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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 <sup>#</sup>	↗ See section „4 Pre-cleaning“ on page 4.		
	Cleaning <sup>#</sup>	Manual <sup>1</sup>		++
		Mechanical <sup>1</sup>		++
		Ultrasound		+
		Alkaline cleaning agent <sup>5</sup> pH 9-12		++ <sup>3</sup> 55-85 °C / 3-20 min.
		Acidic cleaning agent <sup>5</sup>		++ <sup>3</sup> 55-85 °C / 3-20 min.
		Neutral cleaning agent <sup>5</sup>		++ 55-85 °C / 3-20 min.
		Enzyme cleaning agent <sup>5</sup>		+ 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 <sup>6</sup>	↗ See section „5 Cleaning“ on page 5.		++
Sterilization <sup>7</sup>	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](http://www.rki.de))

AKI: Instrumentenaufbereitung richtig gemacht (instrument reprocessing the right way) (8<sup>th</sup> edition, [www.a-k-i.org](http://www.a-k-i.org))

Instruments for use with endoscopes	Reusable containers	Elastic products <sup>1</sup>	HF cables and tool holders
++	++	++	++
+	+	+	+
+	+	+	+
+	+	+	+
+	-	-	-
++ <sup>3</sup> 55-85 °C / 3-20 min.	++ <sup>3</sup> 55-85 °C / 3-20 min.	++ <sup>3</sup> 50-70 °C / 3-20 min.	++ <sup>3</sup> 50-70 °C / 3-20 min.
++ <sup>3</sup> 55-85 °C / 3-20 min.	++ <sup>3</sup> 55-85 °C / 3-20 min.	++ <sup>3</sup> 50-70 °C / 3-20 min.	++ <sup>3</sup> 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 (H<sub>2</sub>O<sub>2</sub>).
- ▲ 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:

Tempera- ture	Pres- sure	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 <sup>1</sup>	Anios Laboratories
Aseptisol <sup>US</sup>	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 <sup>US</sup>	Schülke & Mayr
Gigasept FF <sup>US</sup>	Schülke & Mayr
ID 210	Orochemie
Ido-Scope	Fine Chemicals Division
InstruPlus <sup>US</sup>	Laboratorium Dr. rer. Nat. Deppe
InstruPlus N <sup>US</sup>	Laboratorium Dr. rer. Nat. Deppe

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

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

Machine disinfectants

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

Sekumatic FD <sup>MD</sup>	Henkel Hygiene
Thermosept ED <sup>MD</sup>	Schülke & Mayr
Thermoton Endo <sup>MD</sup>	Dr. Schuhmacher

Cleaning agents

Product name	Manufacturer
Afid	Fresenius
Afid plus	Fresenius
Bodephen	Bode Chemie
Cidezyme <sup>US</sup>	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 <sup>US</sup>	Merz Hygiene
Mucocit-T Neu <sup>US</sup>	Merz Hygiene
Neodisher FA <sup>2</sup> <sup>US</sup>	Dr. Weigert
Neodisher LM 2 <sup>US</sup>	Dr. Weigert
Neodisher Me- diclean <sup>US</sup>	Dr. Weigert
Neodisher Me- dizym	Dr. Weigert
Neodisher Septo DN2 <sup>US</sup>	Dr. Weigert
Sekusept Extra N <sup>US</sup>	Henkel Hygiene
Sekusept Plus <sup>US</sup>	Henkel Hygiene
Sekusept Pulver <sup>US</sup>	Henkel Hygiene
Sporcid FF	Fresenius
Stabisept Cleaner	BRAUN SCC
Stammopur DR 8 <sup>US</sup>	Bandelin electronic
Stammopur GR <sup>US</sup>	Bandelin electronic
Stammopur R <sup>US</sup>	Bandelin electronic
Aniosyme P.L.A. <sup>1</sup> <sup>US</sup>	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 <sup>2</sup> <sup>US</sup>	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 <sup>1</sup>	Antec International Ltd.

<sup>US</sup> Suitable for ultrasound bath

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

<sup>6</sup> Validated

