**Manufactured by:**

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**IMPORTANT: PLEASE READ**

**For more information on the Southern Craniomaxillofacial (CMF) System, please consult the Surgical Manual**

**DESCRIPTION:**

The Southern Craniomaxillofacial (CMF) System includes a variety of plates, meshes, and screws that are intended to facilitate fusion in craniomaxillofacial and mandibular surgeries.

The plates are manufactured from Grade 2 Unalloyed Titanium (ASTM F67), while the screws are manufactured from either Ti-6Al-4V Titanium Alloy (ASTM F1472) or Ti-6Al-4V ELI Titanium Alloy (ASTM F136).

**INDICATIONS FOR USE:**

The Southern CMF System is a craniomaxillofacial plate and screw system intended for osteotomy, reconstruction, and fracture fixation in craniofacial, maxillofacial, and mandibular surgeries, as well as selective orthognathic surgeries of the maxilla and chin.

**CONTRA-INDICATIONS:**

Contra-indications include, but are not limited to:

- Allergy or hypersensitivity to any of the implant materials
- Active systemic or localised infection and/or inflammation
- Fractures of a severely atrophic mandible
- Patients with limited blood supply
- Patients with insufficient quality or quantity of bone
- Patient anatomy or pathology that prevents full insertion and correct usage of the device
- Any other conditions that may place excessive stress on the device and/or bone, such as morbid obesity, tumours, fractures, or inadequate tissue coverage. The decision to use a device in patients with such conditions must be made by a healthcare professional after taking into consideration the benefits and risks to the patient.
- Use of this device is relatively contra-indicated in patients whose activity, occupation, mental or neurological capacity, history of substance abuse or other lifestyle factors may prohibit their ability to comply with post-operative care instructions. These patients may place undue stress on the device and may be at higher risk of implant failure.

**ADVERSE EFFECTS AND RISK OF USE:**

Risks and adverse events include, but are not limited to:

- Pain, discomfort, or abnormal sensation due to the presence of the device
- Injury
- Metal sensitivity or hypersensitivity or allergic reaction to orthopaedic hardware
- Nerve damage resulting in loss of sensation, facial movement, smell, taste, or vision
- Malocclusion
- Damaged tooth or loss of tooth
- Implant loosening, migration, bending, cracking, or fracture
- Haemorrhage and/or Haematoma
- Thrombosis / thromboembolic event
- Complex regional pain syndrome
- Permanent or temporary facial deformity
- Postsurgical relapse
- Chronic sinusitis
- Delayed union, malunion or non-union
- Infection and/or inflammation
- Inhibited revascularization
- Increased fibrous tissue responses
- Restricted or impaired bone growth
- Bone necrosis
- General anaesthesia complications (including nausea, vomiting, neurological impairments)
- General surgical complications (including postoperative ileus, incisional hernia, and cyst formation)
- Reoperation
- Death

**USAGE WARNING:**

Implantation of this device(s) is limited to qualified surgeons in a sterile environment. The desired clinical outcome may not be achieved if the usage instructions are not followed. Improper technique in implant placement can result in implant failure. Refer to the surgical manual. If uncertain, contact a Southern Medical representative.

**STERILITY INFORMATION AND WARNINGS:**

The devices are provided **NON-STERILE** and are intended to be cleaned and sterilised in accordance with the manufacturer's instructions. Refer to **IFU-100.**

The devices may be temporarily packaged prior to placement on an implant tray. Do not use if the packaging is damaged, or if the expiry date indicated on the packaging has been exceeded.

**RE-USE WARNING:**

All implants are intended for **SINGLE USE** only and **MAY NOT BE RE-USED**. An explanted device must never be re-implanted. Re-use or re-implantation may result in cross-contamination or infection.

**INSTRUMENTATION:**

Surgical instruments are provided by the manufacturer. No other instruments may be used.

The instruments are provided non-sterile on instrument trays that are intended to be cleaned and sterilised in accordance with the instructions provided by the manufacturer. Refer to IFU-100.

**STORAGE:**

No special storage instructions apply. Handle with care.

**MAGNETIC RESONANCE IMAGING (MRI) SAFETY INFORMATION:**

The Southern Craniomaxillofacial (CMF) System has not been evaluated for safety in the MR environment. The devices have not been tested for heating or unwanted movement in the MR environment. The safety of the Southern CMF System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

**POST-OPERATIVE CARE INSTRUCTIONS**:

The surgeon/physician should provide appropriate postoperative care instructions to the patient and should ensure that the patient understands the potential consequences of non-compliance. Follow-up consultations should be arranged with the patient at appropriate intervals, as deemed necessary by the physician. The patient should only resume their normal activities once cleared to do so by their physician.

**DEVICE REMOVAL:**

The devices are intended to remain in place for the duration of the patient's life. Surgical removal of the device is possible. Any decision to remove the device must be made by a healthcare professional after taking into consideration the patient's general medical condition and the potential risk of a subsequent surgical procedure. Refer to the surgical manual for removal instructions.

**DEVICE DISPOSAL:**

Single-use devices should be disposed of in accordance with the hospital's procedure for disposal of hazardous and/or biological waste.

**REPORTING:**

Any device-related adverse events must be reported to the manufacturer as soon as possible.

**DESCRIPTIONS OF SYMBOLS USED IN PACKAGING:**

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| --- | --- | --- | --- |
| **USE BY** | | **CAUTION** | |
| **LOT NUMBER** | LOT | **CONSULT THE INSTRUCTIONS FOR USE** | southmed.co.za |
| **MANUFACTURER** | | **DO NOT USE IF PACKAGING IS DAMAGED** | |
| **DATE OF MANUFACTURE** | | **NON-STERILE** | NON STERILE |
| **DO NOT REUSE** | | **CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN** | Rx ONLY |
| **CATALOGUE NUMBER** | REF | | |