RUDOLF
BECAUSE WE CARE

INSTRUCTIONS FOR USE (EN)
VERESS CANNULAS

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PLEASE READ BEFORE REPROCESSING AND KEEP IN A SAFE PLACE

PRODUCT

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

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

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

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

The instrument must only be used by qualified, medically and technically trained personnel.

CONTRAINDICATION

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

⚠ WARNINGS AND PRECAUTIONS

- **Please also observe the instructions in the "PUTTING INTO OPERATION" section.**
- There is a risk of injury due to incorrect handling and worn instruments. One of the possible consequences is the loss of the pneumoperitoneum due to leaking stopcocks.
- Exceeding the product service life results in material fatigue and loss of function.
- If the inner sheath is not released immediately after penetration, there is a risk of injury to internal organs from sharp points.
- The inner and outer sheaths of the same insufflation cannulas **must not** be interchanged.
- Use only original accessories.
- Take care when handling sharp tips and cutting edges, as there is a risk of injury.
- 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

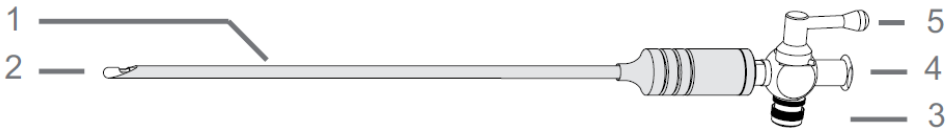
The functional inspection shows whether the instrument and its components are functioning properly. Carry out the functional inspection after assembly and after reprocessing.

Check for the following:
- External damage (e.g. deformed sheath, dents, burrs, cracks or sharp edges)
- Correct function
- Residues of cleaning agent or disinfectant
- Free passage through working channels

After cleaning and disinfection or before sterilization, we recommend lubricating the stopcock with instrument grease.

PRODUCT DESCRIPTION

- The insufflation cannula is used to introduce carbon dioxide into the abdomen during laparoscopic procedures. The inflowing gas lifts the abdominal wall and thus minimizes the risk of injury to the internal organs during the procedure.
- The insufflation cannula consists of an inner and outer sheath. A spring pushes back the inner sheath at the moment of the incision, exposing the sharp tip of the outer sheath. The blunt distal end of the inner sheath then slides forward again and covers the sharp tip of the outer sheath to prevent injury to internal organs.
- Spare parts are available on request.



1 Outer sheath
2 Inner sheath
3 Spring cap
4 Luer lock connection
5 Stopcock

* These instructions for use apply to several models. Therefore, the pictures may slightly differ from the instruments.

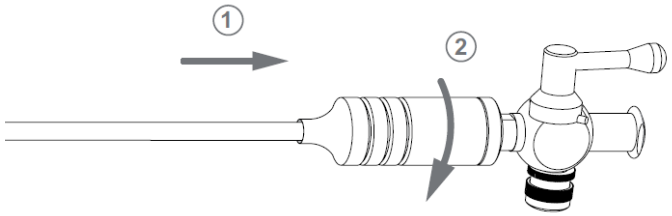
Notes:

The high-flow version of the insufflation cannula has a larger diameter to ensure a higher gas flow rate.

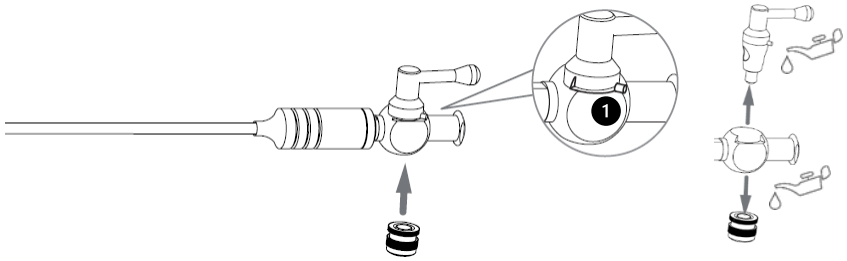
MOUNTING THE INSTRUMENT

⚠ **There is a risk of infection from non-sterile instruments. The instrument must be reprocessed before assembly**.

Insert the outer sheath (1) and screw it tight (2).

