I.F.U – Re/Processing
Reusable Medical Devices

Distributed by:

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# Overview of preparation methods

<table>
<thead>
<tr>
<th>Preparation methods</th>
<th>Preparation agents</th>
<th>Re-usable surgical instruments</th>
<th>Endoscopes (thermostable)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-clean directly after use</td>
<td>Wet</td>
<td>Soften in cleaning and disinfectant solution and rinse with water</td>
<td>++</td>
</tr>
<tr>
<td></td>
<td>Dry</td>
<td>Wipe with a moist cloth or with cleaning and disinfectant solution</td>
<td>+</td>
</tr>
<tr>
<td>Decontaminate</td>
<td>Pre-clean*</td>
<td>See chapter „4 Preparing decontamination“ on page 4.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Clean*</td>
<td>Manual</td>
<td>++</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Mechanical</td>
<td>++</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ultrasound</td>
<td>+</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Alkaline cleaning agent</td>
<td>++</td>
</tr>
<tr>
<td></td>
<td></td>
<td>± pH 9-12</td>
<td>55-85 °C / 3-20 min.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Acid cleaning agent</td>
<td>++</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Neutral cleaning agent</td>
<td>++</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Enzymatic cleaning agent</td>
<td>+</td>
</tr>
<tr>
<td></td>
<td>Rinse</td>
<td>Demineralised water</td>
<td>+</td>
</tr>
<tr>
<td></td>
<td>Disinfect</td>
<td>Chemically up to max. 60 °C</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Thermally up to max. 93 °C</td>
<td>+</td>
</tr>
<tr>
<td></td>
<td>Dry</td>
<td>Temperature</td>
<td>++</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>++</td>
</tr>
<tr>
<td>Care 6</td>
<td>See chapter „6 Cleaning“ on page 5.</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td>Sterilise 7</td>
<td>Moist heat, autoclave, prevacuum</td>
<td>++</td>
<td>134-137 °C</td>
</tr>
<tr>
<td></td>
<td>Low temperature (steam+formaldehyde)</td>
<td>+</td>
<td>134-137 °C</td>
</tr>
<tr>
<td></td>
<td>Ethylene oxide</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hot air</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Liquid sterilant</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Gas plasma</td>
<td>-</td>
<td></td>
</tr>
</tbody>
</table>

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1 Deionized water is recommended for final rinsing.
2 Rubber and/or latex, silicone elastomers.
3 Does not apply to (anodised) aluminium alloys.
4 Not suitable for ultrasonic-assisted cleaning.
5 Follow the cleaning agent’s Instructions for Use.
6 For detailed information see chapter „7 Care“ on page 7.
7 Duration of sterilisation see chapter „9 Packaging“ on page 8.

### Overview of preparation methods

<table>
<thead>
<tr>
<th>Endoscopes (thermolabile)</th>
<th>Instruments for use with endoscopes</th>
<th>Re-usable containers</th>
<th>Elastic devices</th>
<th>HF cables and handpieces</th>
</tr>
</thead>
<tbody>
<tr>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
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<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>-</td>
<td>55-85 °C / 3-20 min.</td>
<td>55-85 °C / 3-20 min.</td>
<td>50-70 °C / 3-20 min.</td>
<td>50-70 °C / 3-20 min.</td>
</tr>
<tr>
<td>50-70 °C / 3-20 min.</td>
<td>++</td>
<td>++</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>50-70 °C / 3-20 min.</td>
<td>++</td>
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<tr>
<td>50-70 °C / 3-20 min.</td>
<td>++</td>
<td>++</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>50-70 °C / 3-20 min.</td>
<td>++</td>
<td>++</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>45-50 °C / 5-20 min.</td>
<td>++</td>
<td>++</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>+</td>
<td>+</td>
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<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>50-60 °C / &gt; 10 min.</td>
<td>++</td>
<td>++</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>50-100 °C / &gt; 10 min.</td>
<td>++</td>
<td>++</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>50-100 °C / &gt; 10 min.</td>
<td>++</td>
<td>++</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>50-100 °C / &gt; 10 min.</td>
<td>++</td>
<td>++</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>134-137 °C</td>
<td>++</td>
<td>++</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>+</td>
<td>+</td>
<td>+</td>
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<td>+</td>
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<tr>
<td>++</td>
<td>+</td>
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<tr>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

**Symbol** | **Explanation**
--- | ---
+++ | Method with validated microbiological effectiveness and verified material compatibility
+ | Method with verified material compatibility
- | Incompatibility
0 | For further information contact the manufacturer
# | For more detailed information see chapter „6 Cleaning“ on page 5.
2 Safety and responsibility

Before preparing instruments

← Read and follow the preparation instructions.
← Keep these instructions in a place where they can be easily seen for reference at a later date.

TROKAMED does not assume any liability for damage as a result of incorrect preparation and care. The user is responsible for validating alternative cleaning and sterilisation methods.

