RUDOLF
BECAUSE WE CARE

INSTRUCTIONS FOR USE (EN)
# RIGID AND SEMI-RIGID ENDOSCOPES

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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 rigid and semi-rigid endoscopes. You are receiving a high-quality product, the proper handling and use of which are described below.
The instruments are intended for use by the professional user (surgeons, operating room nurses, medical device reprocessing technicians).
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.

NON STERILE RUDOLF Medical endoscopes 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

Endoscopes are intended to illuminate and visualize inner anatomic structures during diagnostic and surgical procedures.

## INDICATIONS

**Laparoscopes** are used for the visual examination and for performing minimally invasive surgery in the abdominal cavity.

**ENT endoscopes (Otoscopes, Sinuscopes)** are used for the visual examination and diagnosis of diseases in the ear, nose, and throat areas.

**Cystoscopes** are used for the visual examination and diagnosis of diseases of the urinary bladder and urethra, whereby the endoscope is mounted to a shaft system.

**Hysteroscopes** are used for the visual examination and diagnosis of diseases of the uterus, whereby the endoscope is mounted to a shaft system.

**Arthroscopes** are used for the visual examination and diagnosis of diseases at a joint.

**Uretero-renoscopes** are used for the visual examination and diagnosis of diseases of the ureter and kidney. The working channel of the endoscope enables additional procedures with flexible and semi-rigid instruments.

## CONTRAINDICATIONS

There are no known contraindications that are directly related to the use of an endoscope. In principle, the use of rigid and semi-rigid endoscopes for a single endoscopic procedure is contraindicated when endoscopic procedures are generally contraindicated.

⚠ The endoscopes are manufactured exclusively from materials that are suited for the use in the medical field. In rare cases, hypersensitized patients may experience pseudoallergic reactions when in contact for a prolonged time. Therefore, it is necessary to test for allergies against silicone, nickel and, possibly, brass before a procedure.

## ⚠ WARNINGS AND PRECAUTIONS

**General**

- Improper use may result in injury to the patient and/or user and in damage to the endoscope.
- Improper use and overstraining due to twisting / levering can lead to breaks and permanent deformation of the endoscope.
- Semi-rigid endoscopes are designed for low bending loads, that is for a bending deflection of the sheath up to a maximum of 20 degrees. Higher bending loads result in permanent deformation and in damage to the product and are therefore not permitted.
- Prior to each use, endoscopes must be checked for sharp edges, bent, loose, or broken parts. Be careful when handling sharp tips and cutting edges as there is a risk of injury.
- When the endoscope is used in a trocar, avoid bending load when inserting and removing the endoscope.
- Do not use metal brushes or abrasives, because they can damage the surface which can lead to corrosion.
- When treating patients with Creutzfeldt-Jakob disease (CJD) or suspected CJD, we recommend using single-use instruments. If the instruments are CJD-contaminated or if it is merely suspected that the instruments are CJD-contaminated, please follow the applicable national regulations regarding disposal.
- Never leave the instruments for too long in the disinfectant solution. Follow the instructions of the disinfectant solution manufacturer.

Please note the risks related to the respective area of application:

**Risk of infection:**

- During endoscopic examinations, great attention must be paid to risks of infection.
- The use of the endoscope in the clinical environment is associated with an increased risk of infection. Therefore, precautions must be taken to prevent infections.
- Prior to first and each subsequent use, the endoscopes must be reprocessed according to these instructions for use.
-  To prevent infection, personnel must wear personal protective equipment: protective hood to completely cover the hair; protective equipment for eye, mouth, and nose; gloves, protective gown, and suitable moisture-proof shoes. Please also observe the instructions of your organization.

**Procedure-related risks:**

- Type and extent of tissue damage during medical interventions
- Circumstances accompanying the endoscopic intervention (emergency or elective intervention)
- Competence and experience of the physician/user
- Correct cleaning and disinfection of the endoscope and accessories

**Patient-related risks:**

- Reduced immunity or immunosuppression of the patient (HIV, leukemia, lymphoma, immunosuppressive therapy, advanced liver or kidney diseases, advanced age)
- Existence of certain sources of infections or anatomic conditions
- Conditions that promote the docking of bacteria in the organism (heart valve defect, heat valve replacement, endoprostheses, intravenous indwelling catheters)
- Endoscopic examinations can lead to an endogenous transfer of the body's own microorganisms with subsequent bacteremia. Therefore, the national and international recommendations regarding prophylactic administration of antibiotics before certain interventions must be observed (ESGE Guidelines 1998).

