RUDOLF
BECAUSE WE CARE

INSTRUCTIONS FOR USE (EN)
DISMOUNTABLE LIVER ELEVATORS

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PLEASE READ BEFORE REPROCESSING AND KEEP IN A SAFE PLACE

PRODUCT

These instructions for use are valid for RUDOLF Medical liver elevators.
You have received a high-quality product, the proper handling and use of which is described below.

NON STERILE RUDOLF Medical instruments are supplied 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 beforehand.

INTENDED PURPOSE

Elevators are intended to lift and push away tissue and organs during a surgical procedure.

INDICATION

The instruments are intended for use in minimally invasive surgery, in particular in laparoscopy. The instruments are used to hold away interfering structures in the surgical site.

The instruments are not limited to a specific population. The instrument should not be used if, in the opinion of the attending physician, the risks exceed the benefits for the patient.

CONTRAINDICATION

The instruments are not intended for use on the central nervous and circulatory system.

⚠ WARNINGS AND PRECAUTIONS

- RUDOLF Medical instruments must be cleaned, disinfected and sterilized prior to first use. Protective caps and transport packaging must be removed beforehand.
- Defective instruments must never be used under any circumstances.
- The safe combination of instruments with each other must be checked by the user before clinical use.
- When used together with HF instruments, avoid contact with conductive parts.
- Incorrect use and overstressing by twisting/levering can lead to breaks and permanent deformation. Avoid large manual movements with great exertion of strength. Handle the instrument with the utmost care.
- In the case of patients with Creutzfeldt-Jakob disease (CJD), possible variants of this disease or suspected CJD, the applicable national regulations regarding the disposal and reprocessing of instruments must be applied.

PRIOR TO EACH USE: VISUAL AND FUNCTIONAL INSPECTION

Check for the following:

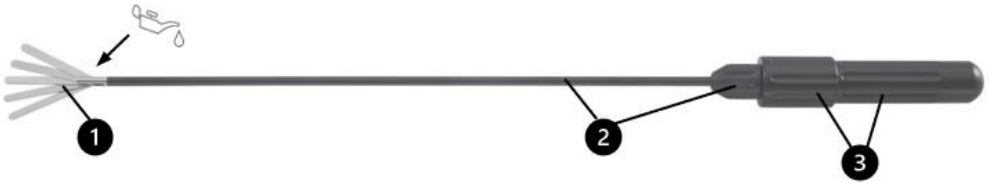
- External damage (e.g. deformed shaft, dents, burrs, cracks or sharp edges)
- Correct function
- Cleaning agent or disinfectant residues
- Free passage through working channels

After each cleaning and before sterilization, the moving parts must be oiled and maintained with a silicone-free, biocompatible, medical white oil.

PRODUCT DESCRIPTION OF THE LIVER ELEVATOR SYSTEM "SCREW-IN"

– The laparoscopic liver elevators of the "SCREW-IN" system are three-part detachable instruments, available in system diameters of 5 mm and 10 mm.

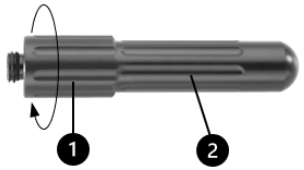
Example: liver elevator with shaft diameter 5 mm, working length 330 mm

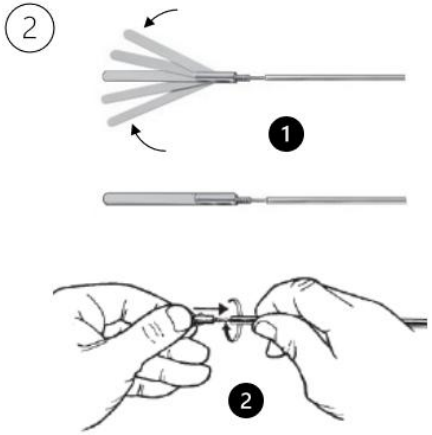
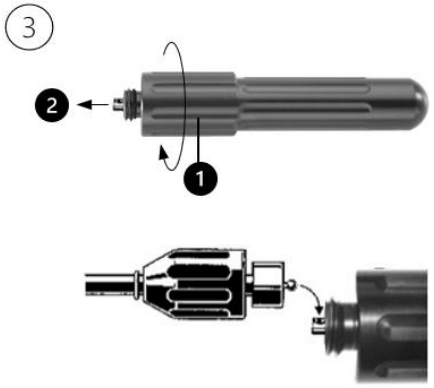
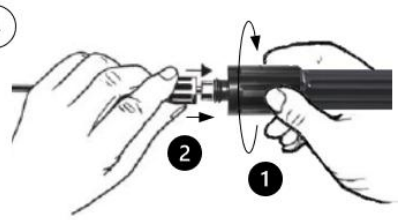


