REUSABLE ENDOSCOPY INSTRUMENTS  
(thermo resistant)

Field of application
- The following instructions are for all reusable endoscopy instruments delivered by RUDOLF MEDICAL and that are made of stainless steel in compliance with DIN EN ISO 7153-1. Instruments with long lumen, stop-cocks, insulation and/or made of combinations of materials may require modified or special procedures during preparation. These additional instructions and the reference to this preparation instructions will be given by RUDOLF MEDICAL in the respective instructions for use of the specific instruments.

Notes
- Please observe the national regulations and standards regarding the preparation of medical products.
- In case of patients suffering from Creutzfeldt-Jakob-Disease (CJD), or suspected of having CJD or possible variants thereof, the preparation of the instruments must be done in accordance to the respective national laws and regulations.

Warnings and precautions
- Please follow the instructions for use of the specific instruments.
- Experimental series have shown that the colour of titanium instruments can change by using hydrogen peroxide H2O2 (for example Miele's Oxivario® and Oxivario® Plus-procedures) during cleaning- and sterilisation procedures. These colour changes have no influence on the quality of the instrument, but are only caused by the change of the oxide layer thickness. Aluminium and black chromed instruments are not suitable for this procedure.
- During preparation the temperature acting upon the instrument must not exceed 137°C.
- In principle automatic cleaning and disinfection is to be preferred to manual cleaning and disinfection. The automatic cleaning and disinfection procedure is much safer.
- Alkaline cleaning agents (pH >10) are not suitable for all materials. The Robert-Koch-Institute points out several potential problems of increased wear in case of aluminium, silicon elastomers, adhesive joints, soldered joints of silver and tin, sealing materials, plastic coatings, optical glass fibres and optical surfaces with anti-reflexive coating.
- Never use metal brushes/sponges or abrasive cleaning agents for manual cleaning.
- Only clean instruments and instruments of low microbiological contamination enable a successful sterilisation.
- In case of damage the device should be reprocessed before sending back to the manufacturer for repair.

Restrictions of preparation:
- Repeated/frequent preparation has only little effect on the instrument life when following the instructions at hand.
- The life of a reusable endoscopy instrument strongly depends on wearout and damages caused by its use.
- If there are any restrictions or special procedures are necessary it will be indicated in the instructions for use of the respective instrument.
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## Instructions

### Application area:
- Remove residues and stains on the instrument immediately after use with a single-use cloth or tissue.
- Don’t use a fixing detergent or hot water (>40°C) as this can cause the fixation of residua which may influence the result of the reprocessing process.
- After use, the instruments must be prepared as fast as possible.
- Put the instruments in suitable wire baskets.
- Store them preferably in a dry place.
- If necessary; soak the instruments in a solution with a suitable combination of cleaning and disinfecting agents. Please, observe the manufacturers' instructions of the cleaning and disinfecting agents.

### Transportation:
- Safe storage and transportation in a closed container to the reprocessing area to avoid any damage and contamination to the environment.

### Preparation for decontamination:
- Soaked instruments must be rinsed thoroughly with cold running water before cleaning and disinfection.
- Temperature < 35°C
- The devices must be reprocessed in an opened or disassembled state.
- If any instrument requires to be dismantled for preparation or if covering of connections is required, if sealings must be removed, if stop-cocks must be open or dismantled, or if the instrument needs to be checked for leakiness, it will be indicated in the instructions for use of the respective instrument.
- Please observe the dismantling and assembly instructions given in the instructions for use of the respective instrument.
- Immerse the instrument into cold tap water for at least 5 minutes. Dismantle the instruments if possible and brush under cold tap water until all visible residues are removed. Inner lumens, threads and holes are flushed each with a water jet pistol for minimum 10 seconds in the pulsed mode.

### Cleaning in ultrasonic cleaner:
Facilitates manual cleaning and to remove encrusted residues before automatic cleaning.
- Fill bath according the manufactures' instructions
- Solution made of water and suitable cleaning agents or combined cleaning and disinfecting agents
- Please, observe the manufactures’ instructions of (alkaline or enzymatic detergent – 0,5%) the cleaning and disinfecting agents regarding concentration, temperature and exposure to sonic waves.
- Bath temperature 40°C, higher temperatures lead to blood incrustations
- Cleaning-/exposure time approx. 15 minutes
- Frequency at approx. 35 kHz
- Put instruments in wire baskets
- Renew ultrasonic bath every day, observe the national guidelines and the manufacturers’ instructions
- Rinse the instruments afterwards with desalinated/cold water
- Check the instruments for loose parts

Cleaning in ultrasonic bath increases wear and tear of the product.

