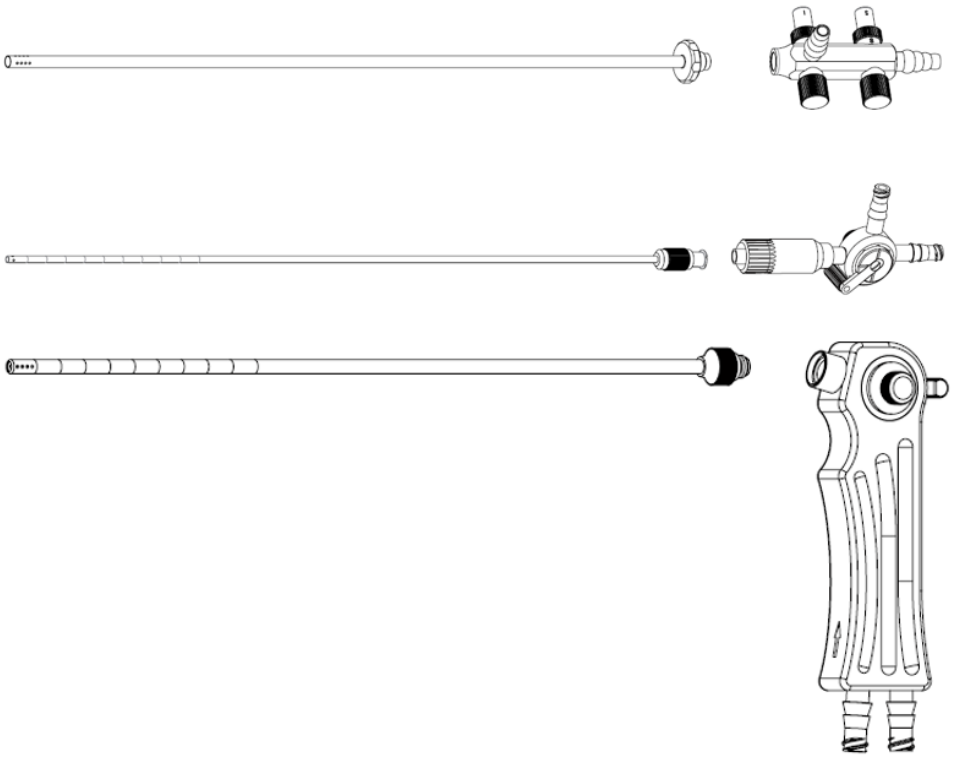
RUDOLF
BECAUSE WE CARE

INSTRUCTIONS FOR USE (EN)

SUCTION-IRRIGATION SYSTEM WITH TRUMPET OR SLIDING VALVE



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PLEASE READ BEFORE REPROCESSING AND KEEP IT IN A SAFE PLACE

PRODUCT

These instructions for use are valid for the RUDOLF Medical suction-irrigation instruments. They describe the models with trumpet and sliding valves.

You are receiving a high-quality product whose proper handling and use are described below.

⚠ Remove the packaging with great care. Do not touch the sharp edges and tips. Do not use damaged instruments, and do not carry out repairs on the instruments.

NON STERILE RUDOLF Medical instruments 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 beforehand.

INTENDED PURPOSE

The instruments are intended for suction and irrigation during surgical procedures.

CONTRAINDICATION

This instrument is not intended for the use on the central nervous and circulatory system.

⚠ WARNINGS AND PRECAUTIONS

- During suction, tissue pieces can get stuck in the suction-irrigation holes. Therefore, rinse the suction-irrigation tube several times during the procedure outside the surgical site.
- **Note**: With suction-irrigation handles with the sliding valve, you can select which connection should be used for suction and which for irrigation.
- The instrument may only be used by qualified, medically and technically trained professionals.
- Exceeding the product lifetime leads to material fatigue and loss of the function.
- Improper use and overstraining due to twisting / levering can lead to breaks and permanent deformation.
- When a trocar sleeve with a larger dimension is used the tissue will be punched.
- Use only original equipment.

Risk of infection

For suspected or confirmed CJD patients or CJD variants please observe the applicable national regulations regarding disposal and/or reprocessing.