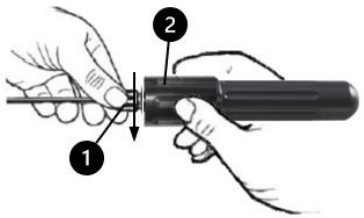
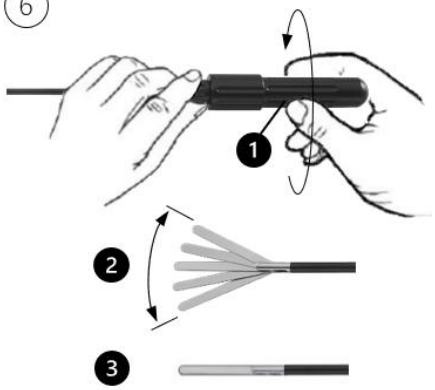
Combination and components:
(1) Instrument insert of the liver elevator
(2) Tube with removable fixing nut. The fixing nuts are optionally available in different colours.
(3) Handle, with unscrewable rotating mechanism, for spreading the liver elevator

ASSEMBLY

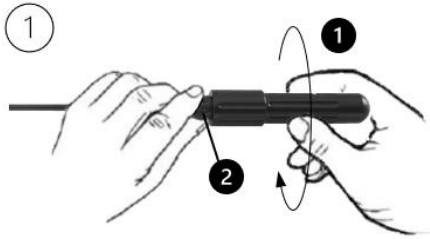
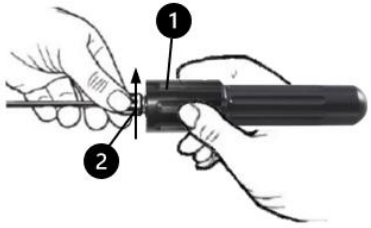
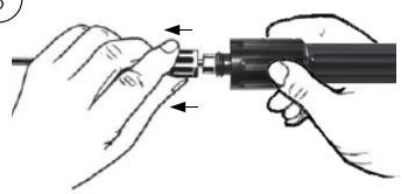
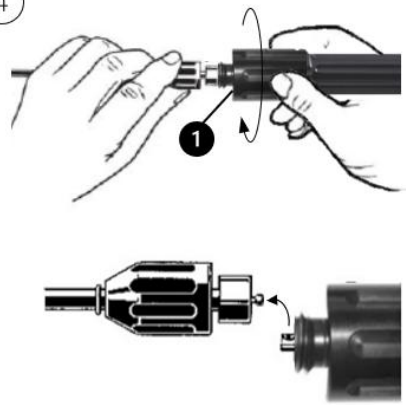
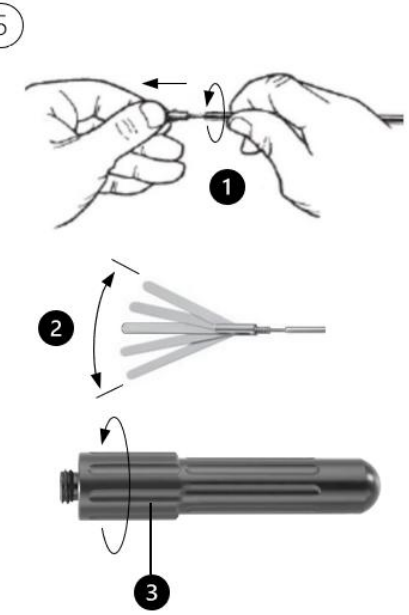
⚠ Jaw inserts can be combined only with tubes with the same system diameter.

