MediSurge s.a.s.

17, Boulevard SCHLOESING – 13010 MARSEILLE - Tel. +33 4 96 14 00 84 – Fax. +33 4 96 14 04 91 - Email : info@medisurge.net

Product: INSTRUMENTS Status: REUSABLE Use/Destination: THERAPEUTIC BRONCHOSCOPY Packaging: 1 PIECE

Manufacturer: Medisurge s.a.s.

With the purchase of this instrument, you will receive a high quality product, whose proper handling and use are described below.
To keep the risks for patients and users to a minimum, we ask you to follow the instructions carefully.
The use, disinfection, cleaning and sterilization of instruments may only be performed by trained specialist staff.

Presentation

Description: The product is a tubular shaft instrument in stainless steel made to; maintain, cut, remove and position anatomical or foreign bodies.
Functional Purpose: These instruments are used in Interventional Pulmonology under Endoscopic control.

Features

Working Length: Adult: 600 mm / Children : 400mm	1 or 2 mobile jaws depending on the instrument
Head Diameter: 2.0 to 4.0 mm (1 instrument 5.0mm)	Light colored handle with or without ratchet
Shaft Diameter: 1.5 to 3.5 mm (1 instrument 5.0mm)	All materials used are medical grade and autoclavable
Luer flush port	

Identification and Traceability

Each unit is marked with: Serial number • CE Mark – Class 1 • Manufacturer name

Symbols

Note: additional help or other useful information

Identifies a potential hazard to persons or property

Identification of products marketed in accordance with Directive 93/42EEC

Symbol for “Non-sterile”

Symbol for “Keep dry”

Symbol for “Keep away from sunlight”

Inspections

The instruments must be checked for functionality before each use.
Damage to the surface, such as scratches, cracks, nicks, scores, etc., as well as bent parts, means that they cannot be used. In that case, the products should be repaired or disposed of in accordance with standard hospital/practice procedure. Do not use damaged products!

Area of application

We provide our instruments for Interventional Pulmonology procedures. The treating physician is responsible for the selection of instruments for specific applications, or in the surgical setting. The physician is also responsible for ensuring that support staff have adequate training and sufficient information, and for having sufficient experience in the handling of the instruments.

Handling

The instruments must not be overstressed by twisting or prying, as this may result in damage to or failure of instrument parts.

Risks

- Injury to nerves, blood vessels and tissue
- Bleeding
- Infections

Complications:

In general, complications are rare. The frequency and severity of the complications depend on the nature of the examination.

Combination with other products / instruments

The products of MediSurge may not under any circumstances be combined with products, components and instruments from other manufacturers out of the Bronchoscope tubes and bases. Combinations with other products may adversely affect the outcome of the procedure and are not permitted because it may not be possible to adapt the components to each other.
It is recommended that only instruments and accessories from MediSurge be used.

Disposal

If the instruments can no longer be repaired and processed, they should be disposed of in accordance with standard hospital/practice procedure.

Materials:

The materials used are stainless steels under DIN EN ISO 7153-1.

Instructions for processing

Procedures:	• **Cleaning** • **Disinfection** • **Moist heat sterilization (DIN EN ISO 17665-1)**
Warnings: 	As supplied, the instruments are non-sterile and must be cleaned before use, and, if necessary, disinfected and sterilized. Instruments should be prepared only by those persons who possess the necessary training, and who are able to assess the risks that may occur and the corresponding effects.
Restriction on reprocessing:	Frequent reprocessing has little effect on the instruments. The end of the product life cycle is usually determined by wear and damage from use. The products should then be disposed of in accordance with standard hospital procedure. Do not use damaged products!

