

– IMPORTANT ADVICES – PLEASE READ CAREFULLY – AND KEEP THE INSTRUCTIONS FOR FUTURE REFERENCE –

RIGID AUTOCLAVABLE ENDOSCOPES



(The figure shows a NS200-001 Ventriculoscope)

Applications

- **RUDOLF** endoscopes serve the purpose of illumination and visualisation during diagnostic and operative interventions. They may only be used in accordance with the designated area of application. This can be found in the relevant product catalogue.

Safe handling

- Prepare a brand-new endoscope before initial use (unsterilised in delivery condition)
- Check the endoscope for sharp edges, bent, loose or broken components before each use.
- Check the endoscope for correct functioning and for damage after each preparation.
- Segregate damaged endoscopes immediately.
- When using the endoscope in a trocar, avoid bending loads during insertion and withdrawal.
- Endoscopes may only be used by physicians or by medical personnel under the supervision of a physician. Adequate training, knowledge and experience in the clinical application of endoscopic techniques is required.
- Read the instructions for use carefully and follow the instructions.

Visual and functional inspection

Check for:

- external damage (shaft deformed, dents or sharp edges)
- cleaner or disinfectant residues.
- condition of the three optical surfaces – 1. objective window, 2. ocular window, 3. light cable connection – using reflected light or magnifying glass (smooth, clean and undamaged)
- optimal image quality (sharp, bright and unclouded)
- loss-free light transmission from light cable connection to light output (compare with new device, if necessary)
- free passage through working channels.



Warnings and precautions

- During use, the distal end and the light cable connection can become very hot due to the emission of light and thermal energy. Avoid direct contact with tissue and flammable materials. If possible, do not select the maximum illumination setting, but only the brightness level that is actually required.

Danger of burns!

- When operating the device with RF electrodes, ensure that the active electrode is always within the field of view and that there is no contact with the endoscope or other metal components of the instruments.

Danger of burns!

- In the case of laser surgery, do not use reflective objects in the working area and do not direct the laser beam towards the endoscope.

Danger of burns!

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- All **RUDOLF** endoscopes must be prepared according to the instructions for use before initial and each application.
Danger of infection!

- Do not use damaged endoscopes (see section "Visual and functional inspection")
Risk of injury!

Note:

- In case the endoscope is damaged during use, it is useful to have a second, sterile endoscope available as a replacement.

Material stability

- Cleaners and disinfectants can cause substantial damage to endoscopes. They should not contain the following components:
 - Oxidising agents
 - Organic, mineral and oxidising acids (minimum permissible pH value: 5)
 - Strong alkalis (maximum permissible pH value: 10)
 - Phenols or halogens (e.g. chlorine, iodine, bromine)
 - aromatic/halogenated hydrocarbons
- Cleaners or disinfectants used in combination must be compatible with one another. Neutral or slightly alkaline cleaners are recommended.
 - Never accelerate the cooling process of **RUDOLF** endoscopes (e.g. with cold water); sudden temperature fluctuations can result in the destruction of optical components.
 - **RUDOLF** endoscopes must not be exposed to temperatures exceeding 137°C (279°F).
 - Do not use abrasive cleaners, steel wool or metal brushes for cleaning purposes.
 - Never clean **RUDOLF** endoscopes in ultrasonic baths (results in damage to the optical system).
 - Do not use hot-air sterilisation, flash sterilisation, radiation sterilisation, formaldehyde sterilisation, ethylene oxide sterilisation or plasma sterilisation.
- If the instructions for use are observed, the number of reprocessing cycles has little effect on the service life of the products.
The durability of the endoscopes depends mainly on the loading to which they are subjected in use and the handling during preparation.