1 	Screw the rotating mechanism (1) counterclockwise onto the handle (2)

2 	1. Close the instrument insert / fan (1). 2. Push the instrument insert into the tube and screw the tube clockwise onto the instrument insert (2). 3. Tighten the tube only so firmly that the instrument insert cannot come loose by itself during use
3 	1. Rotate the handle to its open position. To do this, turn the rotating mechanism counterclockwise (1) until the ball socket (2) is fully stuck out of the handle. 2. Now insert the tube together with the screwed-in instrument insert with its ball end into the ball socket of the handle. 3. Make sure that the fan is completely closed
4 	1. Turn the rotating mechanism of the handle (1) clockwise until the metal cylinder of the tube (2) rests against the handle. 2. Now slide the fastening nut over the metal cylinder of the tube (2) towards the threaded mount of the handle (1)

5 	Screw the fastening nut (1) clockwise onto the mounting thread of the handle and tighten it. Hold the rotating mechanism (2) firmly by the handle.
6 	1. Check for correct function after assembly. 2. Turn the end of the handle (1) clockwise to open the fan respectively to spread the instrument insert (2). Turn the end of the handle counterclockwise to close the fan / instrument insert (3). See section "Prior to each use: visual and functional inspection"

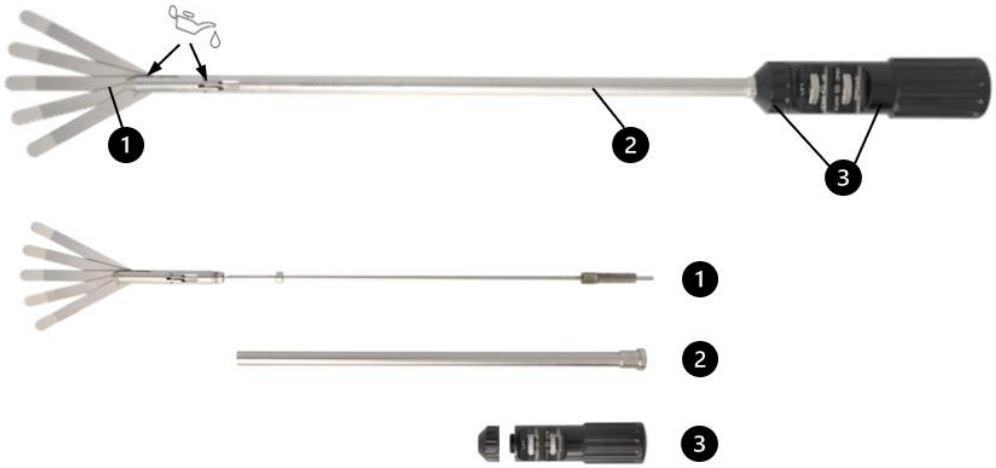
DISASSEMBLY

1 	1. Close the fan / instrument insert by turning the end of the handle (1) counterclockwise. 2. Hold the instrument by the tube and the fastening nut (2)
2 	1. Hold the rotating mechanism (1) by the handle. 2. Unscrew the fastening nut (2) of the tube by turning it counterclockwise.
3 	Pull the fastening nut back over the metal cylinder of the tube.
4 	1. Detach the handle from the tube by turning the rotating mechanism (1) counterclockwise until the ball socket is completely visible. 2. Now remove the tube together with the instrument insert from the ball socket of the handle.
5 	1. Unscrew the tube from the instrument insert counterclockwise and pull the instrument insert out of the tube (1). 2. Open or spread the fan / instrument insert (2). 3. Unscrew the rotary mechanism (3) for cleaning completely from the handle. 4. Place the individual components in a suitable perforated basket for reprocessing.

DEFLECTABLE LIVER ELEVATOR

– The laparoscopic liver elevator is deflectable, three-part instrument with a system diameter of 10 mm and a working length of 330 mm.

⚠ The maximum load on the liver elevator is 3 kg (6.5 lbs).



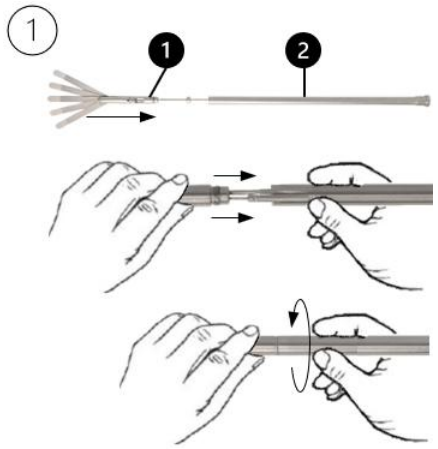
Components:

(1) Instrument insert of the liver elevator, can be spread and deflected
(2) Tube
(3) Handle with fastening nut, with knurled adjusting wheels for spreading and deflecting the instrument insert of the liver elevator

