Aesculap®
Validated Reprocessing Procedures

AVA-V6

B|BRAUN
SHARING EXPERTISE

Validated Reprocessing Procedures

Preface

Premium quality instruments are a valuable commodity that deserve to be treated with care and respect. The surgical instrumentation of a hospital represents a considerable proportion of its fixed assets. In view of this, it is essential that the functionality and value of reusable medical devices, particularly surgical instruments, are preserved for the long term through professional reprocessing. The measures recommended here should be implemented in accordance with the manufacturer's instructions, hygiene requirements, and health and safety regulations.

Instrument reprocessing is becoming increasingly regulated by the German Medical Devices Act, a global harmonization of standards, and specific national laws and regulations (such as the MPBetreibVO (Medical Devices Operator Ordinance) as part of the MPG (Medical Devices Act) within Germany), which explicitly demand validation measures for reprocessing. The best way to comply with such requirements, and demonstrate compliance, is to implement a dedicated quality management system incorporating these measures.

This brochure provides details of the validated reprocessing procedures used for Aesculap AG products.

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1. About these instructions for use

These instructions for use:

- contain information about the various validated reprocessing procedures and notes on sterilization for all Aesculap products.
- do not replace the instructions for use of the product being reprocessed.

Note

Before reprocessing, take note of the product-specific characteristics.

2. Product-specific characteristics

► Before each clean, take note of any restrictions on handling the product.

If product-specific instructions for use are available, the following proscriptions/restrictions may have to be observed:

- Reprocessing
- Oxidizing chemicals
- Immersion/insertion
- Disassembling
- Chemicals and temperature
- Ultrasonic cleaning
- Positioning aids
- Cleaning
- Cleaning brush and other accessories
- Medical compressed air
- Sterilization

3. Validated instrument reprocessing procedure

3.1 General safety instructions

Note

Adhere to national statutory regulations, national and international standards and directives, and local, clinical hygiene instructions for sterile processing.

Note

For patients with Creutzfeldt-Jakob disease (CJD), suspected CJD or possible variants of CJD, observe the relevant national regulations concerning the reprocessing of products.

Note

Mechanical reprocessing should be favored over manual cleaning as it gives better and more reliable results.

Note

Successful processing of this medical device can only be ensured if the processing method is first validated. The operator/sterile processing technician is responsible for this.

The recommended chemistry was used for validation.

Note

If there is no final sterilization, then a virucidal disinfectant must be used.

Note

For the latest information on reprocessing and material compatibility see also the Aesculap extranet at www.extranet.bbraun.com

The validated steam sterilization procedure was carried out in the Aesculap sterile container system.

3.2 General information

Dried or affixed surgical residues can make cleaning more difficult or ineffective and lead to corrosion. Therefore, the time interval between application and reprocessing should not exceed 6 hours; also, neither fixating pre-cleaning temperatures >45 °C nor fixating disinfecting agents (active ingredient: aldehydes/alcohols) should be used.

Excessive dosages of neutralizing agents or basic cleaners may result in a chemical attack and/or fading and the laser marking on stainless steel becoming unreadable either visually or by machine.

Residues containing chlorine or chlorides, e.g., in surgical residues, medicines, saline solutions, and in the service water used for cleaning, disinfection, and sterilization, will cause corrosion damage (pitting, stress corrosion) and result in the destruction of stainless steel products. These must be removed by rinsing thoroughly with demineralized water and then drying.

Perform additional drying, if necessary.

Only process chemicals that have been tested and approved (e.g., VAH/DGHM or FDA approval or CE mark) and which are compatible with the product's materials according to the chemical manufacturer's recommendations may be used for processing the product. All the chemical manufacturer's application specifications must be strictly observed. Failure to do so can result in the following problems:

- Optical changes in materials, e.g., fading or discoloration of titanium or aluminum. For aluminum, the application/process solution only needs to be of pH >8 to cause visible surface changes
- Material damage such as corrosion, cracks, fracturing, premature aging or swelling

► Do not use metal cleaning brushes or other abrasives that would damage the product surface and could cause corrosion

► For further detailed advice on hygienically safe and material-/value-preserving reprocessing, see www.a-k-i.org Publications, Red Brochure – Proper maintenance of instruments

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3.3 Validated cleaning and disinfecting procedure

Note

See the instructions for use pertaining to the instrument in question for product-specific information about appropriate equipment.

