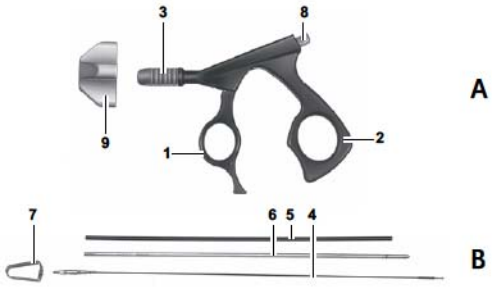

Fig. 1

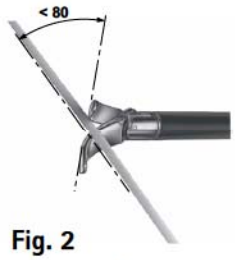

Fig. 2

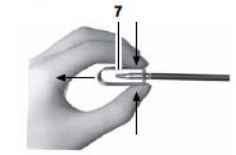

Fig. 3

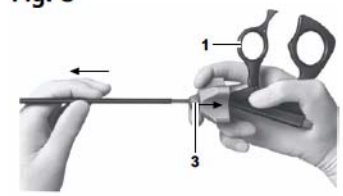

Fig. 4

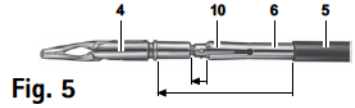

Fig. 5

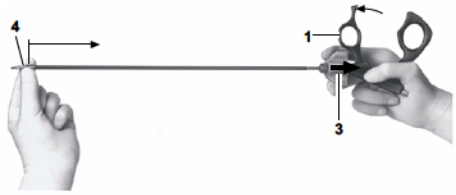

Fig. 6

Fig. 7

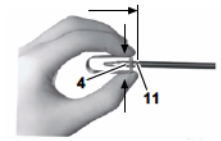

Fig. 8

Aesculap®

Bipolar, detachable tubular shaft instruments

Legend

1 Moveable ring
2 Fixed ring
3 Rotating sleeve
4 Working insert
5 Insulating outer tube
6 Inner tube
7 Pin protection
8 HF connection
9 Star wheel
10 Flexible switches
11 Groove
A Handle
B Sheath

Symbols on product and packages

	Caution, general warning symbol Caution, see documentation supplied with the product
	Date of manufacture

Intended use

Indicated for use in adult and pediatric (3.5mm instruments only) diagnostic and therapeutic general endoscopy and laparoscopy surgery.

Safe handling and preparation

CAUTION

Federal law restricts this device to sale by, or on order of a physician!

- ► 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.
- ► To avoid damage to the working end: Carefully insert the product through the working channel (e.g. trocar).


WARNING

Risk of injury from ignition or explosion of flammable gases!
Sparks may occur when using the HF device as directed.
- ► **Observe the safety guidelines in the instructions for use of the HF device.**


WARNING

Burns due to tissue contact with non-insulated areas of the working tip outside the coagulation site!
- ► **Avoid tissue contact with non-insulated areas of the working tip.**


WARNING

Thermal injuries to patients/users due to insufficient insulation of leads in active accessories!
- ► **Adjust the HF device to an appropriate setting to ensure that the peak output voltage does match or not exceed the accessory voltage rating specified for the product.**


CAUTION

Damage to the working insert due to incorrect handling or operation! To avoid damage to the working tip, especially to the ceramic insulation:
- ► **Apply caution when operating the product.**
- ► **Do not apply excessive force.**
- ► **Protect the working tip against knocks and impacts.**
- ► **Use the pin protector when the product is not in use.**

The manufacturer has tested the product and verified that its insulation can withstand a certain number of reprocessing cycles. In clinical practice, the service life will depend on the individual intraoperative usage and the hospital's specific reprocessing conditions.

Product component	Number of reprocessing cycles
Working insert **4**	Maximum 50 cycles
Insulating outer tube **5**	450 cycles
Handle **A**	20 cycles

- ► Prior to each use, inspect the product for: damage or surface changes to the insulation.
- ► Immediately sort out damaged or inoperative products and have them sent to Aesculap Technical Service, see Technical Service.
- ► Adjust the HF power output (and argon flow rate) to the intervention to be carried out. Take into account clinical experience or reference values.
- ► Select the lowest possible HF power output.
- ► Keep the product's contact surfaces clean during surgery. Remove encrusted tissue residues or body fluids with a moistened swab.

The product is furnished with the following connection on the plug side: Aesculap flat connector.

Refer to our brochures to find a compatible cable.

The accessory voltage rating of the product is 1 000 Vp.

The accessory voltage rating must exceed or match the peak output voltage with which the product is operated in combination with a suitable HF device at an appropriate operating mode/setting (see IEC/DIN EN 60601-2-2).

To avoid HF burns:

- ► Always keep the working end of the product in the user's field of vision whenever the HF power is activated.
- ► Prior to activating the HF device, check that the working end of the product is not touching any electrically conductive accessories.
- ► Prior to each use, visually inspect the product for: damage or surface changes to the insulation.
- ► Never place the product on or next to the patient.
- ► When using accessories for endoscopy or laparoscopy, deactivate the automatic switch-on mode of the HF device.
- ► Follow the instructions for use of the HF device.

Safe operation

From the health-and-safety perspective, bipolar is a better alternative than monopolar coagulation, because the current does not flow through the whole body, but only through a narrowly defined tissue region from one jaw piece/scissor blade to the other jaw piece/scissor blade.

