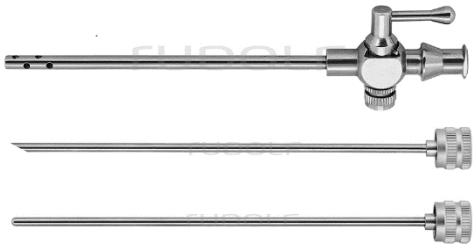
RUDOLF
BECAUSE WE CARE

INSTRUCTIONS FOR USE

IRRIGATION CANNULAS FOR ARTHROSCOPY



RUDOLF Medical GmbH + Co KG
Zollerstrasse 1, 78567 Fridingen an der Donau,
Germany
Phone +49 7463 9956-0
Fax +49 7463 9956-56
sales@RUDOLF-med.com
www.RUDOLF-med.com

D0645 / Rev H / ACR00574 / 2025-02-28

CE 0297

PLEASE READ BEFORE REPROCESSING AND KEEP IN A SAFE PLACE

PRODUCT

These instructions for use are valid for RUDOLF Medical irrigation cannulas for arthroscopy.
You have received a high-quality product, the proper handling and use of which are described below.
The products must only be used and reprocessed in medical facilities by trained and qualified medical personnel.

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

Arthroscopic irrigation cannulas and their trocar spikes/obturators are used to open and irrigate the surgical field.

SIDE EFFECTS

- Pain, swelling and joint effusion
- In rare cases, small blood clots may form.
- During the procedure, the joint itself or neighboring nerves may be injured. In the worst case, this could lead to infections, secondary bleeding or nerve damage.

CONTRAINDICATIONS

- The instruments are not intended for use on the central nervous system and circulatory system.
- Localized and generalized inflammation
- Bone tumors near joints
- Reflex dystrophy
- Immunosuppressive therapy
- Coagulation disorders

⚠ WARNINGS & PRECAUTIONS

- Tissue punching can occur in the following cases:
  - Use of trocar spikes or obturators the diameter of which is too small
  - Use of a sheath with a trocar spike or obturator that is too short
- Incorrect use and overloading due to twisting/levering can lead to fractures and permanent deformation.
- Do not use metal brushes or abrasive cleaners, as they can damage the surface which in turn can lead to corrosion.
- The safe combination of instruments with each other or with implants must be checked by the user before clinical use.
- Only combine instruments with original accessories that are compatible in terms of working length and diameter.
- Be careful when handling sharp tips and cutting edges because 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.
- Do not leave the instruments in the disinfectant for too long. Follow the disinfectant manufacturer's instructions.
- Manual cleaning/disinfection is not applicable for these instruments.

PRIOR TO EACH USE: VISUAL AND FUNCTIONAL INSPECTION

Check for:

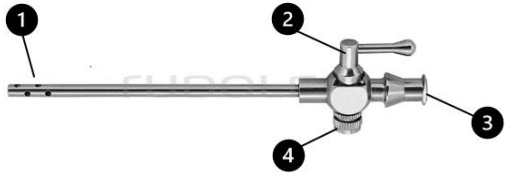
- External damage (e.g. deformed shaft, dents, burrs, cracks or sharp edges)
- Cleaning agent or disinfectant residues
- Corrosion, damaged surfaces, chipping
- Free passage through working channels
- Correct functioning. The function test shows whether the instrument and its components are functioning correctly. Carry out the function test before each use:
  - The instrument is assembled and, if possible, connected to a suction-irrigation device.
  - Compatible obturator or trocar spike can be inserted easily and does not jam.
  - Open the stopcock and close it again. The irrigation fluid runs out of the distal end of the irrigation cannula. After closing the stopcock, the flow is interrupted.

PRODUCT DESCRIPTION

The irrigation cannula provides access to the surgical site with the aid of a trocar spike or obturator and is connected to a suction-irrigation device via a Luer Lock connection. Additional holes at the distal end extend the irrigation area.