Risk of infection

← Prepare the instrument before use.
← Prepare the instrument before returning it to the manufacturer.
← Follow the instructions for use of the cleaning agents and disinfectants used as well as of the cleaning and sterilisation devices used.
← Wear gloves during preparation.
← Discard disposable components after initial use.

Risk of injury

← Do not use damaged instruments and do not repair.
← Only use original accessories.

3 Explanation of symbols

⚠️ DANGER

Indicates a danger which results in death or serious injury if not avoided.

⚠️ WARNING

Indicates a danger which can result in death or serious injury if not avoided.

⚠️ CAUTION

Indicates a danger which can result in injuries if not avoided.

IMPORTANT!

Indicates measures in order to prevent damage to property.

This symbol provides information in order to facilitate handling of the device.

Here measures are given which must be followed to prevent a risk.
← You are requested to take action here.
→ You find out the result of the action taken here.
♦ This symbol indicates additional information.

TIP:

The “TIP” provides useful advice on handling the instrument.

4 Preparing decontamination

To prevent surgical residue from drying on, the following steps must be performed directly after surgery.

⚠️ CAUTION

Risk of infection due to the fixation of residues.

← Rinse the instrument with cold water.
← Remove coarse dirt with cold water.
← Rinse out cavities with cold water.
If it is not possible to rinse with cold water, the instrument must be wrapped in a moist cloth to prevent any residues from drying on.

Always transport the instrument to the preparation site in a closed container to prevent product damage and contamination of the environment.

5 Pre-cleaning

Pre-cleaning prevents germs from spreading and surgical residue from drying on. It must therefore be carried out directly after surgery.

Pre-cleaning was validated with the cleaning agent Neodisher FA from Dr. Weigert:

<table>
<thead>
<tr>
<th>Cleaning</th>
<th>Dosage</th>
<th>pH value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alkaline</td>
<td>0.5 %</td>
<td>11.4-11.9</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(diluted)</td>
</tr>
</tbody>
</table>

⚠️ WARNING

Risk of infection and pyrogenicity if unsuitable cleaning agents are used.

⚠️ Do not use fixing agents.

⚠️ Do not rinse with hot water.

IMPORTANT! Avoid damaging product.

⚠️ Do not use abrasive brushes or scourers.

⚠️ Only use suitable cleaning agents.

⚠️ Use disinfectant with corrosion protection.

Rinse the instrument below the water level. This prevents the spread of germs.

Place the instrument in cold water: > 5 min.

Dismantle the instrument (if possible).

• See instrument’s Instructions for Use.

Open stop cocks (if relevant).

TIP:
Remove caked-on tissue residues with a plastic brush.

Brush the outside and inside under cold water with a round brush until no more residue is visible.

Rinse out cavities, drill holes and threads (if relevant) with a cleaning gun: > 10 s at 3-5 bar.

Remove from the water bath and rinse off with cold water.

Immerse in combined cleaning and disinfectant solution until subsequent cleaning to prevent any residue from drying on.

6 Cleaning

Unless stated otherwise in the instrument’s Instructions for Use, cleaning is performed with the instrument disassembled.

Cleaning was validated with the cleaning agent Neodisher FA from Dr. Weigert:

<table>
<thead>
<tr>
<th>Cleaning</th>
<th>Dosage</th>
<th>pH value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alkaline</td>
<td>0.5 %</td>
<td>11.4-11.9</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(diluted)</td>
</tr>
</tbody>
</table>
**WARNING**
Risk of infection due to insufficient preparation.
- Remove protective caps (if relevant).

**IMPORTANT!** Avoid damaging product.
- Only use suitable cleaning agents.
- Avoid contact with hydrogen peroxide ($\text{H}_2\text{O}_2$).
- Do not use abrasive brushes or scourers.

Choose between manual and mechanical cleaning.

### 6.1 Manual

- Rinse the instrument below the water level. This prevents the spread of germs.

Open stop cocks (if relevant).

- Additionally clean the components in an ultrasonic bath with the following settings:

<table>
<thead>
<tr>
<th>Temperature</th>
<th>Frequency</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>40 °C</td>
<td>35-45 kHz</td>
<td>&gt; 4 min</td>
</tr>
</tbody>
</table>

Turn and move the components several times during cleaning in the ultrasonic bath.

- Clean the inner chambers with a cleaning brush below water.

- Rinse through the inner chambers with a cleaning agent: 3-20 min. at 45-85 °C

Immerse the instrument in cold demineralised water and rinse through the cavities several times with demineralised water.

**Disinfect and dry**

Disinfection was validated with the disinfectant Cidex OPA from Johnson & Johnson:

<table>
<thead>
<tr>
<th>Cleaning</th>
<th>Dosage</th>
<th>pH value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alkaline</td>
<td>0.5 %</td>
<td>7.2-7.8</td>
</tr>
</tbody>
</table>

- Disinfect with disinfectant.
  - See manufacturer’s Instructions for Use.

- Dry on the inside and outside: >10 min at 50-100 °C
  - Blow through with sterile compressed air.