**Risk of burns to the user:**

- During operation, parts of the endoscopes can become very warm so that there is a risk of burns. To prevent injuries adequate protective equipment must be worn.
- During use, the distal end and the light guide connector can become very hot due to emission of light and heat energy. Avoid direct contact with tissue and easily inflammable material. If possible, do not use the maximum illumination setting but only the brightness level that is really needed.
- When using HF electrodes, make sure that the active electrode is always in the field of vision and that it does not have any contact with the endoscope or any other metal parts of the equipment.
- When using a laser for a surgical procedure, no reflecting objects must be used in the working area. The laser beam must not be directed at the endoscope.

**Note:**

**For the likelihood that an endoscope is damaged during the procedure it is recommended to have a second sterile endoscope available as a backup.**

## PRIOR TO EACH USE: VISUAL AND FUNCTIONAL INSPECTION

Check for:

- External damage (e.g., deformed shaft, dents, burrs, cracks, or sharp edges)
- Correct functioning
- Detergent or disinfectant residues
- Condition of the three optical surfaces:
  1. Lens window
  2. Eyepiece window
  3. Light guide connector - with the help of reflected light or a magnifying glass. It must be smooth, clean and intact.
- Optimal image quality (sharp, bright, and clear)
- Free passage through the working channels
- Loss-free light transmission from the light guide connector to the light emission (if necessary, compare with a new instrument)
- Material changes of the metal and plastic surfaces
- Functionality of the stopcocks
- Completeness of the accessories
- Readability of the product labeling

In case the endoscope is defective, it must be taken out of service immediately.

## ASSEMBLY/DISASSEMBLY

⚠ Caution must be exercised when dissembling contaminated endoscopes due to risk of infection.

### Light guide connector

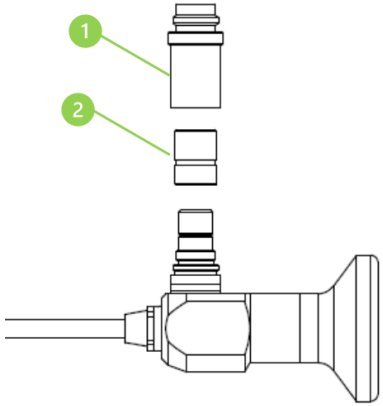
#### Disassembly

1. Unscrew the RUDOLF Medical / Storz adapter (1) and the Wolf adapter (2) from the endoscope.
2. For the working channels of the uretero-renoscope:
   a. Remove the sealing cap.
   b. Unscrew the valve cap.
   c. Remove the valve.

See also the “Special features of uretero-renoscopes” section.

#### Assembly

1. Screw on the Wolf adapter (2) and then the RUDOLF Medical / Storz adapter (1).
2. For the working channels of the uretero-renoscope:
   a. Insert a new valve.
   b. Screw on the valve cap.
   c. Put on the sealing cap.




### Coupling the camera head to the endoscope

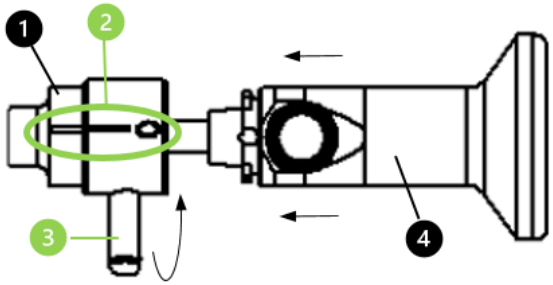
1. Unlock the endoscope coupling of the camera head (1).
2. Place the camera head on the eyepiece cap of the endoscope (2), and then lock it.

⚠ Due to various compatible camera systems, it is necessary to observe the corresponding instructions for use of the manufacturer. The eyepiece cap of the endoscope for coupling the camera head complies with the ISO/TS 18339 specifications.

## Coupling endoscopic instruments or sheaths to an ENT endoscope, cystoscope, hysteroscope and arthroscope

1. Instrument or sheath holder and locking mechanism (1)
   Before an endoscope that is inserted in an instrument or sheath can be locked, it must be ensured that the locking mechanism is open.

   Make sure that the marking lines (2) on the locking mechanism of the instrument or sheath holder are in line with each other (zero position).
2. Insert the endoscope (4) with its groove end into the holder and lock it by turning the locking lever (3) clockwise by 90°.




