INSTRUCTIONS FOR USE
PLATES AND SCREWS FOR CMF SURGERY

INDICATIONS

Plates and screws are indicated for internal fixation, stabilization and support of bone fractures, as well as bone fixation, after reconstructive surgery, fixation of cranial, maxillofacial and oral fractures, orthognathic and orthodontic reconstructions, mandibular reconstruction and any osteotomy surgery or trauma in CMF.

Cranioplasty plates and screws for CMF surgery: Cranial fractures, Cranial osteotomies, Tumor resection
Orthognathic and trauma plates and screws for CMF surgery: Maxillofacial and oral fractures, Orbital fractures, Condylar fractures, Orthognathic and orthodontic surgeries, Mentoplasty, Mandibular osteotomies, as Bilateral sagittal split osteotomy (BSSO)
Reconstruction plates (for CMF) and screws for CMF surgery: Traumatic injuries, Tumors

PRODUCTS AND MATERIALS

Delphos Implants' implantable devices are for single use only. They are sold non-sterile. Non-sterile implants must be cleaned, decontaminated and sterilized before use.
Plates: Titanium ASTM F67 and ISO 5832-2. Screws: Ti-6Al-4V ASTM F136 and ISO 5832-3.

LOCATION	PLATES	SCREWS	SPECIFIC INDICATION
1.2 SYSTEM			
Middle ⅓ Upper ⅓	Straight, Curved, 3D, T, Z, L, Y, H, X and Orbital Plates	Self-Tapping Ø1.2 Self-Drilling Ø1.2 Self-Drilling Hybrid Ø1.2 Emergency Ø1.4	Fixation of cranium maxillofacial fractures
Upper ⅓	Calvarium and Mesh Plates		Fixation of cranium upper ⅓ fractures
1.6 SYSTEM			
Middle ⅓ Upper ⅓	Straight, Curved, 3D, Z, L, Y, H and X Plates	Self-Tapping Ø1.6 Self-Drilling Ø1.6 Self-Drilling Hybrid Ø1.6 Emergency Ø1.9	Fixation of oral and maxillofacial fractures. Any osteotomy surgery
Middle ⅓	Maxillary Plates		Le Fort
Upper ⅓	Calvarium, Net and Mesh Plates		Fixation of cranium upper ⅓ fractures
2.0 SYSTEM			
Middle ⅓ Lower ⅓	Straight, Straight w/ Locking, Straight Adjustment on Local Site, BSSO Straight, BSSO Curved, BSSO Double, BSSO XL, L, L w/ locking, Z, Y, X, BSSO X, Curved, L Adjustment on Local Site, T, Maxillary and 3D Plates	Self-Tapping Ø2.0 Self-Drilling Ø2.0 Self-Drilling Hybrid Ø2.0 Self-Tapping Locking Ø2.0 Emergency Ø2.3	Fixation of oral and maxillofacial fractures. Orthognathic reconstruction. Any trauma or osteotomy in CMF.
Lower ⅓	Condylar fractures plates		Condylar Fractures
Middle ⅓	Mentoplasty Plates		Mentoplasty
Upper ⅓	Mesh Plates		Fixation of cranium upper ⅓ fractures
2.4 SYSTEM			
Lower ⅓	Semi compression Straight, Maxi, Straight Maxi and Angulated Maxi Plates DRS Straight, DRS Angulated and DRS Curved Plates	Self-Tapping Ø2.4 Self-Drilling Ø2.7 Self-Tapping Locking Ø2.4 Self-Tapping Locking Ø2.7 Emergency Ø2.7	Mandibular reconstruction
SCREWS			
Self-Tapping screws Ø 1.2mm, 1.6mm and 2.0mm Self-Drilling screws Ø 1.6mm and 2.0mm			Bone Graft
Self-drilling blocking screw Ø 2.0mm Self-drilling intermaxillary blocking screw Ø 2.0mm			Fracture realignment and immobilization

INSTRUCTIONS TO USE SCREWS

- When loading a screw onto the screwdriver (blade), ensure that you apply a force perpendicular to the fitting screw in the screwdriver.
- It is recommended to limit the number of screw engagements with the blade. After a maximum of three (3) attempts to engage the screw, the connection may become damaged, and proper engagement can no longer be ensured.
- The self-drilling screws can be inserted in a single step. Insert the screw into the screwdriver and take it to the bone by applying an angle of 90°, with a suitable pressure, until it is able to see the head of the screw at the bone surface.

