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Processing instructions



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1 Overview of processing steps

| Reprocessing steps | | Processing medium | Reusable surgical instruments | |
|---------------------------------|--|---|-------------------------------|---|
| Pre-cleaning directly after use | Wet | Soak in cleaning and disinfection solution and rinse with water | ++ | |
| | Dry | Wipe with damp cloth or with cleaning and disinfection solution | + | |
| Decontamination | Pre-cleaning [#] | ↗ See section „4 Pre-cleaning“ on page 4. | | |
| | Cleaning [#] | Manual ¹ | | ++ |
| | | Mechanical ¹ | | ++ |
| | | Ultrasound | | + |
| | | Alkaline cleaning agent ⁵ pH 9-12 | | ++ ³ 55-85 °C / 3-20 min. |
| | | Acidic cleaning agent ⁵ | | ++ ³ 55-85 °C / 3-20 min. |
| | | Neutral cleaning agent ⁵ | | ++ 55-85 °C / 3-20 min. |
| | | Enzyme cleaning agent ⁵ | | + 45-50 °C / 5-20 min. |
| | Rinsing | Demineralized water | | + |
| | Disinfection | Chemical max. 60 °C | | - |
| | | Thermal max. 93 °C | | + |
| | Drying | Temperature | | ++ 50-100 °C / >10 min. |
| Maintenance ⁶ | ↗ See section „5 Cleaning“ on page 5. | | ++ | |
| Sterilization ⁷ | Moist heat autoclave pre-vacuum | | ++ 134-137 °C | |
| | Low temperature (steam + formaldehyde) | | + | |
| | Ethylene oxide | | + | |
| | Hot air | | - | |
| | Liquid sterilant | | + | |
| | Gas plasma | | - | |

1 De-ionized water is recommended for the final rinse.

2 Rubber and/or latex, silicone elastomers.

3 Does not apply to (anodized) aluminum alloys.

4 Not suitable for ultrasound-assisted cleaning.

5 Follow usage instructions supplied with the cleaning agent.

6 ↗ For detailed information, see section „6 Maintenance“.

7 ↗ For the sterilization period, please see section “8 Sterilization”.



Information about reprocessing is provided by the Robert Koch Institute (RKI) and AKI, the working group for instrument reprocessing:

RKI: Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten (hygiene requirements for the reprocessing of medical products) (published Nov. 1, 2011, www.rki.de)

AKI: Instrumentenaufbereitung richtig gemacht (instrument reprocessing the right way) (8th edition, www.a-k-i.org)

| Instruments for use with endoscopes | Reusable containers | Elastic products ¹ | HF cables and tool holders |
|---|---|---|---|
| ++ | ++ | ++ | ++ |
| + | + | + | + |
| + | + | + | + |
| + | + | + | + |
| + | - | - | - |
| ++ ³ 55-85 °C / 3-20 min. | ++ ³ 55-85 °C / 3-20 min. | ++ ³ 50-70 °C / 3-20 min. | ++ ³ 50-70 °C / 3-20 min. |
| ++ ³ 55-85 °C / 3-20 min. | ++ ³ 55-85 °C / 3-20 min. | ++ ³ 50-70 °C / 3-20 min. | ++ ³ 50-70 °C / 3-20 min. |
| ++ 55-85 °C / 3-20 min. | ++ 55-85 °C / 3-20 min. | ++ 50-70 °C / 3-20 min. | ++ 50-70 °C / 3-20 min. |
| ++ 55-85 °C / 3-20 min. | ++ 55-85 °C / 3-20 min. | ++ 50-70 °C / 3-20 min. | ++ 50-70 °C / 3-20 min. |
| + | + | + | + |
| + | + | + | + |
| + | + | + | + |
| ++ 50-100 °C / >10 min. | ++ 50-100 °C / >10 min. | ++ 50-100 °C / >10 min. | ++ 50-100 °C / >10 min. |
| ++ | ++ | ++ | ++ |
| ++ 134-137 °C | ++ 134-137 °C | ++ 134-137 °C | ++ 134-137 °C |
| + | + | + | + |
| + | - | + | + |
| - | - | - | - |
| + | + | + | + |
| - | - | - | - |

| Symbol | Meaning |
|--------|--|
| ++ | Process with validated microbiological effectiveness and verified material compatibility |
| + | Process with verified material compatibility |
| - | Incompatible |
| 0 | Contact the manufacturer for more information |
| # | For detailed information, see section 5 "Cleaning" . |

2 Safety and responsibility

Before you reprocess instruments

- ▶ Read and follow the reprocessing instructions.
- ▶ Keep them available for future use in a clearly visible place.