PRIOR TO EACH USE: VISUAL AND FUNCTIONAL INSPECTION

The functional test is performed to check whether the instrument and its components function properly. Perform the functional test after assembly and reprocessing.

Note: Perform the functional test for the suction-irrigation handle.

Check for:

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

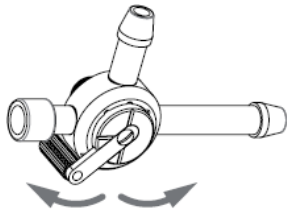
We recommend lubricating the spring plungers, knurled thumb screws, and stopcocks with RU 8880-50 after the cleaning/disinfection process and before sterilization.

Functional test

Suction-irrigation handle with a sliding valve

Requirement: The instrument is assembled.

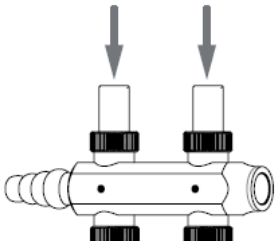
Move the sliding valve in the position "Suction" and then in the position "Irrigation."
The sliding valve should move freely.



Suction-irrigation handle with a trumpet valve

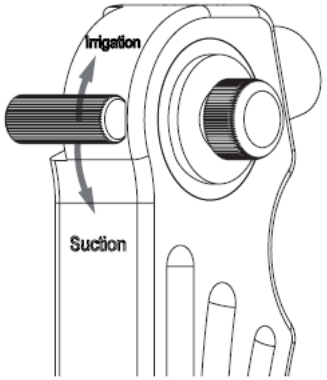
Requirement: The instrument is assembled.

Press the trumpet valve down, and then release it.
The trumpet valve should be pushed back up by the spring.



Suction-irrigation pistol handle with a sliding valve

Move the sliding valve in the position "Suction" and then in the position "Irrigation."
The sliding valve should move freely.



PRODUCT DESCRIPTION

The suction-irrigation tube is mounted to the suction-irrigation handle and inserted into the surgical site via a trocar sleeve.

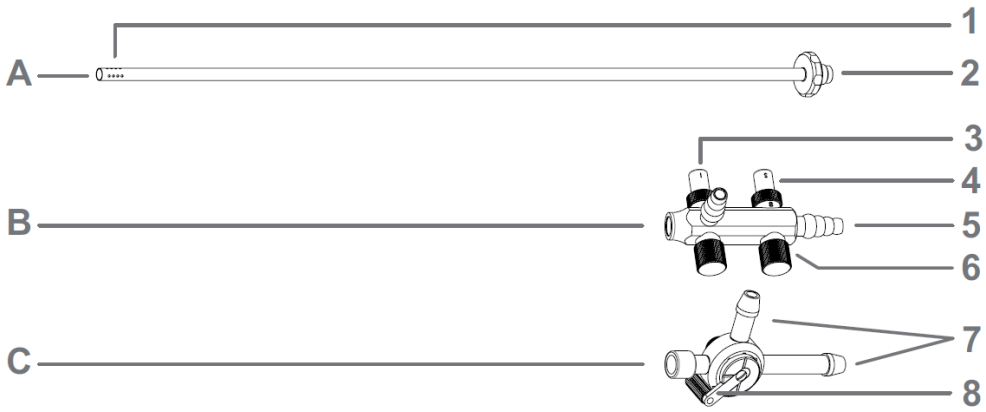
Suction-irrigation tube	Compatible trocar sleeve
Ø 3mm Ø 5mm Ø 10mm	Ø 3.5mm Ø 5.5mm Ø 11mm

Additional holes in the suction-irrigation tube expand the suction-irrigation area.

Depending on the model, a sliding or trumpet valve on the handle is used to switch between the suction and irrigation functions. Labeling on the handle indicate the functions.