Light cable connection

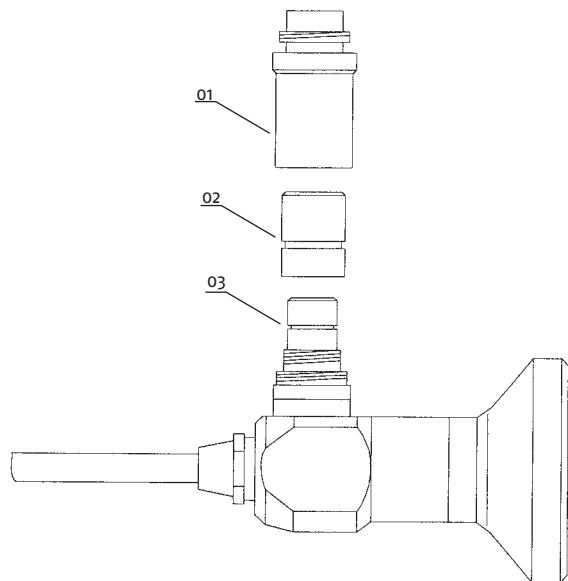
Disassembly:

- Unscrew adapter 01 or 02 from the endoscope.
- On working channels – if present:
 - Detach sealing cap.
 - Unscrew valve body.
 - Remove valve.

Assembly:

- Screw on adapter 01 or 02.
- On working channels – if present:
 - Insert a new valve.
 - Screw on valve body.
 - Attach sealing cap.

- 01 Storz® / Aesculap® / Olympus®-adapter
- 02 Wolf®-adapter
- 03 ACMI®-connection



Warnings and precautions

- Take care when disassembling contaminated endoscopes.
Danger of infection!

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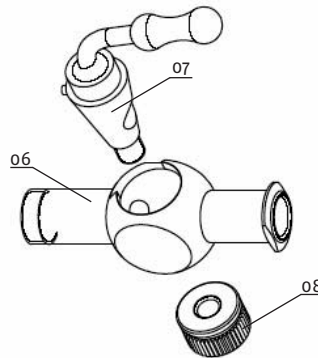
Stop-cocks

Disassembly:

- Unscrew the spring cap 08 and remove the conical valve 07 from the stop-cock 06.

Assembly:

- In order to protect against corrosion and to maintain operability, the conical valve 07 must be treated with a lubricant (e.g. RU 8880-00) before each sterilisation.
- When inserting the conical valve, ensure that the guide pin engages in the guide and that the lever points towards the opening in open condition.
- Screw the spring cap 07 onto the conical valve 08.
- Check stop-cocks for correct functioning.



- 06 Stop-cock
- 07 Conical valve
- 08 Spring cap

Preparation (cleaning, disinfection and sterilisation)

General requirements

- All **RUDOLF** endoscopes must be cleaned, disinfected and sterilised before each application. This applies in particular to brand-new devices, as all **RUDOLF** endoscopes are unsterilised when delivered (cleaning and disinfection following removal of the transport packaging; sterilisation in suitable sterilisation packaging). The following conditions are prerequisites for effective preparation:
 - Determination of configurations for charging the used devices and observance of the relevant manufacturer's instructions for use.
 - Regular maintenance and inspection of the used devices.
 - Validated processes for all preparation steps.
 - Conformance to standardised parameters for each preparation cycle.
 - Checking disinfection and sterilisation efficiency using corresponding indicators.
- Furthermore, the relevant applicable national hygiene regulations and the local medical practice or hospital guidelines must be observed, especially the various specifications regarding effective prion inactivation.

Cleaning and disinfection

Requirements

- The mechanical process in the cleaning and disinfection device described here should be used preferentially.
- If an appropriate machine is not available, a manual process can also be used. However, the low effectiveness and reproducibility must be taken into account here. Furthermore, the manual cleaning and disinfection process must be assured under the responsibility of the user (additional product and process-specific standardisation).
- Effective cleaning and disinfection are prerequisites for effective sterilisation.
- Regardless of this, preparatory treatment must always be performed.