In high-density bone, it may be necessary to use a drill. Only trained professional, following approved technics and protocols, should perform this type of procedure.
- Before insertion of a self-tapping screw, a suitable and sufficiently large drill must be used for pre-drilling. In order to define the screw length, the drill depth is determined by means of a depth gauge

Compatible instruments:

Screw System	Handle	Blade reference	Drill bit diameter (mm)
1.2	DA-0019-800 DA-0019-810	SK-0012-800	1.0
1.6		SK-0016-800	1.3
2.0		SK-0020-800	1.5
2.4		SK-0024-800	2.0

CONTRAINDICATIONS

The use of Delphos Implants plates and screws are not indicated in cases of:
- Patients with known allergies and/or hypersensitivity to the titanium. When sensitivity is suspected, appropriate tests should be performed prior to implantation of the product;
- Patients with active or suspected infection or in patients who are immunocompromised.
- Metabolic or systemic disorders or metabolic treatments that could lead to progressive deterioration of the bones (treatments with corticosteroids, immunosuppressive therapy);
- Patients with tumours in the treatment area.
- Patients who on the basis of their physical and mental condition are not able to keep up with post-operative treatment.
- Serious damage to the bone structure, as well as degenerative disease processes that may interfere with the healing process.
- Obese patients, except if the health professional decides to use it.
- Poor or insufficient bone quality to safely anchor the implant.
- Skeletally immature patients who present bone shortcomings or fragile;
- Patients younger than 16 years. Medical devices may be used on patients under 16 years of age in cases of trauma. In such cases, it is healthcare professionals' responsibility to choose the medical devices.

PATIENT TARGET GROUP

The target group for the application of plates and screws are skeletally mature patients with utilization at the appropriate anatomical structures as defined in the indications. Not indicated in obese patients unless approved by healthcare professional. Not indicated for patients younger than 16 years old, except in cases of trauma if approved by the healthcare professional.
The decision to use plates and screws should be made on a case-by-case basis, based on a thorough evaluation of the patient's medical history, physical condition, and treatment goals. Patient selection criteria are healthcare professionals' responsibility and include fracture type and location, age, health status, activity level, and patient preference

INTENDED USERS

Delphos Implants plates and screws are intended to be used by licensed healthcare professionals. The healthcare professionals should be fully aware of the intended use of the products and the applicable surgical techniques and should be qualified by appropriate training methods.
Additional user groups include nurses and reprocessing staff in handling, cleaning and sterilization of the devices, where applicable.

WARNINGS AND PRECAUTIONS

Warnings and precautions indicate hazardous situation that, if not avoided, could result in death, serious injury, minor or moderate injury.
1. The surgeon must have specific training, experience, and thorough familiarity with the use of devices, surgical techniques and post-operative care;
2. Patients must strictly follow their surgeon's post-operative instructions;
3. Delphos Implants recommends that the user reads all available documents before first use and contacts other users who have practical experience with this type of treatment;
4. Only cleaned and sterilized products may be implanted or used;
5. Compliance with the recommended sterilization parameters is the responsibility of the user, as well as the use of appropriate accessories (trays, wrappings);
6. Use of improperly cleaned and sterilized devices can lead to potential infection/contamination risks;
7. The reuse or reprocessing of explanted, contaminated and used implants is prohibited. The use of implants contaminated with human tissue or blood is prohibited;
8. The use of plates or screws with incompatible sizes can cause implant breakage or implant failure;
9. Do not use any damaged device. Products that do not comply with the conditions determined by the manufacturer should not be implanted and should be discarded; An implant that appears to be damaged may show signs of fatigue due to prior unknown stress, which may lead to premature failure or shortened implant life;
10. Plates and screws are not designated to withstand abnormally excessive functional constraints;

