RUDOLF
BECAUSE WE CARE

INSTRUCTIONS FOR USE (EN)
REUSABLE SURGICAL INSTRUMENTS

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PLEASE READ BEFORE PROCESSING AND KEEP IN A SAFE PLACE

PRODUCTS

This reprocessing instruction applies to reusable surgical and endoscopic instruments supplied by **RUDOLF Medical**.

GENERAL

Reusable surgical instruments from RUDOLF Medical can be used by medical professionals for a surgical procedure and can be reused after qualified reprocessing.

The professional user selects the appropriate instruments according to the intended function, the tissue to be manipulated and the anatomical structures.

WARNINGS AND PRECAUTIONS

- **RUDOLF Medical** instruments must be cleaned, disinfected, and sterilized before first use. Protective caps and transport packaging must be removed beforehand.
- A complete functional check must be carried out before each use.
- Improper use and overstraining due to twisting / levering can lead to breaks and permanent deformation.
- Do not use metal brushes or abrasives, as there is a risk of corrosion due to surface damage.
- The safe combination of instruments with each other or of instruments with implants must be checked by the user before clinical use.
- Be careful when handling sharp tips and cutting edges - risk of injury.
- In the case of patients with Creutzfeldt-Jakob disease (CJK), suspected CJK or possible variants of this disease, the applicable national regulations regarding the preparation of instruments must be applied.
- Never leave instruments in disinfectant solution too long. Follow the instructions of the respective 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 (shaft deformed, dents or sharp edges)
- Correct functioning
- Detergent or disinfectant residues
- Free passage through working channels.

REPROCESSING INSTRUCTIONS

Restrictions

- Repeated / frequent reprocessing according to these instructions has only little effect on the durability of the instruments.
- The durability of a reusable instrument is essentially determined by wear and damage caused by the application.

Initial treatment at the place of use

- The instruments must be reprocessed within 1 hour after use, to prevent dirt from drying on the instruments.
- Heavy soiling on the instrument must be removed with a disposable rag, cloth, or tissue immediately after use.
- Working channels and lumens must be flushed through at least 3 times immediately after use to avoid blockages.
- Do not use any fixing agents or hot water (> 40 ° C), as this leads to the fixing of residues and can affect the success of the cleaning procedure.
- Defective instruments must be identified and clearly marked. They are also to be reprocessed.

Transportation

- Safe storage and transport of the instruments to the reprocessing site in a closed receptacle / container system to avoid damage to the instruments and contamination to the environment.

Preparation for decontamination

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

Manual pre-cleaning

- Instruments with difficult to access areas such as lumens, 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).
- To support manual cleaning and before automated cleaning in case of heavily encrusted soiling, cleaning must be carried out in the ultrasonic cleaning device (cleaning solution < 40 ° C, sonication time min. 10 min.).
- Observe the manufacturer's instructions for the cleaning agent (concentration, temperature, and sonication time).
- Vibration can loosen small parts such as screws and nuts. After ultrasound treatment, ensure that the instruments are complete and pay attention to loosened small parts.

Automated cleaning

- Clean and disinfect the instrument only in suitable washers and disinfectors (WD) and with a procedure / program validated for the WD and this type of instrument (EN ISO 15883).
- Instruments with cavities (tubes, shafts, hoses) must be connected to appropriate flushing devices to ensure that these cavities are flushed.
- The operating and loading instructions of the WD manufacturers must be observed.
- Instruments with joints must be opened approx. 90 ° for cleaning.
- When choosing the cleaning agent, please observe the material and properties of the instrument, the cleaning agents recommended by the WD manufacturer for the respective application and the relevant lists and recommendations of the Robert Koch Institute (RKI) and of the Deutsche Gesellschaft für Hygiene und Mikrobiologie (DGHM, German society for hygiene and microbiology).

Detergent for automated cleaning in washers and disinfectors (WD)

Process Type	Detergent	pH value	Manufacturer
Alkaline	Neodisher® FA	12.2	Dr. Weigert
Enzymatic	deconex® 23 Neutrazym	9.7	Borer

Automated cleaning program with thermal disinfection in the WD using an alkaline OR enzymatic process

Process	Reagents	Time / min	Temp / °C
Pre-cleaning	Water	1	cold
Drain			
Pre-cleaning	Water	3	cold
Drain			
Cleaning	Water, 0.5% alkaline detergent	5	55
	OR		
	Water, 0.5% enzymatic detergent		45
Drain			
Neutralization	Water	3	cold
Drain			
Rinsing	Water	2	cold
Drain			
Disinfection *	Demineralized water	> 5	> 90
Drying **		> 20	max. 93

* Carry out mechanical thermal disinfection by considering the national requirements regarding the A0 value from ISO 15883-1 (A0 = 3000).