### Cleaning: automatic
- Clean and disinfect the instrument only in suitable washers and disinfectors (WD) and with for the WD and the instrument validated procedure / program (EN ISO 15883).
- Suitable WD are provided with special cleaning baskets / slide-in carts for endoscopy instruments.
- Avoid any rinsing shadows when loading the WD slide-in cart with instruments in order to obtain an ideal rinsing pressure for the entire instrument. Pay special attention to the jaws.
- Put the instruments opened and or, if possible, in a disassembled state on a special key hole surgery rack. Not suitable instruments are placed on an instrument tray.
- Instruments with hollow spaces (tubes, shafts, tubings) must be connected to special irrigations devices in order to guarantee a complete rinsing of these hollow spaces.
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- Do not overload the WD slide-in carts.
- Please observe the instructions for use and loading indications of the WD manufacturer.
- For choosing the appropriate cleaning agents see the respective lists and recommendations of the Robert-Koch Institute (RKI) of the DGHM Deutsche Gesellschaft für Hygiene und Mikrobiologie (German society for hygiene and microbiology) and consider the instrument’s material and characteristics. See additional information of the preparation instructions at hand.

Cleaning agents for automatic cleaning in WD:

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Trade name</th>
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<tbody>
<tr>
<td>Dr. Weigert GmbH &amp; Co. KG</td>
<td>neodisher® FA</td>
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<td>neodisher® FA forte</td>
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<td>neodisher® MediClean forte</td>
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<td>neodisher® MediClean</td>
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<tr>
<td>BODE CHEMIE HAMBURG</td>
<td>Dismoclean® 21 plus</td>
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<td>Dismoclean® 21 pur</td>
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<td>Dismoclean® 24 Vario</td>
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<td>Dismoclean® 21 alka one</td>
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<tr>
<td>ECOLAB GmbH</td>
<td>Secumatic® FR</td>
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<td></td>
<td>Secumatic® FRE</td>
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<tr>
<td>Schülke &amp; Mayr GmbH</td>
<td>Thermosept® alka clean</td>
</tr>
</tbody>
</table>

Water quality requirements for pre-rinse, cleaning and intermediate rinsing steps:

- Total water hardness $< 3^\circ$d $(< 0.5$ mmol CAO/l)
- Total salt content $< 500$ mg/l
- Chloride content $< 100$ mg/l
- pH value $5 – 8$

Water quality requirements for final rinse (desalinated water):

- Conductivity $< 15\mu S/cm$
- pH value $5 – 7$
- Total water hardness $< 0.02$ mmol CaO/l
- Salt content $< 10$ mg/l
- Phosphate (as P$_2$O$_5$) $< 0.5$ mg/l
- Silicates (as SiO$_2$) $< 1$ mg/l
- Chlorides $< 2$ mg/l

For optimization of the procedure steps we recommend the general use of desalinated water.

Cleaning program with thermal disinfection of WD:

1. 1 min. pre-cleaning with cold water
2. Draining
3. 3 min. pre-cleaning with cold water
4. Draining
5. 5 min. cleaning at 55°C, 45°C with 0.5 % alcaline, enzymatic detergent (if enzymatic detergent is used the cleaning temperature is 45°C).
6. Draining
7. 3 min. neutralisation with warm water (>40°C) and neutralizer
8. Draining
9. 2 min. rinse with warm water (>40°C)
10. Draining
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### Disinfection:
- **Thermal disinfection/final rinsing:**
  - Final rinsing with desalinated water
  - Disinfection temperature 93°C
  - Reaction time 10 minutes

  The indications of the disinfecting temperature refer to the upper switchpoint of the thermostat of the respective WD. During reaction time the temperature must not go below 90°C.

  - Automated Thermal Disinfection in washer/disinfector under consideration of national requirements in regards to Ao-Value (see ISO 15883).
  - The program of the WD must imply a sufficient drying phase of at least 20 minutes at a maximum temperature of 93°C.
  - Drying of outside of instrument through drying cycle of washer/disinfector. If needed, additional manual drying can be performed through lint free towel. Insufflate cavities of instruments by using sterile compressed air.
  - The instruments must be taken out immediately of the WD after termination of the cleaning and disinfecting program.

