

en	<b>Instructions for use</b> Multi-piece instruments with fitted top
USA	Note for U.S. users This Instructions for Use is NOT intended for United States users. Please discard. The Instructions for Use for United States users can be obtained by visiting our website at <a href="http://www.aesculapusa.com">www.aesculapusa.com</a> . If you wish to obtain a paper copy of the Instructions for Use, you may request one by contacting your local Aesculap representative or Aesculap's customer service at 1-800-282-9000. A paper copy will be provided to you upon request at no additional cost.
de	<b>Gebrauchsanweisung</b> Mehrteilige Instrumente mit aufgelegtem Schluss
fr	<b>Mode d'emploi</b> Instruments en plusieurs parties avec fermeture sur le dessus
es	<b>Instrucciones de manejo</b> Instrumental de varias piezas con cierre
it	<b>Istruzioni per l'uso</b> Strumenti compositi con chiusura applicata
pt	<b>Instruções de utilização</b> Instrumentos de vários elementos com fecho aplicado
nl	<b>Gebruiksaanwijzing</b> Meerdelige instrumenten met aangehechte sluiting
da	<b>Brugsanvisning</b> Instrumenter i flere dele med påsat lukning
sv	<b>Bruksanvisning</b> Flerdelade instrument med upplagt slut
fi	<b>Käyttöohje</b> Moniosaisset instrumentit, joihin on asetettu päätte
lv	<b>Lietošanas instrukcijas</b> Daudzdaļīgi instrumenti ar uzlietamu galu
lt	<b>Naudojimo instrukcija</b> Sudėtiniai instrumentai su uždedamu galu
ru	<b>Инструкция по применению</b> Многокомпонентные инструменты с установленным запорным элементом
cs	<b>Návod k použití</b> Vícedílné nástroje s nasazeným uzávěrem
pl	<b>Instrukcja użytkowania</b> Instrumenty wieloczęściowe z nalożonym zamknięciem
sk	<b>Návod na použitie</b> Viacdielne nástroje s nasadzovacím koncom
hu	<b>Használati útmutató</b> Többrészes műszerek ráilleszhető felsőrészsel
sl	<b>Navodila za uporabo</b> Večdelni instrumenti s pritrjenim zapiralom
hr	<b>Upute za uporabu</b> Višedjeljni instrumenti s položenim završetkom
ro	<b>Manual de utilizare</b> Instrumente pluripartite cu închidere prin suprapunere
bg	<b>Упътване за употреба</b> Разглобяеми инструменти с поставено заключване
tr	<b>Kullanım Kılavuzu</b> Ucu kapanan çok parçalı aletler
el	<b>Οδηγίες χρήσης</b> Όργανα πολλαπλών μερών με ανοιχτό άκρο



## 1. About this document

### Note

General risk factors associated with surgical procedures are not described in these instructions for use.

### 1.1 Scope

Multi-part instrument, which, apart from a fitted top, has directly accessible and visible surfaces:

- with fitted screw or rivet top
- with and without sector spring
- with and without screw lock

### Note

The applicable CE marking for the product can be found on the label or packaging of the product.

- ▶ For article specific instructions for use and material compatibility and lifetime information, see B. Braun eFU at [eifu.bbraun.com](http://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 use

The surgical instruments are intended for universal use in various surgical disciplines.

#### 2.1.2 Indications

##### Note

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

For indications, see Intended use.

#### 2.1.3 Absolute contraindications

No known absolute contraindications.

#### 2.1.4 Relative contraindications

The following conditions, individual or combined, can lead to delayed healing or compromise the success of the operation:

- Medical or surgical conditions (e.g. comorbidities) which could hinder the success of the operation.

In the presence of relative contraindications, the user decides individually regarding the use of the product.

## 2.2 Safety information

### 2.2.1 Clinical user

#### General safety information

To prevent damage caused by improper setup or operation, 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 operated and used only by persons with the requisite training, knowledge and experience.
- ▶ 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 delivered in an unsterile 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 reprocessing procedure

### 3.1 General 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 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.

#### Note

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

#### Note

For up-to-date information about reprocessing and material compatibility, see B. Braun eFU at [eifu.bbraun.com](http://eifu.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 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](http://www.a-k-i.org), link to "AKI-Brochures", "Red brochure".

### 3.3 Reusable products

Influences of the reprocessing which lead to damage to the product are not known.

A careful visual and functional inspection before the next use is the best opportunity to recognize a product that is no longer functional, see Inspection.