If you need a spare part, contact your local RUDOLF Medical representative**.**

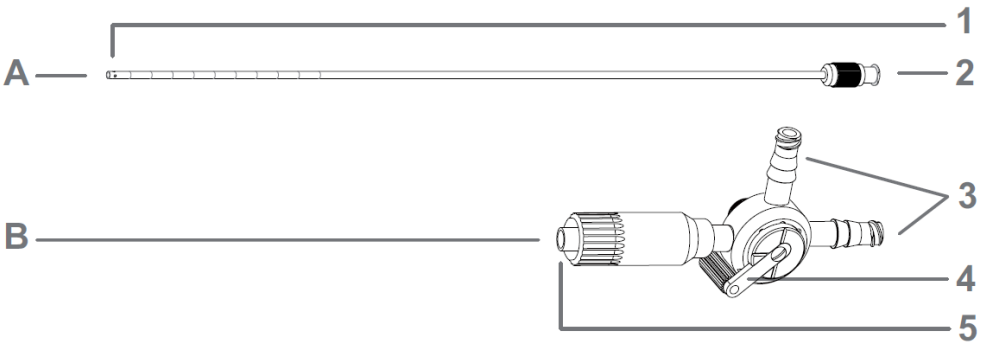
Suction-irrigation system*



A Suction-irrigation tube
B Suction-irrigation handle with trumpet valve
C Suction-irrigation handle with sliding valve
1 Suction-irrigation holes
2 Thread
3 Valve for irrigation
4 Valve for suction
5 Hose connection
6 Knurled thumb screw
7 Hose connection
8 Sliding valve for the suction-irrigation function

* These instructions for use apply to several instrument models. Deviations from the images are therefore possible.

Suction-irrigation system with Luer-Lock*

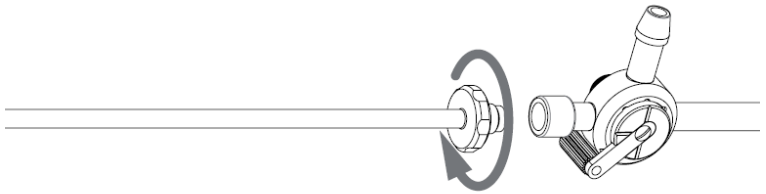


A Suction-irrigation tube
B Suction-irrigation handle with sliding valve
1 Suction-irrigation holes
2 Luer-Lock connection
3 Combined connection for Luer-Lock and hose
4 Sliding valve for the suction-irrigation function
5 Luer-Lock connection

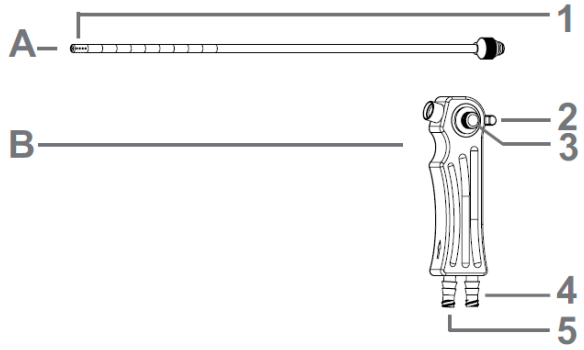
* These instructions for use apply to several instrument models. Deviations from the images are therefore possible.

Note: The suction-irrigation tube cannot be disassembled.

Screw the suction-irrigation tube into the thread of the sliding valve handle.



Suction-irrigation pistol handle with a sliding valve



A Suction-irrigation tube
B Suction-irrigation pistol handle with sliding valve
1 Suction-irrigation holes
2 Stopcock with sliding valve
3 Spring cap
4 Combined connection for Luer-Lock and hose for suction
5 Combined connection for Luer-Lock and hose for irrigation

Note: The suction-irrigation tube cannot be disassembled.

Screw the suction-irrigation tube into the thread of the pistol handle.

TECHNICAL SPECIFICATIONS

Operating conditions

Specification	Value
Irrigation pressure	maximum 600 mbar

Product lifetime

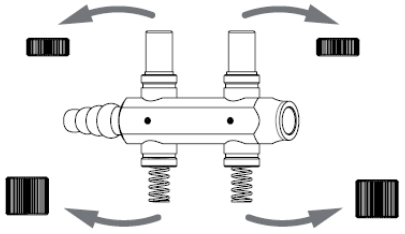
Specification	Value
Reprocessing	≤ 1000 cycles
Time	≤ 5 years

DISASSEMBLY OF THE INSTRUMENT

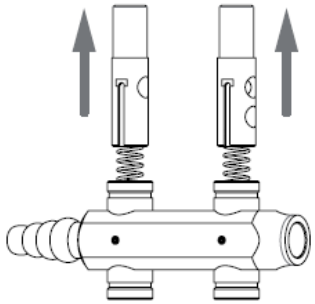
Note: The suction-irrigation tube cannot be disassembled.

