AESCULAP®

en **Instructions for use/Technical description**
Haemostatic forceps

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de **Gebrauchsanweisung/Technische Beschreibung**
Hämostatische Pinzette

fr **Mode d'emploi/Description technique**
Pince hémostatique

es **Instrucciones de manejo/Descripción técnica**
Fórceps hemostáticos

it **Istruzioni per l'uso/Descrizione tecnica**
Pinze emostatiche

pt **Instruções de utilização/Descrição técnica**
Pinças hemostáticas

nl **Gebruiksaanwijzing/Technische beschrijving**
Hemostatische tang

da **Brugsanvisning/Teknisk beskrivelse**
Hæmostatiske pincetter

no **Bruksanvisning/Teknisk beskrivelse**
Hemostatiske pinsetter

sv **Bruksanvisning/Teknisk beskrivning**
Hemostatisk pincett

fi **Käyttöohje/Tekninen kuvaus**
Hemostaattiset pihdit

et **Kasutusjuhend/Tehniline kirjeldus**
Hemostaatilised tangid

lv **Lietošanas instrukcijas/tehniskais apraksts**
Hemostātiskās knaibles

lt **Naudojimo instrukcija/techninis aprašas**
Hemostatinės žnyplės

ru **Инструкция по примению/Техническое описание**
Кровоостанавливающие зажимы

cs **Návod k použití/Technický popis**
Hemostatické kleště

pl **Instrukcja użytkowania/Opis techniczny**
Kleszcze hemostatyczne

sk **Návod na použitie/Technický opis**
Hemostatické kliešte

hu **Használati útmutató/Műszaki leírás**
Vérzéscsillapító csipesz

sl **Navodila za uporabo/Tehnični opis**
Hemostatične prijemalke

hr **Upute za uporabu/Tehnički opis**
Hemostatska kliješta

ro **Manual de utilizare/Descriere tehnică**
Forcepsul hemostatic

bg **Упътване за употреба/Техническо описание**
Хемостатичен форцепс

tr **Kullanım Kılavuzu/Teknik açiklama**
Hemostatik forseps

el **Οδηγίες χρήσης/Τεχνική περιγραφή**
Αιμοστατικές λαβίδες

br **Instruções de uso/Descrição técnica**
Fórceps hemostático

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AESCULAP®

Haemostatic forceps

1 About this document

Note

General risk factors associated with surgical procedures are not described in this document.

1.1 Scope

These instructions for use apply to Haemostatic forceps.

Note

Instructions for use and further information about B. Braun/AESCULAP products can be found on the B. Braun eIFU website at eifu.bbraun.com

1.2 Safety messages

Safety messages make clear the dangers to patient, user and/or product that could arise during the use of the product. Safety messages are labeled as follows:

⚠ WARNING
Indicates a possible threat of danger. If not avoided, minor or moderate injury may result.

⚠ CAUTION
Indicates a possible threat of material damage. If not avoided, the product may be damaged.

2 Clinical use

2.1 Areas of use and limitations of use

2.1.1 Intended purpose

Haemostatic clamps are used for clamping of tissue and small vessels.

2.1.2 Intended use

Haemostatic clamps are used for clamping of tissue and small vessels.

2.1.3 Indications

Note

The manufacturer is not responsible for any use of the product against the specified indications or the described applications.

For indications, see Intended use.

2.1.4 Contraindications

No known contraindications.

2.1.5 Intended patient population

There are no general gender, age or ethnic limitations on patient population for the use of the product when used within its intended use. Restrictions are defined by the contraindications.

2.2 Safety information

2.2.1 Clinical user

General safety information

To prevent damage caused by improper setup or use and to not compromise the manufacturer warranty and liability:

- ► Use the product only according to these instructions for use.
- ► Follow the safety and maintenance instructions.
- ► Ensure that the product and its accessories are only operated and used by qualified personnel.
- ► Store any new or unused products in a dry, clean and safe place.
- ► Prior to use, check that the product is in good working order.
- ► Keep the instructions for use accessible for the user.

Note

The user is obligated to report all severe events in connection with the product to the manufacturer and the responsible authorities of the state in which the user is located.

Notes on surgical procedures

It is the user's responsibility to ensure that the surgical procedure is performed correctly.

Appropriate clinical training as well as a theoretical and practical proficiency of all the required operating techniques, including the use of this product, are prerequisites for the successful use of this product.