MediVision accepts no liability for consequences arising from improper processing and care. The validation of alternative cleaning and sterilization methods is the responsibility of the user.

Risk of infection

- ▶ Process the instrument before use.
- ▶ Process the instrument before returning to the manufacturer.
- ▶ Follow the usage instructions for the cleaning and disinfection agents used, and for the cleaning and sterilization equipment used.
- ▶ Wear gloves during processing.
- ▶ Dispose of single-use components after the first use.

Risk of injury

- ▶ Do not use and do not repair damaged instruments.
- ▶ Use only original accessories.

3 Key to symbols

DANGER

Indicates a hazard which will result in death or serious injury if not avoided.

WARNING


Indicates a hazard which may result in death or serious injury if not avoided.

CAUTION

Indicates a hazard which may result in injury if not avoided.

NOTICE!

Indicates measures to avoid damage to property and equipment.

 This symbol provides information to facilitate use of the instrument.

- ▶ Here you are asked to take action.
- ↳ This tells you the result of an action.
- ↗ This symbol refers you to additional information.

4 Pre-cleaning

Pre-cleaning prevents the transmission of germs and stops operation residues from drying on. It therefore needs to be performed immediately after the operation

WARNING

Risk of infection and pyrogenicity through the use of unsuitable cleaning agents.

- ▲ Do not use any fixatives.
- ▲ Do not rinse under hot water.

NOTICE! Avoid damaging the product.

- ▲ Do not use abrasive brushes or sponges.
- ▲ Use only suitable cleaning agents.
 - ↗ See section “11 Cleaning and disinfection agents” .
- ▲ Use disinfectants with corrosion inhibitor.

TIP:

Use the validated cleaning agent called neodisher FA produced by Dr. Weigert.

| Cleaning | Dosage | pH value |
|----------|--------|------------------------|
| Alkaline | 0,5 % | 11.4-11.9 (diluted) |

TIP:

Rinse the instrument below the surface of the water. This way, you will prevent the transmission of germs.

- ▶ Use cleaning gun to rinse out internal spaces via rinsing openings (if present): 3 min. at 4 bar.
- ▶ Dismantle the instrument (if possible).
 - See the instructions supplied with the instrument.
- ▶ Open stopcocks (if present).
- ▶ Rinse all components with cold water and brush inside and out using a round brush.

TIP:

Use a plastic brush to remove heavily encrusted tissue residues.

- ▶ Clean internal spaces (e.g. guide channels) using a cleaning brush and swab.
- ▶ Place components in combined cleaning and disinfection agent solution until subsequent cleaning.

5 Cleaning

Except as provided otherwise in the usage instructions for the instrument, instruments should be dismantled for cleaning.

WARNING

Risk of infection due to improper processing.

- ▲ Remove protective caps (if fitted).

NOTICE! Avoid damaging the product.

- ▲ Use only suitable cleaning agents.
 - See section “11 Cleaning and disinfection agents” .
- ▲ Avoid contact with hydrogen peroxide (H₂O₂).
- ▲ Do not use abrasive brushes or sponges.

TIP:

Use the validated cleaning agent called neodisher FA produced by Dr. Weigert.

| Cleaning | Dosage | pH value |
|----------|--------|------------------------|
| Alkaline | 0.5 % | 11.4-11.9 (diluted) |

- ① Choose between manual or automatic cleaning.

5.1 Manual

TIP:

Rinse the instrument below the surface of the water. This way, you will prevent the transmission of germs.

- ▶ Open stopcocks (if present).
- ▶ Clean internal spaces with cleaning brush and use cleaning gun to rinse: 3-20 min. at 45-85 °C.

