OSP
Osteosynthesis plates (Slotplates)

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Intended use
Surgi-Tec osteosynthesis plates are used in orthognathic and orthofacial surgery for the fixation of fractures, corrective osteotomies or reconstructive procedures to the facial skeleton.
OSP's consists of a plate fixed with monocortical mini screws.
Different models accommodate specific anatomical conditions

Indications
- Fixation of the segments after zygoma, maxillary and chin osteotomies
- Fixation of the segments after facial bones trauma

Contra indications
- Patients with pre-existing or suspected infection at or near the implantation site
- Patients with known allergies and/or hypersensitivity to implant materials
- Limited blood supply and inferior or insufficient mandibular or maxillar bone quality to hold the fixation screws
- 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 OSP must not be used if the patient receives radiotherapy of the head

Possible adverse effects
- Loosening of the implant from loosening of screws or screw failure.
- 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, premature plate removal.
- Postsurgical swelling.
- Pseudo-arthrosis.
- Morbidities related to orthognathic surgery: postoperative haemorrhage 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.

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 already cleaned and delivered in non-sterile see through pouches. They only have to be sterilized in their original packaging before use.
- Osteosynthesis plates may only be used by medical personnel who hold the correct professional qualifications and are familiarised with the procedure.
- 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
- It is necessary to explain to patients the risks of plate removal and the importance of long-term follow-up
- 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 plate for each specific case.
- Surgi-Tec advises to use only suitable Surgi-Tec screws and related Surgi-Tec instruments
  Repeatedly bending the plate in opposite directions may cause the plate to break during or after surgery.
- Osteosynthesis plates 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 osteosynthesis plates can be removed.
  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

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Sterilization

- Surgi-Tec OSP slot plates are made of Titanium Grade 1 – DIN 3.7025
- OSP's 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

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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

CE

1639

Medical device Class II.b

BASIC UDI-DI : 540700775OSPH7

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