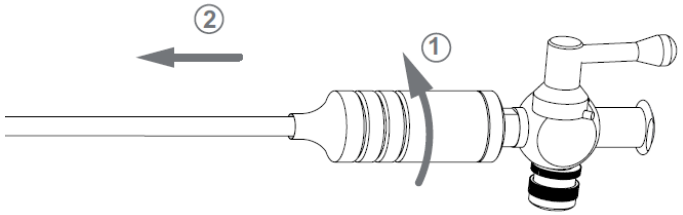


Insert the stopcock plug into the stopcock body, so that the pin (1) is positioned in the recess. Then screw the stopcock plug to the spring cap.

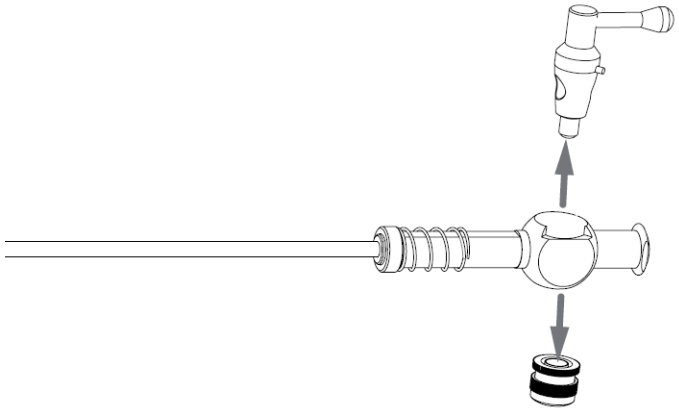


DISASSEMBLY OF THE INSTRUMENT

Unscrew the outer sheath (1) and pull off the outer sheath (2).



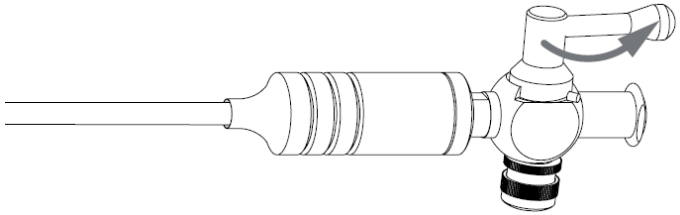
Unscrew the spring cap and remove the stopcock plug.



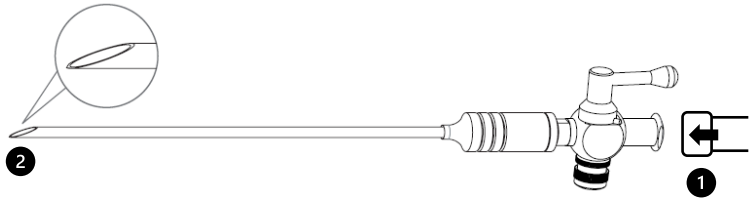
PUTTING INTO OPERATION

⚠ **Please also note the information in the "WARNINGS AND PRECAUTIONS" section.**

Rest position: as long as the stopcock lever is closed, no gas can escape.



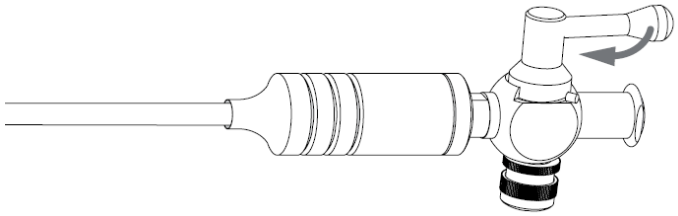
1. Connect the instrument to the insufflator via the Luer lock connection using an insufflation tube. (1)
2. Pull back the inner sheath so that the sharp tip (2) of the outer sheath can pierce the body.



⚠ **Risk of injury due to kinking of the instrument sheath:**
During the incision, hold the instrument between your thumb and index finger and stabilize the instrument with your index finger at the middle of the sheath.

⚠ **Distal end of the outer sheath is sharp:**
Make the incision carefully via the navel and release the inner sheath immediately to avoid damaging internal organs.

3. Now open the stopcock lever to allow the gas to flow.



4. Finally, remove the Veress cannula after the pneumoperitoneum has been created.

REPROCESSING INSTRUCTIONS

- Wear personal protective equipment during reprocessing.
- 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 washer-disinfector (WD) manufacturer for the respective application and the 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.
- 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.
- Plastic components must not come into contact with hydrogen peroxide (H_2O_2).
- Do not use abrasive brushes, sponges or 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

- Do not use fixing agents or hot water (> 40°C), as this can lead to hardening of residues and thus impair the cleaning success.

