Aesculap®
Bipolar coagulation forceps

Symbols on product and packages

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

Applicable to
- For item-specific instructions for use and information on material compatibility, see also the Aesculap Extranet at www.extranet.braun.com

Intended use
Bipolar coagulation forceps are used for hemostatic coagulation in surgical procedures.

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 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.

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.
- Adjust the HF power output to the intended surgical intervention. 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 accuracy voltage rating of the product is 600 Vp.

The accuracy 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 (see IEC/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

WARNING
- Risk of injury and/or malfunction
- Always carry out a function check prior to using the product.

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 assured if the processing method is first validated. The operator/sterilization 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.braun.com.

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

General information

Brult or eroded surgical residues can make cleaning more difficult or ineffective and lead to corrosion. Therefore the time interval between application and processing should not exceed 8 h. Gas or infrared sterilizing agents (e.g., ethylene oxide) should be used. Excessive measures of neutralizing agents or basic cleaners may result in a chemical attack of the decontamination facility, leading to corrosion of stainless steel components. 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., ETH or ETHF approval or CE mark) 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 of materials, e.g., fading or discoloration of titanium or aluminum. For aluminum, the application process solution only needs to be pH > 8 to cause visible surface changes.
- Material damage such as corrosion, erosion, fracture, 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-safe preserving reprocessing can be found at www.a-b-i-lang.de, link to Publications, Red Brochure – Proper maintenance of instruments.

Preparations at the place of use

- If applicable, rinse non-visible surfaces preferentially with deionized water, with a disposable sponge for example.
- Remove any visible surgical residues to the extent possible with a damp, lint-free cloth.
- Transport the product in a sealed container containing a desiccant and subjected to vacuum to reduce the formation of moisture.

Cleaning/disinfection

Product-specific safety notes on the reprocessing procedure

CAUTION
Use cleaning and disinfecting agents according to the manufacturer's instructions which:
- are approved for use on aluminum, plastic materials, and stainless steel for instance.
- do not attack softeners (e.g., in silicone).
- Observe specifications regarding concentration, temperature, and exposure time.

Immersion treatment in a 1.4 M NaOCl solution for approx. 8 min is a particularly effective and gentle method to dissolve encrustations from HF instruments. Subsequently, the debris can be removed by hand, with a medium-hard brush and/or in an ultrasonic bath. This is followed by the conventional reprocessing steps.

- 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

Validated cleaning and disinfection procedure

<table>
<thead>
<tr>
<th>Validated procedure</th>
<th>Specific requirements</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manual cleaning with ultrasound and immersion disinfection</td>
<td>20 mL disposable syringe, keep working ends open for cleaning, drying phase: use a lint-free cloth or medical compressed air</td>
<td>Chapter Manual cleaning with ultrasound and immersion disinfection</td>
</tr>
<tr>
<td>Manual pre-cleaning with ultrasound and brush, and subsequent mechanical alkaline cleaning and thermal disinfection</td>
<td>Place the instrument in a tray that is suitable for cleaning (avoiding nesting blind spots), keep working ends open for cleaning, place instruments in the tray with their hinges open</td>
<td>Chapter Manual pre-cleaning with ultrasound and brush, Chapter Mechanical alkaline cleaning and thermal disinfection</td>
</tr>
</tbody>
</table>

The validated steam sterilization procedure was carried out in the Aesculap sterile container system.
Manual cleaning/disinfection

- Prior to manual disinfecting, allow water to drip off for a sufficient length of time to prevent dilution of the disinfectant 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