TIP:

Also clean the components in an ultrasound bath with the following settings:

| Temperature | Frequency | Duration |
|-------------|-----------|----------|
| 40 °C | 35-45 kHz | > 4 min. |

Turn the components several times while they are being cleaned in the ultrasound bath.

- ▶ Clean components in ultrasound bath.
- ▶ Rinse with demineralized water.
- ▶ Disinfect at 93-98 °C.
- ▶ Dry inside and out: >10 min. at 50-100 °C.

TIP:

Use medical compressed air to dry the components.

5.2 Mechanical

TIP:

Use a washer-disinfector model 7735 CD or 7736 CD made by Miele.

It is essential to select the right cleaning program for cleaning to be successful.

Compare the following cleaning program with your machine's program and store it if necessary:

1. Pre-cleaning with demineralized water: 10 min. at 40 °C
2. Cleaning followed by rinsing with demineralized water: 30 min. at 60 °C
3. Disinfection: 5 min. at 93 °C
4. Drying: 15 min. at 110 °C

- ▶ Place components into the cleaning machine's slide-in tray in such a way as to ensure that the cleaning agent can reach all internal and external surfaces.
- ▶ Connect rinsing opening (if present) to the MIS slide-in tray.

TIP:

Also clean the components in an ultrasound bath with the following settings:

| Temperature | Frequency | Duration |
|-------------|-----------|----------|
| 40 °C | 35-45 kHz | > 4 min. |

Turn the components several times while they are being cleaned in the ultrasound bath.

- ▶ Start the cleaning program:
3-20 min. at 45-85 °C.
- ▶ Rinse with demineralized water.
- ▶ Disinfect at 93-98 °C.
- ▶ Dry inside and out: >10 min.
at 50-100 °C.

TIP:

Use medical compressed air to dry the components.

6 Maintenance

Taking good care of the instruments extends their life. The following steps should therefore be carried out after every cleaning.

WARNING

Risk of injury from damaged components

- ▲ Do not reuse damaged instruments.
- ▶ Check all components of the instrument for damage (e.g. sharp edges, rough surfaces).
- ▶ Replace brittle or cracked seals (if present).
- ▶ Do not reuse damaged instruments.
- ▶ Lubricate moving parts (e.g. linkages, rotatable stopcocks) with instrument oil.
- ▶ Remove excess oil.
- ▶ Assemble instrument (if possible) and check that it works perfectly.

7 Wipe disinfection

Wipe disinfection is not suitable for all instruments.

- ↗ For detailed information on suitable instruments, see section “1 Over-view of processing steps” .

NOTICE! Avoid damaging the product.

- ▲ Do not use abrasive brushes or sponges.
- ▲ Use suitable disinfectants.
 - ↗ See section “2 Safety and responsibility”

TIP:

Use the wiping disinfectant called Neoform MED AF produced by Dr. Weigert.

| Dosage | Exposure time |
|--------|---------------|
| 1% | 15 min. |
| 2% | 5 min. |

- ▶ Wipe instrument with wipe disinfectant.

8 Sterilization

Except as provided otherwise in the usage instructions for the instrument, instruments should be assembled for sterilization.

- ↗ For detailed information on assembling the instrument, please consult its usage instructions.

Sterilization period

Sterilization takes between 8-30 minutes.

For the following countries compliance with different specifications is required:

| Country | Sterilization period |
|-------------|----------------------|
| France | ≥ 18 minutes |
| Switzerland | ≥ 18 minutes |

TIP:

Use the sterilizer model Selectomat S 3000 made by MMM Group or Vario-calv 400 E made by Fisher Scientific.

- ▶ Open stopcocks (if present).
- ▶ Place instruments in the sterilizer in such a way that components are not touching and the steam can circulate freely.
- ▶ Set sterilization parameters:

| Temperature | Pressure | Duration |
|-------------|-----------------|---|
| 134-137 °C | 3 bar 44 psi | ↗ See section „Sterilization period“ in this chapter. |

- ▶ Start the sterilization process.