Suction-irrigation handle with a trumpet valve

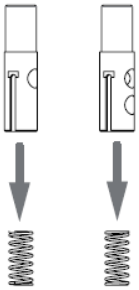
1. Unscrew the knurled thumb screws.



2. Remove the valve.

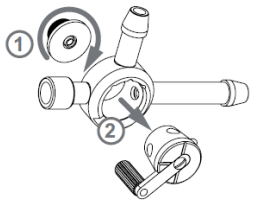


3. Remove the springs.



Suction-irrigation handle with a sliding valve

Unscrew the spring cap (1) and remove the stopcock (2).



Suction-irrigation pistol handle with a sliding valve

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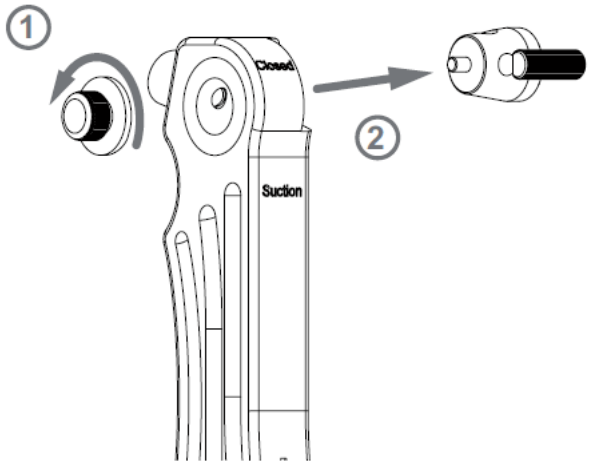
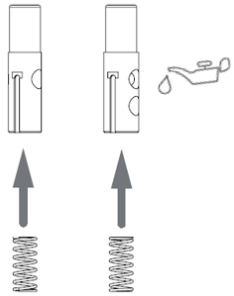


ASSEMBLY OF THE INSTRUMENT

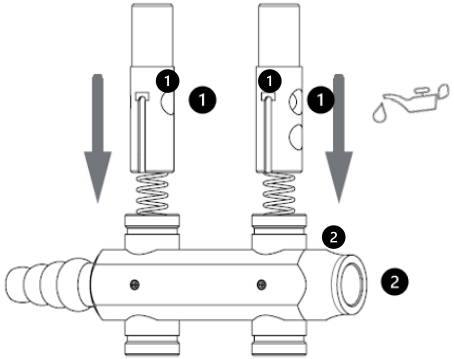
⚠ **There is risk of infection from unsterile instruments. The instrument must be reprocessed before assembly**.

Suction-irrigation handle with a trumpet valve

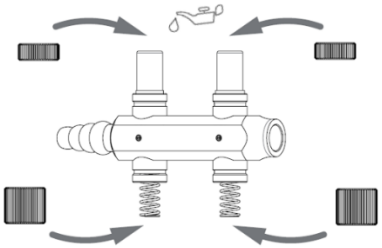
1. Insert the springs into the spring plungers.



2. Insert the valve with the openings (1) in the corresponding alignment on the handle.

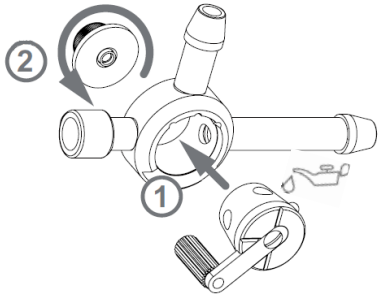


3. Screw on the knurled thumb screws.



Suction-irrigation handle with a sliding valve

Insert the stopcock (1), and screw it on using the spring cap (2).