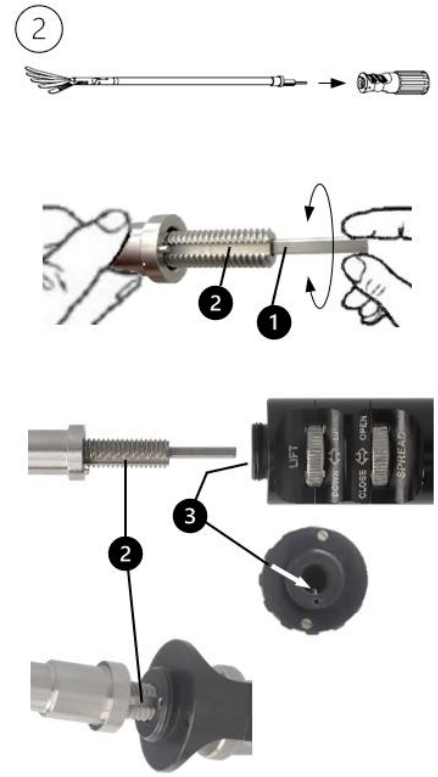
Function description

1. The knurled adjusting wheel "SPREAD" (1) is used to open the fan respectively spread the instrument insert of the liver elevator.
   a) Spread the fan / instrument insert of the liver elevator by turning it in the direction of the arrow "OPEN".
   b) Close the fan / instrument insert of the liver elevator by turning it in the direction of the arrow "CLOSE".
2. The knurled adjusting wheel "LIFT" (2) is used to lift, deflect and lower the liver elevator.
   a) Lift the fan of the elevator by turning it in the direction of the arrow "UP".
   b) Lower the fan of the elevator by turning it in the direction of the arrow "DOWN".

ASSEMBLY

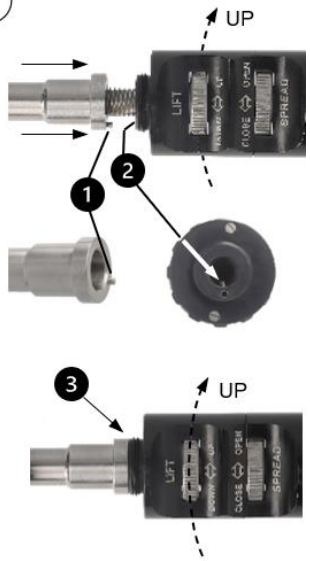
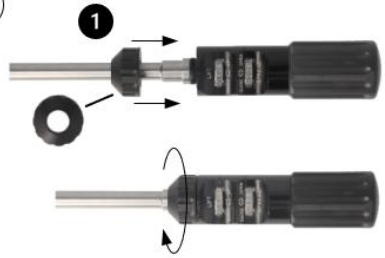
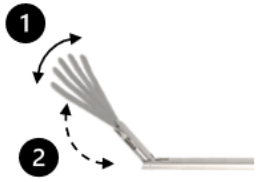


1. Push the instrument insert (1) into the tube (2) and screw the tube clockwise onto the instrument insert.
2. Tighten the tube only so firmly that the instrument insert cannot come loose by itself during use.

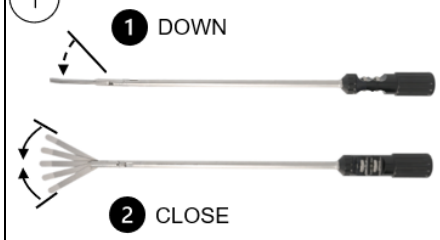
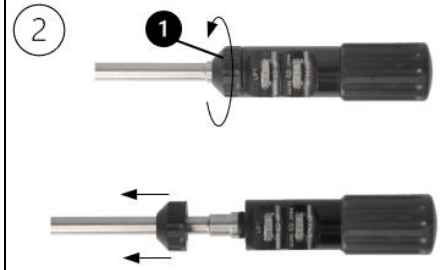
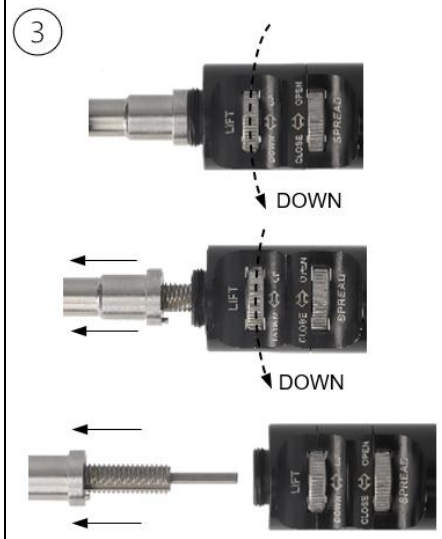