Irrigation cannula with stopcock:

(1) Side irrigation openings
(2) Stopcock plug
(3) Luer Lock connection
(4) Spring cap



Trocar spike with Luer Lock cap:

Obturator with Luer Lock cap:

APPLICATION

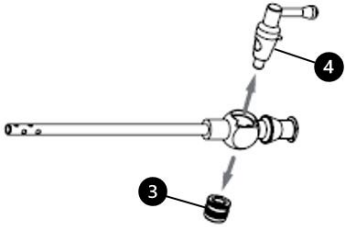
When using the obturator, a skin incision must be made before inserting the irrigation cannula:

1. Insert the trocar spike or obturator into the irrigation cannula.
2. Make an incision using the obturator.
3. Remove the trocar spike respectively the obturator from the irrigation cannula.
4. Connect the irrigation cannula to a suction irrigation device.
5. Carry out the procedure.
6. Remove the irrigation cannula from the surgical site.
7. Disconnect the irrigation cannula from the suction-irrigation device.
8. Reprocess the instrument.

Notes: The instruments must be disassembled for cleaning and disinfection and reassembled for sterilization.

DISASSEMBLY OF THE IRRIGATION TUBE

Unscrew the spring cap (3) and remove the stopcock plug (4) from the stopcock.

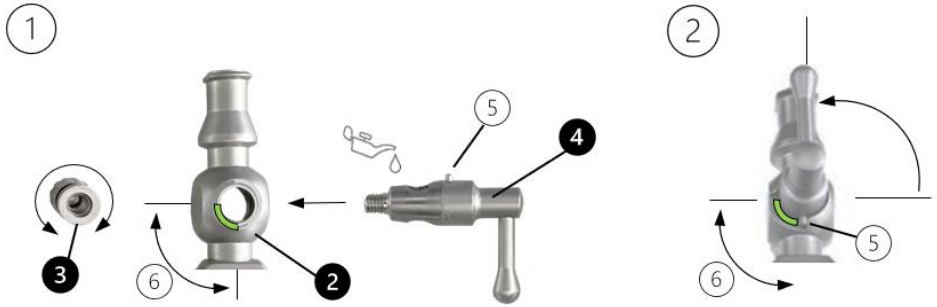


ASSEMBLY OF THE IRRIGATION TUBE

1. Insert the stopcock plug (4) into the stopcock holder (2). Make sure that the guide pin (5) of the stopcock plug runs in the recess (6) of the stopcock holder (2).
2. Then screw the spring cap (3) on the opposite side of the stopcock to the stopcock plug. Check the mobility of the stopcock plug.
3. The stopcock must be open for sterilization. To do this, swivel the lever of the stopcock plug towards the opening of the Luer lock connection.

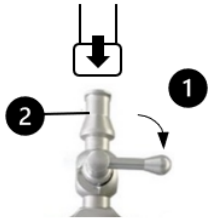
   Note: After cleaning and disinfection or before sterilization, the thread and cone of the stopcock plug must be lubricated as follows:
   - Thread: medical white oil
   - Stopcock plug: Maintenance grease for stopcocks

   Note: Make sure that the care products are approved for medical devices.



CONNECTING THE FLUSHING HOSE

1. Close the irrigation stopcock (1).
2. Connect the irrigation tube (Luer Lock connection) to the irrigation cannula.
3. Now carry out a function test. The instructions for this can be found in the section "PRIOR TO EACH USE: VISUAL AND FUNCTIONAL INSPECTION".



REPROCESSING INSTRUCTIONS

- The instruments must be disassembled for cleaning and disinfection and reassembled for sterilization:
  - The stopcock must be removed from the irrigation cannula for reprocessing. See section "DISASSEMBLY OF THE IRIGATION TUBE" above.
  - The trocar spike and obturator must be removed from the irrigation tube for cleaning and disinfection.
  - The stopcock must be open for sterilization. To do this, swivel the lever of the stopcock plug towards the opening of the Luer lock connection. See section "ASSEMBLY OF THE IRRIGATION TUBE" higher above.
- When selecting the cleaning agent, consider the material and properties of the instrument, the cleaning agent recommended by the washer and disinfector manufacturer for the respective application and the recommendations of the Robert Koch Institute (RKI) and the DGHM (German Society for Hygiene and Microbiology).
- Do not use fixing agents, only aldehyde-free cleaning agents, and do not use hot water (> 40°C), as this can lead to hardening of residues and thus impair the cleaning success.
- Only use the specified cleaning agents. If you use other cleaning agents, they must be validated by you.
- Use a disinfectant with corrosion protection.
- Do not use metal brushes, sponges or abrasive cleaners, as they can damage the surface, which in turn can lead to corrosion.
- Do not leave the instruments in the disinfectant for too long. Follow the disinfectant manufacturer's instructions.
- Observe the instructions for use of the cleaning agents and disinfectants as well as the cleaning and sterilization devices used.