INSTRUCTIONS	
Preparation at the site of use:	The instruments should be cleaned and disinfected as soon as possible after use. Remove surface dirt using a disposable cloth/paper towel. Do not use a fixing agent or hot water (> 40°C), since it results in the fixation of residues that could affect the success of cleaning. Instruments must not under any circumstances be deposited in physiological saline solution, because prolonged contact will cause pitting and rust. For dry removal, the instruments must be immediately machine-processed to avoid encrustation and corrosion. For this purpose, the instruments must be stored on machine-compatible instrument carriers. Please make sure that jointed instruments such as scissors, forceps, grasper, etc., are open. In the selection of removal methods, long waits until processing, e.g., overnight or over the weekend, should absolutely be avoided because of the risk of corrosion.
Preparation for decontamination:	If instruments can be disassembled in parts, disassemble before processing.
Step 1	**Recommended methods for cleaning:**
<u>Manual</u>	The instruments must, if possible, be brushed under running water with a soft brush, until all visible contamination has been removed. For cavities, holes and threads, pressure rinse (with at least 4 bar pressure) with a water jet for least 10 seconds. Use the Luer port for internal rinsing If brushing and/or rinsing do not produce the desired result, the instruments must be placed in cold water for at least 5 minutes. The instruments must be placed in an ultrasound bath for 10 minutes and sonicated in the cleaning liquid (0.5%). After removal of the tools, they need to be rinsed with the water jet.
Ultrasonic cleaning:	• Use an ultrasound device that is suitable for medical use • The ultrasonic cleaning bath should be heated before cleaning to a temperature recommended by the manufacturers of cleaning or cleaning/disinfecting solutions • In general, temperatures between 40°C and 50°C promote the cleaning effect • Place the instruments into the strainer basket • Load the instruments in the ultrasonic bath with 40 kHz output power for 5 min. • After ultrasonic cleaning, instruments must be rinsed with clear running water and dried • The cleaning or cleaning/disinfecting solutions used must be used according to the manufacturer's instructions • An overdose of cleaning or cleaning/disinfecting solutions should be avoided • The cleaning or cleaning/disinfecting solutions used must be suitable for cleaning steel products Also, the following points should be noted: • The strainer basket of the ultrasonic device must be sufficiently large and deep to ensure complete immersion of the instruments • Products must be completely covered by the cleaning solution • Only use trays that do not affect the cleaning action • Do not overload trays

