**Aesculap®**

**Monopolar 3.5-mm hook electrode**

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### Legend

- **1** Hook electrode
- **2** Hexagon
- **3** Electrode handpiece

### Symbols on product and packages

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

### Intended use

The monopolar 3.5-mm hook electrode is used in combination with an electrode handle in endoscopic procedures. It serves to prepare, dissect and coagulate tissue by means of monopolar HF current.

### 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.
- Do not use products that are in open or damaged sterile packaging.
- To avoid damage to the working end: Carefully insert the plug end of the product into the driving sleeve (e.g. trocar).

### Disassembling

- Pull out hook electrode 1 from electrode handle 3.
- Fully insert hook electrode 1 with hexagon 2 in electrode handle 3.
- The anti-twist guard at hexagon 2 is now effective, see Fig. 2.

### 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 reprocesing 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.extranet.bbraun.com

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

### General information

Dry or atraumatic 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 fixing pre-cleaning temperatures >45 °C nor fixing disinfecting agents (active ingredient: aldehyde) 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, medics, saline solutions and in the service water used for cleaning, disinfection and sterilization will cause corrosion damage (fitting, 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 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 aluminium. For aluminium, 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-related preservation reprocessing can be found at www.a-a-lang.de, link to Publications, Red Book – 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.

### 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.
- Follow the instructions for use of the HF device.

### Preparation before cleaning

- Disassemble the product prior to cleaning, see Disassembling.

### Cleaning/disinfection

#### Product-specific safety notes on the reprocessing procedure

- **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:
    - be approved for plastic material and high-grade steel
    - Observe specifications regarding concentration, temperature and exposure time.
    - Do not exceed the maximum permitted cleaning temperature of 94 °C.

- **Immersion treatment in a 3% NaOCl solution for approx. 6 minutes 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.**

- 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

<table>
<thead>
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<th>Validated procedure</th>
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<td>Drying phase: Use a lint-free cloth or medical compressed air</td>
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<tr>
<td>Mechanical alkaline cleaning and thermal disinfection</td>
<td>Place the instrument in a tray that is suitable for cleaning (avoiding rinsing blind spots)</td>
<td>Chapter Mechanical alkaline cleaning and thermal disinfection and sub-chapter:</td>
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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
<table>
<thead>
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<tr>
<td>I</td>
<td>Disinfecting cleaning</td>
<td>RT (cold)</td>
<td>&gt;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>
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<td>1</td>
<td>-</td>
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<td>-</td>
</tr>
<tr>
<td>V</td>
<td>Drying</td>
<td>RT</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
- RT: Room temperature

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

Rinse/flush the product thoroughly (all accessible surfaces).

Check visible surfaces for residues after mechanical cleaning/disinfecting.

**Mechanical cleaning/discharging**

- Thoroughly rinse through these components with the cleaning disinfectant solution (at least five times), using a disposable syringe.

**Effective cleaning and disinfection**

- Give the product the drying phase with suitable equipment (e.g., cloth, compressed air), see Validated cleaning and disinfection procedure.

**Mechanical alkaline cleaning and thermal disinfecting**

| Phase | Step | T [°C/°F] | t [min] | Conc. [%] | Water quality | Chemical/Note
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>I</td>
<td>Prerinse</td>
<td>&lt;25/77</td>
<td>3</td>
<td>-</td>
<td>D–W</td>
<td>-</td>
</tr>
</tbody>
</table>
| 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 |

**Steam sterilization**

- Note: The product may only be sterilized when dismantled.

- 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 205 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.

**FDA cleared accessory to maintain sterility during processing**

- 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.

**Accessories/Spare parts**


**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

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