## Special features of uretero-renoscopes

⚠ Semi-rigid endoscopes are designed for low bending loads, that is for a bending deflection of the sheath up to a maximum of 20 degrees. Higher bending loads result in permanent deformation and in damage to the product and are therefore not permitted.

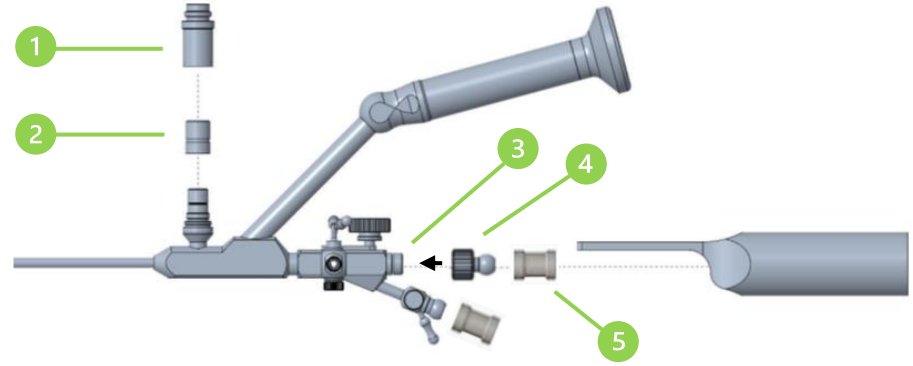
- Uretero-renoscopes with working channels (lumen) must be cleaned thoroughly to prevent deposits in the slim channels.
- All detachable parts of the endoscope must be disassembled for cleaning and disinfection to expose hidden surfaces. This is the only way to achieve appropriate reprocessing.

### Disassembly

1. Unscrew the RUDOLF Medical / Storz adapter (1) and the Wolf adapter (2) from the endoscope.
2. Remove the sealing cap (5).
3. Unscrew the valve cap (4).
4. Remove the valve (3).

### Assembly

1. Screw on the Wolf adapter (2) and then the RUDOLF Medical / Storz adapter (1).
2. Insert a new valve (3).
3. Screw on the valve cap (4).
4. Put on the sealing cap (5) on the valve cap.



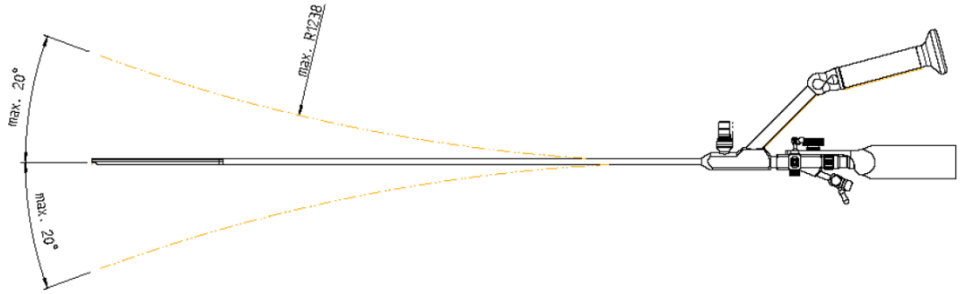
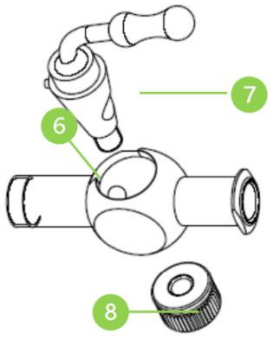




Figure: Endoscope with working channel for a guided insertion of a lithotripsy probe

## Stopcocks

### Disassembly

Unscrew the spring cap (8) and remove the stopcock plug (7) from the stopcock (6).




### Assembly

Screw the stopcock plug (7) to the spring cap (8). When inserting the stopcock plug, make sure that the guide pin is in the guide and the lever points to the opening in the open position.

**Notes:**

- To protect against corrosion and to maintain the functionality, prior to each sterilization step, treat the stopcock plug (7) with a lubricant that is approved for the intended application and reprocessing step, for instance, lubricant RU 8880-50 for stopcocks.
- Inspect the stopcocks for proper functioning. See the “Prior to each use: visual and functional inspection” section.