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Preparatory treatment

Work steps immediately after use:

- Remove all light cable adapters before preparation. Disassembly: all stop-cocks, if present (see section "Disassembly/Assembly of stop-cocks").
- Thorough rinsing with cold, running water (max. 20°C) in order to remove coarse contamination from the endoscopes.
- Remove stubborn contamination using a mild cleaning solution, which is approved for medical endoscopes (see section "Material stability").
- Do not use coarse abrasive cleaners or metal brushes and avoid applying excessive force during the manual removal of contamination.
- Reassemble the stop-cocks, if present (see specific instruction) and flush out all empty channels five times using a disposable syringe (minimum volume: 50 ml).
- Final rinsing of the endoscope with fully desalinated water in order to prevent the formation of marks.
- Complete drying with compressed air (cavities) or a lint-free cloth.

Mechanical cleaning and disinfection

Prerequisites for suitable cleaning/disinfection devices:

- Programme selection for optimal endoscope cleaning with sufficient rinsing cycles.
- Controlled programme for thermal disinfection (A0 value > 3000 or at least 5 minutes at 90 °C) with proven effectiveness.
- Regular maintenance and verified effectiveness (e.g. DGHM or FDA approval or CE mark certification according to DIN EN ISO 15883).
- Final rinsing with water which is sterile or of low microbiological contamination (max. 10 bacteria/ml) and low in endotoxins (max. 0.25 endotoxin units/ml) (e.g. purified water/highly purified water).
- Controlled drying phase.

- With chemo-thermal disinfection, there is a risk of disinfectant residues on the endoscopes.

Prerequisites for suitable cleaners and disinfectants:

- Approval for the cleaning of endoscopic instruments with verified effectiveness (e.g. DGHM or FDA approval or CE mark certification).
- Compatibility of cleaners/disinfectants with one another (especially with chemo-thermal disinfection).
- Listed chemicals (see section "Material stability") should not be present.
- Use an enzyme-based agent with neutral pH value.

- An increased chloride concentration in the feedwater circuit can result in material damage (pitting corrosion). The rinsing water must be prepared in such a way that recontamination with bacteria is avoided.

The manufacturer's specifications regarding concentration, temperature and exposure time for the cleaners and disinfectants and must be observed.

Process:

1. Securely fasten the endoscopes to the inserts of the disinfection device. Prevent impairment of rinsing and contact between the endoscopes and other instruments.
2. Open the stop-cocks (if present) and connect all endoscope channels to the special inserts with rinsing device.
3. Do not overload the disinfection device.
4. Start the programme.
5. Remove the endoscopes from the disinfection device immediately after completion of automatic cleaning, in order to prevent corrosion.
6. Avoid accelerated cooling (e.g. in water).
7. Inspection and maintenance (see separate section).
8. Packaging of endoscopes (see section "Packaging").

- Proof of the basic suitability of **RUDOLF** endoscopes for effective mechanical cleaning and disinfection was provided by an independent accredited testing laboratory, using the G 7836 GD disinfectant (thermal disinfection, Miele & Cie GmbH & Co., Gütersloh) and Neodisher mediclean cleaner (Dr. Weigert GmbH & Co. KG, Hamburg). The above-described process was observed for this purpose.

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Other processes for cleaning and disinfection (not recommended)

- **RUDOLF** endoscopes were successfully tested for the basic stability of the used materials using the per-acetic acid process (STERIS system 1).
However, utilisation is only permissible if this process is approved for your clinic and in your country and the effectiveness has been proven by the user within the scope of a product/geometry/material process and device-specific qualification, taking account of EN ISO 15883 specifications (including basic suitability of device and process) and, if necessary, supplementation through additional effective processes has occurred.
- However, the above-described preparation processes must be used preferentially for the purpose of risk minimisation.

Inspection

- Before each sterilisation, the endoscope must be assembled and inspected (see section "Assembly instructions" and "Visual and functional inspection").
- Visual inspection of the three optical surfaces (see section "Visual and functional inspection") and, if necessary, cleaning with an alcohol-soaked swab (70%).
- Examination of corrosion, wear, sharp edges or splintering in the distal area.
- Segregate damaged endoscopes.

