



orthognathic

Indication

Osteosynthesis plates are applicable to orthognathic surgery procedures and assist in the repositioning of facial bones, contributing to stabilization and fixation, in conventional oral and maxillofacial procedures that require bone augmentation and/or replacement of the bone structure, or for minimally invasive corrective and/or aesthetic maxillofacial surgeries.

Implants are manufactured to adapt to the patient's anatomy and specific needs, according to a design specified by the responsible professional.



Contraindication

Osteosynthesis plates should not be used in patients with one or more of the following conditions:

- Infections present in the implantation region;
- Systemic conditions with increased susceptibility to infections, such as immunosuppression and/or conditions that hinder the repair process, such as uncontrolled diabetes, alcoholism, smoking;
- Presence of bone deficiency, qualitative and/or quantitative, a potential situation that may affect the support/fixation of the prosthesis.
- Allergy to any of the components present in the prosthesis;
- Presence of disorders that make it impossible to follow medical advice;
- Incomplete/immature bone development, such as in children for example.

Surgical procedures

Step 1: Anesthetize the patient.

Step 2: Expose the plate attachment area using a standard surgical approach.

Step 3: Position the surgical guide.

Step 4: Drill the guide screw attachment points with the appropriately sized drill bit.

Step 5: Remove the surgical guide.

Step 6: Test the adaptation of the osteosynthesis plates on the bone preparation performed. If necessary, make adjustments to the bone to obtain a precise adaptation.



Step 7: Fix the osteosynthesis plates through the most anterior perforations. Any perforations not present should be performed using the 1.5 mm drill bit.

Step 8: Install the screws alternately, without tightening them completely. After positioning all the screws, apply the final torque to tighten the screws.

Note: Screw lengths are provided in the report accompanying the osteosynthesis plates for the orthognathic surgery and must be strictly followed.

Step 9: Suture the incision site.

Cautions and Warnings

- ✓ The components are provided STERILE.
- ✓ Single-use product. DO NOT REUSE OR REPROCESS.
- ✓ Applying excessive loads increases the risk of deformation, cracks, and fractures in the implant.
- ✓ Improper use of the implant or improper fixation may lead to screw loosening, fractures, and/or treatment failure.
 - ✓ Electrosurgery, radiation exposure, and chemotherapy may affect the functionality of osteosynthesis plates.
- ✓ Do not use in case of fractures or signs of fragility in the structure of the implant.
 - ✓ Do not use the product if the packaging is damaged or if the seal is broken.
 - ✓ Do not use the product if it is damaged.
- ✓ Do not use the product past the expiration date.
 - ✓ Do not use if the model/reference presents discrepancies.
- ✓ Use only compatible products manufactured by CPMH to ensure the safety and efficacy of the device installation.

Adverse Events

- Every surgical procedure carries risks and the possibility of complications. Some common risks associated with any surgical procedure include:
- Infection, bleeding, paresthesia, anesthetic risk, among others.
- Loosening, displacement, or fracture of the components.
- Vascular or neurological impairment due to the surgical act.
- Sensation of pain, discomfort, or unease.
- Edema, hematomas, inflammation, infection, peeling, abscess formation, hyperplasia, gum irregularities, complications associated with anesthesia, implant failure, or exposure.