3.4 Preparations at the place of use

- If applicable, rinse non-visible surfaces (preferably with deionized water), using a disposable syringe, for example.
- Remove any visible surgical residues as much as possible with a damp, lint-free cloth.
- Place the dry product in a sealed waste container and forward it on for cleaning and disinfection within 6 hours.

3.5 Preparations before cleaning

- Carry out non-fixating/NaCl-free pre-cleaning immediately after use.
- During disassembly, take note of the product-specific characteristics described in the corresponding instructions for use.

3.6 Cleaning/Disinfection

- Observe the product-specific safety notes relating to the reprocessing procedure contained in the corresponding instructions for use.

3.7 Wipe disinfection for electrical devices without sterilization

Phase	Step	T [°C/°F]	t [min]	Conc. [%]	Water quality	Chemical
I	**Wipe disinfection**	RT	≥1	-	-	Meliseptol HBV wipes 50 % Propan-1-ol

RT: Room temperature

Phase I

- ► Remove any visible residues with a disposable disinfectant wipe.
- ► Wipe all surfaces of the optically clean product with a fresh, disposable disinfectant wipe.
- ► Observe the specified application time (1 min minimum).

3.8 Manual cleaning/disinfection

- ► Prior to manual disinfection, allow water to drip off for a sufficient length of time to prevent dilution of the disinfecting solution.
- ► After manual cleaning/disinfection, visually check visible surfaces for residues.
- ► Repeat the cleaning/disinfection process if necessary.

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3.8.1 Manual cleaning and wipe disinfecting

Phase	Step	T [°C/°F]	t [min]	Conc. [%]	Water quality	Chemical
I	**Cleaning**	RT (cold)	-	-	D–W	-
II	**Drying**	RT	-	-	-	-
III	**Wipe disinfection**	-	>1	-	-	Meliseptol HBV wipes 50 % Propan-1-ol
IV	**Final rinse**	RT (cold)	0.5	-	FD-W	-
V	**Drying**	RT	-	-	-	-

D–W: Drinking water
FD–W: Fully desalinated water (demineralized, low microbiological contamination: drinking water quality at least)
RT: Room temperature

Phase I

- ► Clean the product under running faucet water, using a suitable cleaning brush until all visible residues have been removed from the surfaces.
- ► Mobilize non-rigid components, such as set screws, links, etc. during cleaning.

Phase II

- ► Dry the product in the drying phase with suitable equipment (e.g. cloth, compressed air), see Validated cleaning and disinfecting procedure.

Phase III

- ► Wipe all surfaces of the product with a single-use disinfectant wipe.

Phase IV

- ► After the specified exposure time (at least 1 min), rinse the disinfected surfaces under running FD water.
- ► Drain any remaining water fully.

Phase V

- ► Dry the product in the drying phase with suitable equipment (e.g. cloth, compressed air), see Validated cleaning and disinfecting procedure.

3.8.2 Manual cleaning with immersion disinfection

Phase	Step	T [°C/°F]	t [min]	Conc. [%]	Water quality	Chemical
I	**Disinfecting cleaning**	RT (cold)	>15	2	D–W	Aldehyde-free, phenol-free, and QUAT-free concentrate, pH ~ 9*
II	**Intermediate rinse**	RT (cold)	1	-	D–W	-
III	**Disinfection**	RT (cold)	15	2	D–W	Aldehyde-free, phenol-free, and QUAT-free concentrate, pH ~ 9*
IV	**Final rinse**	RT (cold)	1	-	FD-W	-
V	**Drying**	RT	-	-	-	-

D–W: Drinking water
FD–W: Fully desalinated water (demineralized, low microbiological contamination: drinking water quality at least)
RT: Room temperature
*Recommended: BBraun Stabimed

- ► Note the information on appropriate cleaning brushes and disposable syringes, see Validated cleaning and disinfecting procedure.

Phase I

- ► Fully immerse the product in the cleaning/disinfectant for at least 15 min. Ensure that all accessible surfaces are moistened.
- ► Clean the product with a suitable cleaning brush in the solution until all discernible residues have been removed from the surface.
- ► If applicable, brush through non-visible surfaces with an appropriate cleaning brush for at least 1 min.
- ► Mobilize non-rigid components, such as set screws, links, etc. during cleaning.
- ► Thoroughly rinse through these components with the cleaning disinfectant solution (at least five times), using a disposable syringe.

