INSTRUCTIONS FOR USE
REUSABLE INSTRUMENTS

These instructions apply to invasive surgical hand instruments, such as screw blades, drills, taps, countersinks, depth gauges and drill guides.
Surgical instruments are medical devices designed to be durable and reusable. They are supplied non-sterile and must be cleaned, decontaminated, and sterilized before use.

CLINICAL INDICATIONS
Delphos surgical instruments aim to facilitate the safe use of implants in craniomaxillofacial and orthopedic surgeries. These instruments aim to provide surgeons with the essential tools needed for the precise implantation of screws and plates during these procedures.

PRODUCTS AND MATERIALS
Applicable to class Ir invasive instruments with Basic UDI-DI:

Reference	Description	Material	Purpose	Basic UDI-DI
SK-XXXX-600	Drilling guides	Stainless steel	Allows access to the puncture site	56004617INST06GB
AL-XXXX-WIRE	Depth gauge	Aluminum	Assessing the depth of drilling in the bone	56004617INST09GH
SK-XXXX-8XX	Drill bits[1]	Stainless steel	Manual drilling of the bone to allow the insertion of screws	56004617INST12G6
SK-XXXX-8XX	Taps[1]	Stainless steel	Create threads in the pre-drilled holes in the bone	56004617INST12G6
SK-XXXX-8XX	Countersinks[1]	Stainless steel	Create a conical depression in the drilled holes to allow the screw head to fit in	56004617INST12G6
SK-XXXX-800	Screw guides	Stainless steel	Protects soft tissue during screw insertion	56004617INST13G8
SK-XXXX-8XX	Blades (for screws)[1]	Stainless steel	Allow screw placement	56004617INST14GA
DT5-3525-263	Anti-deformation screw	Titanium	Maintain the thread of DT3 locking plates during forming	56004617INST05G9
DT3-XXXX-99	Non-implantable plates	Aluminum	Non-implantable plates used for surgery planning	56004617INST15GC

1) Blades, drills, taps and countersinks must be used with a screwdriver handle:
- CMF surgery: Handle DA-0019-800 or DA-0019-810
- Extremities surgery: Handle DA-C-0019-830, DA-C-0019-830 or DA-NC-0019-820

Instruments made of stainless steel: ASTM F899
Instruments made of polypropylene: ASTM D4101
Instruments made of titanium: ASTM F67
Instruments made of aluminum: EN 573-3

INTENDED USERS
The instruments are intended for use by licensed healthcare professionals. These professionals must be fully aware of the products' intended use and the applicable surgical techniques and must be qualified by appropriate training methods.

Additional user groups include nurses and reprocessing staff: handling, cleaning and sterilizing devices, where applicable.

TARGET PATIENT GROUP
The instruments are intended for use by surgeons during craniomaxillofacial and orthopaedic surgery on individuals over the age of 16.

MAINTAIN THE EFFICACY AND SAFETY OF THE PRODUCTS
- Handle all instruments carefully so as to maintain their configuration and mechanical characteristics.
- Always inspect the condition of the instruments before use. If you notice any alterations, dispose of them immediately.
- The reuse of products, the application of excessive mechanical loads and sterilization cycles can lead to continued wear and tear of the devices, which can cause their performance to fail;
- The device does not have a defined lifespan; it depends on the conditions in which it is stored and used. The end of the useful life is usually determined by wear or damage in surgical use. Carefully inspect the instruments between uses to verify proper functioning. If performance variations, precision failures or visible deformations/defects are found, the device should not be used.

Note: *Please notify the manufacturer if you notice any of the above.*

The cleaning, decontamination and sterilization instructions below must be followed by the user to avoid premature deterioration of the products (wear, corrosion and contamination).

CONTRAINDICATIONS
There are no known contraindications associated with the use of these devices.

WARNINGS AND PRECAUTIONS
Do not use the instruments for purposes other than those recommended by the manufacturer, as this may damage the products and/or cause injury to users and/or patients.