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.
- Rinse the instrument with cold water.
- Remove contamination with cold water. A plastic brush is recommended for heavily encrusted tissue 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 machine cleaning and disinfection to prevent surgical residues from drying.

Cleaning	Cleaning agent	Dosage	pH Value
Enzymatic	Cidezyme by 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 section "Dismantling the instrument".
4. Brush the inside and outside of the instrument in a water bath with a round brush until no more residue is visible.
5. 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

Automated cleaning and disinfection

- Automated cleaning/disinfection should be preferred to manual cleaning/disinfection, as automated processes can be standardized, reproduced and therefore validated.
- The instrument must be disassembled for cleaning. Remove the any protective caps.
- Instruments with cavities (tubes, sheaths, hoses) must be connected to an appropriate rinsing device to ensure that these cavities are rinsed.

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 instrument components in the ultrasonic bath during cleaning.

Cleaning agent for alkaline automated cleaning in the WD

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

Washer-disinfector (WD): Miele G 7735 CD

Preparation:

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

Program	Cleaning agent	Duration	Temp.°C
1. Pre-rinse	Cold tap water	1 minute	Cold
2. Draining	----	----	----
3. Repeated pre-rinsing	Cold tap water	3 minutes	Cold
4. Draining	----	----	----
5. Cleaning	0.5% Alkaline cleaning agent	5 minutes	55°C
6. Draining	----	----	----
7. Neutralizing	Deionized water	2 minutes	----
8. Draining	----	----	----
9. Rinsing	Deionized water	2 minutes	----
10. Draining	----	----	----
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, ratchets, joints and other areas that are difficult to access.
- If contamination residues/liquids are still visible, cleaning and disinfection must be repeated.
- Before sterilization, the instrument must be assembled and checked for function, wear & tear and damage (cracks, rust) and, if necessary, replaced.
- After each cleaning and before sterilization, the moving parts must be oiled and maintained with a silicone-free, biocompatible, medical white oil.
- Defective products must have undergone the entire reprocessing process before being returned for repair or complaint.
- See also "PRIOR TO EACH USE: VISUAL AND FUNCTIONAL INSPECTION" in these instructions.

PACKAGING

- Standardized packaging of instruments for sterilization is carried out according to DIN EN ISO 11607 and DIN EN 868.
- Tips and sharp edges must not perforate the sterilization packaging.
- In the case of individual packaging, make sure that it is large enough to hold the product without putting tension on the sealing seam or tearing the packaging.

STERILIZATION

- The instrument must be assembled for sterilization. See section "Assembling the instrument".
- Sterilization was validated using the Selectomat S 3000 sterilizer by MMM Group and the Varioclaov 400 E from Fisher Scientific. The sterilizers are validated according to 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

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

ADDITIONAL NOTES

- If the specified chemical agents and machines are not available, it is the responsibility of the user has to validate their process.

DISPOSAL

- Products should be disposed of accordingly after they have been cleaned and disinfected properly.
- Comply with the 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 AND RETURNS

- Never carry out repairs yourself. Service and repairs must 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.
- Due to the risk of infection, 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 with the products, the user must report this to RUDOLF Medical as the manufacturer and to the competent authority of the member State in which the user resides.

WARRANTY

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

APPLICABLE STANDARDS AND DIRECTIVES

– DIN EN 285 Sterilization - Steam sterilizers - Large sterilizers
– DIN EN 868 Packaging materials and systems for medical devices to be sterilized - Part 8: Reusable sterilization containers for steam sterilizers according to EN 285; requirements and test methods
– DIN EN ISO 11607: Packaging for medical devices to be sterilized in the final packaging - Part 1: Requirements for materials, sterile barrier systems and packaging systems
– DIN EN 13060: Small steam sterilizers
– DIN EN ISO 15883: Washer-disinfectors - Part 1: General requirements, terminology and test methods
– DIN EN ISO 17664: Reprocessing of health care products - Information to be provided by the medical device manufacturer for the reprocessing of 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 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 approved for steam sterilization.
	Keep dry
	Keep away from sunlight
MD	Medical Device