Restrictions

- 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.

Material resistance

When selecting cleaning agents and disinfectants, make sure that they **do not** contain the following ingredients:

- Organic, mineral and oxidizing acids (minimum permissible pH value 5.5)
- Alkalis / strong alkaline solutions, recommendation:
  - Neutral/enzymatic or alkaline cleaner
  - Required for instruments made of aluminum or other alkali-sensitive materials: Neutral/enzymatic cleaner with a maximum pH value of 8.5
  - Required for products intended for use in prion-critical areas: alkaline cleaner with a maximum pH value of 11
- Organic solvents (e.g., alcohol, ethers, ketones, benzenes)
- Oxidizing agents (e.g., hydrogen peroxides)
- Halogens (chlorine, iodine, bromine)
- Aromatic/halogenated hydrocarbons

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.
- The instruments must be reprocessed within 1 hour after use to prevent the drying of contamination on the instrument.
- Rinse the instrument with cold water.
- Remove heavy contamination with a disposable cloth and cold water. A plastic brush is recommended for heavily encrusted tissue residues.

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

- The working channels and lumen must be rinsed at least three times immediately after use to prevent blockages.

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.

Preparation before cleaning

- The instruments must be disassembled for cleaning and disinfection and reassembled for sterilization. See the "Assembly" and "Disassembly" sections above.

Manual pre-cleaning

1. Rinse the instrument under running water for at least one minute. To avoid environmental contamination, rinse below the water level.
2. Instruments with hard-to-reach areas such as lumens, cavities, bores, threads and slots must be rinsed at least three times.
3. Prepare the ultrasonic bath according to the instructions of the manufacturer of the ultrasonic device and of the cleaning agent. The cleaning agent used was neodisher® MediClean forte from Dr. Weigert.
4. Place the disassembled instrument in an appropriately sized pre-cleaning bath for the specified exposure time. The ultrasonic bath must not yet be activated. The instrument must be completely immersed and must not touch any other instruments.
5. Brush the inside and outside surfaces thoroughly with a soft brush. To clean the ducts, select a cleaning brush that is slightly larger than the respective internal duct diameter. The shaft length of the brush must be at least as long as the duct. Make sure that no bristles get stuck in narrow gaps.
6. Move moving parts back and forth at least three times.
7. Rinse the lumen at least three times at the beginning and at least three times at the end of the exposure time. Auxiliaries and minimum volume depend on the channels to be flushed.
8. Activate the ultrasonic device for a new exposure time of at least 5 minutes.
9. Remove the instrument from the ultrasonic bath.
10. Rinse the instrument thoroughly with water at least three times for at least 1 minute and move the moving parts back and forth at least three times during the rinsing procedure.
11. Rinse the lumen at least three times. Auxiliaries and minimum volume depend on the channels to be flushed.

Automated cleaning and disinfection

- Clean and disinfect the instruments only in suitable washer-disinfectors (WD) and with a procedure / program validated for the WD and surgical instruments (EN ISO 15883).
- Instruments with cavities (tubes, shafts, hoses) must be connected to an appropriate rinsing device to ensure that these cavities are rinsed.
- Observe the operating and loading instructions of the WD manufacturer.
- When selecting the cleaning agent, consider the material and properties of the instrument, the cleaning agents recommended by the WD 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).

Cleaning agents for automated cleaning in the washer and disinfector (WD)

Cleaning agent	Manufacturer
neodisher® MediClean forte	Dr. Weigert

Automated cleaning program with thermal disinfection in the WD

1. Place the disassembled instrument in the WD. Make sure that the individual parts do not touch each other.
2. Connect instruments with cavities (tubes, shafts, hoses) to an appropriate rinsing device to ensure that these cavities are rinsed.
3. Start the program.
4. Remove the instruments from the rinsing device and take them out.