The user is required to obtain information from the manufacturer if there is an unclear preoperative situation regarding the use of the product.

2.2.2 Sterility

The product is supplied non-sterile and intended to be used in sterile condition.

- ► Clean the new product after removing its transport packaging and prior to its initial sterilization.

2.3 Application

⚠ WARNING
Risk of injury and/or malfunction!

- **► Prior to each use, inspect the product for loose, bent, broken, cracked, worn or fractured components.**
- **► Always carry out a function test prior to each use of the product.**

3 Validated processing procedure

3.1 Safety information

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 processing of products.

Note

Mechanical processing 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.

Note

Up-to-date information about processing and material compatibility can be found on the B. Braun eIFU site at eifu.bbraun.com

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

3.2 Service life

Materials for reusable surgical instruments are generally chosen to be suitable for repeated processing. However, it should be noted that each mechanical, chemical and thermal treatment can lead to stress and thus to aging of the material.

The service life of the product is limited by damage, normal wear, type and duration of use, as well as by handling, storage and transport of the product.

End-of-life indicators for these products are signs of corrosion and cracks as well as deformation in the jaw area and loss of tension.

Influences of processing using the validated procedure that lead to damage to the product are not known.

Careful visual and functional inspection before each use is the best way to detect a product that is no longer functional, see Visual inspection and see Functional test.

3.3 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 precleaning 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 "AKI-Brochures", "Red brochure".

3.4 Initial treatment and disposal at the point 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.

3.5 Preparation before cleaning

- ► Remove coarse contamination by rinsing and flushing with cold, clean water.

3.6 Cleaning, disinfecting and drying

3.6.1 Product-specific safety information on the processing procedure

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

- ► Use cleaning and disinfecting agents according to the manufacturer's instructions.
- ► Observe specifications regarding concentration, temperature and exposure time.
- ► Do not exceed the maximum allowable disinfection temperature of 95 °C.

3.6.2 Validated cleaning and disinfection procedure

Note

Processing may only take place in accordance with the following listed procedures in version V6. These are documented in the brochure "Validated Reprocessing Procedures" (AVA-V6) C63402. You will also find this brochure on the B. Braun eIFU site at eifu.bbraun.com

Validated procedure	Short description	Specific requirements
Manual cleaning with immersion disinfection	► Use a suitable cleaning brush. ► Use a disposable syringe 20 ml. ► Drying phase: Use a lint-free cloth or medical compressed air. ► Clean the product having movable hinges in the open position or while moving the joints.	see Manual cleaning and disinfection and subsection: ■ see Manual cleaning with immersion disinfection
Mechanical alkaline cleaning and thermal disinfection	► Place the product in a tray that is suitable for cleaning (avoiding rinsing blind spots). ► Place the product on the tray with all product links and joints open.	see Mechanical cleaning/disinfection and subsections: ■ see Mechanical alkaline cleaning and thermal disinfecting

3.7 Manual cleaning and disinfection

3.7.1 Manual cleaning with immersion disinfection

Phase	Step	T [°C/°F]	t [min]	Conc. [%]	Water quality	Chemical/Note
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 demineralized water (low-germ, max. 10 CFU / 100 ml, as well as low endotoxin contamination, max. 0 25 endotoxin units/ml)
RT	Room temperature
*Recommended	B. Braun Stabimed fresh

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.

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 disinfection procedure.

3.8 Mechanical cleaning/disinfection

Note

The cleaning and disinfection device must be of tested and approved effectiveness (e.g. compliance with EN ISO 15883).

Note

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

3.8.1 Mechanical alkaline cleaning and thermal disinfecting

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 – less than 5 % anionic surfactant ■ 0,5% working solution – pH = 11*
III	Intermediate rinse	> 10/50	> 1	FD-W	–
IV	Thermal disinfection	90/194	5	FD-W	–
V	Drying	–	–	–	According to the program for cleaning and disinfection device

D-W	Drinking water
FD-W	Fully demineralized water (low-germ, max. 10 CFU / 100 ml, as well as low endotoxin contamination, max. 0 25 endotoxin units/ml)
*Recommended	B. Braun Helimatic Cleaner alcaline

- ► Check visible surfaces for residues after mechanical cleaning/disinfecting.
- ► Repeat the cleaning/disinfecting process if necessary.

3.9 Inspection

- ► Allow the product to cool down to room temperature.
- ► Dry the product if it is wet or damp.
- ► Any damages, signs of corrosion, cracks, missing labels, loose or missing parts, functional impairments like loss of tension are end-of-life indicators.