Suction-irrigation pistol handle with a sliding valve

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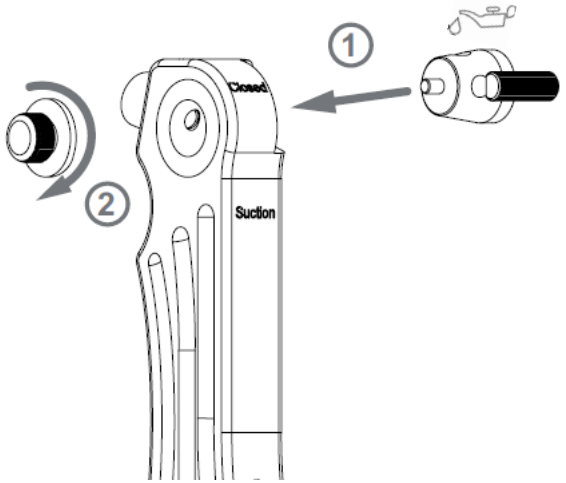

REPROCESSING INSTRUCTIONS

⚠ The instrument must be disassembled before reprocessing.

- Wear personal protective equipment during reprocessing.
- The instruments must be reprocessed within an hour after use to prevent contamination from drying on the instruments.
- When choosing the cleaning agent, consider the material and properties of the instrument, the cleaning agents recommended by the washer/disinfector manufacturer for the respective application and the relevant recommendations of the Robert Koch Institute (RKI) and the German Society for Hygiene and Microbiology (Deutsche Gesellschaft für Hygiene und Mikrobiologie, DGHM).
- Do not use any fixing agents.
- Use only the specified agents. If other agents are used, those agents must be validated.
- Use disinfectants with corrosion protection.
- Do not rinse with hot water.
- Plastic components must not come into contact with hydrogen peroxide (H_2O_2).
- Do not use scratchy brushes, sponges, or abrasives because they can damage the surface which can lead to corrosion.
- Never leave the instruments for too long in the disinfectant solution. Follow the instructions of the disinfectant solution manufacturer.

Restrictions

- The product lifetime 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 instruments.

Initial treatment at the place of use

- Defective instruments must be clearly marked as such. They have to be reprocessed before being disposed of or returned.
- Rinse the instrument with cold water.
- Remove coarse soiling with cold water. A plastic brush is recommended for heavily encrusted tissue residues.
- Flush lumen with cold water.

Note: If it is not possible to rinse the instrument with cold water, wrap the instrument in a moist cloth to prevent any residues from drying.

Transportation

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

Manual pre-cleaning

A manual pre-cleaning is necessary before the automated cleaning and disinfection to prevent surgery residues from drying.

Cleaning	Detergent	Dosage	pH value
Enzymatic	Cidezyme of Johnson & Johnson	0.8%	7.8 – 8.8 (diluted)

1. Immerse the instrument into a cold-water bath with a 0.8% cleaning solution and let the instrument soak for 5 minutes. To avoid contamination of the surrounding are rinse the instrument in the water.
2. Brush the instrument under cold water until all visible soiling is removed.
3. Disassemble the instrument as far as possible. See the “Disassembly of the instrument” section.
4. While the instrument is in the water bath, brush the instrument using a round brush until all visible soiling has been removed.
5. Where applicable, rinse lumen, drillings, and threads using a spray gun: > 10 seconds with 3 – 5 bar.
6. Remove the instrument from the water bath, and rinse it with cold water.
7. Immerse the instrument into a combined cleaning-disinfectant solution to prevent any residue from drying.

Automated cleaning and disinfection

- Automated cleaning / disinfection should be preferred to manual cleaning / disinfection, since automated processes can be standardized, reproduced, and thus validated.
- Clean the instrument when disassembled. If present, remove protective caps.

Cleaning in the ultrasonic bath

Clean the components in the ultrasonic bath before or in combination with the 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.