### 6.2 Mechanical

Mechanical cleaning was validated with the cleaning device 7735 CD and 7736 CD from Miele

Proper cleaning depends on the right cleaning program. Compare the cleaning program with that of your cleaning system and save where necessary:

1. Pre-rinse with cold water: 1 min.
2. Empty.
3. Repeated pre-rinsing with cold water: 3 min.
4. Empty.
5. Clean with 0.5% mild alkaline cleaning agent: 5 min. at 45°-55°C
6. Empty.
7. Neutralise with warm tap water and a suitable neutraliser: 3 min. at > 40°C
8. Empty.
9. Rinse with warm tap water: 2 min. at > 40°C
10. Empty.
11. Disinfect: Observe the national requirements as regards the A0 value (see ISO 15883)
12. Dry: 15-25 min. at 90°-110°C

← Open stop cocks (if relevant).
← Place instruments in a sieve tray on the MIC cleaning device trolley so that the cleaning agent can reach all inner and outer surfaces.
← Connect the flush port (if relevant) to the MIC cleaning device trolley.
← Start the cleaning program.
← If necessary, additionally dry the instrument after cleaning with sterile compressed air.

Additionally clean the components in an ultrasonic bath with the following settings:

<table>
<thead>
<tr>
<th>Temperature</th>
<th>Frequency</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>40 °C</td>
<td>35-45 kHz</td>
<td>&gt; 4 min</td>
</tr>
</tbody>
</table>

Turn the components over several times during cleaning in the ultrasonic bath.

7 Care

Caring for the instruments properly will lengthen their service life and should therefore be carried out after every cleaning process.

⚠️ WARNING

Risk of injury from faulty or damaged components
← Do not use faulty or damaged instruments.

8 Wipe-down disinfection

Wipe-down disinfection serves to reduce the germs on the surfaces of devices. Wipe-down disinfection was validated with the wipe-down disinfectant Neoform MED AF from Dr. Weigert:

<table>
<thead>
<tr>
<th>Dosage</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>1%</td>
<td>15 min.</td>
</tr>
<tr>
<td>2%</td>
<td>5 min.</td>
</tr>
</tbody>
</table>

**IMPORTANT!** Avoid damaging product.
← Do not use abrasive brushes or scourers.
← Use a suitable disinfectant.
← Wipe down the device surface with a wipe-down disinfectant.
9 Packaging

The instrument must be packaged appropriately to prevent recontamination with the environment.

← Package the instrument to comply with ISO 11607 and EN 868.

10 Sterilising

Unless stated otherwise in the instrument’s Instructions for Use, sterilisation is performed with the instrument assembled.

• You will find detailed information on the assembly of the instrument in the latter’s Instructions for Use.

Sterilisation was validated with the sterilisation device Selectomat S 3000 from MMM Group and Variocalv 400 E from Fisher Scientific.

IMPORTANT! Avoid damaging product.
← Observe the device’s maximum load.

• See manufacturer’s Instructions for Use.

⚠️ WARNING

Risk of infection due to excessively short sterilisation time.
← If there is a suspicion of prions and Creutzfeldt-Jakob disease, the sterilisation time must be ≥ 18 min.

The sterilisation time is between 4-30 min. The following countries make different stipulations which must be observed:

<table>
<thead>
<tr>
<th>Country</th>
<th>Sterilisation time</th>
</tr>
</thead>
<tbody>
<tr>
<td>France</td>
<td>≥ 18 min.</td>
</tr>
<tr>
<td>Switzerland</td>
<td>≥ 18 min.</td>
</tr>
</tbody>
</table>

← Open stop cocks (if relevant).
← Place in the sterilisation device so that the components are not touching each other and the steam can circulate freely.
← Select sterilisation parameters:

<table>
<thead>
<tr>
<th>Temperature</th>
<th>Pressure</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>134-137 °C</td>
<td>3 bar</td>
<td>44 psi</td>
</tr>
</tbody>
</table>

← See details in this chapter.

11 Storing sterile devices

To prevent reducing durability and forfeiting any resistance to bacteria, the following storage conditions must be observed:

← Store the sterile device sealed in a clean, dust-free and dry sterile container.
← Store the sterile container in a clean and dry environment with controlled humidity at room temperature.
← Do not store the sterile container in the vicinity of aggressive substances (e.g., alcohols, acids, bases, solvents and disinfectants).

Also observe your internal storage standards for sterile devices.
12 Disposal

Environmentally sound disposal enables valuable raw materials to be recycled.

Dispose of the device in an environmentally friendly manner in accordance with the valid hospital guidelines.

13 Information on validation

The following materials and machines were used for validation:

- Cleaning agent: Neodisher FA from Dr. Weigert.
- Cleaning and disinfection device: 7735 CD and 7736 CD from Miele.
- Sterilisation device: Selectomat S 3000 from MMM Group and Variocalv 400 E from Fisher Scientific
- Sterilizing agent: Moist heat