9 Storage

If the following storage conditions are not met, the storage life will be reduced and the germ-tight seal may be compromised:

- Store container in clean, dry surroundings at room temperature with controlled humidity.
 - Do not store the container near to aggressive substances (e.g. alcohols, acids, bases, solvents, disinfectants).
- ① Please also comply with your internal storage standards for sterile products.

10 Disposal

Environmentally sound disposal means valuable raw materials can be recycled.



Dispose of product in an environmentally sound manner in accordance with the applicable regulations for hospitals.

11 Cleaning and disinfection agents

The following overview indicates suitable cleaning and disinfection agents. They are classified as follows:

- Disinfectants
- Machine Disinfectants
- Cleaning agents
- Machine cleaning agents

Disinfectants

| Product name | Manufacturer |
|----------------------------|----------------------------------|
| Afid | Fresenius |
| Afid plus | Fresenius |
| Aniosyme P.L.A. * US | Anios Laboratories |
| Anioxyde 1000 ¹ | Anios Laboratories |
| Aseptisol ^{US} | Bandelin electronic |
| Aseptisteril | Huntington Laboratories |
| Bodedex Forte | Bode Chemie |
| Cidex | Johnson & Johnson Medical |
| Cidex OPA | Johnson & Johnson Medical |
| Deconex 50 FF | Bohrer Chemie AG |
| Desconton forte | Dr. Schuhmacher |
| Desomedan | Desomed Freiburg |
| Dodarcana-S | REARAL |
| EndoStar | Laboratorium Dr. rer. Nat. Deppe |
| Gigasept ^{US} | Schülke & Mayr |
| Gigasept FF ^{US} | Schülke & Mayr |
| ID 210 | Orochemie |
| Ido-Scope | Fine Chemicals Division |
| InstruPlus ^{US} | Laboratorium Dr. rer. Nat. Deppe |
| InstruPlus N ^{US} | Laboratorium Dr. rer. Nat. Deppe |

| Product name | Manufacturer |
|--------------------------------|----------------------------------|
| InstruStar ^{US} | Laboratorium Dr. rer. Nat. Deppe |
| InstruZym ^{US} | Laboratorium Dr. rer. Nat. Deppe |
| Korsolex AF ^{US} | Bode Chemie |
| Korsolex Basic ^{US} | Bode Chemie |
| Korsolex Extra | Bode Chemie |
| Korsolex FF | Bode Chemie |
| Korsolex Plus | Bode Chemie |
| Korsolin iD ^{US} | Bode Chemie |
| Lyselot AF ^{US} | Schülke & Mayr |
| Lyselot V | Schülke & Mayr |
| Mucocit-T ^{US} | Merz Hygiene |
| Mucadont-IS ^{US} | Merz Hygiene |
| Noeform MED AF | Dr. Weigert |
| Omnicide | AMC MEDICAL DIVISION |
| Omnicide 14 | AMC MEDICAL DIVISION |
| Sekusept Extra ^{US} | Henkel Hygiene |
| Sekusept Extra N ^{US} | Henkel Hygiene |
| Sekusept forte ^{US} | Henkel Hygiene |
| Sekusept Plus ^{US} | Henkel Hygiene |
| Sekusept Pulver ^{US} | Henkel Hygiene |
| Somplex IR | TH. GOLD-SCHMIDT |
| Sporcid | Fresenius |

| Product name | Manufacturer |
|--------------------------------|----------------------------------|
| Sporcid FF | Fresenius |
| Stammopur DR ^{US} | Bandelin electronic |
| Stammopur DR 8 ^{US} | Bandelin electronic |
| TEGO CID | TEGOMENT HEALTHCARE PRODUCT INC. |
| TEV-A-SEPT | CHEMITRON S.A |
| Ultrademit Konz. ^{US} | Esteer |
| Virkon ¹ | Antec International Ltd. |
| Wescodyne | AMSCO MEDICAL PRODUCT DIV. |

