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 single-use, product labels have indication for single-use only, ensuring patient safety. It is no way allowed to reuse the implants when they have already had contact with a patient or when they were dirtied with blood/tissue.

DELPHOS IMPLANTS' does not guarantee the safety and efficacy of the implants if they are reused.

The implants are compatible with MRI (Magnetic Resonance Imaging) and X-ray computed tomography.

The instruments used for the implantation of the products are reusable.

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	Product	Compatible Screws	Specific Indication
1.2	1/3 Medium & 1/3 Higher	Straight Plates, Z Plates, L Plates, Y Plates, H Plates, X Plates, Curved Plates 3D Plates, T Plates, Orbital Plates	Self-tapping screws Ø 1.2 mm, L: 3 to 14mm Self-drilling screws Ø 1.2mm, L: 3 to 14mm Hybrid self-drilling screws Ø 1.2mm, L: 3 to 14mm Emergency screws Ø 1.4mm, L: 4 to 7mm	Fixation of 1/3 Medium & 1/3 Higher fractures of the face, and Orthodontic treatments
	1/3 Higher	Calvarium Plates, Mesh Plates		Fixation of 1/3 Higher fractures of the face
1.6	1/3 Medium & 1/3 Higher	Straight Plates, Z Plates, L Plates, Y Plates, H Plates, X Plates, 3D Plates, Curved Plates	Self-tapping screws Ø1.6 mm, L: 3 to 14mm Self-drilling screws Ø 1.6mm, L: 3 to 14mm Hybrid Self-drilling screws Ø 1.6mm, L: 4 to 14mm Emergency screws Ø 1.9mm, L: 4 to 12mm	Fixation of cranial, maxillary, facial and oral fractures. Any osteotomy surgery in CMF, & Orthodontic treatments
	1/3 Medium	Maxillary Plates		Le Fort 1
	1/3 Higher	Calvarium Plates, Mesh Plates		Fixation of 1/3 Higher fractures of the face
2.0	1/3 Medium & 1/3 Lower	Straight Plates, Straight Plates with Locking, Straight Adjustment on Local Site Plates, Curved 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, Curved Plates, L Adjustment on Local Site Plates, T Plates, BSSO X Plates, Maxillary Plates, 3D Plates	Self-tapping screws Ø 2.0mm, L: 4 to 20mm Self-drilling screws Ø 2.0mm, L: 4 to 18mm Hybrid self-drilling screws Ø 2.0mm, L: 5 to 19mm Self-tapping locking screws Ø 2.0mm, L:6 to 20mm Emergency screws Ø 2.3mm, L: 4 to 12mm	Fixation of cranial, maxillary, facial and oral fractures. Orthognathic reconstruction. Any trauma or osteotomy surgery in CMF. Orthodontic treatments
	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 of the face
2.4	1/3 Lower	Semi Compression Straight Maxi Plates, Straight Maxi Plates, Angulated Maxi Plates	Self-tapping screws Ø 2.4mm, L:4 to 18mm Emergency screws Ø 2.7mm, L: 6 to 14mm	Fixation of maxillary fractures. Reconstructive surgeries
		DRS Straight Plates, DRS Angulated Plates, DRS Curved Plates.	Reconstruction Self-tapping screws Ø 2.4mm, L:8 to 18mm Reconstruction Self-drilling screws Ø 2.7mm, L: 8 to 16mm Reconstruction Self-tapping lock screws Ø 2.4mm, L: 8 to 16mm Reconstruction Self-tapping lock screws Ø 2.7mm, L: 8 to 16mm	Mandibular reconstruction

Screws	Dimensions	Specific Indication
Self-tapping Screws – Ø 1.2mm	L: 4 to 16mm	Bone graft
Self-tapping Screws – Ø 1.6mm	L: 6 to 20mm	
Self-drilling Screws – Ø 1.6mm	L: 6 to 20mm	
Self-tapping Screws – Ø 2.0mm	L: 6 to 20mm	
Self-drilling Screws – Ø 2.0mm	L: 6 to 20mm	

CONTRAINDICATIONS

The use of DELPHOS IMPLANTS' rigid fixation systems is not indicated in cases of:

- Active infection or suspicion of the same in patients with limited blood flow which can slow the healing 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 medical treatments leading to progressive deterioration of the bones (treatments with corticosteroids, immunosuppressive therapy);
- Skeletally immature patients who present bone shortcomings or fragile bones;
- Patients younger than 16 years. With the exception of traumatic cases, and if the health professional wants, he may use medical devices;
- Conditions, individual or concomitantly, tend to impose severe loads on the fixation points such as obesities, heavy-duty, active sports, history of fractures and trauma, use of alcohol or drugs.