Phase II

- ► Rinse/flush the product thoroughly (all accessible surfaces) under running water.
- ► Mobilize non-rigid components, such as set screws, joints, etc. during rinsing.
- ► Drain any remaining water fully.

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Phase III

- ► Fully immerse the product in the disinfectant solution.
- ► Mobilize non-rigid components, such as set screws, joints, etc. during rinsing.
- ► Rinse lumens at least 5 times at the beginning of the exposure time using an appropriate disposable syringe. Ensure that all accessible surfaces are moistened.

Phase IV

- ► Rinse/flush the product thoroughly (all accessible surfaces).
- ► Mobilize non-rigid components, such as set screws, joints, etc. during final rinse.
- ► Rinse lumens with an appropriate disposable syringe at least five times.
- ► Drain any remaining water fully.

Phase V

- ► Dry the product in the drying phase with suitable equipment (e.g. cloth, compressed air), see Validated cleaning and disinfecting procedure.

3.8.3 Manual cleaning with ultrasound and immersion disinfection

Phase	Step	T [°C/°F]	t [min]	Conc. [%]	Water quality	Chemical
I	**Ultrasonic cleaning**	RT (cold)	>15	2	D–W	Aldehyde-free, phenol-free, and QUAT-free concentrate, pH ~ 9*
II	**Intermediate rinse**	RT (cold)	1	-	D–W	-
III	**Disinfection**	RT (cold)	15	2	D–W	Aldehyde-free, phenol-free, and QUAT-free concentrate, pH ~ 9*
IV	**Final rinse**	RT (cold)	1	-	FD-W	-
V	**Drying**	RT	-	-	-	-

D–W: Drinking water

FD–W: Fully desalinated water (demineralized, low microbiological contamination: drinking water quality at least)

RT: Room temperature

*Recommended: BBraun Stabimed

► Note the information on appropriate cleaning brushes and disposable syringes, see Validated cleaning and disinfecting procedure.

Phase I

► Clean the product in an ultrasonic cleaning bath (frequency 35 kHz) for at least 15 min. Ensure that all accessible surfaces are immersed and acoustic shadows are avoided.

► Clean the product with a suitable cleaning brush in the solution until all discernible residues have been removed from the surface.

► If applicable, brush through non-visible surfaces with an appropriate cleaning brush for at least 1 min.

► Mobilize non-rigid components, such as set screws, links, etc. during cleaning.

► Thoroughly rinse through these components with the cleaning disinfectant solution (at least five times), using a disposable syringe.

Phase II

► Rinse/flush the product thoroughly (all accessible surfaces) under running water.

► Mobilize non-rigid components, such as set screws, joints, etc. during rinsing.

► Drain any remaining water fully.

Phase III

► Fully immerse the product in the disinfectant solution.

► Mobilize non-rigid components, such as set screws, joints, etc. during rinsing.

► Rinse lumens at least five times at the beginning of the exposure time with an appropriate disposable syringe. Ensure that all accessible surfaces are moistened.

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Phase IV

- ► Rinse/flush the product thoroughly (all accessible surfaces) under running water.
- ► Mobilize non-rigid components, such as set screws, joints, etc. during final rinse.
- ► Rinse lumens with an appropriate disposable syringe at least five times.
- ► Drain any remaining water fully.

Phase V

- ► Dry the product in the drying phase with suitable equipment (e.g. cloth, compressed air), see Validated cleaning and disinfecting procedure.

3.9 Mechanical cleaning/disinfection

Note

The cleaning and disinfection device must be of tested and approved effectiveness (e.g. FDA approval or CE mark according to DIN EN ISO 15883).

Note

The cleaning and disinfection device used for processing must be serviced and checked at regular intervals.

