Aesculap®

Aesculap Surgical Instruments

GB
USA

Instructions for use
Aesculap composite instruments

B|BRAUN
SHARING EXPERTISE

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CE - DIR 93/42/EEC

GB USA

Aesculap®

Aesculap composite instruments

Symbols on product and packages

Caution, general warning symbol
Caution, see documentation supplied with the product

Intended use

Aesculap composite instruments are used to prepare light-curing composites.

Note

The gilding of the Aesculap composite instruments is intended to help avoid any mix-up with Aesculap amalgam instruments.

The gold plating of the Aesculap composite instruments can wear off after extended use. However, the instruments still remain fully functional.

Safe handling and preparation

CAUTION

Federal law restricts this device to purchase by, or on instruction by a physician!

WARNING

Risk of injury caused by incorrect operation of the product!

- ► **Do not use the product for chemically curing composites and amalgam.**
- ► **Do not apply any abrasive material or object to the product.**

- ► Ensure that the product and its accessories are operated and used only by persons with the requisite training, knowledge, or experience.
- ► Read, follow, and keep the instructions for use.
- ► Use the product only in accordance with its intended use, see Intended use.
- ► Remove the transport packaging and clean the new product, either manually or mechanically, prior to its initial sterilization.
- ► Store any new or unused products in a dry, clean, and safe place.
- ► Prior to each use, inspect the product for loose, bent, broken, cracked, worn, or fractured components.
- ► Do not use the product if it is damaged or defective. Set aside the product if it is damaged.
- ► Replace any damaged components immediately with original spare parts.

Validated reprocessing procedure

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.aesculap-extra.net

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

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 processing should not exceed 6 h; also, neither fixating pre-cleaning temperatures >45 °C nor fixating disinfecting agents (active ingredient: aldehydes/alcohols) should be used.

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

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.

Additional drying, if necessary.

Only process chemicals that have been tested and approved (e.g. VAH or FDA approval or CE mark) and which are compatible with the product's materials according to the chemical manufacturers' 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 of 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 surfaces and could cause corrosion.
- ► Further detailed advice on hygienically safe and material-/value-preserving reprocessing can be found at www.a-k-i.org, link to Publications, Red Brochure – Proper maintenance of instruments.

Preparations at the place of use

- ► If applicable, rinse non-visible surfaces preferably with deionized water, with a disposable syringe for example.
- ► Remove any visible surgical residues to the extent possible with a damp, lint-free cloth.
- ► Transport the dry product in a sealed waste container for cleaning and disinfection within 6 hours.

Cleaning/disinfection

Product-specific safety notes on the reprocessing procedure

CAUTION

Damage to the product due to inappropriate cleaning/disinfecting agents and/or excessive temperatures!

- ► **Use cleaning and disinfecting agents according to the manufacturer's instructions which**
  - **are approved for use e.g. on aluminum, plastic materials and stainless steel,**
  - **do not attack softeners (e.g. in silicone).**
- ► **Observe specifications regarding concentration, temperature and exposure time.**
- ► **Do not exceed the maximum permitted cleaning temperature of 55 °C.**

- ► Carry out ultrasound cleaning:
  - as an effective mechanical supplement to manual cleaning/disinfection.
  - as a pre-cleaning procedure for products with encrusted residues, in preparation for mechanical cleaning/disinfection.
  - as an integrated mechanical support measure for mechanical cleaning/disinfection.
  - for additional cleaning of products with residues left after mechanical cleaning/disinfection.
- ► Clean and disinfect microsurgical products mechanically if they can be placed securely in the machine or on the positioning aids.

Validated cleaning and disinfection procedure

Validated procedure	Specific requirements	Reference
Manual cleaning with ultrasound and immersion disinfection	■ Cleaning brush ■ 20 ml disposable syringe ■ Drying phase: Use a lint-free cloth or medical compressed air	Chapter Manual cleaning/disinfection and sub-chapter: ■ Chapter Manual cleaning with ultrasound and immersion disinfection
Mechanical alkaline cleaning and thermal disinfection	■ Place the instrument in a tray that is suitable for cleaning (avoiding rinsing blind spots).	Chapter Mechanical cleaning/disinfecting and sub-chapter: ■ Chapter Mechanical alkaline cleaning and thermal disinfecting

Manual cleaning/disinfection

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

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 disinfection 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.

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 disinfection procedure.

Mechanical cleaning/disinfecting

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.

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.

Inspection, maintenance and checks

► Allow the product to cool down to room temperature.
► After each complete cleaning, disinfecting and drying cycle, check that the instrument is dry, clean, operational, and free of damage (e.g. broken insulation or corroded, loose, bent, broken, cracked, worn, or fractured components).
► Dry the product if it is wet or damp.
► Repeat cleaning and disinfection of products that still show impurities or contamination.
► Check that the product functions correctly.
► Immediately put aside damaged or inoperative products and send them to Aesculap Technical Service, see Technical Service.
► Check for compatibility with associated products.

Packaging

► Appropriately protect products with fine working tips.
► Place the product in its holder or on a suitable tray. Ensure that all cutting edges are protected.
► Pack trays appropriately for the intended sterilization process (e.g. in sterile Aesculap containers).
► Ensure that the packaging provides sufficient protection against recontamination of the product during storage.

Steam sterilization

Note

The product may be sterilized in fully assembled condition.

► 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.

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.

Storage

► Store sterile products in germ-proof packaging, protected from dust, in a dry, dark, temperature-controlled area.

Technical Service

Risk of injury and/or malfunction!
► Do not modify the product.

► For service and repairs, please contact your national B. Braun/Aesculap agency.

Modifications carried out on medical technical equipment may result in loss of guarantee/warranty rights and forfeiture of applicable licenses.

Service addresses

Aesculap Technischer Service
Am Aesculap-Platz
78532 Tuttlingen / Germany
Phone: +49 (7461) 95-1602
Fax: +49 (7461) 16-5621
E-Mail: ats@aesculap.de
Or in the US:
Aesculap Inc.
Attn. Aesculap Technical Services
615 Lambert Pointe Drive
Hazelwood
MO, 63042
Aesculap Repair Hotline
Phone: +1 (800) 214-3392
Fax: +1 (314) 895-4420
Other service addresses can be obtained from the address indicated above.

Disposal

► Adhere to national regulations when disposing of or recycling the product, its components and its packaging!

Distributor in the US/Contact in Canada for product information and complaints

Aesculap Inc.
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USA

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