

REUSABLE SURGICAL INSTRUMENTS – INSTRUCTION FOR USE

Description: Surgical instruments for orthopaedic surgery

Intended use: Orthopaedic Surgery

Risk class: I Surgical instruments

Manufacturer: Episcan Srl - Via Custoza, 10 - 20811 Cesano Maderno (MB) - Italia

LIST OF REUSABLE SURGICAL INSTRUMENTS AND CONSTRUCTION MATERIAL			
Instruments	Material	Instruments	Material
Quick coupling handles	Stainless steel and silicone	Depth gauges	Stainless steel or aluminium
Complete screwdrivers	Stainless steel and silicone	Guides of various kinds	Stainless steel
Screwdriver inserts	Stainless steel	Wire guides	Stainless steel
Forceps of various kinds	Stainless steel	Rasps and peelers	Stainless steel
Drills and trocars for drilling	Stainless steel	Hammers and impactors	Stainless steel
Countersink and taps	Stainless steel	Removal tools	Stainless steel
Drills	Stainless steel	Instruments boxes and trays	Stainless steel or aluminium
Try plates and testing bulb	Aluminium	Stands for instruments	Silicone

1. Information about cleaning, sterilization and maintenance

The instruments are supplied non-sterile and uncleaned, therefore before use on the patient, they must undergo a complete cleaning and sterilization treatment with a validated method.

The health care facility is responsible for ensuring that cleaning and sterilization methods are correct and validated.

Preparation, sterilization and functional tests must be performed by qualified personnel.

All tools, trays and containers require continuous and professional maintenance.

For maintenance, only specific products for surgical instruments must be used.

IMPORTANT:

The following cleaning and sterilization instructions should be integrated with the health care facility procedures.

National rules, regulations and / or restrictions must be included in this process

2. Pre-treatment:

Once the sales packaging has been removed and before cleaning / sterilization, all instrument components - where possible - must be disassembled.

Episcan surgical instruments can be cleaned with alkaline or enzymatic detergents, specific for materials for hospital use, considering the raw material of construction.

Highly alkaline cleaning detergents can create stains on anodized surfaces and loss of elasticity in the case of silicone parts.

Cleaning detergents containing acid neutralizing agents or natron should not be used for cleaning sterilization containers.

The use of demineralized water prevents the formation of stains and corrosion; for this purpose, we recommend the use of disinfectants with corrosion protection.

The products must be positioned in such a way that water can flow from the empty parts and no unwashed areas remain.

Do not use abrasive fixing agents or hot water (> 40 ° c / 104 ° F).

3. Cleaning method

Proper washing of surgical instruments decreases the risk of transferring infectious agents from patients to the surgical team and to other patients and ensures that the instruments function properly by preventing rust and deterioration.

The instruments must be washed within 30 'of the end of the surgery.

Handwash

1. Completely immerse the instruments in an enzymatic or alkaline solution (pH ≤12) and leave to soak for 20 minutes. Use a soft nylon bristle brush to gently clean the tool until all visible dirt is removed.
2. Cannulated instruments must be freed of any bone residues that may be inside the central canal of the device.
3. After washing, rinse the instruments with running water.
4. Rinse with distilled water to remove residual running water.
5. Dry with a sterile, lint-free disposable cloth or dry in a hot air oven for 7-30 minutes (116 ° C).
6. Store in a clean dry place.

Ultrasonic washing

1. After the operations referred to in points 1/2/3, immerse the instruments in the ultrasonic tank and program a cycle for 30' at 60 °. Use only suitable detergent (aluminium devices are not designed to undergo ultrasonic cleaning).
2. Rinse instruments in purified water for at least 3 minutes or until all blood and bone remains have been removed.
3. Thoroughly and abundantly flush lumens, cavities and other hard-to-reach areas.
4. Rinse with distilled water to remove water residues.
5. Dry with a sterile, lint-free disposable cloth or dry in a hot air oven for 7-30 minutes (116 ° C).
6. Store in a dry and clean place.

Automated washing

1. After the operations referred to in points 1/2/3, carry out a preliminary rinse with cold running water for 5 minutes
2. Wash with 0.7% cleaning agent at 55 ° C for 10 minutes
3. Disinfection at 93 ° C with purified hot water until A0 3000 (10 ') is reached
4. Hot air drying at 110 ° C for 40 minutes
5. Store in a clean dry place

Note

N1: Cleaning personnel must always be adequately protected from splashes of infected water.

N2: Scissors, needle holders, pliers, retractors must be opened in order to thoroughly clean the entire instrument.

N3: Instruments must not be immersed in caustic or physiological saline solutions which could cause corrosion.

N4: Do not use abrasive fixing agents or metal brushes which could scratch or deposit metal particles on the instrument.

N5: For both ultrasonic and automated washing, it is necessary to strictly comply with the instructions for use of the manufacturer of the washing or disinfection system.

N6: All cleaning methods must be validated according to the technical specifications of the detergents used for the specific type of washing system

N7: In general, the colouring of aluminium instruments can undergo alterations with the use of some chemical products. Do not use too acidic or alkaline products, as well as products containing Sodium or Potassium. Carefully read the instructions for use of the washing products without forgetting the incompatibilities with aluminium. It is recommended to use chemical solutions with a pH between 4 and 8.

4. Functional test / visual inspection:

After cleaning it is necessary to visually check the presence or absence of contaminants; if so, the cleaning cycle must be repeated.

The functional test and / or visual check must be performed after cleaning and assembling the previously disassembled parts.

The instruments must be examined in order to highlight mechanical damage (e.g. fractures, deformations, corrosion, etc.)

Damaged instruments must be discarded and replaced.

5. Sterilization (non-sterile products)

Cleaned and dried instruments must undergo a validated sterilization cycle before use in the surgical field.

Sterilization in steam autoclave: 20min at 121 ° C or 10min at 134 ° C.

Strictly follow the instructions for use that are provided by the manufacturer of the sterilizer.

Aluminium products must be sterilized separately from stainless steel products.

All sterilization methods must be validated.

6. Care of stainless steel surgical instruments

When an instrument is damaged, it must be replaced or repaired

Improper cleaning, disinfection and sterilization will contribute more to rust or stains than the carbon content of stainless steel.

7. Common problems

- 7.1. Incorrect drying of the instrument after cleaning, disinfection or sterilization, can cause rust.
- 7.2. Use of corrosive detergents (Do not use chemical products with pH higher than 10.5).
- 7.3. In the case of aluminium products, the use of too acidic or alkane products, as well as products containing Sodium or Potassium
- 7.4. Improper rinsing to remove detergent or disinfectant solutions.
- 7.5. Use of tap water without following a rinse with distilled water. Tap water can contain chemicals and minerals such as iron which can leave deposits on the surface.
- 7.6. Faulty autoclave / cleaner that can leave deposits and attack the surface finish of the instrument.
- 7.7. Using rigid metal brushes roughen the surface of the instrument and make it sensitive

8. Disclaimer

Episcan Srl declines all responsibility for damage to property and / or persons deriving from:

- 1.1 Improper use of products.
- 1.2 Use of incompatible materials or tools.
- 1.3 Use of medical devices by surgeons other than orthopaedic surgeons.

The use of each surgical instrument in accordance with its natural intended use is left to the orthopaedic surgeon who determines the surgical technique according to the specific case to be treated.

Episcan disclaims any responsibility for use of the instrument that differs from its intended use.

9. Disposal of products

Always proceed according to hospital protocols and / or reference standards established for hazardous medical waste with blood contamination.