Program	Cleaning agent	Duration	Temperature
1. Pre-rinse	Deionized water	3 minutes	Cold
2. Cleaning	Deionized water 0.2% alkaline cleaning agent	5 minutes	50°C
3. Rinsing	Deionized water	≥ 1 minute	Cold
4. Thermal disinfection (1)	----	5 minutes	90°C
5. Drying (2) (drying phase in the WD)	----	20 minutes	max. 93°C

- (1) For mechanical thermal disinfection, observe the national requirements for the A_0 value from ISO 15883-1 ($A_0 = 3000$).
- (2) If necessary, manual drying can also be carried out using a lint-free cloth. 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 slits, 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 and 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 in accordance with DIN EN ISO 11607 and DIN EN 868.
- In the case of individual packaging, ensure that the packaging is large enough to hold the product without putting tension on the sealing seam or tearing the packaging. Tips and sharp edges must not perforate the sterilization packaging.

STERILIZATION

- The irrigation tube must be assembled for sterilization. See section "ASSEMBLY OF THE IRRIGATION TUBE".
- The sterilizers are validated according to DIN EN 13060 and DIN EN 285.
- The steam sterilization process (fractionated vacuum process with at least three vacuum steps) is validated according to DIN EN ISO 17665-1. The gravitation method is not recommended.
- The following sterilization procedures must not be used: flash sterilization, hot air sterilization, radiation sterilization, formaldehyde or ethylene oxide sterilization.
- The manufacturer's instructions for the sterilization device must be observed.
- Maximum sterilization temperature of 134°C (273°F)
- Drying time of at least 20 minutes must be observed.

Country	Temperature	Sterilization time
Germany	134°C (273°F)	≥ 5 minutes
France	134°C (273°F)	≥ 5 minutes
USA	132°C (270°F); drying time min. 20 minutes	≥ 4 minutes
Other countries	132°C (270°F) / 134°C (273°F)	≥ 5 minutes

Note: Extended sterilization times (e.g., 18 minutes) apply for prion inactivation in accordance with national regulations.

STORAGE

- Store the sterilized instruments in a low-germ, dry, clean and dust-free environment at room temperature with controlled humidity.
- Protect the sterilized instruments from direct light.
- **Do not** store the sterilization packaging in the vicinity of aggressive substances (e.g. alcohols, acids, alkali, solvents and disinfectants).

INFORMATION ON THE VALIDATION OF THE REPROCESSING

The following tools and machines were used in the validation:

Pre-cleaning	• neodisher® MediClean forte, Dr. Weigert • Ultrasonic bath
Automated cleaning	neodisher MediClean forte, Dr. Weigert
Automated disinfection	Thermal **Note**: With chemical disinfection, there is a risk of disinfectant residues on the instruments.
Washer / Disinfector	Miele G 7836 CD
Sterilization	• Steam sterilization (moist heat) • Sterilizer HST 6x6x6, Zirbus technology • Fractionated vacuum process with at least three vacuum steps

ADDITIONAL NOTES

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

DISPOSAL

- The products should be disposed of accordingly only after they have been cleaned and disinfected properly.
- 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 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.
- 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

- Hygiene requirements for the reprocessing of medical devices, status: 10/2012, KRINKO/RKI/BfArM
- DIN EN 285:2016-05: Sterilization - Steam sterilizers - Large sterilizers
- DIN EN ISO 11607:2017-10: Packaging for medical devices to be sterilized in the final packaging - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- DIN EN 13060:2019-02: Small steam sterilizers
- DIN EN ISO 15223-1:2017-04: Medical devices - Symbols to be used on medical device labels, labelling and information to be provided - Part 1: General requirements
- DIN EN ISO 15883-1:2014-10: Washer / disinfectors - Part 1: General requirements, terminology and test methods
- DIN EN ISO 17664:2018-04: Reprocessing of healthcare products - Information to be provided by the medical device manufacturer for the reprocessing of medical devices
- DIN EN ISO 17665:2006-11: Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and control of the use of a sterilization process for medical devices

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 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 white oil approved for medical devices and steam sterilization. Lubricate stopcocks, threads and sealing rings with instrument grease approved for medical devices and steam sterilization.
UDI	Unique Device Identification
MD	Medical Device