INSTRUCTIONS FOR USE

CLINICAL INDICATIONS

DELPHOS IMPLANTS' rigid fixation systems, are indicated for reconstructive surgery, for fixation of cranial, maxillofacial and oral fractures, orthognathic and orthodontic reconstructions, mandibular reconstruction and any osteotomy surgery or trauma in CMF.

DELPHOS IMPLANTS' rigid fixation systems are for single use only, and is completely forbidden to reuse the devices when they have already been in contact with the patient with residues of blood/tissue.

PRODUCTS AND MATERIALS

Screws: Ti-6Al-4V and Ti-6Al-4V ELI ASTM F 136 and ISO 5832-3;
Plates: Titanium ASTM F 67 and ISO 5832-2 and Ti-6Al-4V and Ti-6Al-4V ELI ASTM F 136 and ISO 5832-3;
Mesh Plates: Titanium ASTM F 67 and ISO 5832-2.

SYSTEM	LOCATION	PLATES	COMPATIBLE SCREWS	SPECIFIC INDICATION
1.2	1/3 Medium & 1/3 Higher	Straight, Curved, 3D, T Plates, Z Plates, L Plates, Y Plates, H Plates, X Plates, Orbital Plates	Self-Tapping Ø1.2 Self-Drilling Ø1.2 Self-Drilling Hybrid Ø1.2 Emergency Screws Ø1.4	Fixation of cranium maxillofacial
	1/3 Higher	Calvarium Plates; Mesh Plates		Fixation of 1/3 higher fractures
1.6	1/3 Medium & 1/3 Higher	Straight, Curved, 3D, Z Plates, L Plates, Y Plates, H Plates, X Plates	Self-Tapping Ø1.6 Self-Drilling Ø1.6 Self-Drilling Hybrid Ø1.6 Emergency Screws Ø1.9	Fixation of maxillary facial and oral fractures. Any osteotomy surgery
	1/3 Medium	Maxillary Plates		LeFort1
	1/3 Higher	Calvarium Plates; Mesh Plates		Fixation of 1/3 higher fractures
2.0	1/3 Medium & 1/3 Lower	Straight, Straight with Locking, Straight Adjustment on Local Site Plates, BSSO Straight Plates, BSSO Curved Plates, BSSO Double Plates, BSSO XL Plates, L Plates, L Plates with locking, Z Plates, Y Plates, X Plates, BSSO X Plates, Curved Plates, L Adjustment on Local Site Plates, T Plates, Maxillary Plates, 3D Plates	Self-Tapping Ø2.0 Self-Drilling Ø2.0 Self-Drilling Hybrid Ø2.0 Self-Tapping Locking Ø2.0 Emergency Screws Ø2.3	Fixation of maxillary, facial and oral fractures. Orthognathic reconstruction. Any trauma or osteotomy in CMF.
	1/3 Lower	Condylar fractures plates		Condylar Fractures
	1/3 Medium	Mentoplasty Plates		Mentoplasty
	1/3 Higher	Mesh Plates		Fixation of 1/3 higher fractures
2.4	1/3 Lower	Semi compression Straight Maxi Plates Straight Maxi Plates, Angulated Maxi Plates	Self-Tapping Ø2.4 Self-Drilling Ø2.7 Self-Tapping Locking Ø2.4 Self-Tapping Locking Ø2.7 Emergency Screws Ø2.7	Mandibular Reconstruction
		DRS Straight Plates, DRS Angulated Plates, DRS Curved Plates		
SCREWS				**SPECIFIC INDICATION**
Self-Tapping Ø1.2mm; Self-Tapping Ø1.6mm; Self-Drilling Ø1.6mm; Self-Tapping Ø2.0mm; Self-Drilling Ø2.0mm				Bone Graft

CONTRAINDICATIONS

The use of Delphos Implants rigid fixation system is not indicated in cases of:
- Active infection or suspicion of the same in patients with limited blood flow which can slow the healing process or increase the possibility of infection or rejection of the implant;
- Patients sensitive to titanium. When sensitivity is suspected, appropriate tests should be performed prior to implantation of the product;
- Metabolic or systemic disorders or metabolic treatments that could lead to progressive deterioration of the bones (treatments with corticosteroids, immunosuppressive therapy);
- Skeletally immature patients who present bone shortcomings or fragile;
- Patients younger than 16 years. With the exception of traumatic cases, and if the health professional wants, he may use medical devices.