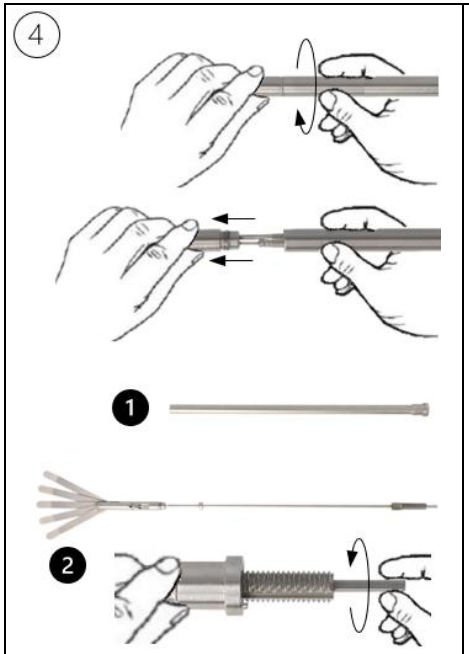
Insert the tube with the assembled instrument insert into the handle.

a) Turn the shaft (1) until one of the flattened sides is positioned parallel to the threaded groove (2).
b) Ensure that the guide pin, located inside the handle hole (3), runs in the threaded groove (2) of the instrument insert in the tube.

3 	1. Screw the handle onto the tube by turning the knurled adjustment wheel "LIFT" in the "UP" direction. Ensure that the fixing pin of the tube (1) is inserted into the hole in the handle (2). 2. Tighten the tube (3) by turning the knurled adjusting wheel "LIFT" further in the "UP" direction
4 	1. Slide the fastening nut (1) over the tube. 2. Screw the fastening nut clockwise onto the handle and tighten it.
5 	1. Check for correct function after assembly. a) Spread the fan and close it (1) with the knurled adjusting wheel "SPREAD". b) Lift (deflect) and lower the fan (2) with the knurled "LIFT" adjusting wheel. See section "Function description".

DISASSEMBLY

1 	1. Lower the fan / instrument insert of the liver elevator (1) until it is in a completely straight position. To do this, turn the knurled adjusting wheel "LIFT" in the direction of the arrow "DOWN". 2. Close the fan of the instrument insert (2) by turning the knurled adjusting wheel "SPREAD" in the direction of the arrow "CLOSE" See section "Function description".
2 	Unscrew the fastening nut (1) from the handle by turning it counterclockwise and remove it from the tube.
3 	Detach the tube together with the fan / instrument insert from the handle by turning the knurled "LIFT" adjusting wheel in the direction of the arrow "DOWN" until it can be removed from the handle.



1. Separate the tube (1) from the fan / instrument insert (2). To do this, hold the fan / instrument insert firmly and unscrew the tube counterclockwise.
2. Then remove the fan / instrument insert from the tube.
3. Open the fan / instrument insert for cleaning. To do this, hold the shaft of the fan / instrument insert and turn the shaft clockwise until the fan / instrument insert is completely fanned out / spread open.
4. Place the individual components in a suitable perforated basket for reprocessing.

REPROCESSING INSTRUCTIONS

- The instrument must be disassembled before reprocessing.
- The instrument must be reprocessed within one hour after use to prevent contamination from drying.
- When selecting the cleaning agent, consider the material and properties of the instrument, the cleaning agent recommended by the washer-disinfector manufacturer for the respective application and the recommendations of the Robert Koch Institute and the German Society for Hygiene and Microbiology.
- Do not use any fixing agents.
- Only use the specified cleaning agents. If you use other cleaning agents, they must be validated by you.
- Use disinfectant with corrosion protection.
- Do not rinse under hot water.
- Do not use abrasive brushes, sponges or scouring agents, as corrosion can occur if the surface is damaged.
- Do not leave the instruments in the disinfectant for too long. Follow the disinfectant manufacturer's instructions.