3.9.1 Mechanical alkaline cleaning and thermal disinfecting

Machine type: single-chamber cleaning/disinfection device without ultrasound

Phase	Step	T [°C/°F]	t [min]	Water quality	Chemical/Note
I	**Prerinse**	<25/77	3	D–W	-
II	**Cleaning**	55/131	10	FD-W	■ Concentrate, alkaline: – pH = 13 – <5 % anionic surfactant ■ 0.5 % working solution – pH = 11*
III	**Intermediate rinse**	>10/50	1	FD-W	-
IV	**Thermal disinfecting**	90/194	5	FD-W	-
V	**Drying**	-	-	-	According to the program for cleaning and disinfection device

D–W: Drinking water

FD–W: Fully desalinated water (demineralized, low microbiological contamination: drinking water quality at least)

*Recommended: BBraun Helimatic Cleaner alkaline

► Check visible surfaces for residues after mechanical cleaning/disinfecting.

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3.9.2 Mechanical neutral or mild alkaline cleaning and thermal disinfecting

Machine type: single-chamber cleaning/disinfection device without ultrasound

Phase	Step	T [°C/°F]	t [min]	Water quality	Chemical
I	**Prerinse**	<25/77	3	D–W	-
II	**Cleaning**	55/131	10	FD-W	**Neutral**: ■ Concentrate: – pH neutral – <5 % anionic surfactant ■ 0.5 %* working solution **Mildly alkaline**: ■ Concentrate: – pH = 9.5 – <5 % anionic surfactant ■ 0.5 % solution
III	**Intermediate rinse**	>10/50	1	FD-W	-
IV	**Thermal disinfecting**	90/194	5	FD-W	-
V	**Drying**	-	-	-	According to the program for cleaning and disinfection device

D–W: Drinking water

FD–W: Fully desalinated water (demineralized, low microbiological contamination: drinking water quality at least)

*Recommended: BBraun Helimatic Cleaner neutral

► Check visible surfaces for residues after mechanical cleaning/disinfecting.

► Repeat the cleaning/disinfecting process if necessary.

3.10 Mechanical cleaning/disinfection with manual pre-cleaning

Note

The cleaning and disinfection device must be of tested and approved effectiveness (e.g. FDA approval or CE mark according to DIN EN ISO 15883).

Note

The cleaning and disinfection device used for processing must be serviced and checked at regular intervals.

3.10.1 Manual pre-cleaning with a brush

Phase	Step	T [°C/°F]	t [min]	Conc. [%]	Water quality	Chemical
I	**Disinfectant cleaning**	RT (cold)	>15	2	D–W	Aldehyde-free, phenol-free, and QUAT-free concentrate, pH ~ 9*
II	**Rinsing**	RT (cold)	1	-	D–W	-

D–W: Drinking water

RT: Room temperature

*Recommended: BBraun Stabimed

- ► Note the information on appropriate cleaning brushes and disposable syringes, see Validated cleaning and disinfecting procedure.

Phase I

- ► Fully immerse the product in the cleaning/disinfectant for at least 15 min. Ensure that all accessible surfaces are moistened.
- ► Clean the product with a suitable cleaning brush in the solution until all discernible residues have been removed from the surface.
- ► If applicable, brush through non-visible surfaces with an appropriate cleaning brush for at least 1 min.
- ► Mobilize non-rigid components, such as set screws, links, etc. during cleaning.
- ► Thoroughly rinse through these components with the cleaning disinfectant solution (at least five times), using a disposable syringe.

Phase II

- ► Rinse/flush the product thoroughly (all accessible surfaces) under running water.
- ► Mobilize non-rigid components, such as set screws, joints, etc. during rinsing.

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3.10.2 Manual pre-cleaning with ultrasound and brush

Phase	Step	T [°C/°F]	t [min]	Conc. [%]	Water quality	Chemical
I	**Ultrasonic cleaning**	RT (cold)	>15	2	D-W	Aldehyde-free, phenol-free, and QUAT-free concentrate, pH ~ 9*
II	**Rinsing**	RT (cold)	1	-	D-W	-

D-W: Drinking water
RT: Room temperature
*Recommended: BBraun Stabimed

► Note the information on appropriate cleaning brushes and disposable syringes, see Validated cleaning and disinfecting procedure.

Phase I

► Clean the product in an ultrasonic cleaning bath (frequency 35 kHz) for at least 15 min. Ensure that all accessible surfaces are immersed and acoustic shadows are avoided.
► Clean the product with a suitable cleaning brush in the solution until all discernible residues have been removed from the surface.
► If applicable, brush through non-visible surfaces with an appropriate cleaning brush for at least 1 min.
► Mobilize non-rigid components, such as set screws, links, etc. during cleaning.
► Thoroughly rinse through these components with the cleaning disinfectant solution (at least five times), using a disposable syringe.