### Drying:

### Cleaning and disinfection: manual

- For choosing the appropriate cleaning agents see the respective lists and recommendations of the Robert-Koch Institute (RKI) of the DGHM Deutsche Gesellschaft für Hygiene und Mikrobiologie (German society for hygiene and microbiology). See additional information of the preparation instructions at hand.
- Please, observe the manufactures’ instructions of the cleaning and disinfecting agents regarding concentration/dosage, temperature, compatibility of material and reaction time.

#### Manual cleaning and disinfection agents:

<table>
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<tr>
<td>Dr. Weigert GmbH &amp; Co. KG</td>
<td>neodisher® Septo MED</td>
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<td>neodisher® Septo 3000</td>
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<tr>
<td>BODE CHEMIE HAMBURG</td>
<td>Korsolex® AF</td>
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<td></td>
<td>Korsolex® basic</td>
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<td>Korsolex® plus</td>
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<td>Korsolex® extra</td>
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<tr>
<td>ECOLAB GmbH</td>
<td>Sekusept® PLUS</td>
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<td>Sekusept® aktiv</td>
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<tr>
<td>Schülke &amp; Mayr GmbH</td>
<td>Gigasept® Instru AF</td>
</tr>
<tr>
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<td>Gigazyme®</td>
</tr>
</tbody>
</table>

- Renew working solutions every day, if it is highly contaminated more often.

#### Water quality requirements for pre-rinse, cleaning and intermediate rinsing steps:
- Total water hardness < 3°d (&lt; 0.5 mmol CaO/l)
- Total salt content < 500 mg/l
- Chloride content < 100 mg/l
- pH value 5 – 8

#### Water quality requirements for final rinse (desalinated water):
- Conductivity ≤ 15 µS/cm
- pH value 5 – 7
- Total water hardness ≤ 0.02 mmol CaO/l
- Salt content ≤ 10 mg/l
- Phosphate (as P₂O₅) ≤ 0.5 mg/l
- Silicate (as SiO₂) ≤ 1 mg/l
- Chloride ≤ 2 mg/l
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Drying:
- For optimization of the procedure steps we recommend the general use of desalinated water.
- All surfaces, hollow spaces and orifices must be wetted with the cleaning and disinfection agents. Remove air bubbles.
- Remove soiling with soft synthetic sponges, soft lint-free cloth or soft plastic brushes and cleaning pistols.
- Rub off soil with care.
- Sufficient intermediate rinsing with clear running water. Rinse all hollow spaces. Temperature < 35°C
- Following cleaning finally rinse thoroughly with desalinated water. Temperature < 35°C
- If necessary, repeat the whole procedure several times.
- After the manual cleaning, disinfection and rinsing of the instrument, immediately dry it thoroughly with an absorptive, soft and lint-free cloth. Hollow spaces, channels and lumen must be blown out and dried with compressed air.

Maintenance, Control and Inspection:
- Following cleaning and disinfection visually inspected the instruments for cleanliness. They must be macroscopically clean (no visible residues/soiling). Pay special attention to grooves, ratchets, closures and other difficult accessible areas.
- Should there still be any visible residues or liquids repeat the cleaning and disinfecting procedure.
- Prior to any sterilization the instruments must be assembled and inspected for function, wear and tear and for damages, and where necessary changed. Following inspection, dismantle the instrument if necessary for sterilization.
- Sealings, sealing rings, valves, caps and if applicable other expendable parts mentioned in the respective instructions for use must be inspected after cleaning and disinfection for integrity and must be changed if damage or wear and tear can be observed.
- Please observe the dismantling and assembly instructions of the respective instructions for use.
- Instruments with ratchets must be closed in the first tooth of the ratchet only or held open.
- Following each cleaning and prior to sterilization lubricate all movable parts with physiologically inoffensive oil (paraffin oil according DAB 8 and Ph. Eur. Respectively or USP); especially closings, joints, ratchets and lockings.

Packing:
- Appropriate packaging for sterilization according ISO 11607 and EN 868.
- Generally adjust the sterilizing accessories and the sterile packing to the packing content/instrument and the sterilization procedure.
- Please, observe the manufactures’ instructions of the sterilizer.
### Sterilization:
- Sterilization is to be carried out using a steam sterilization procedure validated by DIN EN ISO 13060/ISO 17665 (fractionated vacuum procedure) in a sterilizer in accordance with EN 285/DIN 58946.
  - 3 prevacuum phases with at least 60 milli bar
  - Heat up to a minimum sterilization temperature of 132°-134°C;
  - Maximum temperature 137°C
  - Minimum Holding time: 4 min.
  - Drying time: minimum 10 min.
- Please, observe the manufactures' instructions of the sterilizer.