** If necessary, manual drying with a lint-free cloth can also be carried out. Dry instrument cavities with sterile compressed air.

MAINTENANCE, CONTROL AND INSPECTION

- After cleaning and disinfection, the instruments must be subjected to a visual and functional inspection. The instruments must be macroscopically clean (free of visible residues). Particular attention should be paid to slots, ratchets, locks, and other areas that are difficult to access.
- If dirt residues / liquids are still visible, the cleaning and disinfection process must be repeated.
- Before each sterilization, the instrument must be assembled and checked for function, wear, and damage (cracks, rust) and replaced, if necessary.
- Close instruments with a ratchet only in the first notch of the ratchet before sterilization or keep them open.
- After each cleaning and before sterilizing, the moving parts must be oiled and maintained with a physiologically harmless oil (paraffin oil according to

DAB or Ph. Eur. Or USP); especially locks, joints, and ratchets.
- Defective products must have gone through the entire reprocessing process before being returned for repair or complaint.

PACKAGING
- Packaging of the instruments for sterilization according to standards ISO 11607 and EN 868.
- Pointed and sharp cutting edges must not perforate the sterilization packaging.
- In case of individual packaging, care must be taken to ensure that the packaging is large enough to hold the product without putting tension on the sealing seam or tearing the packaging.

STERILIZATION
- Sterilization has to be carried out according to DIN EN ISO 13060 / ISO 17665 or a validated steam sterilization method (fractionated vacuum method) in a sterilizer according EN 285 / DIN 58946.

Sterilization temperature	Minimum holding time (exposure time)	Drying time
134 °C - 137 °C	3-5 minutes	Minimum of 10 minutes

or

Sterilization according ANSI AAMI ST77

Sterilization temperature	Minimum holding time (exposure time)	Drying time
132°C - 135°C (270°F - 275°F)	4 minutes	20 minutes

Please observe the manufacturers' instructions of the sterilizer.

STORAGE
- Storage of the sterilized instruments in a low-germ, dry, clean and dust-free environment at 5 - 40°C.

INFORMATION REGARDING THE VALIDATION OF THE REPROCESSING PROCEDURE

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

Table 1: Materials and machines

Alkaline detergent	Neodisher® FA
Enzymatic detergent	deconex® 23 Neutrazym
Washer / Disinfector	G 7735 CD (Miele)
Slide-in cart	Slide-in cart E 327 – 06 MIS–Slide-in cart E 450

ADDITIONAL NOTES
- If the described chemical agents and machines are not available, it is the duty of the user to validate his process.

DISPOSAL
- Products may be disposed of correctly, only after they have been cleaned and disinfected properly.
- Comply with national regulations when disposing of or recycling the product or its components.
- Dispose of the product in an environmentally friendly manner in accordance with the applicable hospital guidelines.
- Be careful with sharp tips and cutting edges. Use suitable protective caps or containers to prevent third parties from being injured.

RETURNS
- If an instrument is damaged, it should go through the complete reprocessing process before it is sent back to the manufacturer for repair. No own repairs may be carried out on the instrument.
- Be careful with sharp tips and cutting edges. Use suitable protective caps or containers to prevent third parties from being injured.

PROBLEMS / EVENTS
- The user should report any problems with our products to the respective specialist dealer.
- In the event of serious incidents with the products, he must report this to RUDOLF Medical as the manufacturer and the competent authority of the member state in which the user is established.

WARRANTY
- The instruments are made of high-quality materials and are subjected to a strict quality control before delivery. If there are any discrepancies, please contact RUDOLF Medical.

SYMBOLS

	Consult instructions for use.
	Batch code
REF	Article no.
QTY	No. per package
	Non-sterile
	Lubricate with silicon-free, biocompatible white medical oil approved for steam sterilization.
	Caution
	CE marking, according to EG directive 93/42/EWG and Medical Device Regulation (EU) 2017/745 (MDR)
 0297	CE marking according to EG directive 93/42/EWG with the identification number of the notified body
	Manufacturer
	Manufacture date
MD	Medical Device