Note

If both jaw pieces come into direct contact, coagulation cannot occur as the power source is short-circuited.

The coagulation will be particularly safe and effective if the tissue is grasped and appropriately compressed before the HF current is activated.

- ► Make certain the grasping surfaces are clean and metallic bright.

Mode of operation of the bipolar scissors

The most effective coagulation will be achieved by first compressing the tissue between the two scissor blades and then cutting slowly through the tissue while the HF current is activated.

The slower the cut, the larger the coagulation zone at the edge of the cut.

Note

*To ensure effective coagulation, make certain, e.g., by setting the scissor blades at various angles to the tissue, that the tissue cut by the metal-ceramic scissor blade is in contact with the metal part, see Fig. **2**.*

Grasping variants

The bipolar handle **A** can be operated either in the traditional ring grip hold or in the more ergonomic hand-embrace hold, see Fig. **7**.

Disassembling

Removing the pin protector

- ► Compress pin protector **7** and slide it off carefully towards the sheath, see Fig. **3**.

Releasing the handle A/sheath B connection

- ► Pull back rotating sleeve **3** in the direction of the arrow (towards the handle **A**) as far as it will go, see Fig. **4**.
- ► Hold the sleeve to the stop while simultaneously pulling out the sheath **B** with moveable ring **1** left loose, see Fig. **4**.

Disassembling the sheath B

- ► Slide off insulating outer tube **5**.
- ► Detach inner tube **6** from working insert **4**, see Fig. **1**.

Assembling

Assembling the sheath B

- ► Slide inner tube **6** onto working insert **4** until leaf springs **10** snap into position, see Fig. **5**.
- ► Slide insulating outer tube **5** over inner tube **6** with working insert **4** as far as it will go, see Fig. **5**.

Establishing the handle A/sheath B connection


CAUTION

Damage to handle A/sheath B or working insert due to incorrect handling!
- ► **When establishing the connection, do not hold the product at the insulating outer tube when pushing the sheath into the handle as, otherwise, the outer tube will be displaced.**
- ► **Do not hold or pull at the moveable ring since, by doing so, the ball end of the working insert could get bent.**

- ► Pull back rotating sleeve **3** in the direction of the handle **A** as far as it will go and hold it there, see Fig. **6**.
- ► Swivel moveable ring **1** towards distal. Grasp the sheath **B** at working insert **4** and slightly rotate and push it into handle **A** until the rotating sleeve **3** snaps towards distal, see Fig. **6**.

Attaching the pin protector

- ► Compress pin protector **7** and guide it carefully over the jaw pieces. Engage the pin protector in groove **11** of working insert **4**, see Fig. **8**.

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 up-to-date information about reprocessing and material compatibility, see also the Aesculap Extranet at https://extranet.bbraun.com.

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.

Disassembling the product before carrying out the reprocessing procedure

► Disassemble the product immediately after use, as described in the respective instructions for use.

► Open up instruments with hinges.

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.

Preparation before cleaning

► Dismantle the product prior to cleaning, see Disassembling.

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 approved for plastics and high-grade steel according to manufacturer's instructions.**

► **Observe specifications regarding concentration, temperature and exposure time.**

► **Do not exceed the maximum permitted cleaning temperature of 93 °C.**

Immersion treatment in a 3 % H_2O_2 solution for approx. 5 minutes is a particularly effective and gentle method to dissolve encrustations from HF instruments. The debris can be removed manually and/or with a medium-hard brush. This is followed by the conventional reprocessing steps.

► Use suitable cleaning/disinfecting agents if the product is put away in a wet condition. To prevent foam formation and reduced effectiveness of the process chemicals: Prior to mechanical cleaning and disinfection, rinse the product thoroughly with running water.

Validated cleaning and disinfection procedure

Validated procedure	Specific requirements	Reference
Manual cleaning with immersion disinfection	■ Cleaning brush, e.g., PM995R or GK469R ■ 20 ml disposable syringe ■ When cleaning instruments with movable hinges, ensure that these are in an open position and, if applicable, move the joint while cleaning. ■ Drying phase: Use a lint-free cloth or medical compressed air	Chapter Manual cleaning/disinfection and sub-chapter: ■ Chapter Manual cleaning with immersion disinfection
Manual pre-cleaning with brush and subsequent mechanical alkaline cleaning and thermal disinfection	■ Cleaning brush, e.g., PM995R or GK469R ■ 20 ml disposable syringe ■ Place the instrument in a tray that is suitable for cleaning (avoiding rinsing blind spots). ■ Connect components with lumens and channels directly to the rinsing port of the injector carriage. ■ Keep working ends open for cleaning. ■ Place instruments in the tray with their hinges open.	Chapter Mechanical cleaning/disinfection with manual pre-cleaning and sub-chapter: ■ Chapter Manual pre-cleaning with a brush ■ 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 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 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.

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.

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 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.

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.

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.
► Assemble dismountable products, see Assembling.
► Check for compatibility with associated products.

Packaging

► 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 can be sterilized either in disassembled or in assembled condition.

► 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 using 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.

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.

Accessories/Spare parts

The following parts can be ordered separately:
■ Handle **A**
■ Outer tube **5**
■ Inner tube **6**
■ Working inserts **4**
■ HF cable with Aesculap flat connector
For article numbers, please refer to the respective Aesculap brochure.

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.
3773 Corporate Parkway
Center Valley, PA, 18034,
USA

SOP-AIC-5001604 Rev. 1 06/16