11. Excessive or repeated bending of the plates may weaken the structure of the plates, increasing the risk of failure. This may result in fracture of the implant and failure during post-operative treatment;
12. Incorrect product selection may lead to a loosening, bending or breakage of the product or fracture of the bone;
13. The use of screws in high dense bone can lead to fracture or failure of the implant during insertion;
14. Excessive load during the insertion of the screws may lead to its failure or breakage;
15. Use of excessive torque during insertion of screws may lead to implant failure;
16. In case of shortening of the bone plate, the cut surfaces must be trimmed with appropriate instruments. The surgeon must ensure that plate stability, load capacity and fixation are maintained;
17. Locking screws are intended for use through threaded plate holes only.
18. Removal of implants is not necessary. The decision to do so is the responsibility of both the healthcare professional and the patient;
19. Plate positioning must allow adequate clearance of nerves, tooth buds and/or tooth roots and any other critical structures;
20. When placing additional screws, guarantee that the subsequent screw placement does not interfere with the new screws;
21. The plates and screws are for single use only, being this indication described on the product labels, guaranteeing the safety of the patient; The instruments required for the implantation of the implants are reusable;
22. The surgeon should avoid insertion and removal of the same screw in the screwdriver more than 3 times, in order to prevent failure when placing the screw;
23. The plates and screws manufactured by Delphos Implants were designed for the union of bone fragments while osteogenesis occurs;
24. Osteosynthesis devices are recommended for use in patients with sufficient bone quality to maintain the effectiveness and benefits of internal fixation.
25. All plates and screws require specific instruments for its implantation. The non-use of the instruments provided by Delphos Implants may compromise the success of the procedure, increasing the risk of premature failure of the devices.
26. Plates and screws manufactured by Delphos Implants are intended to be used together. The non-use of the devices provided by Delphos Implants may compromise the success of the procedure, increasing the risk of premature failure of the devices.
27. Use only devices whose original packaging has not been tampered with.
28. Delphos Implants' implants are manufactured from non-ferromagnetic materials. The implants have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of the Delphos Implants' implants in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

ADVERSE EFFECTS

Adverse effects are potentially undesirable harmful effects related to the use of the implants or to the surgical procedure. Consider the contraindications to avoid adverse effects. Nevertheless, the following adverse effects may occur while using the product as intended and may be clinically, rather than implant related: infection (local or systemic), restricted joint movement, inflammation (local or systemic), severe sepsis, refracture, non-union or malunion of the bone, soft tissue irritation, impaired joint function, osteomyelitis, surgical site complications, discomfort, pain, systemic toxicity, trismus, growth interference, breakage, failure or rejection of the implant, patient reaction or allergic reactions, impaired bone healing. Any serious incident that has occurred in relation to the device should be reported to Delphos Implants and the competent authority of the Member State in which the user and/or patient is established.

CLEANING, DISINFECTION AND STERILIZATION

The plates and screws are supplied non-sterile and must be carefully cleaned, disinfected and sterilized prior to use, in accordance with requirements of ISO 17664-1.

Characteristics of cleaning agents

- Enzymatic detergents with neutral pH between 7 and 9
- Detergents with non-ionic, non-foaming and biodegradable surfactants

NOTE: The instructions provided by the manufacturer must be carefully read in order to use the detergent correctly, according to the exposure time, temperature and concentration.

