INSTRUCTIONS FOR USE
CANNULATED AND NON-CANNULATED SCREWS

INDICATIONS
Cannulated and non-cannulated screws for upper and lower extremities consist of screws for skeletal osteosynthesis of small bone fragments and are intended to support normal bone healing for fractures, osteotomies and arthrodesis, in the hand and foot.

PRODUCTS AND MATERIALS
Screws are for single use only. They are sold non-sterile. Non-sterile screws must be cleaned, decontaminated and sterilized before use.
Material: Ti-6Al-4V ASTM F136 and ISO 5832-3.

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 two (2) attempts to engage the screw, the connection may become damaged, and proper engagement can no longer be ensured.
- It is recommended the application of cannulated screws into the bone by means of bone wires.

Compatible instruments – Cannulated screws (**Handle:** DA-C-0019-830; DA-C-0019-850)

Screw System	Screw reference[1]	Blade reference	Bone Wire Ø (mm)	Drill bit Ø (mm)	Screw tap Ø (mm)	Countersink
1.7	DTE-C-17**-65H DTE-C-17**-65D	SK-09T06-800	0.8	1.5	1.7	SK-C-2024-814
2.0	DTE-C-20**-365	SK-11T08-800	1.0	1.5	2.0	SK-C-2024-814
2.3	DTE-C-23**-65H DTE-C-23**-65D	SK-09T06-800	0.8	2.0	2.4	SK-C-2024-814
2.4	DTE-C-24**-365	SK-11T08-800	1.0	2.0	2.4	SK-C-2024-814
2.8	DTE-C-28**-65H	SK-09T06-800	0.8	2.4	3.0	SK-C-2024-814
	DTE-C-28**-65D	SK-11T08-800	1.0	2.4	3.0	SK-C-2024-814
3.0	DTE-C-30**-65T	SK-09T06-800	0.8	2.7	3.0	SK-C-3045-814
	DTE-C-30**-365	SK-13T10-800	1.2	2.7	3.0	SK-C-3045-814
3.4	DTE-C-34**-65H DTE-C-34**-65D	SK-11T08-800	1.0	3.0	3.5	SK-C-3045-814
3.5	DTE-C-35**-365	SK-13T10-800	1.2	3.0	3.5	SK-C-3045-814
4.0	DTE-C-40**-365	SK-13T15-800	1.2	3.5	4.0	SK-C-3045-814
4.2	DTE-C-42**-65H DTE-C-42**-65D	SK-13T10-800	1.2	3.5	4.0	SK-C-3045-814
4.5	DTE-C-45**-365	SK-13T15-800	1.2	4.0	4.5	SK-C-3045-814
5.2	DTE-C-52**-65H	SK-13T15-800	1.2	4.0	5.0	SK-C-3045-814
5.5	DTE-C-55**-365	SK-22T25-800	2.0	5.0	5.5	SK-C-5570-814
6.0	DTE-C-60**-65D	SK-22T25-800	2.0	5.0	6.0	SK-C-5570-814
6.5	DTE-C-65**-365	SK-22T25-800	2.0	5.0	6.5	SK-C-5570-814
7.0	DTE-C-70**-65H DTE-C-70**-65D	SK-22T25-800	2.0	6.0	7.0	SK-C-5570-814
	DTE-C-70**-365	SK-22T25-800	2.0	6.0	7.0	SK-C-5570-814
8.0	DTE-C-80**-65H DTE-C-80**-65D	SK-22T25-800	2.0	7.0	8.0	SK-C-5570-814

[1] The screw references can have additional letters at the end of the reference for variations of the screw design. Ex: DTE-C-17**-65HS, DTE-C-20**-365L. ** Represent the length of the screw, in mm.

Compatible instruments – Non-Cannulated screws

Screw System	Screwdriver handle	Blade reference
1.6	DA-C-0019-830 DA-NC-0019-820	SK-NCT05-816
2.0		SK-NCT06-820

CONTRAINDICATIONS
The use of Delphos Implants 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.
- Patients with metabolic or systemic disorders or under 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 the 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 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
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. 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;
9. Screws are not designated to withstand abnormally excessive functional constraints;
10. Incorrect product selection may lead to a loosening, bending or breakage of the product or fracture of the bone;
11. The use of screws in high dense bone can lead to fracture or failure of the implant during insertion;
12. Excessive load during the insertion of the screws may lead to its failure or breakage;
13. Use of excessive torque during insertion of screws may lead to implant failure;
14. Removal of implants is not necessary. The decision to do so is the responsibility of both the healthcare professional and the patient;
15. When placing additional screws, guarantee that the subsequent screw placement does not interfere with the new screws;
16. The 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;
17. The surgeon should avoid insertion and removal of the same screw in the screwdriver more than 2 times, in order to prevent failure when placing the screw;
18. The screws manufactured by Delphos Implants were designed for the union of bone fragments while osteogenesis occurs;
19. Osteosynthesis devices are recommended for use in patients with sufficient bone quality to maintain the effectiveness and benefits of internal fixation.
20. All 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.
21. Use only devices whose original packaging has not been tampered with.
22. Weight bearing is not recommended until hand or foot bone fusion has occurred.
23. Delphos Implants' screws 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, re-fracture, non-union or malunion of the bone, soft tissue irritation, impaired joint function, osteomyelitis, surgical site complications, discomfort, pain, systemic toxicity, dysesthesia, paresthesia, 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. 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 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 in a pre-vacuum autoclave (moist heat), taking into account the requirements of 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.

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.

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.

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.

The application of excessive mechanical loads can cause failures in the performance.

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: 56004617SCEXTJU

SYMBOLS GLOSSARY

Symbol	Description	Symbol	Description
	Manufacturer		Unique device identification
	Manufactured in Portugal Date of manufacture	Rx Only	Use under medical prescription
	Medical device		Non-sterile
	Lot number		Catalog Number
	Caution		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/*		

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