Machine disinfectants

| Product name | Manufacturer |
|--|----------------------------------|
| BHT Scope Desinfectant ^{MD} | BHT Hygiene Technik |
| Deconex 55 Endo B ^{MD} | Borer Chemie |
| Endomat Plus ^{MD} | Laboratorium Dr. rer. Nat. Deppe |
| Endozime (AW) ^{MD} | RUHOF CORPORATION |
| Korsolex Endo-Desinfectant ^{MD} | Bode Chemie |
| Neodisher Septo DA ^{MD} | Dr. Weigert |
| Neodisher Septo DN ^{MD} | Dr. Weigert |

| | |
|------------------------------|-----------------|
| Sekumatic FD ^{MD} | Henkel Hygiene |
| Thermosept ED ^{MD} | Schülke & Mayr |
| Thermoton Endo ^{MD} | Dr. Schuhmacher |

Cleaning agents

| Product name | Manufacturer |
|------------------------|----------------------------------|
| Afid | Fresenius |
| Afid plus | Fresenius |
| Bodephen | Bode Chemie |
| Cidezyme ^{US} | Johnson & Johnson Medical |
| Deconex 23 Neutrazym | Borer Chemie |
| Deconex 23 Alka One | Borer Chemie |
| Deconex 36 Intensiv | Borer Chemie |
| Enzol | Johnson & Johnson Medical |
| Enzy-Clean | BURNISHINE PRODUCTS |
| InstruPlus | Laboratorium Dr. rer. Nat. Deppe |
| InstruPlus N | Laboratorium Dr. rer. Nat. Deppe |
| InstruStar | Laboratorium Dr. rer. Nat. Deppe |
| Klenzyme | CALGON VESTAL LABORATORIES |
| Lyselot AF | Schülke & Mayr |

| | |
|---|---------------------|
| Mucocit-T ^{US} | Merz Hygiene |
| Mucocit-T Neu ^{US} | Merz Hygiene |
| Neodisher FA ² ^{US} | Dr. Weigert |
| Neodisher LM 2 ^{US} | Dr. Weigert |
| Neodisher Me- diclean ^{US} | Dr. Weigert |
| Neodisher Me- dizym | Dr. Weigert |
| Neodisher Septo DN2 ^{US} | Dr. Weigert |
| Sekusept Extra N ^{US} | Henkel Hygiene |
| Sekusept Plus ^{US} | Henkel Hygiene |
| Sekusept Pulver ^{US} | Henkel Hygiene |
| Sporcid FF | Fresenius |
| Stabisept Cleaner | BRAUN SCC |
| Stammopur DR 8 ^{US} | Bandelin electronic |
| Stammopur GR ^{US} | Bandelin electronic |
| Stammopur R ^{US} | Bandelin electronic |
| Aniosyme P.L.A. ¹ ^{US} | Anios Laboratories |

Machine cleaning agents

| Product name | Manufacturer |
|----------------------|------------------------|
| BHT Scope Cleaner | BHT Hygiene Technik |

| | |
|---|-------------------------------------|
| Deconex 23 Neutrazym | Borer Chemie |
| Deconex 23 Alka One | Borer Chemie |
| Dismoclean twin basic | Bode Chemie |
| Dismoclean twin zyme | Bode Chemie |
| Dismoclean 24 Vario | Borer Chemie |
| Endomat Plus | Laboratorium Dr. rer. Nat. Deppe |
| Korsolex Endo- Cleaner | Bode Chemie |
| Neodisher FA ² ^{US} | Dr. Weigert |
| Sekumatic FRE | Henkel Hygiene |
| Sekumatic +oxi- VARIO | Henkel Hygiene |
| Sumatox E | DiverseyLever |
| Thermosept Alka clean | Schülke & Mayr |
| Thermosept ER | Schülke & Mayr |
| Thermosept NKZ | Schülke & Mayr |
| Thermosept RKF | Schülke & Mayr |
| Thermosept RKN-zym | Schülke & Mayr |
| 3E-Zyme | Medisafe UK, Ltd. |
| Perasafe ¹ | Antec International Ltd. |

^{US} Suitable for ultrasound bath

⁵ increased requirements for processing and causes a higher degree of abrasion. A shorter service life cannot be ruled out.

⁶ Validated