WARNINGS AND PRECAUTIONS

1. The use of plates and screws with incompatible sizes for the restraint areas of high functions, may cause a break or failure of the implants;
2. Excessive or repeated folding of the plates may weaken the structure of the plates, increasing the risk of failure;
3. The use of screws in high dense bone can lead to fracture or failure of the implant during insertion;
4. Excessive load during the insertion of the screws may lead to its failure or breakage;
5. 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;
6. When placing additional screws, guarantee that the subsequent screw placement does not interfere with the new screws;
7. The reuse of implants that have been in contact with human tissues and blood its prohibited;
8. Removal of the implants is not required, therefore the decision to do it is exclusively of the health professional and patient responsibility;
9. Plate positioning must allow adequate clearance of nerves, tooth buds and/or tooth roots or any other critical structures;
10. The plates and screws are for single use only, being this indication described on the product labels, guaranteeing the safety of the patient;
11. The instruments required for the implantation of the implants are reusable;
12. Delphos Implants Rigid Fixation System have not been tested for safety and compatibility in the MR environment, nor has it been tested for heating, migration, or image artifact in the MR environment. The safety of Delphos Implants in the MR environment is unknown. Scanning a patient who has these devices, may result in patient injury;
13. The compliance with the recommended sterilization parameters indicated is a responsibility of the user, as well the use of the accessories (wraps);
14. The surgeon should have specific information, training, experience, deep expertise in the use of products and rigid fixation techniques;
15. The surgeon should be trained to make the correct selection of the type of plate and screw used for specific indications;
16. The rigid fixation plates and screws are not designed to withstand abnormally excessive functional constraints;
17. When loading a screw on the screwdriver (blade), apply a force perpendicular to the fitting screw in the screwdriver. The surgeon should avoid insertion and removal of the same screw in the screwdriver multiple times, in order to prevent failure when placing the screw;
18. The plates and screws manufactured by Delphos were designed for the union of bone fragments while osteogenesis occurs;
19. All plates and screws require specific instruments for its implantation. The non-use of the instruments provided by Delphos may compromise the success of the procedure, increasing the risk of premature failure of the devices.

ADVERSE EFFECTS

Any surgical procedure entails risks and possibility of complications, which may or not be related to the implant placement. The main complications and adverse effects associated with these products are: infection, debridement of sequestrum, presence of teeth in the line of fracture, prosthetic consideration, sensory disturbances, discomfort, exposed plates, osteomyelitis, plate/screw being palpable, exposed plates due to dental-alveolar fracture, clinical irritation, dental implant placement, tooth extraction, dysesthesia of the nerve, abscess formation, inflammatory

reactions, swelling, trismus, intraoral and/or extra oral drainage of purulent material, secondary callus, arteriovenous fistula of the maxillary artery, temporomandibular dysfunction, maxillary sinusitis and nerve dysfunction.

INSTRUCTIONS TO USE SELF-DRILLING SCREWS

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.

NOTE: 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.

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.

CHARACTERISTICS OF THE CLEANING AGENTS

- Enzyme washers with neutral pH between 7 and 9
- Alkaline detergents with nonionic, non-foaming and biodegradable surfactants

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

AUTOMATED CLEANING AND DISINFECTION

When using a washer-disinfector it is required to.:

1. Start the cycle:
   - Prewash without product for 1 minute at room temperature
   - Wash: 40°C water + detergent
2. Bring temperature up to 50°C and maintain it for 5 minutes
3. Perform 3 serial rinses with cold water for 1 minute at room temperature
4. Unload the instruments and inspect the surface and cavities of each device to make sure all visible dirt has been removed.

A final rinsing step with thermal disinfection (demineralized water temperature increased to 90°C and held for 5 minutes) can be added. The hold time depends on the size and power of the unit (ISO 15883-1).

DRYING

This step prevents microbial growth, removes any traces left from the washing and rinsing steps and also optimizes sterilization effectiveness.

- If using the washer-disinfector, do not exceed 120°C (drying for 20 minutes at 95°C)

STERILIZATION

DELPHOS IMPLANTS recommend sterilization by autoclave (Moist heat), taking into account the requirements of EN ISO 17665-1. 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

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 does 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.

Sort the cleaned and disinfected implants in the sterilization trays and wrap them in one-way sterilization packaging (single or double packaging) complying with the specifications of standards ISO 11607-1/ISO 11607-2.

HANDLING STORAGE AND TRANSPORT CONDITIONS

These products don't have special handling, storage and transport conditions.

DISPOSAL

The product should be disposed off at the end of its useful life and should be discarded in accordance with the current environmental legislation. Whenever possible cut or fold, preventing the reuse.

SYMBOLS

 Consult instructions for use	 Catalog Number	Rx Only Use under Medical Prescription	 Caution
 Date of manufacture	 Batch Code	 Do not re-use	 Manufacturer
 Non-Sterile	 Medical Device	 Patient information website	 Unique device Identifier


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