Restrictions on reprocessing

- The product service life depends on the following:
  - Number of applications and the associated reprocessing cycles
  - Care and maintenance
- Do not use fixing agents or hot water (> 40°C), as this can lead to hardening of residues and thus impair the cleaning success.
- ⚠ **Important:**
  - **The plastic handles must not be treated with hydrogen peroxide (H_2O_2) as this can damage them.**
  - **The instruments are not intended for manual reprocessing.**

Initial treatment at the place of use

- Defective instruments must be visibly labelled. They must also be reprocessed before they are disposed of or returned.
- Heavy contamination on the instrument must be removed immediately after use with a disposable cloth.
- Remove coarse dirt with cold water. A plastic brush is recommended for heavily encrusted fabric residues.
- Rinse cavities with cold water.

Note: If rinsing with cold water is not possible, wrap the instrument in a damp cloth to prevent the residue from drying.

Transportation

- The instruments should be transported safely to the reprocessing site in a closed receptacle/container system to prevent damage to the instruments and contamination of the environment.

Manual pre-cleaning

- Manual pre-cleaning is necessary before automated cleaning and disinfection in order to prevent surgical residues from drying.

Cleaning	Cleaning agent	Dosage	pH value
Enzymatic	Cidezyme of Johnson & Johnson	0,8 %	7.8 - 8.8 (diluted)

1. Place the instrument in a cold-water bath with a 0.8% cleaning solution and leave to soak for 5 minutes. To avoid environmental contamination, rinse the instrument under the water level.
2. Brush the instrument under cold water until all visible contamination has been removed.
3. Disassemble the instrument as far as possible. See the respective disassembly sections.
4. Brush the inside and outside of the instrument in a water bath with a round brush until no more residue is visible.
5. If available, flush out cavities, holes and threads with a cleaning gun: >10 seconds at 3 - 5 bar.
6. Remove the instrument from the water bath and rinse it with cold water.
7. Place the instrument in a combined cleaning and disinfectant solution to prevent any residues from drying.

Cleaning in an ultrasonic bath

Clean the components additionally in an ultrasonic bath before or in combination with automated cleaning:

Temperature	Frequency	Duration
40 - 45°C	35 - 45 kHz	10 - 15 minutes

Turn and move the components during cleaning in the ultrasonic bath.

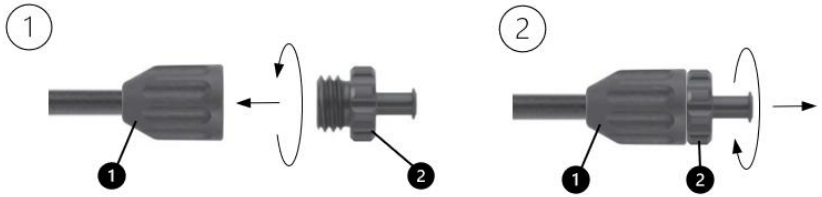
Automated cleaning and disinfection

- The instrument must be disassembled for cleaning. Remove the protective caps, if there are any.
- The operating and loading instructions of the washer-disinfector manufacturer must be observed.
- The elevator fan / instrument inserts must be opened for cleaning.
- The tube of the liver elevators of the "SCREW-IN" system must be connected to appropriate flushing devices to ensure that the cavities are flushed.

  Tip: For tube of the liver elevators of the "SCREW-IN" system with a diameter of 5 and 10 mm, we recommend using the RUDOLF Medical rinsing attachment with Luer lock (REF: RS000-010) for automated cleaning.

Assembly (1): Screw the flushing attachment (2) clockwise into the fastening nut of the tube and hold the fastening nut (1) firmly.

Dismantling (2): Unscrew the flushing attachment (2) counterclockwise from the fastening nut of the tube. Hold the fastening nut (1) firmly while doing so.



(1) Tube of the "SCREW-IN" system with fastening nut
(2) Flushing attachment with Luer-Lock connection

Cleaning agent for alkaline automated cleaning in the cleaning device

Cleaning	Cleaning agent	Dosage	pH value
Alkaline	neodisher® FA of Dr. Weigert	0,5 %	12,2 - 14 (diluted)

Washer-disinfector: Miele G 7735 CD

Preparation:

1. Place the components in a perforated tray on the MIS trolley of the cleaning device so that the cleaning agent rinses out all internal and external surfaces.
2. If available, close the flushing opening on the MIS push-in trolley.
3. Start the cleaning program.

