INSTRUCTIONS FOR USE
REUSABLE INSTRUMENTS

CLINICAL INDICATIONS

Reusable instruments are used during surgical procedures. Delphos does not recommend the number of reprocessing cycles, as it is not aware that this process will damage, compromise or disable the performance of the implants.
The use of these instruments requires specific training and experience in the surgical procedures for which they are intended.

PRODUCTS AND MATERIALS

Surgical instruments are designed to be durable and reusable. Surgical instruments will be supplied non-sterile and must be cleaned, decontaminated and sterilized before further use.
Stainless steel instruments: ASTM F899
Instruments made of polypropylene: ASTM D4101
Instruments manufactured in titanium: ASTM F67
Instruments made of aluminum: EN 573-3

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.

MAINTAIN PRODUCT EFFECTIVENESS AND SAFETY

- Handle all instruments carefully in order to maintain their configuration and mechanical characteristics.
- Always inspect the condition of the instruments before using them. In the event of any change, proceed to discard it immediately.
- The reuse of the products, the application of excessive mechanical loads and the sterilization cycles, can lead to a continuous wear of the devices, which can cause failures in their performance;
- The device does not have a defined useful life, it depends on the conditions for its preservation and use. End of useful life is generally determined by wear or damage in surgical use. Carefully inspect 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 notice any of the above situations, please notify the manufacturer.*

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

PRE-TREATMENT AT THE POINT OF USE

Remove contamination. Clean instruments as soon as possible after use. If cleaning must be delayed, immerse instruments in a compatible detergente Solutions to prevent drying and encrustation of surgical soil.
Reprocess instruments as soon as is reasonably possible after use.

CLEANING, DISINFECTION AND STERILIZATION

The instruments are supplied Non-Sterile and must be thoroughly cleaned and disinfected before being sterilized, in accordance with the requirements of ISO 17664.

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

When using a washing / disinfection machine, you must:
1. Start the cycle:
   - Perform a pre-wash without products for 1 minute at room temperature
   - Wash: 40 ° C water + detergent
2. Increase the temperature to 50 ° C and keep for 5 minutes
3. Rinse 3 times in series with cold water for 1 minute at room temperature
4. Dismantle the instruments and inspect the surface and cavities of each device to ensure that all dirt has been removed.

A final rinse with thermal disinfection (demineralized water with temperature up to 90 ° C and maintained 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 trace derived from washing and also promotes the effectiveness of sterilization.
- When using a machine, do not exceed 120 ° C (drying for 20 minutes at 95 ° C)

CLEANING INSPECTION

Inspect all instruments prior to sterilization or storage to ensure complete removal of debris and blood from surfaces. If there is still soil or blood, clean the instrument again.

INSPECTION AND FUNCTIONAL TESTING

Visually inspect the instrument and check for damage and wear. Moveable parts should have smooth movement without excessive play. Instruments should be free of bending and distortion

STERILIZATION

DELPHOS IMPLANTS recommends sterilization by autoclave (wet steam) taking into account the requirements of EN ISO 17665-1. It is recommended to comply with the following physical sterilization parameters:

CYCLE	TEMPERATURE	EXPOSURE TIME
Steam (1 atm of pressure)	134°C (273°F)	18 minutes

INSPECTION AFTER STERILIZATION

Before using the instrument, perform a visual inspection and check for damage or residues resulting from the cleaning and sterilization processes. If any situation is detected that could compromise the safe use of the devices, contact the manufacturer and / or discard.

HANDLING, STORAGE AND TRANSPORTATION CONDITIONS

Use only devices whose original packaging has not been tampered with.
Products should be stored at room temperature and protected from sunlight.
Store sterile packaged instruments in a manner that provides protection from dust, moisture and extremes temperature and/or humidity.

LIMITATIONS ON REPROCESSING

The end of useful life of instruments is usually determined by wear and damage due to their surgical use. Repeated processing has minimal effects on instruments life and function.
Carefully inspect instruments between uses to verify proper functioning.

DISPOSAL

Products should not be disposed of with household waste at the end of their useful life. It must be disposed of in accordance with the environmental legislation in force.

SYMBOLS

 See Instructions for Use	 Catalog Number	Rx Only Use under medical prescription	 Caution
 Date of Manufacture	 Lot number	 Unique device identification	 Manufacturer
 Non-sterile	 Medical device	 website Patient information	

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