Automatic washing and disinfection

Use a standard washing and thermal disinfection cycle in a washer-disinfector compliant with EN ISO 15883-1 and EN ISO 15883-2 or equivalent national standards:
1. Pre-washing for 10 minutes, with water at room temperature;
2. Wash with detergent at 55 °C for 5 minutes;
3. Rinse with water at room temperature for 2 minutes;
4. Perform an additional rinse at room temperature for 1 minute;
5. A final rinse with thermic disinfection must be included (demineralized water at 93 °C for 5 minutes).

The duration of the bath depends on the size and energy of the unit (ISO 15883-1).

Drying

This step prevents microbial growth and removes any trace derived from washing. Drying for 25 minutes at 110 °C.

Sterilization

Delphos Implants recommend sterilization by a pre-vacuum autoclave (Moist heat), taking into account the requirements of EN ISO 17665. It is recommended that the following physical parameters of sterilization are followed:

CYCLE	TEMPERATURE	EXPOSURE TIME
Steam (1 atm of pressure)	134 °C (273 °F)	18 minutes

Drying after sterilization

Delphos Implants recommends a drying time of at least 30 minutes.

INSPECTION

Before use, perform a visual inspection and check for damages or residues derived by the cleaning and sterilization processes. If any situation is found that could compromise the safe use of the device(s), contact the manufacturer or discard. Delphos Implants do not recommend a number of reprocessing cycles, as to date it has no knowledge if the process will damage, compromise or disable the performance of the implants.

PACKAGING

The original packaging of the devices does not support high temperatures, so it is recommended to use sterilization trays manufactured by Delphos Implants. The implants are cleaned and disinfected in the sterilization trays. Before sterilization, wrap them in one-way sterilization packaging (single or double packaging) complying with the specifications of standards ISO 11607-1/ISO 11607-2.
The packaging must be checked for possible damage before the product is stored and used. If the packaging is damaged, do not use the device and discard it, as the cleanliness of the product cannot be guaranteed.

HANDLING, STORAGE AND TRANSPORTATION CONDITIONS

All devices must be stored in a clean, dry environment and be protected from sunlight and extremes temperatures. Handle all devices carefully in order to maintain their configuration and mechanical characteristics.
Always inspect the condition of the devices before using them. In the event of any change, proceed to discard it immediately.

DISPOSAL

The devices must not be disposed of with household waste. They must be disposed of in accordance with current environmental legislation. Where applicable, the devices must be decontaminated prior to disposal in order to minimise biological risks. To prevent unauthorised reuse, it is recommended that they be rendered physically unusable (for example, by cutting or deforming them).

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP)

The SSCP is available in the Eudamed (https://ec.europa.eu/tools/eudamed).

Basic UDI-DI

Plates		Screws for CMF surgery
Cranioplasty	56004617PLCUF	56004617SCMFLH
Orthognathic and trauma	56004617PLMV3	
Reconstruction (for CMF)	56004617PLRVD	

SYMBOLS GLOSSARY

Symbol	Description	Symbol	Description
	Manufacturer	UDI	Unique device identification
PT	Manufactured in Portugal Date of manufacture	Rx Only	Use under medical prescription
MD	Medical device	NON STERILE	Non-sterile
LOT	Lot number	REF	Catalog Number
	Caution	CE	CE marking of conformity
	Do not re-use		Keep dry
Mat	Medical device's material		Keep away from sunlight
	Consult instructions for use or consult electronic instructions for use at *https://delphosimplants.com.pt/qualidade-regulamento-e-ifu/*		

DELPHOS IMPLANTS – INDÚSTRIA, COMÉRCIO, IMPORTAÇÃO E EXPORTAÇÃO DE IMPLANTES MÉDICOS, S.A.
Estrada Manuel Correia Lopes, Parque Empresarial Progresso, Armazém 5
2785-126, São Domingos de Rana, PORTUGAL
E-mail: delphos@delphosimplants.com.pt
Tel.: (+351) 211 955 986
www.delphosimplants.com.pt

CE 0197

Last review date: March 2026