Program	Cleaning agent	Duration	Temp. °C
1. Pre-rinse	Cold tap water	1 minute	Cold
2. Emptying	----	----	----
3. Repeated pre-rinsing	Cold tap water	3 minutes	Cold
4. Emptying	----	----	----
5. Cleaning	0.5 % alkaline cleaning agent	5 minutes	55°C
6. Emptying	----	----	----
7. Neutralize	Deionized water	2 minutes	----
8. Emptying	----	----	----
9. Rinsing	Deionized water	2 minutes	----
10. Emptying	----	----	----
11. Drying (drying phase in the WD)	----	15 - 25 minutes	90 - 110°C
12 Remove the instrument immediately after the WD program has ended.	----	----	----
13 If necessary, blow out the instrument with medical compressed air until it is dry.	----	----	----

Disinfect

Device	Disinfectant	Temp. °C	Holding time
Getinge 88 Series	Deionized water	90 + 3°C	≥ 5 minutes

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, latches, locks and other areas that are difficult to access. See also section "Before each use: Visual and functional inspection".
– If contamination residues/liquids are still visible, cleaning and disinfection must be repeated.
– After each cleaning and before sterilization, the moving parts must be oiled and maintained with a silicone-free, biocompatible, medical white oil.
– Before sterilization, the instrument must be assembled and inspected for function, wear and tear and damage (cracks, rust) and, if necessary, replaced.
– Defective products must have undergone the entire reprocessing process before being returned for repair or complaint.

PACKAGING

– Standard-compliant packaging of instruments for sterilization is carried out in accordance with DIN EN ISO 11607 and DIN EN 868.
– In the case of individual packaging, it must be ensured that it is large enough to hold the product without causing tension on the seal seam or tearing the packaging. Tips and sharp edges must not perforate the sterilization packaging.

STERILIZATION

- For sterilization, the instruments must be assembled but sterilized in their open state. See the respective assembly sections
- Steam sterilization was validated with the sterilizers Selectomat S 3000 from MMM Group and Varioclaov 400 E of Fisher Scientific. The sterilizers are validated in accordance with DIN EN 13060 and DIN EN 285.
- Observe the sterilizer manufacturer's instructions.
- Place the instruments in the sterilizer so that they do not touch each other, and steam can circulate freely.

Triple fractionated pre-vacuum, steam sterilization:

Sterilization temperature	Minimum holding time	Pressure	Drying time
134°C - 137°C	3 - 5 minutes	3 bar 44 psi	At least 10 minutes

STORAGE

- Store the sterilized instruments in a low-germ, dry, clean and dust-free environment, preferably in sterile containers.
- Store the sterile containers in a clean and dry environment with controlled humidity at room temperature.
- Do not store the sterile containers in the vicinity of aggressive substances such as alcohol, acids, bases, solvents and disinfectants.
- Protect the instruments from direct light.

INFORMATION ON THE VALIDATION OF THE REPROCESSING

The following tools and machines were used in the validation:

Pre-cleaning	Cidezyme of Johnson & Johnson
Alkaline cleaning agent for machine cleaning	neodisher® FA of Dr. Weigert
Cleaning device	Miele G 7735 CD
Disinfection device	Getinge 88 Series
Sterilization device	– Selectomat S 3000 of MMM Group – Varioclaov 400 E of Fisher Scientific
Sterilizing agent	Moist heat

ADDITIONAL NOTES

– If the means and machines described above are not available, it is the responsibility of the user to validate his process accordingly.

DISPOSAL

– Products may only be disposed of properly after successful cleaning and disinfection.
– When disposing of or recycling the product or its components, the national regulations and hospital guidelines must be observed.
– Take care with sharp tips and cutting edges. Use suitable protective caps or containers to protect third parties from injury.

REPAIRS & RETURNS

- Never carry out repairs yourself. Service and repairs may only be carried out by trained and qualified persons. Please contact RUDOLF Medical or your medical technology department if you have any questions in this regard.
- Defective products must have undergone the entire reprocessing process before being returned for repair or complaint.

PROBLEMS / EVENTS

- The user should report all problems with RUDOLF Medical products to the respective distributor.
- In the event of serious incidents involving the products, the user must report them to RUDOLF Medical as the manufacturer and to the competent authority of the member state in which the user resides.

GUARANTEE

- The instruments are made of high-quality materials and undergo strict quality control before delivery. If any discrepancies occur, please contact RUDOLF Medical.

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 mark in accordance with Regulation (EU) 2017/745 for medical devices (MDR) with the identification number of the notified body
	Lubricate with silicone-free, biocompatible medical white oil that is approved for steam sterilization.