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.

Intended users
- Suitably trained and qualified oral and maxilla-facial surgeons.

Intended patient population
- People needing fixation of bone, distraction devices, ortho bone anchors and osteosynthesis plates.

Intended environment
- The intended environment for the use of osteosynthesis screws is Hospitals and Clinics.

Performance characteristics
- Osteosynthesis screws are accessories for the placement of distraction devices, orthodontic bone anchors and osteosynthesis plates.
- Micro screws are performant in providing bone to bone anchorage in bone grafting.
- Self-drilling screws are performant for self-drilling applications
- Self-tapping screws are performant for self-tapping applications

Material information
Surgi-Tec Osteosynthesis screws are made of Titanium grade 5

Composition of Titanium grade 5 (EN- TiAl6V4):

Carbon	Iron	Oxygen	Nitrogen	Hydrogen	Aluminium	Vanadium	Yttrium	Titanium
Max 0,08 %	Max 0,25%	Max 0,13%	Max 0,05%	Max 0,012%	5,50-5,60 %	3,50-4,50 %	Max 0,005%	Balance

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.

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

- All implants in the Surgi-Tec Osteosynthesis screws portfolio 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 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 Osteosynthesis screws 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’

- Surgi-Tec TPD osteosynthesis screws are made of Titanium Grade 5 – DIN 3.7165
- 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 is 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 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 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

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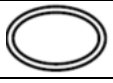
Explanation of symbols

	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

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CE
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Medical device Class II.b

BASIC UDI-DI : 540700775OSRH

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