

## 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.

**For professional use only:** The instruments are intended for use by the professional users only (surgeons, operating room nurses, medical device reprocessing technicians).

**Patient population:** There are no restrictions concerning the patient population. It may be left to the discretion and experience of the medical professional to decide whether the benefit outweighs the risk in the given population.

 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.

 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.

#### CONTRAINDICATION

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

#### WARNINGS AND PRECAUTIONS

- **Please also observe the instructions in the "USING THE MEDICAL DEVICE" 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.
- 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.
- Be careful when handling sharp tips and cutting edges as there is a risk of injury.
- Improper use and overstraining due to twisting / levering can lead to breaks and permanent deformation.
- Do not use metal brushes, sharp tools, or abrasives, because they can damage the surface which can lead to corrosion.
- For patients with incurable infections such as CJD (Creutzfeldt-Jakob disease), hepatitis, HIV, possible variants of these infections, or suspected infections, the applicable national regulations regarding the disposal and reprocessing of the medical devices 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 sheaths, dents, burrs, cracks or sharp edges)
- Correct function
- Residues of cleaning agent or disinfectant
- Free passage through working channels



After cleaning and disinfection and 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.

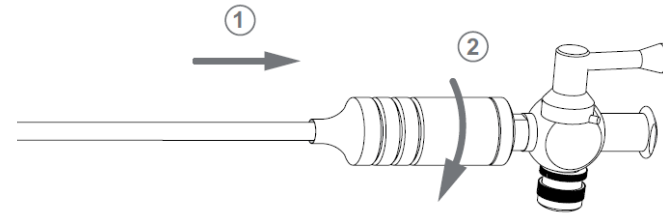
### Notes:

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

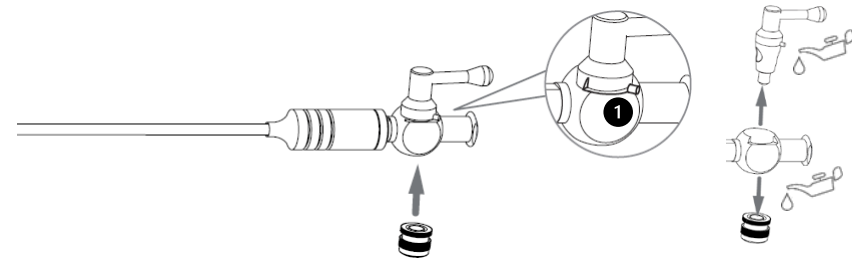
## ASSEMBLY OF THE INSTRUMENT

**⚠ 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).

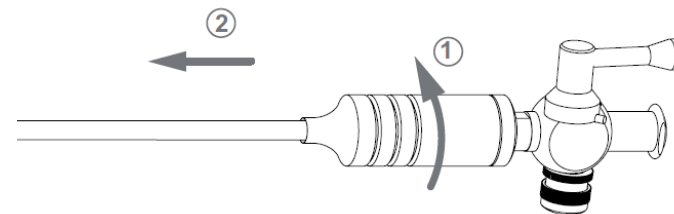


Insert the stopcock plug into the stopcock body, so that the pin (1) is positioned in the recess. Then screw the stopcock plug to the spring cap.

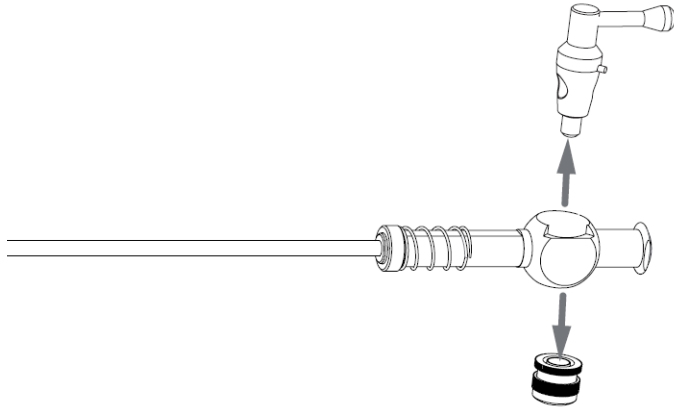


## DISASSEMBLY OF THE INSTRUMENT


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



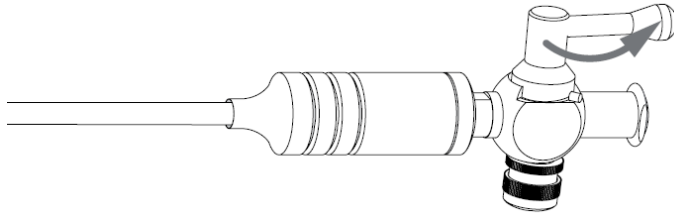
Unscrew the spring cap and remove the stopcock plug.



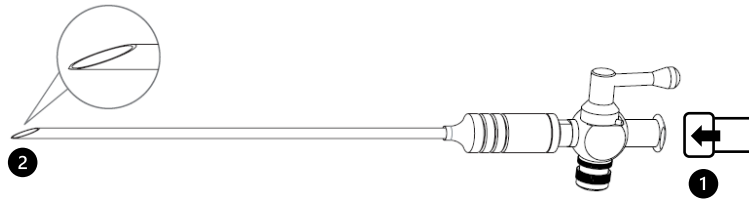
## USING THE MEDICAL DEVICE


 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.