Phase II

► Rinse/flush the product thoroughly (all accessible surfaces) under running water.
► Mobilize non-rigid components, such as set screws, joints, etc. during rinsing.

3.10.3 Mechanical alkaline cleaning and thermal disinfecting

Machine type: single-chamber cleaning/disinfection device without ultrasound

Phase	Step	T [°C/°F]	t [min]	Water quality	Chemical
I	**Prerinse**	<25/77	3	D–W	-
II	**Cleaning**	55/131	10	FD-W	■ Concentrate, alkaline: – pH = 13 – <5 % anionic surfactant ■ 0.5 % working solution – pH = 11*
III	**Intermediate rinse**	>10/50	1	FD-W	-
IV	**Thermal disinfecting**	90/194	5	FD-W	-
V	**Drying**	-	-	-	According to the program for cleaning and disinfection device

D–W: Drinking water

FD–W: Fully desalinated water (demineralized, low microbiological contamination: drinking water quality at least)

*Recommended: BBraun Helimatic Cleaner alkaline

► Check visible surfaces for residues after mechanical cleaning/disinfecting.

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3.10.4 Mechanical neutral or mild alkaline cleaning and thermal disinfecting

Machine type: single-chamber cleaning/disinfection device without ultrasound

Phase	Step	T [°C/°F]	t [min]	Water quality	Chemical
I	**Prerinse**	<25/77	3	D–W	-
II	**Cleaning**	55/131	10	FD-W	**Neutral:** ■ Concentrate: – pH neutral – <5 % anionic surfactant ■ 0.5 %* working solution **Mildly alkaline:** ■ Concentrate: – pH = 9.5 – <5 % anionic surfactant ■ 0.5 % solution
III	**Intermediate rinse**	>10/50	1	FD-W	-
IV	**Thermal disinfecting**	90/194	5	FD-W	-
V	**Drying**	-	-	-	According to the program for cleaning and disinfection device

D–W: Drinking water

FD–W: Fully desalinated water (demineralized, low microbiological contamination: drinking water quality at least)

*Recommended: BBraun Helimatic Cleaner neutral

► Check visible surfaces for residues after mechanical cleaning/disinfecting.

► Repeat the cleaning/disinfecting process if necessary.

3.11 Steam sterilization

- ► Take note of the product-specific characteristics relating to sterilization described in the corresponding instructions for use, such as whether or not the product needs to be disassembled.
- ► To prevent breakage due to stress corrosion, sterilize the instruments with the locking mechanism open, or locked on the first ratchet tooth.
- ► Check to ensure that the sterilizing agent will come into contact with all external and internal surfaces (e.g., by opening any valves and faucets).
- ► Validated sterilization process
  - Steam sterilization through fractionated vacuum process
  - Steam sterilizer according to DIN EN 285 and validated according to DIN EN ISO 17665
  - Sterilization using fractionated vacuum process at 134 °C/holding time 5 min
- ► When sterilizing several instruments at the same time in a steam sterilizer, ensure that the maximum load capacity of the steam sterilizer specified by the manufacturer is not exceeded.

3.12 Sterilization for the US market

- Aesculap advises against sterilizing the device by flash sterilization or chemical sterilization.
- Sterilization may be accomplished by a standard prevacuum cycle in a steam autoclave.

To achieve a sterility assurance level of 10^{-6}, Aesculap recommends the following parameters:

Aesculap Orga Tray/Sterile container (perforated bottom)
Minimum cycle parameters*

Sterilization method	Temp.	Time	Minimum drying time
Prevacuum	270 °F/ 275 °F	4 min	20 min

*Aesculap has validated the above sterilization cycle and has the data on file. The validation was accomplished in an Aesculap sterile container cleared by FDA for the sterilization and storage of these products. Other sterilization cycles may also be suitable, however individuals or hospitals not using the recommended method are advised to validate any alternative method using appropriate laboratory techniques. Use an FDA cleared accessory to maintain sterility after processing, such as a wrap, pouch, etc.

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