<table>
<tr><td></td><td>
• Avoid “acoustic shadowing”
• Fill all channels and cavities through the luer port with cleaning solution, making sure that there are no bubbles
• Remove instruments from the ultrasonic device
• Blow out all the channels with air to remove residual liquid
• The cleaning solution in the ultrasonic bath should be changed at least each working day, and even several times a day if contamination is found
</td></tr>
<tr><td>Rinse</td><td>
• Load cleaned instruments in tanks with clean tap water; use fresh tap water for each rinse
• Rinse all channels completely and thoroughly with water
• Rinse the outer surfaces of the instruments thoroughly with tap water
• Remove instruments from the water
• Blow out all the channels with air to remove the rinse water
</td></tr>
<tr><td>Disinfection: <u>Manual</u></td><td>
• The disinfectant solution used must be suitable for the disinfection of steel products
• Load cleaned instruments into a tub with disinfectant solution
• Fill all channels and cavities with disinfectant solution, making sure that there are no bubbles
• Cover the tub with its matching lid
• Follow the manufacturer's instructions for disinfectant concentration and application time
• Wear disposable gloves while removing instruments from the disinfectant solution
</td></tr>
<tr><td>Step 2</td><td>Recommended procedure for cleaning and disinfection:</td></tr>
<tr><td><u>Automatic</u></td><td>
Cleaning and disinfection device: G 7835 CD (Miele)
<u>Cleaning program:</u> Oxivario (Validation Document N°.10109011407-3-1 / Process4)
<table>
<tr><th>Step</th><th>Time (min)</th><th>Process step</th><th>Reagents</th><th>Temp. (°C)</th></tr>
<tr><td>1</td><td>3</td><td>Pre-cleaning</td><td>Tap water</td><td>Cold</td></tr>
<tr><td>2</td><td></td><td>Drain water</td><td></td><td></td></tr>
<tr><td>3</td><td>3</td><td>Clean</td><td>Tap water
Dispense: 0.5% Sekumatic FR (Ecolab) at 45°C</td><td>55</td></tr>
<tr><td>4</td><td></td><td>Drain water</td><td></td><td></td></tr>
<tr><td>5</td><td>2</td><td>Clean</td><td>Tap water
Dispense: 0.5% Sekumatic FR (Ecolab) at 45°C</td><td>55</td></tr>
<tr><td>6</td><td></td><td>Drain water</td><td></td><td></td></tr>
<tr><td>7</td><td>1</td><td>Neutralize</td><td>Deionized water
Dispense: 0.1% Sekumatic FNZ (Ecolab)</td><td>Cold</td></tr>
<tr><td>8</td><td></td><td>Drain water</td><td></td><td></td></tr>
<tr><td>9</td><td>1</td><td>Rinse</td><td>Deionized water</td><td>Cold</td></tr>
</table>
</td></tr>
<tr><td>Disinfection: <u>Automatic</u></td><td>Perform automatic thermal disinfection, taking into account national requirements with regard to the A0 value (see ISO 15883).</td></tr>
<tr><td>Neutralization / rinse</td><td>
• Insert disinfected instruments into pool/tub with microbiologically pure/sterile water; use fresh water for each instrument
• Rinse outer surfaces of the instruments, all channels and cavities thoroughly with water to remove residual disinfectant
• Remove the instruments from the water
</td></tr>
<tr><td>Drying and function testing:</td><td>
• Dry outer surface with a lint-free cloth and compressed air
• Completely dry all channels and cavities with compressed air
• Check instruments for correct operation
</td></tr>
<tr><td>Maintenance, inspection:</td><td>Separate damaged instruments and send for repair.
Before shipment to the repair service, it is essential that the instruments are additionally sterilized.</td></tr>
<tr><td>Packaging:</td><td>Before sterilization the instruments should be packed in a suitable container or suitable sterilization packaging (EN 868, Part 1- 10). The sterilization packaging is dependent on the method of sterilization, as well as on transport and storage. The packaging has a considerable influence on the sterilization result. The packaging should be chosen so that the instruments fit into the package.
Use a sterilization indicator for the packaging and note the sterilization and expiration date on the package.</td></tr>
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Recommended procedure for sterilization:	*Recommended sterilization method:*	Steam sterilization with saturated steam with a fractionated vacuum (FR EN ISO 17665-1)
	Recommended temperature:	134°C
	Recommended pressure:	3 bar
	Hold time:	≥ 5 mins.
	Drying time:	≥ 15 mins.
	After sterilization, sterile check for damage, check sterilization indicators.	
Sterilization: 	Enclose sterilized instruments in sterile packaging in a closed cabinet, protected from dust, moisture and temperature variations.	

Additional Information: 	Further advice for reprocessing of medical devices: • Internet: http://www.rki.de • Internet: http://www.a-k-i.org • Hygiene requirements for the reprocessing of medical devices from the Committee for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (RKI) and the German Federal Institute for Drugs and Medical Devices (BfArM), concerning “hygiene requirements in the processing of medical devices” • For your information, Sterilization of medical devices. Information to be provided by the manufacturer for the processing of re-sterilizable medical devices (ISO 17664);
Contact the manufacturer:	See the manufacturer and service address

The above instructions have been validated by the medical device manufacturer as SUITABLE for preparation of a medical product for re-use. The processor is responsible for ensuring that the actually performed processing achieves the desired results, using the equipment, materials and personnel in the processing facility. For this, validation and routine monitoring of the process are required.

Information for validating the treatment

Detergent, pre-cleaning:	Tap Water
Exposure time:	4 min. at ambiant Temperature
Detergent, automatic cleaning:	Neodisher Mediclean (Dr. Weigert; Hamburg)
Concentration:	0.5%
Exposure time:	5 min. at 55°C
Cleaning and disinfection device:	Miele G 7735 CD
Software:	Software Ebro Winlog 2000 Version 1.21
Machine program:	Vario TD
Slide-in loading racks:	MIC slide-in loading racks (Miele)

Warranty

The products are made from high quality materials and undergo quality control before delivery. Please contact our service department if any defects are found.
However, we cannot accept any liability if the products are not suitable for the particular procedure. This must be determined by the user himself.
We cannot accept any liability for incidental or consequential damages.
Medisurge accepts no liability if these instructions are not followed.

Warning:

In the event of use of the instruments in patients with Creutzfeldt-Jakob disease, or HIV infection, we disclaim any responsibility for reuse.