## REPROCESSING INSTRUCTIONS

Before each use, endoscopes must be cleaned, disinfected and sterilized. This also applies to brand-new endoscopes because those are delivered non-sterile (cleaning and disinfection after removing transport packaging; sterilization in appropriate sterilization packaging).
The following conditions are basic prerequisites for effective reprocessing:

- Carrying out cleaning and reprocessing immediately after use (maximum an hour after last use) because dry disposal causes incrustations and corrosion.

  If this period cannot be observed immerse the endoscopes in a cleaning/disinfectant solution to prevent the contamination from drying. However, during the wet disposal, make sure that endoscopes do not remain for too long in the cleaning/disinfection solution. Observe the concentration specifications of the manufacturer.
- Determining the loading configuration of the machines used and observing the instructions for use of the machine's manufacturers
- Regular maintenance and inspection of the machines used
- Validated procedures for all reprocessing steps
- Observing the standardized parameter for each reprocessing cycle
- Checking the disinfection and sterilization results using appropriate indicators
- Using cleaning agents that have been tested and approved according to the national hygiene regulations and local guidelines
- For endoscopes with channels (suction and/or working channels), the lumens must be thoroughly cleaned and disinfected to prevent fixation and preservation of organic residues by aldehydes.
- Inappropriate cleaning poses a risk of infection. A contamination by germs must be prevented.

## 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.

### Material resistance

Cleaning and disinfectant agents can cause considerable damage to the endoscopes. The following components must not be contained in the agents:

- Organic, mineral and oxidizing acids. The minimal permissible pH value is 5.
- Strong alkalis. The maximum permissible pH value is 10.
- Phenols or halogens (e.g., chlorine, iodine, bromine)
- Aromatic/halogenated hydrocarbons
- Agents used in combination must be compatible with each other. Neutral or slightly alkaline agents are recommended.
- Never accelerate the cooling process of the endoscopes by using, e.g., water. Sudden temperature fluctuations can destroy the optical components.
- The maximum temperature the endoscopes can be exposed to is 137°C (279°F).
- Abrasive agents, steel wool or metal brushes must never be used for cleaning.
- The endoscopes must never be cleaned in an ultrasonic bath, otherwise the optical system will be damaged.
- Hot air sterilization, flash sterilization and radiation sterilization must never be used.

## 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.
- The endoscopes must be reprocessed within an hour after use to prevent contamination from drying on the instruments.
- Heavy contamination on the instruments must be removed with a disposable cloth immediately after use.
- Working channels and lumen, e.g., in the case of the uretero-renoscope, must be flushed through at least 3 times immediately after use to avoid blockages.

## 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.

## Preparation before cleaning

- The instruments must be disassembled or opened for reprocessing as far as possible without using tools.

## Manual pre-cleaning and disinfection

Manual pre-cleaning and disinfection precede the automated cleaning and disinfection:

1. Before reprocessing, unscrew both adapters (RUDOLF Medical/Storz and Wolf) of the light guide connector. For information about disassembly of the stopcocks (only the case with the uretero-renoscopes) see the “Stopcocks” section.
2. Prepare the cleaning and disinfection solution according to the manufacturer's instructions.
3. Carry out all cleaning steps below the solution surface to avoid splashes with the contaminated solution.
4. Fill the lumens of the endoscopes free of bubbles, and flush them towards the distal end.
5. Rinse the instruments under running, cold, fully demineralized water (maximum of 20°C) to remove coarse contamination from the endoscopes.
6. Remove strongly adherent contamination with a mild agent that is approved for medical endoscopes. See the “Material resistance” section.
7. Flush all empty channels at least five times using a single-use syringe (minimum volume of 50ml).
8. Do not use abrasives or metal brushes. Avoid exerting excessive force on the instruments when manually removing the contamination.
9. The final rinsing of the endoscopes is performed for a minute using fully demineralized water (according to DIN EN ISO 15883-1) to prevent discolorations, corrosion, and chemical deposits.
10. Use sterile compressed air to completely dry the lumens. To dry the other components, you can use a lint-free cloth.

### Cleaning agents for the manual pre-cleaning

| | |
|---|---|
| **Cleaning agents for the manual pre-cleaning/disinfection** | neodisher Mediclean of Dr. Weigert<br>0.5% solution<br>5 minutes exposure time |

## Automated cleaning and disinfection

Automated cleaning / disinfection should be preferred to manual cleaning / disinfection, since automated processes can be standardized, reproduced, and thus validated.

