uncontrolled endocrinological disease, rheumatic disease, bone disease, cirrhosis of the liver or any other acute disease. OBA’s must not be used if the patient has an active infection, a metal allergy or foreign body sensitivity, a limited blood supply or insufficient quality or quantity of bone, unstable physical and/or mental health conditions, 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 depression or other types of psychopathologies.

Local contra-indications
The OBA must not be used if the patient suffers from osteomyelitis, receives radiotherapy of the head, has receding gingival or periodontal diseases, diabetic problems or unsatisfactory oral hygiene. Furthermore, the OBA must not be used if there is insufficient bone structure or possible bone defects in the area in which the mini plate is to be inserted.

Possible system adverse effects
- In many cases, adverse results may be clinically related rather than implant related.
- Loosening of the OBA as a result of insecure tightening of the osteosynthesis screws, or local infections.
- If the neck of the miniplate is penetrating the non-attached gingiva, gives high risk of local inflammation and loosing of the miniplate as result.
- Metal sensitivities or allergic reaction.
- Bony necrosis, osteoporosis, inhibited revascularisation, bone resorption, and poor bone formation can cause premature loosing of the osteosynthesis screws.
- Risk for inflammation if placement of a bone anchor in combination with tooth extractions.
- Severe bending or bending the hooks in opposite direction may fracture the plate.
- 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 OBA and the decision to leave or remove the OBA postoperatively, rests with the clinician.
- OBA are designed for single use only.
- OBA may only be placed by oral surgeons and facial surgeons.

The user (surgeon) must ensure to have read and understood the instructions for use supplied with the product. Only original OBA components may be used according to the instructions for use. Each patient must be examined and informed about the OBA and how to put into use. Once a OBA has been applied, the product should not be re-used. Although it may appear undamaged, previous stresses may have created imperfections which reduce its function and can lead to fracture of the device. There is also a risk of cross infection. Surgi-Tec guarantees the packing of the OBA in their undamaged, original packaging.

Operation warnings and precautions
- Responsibility for proper selection of patients, adequate training and experience, correct choice and placement of the OBA is required.
- Leveling of both dental arches is necessary prior the placement of OBA.
- Selection of a correct OBA is important.
- Choose an adequate technique and correct insert able place to insert the OBA.
• The OBA should be placed in the correct anatomic location, with precautions to avoid drilling or screwing into dental roots.
• The surgeon should discuss the expectations of surgery inherent in the use of the product with the patient.
• Necessity for periodical follow-up and cooperation.
• Inform the patient that possible postoperative swelling can occur.
• Give appropriate medication prior to surgery.
• Implant of the OBA simultaneous with extractions may cause inflammations.
• Orthodontic traction by adult patients is recommended 2 weeks after surgery. Use light forces in the first months. By young children 4 weeks is recommended.
• Follow specific oral hygiene instructions from the orthodontist 10 days after surgery.
• Light orientation of the hook or fixation element is possible with small forceps without local anesthesia.
• Avoid bending several times the fixation element of the plate hooks. This cause possible fracture of the mini plate.
• Remove the OBA as far no skeletal anchorage is no more needed.

**OBA NON-STERILE packing**
OBA package contains one ST Bone Anchor, no screws subjoin
OBA 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).

**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.

**Additional Information**
Additional information on the product(s) (e.g. the surgical technique, care, cleaning, disinfection and sterilization) can be requested from Surgi-Tec N.V. or from your local Surgi-Tec Territory partner. In addition, all relevant information can be found on the internet at [www.surgi-tec.com](http://www.surgi-tec.com)

**Explanation of symbols**

![Symbol]
Please observe instructions for use

![Symbol]
Do Not Re-use

![Symbol]
Reference number

![Symbol]
Lot number

![Symbol]
Manufacturer

![Symbol]
Non sterile product

![Symbol]
Do not use if package is damaged

![Symbol]
Designation system for teeth and areas of oral cavity

![Symbol]
Medical device Class II.b

**MANUFACTURED BY**
“SURGI-TEC”
Poortakkerstraat 43
9051 SINT-DENIJS-WESTREM – BELGIUM
[www.surgi-tec.com](http://www.surgi-tec.com)