<table>
<thead>
<tr>
<th>Phase</th>
<th>Step</th>
<th>T [°C/°F]</th>
<th>t [min]</th>
<th>Conc. [%]</th>
<th>Water quality</th>
<th>Chemical</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Ultrasound cleaning</td>
<td>RT (cold)</td>
<td>-15</td>
<td>2</td>
<td>D-W</td>
<td>Aldehyde-free, phenol-free, and QUAT-free concentrate, pH = 9*</td>
</tr>
<tr>
<td>II</td>
<td>Intermediate rinse</td>
<td>RT (cold)</td>
<td>1</td>
<td>-</td>
<td>D-W</td>
<td>-</td>
</tr>
<tr>
<td>III</td>
<td>Disinfection</td>
<td>RT (cold)</td>
<td>15</td>
<td>2</td>
<td>D-W</td>
<td>Aldehyde-free, phenol-free, and QUAT-free concentrate, pH = 9*</td>
</tr>
<tr>
<td>IV</td>
<td>Final rinse</td>
<td>RT (cold)</td>
<td>-</td>
<td>1</td>
<td>-</td>
<td>D-W</td>
</tr>
<tr>
<td>V</td>
<td>Drying</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

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

Note: The information on appropriate cleaning brushes and disposable syringes, see Validated cleaning and disinfection procedure.

### Mechanical alkaline cleaning and thermal disinfecting

#### Machine type: Single-chamber cleaning and disinfection device without ultrasonic

<table>
<thead>
<tr>
<th>Phase</th>
<th>Step</th>
<th>T [°C/°F]</th>
<th>t [min]</th>
<th>Water quality</th>
<th>Chemical</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Pre rinse</td>
<td>-25/77°F</td>
<td>3</td>
<td>D-W</td>
<td>-</td>
</tr>
<tr>
<td>II</td>
<td>Cleaning</td>
<td>55/131°F</td>
<td>10</td>
<td>FD-W</td>
<td>Concentrate, alkaline: pH = 13</td>
</tr>
<tr>
<td>III</td>
<td>Intermediate rinse</td>
<td>-10/50°F</td>
<td>1</td>
<td>-</td>
<td>FD-W</td>
</tr>
<tr>
<td>IV</td>
<td>Thermal disinfecting</td>
<td>90/194°F</td>
<td>5</td>
<td>FD-W</td>
<td>-</td>
</tr>
<tr>
<td>V</td>
<td>Drying</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

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

*Recommended: Bilusan Adhesive Cleaner alkaline

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

### Inspection, maintenance and checks

#### CAUTION

**Damage (metal scuffing/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: Aesculap STERILIT® I oil spray J56600 or STERILIT® I dry lubrication J56658).

- Allow the product to cool down to room temperature.
- After each 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.
- Reheat cleaning and disinfecting products that show impurities or contamination.
- Check that the product functions correctly.
- If products is damaged or inoperative, set aside immediately and send to Aesculap Technical Service, see Technical service.
- Check for compatibility with associated products.

### Packaging

- Appropriate quantity per package with appropriate marking.
- 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

- 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 (gassing time 6 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 advices against sterilizing the device by flash sterilization or chemical sterilization.
- Sterilization may be accomplished by a standard prewater cycle in a steam autoclave.
- To achieve a sterility assurance level (SAL) of 10⁻⁶, Aesculap recommends the following parameters:

#### Aesculap Orga Tray/Sterile container (perforated bottom)

<table>
<thead>
<tr>
<th>Sterilization method</th>
<th>Temp.</th>
<th>Time</th>
<th>Minimum drying time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prewater</td>
<td>270 °F (225 °C)</td>
<td>4 min</td>
<td>20 min</td>
</tr>
</tbody>
</table>

Aesculap has validated the above sterilization cycle and has the data on file. The validation was accomplished in an Aesculap sterile container cleaned 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 a FDA cleaned accessory to maintain sterility after processing, such as a wrap, pouch, etc.

**WARNING** for the US market

If this device (was) used in a patient with, or suspected of havingacutejudicial Disease (JUD), the device cannot be reused and must be destroyed due to the inability to reprocess or sterilize to eliminate the risk of crosscontamination.

### Storage

- Store sterile products in prewater 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
78552 Tuttlingen / Germany
Phone: +49 (7461) 95-1502
Fax: +49 (7461) 16-5621
E-Mail: std@aesculap.de

Or in the US:
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
3773 Corporate Parkway
Center Valley, PA, 18034,
USA
TA-Nr. 012932  11/12  V6  Änd.-Nr. 46258