Detergent for the automated alkaline cleaning in the washer

Cleaning	Detergent	Dosage	pH value
Alkaline	neodisher® FA of Dr. Weigert	0.5%	12.2 – 14 (diluted)

Washer: Miele G 7735 CD

Preparation:

1. Place the instruments in a sieve tray of the MIS slide-in cart of the cleaning device in such a way that the inner and outer surfaces can be properly cleaned.
2. If applicable, close the irrigation connection of the MIS slide-in cart.
3. Start the cleaning program.

Program	Detergent	Duration	Temp. °C
1. Pre-rinsing	Cold tap water	1 minute	Cold
2. Draining	----	----	----
3. Pre-rinsing repeated	Cold tap water	3 minutes	Cold
4. Draining	----	----	----
5. Cleaning	0.5% alkaline detergent	5 minutes	55°C
6. Draining	----	----	----
7. Neutralization	Deionized water	3 minutes	----
8. Draining	----	----	----
9. Rinsing	Deionized water	2 minutes	----
10. Draining	----	----	----
11. Drying (drying program in the device)	----	15 – 25 minutes	90 – 110°C
12. At the end of the cycle, immediately remove the instrument, if it is not too hot.	----	----	----
13. If necessary, dry the instrument using sterile compressed air.	----	----	----

Disinfection

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 inspected visually and for functionality. The instruments must be macroscopically clean (free of visible residues). Particular attention should be paid to slots, lumen, locks, 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 instrument must be assembled and checked for function, wear & tear, and damage (cracks, rust) and replaced, if necessary.
- After each cleaning and before sterilization, the moving parts must be lubricated with a silicone-free, biocompatible white medical oil.
- Defective products 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 instruments for sterilization is according to standards DIN EN ISO 11607 and DIN EN 868.
- 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. Pointed and sharp cutting edges must not perforate the sterilization packaging.

STERILIZATION

- Before sterilization, the instrument must be assembled. See the “Assembly of the instrument” section.
- Sterilization was validated using the sterilizers Selectomat S 3000 of the MMM Group and Varioclav 400 E of Fisher Scientific.
- Observe the manufacturer’s instructions of the sterilizer.
- The sterilizers are validated according to DIN EN 13060 and DIN EN 285, respectively.
- Place the instruments in the sterilizer so that the instruments do not touch each other and steam can circulate freely.

Triple fractionated pre-vacuum:

Sterilization temperature	Minimum holding time (exposure time)	Pressure	Drying time
134°C – 137°C	3 - 5 minutes	3 bar 44 psi	Minimum of 10 minutes

STORAGE

- Store the sterilized instruments in a low-germ, dry, clean, and dust-free area, preferably in sterilization containers.
- Store the sterilization container in a clean and dry area at room temperature and with controlled humidity.
- Do not store the sterilization containers near aggressive substances such as alcohol, acids, bases, solvents, and disinfectants.
- Keep the sterile instruments away from sunlight.

INFORMATION REGARDING THE VALIDATION OF THE REPROCESSING PROCEDURE

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

Pre-cleaning	Cidezyme of Johnson & Johnson
Alkaline detergent for the automated cleaning	neodisher® FA of Dr. Weigert
Cleaning device	Miele G 7735 CD
Disinfectant device	Getinge 88 Series
Sterilizer	– Selectomat S 3000 of MMM Group – Varioclav 400 E of Fisher Scientific
Sterilization agent	Moist heat

ADDITIONAL NOTES

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

DISPOSAL

- Only after the products have been cleaned and disinfected properly, they should be disposed of accordingly.
- Comply with national regulations and applicable hospital guidelines when discarding or recycling the product / components.
- 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 persons. If you have any questions, contact RUDOLF Medical or your medical technology department.
- Defective products must have gone through the entire reprocessing cycle before being returned for repair or complaint.

PROBLEMS / EVENTS

- The user should report any problems with our products to the respective distributor.
- In the event of serious incidents with the products, 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 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.
LOT	Batch code
REF	Article no.
QTY	No. per package
	Non-sterile
	Caution
	Manufacturer
	Date of manufacture
	Keep away from sunlight
CE 0297	CE marking according to EG directive 93/42/EWG with the ID of the notified body
	Lubricate with silicone-free, biocompatible white medical oil approved for steam sterilization.
MD	Medical Device