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 fixation of Surgi-Tec distraction osteogenesis systems or Surgi-Tec skeletal anchorage systems.
Screws can be self-tapping or self-drilling

Indications
The osteosynthesis screws are indicated for use in bone- fixation of :

- Surgi-Tec's distraction devices
- Surgi-Tec's and Mommaerts ortho 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
- 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
- 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, postoperative nausea or vomiting (PONV)

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
- Osteosynthesis screws may only be used by medical personnel who hold relevant 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.
  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 and eliminated 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

- Surgi-Tec Osteosynthesis screws are made of Titanium Grade 5 – DIN 3.7165
- Osteosynthesis screws 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
REF	Reference number
LOT	Lot number
	Manufacturer
	Non sterile product
	Do not use if package is damaged

CE
1639

Medical device Class II.b

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