

## CLEANING AND STERILIZATION INSTRUCTIONS FOR REUSABLE INSTRUMENTS

### **Products:**

OPERACE Reusable Instruments.

### **Limitations associated with reprocessing**

The life of the instruments is not unlimited. The maximum number of processing cycles cannot be determined in advance. The life of the instruments is normally determined by wear and damage due to the intended surgical use and not to reprocessing. The instruments should be meticulously examined before every use in order to ensure that they are fully functional.

### **Point of use**

Remove excess dirt with disposable cloth/paper wipe.

### **Transport to processing area**

The reusable instruments should be cleaned and disinfected as soon as possible after use.

### **Preparation for cleaning**

Disassembly of the individual instruments is not possible.

### **Cleaning / disinfection**

Since automated methods can be standardized, they should be given preference over manual methods.

### **Automated cleaning / disinfection**

In case highly contaminated medical devices are subjected to an automatic cleaning process, pre-cleaning similar to the manual cleaning method along with an ultrasonic bath is recommended.

Equipment required:

Washers-disinfectors (WDs) in accordance with ISO 15883, cleaning detergents

Procedure:

The operating instructions of the WD manufacturers must be observed. Detergents with a pH of 7 – 10 are recommended, subject to a maximum pH of 12. The instruments must be loaded with the holes face down so that the detergent can drain properly.

Minimum cycle parameters:

1. Pre-rinse for minimum 3 min with cold tap water
2. Primary wash for minimum 2 minutes at <40 °C. Add detergent
3. Wash for minimum 5 minutes at 55°C with detergent
4. Pre-rinse for minimum 1 minutes with tap water at > 40°C
5. Rinse for minimum 1 minutes with demineralized cold water
6. Thermal disinfection with demineralized water at least 5 minutes at >90°C
7. Dry at least 40 minutes at >90°C. If necessary, continue drying cannulations with sterile-filtered compressed air

When unloading check the instruments for complete removal of visible dirt. If necessary repeat the cycle or use manual cleaning.

### **Manual cleaning**

Equipment required:

Ultrasonic cleaner, cleaning agent intended for manual cleaning/disinfection and suitable for ultrasonic treatment, suitable soft brushes.

Procedure:

For manual cleaning, the components are placed in a solution of a combined detergent / disinfectant with a proven disinfectant action. The solutions must be prepared according to the manufacturer's

instructions (concentration, temperature, contact time). Detergents and disinfectants with a pH of 7–10 are recommended, subject to a maximum pH of 12.

#### Pre Clean

1. Rinse soiled device under running cold tap water for a minimum of two minutes. Use a soft-brush to assist in the removal of majority of dirt and debris.

#### Manual cleaning

2. Soak device in an enzymatic cleaner or detergent solution for a minimum of 10 minutes. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct exposure time, temperature, water quality and concentration.
3. Manually clean device until no residue on the surface can be seen. Use a soft brush to remove dirt and debris. Actuate joints, and other movable device features to expose all areas to the detergent solution, if applicable.
4. Prepare an ultrasonic bath with a fresh detergent solution using an enzymatic cleaner or detergent solution at the concentration and temperature specified in the detergent manufacturer's instructions.
5. Clean the instruments ultrasonically for a minimum of 10 minutes, using a minimum frequency of 30 kHz.
6. Visually inspect device. Repeat steps 2–5 until no visible residuals remains on device.

#### Manual disinfection:

7. Soak device in an enzymatic cleaner / disinfection solution for a minimum of 15 minutes. Follow manufacturer's instructions for use for correct exposure time, temperature, water quality and concentration.
8. Rinse device thoroughly in purified water for a minimum of two minutes. Ensure that blind holes are repeatedly filled and emptied.
9. Dry the instruments. If necessary, continue drying cannulations with sterile-filtered compressed air.

#### Inspection

##### Cleanliness:

After every cleaning/disinfection process the products must be free of visible residues and other contaminants. The products, and particularly the cannulations on the couplings, should be carefully inspected for possible residues. If necessary, the cleaning process should be repeated until the product is visually clean.

##### Function:

Before each use the surgical instruments should be checked for fractures, cracks, distortions, corrosion and correct function. On couplings, it must be possible to move the slide ring gently back and forth.

#### Packing and labelling

Pack the products as soon as possible after reprocessing in a sterilization pouch according to ISO 11607 or an equivalent container and label the packaging accordingly.

#### Sterilization

The sterilization must be carried out in validated, properly maintained steam sterilizers according to ISO 17665.

We recommend the following steam sterilization parameters<sup>1</sup>.

- Vacuum autoclave, with pre-vacuum phases
- minimum 3 minutes holding time at 134°C or minimum 5 minutes holding time at 132°C
- Drying time at least 20 minutes\*

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<sup>1</sup> Holding time can be extended to 18 minutes to comply with the recommendation from World Health Organization (WHO) where there is concern regarding TSE/CJD contamination. PB Swiss Tools medical devices are able to sustain such sterilization cycles.

\*Drying times generally range from 20 to 60 minutes due to different packaging materials and sterilizer performance.

**Storage**

The instruments should be stored in a clean, dry environment, protected from direct sunlight, vermin/insects, extreme temperatures and humidity.

**Information on the validation of processing**

The following material and machines were used during validation:

Cleaning agents:	For manual and automated cleaning: neodisher® MediClean forte For disinfection: neodisher® Septo Fin
Washer-disinfector:	MIELE PG 8535