RUDOLF
BECAUSE WE CARE

REPROCESSING INSTRUCTIONS FOR USE (EN)
REUSABLE MEDICAL DEVICES

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PLEASE READ BEFORE REPROCESSING AND KEEP IT IN A SAFE PLACE

SCOPE

These reprocessing instructions are valid for all reusable medical devices of RUDOLF Medical where the device label or the corresponding instructions for use specifically references these reprocessing instructions.

The medical devices are intended to be used by professional users (surgeons, operating room nurses, medical device reprocessing technicians).

NON STERILE Reusable medical devices of RUDOLF Medical are delivered non-sterile and must be cleaned, disinfected, and sterilized before first use and immediately after each use. Protective caps and transport packaging must be removed before reprocessing.

Make sure that the packaging is not damaged upon delivery.

⚠ WARNINGS AND PRECAUTIONS

- Improper use and overstraining due to twisting / levering can lead to breaks and permanent deformation.
- Do not use metal brushes, sharp tools or abrasive cleaners as they can damage the medical device. Damage to the surface can lead to corrosion.
- Defective and worn-out medical devices must not be used.
- Alkaline detergents (pH < 12) can cause coloring on the medical devices made from aluminum. However, they do not have any effect on the mechanical strength of the medical devices.
- The safe combination of medical devices with each other or with implants must be verified by the user before clinical use.
- Be careful when handling sharp tips and cutting edges because there is a risk of injury.
- For suspected or confirmed Creutzfeldt-Jakob Disease (CJD) patients or CJD variants the applicable national regulations regarding the disposal and reprocessing of medical devices must be applied.
- Never leave the medical devices for too long in the disinfectant solution. Follow the instructions of the disinfectant solution manufacturer.
- Automated cleaning / disinfection should be preferred to manual cleaning / disinfection, since automated processes can be standardized, reproduced, and thus validated.

PRIOR TO EACH USE: VISUAL AND FUNCTIONAL INSPECTION

Check for:

- External damage (e.g., deformed shaft, dents, burrs, cracks or sharp edges)
- Loose parts, especially joints
- Wear and tear
- Correct functioning
- Detergent or disinfectant residues
- Free passage through the working channels
- Damage to plastic and metal parts

REPROCESSING INSTRUCTIONS

Limitations and restrictions on processing

- The lifetime of the medical device depends on the following:
  - Number of applications and along with this the number of reprocessing cycles
  - Maintenance and care
- Do not use any fixing agents or hot water (>40°C), because this causes a hardening of residues which can impede the cleaning of the medical device.

Initial treatment at the point of use

- Defective medical devices must be clearly marked as such. They have to be reprocessed before being disposed of or returned.
- The medical devices must be reprocessed within an hour after use to prevent contamination from drying on the medical devices.
- Do not use metal brushes, sharp tools or abrasive cleaners as they can damage the medical device. Damage to the surface can lead to corrosion.
- Heavy contamination on the medical devices must be removed with a disposable cloth immediately after use.
- Working channels and lumen must be flushed through several times immediately after use to avoid blockages.

Transportation

- Safe storage and transport of the medical devices to the reprocessing site should be carried out in a closed receptacle / container system to avoid damage to the medical devices and contamination of the environment.

Preparation before cleaning

- The medical devices must be disassembled or opened for reprocessing as far as possible without using tools.

Manual pre-cleaning

- Medical devices with difficult to access areas such as lumen, cavities, bores, threads, and slots must be soaked in cold water for at least 5 minutes and rinsed under water with a water jet gun for at least 10 seconds (pulsed procedure).
- Do not use metal brushes, sharp tools or abrasive cleaners as they can damage the medical devices. Damage to the surface can lead to corrosion.
- Observe the manufacturer's instructions for the detergent (concentration, temperature, and sonication time). If the concentration is too low, the water too warm or the sonication time too short, there will be a risk that the contamination will not be sufficiently removed. However, observe the maximum sonication time of 10 minutes.