### 3.4 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.

### 3.5 Cleaning/Disinfection

#### 3.5.1 Product-specific safety information on the reprocessing method

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

- ▶ Use cleaning agents and disinfectants 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.
- ▶ With PVD coated products, do not use oxidizing process chemicals (e.g. H<sub>2</sub>O<sub>2</sub>), as these can cause bleaching or layer loss.

#### 3.5.2 Validated cleaning and disinfection procedure

Validated procedure	Specific requirements	Reference
Manual cleaning with immersion disinfection	<ul style="list-style-type: none"> <li>■ Suitable cleaning brush</li> <li>■ Disposable syringe 20ml</li> <li>■ Keep working ends open for cleaning.</li> <li>■ Clean the product having movable hinges in the open position or while moving the joints.</li> </ul>	Chapter Manual cleaning/disinfection and subsection: <ul style="list-style-type: none"> <li>■ Chapter Manual cleaning with immersion disinfection</li> </ul>
Mechanical alkaline cleaning and thermal disinfection	<ul style="list-style-type: none"> <li>■ Place the product on a tray that is suitable for cleaning (avoid rinsing blind spots).</li> <li>■ Place the product on the tray with all product links and joints open.</li> </ul>	Chapter Mechanical cleaning/disinfection and subsection: <ul style="list-style-type: none"> <li>■ Chapter Mechanical alkaline cleaning and thermal disinfection</li> </ul>

### 3.6 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.

#### 3.6.1 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)	5	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 fresh

- ▶ Note the information on appropriate cleaning brushes and disposable syringes, see Validated cleaning and disinfection 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.

## 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.

### 3.7 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.

#### 3.7.1 Mechanical alkaline cleaning and thermal disinfection

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

Phase	Step	T [°C/°F]	t [min]	Water quality	Chemical/Note
I	Pre-rinse	<25/77	3	D-W	-
II	Cleaning	55/131	10	FD-W	<ul style="list-style-type: none"><li>■ Concentrate, alkaline:<ul style="list-style-type: none"><li>- pH = 13</li><li>- &lt;5 % anionic surfactant</li></ul></li><li>■ 0.5 % working solution<ul style="list-style-type: none"><li>- pH = 11*</li></ul></li></ul>
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.

### 3.8 Inspection

- ▶ Allow the product to cool down to room temperature.
- ▶ Dry the product if it is wet or damp.

#### 3.8.1 Visual inspection

- ▶ Ensure that all soiling has been removed. In particular, pay attention to mating surfaces, hinges, shafts, recessed areas, drill grooves and the sides of the teeth on rasps.
- ▶ If the product is dirty: repeat the cleaning and disinfection process.
- ▶ Check the product for damage, e.g. insulation or corroded, loose, bent, broken, cracked, worn or severely scratched and fractured components.
- ▶ Check 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.
- ▶ Immediately put aside damaged or inoperative products and send them to Aesculap Technical Service, see Technical service.

#### 3.8.2 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 property (e.g. hinges, locks/latches, sliding parts etc.).
- ▶ Check for compatibility with associated products.
- ▶ Immediately put aside inoperative products and send them to Aesculap Technical Service, see Technical service.

### 3.9 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. Ensure that sharp edges are covered.
- ▶ Package trays appropriately for the sterilization process (e.g. in Aesculap sterile containers).
- ▶ Ensure that the packaging provides sufficient protection against contamination of the product during storage.

### 3.10 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 will come into contact with all external and internal surfaces (e.g., by opening any valves and faucets).
- ▶ Validated sterilization process
  - Steam sterilization in fractionated vacuum process
  - Steam sterilizer in accordance with DIN EN 285 and validated in accordance with DIN EN ISO 17665
  - Sterilization in fractionated vacuum process at 134 °C, holding time 5 min
- ▶ If several devices are sterilized at the same time in the same steam sterilizer: Ensure that the maximum permitted load according to the manufacturers' specifications is not exceeded.

### 3.11 Storage

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

## 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, please contact your national B. Braun/Aesculap agency.

#### Service addresses

Aesculap Technischer Service  
Am Aesculap-Platz  
78532 Tuttlingen / Germany  
Phone: +49 7461 95-1601  
Fax: +49 7461 16-2887  
E-Mail: ats@aesculap.de

Other service addresses can be obtained from the address indicated above.

## 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!

- ▶ When disposing of or recycling the product, ensure that the packaging prevents injury by the product.

#### Note

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

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