INSTRUCTIONS FOR USE
REUSABLE INSTRUMENTS

These instructions apply to non-invasive manual medical instruments, such as sterilisation boxes and trays, screwdriver handle, diamond file, plate bender, plate cutter plier and plate shear. Medical instruments are medical devices designed to be durable and reusable. The instruments are supplied non-sterile and must be cleaned, decontaminated and sterilised before use.

CLINICAL INDICATIONS

Delphos instruments aim to facilitate the safe use of implants in craniomaxillofacial and orthopaedic 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 I non-invasive instruments with Basic UDI-DI:

Reference	Description	Material	Purpose	UDI-DI Basic
SK-XXXX-800	Plate bender, plate cutter plier and plate shear	Stainless steel	Plate cutting and forming	56004617INST01FZ
DA-XXXX-XX	Screwdriver handle	Stainless steel, Aluminium Polypropylene/ Silicone*	Handle for screw blades	56004617INST02G3
SK-XXXX-XX	Handle	Stainless steel	Handle for drilling guides	56004617INST03G5
DAX-XXXX-XX	Sterilisation tray	Aluminium*	Secure and protect medical devices during the sterilisation process	56004617INST04G7
SK-2475-800	Diamond file	Stainless steel	Smooth the surface of the plate after cutting	56004617INST01FZ

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

* Other materials may be present. Consult the label or manufacturer for more information.

INTENDED USERS

The instruments are intended for use by licensed healthcare professionals. Healthcare professionals must be fully aware of the intended use of the products and the applicable surgical techniques, and must be qualified by appropriate training methods.
Additional user groups include nurses and reprocessing staff: handling, cleaning and sterilising devices, where applicable.

PATIENT TARGET GROUP

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

MAINTAIN THE EFFICACY AND SAFETY OF THE PRODUCTS

- Handle all instruments carefully to maintain their configuration and mechanical characteristics.
- Always check 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 sterilisation cycles can lead to continued wear and tear on 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 its useful life is usually determined by wear and tear or damage during 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: *If you experience any of the above, please notify the manufacturer.*

The cleaning, decontamination and sterilisation 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 instruments, when not used as intended or when the indications for use are not followed, are: discomfort, inflammation, prolonged surgery, infection, pain and tissue damage.

CLEANING, DISINFECTION AND STERILISATION

The instruments are supplied non-sterile. Cleaning, decontamination and sterilisation 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 the most superficial dirt by immersing the instrument in cold water (<40 °C) immediately after use.
Do not use fixative detergent or hot water (>40 °C), as this can cause residues to settle which can influence the outcome of the cleaning process.

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 in order to use the detergent correctly, according to the exposure time, temperature and concentration.

Automatic washing and disinfection

Use a standard thermal washing and disinfection cycle in a washing/disinfecting machine that complies 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 (demineralised water at 93 °C for 5 minutes) should be included.

The duration of the bath depends on the size and power of the equipment (ISO 15883-1).

Drying

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

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

STERILISATION
DELPHOS IMPLANTS recommends sterilisation in a pre-vacuum autoclave (wet steam) taking into account the requirements of EN ISO 17665. It is recommended to comply with the following physical sterilisation parameters:

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

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

Post-sterilisation 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 jeopardise the safe use of the devices, contact the manufacturer and/or dispose of them.

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 instruments is determined by wear and damage resulting from surgical use. Carefully inspect the instruments between uses to verify proper functioning (see section "INSPECTION AND FUNCTIONAL TESTS").

HANDLING, STORAGE AND TRANSPORT 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
Products must not be disposed of with household waste at the end of their useful life. It must be disposed of in accordance with current environmental legislation.

SYMBOLS

Symbol	Description	Symbol	Description
	Manufacturer	UDI	Unique device identification
PT	Manufactured in Portugal Date of manufacture	Rx Only	Use under medical prescription
MD	Medical device	NON STERILE	Non-sterile
LOT	Lot number	REF	Catalog Number
	Caution	CE	CE marking of conformity
	Consult instructions for use or consult electronic instructions for use at *https://delphosimplants.com.pt/qualidade-regulamento-e-ifu/*		

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