3.9.1 Visual inspection

- ► Make sure all contaminants have been removed. Pay particular attention to mating surfaces, hinges, shafts, recessed areas, drill grooves and the sides of teeth on rasps.
- ► If the product is still dirty: Repeat the cleaning and disinfection procedure.
- ► Inspect the product for damage, e.g., damaged insulation or corroded, loose, bent, broken, cracked, worn or severely scratched and fractured components.
- ► Inspect the product for missing or faded labels.
- ► Check the surfaces for rough spots.
- ► Check the product for burrs that could damage tissue or surgical gloves.
- ► Check the product for loose or missing parts.
- ► Inspect the product carefully: The surface of the product shall be clean and free of any signs of corrosion and cracks.
- ► Especially check the area of the joint and the jaw in open position from both sides. If in doubt, use magnification.
- ► Immediately put aside damaged or inoperative products and send them to Aesculap Technical Service, see Technical service.

3.9.2 Functional test

⚠ CAUTION

Damage (metal cold welding / friction corrosion) to the product caused by insufficient lubrication!

- ► **Prior to function checks, lubricate moving parts (e.g., joints, pusher components and threaded rods) with maintenance oil suitable for the respective sterilization process (e.g., for steam sterilization: STERILIT® I oil spray JG600 or STERILIT® I drip lubricator JG598).**
- ► Check that the product functions correctly.
- ► Check that all moving parts are working properly (e.g. hinges, locks/latches, sliding parts etc.).
- ► Check for compatibility with associated products.
- ► Check the jaw area for deformation and loss of tension.
- ► Immediately put aside damaged or inoperative products and send them to Aesculap Technical Service, see Technical service.

3.10 Packaging

- ► Appropriately protect products with fine working tips.
- ► Store products with ratchet locks fully opened or locked no further than in the first notch.
- ► Place the product in its holder or on a suitable tray, making sure it is positioned to prevent damage.
- ► Ensure that any fine working tips, blades and/or sharp edges are covered.
- ► Pack trays appropriately for the sterilization process (e.g., in AESCULAP sterile containers).
- ► Use sterile barrier packaging system in accordance with ISO 11607-1.
- ► Ensure that the packaging provides sufficient protection against contamination of the product during storage.

3.11 Steam sterilization

Note

To avoid breakage due to stress crack corrosion, sterilize the instruments with the lock fully open or locked no further than on the first ratchet tooth.

- ► Check to ensure that the sterilizing agent comes into contact with all external and internal surfaces (e.g., by opening any valves and faucets).
- ► Use validated sterilization process.
  - – Steam sterilization using fractional vacuum process
  - – Steam sterilizer according to EN 285 and validated according to ISO 17665
  - – Allowed sterilization parameters, see table below
- ► If several devices are sterilized simultaneously in the same steam sterilizer: Make sure that the maximum allowed load according to the specifications of the manufacturer is not exceeded.

Allowed sterilization parameters

Sterilization process	T [°C]	Holding time [min]	Drying time (at least recommended) [min]
Steam sterilization (fractionated vacuum process)	134	3 - 18	20

The sterilization of products approved for 134 °C is permissible in the temperature range from 134 °C to 137 °C.

3.12 Storage

Shelf life depends on the quality of the packaging system or material, the tightness of the seals, and the storage conditions.

- ► Store sterile products at room temperature in a dust-free, clean, dry, and pest-free environment.
- ► Follow the storage instructions provided by the sterile barrier system manufacturer.

3.13 Transport

Transport and storage must not adversely affect the characteristics of the processed medical device.

- ► Use appropriate transport systems and aids to prevent damage or recontamination.

4 Technical service

⚠ CAUTION

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

- ► **Do not modify the product.**
- ► **For service and repairs, contact the national B. Braun/AESCULAP agency.**

Service address

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Fax: +49 7461 16-2887
E-Mail: ats@aesculap.de

5 Disposal

⚠ WARNING

Risk of infection due to contaminated products!

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

⚠ WARNING

Risk of injury due to sharp-edged and/or pointed products!

- ► **Ensure that the packaging prevents injury by the product when disposing of or recycling the product.**

Note

The user institution is obliged to process the product before its disposal, see Validated processing procedure.

- ► Detailed information concerning the disposal of the product is available through the national B. Braun / AESCULAP agency, see Technical service.