INSTRUCTIONS FOR USE - EXTREMITIES

CLINICAL INDICATIONS

DELPHOS IMPLANTS' devices for upper and lower extremities consist of various system components for skeletal osteosynthesis of small bone fragments and are intended to support normal bone healing for osteotomies, fractures and reconstruction.

DELPHOS IMPLANTS' extremities 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

Plates: Titanium Grade 2 according ISO 5832-2/ASTM F 67

Cannulated and Non-Cannulated Screws: Ti-6Al-4V and Ti-6Al-4V ELI according ISO 5832-3/ASTM F 136;

Guide Wires: Stainless Steel according ISO 5832-1/ASTM F138

SYSTEM		PRODUCT	COMPATIBLE SCREWS	SPECIFIC INDICATION
HAND	1.2	LOCKING PLATES Straight plates Y Plates, L Plates, T Plates, Grid Plates	Self-tapping screws – Ø 1.2 mm Self-tapping LAG screws - Ø 1.2mm	For fractures of the distal, middle and proximal phalanges
	1.6	LOCKING PLATES Straight Plates, Y Plates, L Plates, Grid Plates, Condylar Plates, Subcondylar Plates	Self-tapping screws – Ø 1.6 mm Self-tapping LAG screws - Ø 1.6mm	For fractures, osteotomies and arthrodesis of the proximal phalanges and metacarpals.
	2.0	LOCKING PLATES Straight Plates, Y Plates, L Plates, Offset Grid Plates, Condylar Plates, Subcondylar Plates, Z Plates, Straight LCDCP	Self-tapping screws – Ø 2.0 mm Self-tapping LAG screws - Ø 2.0 mm	For fractures of the phalanges, metacarpals, and carpal bones. And also intended for osteotomies and arthrodesis and interphalangeal joints
	2.4	LOCKING PLATES Straight Plates, Y Plates, L Plates, Offset Grid Plates, Condylar Plates, Subcondylar Plates, Z Plates, Straight LCDCP	Self-tapping screws – Ø 2.4 mm Self-tapping LAG screws - Ø 2.4 mm	For compression fractures; displaced fractures; intraarticular fractures; surgical reduction), for osteosynthesis in distal radius surgery and for wrist arthrodesis.
	ZYON	Zyon Regular Plates	Self-tapping PEG screws – Ø 2.0 mm and 2.7mm Self-tapping Locking screws – Ø 2.5 mm Self-tapping screws – Ø 2.7 mm and 3.7mm Self-tapping LAG screws – Ø 2.7 mm	fixation of intra and extra- articular fractures, osteotomies and non-unions of the distal radius
FOOT	2.7	Hiatus Plates, Multiple Fusion Plates (MFP), Meta Fusion Plates	Self-tapping screws – Ø 2.7 mm Self-tapping LAG screws - Ø 2.7mm	Forefoot arthrodesis and osteotomies (e.g. Akin, Austin-Chevron, distal metatarsal osteotomy (DMO), PIP arthrodesis in hammer toes, Moberg osteotomy, Scarf, proximal osteotomies of the first ray and proximal osteotomies of the small metatarsals).
FOOT	3.5	Leap Plates, Gap Plates, Multiple Fusion Plate (MFP), Centipede Plate, Flat Fusion Plate (FFP), Calcaneus Shift Plate, Web Plate	Self-tapping screws – Ø 3.5 mm Self-tapping LAG screws - Ø 3.5mm	Revision surgeries (e.g. Keller-Brandes revisions, first metatarsophalangeal (MTP I) lengthening arthrodesis, revisions after MTP I prosthesis, first metatarsal

SYSTEM	PRODUCT	SPECIFIC INDICATION
HAND & FOOT	Guide Wires	To hold bone fragments together
	Cannulated Screws	To reduce a fragment fracture by being precisely guided into position over a Guide Wire

CONTRAINDICATIONS

The use of Delphos Implants devices for extremities is not indicated in cases of:

- Patients with known allergies and/or hypersensitivity to the titanium and/or stainless steel;
- Patients with active or suspected infection or in patients who are immunocompromised.
- Patients with certain metabolic diseases, circulatory disorders and systemic diseases such as active infections that could retard healing
- Patients with tumors 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.
- Cases where the patient is obese, except if the health professional decides to use it.
- Inferior or insufficient bone quality to securely anchor the implant.
- Patients who are incapacitated and/or uncooperative during the treatment phase.
- 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 surgeon must have specific training, experience, and thorough familiarity with the use of devices, surgical techniques and post-operative care;

2. Patients must closely follow the post-operative instructions from their surgeon;

3. Delphos, as manufacturer, 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 for the product application.

5. Implants are intended for single use only.

6. The use of inadequate cleaned and sterilized devices may lead to potential risks of infection/contamination.

7. Use, reuse or reprocessing of explanted, contaminated, used or damaged implants (e.g. by scratches), is prohibited. This also applies to contact with human tissues and blood.

8. Excessive or repeated bending of the plates may weaken the structure of the plates, increasing the risk of failure and could result in implant fracture and failure during postoperative treatment;

9. An implant that appears damaged can show signs of fatigue due to previous unknown stress, which can lead to a premature failure or shortening of the lifetime of the implant.

10. Incorrect product selection may lead to a loosening, bending or breakage of the product or fracture of the bone.

11. For the success of the procedure the instruments used should be also provided by DELPHOS in order to guarantee the compatibility with the implants. Failure to use dedicated, unique instruments for every step of the implantation technique may compromise the integrity of the implanted device, leading to premature device failure and subsequent patient injury. may require reoperation and/or removal.

12. The osteosynthesis devices are recommended for use in patients with sufficient bone quality to sustain effectiveness and benefits of internal fixation.

13. In the case of shortening of the bone plate, cutting surfaces must be trimmed with appropriate instruments. The surgeon must ensure that the stability, load-bearing capacity and fixation of the plate are maintained.

14. Before insertion of the 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.

15. Use of excessive torque during insertion of screws may lead to implant failure.
16. Weight bearing is not recommended until fusion has occurred.
17. Locking screws are intended for use through locking plate holes/slots only.
18. It is recommended the application of cannulated screws into the bone by means of guide wires.
19. Delphos Implants extremities 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;

ADVERSE EFFECTS
- Early or late infection, both superficial and deep;
- Elevated fibrotic tissue reaction around the surgical area;
- Pain.
- Nerve damage, vascular injury and wound healing disorders.
- Movement restrictions.
- Insufficient and/or delayed bone healing.
- Displacement of the implant with bone growth.
- Loosening of the implant from insufficient fixation.
-Bone necrosis, osteoporosis, insufficient revascularization, bone resorption and poor bone formation that can cause premature loss or fixation;
- Risk of rupture, bending, loosening or migration of the implant in case of excessive force and/or weight influence.

REMOVAL OF THE DEVICES

The surgeon must make the final decision on implant removal, whenever possible and practical for the individual patient. In the event that the devices must be removed, select the appropriate instruments.

To remove locking screws, first unlock all locking screws before removing them completely, otherwise the plate may rotate and damage the soft tissue.

CLEANING, DISINFECTION AND STERILIZATION

The plates, screws and wires 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
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.

AUTOMATED DISINFECTION

When 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

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

Due to its physical and chemical properties, these products don't have special handling, storage and transport conditions.

DISPOSAL

The product should 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, 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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CE 0197

Date of last review:
January 2020