OS
Osteosynthesis screws

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

Intended use
The osteosynthesis screws are indicated for use in the fixation of bone, of Surgi-Tec Transpalatal Distractors (DIS/TPD), Surgi-Tec Orthodontic Bone Anchors (OBA) and Surgi-Tec Osteosynthesis Plates (OSP).
Screws can be self-tapping or self-drilling.

Indications
The osteosynthesis screws are indicated for use in fixation of bone and Surgi-Tec devices to bone:
- Surgi-Tec's Transpalatal Distractors
- Surgi-Tec's Orthodontic Bone Anchors
- Surgi-Tec's Osteosynthesis Plates

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 hold the screw.
- 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
- The OS must not be used if the patient receives radiotherapy of the head.

Possible adverse effects
- Loosening of the screws from insufficient fixation.
- Hypersensitivity to metal or allergic reactions.
- Difficult removal due to bone overgrowth
- Mechanical failure
- Morbidities related to orthognatic surgery:
    - Postoperative haemorrhage
    - Postoperative pain
    - 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
    - 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

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 ‘non sterile’ are already cleaned and delivered in non-sterile see-through pouches. They only have to be sterilized in their original packaging before use.
- 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..
- Osteosynthesis screws may only be used by medical personnel who hold the correct professional qualifications and are familiarised with the procedure.
- Follow appropriate 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.
- Surgi-Tec does not recommend a specific surgical procedure for a specific patient. The operating surgeon is responsible for choosing the appropriate osteosynthesis screws for each specific case
- Surgi-Tec advises related Surgi-Tec instruments to place the screws.
  Use the right bone drill for self-tapping screws.

Surgi-Tec recommends the following Ø drills for its different screws:
Ø1mm drills: are commonly used with the micro screws (Ø1.2mm)
Ø1,20mm drills: for drilling a gliding hole Ø1,20mm screws (lag screw)
Ø1.65mm drills are recommended with Ø2.3mm screws in the Maxilla
Ø1.8mm drills are recommended with Ø2.3mm screws in the Mandible.
Note that the operating surgeon is always responsible for choosing the appropriate drill size for each specific case

- Adjusting the direction of the screw during insertion or using excessive screw force may cause the screw tip to break during or after surgery
- Screws 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 screws shall be removed when no longer needed for treatment.
  Screws 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 Products labelled as ‘non sterile’

- Surgi-Tec Osteosynthesis screws are made of Titanium Grade 5 – DIN 3.7165
- Osteosynthesis screws 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/instructions.
The summary of safety and performance can be found in Eudamed public website:
https://ec.europa.eu/tools/eudamed

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

Sterilized using irradiation

 Use-by date

 Caution

CE

1639

Medical device Class II.b

BASIC UDI-DI : 540700775OSRH

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