ADVERSE EFFECTS
Any surgical procedure carries risks and the possibility of complications, which may or may not be related to the device. The main complications and adverse effects associated with the instruments, when not used as intended or when the instructions for use are not followed, are: discomfort, inflammation, prolonged surgery, infection, pain and tissue damage. Any serious incident that has occurred in relation to the device must be reported to Delphos Implants and to the competent authority of the Member State in which the user and/or patient is established.

CLEANING, DISINFECTION AND STERILIZATION
The instruments are supplied non-sterile. Cleaning, decontamination and sterilization instructions in accordance with the requirements of ISO 17664-1 must be followed by the user in order to prevent premature deterioration of the devices (wear, corrosion and contamination).

Pre-treatment at the point of use
Remove gross soiling by submerging the instrument into cold water (< 40 °C) immediately after use.
Do not use a fixating detergent or hot water (> 40 °C) as this can cause the fixation of residuals which may influence the result of the cleaning process.

Preparation before cleaning
Instruments do not need to be disassembled.

Characteristics of cleaning agents
- Enzymatic detergents with a neutral pH between 7 and 9
- Detergents with non-ionic, non-foaming and biodegradable surfactants

NOTE: The instructions provided by the manufacturer should be carefully read 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-wash 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 thermal disinfection (demineralized water at 93 °C for 5 minutes) must be included.
The duration of the bath depends on the size and energy of the unit (ISO 15883-1).

Drying
This step prevents microbial growth, removes any traces from washing and also promotes the effectiveness of sterilization. Dry for at least 25 minutes at 110°C.

Cleaning inspection
Inspect all instruments before sterilization or storage to ensure complete removal of residue and blood from surfaces. If there is still residue or blood, clean the instrument again.

Sterilization
DELPHOS IMPLANTS recommends sterilization in pre-vacuum autoclave (moist heat) taking into account the requirements of EN ISO 17665. It is recommended to comply with the following physical sterilization parameters:

CYCLE	TEMPERATURE	EXPOSURE TIME
Vapor (1 atm)	134°C (273°F)	18 minutes

Drying after sterilization
DELPHOS IMPLANTS recommends a drying time of at least 30 minutes.

Post-sterilization inspection
Do not store or use sterile devices if they are not dry. Moisture can corrode the metal and damage sharp edges. Inspect the sterile barrier for signs of damage. Do not use the product if the sterile barrier is compromised.

INSPECTION AND FUNCTIONAL TESTING
Visually inspect the instrument for damage and wear. Moving parts should move smoothly, without excessive play. The instruments must be free of bends and distortions. The laser marks must be legible.
If any situation is detected that could compromise the safe use of the devices, contact the manufacturer and/or discard.

REPROCESSING LIMITATIONS AND END-OF-LIFE INDICATORS
Delphos does not recommend a maximum number of reprocessing cycles. Repeated processing has minimal effects on the performance, safety or function of the instruments. The end of life of the instruments is determined by the wear and damage resulting from their surgical use. Carefully inspect the instruments between uses to verify proper functioning (see section “INSPECTION AND FUNCTIONAL TESTS”).

PACKAGING
The original packaging of the devices does not support high temperatures, so it is recommended to use sterilization trays manufactured by DELPHOS. The instruments 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
Only use devices whose original packaging has not been tampered with. Products should be stored at room temperature and away from sunlight.
Store sterile packaged instruments in a way that protects them from dust, moisture and extreme temperatures and/or humidity.
Improper handling or disposal of sharp devices can cause injury to the user.

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).

SYMBOLS

Symbol	Description	Symbol	Description
	Manufacturer		Unique device identification
	Manufactured in Portugal Date of manufacture		Medical Device
	Batch number	Rx Only	Use on prescription
	Attention		Non-sterile
	Catalog number		CE conformity mark
	Consult the instructions for use or consult the electronic instructions for use at *https://delphosimplants.com.pt/qualidade-regulamento-e-ifu/*		

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