Maintenance

- The stop-cocks must be lubricated following each cleaning and each sterilisation (see section "Disassembly/assembly of stop-cocks").
- Only lubricants which have verified bio-compatibility may be used. The lubricant must be suitable for this application and must be approved for steam sterilisation (e.g. RU 8880-00).
- Regular cleaning of the optical surfaces with 70% alcohol (ethanol, isopropanol) prevents consolidation/baking of deposits.

Packaging

- Open all stop-cocks, if present.
- Use only disposable sterilisation packaging and/or sterilising containers which are suitable for steam sterilisation (adequate temperature resistance, air and steam permeability - DIN EN ISO/ANSI AAMI ISO 11607).
- The packaging must ensure optimal protection of the sterile endoscopes during transport and storage.
- Reusable sterilising containers must be maintained in accordance with manufacturer's specifications. The endoscopes must be fixed securely in the containers and protected against damage.
- As the suitability of the packaging considerably influences the sterilisation results, this should have been checked within the scope of the determination of sterilisation parameters.

Sterilisation

- The following sterilisation processes have been validated for their germicidal effect on **RUDOLF** endoscopes.

Steam sterilisation

- Fractionated vacuum process (with pre-vacuum) for endoscopes with and without empty channel.
- Gravitation process - only for endoscopes without empty channel (less effective and only permissible if the fractionated vacuum process is not available).

Conditions for steam sterilisation

- Sterilisation temperature:
Max. 134°C (273°F); plus tolerance according to DIN EN ISO 17665 (formerly DIN EN 554/ANSIAAMI ISO 11134).
- Sterilisation time at sterilisation temperature:
At least 4 minutes at 132°C (270°F) / 134°C (273°F) and 2.3 bar, or 18 minutes (prion inactivation).
- Steam steriliser approved according to DIN EN 13060 or DIN EN 285 and tested according to DIN EN ISO 17665 (formerly DIN EN 554/ANSI AAMI ISO 11134).
- Observe cooling time. Accelerated cooling (e.g. with cold water) can result in the destruction of the endoscopes.
- Proof of the basic suitability of **RUDOLF** endoscopes for effective steam sterilisation was provided by an independent accredited testing laboratory, using the Systec V-150 steam steriliser (Systec GmbH Labor-Systemtechnik, Wetztenberg) and the fractionated vacuum process as well as the gravitation process. For this purpose, typical conditions in clinics and in medical practices as well as the above-described process were taken into account.

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Other sterilisation processes (not recommended)

- **RUDOLF** endoscopes were successfully tested for the basic stability of the used materials using the low-temperature plasma process (STERRAD 100S).
However, utilisation is only permissible if this process is approved for your clinic and in your country and the effectiveness has been proven by the user within the scope of a product/geometry/material process and device-specific qualification, taking account of EN ISO 15883 specifications (including basic suitability of device and process).
However, the steam sterilisation process must be used preferentially for the purpose of risk minimisation.
- Further sterilisation processes are impermissible (see section "Material stability").

Storage

- Following sterilisation, store the endoscopes in a sterilising container or single/double sterile packaging until they are reused.
The storage location must be dust-free, of low microbiological contamination, dry, dark and free from temperature fluctuations.

Service

- **RUDOLF** offers a comprehensive repair and exchange programme for endoscopes.
Repairs may only be performed by **RUDOLF** or by authorised service points using original spare parts.

Hygiene

- For safety reasons, thoroughly clean, disinfect and sterilise defective endoscopes before returning them. In the case of contaminated devices, we reserve the right to charge the customer for the cost of preparation.

Loss of guarantee

- The use of damaged and/or contaminated **RUDOLF** endoscopes is the responsibility of the user. Disregarding these instructions for use will void the guarantee or warranty claims. We accept no liability in the case of improper handling, incorrect or inadequate preparation or unauthorised repairs.