Cleaning in the ultrasonic bath

Step	Cleaning agents	Time (min)	Temp. (°C)
Cleaning in the ultrasonic bath with a detergent. The medical devices must be fully immersed in the bath.	Tap water, 0.5% alkaline cleaning agent	10	< 40
Remove the medical devices from the ultrasonic bath. Rinse them under running water until all visible contamination is removed.	Tap water	---	Cold

Detergent and ultrasonic bath for the manual pre-cleaning

Detergent	neodisher MediClean forte by Dr. Weigert Concentration: 0.5% Exposure time: 5 minutes
Sonication time in the ultrasonic bath	Maximum of 10 minutes
Ultrasonic bath	Elmasonic S 300H by Elma Schmidbauer GmbH

Automated cleaning and disinfection

- Clean and disinfect the medical devices only in suitable washer-disinfectors (WD) and with a procedure / program validated for the WD and medical devices (EN ISO 15883 for the WD and DIN EN ISO 17664-1 for the procedure).
- The operating and loading instructions of the WD manufacturers must be observed.
- For cleaning, medical devices with joints must be opened by approximately 90 degrees.
- Medical devices with lumen (tubes, shafts, hoses) must be connected to a rinsing system to ensure a flush of the lumen.
- When choosing the detergent, consider the material and properties of the device and the cleaning agents recommended by the WD manufacturer for the respective application.

Detergent and WD for the automated cleaning and disinfection

Detergent for the automated cleaning	neodisher MediClean forte by Dr. Weigert Concentration: 0.5%
Disinfection process	Thermal disinfection (no chemothermal disinfection)
WD	Miele PG 8535

Automated cleaning program with thermal disinfection in a WD with an alkaline detergent

Step	Cleaning agents	Time (min)	Temp. (°C)
Pre-rinsing	Tap water	1	Cold
Pre-rinsing	Tap water	1	Cold
Cleaning	Tap water, 0.5% alkaline detergent	5	55
Post-rinsing	Demineralized water*	2	Cold
Disinfection**	Demineralized water	> 5	> 90

* To avoid build-up and stains on the medical device, use demineralized water for the final rinsing step.
** When carrying out an automated thermal disinfection, consider the national requirements regarding the A0 value in ISO 15883-1 (A0 = 3000).
For the UK, the requirements of A0 = 600 at 90°C and 60 seconds have also been validated.
If necessary, manual drying with a lint-free cloth can also be carried out. Dry medical device cavities with sterile compressed air.

INSPECTION AND MAINTENANCE

- After cleaning and disinfection, the medical devices must be inspected visually and for function. The medical devices must be macroscopically clean (free of visible residues). Particular attention should be paid to slots, locks, ratchets and other areas that are difficult to access.
- If residues / liquids are still visible, the cleaning and disinfection process must be repeated.
- Before sterilization, the medical device must be assembled, if applicable, and checked for function, wear & tear, and damage (cracks, rust) and, if necessary, replaced.
- Medical devices with a ratchet (lock) are sterilized either in an open position or locked in the first tooth.
- After each cleaning/disinfection, i.e., before sterilization, the moving parts, joints, locks and ratchets must be lubricated with a silicone-free, biocompatible white medical oil.
- Defective medical devices must have gone through the entire reprocessing cycle before being returned for repair or complaint.
- Please see also “Prior to each use: visual and functional inspection” in these instructions.

PACKAGING

- Packaging of the medical devices for sterilization is according to standards DIN EN ISO 11607 and DIN EN 868.
- In case of individual packaging, make sure that the packaging is large enough to hold the medical device without putting tension on the sealing seam or tearing the packaging. Pointed and sharp cutting edges must not perforate the sterilization packaging.

