

# Instrument reprocessing

## Reprocessing of healthcare products

Information to be provided  
by the medical device manufacturer for the  
reprocessing of medical devices (ISO 17664:2017)

Applies to instruments before first use and reuse

# Instrument reprocessing

## Safety instructions

National and international valid legal regulations for the reprocessing of medical devices must be observed.

The recommendations of the Robert Koch Institute on reprocessing and the red brochure of the Instrument Reprocessing Working Group are an important foundation.

Mechanical reprocessing is preferable to manual cleaning due to a better and safer cleaning result.

It should be noted that successful reprocessing can only be ensured, after prior validation of the reprocessing process and through routine monitoring of the procedure. The responsibility for this lies with the operating company/reprocessor.

Any deviation from these provided instructions should be carefully evaluated by the safety officer of the practice, for effectiveness and possible adverse consequences.

## General notes

Do not use metal brushes or other abrasive cleaners that may damage the surface.

Observe product-specific safety instructions for the units as well as disinfectants and cleaning agents in the corresponding instructions for use.

## Devices

All reusable instruments, supplied by HELLMUT RUCK GmbH, which include fixed constructions (no moving parts), simple joint constructions, return springs and threaded constructions. All instruments are suitable for both manual and mechanical reprocessing.

## Restriction of reprocessing

If the instructions provided for reprocessing the products are followed, they will not lead to damage that limits the service life. The service life of the instruments is determined by their use and careful handling.

## Instructions

### Initial treatment at the place of use

It is recommended to reprocess an instrument as soon as possible after its use.

In the case of dry disposal, waiting times of up to 6 hours before reprocessing are considered unproblematic.

### Cleaning preparation

Instruments that can be disassembled, e.g. with a threaded construction, are disassembled.

### Pre-cleaning

Remove coarse dirt with a plastic brush under running tap water. Do not use a fixating detergent or hot water (>45 °C), as this can lead to fixation of residues and affect the cleaning success.

# Instrument reprocessing

## Cleaning/disinfection and drying

### Notes

Before manual disinfection, allow the rinsing water to drip off the product sufficiently to prevent dilution of the disinfectant solution. After cleaning/disinfection, visually check visible surfaces for residues. If necessary, repeat the cleaning/disinfection process.

### Mechanical

#### Cleaning and thermal disinfection

Use of a cleaning and disinfection unit, according to DIN EN ISO 15883, with a cleaning agent recommended by the manufacturer of the cleaning and disinfection unit.

Pre-cleaning phase with cold water

Cleaning phase at min. 50 °C with demineralised water

Thermal disinfection phase at max. 95 °C

#### Drying

According to programme for cleaning and disinfection unit

### Manual

#### Cleaning in an ultrasonic bath

Use of a cleaning instrument disinfecting solution (alkaline, aldehyde- and alcohol-free). Suitable for use in the ultrasonic bath. Follow the manufacturer's instructions on concentration, exposure time and temperature. Insert articulated instruments so that the cutting edges are open. All parts of the instruments must be completely covered by the solution.

Ultrasonic frequency: > 35 KHz

Temperature: < 45 °C

After removal from the ultrasonic bath, the instruments are thoroughly rinsed under running tap water (at least drinking water quality).

#### Disinfection in an ultrasonic bath

Use of an instrument disinfecting solution (alkaline, aldehyde- and alcohol-free). Suitable for use in the ultrasonic bath. Follow the manufacturer's instructions on concentration, exposure time and temperature. Disinfectants for instrument disinfection must bear a CE mark with a four-digit number. In the case of a final chemical disinfection, it should be noted that the agent used must be virucidal.

Insert articulated instruments so that the cutting edges are open. All parts of the instruments must be completely covered by the solution.

Ultrasonic frequency: > 35 KHz

Temperature: < 45 °C

After removal from the disinfectant solution, the instruments are thoroughly rinsed under running tap water (at least drinking water quality). To avoid lime stains, demineralised water should be used.

#### Disinfection/insertion method

Use an instrument disinfection solution (alkaline, aldehyde- and alcohol-free), follow manufacturer's instructions on concentration, exposure time and temperature. Disinfectants for instrument disinfection must bear a CE mark with a four-digit number. In the case of a final chemical disinfection, it should be noted that the agent used must be virucidal. Place articulated instruments in an instrument disinfection tray so that the cutting edges are open. All parts of the instruments must be completely covered by the solution.

After removal from the disinfectant solution, the instruments are thoroughly rinsed under running tap water (at least drinking water quality). To avoid lime stains, demineralised water should be used.

#### Drying

After rinsing, the instruments are dried with a lint-free disposable cloth.

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## Checking and function test

For articulated instruments: check for ease of movement.

For all instruments: Carry out a visual inspection for damage and wear

## Packaging

With sterilisation packaging suitable for the instrument and the sterilisation process according to EN ISO 11607-1/2 and EN 868. The packaging must be large enough so that the seal is not under tension.

## Sterilisation

Validated sterilisation process (steam sterilisation in fractionated vacuum process) with the following sterilisation parameters:

sterilisation temperature: 134 °C

holding time (full cycle): 5 min.

The instructions for use of the unit manufacturer must be observed.

## Storage and transport

Dust, moisture and recontamination protected

## Manufacturer contact details



HELLMUT RUCK GmbH

Daimlerstr. 23 | 75305 Neuenbürg | phone +49 (0)7082 9442-0 | kontakt@hellmut-ruck.de | hellmut-ruck.de

## The above process was carried out with the following chemicals and equipment:

RUCK instrument disinfectant (REF 29401)

RUCK PODOLOG SONIC ultrasonic device (REF 26035)

RUCK PODOLOG Thermo HD 450 cleaning and disinfection unit, in accordance with DIN EN 15883

Cleaning tablets for THERMO HD 459 (alkaline cleaner, pH 10.6) (REF 26205)

MELAG EUROKLAV 29VS+ steam steriliser according to DIN EN 13060 – type S