**Requirements for suitable washer/disinfectors:**

- Program selection for optimized endoscope cleaning with sufficient rinsing cycles. The manufacturer's specifications for loading the baskets must not be exceeded.
- The washer/disinfector must have suitable racks and connections to allow a safe cleaning and disinfection in the selected program.
- Controlled program for thermal disinfection ($A_0$ value > 3000 or at least 5 minutes at 90°C) with proven effectiveness
- Regular maintenance and tested effectiveness: The machines must meet the requirements of DIN EN ISO 15883-1. Country-specific requirements must be complied with.
- Final rinsing with cold fully demineralized water (according to DIN EN ISO 15883-1) for at least 2 minutes
- Controlled drying phase
- A quarterly microbiological check as a quality assurance of the reprocessing procedure is recommended.

**Requirements for suitable cleaning and disinfection agents:**

- Approval for the cleaning of endoscopic instruments with tested effectiveness
- Compatibility of the cleaning / disinfection agents used with each other
- The chemicals listed in the “Material resistance” section must not be contained in the agents.
- If powder agents are used it is necessary to ensure that those are completely dissolved before the cleaning process. Any remaining powder could, e.g., clog the lumens.
- Use an enzyme-based agent with a neutral pH value.
- An increased chloride concentration in the feed water cycle can lead to material damage (pitting corrosion). The rinse water must be prepared in such a way that recontamination is avoided.
- The manufacturer's specifications for the cleaning and disinfection agents regarding concentration, temperature, and exposure time must be observed.

### Automated cleaning and disinfection process:

**Cleaning agent and washer for the automated cleaning/disinfection**

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|---|---|
| **Cleaning agent for the automated cleaning/disinfection** | neodisher Mediclean of Dr. Weigert |
| **Disinfection method** | Thermal disinfection (no chemothermal disinfection) |
| **Washer/disinfector** | Miele PG 8535 |

1. Securely attach the endoscope at the inserts of the disinfector. Make sure that the endoscopes do not touch other instruments and that there is no possibility for forming rinse water residues.
2. Open the stopcocks.
3. Connect all lumens of the endoscopes to the special irrigation inserts to ensure a complete and thorough rinsing of all lumens.
4. Make sure that the inserts or baskets of the washer/disinfector are not overloaded.
5. Start the program.
6. At the end of the program, check whether the program was carried out properly and whether all control parameters have been fulfilled.
7. Remove the endoscope from the disinfector immediately after the end of the program to prevent corrosion. Wear single-use gloves to avoid contamination. Please mind any hot instruments.
8. Avoid accelerated cooling, e.g., with water.
9. Dry tubing and channels with sterile compressed air and, if necessary, wipe the endoscopes dry with a lint-free cloth.
10. Inspect the endoscopes. See the “Maintenance, control, and inspection” section.
11. Pack the endoscopes for the next reprocessing step. See the “Packaging” section.

## MAINTENANCE, CONTROL, AND INSPECTION

After cleaning, disinfecting, drying, and before the sterilization process, the adapters of the light guide connectors and the stopcocks of the endoscope must be assembled (see the “Assembly/Disassembly” section). Subsequently, the following tests are necessary:

- Visual inspection of the optical surfaces and, if necessary, cleaning with cotton soaked in alcohol (70%)
- Deposits on the light guide can lead to a significant illumination loss and impair the optical performance of the endoscope. Cleaning the optical surfaces with 70% alcohol (ethanol, isopropanol) prevents residues from adhering or burning in. See also the “Prior to each use: visual and functional inspection” section.
- Inspection of the surfaces for corrosion, wear & tear, sharp edges or spalling in the distal end
- If there are still residues or contamination the disinfection process must be repeated after a preceding manual pre-cleaning. Particular attention should be paid to lumen and other areas that are difficult to access.
- Damaged endoscopes must be taken out of circulation.
- After each cleaning and prior to sterilization, the moving parts including the stopcocks must be lubricated and maintained with a silicone-free, biocompatible white medical oil. Only lubricants that have been tested for biocompatibility can be used. The lubricant must be suitable for this use and approved for steam sterilization.
- For safety reasons, defective products must have gone through the entire reprocessing cycle before being returned for repair or complaint.

## PACKAGING

- Packaging of the instruments for sterilization is according to standards DIN EN ISO 11607 and DIN EN 868.
- The distal end of the endoscope 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. Pointed and sharp cutting edges must not perforate the sterilization packaging.