STERILIZATION

- The sterilizers are validated according to DIN EN 13060 and DIN EN 285, respectively; the sterilization process is validated according to DIN EN ISO 17665.
- Please observe the manufacturer’s instructions of the sterilizer.

The following parameters of the steam sterilization (fractionated vacuum method) have been validated:

Sterilization validated according to DIN EN ISO 17665:

Sterilization temperature	Minimum holding time (exposure time)	Drying time
134°C, minimum 132°C; maximum 137°C	4 minutes	Minimum 10 minutes

or

Sterilization according to ANSI AAMI ST79:

Sterilization temperature	Minimum holding time (exposure time)	Drying time
132°C – 135°C	4 minutes	20 minutes

STORAGE

- Store the sterilized medical devices in a low-germ, dry, clean, and dust-free area at 5 - 40°C.

INFORMATION REGARDING THE VALIDATION OF THE REPROCESSING PROCEDURE

The following materials and machines have been used during the validation procedure:

Manual pre-cleaning in the ultrasonic bath	• Detergent: neodisher MediClean forte by Dr. Weigert, alkaline, concentration 0.5% • Ultrasonic bath device: Elmasonic S 300H by Elma Schmidbauer GmbH • Temperature: < 40°C • Duration: 10 minutes
Automated cleaning and disinfection	• Detergent: neodisher MediClean forte by Dr. Weigert, alkaline, concentration 0.5% • Thermal disinfection (no chemothermal disinfection) • Washer-disinfector: Miele PG 8535
Sterilization	• Steam sterilization, fractionated vacuum method • Sterilizer: HX-320 2D by Systec GmbH & Co. KG

Validation records

Process	Report no.	Testing facility
Cleaning and Disinfection	43633	CleanControlling GmbH
Steam sterilization	13m217	MDT Medical Device Testing GmbH

ADDITIONAL NOTES

- If the specified process agents and machines are not available, the user needs to validate their process.

DISPOSAL

- Only after the medical devices have been cleaned and disinfected properly, they should be disposed of accordingly.
- Comply with national regulations and applicable hospital guidelines when discarding or recycling medical devices.
- Be careful with sharp tips and cutting edges. Use suitable protective caps or containers to prevent third parties from being injured.

REPAIRS & RETURNS

- Never carry out repairs yourself. Service and repairs should only be carried out by appropriately instructed and qualified staff. If you have any questions, contact RUDOLF Medical, your distributor or your medical technology department.
- Defective medical devices must have gone through the entire reprocessing cycle before being returned for repair or complaint.

PROBLEMS / EVENTS

- Report any problems with the medical devices of RUDOLF Medical to your distributor.
- In the event of serious incidents with the medical devices, the user must report this to RUDOLF Medical as the manufacturer and the competent authority of the member state in which the user resides.

WARRANTY

- The medical devices are made of high-quality materials and are subjected to strict quality control before delivery. If there are any discrepancies, please contact RUDOLF Medical or your distributor.

REPROCESSING – APPLIED STANDARDS AND GUIDELINES

- DIN EN 285 Sterilization – Steam sterilizers – Large sterilizers
- DIN EN 13060 Small steam sterilizers
- DIN EN ISO 15883 Parts 1, 2 and 5 Washer-disinfectors
- DIN EN 868 Packaging for terminally sterilized medical devices
- DIN EN ISO 11607 Packaging for terminally sterilized medical devices
- DIN EN ISO 17664 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices
- DIN EN ISO 17665 Sterilization of health care products - Moist heat - Requirements for the development, validation and routine control of a sterilization process for medical devices

SYMBOLS

	Consult instructions for use.
LOT	Batch code
REF	Article no.
QTY	No. per package
	Non-sterile
	Caution
	Manufacturer
	Date of manufacture
CE 0297	CE marking according to the Medical Device Regulation (EU) 2017/745 (MDR) with the ID of the notified body
	Lubricate with silicone-free, biocompatible white medical oil approved for steam sterilization
MD	Medical Device