WARNINGS AND PRECAUTIONS

1. The use of plates or screws with incompatible size with the necessary for the restraint areas of high functions, may cause a break or failure of the implant;
2. Excessive or repeated folding of the plates may weaken the structure of the plates, increasing the risk of rupturing;
3. The use of screws in high dense bone can lead to fracture or failure of the implant during inserting;
4. Excessive load for insertion of the screws may lead to its failure or breakage.
5. During surgery, any damaged device should be removed from the patient in case of implantation. Products that do not have the conditions determined by the manufacturer should not be implanted and should be discarded.
6. When placing additional screws, make sure that the subsequent screw placement does not interfere with the new screws.
7. The use of implants which have been in contact with human blood prior to its implantation is prohibited;
8. Implant removal is not necessary, so the decision to do it is exclusively of the health professional and the patient responsibility.
9. Plate positioning must allow adequate clearance of nerves, tooth buds and/or tooth roots and any other critical structures.

ADVERSE EFFECTS

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

KEEPING THE EFFECTIVENESS AND PRODUCT SAFETY

1. The surgeon should have specific information, experience, deep expertise in the use of products and rigid fixation techniques;
2. The surgeon should be trained to make the correct choice of the type of plate and screw used for specific indications;
3. The rigid fixation plates and screws are not designed to withstand abnormally excessive functional constraints;
4. 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, thereby avoiding the failure in the automatic function of the "handle" of the screw;
5. The rigid fixation systems DELPHOS IMPLANTS were designed for the union of bone fragments while Osteogenesis occurs.
6. All plates and screws have DELPHOS IMPLANTS specific instruments for its implantation. Use DELPHOS IMPLANTS instruments for each technical step of implantation. The non-use of DELPHOS IMPLANTS instruments may compromise the success of the implanted device, increasing the risk of premature failure of the device.
7. Drill using the pilot drill indicated. Use irrigation during the use of the drills.

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 you can 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 professionals, following technics and approved protocols, should perform this type of procedure.

CLEANING DISINFECTION AND STERILIZATION

The implants are supplied Non Sterile and must be carefully cleaned, disinfected and sterilized prior to use in accordance with the requirements of EN ISO 17664.

Characteristics of the cleaning agents

- Cleaning agent containing alkalis (pH 10-11 when diluted in water), surfactants (<5%) and enzymes.
- Directions of use: 2 mL/L of water.
- Alkaline detergents with nonionic, non-foaming and biodegradable surfactants.

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

Manual cleaning

Note: *Be careful not to collide medical devices against each other and cause damage that may affect their use.*

1. Prepare an ultrasonic bath with a cleaning solution at the concentration and temperature specified in the detergent instructions.
2. Fully submerge the medical devices in the cleaning bath at a temperature below 50 °C (Room temperature < 30 °C). Respect the bath time advised by the product manufacturer (which should last for at least 15 minutes).
3. Brush the medical device inside and out, and any engraving, to remove persistent stains. Run the solution through device cavities to remove any residue.
4. Rinse thoroughly (Temp < 30°C) by soaking and/or spraying with water to remove detergent and dirt; demineralized water should be used whenever possible.

Automated cleaning

Note: *The preferred method consists of manual cleaning reinforced by the washing machine. Only use washing machines with CE marking and which have been validated by the manufacturer of the equipment.*

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. If needed, repeat the cycle or perform manual cleaning.

Manual disinfection

Note: *Some detergents also act as disinfectants (see manual cleaning step).*

Automated disinfection

If using a washer-disinfector, 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

Note: *This step prevents microbial growth, removes any traces left from the washing and rinsing steps and optimizes sterilization effectiveness.*
- If **using the washer-disinfector**, do not exceed 120°C (Drying for 20 min at 95°C).
- **Manual drying** can be performed using a clean non-woven absorbent tissue or a clean lint-free cloth, and medical compressed air.

Sterilization

DELPHOS IMPLANTS recommends 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 in autoclaves are followed:

Cycle	Temperature	Exposure time
Steam (1atm of pressure)	134°C (273°F)	18 minutes

Inspection

Before use, visually inspect and check for damage or residue caused by the washing 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 is not aware that this 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 disinfected implants in the sterilization trays and package them in one-way sterilization packaging (single or double packaging) which correspond to the following specifications 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 not be disposed off with household garbage at the end of its useful life and should be discarded in accordance with the current environmental legislation. Whenever possible cut or fold, avoiding reuse.

SYMBOLS

 Consult Instructions of Use	 Product Reference	Rx Only Use under Medical Prescription	 CAUTION!	 Non sterile
 Date of Manufacture	 Product Batch	 Do not reuse	 Manufacturer	

DELPHOS IMPLANTS INDÚSTRIA,
COMÉRCIO, IMPORTAÇÃO E EXPORTAÇÃO DE IMPLANTES MÉDICOS, S.A.

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