## STERILIZATION

Prior to the sterilization process, the following steps must be performed.

**Preparation and packaging for sterilization**

- Open all stopcocks.
- Use only single-use sterilization packaging and/or sterilization containers that are suitable for steam sterilization: sufficient temperature resistance, air and steam permeability according to DIN EN ISO 11607
- During transport and storage, the packaging must provide optimal protection of the sterile endoscopes.
- Reusable sterilization containers must be maintained according to the manufacturer's specifications; the endoscopes must be securely fixed in them and protected against damages.

⚠ **Important:**

- Since the suitability of the packaging has a significant influence on the sterilization results, the packaging should be checked when defining the sterilization parameters.
- The user needs to ensure that only completely cleaned, maintained, dried and disinfected instruments are sterilized.

### Steam sterilization

- The following sterilization method has been validated for germicidal effect:
  fractionated vacuum method with triple pre-vacuum for endoscopes with or without empty channels.

| Sterilization temperature | Minimum holding time (exposure time) | Cooling time |
|---|---|---|
| 132°C – 134°C<br>(270°F – 273°F) | 3 - 5 minutes at<br>132°C | The cooling time must be observed. Accelerated cooling, e.g., with cold water, can damage the endoscope. |

- According to KRINKO, BfArM and RKI (see the “Applied standards and guidelines” section), sterilization in saturated steam at 134°C for 5 minutes is recommended.
- Please observe the manufacturer’s instructions of the sterilizer.

⚠ **Other sterilization methods are not permitted. See the “Material resistance” section.**

## STORAGE

- Store the sterilized instruments in a low-germ, dry, dark and dust-free environment that is free of temperature fluctuations.

## INFORMATION REGARDING THE VALIDATION OF THE REPROCESSING PROCEDURE

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

| | |
|---|---|
| **Cleaning agents for the manual pre-cleaning/disinfection** | neodisher Mediclean of Dr. Weigert<br>0.5% solution<br>5 minutes exposure time |
| **Cleaning agent for the automated cleaning/disinfection** | neodisher Mediclean of Dr. Weigert |
| **Disinfection method** | Thermal disinfection (no chemothermal disinfection) |
| **Washer/disinfector** | Miele PG 8535 |
| **Sterilizer** | Lautenschläger, ZentraCERT |
| **Sterilization method: steam sterilization** | Half-cycle method: 1.5 minutes at 132°C<br>Typical conditions in hospitals and medical offices were emulated and tested in the half-cycle method under lab conditions. Other parameters with longer holding time and/or higher temperature are thus also covered. |

## ADDITIONAL NOTES

- If the specified chemical agents and machines are not available, the user needs to validate their process.
- In addition to the regulations mentioned in these instructions for use, it is necessary to observe country-specific regulations and organizational instructions.

## 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.
- For safety reasons, defective endoscopes must have gone through the entire reprocessing cycle before being returned for repair or complaint.
- If possible, return the endoscopes in their original packaging.

## 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 RUDOLF Medical endoscopes have a warranty of 2 years. The endoscopes 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.

## APPLIED STANDARDS AND GUIDELINES FOR REPROCESSING

- *Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten* (Hygiene requirements for the reprocessing of medical devices), version: 10/2012, KRINKO/RKI/BfArM
- DIN EN 285:2016-05: Sterilization – Steam sterilizers – Large sterilizers
- DIN EN ISO 11607:2017-10: Packaging for terminally sterilized medical devices – 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 with information to be supplied by the manufacturer – Part 1: General requirements
- DIN EN ISO 15883-1:2014-10: Washer-disinfectors – Part 1: General requirements, terms and definitions and tests
- DIN EN ISO 17664:2018-04: Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices
- DIN EN ISO 17665:2006-11: Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
- ISO/TS 18339:2015-11: Endotherapy devices - Eyepiece cap and light guide connector

**SYMBOLS**

| | |
|---|---|
|  | Consult instructions for use. |
| LOT | Batch code |
| REF | Article no. |
| QTY | No. per package |
|  | Non-sterile |
|  | Caution |
|  | Manufacturer |
|  | Date of manufacture |
|  | Wear protective gloves |
|  | Wear eye protection |
| CE<br>0297 | CE marking according to EC directive 93/42/EWG with the ID of the notified body |
|  | Lubricate with silicone-free, biocompatible white oil approved for medical devices and steam sterilization. |
| MD | Medical Device |