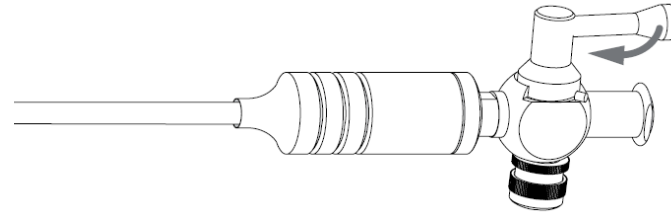
1. Connect the instrument to the insufflator via the Luer Lock connection using an insufflation tube. (1)
2. Pull back the inner sheath so that the sharp tip (2) of the outer sheath can pierce the body.



 **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

- The instrument must be disassembled before reprocessing.
- The instrument must be reprocessed within one hour after use to prevent contamination from drying.
- When choosing another 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), or the respective national recommendations.
- Do not use any fixing agents.
- Only use the specified cleaning agents. If you use other cleaning agents, you need to validate them.
- Use disinfectants with corrosion protection.
- Do not rinse under hot water.
- Plastic components must not come into contact with hydrogen peroxide (H<sub>2</sub>O<sub>2</sub>).
- 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 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.

## **Restrictions**

- The lifespan of the product is influenced by several factors, including:
  - The number of uses and the frequency of reprocessing cycles
  - The quality of care, handling, and maintenance
  - The continued legibility of any direct product markings
- Do not use any fixing agents or hot water (>40°C), because this causes a hardening of residues which can impair the cleaning of the instruments.

## **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 lumen 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**

- 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**

Before automated cleaning and disinfection a manual pre-cleaning is necessary 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 safety trocar spike in a cold water bath with a 0.8% cleaning solution 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. Rinse lumen, drillings and threads using a spray 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, since automated processes can be standardized, reproduced, and thus validated.
- The instrument must be disassembled for cleaning. Remove any protective caps.
- Connect the instruments that have lumen (tubes, sheaths, hoses) to a suitable irrigation system to ensure that the lumina are flushed.

## **Cleaning in an ultrasonic bath**

Clean the components additionally in an 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 instrument components in the ultrasonic bath during cleaning.

## **Cleaning agent for alkaline automated cleaning in the washer/disinfector**

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 sieve tray on the MIS slide-in trolley of the washer/disinfector so that the cleaning agent can rinse all internal and external surfaces.
2. If available, close the opening of the irrigation system on the MIC trolley.
3. Start the cleaning program.

Program	Cleaning agent	Duration	Temp.°C
1. Pre-rinsing	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	----	----	----

Program	Cleaning agent	Duration	Temp.°C
after the WD program has ended.			
13. If necessary, blow out the instrument with medical compressed air until it is dry.	----	----	----

## 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 subjected to a visual and functional inspection. The instruments must be macroscopically clean (free of visible residues). Particular attention should be paid to slots, locks, closures and other areas that are difficult to access.
- If residues/liquids are still visible, the cleaning and disinfection processes must be repeated.
- Before sterilization, the instrument must be assembled and checked for function, wear and tear, and damage (cracks, rust) and, if necessary, replaced.
- After each cleaning and before sterilization, the moving parts must be lubricated 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

- Packaging of the instruments for sterilization is according to standards DIN EN ISO 11607 and DIN 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

- The instrument must be assembled for sterilization. See section "Assembly of the instrument".
- The sterilization was validated using the sterilizers Selectomat S 3000 sterilizer by the MMM Group and the Varioclaov 400 E by Fisher Scientific. The sterilizers are validated according to DIN EN 13060 and DIN EN 285.
- Observe the manufacturer's instructions for the sterilizer.
- 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	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.
- 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:

<b>Pre-cleaning</b>	Cidezyme from Johnson & Johnson
<b>Alkaline cleaning agent for automated cleaning</b>	neodisher® FA from Dr. Weigert
<b>Washer</b>	Miele G 7735 CD
<b>Disinfectant</b>	Getinge 88 Series
<b>Sterilizer</b>	– Selectomat S 3000 from MMM Group – Varioclaov 400 E from Fisher Scientific
<b>Sterilization</b>	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 AND 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 your medical technology department, your distributor, or RUDOLF Medical.
- 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 any problems with the 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 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. In any discrepancies occur, please contact your distributor or RUDOLF Medical.

## APPLICABLE STANDARDS AND GUIDANCES FOR REPROCESSING

- Hygiene requirements for the reprocessing of medical devices, 10/2012, KRINKO/RKI/BfArM
- DIN EN 285: Sterilization - Steam sterilizers - Large sterilizers
- DIN EN 868-8: Packaging for terminally sterilized medical devices - Part 8: Re-usable sterilization containers for steam sterilizers conforming to EN 285 - Requirements and test methods
- DIN EN ISO 11607: Packaging for terminally sterilized medical devices
- DIN EN 13060: Sterilizers for medical purposes – Small steam sterilizers – Requirements and testing
- DIN EN ISO 15223-1: Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
- DIN EN ISO 15883-1: Washer-disinfectors - Part 1: General requirements, terms and definitions and tests

- 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
	Batch code
	Article no.
	No. per package
	Non-sterile
	Caution
	Manufacturer
	Date of manufacture
	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
	Medical Device