### Water quality requirements of the feeder water (EN 285):
- Vaporization residues ≤ 10 mg/l
- Silicate (as SiO₂) ≤ 1 mg/l
- Iron ≤ 0,2 mg/l
- Cadmium ≤ 0,005 mg/l
- Lead ≤ 0,05 mg/l
- Heavy metals except iron, cadmium, lead ≤ 0,1 mg/l
- Chloride (Cl) ≤ 2 mg/l
- Phosphate (as P₂O₅) ≤ 0,5 mg/l
- Conductivity (at 20°C) ≤ 15µS/cm
- pH value (acidity level) 5 – 7
- Color colorless, clear, without residues
- Hardness (Σ alkaline earth ions) ≤ 0,02 mmol/l

### Storage:
- The reprocessed instruments must be stored in suitable and reusable sterilization containers in accordance with DIN EN 868-1 and DIN EN 868-8, and should be stored until use in accordance with DIN 58953–9.
- The sterilizing container should be designed in such a way that the instrument is safely fixed and protected from damage.
- Storage of sterilized instruments in a dry, dark, low microbiologically contaminated clean and dust free environment at modest temperatures of 5°C to 40°C. The storage area have to be free of temperature alternations.

### Reprocessing validation study information:
- The following testing test devices, materials & machines have been used in this validation study;
  - Detergent: Neodisher FA; Dr. Weigert; Hamburg (Alcaline)
  - Endozime, Fa. Ruhof (Enzymatic)
  - Neutralizer: Neodisher Z; Dr. Weigert, Hamburg
  - Washer / Disinfector: Miele G 7736 CD
  - Instrument Rack: Einschubwagen E 327-06
  - MIC-Wagen E 450
  - Details: see validation report

### Additional Instructions:
- If the described chemistry and machines are not available, it is the duty of the user to validate his process.

### Additional information:
- References:
  - Robert-Koch Institute (RKI) list of tested and approved disinfecting agents and procedures and tested and approved washers and disinfectors (WD);
  - Hygiene requirements for he preparation of flexible endoscopes and additional endoscopic accessories, recommendation of the commission for hospital hygiene and infection prevention by the Robert-Koch Institute (RKI);
  - Hygiene requirements for the preparation of medical products, recommendation of the commission for hospital hygiene and infection prevention by the Robert-Koch Institute (RKI);
  - For further information see: [www.rki.de](http://www.rki.de)
  - List of disinfectant agents of the DGHM Deutsche Gesellschaft für Hygiene und Mikrobiologie (German Association for Hygiene and Microbiology);
  - For further information see: [www.dghm.de](http://www.dghm.de)
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- “Correct instrument preparation” of the working group instrument preparation;
  - For further information see: www.a-k-i.org
- Guidelines of DGKH, DGSV and AKI for validation and routine monitoring of automatic cleaning and disinfecting procedures of thermo resistant medical products and principles of instrument selection part 1;

Existing standards:
- DIN 58966: Sterilization; steam sterilizers for medical products;
- DIN 58949 parts 1-7: Disinfection – Steam disinfection-apparatus
- DIN 58953-9: Sterilization – Sterile supply – Part 9: Handling of sterilization container
- DIN EN 285: Sterilization – Steam sterilizers – Large sterilizers
- DIN EN 868-2: Packaging materials and systems for medical devices which are be sterilized – Part 2: Sterilization wrap; requirements and test methods
- DIN EN 868-8: Packaging materials and systems for medical devices which are to be sterilized – Part 8: Re-useable sterilization containers for steam sterilizers conforming to EN 285; requirements and test methods
- DIN EN ISO 11607-1: Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2006);
- DIN EN ISO 15883-1: Washer-disinfectors – Part 1: General requirements, terms and definitions and tests (ISO 15883-1:2006);
- DIN EN ISO 17664: Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices (ISO 17664:2004);
- DIN EN ISO 17665-1: 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 17665-1:2006);
- ISO 7153-1: Surgical instruments – Metallic materials – Part 1: Stainless steel
- Further information at: www.beuth.de

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It is the duty of the user to ensure that the reprocessing processes including resources, materials and personnel are capable to reach the required results. State of the art and often national law requiring these processes and included resources to be validated and maintained properly. Likewise, any modification by the reprocessor from the instructions provided must be properly evaluated for effectiveness and potential adverse consequences.