Aesculap Surgical Instruments

Instructions for use/Technical description

Reusable electrode handles (monopolar)
Reusable electrode handles (monopolar)

Symbols on product and packages

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>⚠</td>
<td>Caution: See documentation supplied with the product</td>
</tr>
<tr>
<td>NON STERILE</td>
<td>The product ships in unsterile condition</td>
</tr>
</tbody>
</table>

Handle shapes

- Fig. 1 Narrow electrode handle without activation keys
- Fig. 2 Wide electrode handle with activation keys
- Fig. 3 Narrow electrode handle with activation keys

Intended use

The reusable electrode handles (monopolar), which are fitted with a fixed cable, are used in open surgical procedures.

The reusable electrode handles (monopolar) are used to conduct the required HF current from the HF device to the operating site, to hold the required working electrode and, if applicable, to activate the cutting or coagulating current from the HF device (handles with activation keys).

Product variants

The reusable electrode handles (monopolar) are available with various handle shapes and connectors and in different sizes (not all combinations available).

<table>
<thead>
<tr>
<th>Designation</th>
<th>Illustration</th>
</tr>
</thead>
<tbody>
<tr>
<td>3-pin plug (e.g. for Aesculap GN300 and GN640 or Valleylab devices)</td>
<td><img src="image1" alt="3-pin plug" /></td>
</tr>
<tr>
<td>Coax plug (e.g. for Aesculap GN300 and GN640)</td>
<td><img src="image2" alt="Coax plug" /></td>
</tr>
<tr>
<td>Metal plug (e.g. for Aesculap GK160, GK170 or GK450)</td>
<td><img src="image3" alt="Metal plug" /></td>
</tr>
<tr>
<td>5-mm ERBE plug (e.g. for ERBE ICC generators)</td>
<td><img src="image4" alt="5-mm ERBE plug" /></td>
</tr>
<tr>
<td>8-mm plug (e.g. for Valleylab units)</td>
<td><img src="image5" alt="8-mm plug" /></td>
</tr>
</tbody>
</table>
Electrode holders

Fig. 4 Hexagon anti-twist guard
The electrode holders are fitted with a hexagon anti-twist guard. The electrode handles can hold electrodes of the following diameters (depending on variant):

- 1.6 mm
- 1.7 mm
- 2.4 mm
- 4.0 mm

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 thoroughly clean the new product, either by hand or by a mechanical process, 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.

- To avoid damage to the working end: Exercise caution when passing products through the working channel (e.g. trocar).
- Disconnect the plug connection only by pulling at the plug.

**WARNING**
Danger of injury from burns and/or explosion from flammable gases!
Application of the HF device according to its intended use can involve spark formation.
- Observe the safety notices in the instructions for use of the HF device.

**WARNING**
Thermal injuries to patients/users due to insufficient insulation of leads to active accessories
- Adjust the HF device to a setting appropriate to ensure that the maximum peak output voltage does not exceed the maximum peak voltage rating specified for the product.
- Adjust the HF power output to the intended operation. Take into account clinical experience or reference values.
- Select the lowest possible HF power output.
- Keep the product’s contact surfaces clean during the operation. Wipe off encrusted tissue residues or body fluids, using a moistened swab.

The plug end of the product is fitted with the following connector: see Product variants.

The rated accessory voltage of the product is 6 000 Vp.
Reusable electrode handles (monopolar)

The rated accessory voltage must be larger than, or equal to, the maximum peak output voltage at which the product is operated in combination with an appropriate HF device at an appropriate operating mode/setting (see IEC 60601-2-2).

To avoid HF burns:
- Guide the handle cable to the operating site in such a way that it is not in contact with the patient or with other leads.
- The product’s working tip must be in the user’s field of vision whenever HF power is activated.
- Prior to activating the HF device, make certain that the working end of the product is not touching any electrically conductive accessories.
- Prior to each use, visually check the product for: damage to, or surface changes on, the insulation.
- Never put down the product on or near to the patient.
- Follow the instructions for use of the HF device.

Safe operation

- Risk of injury and/or malfunction!
  - Always carry out a function check before using the product.

- Risk of injury when applying the product outside the field of view!
  - Apply the product only under visual control.

Connecting the working electrode

Fig. 5 Inserting the working electrode in the handle
- Insert the working electrode in the handle so that the hexagon anti-twist guard is effective.
Connecting the handle at the HF device

![Diagram of handle connection](image)

1. Insert the plug in the appropriate monopolar output socket of the HF device.

**Activate HF**

- When using a handle with activation keys, the HF output can be activated by pressing the keys.
  - Press the yellow key: activation of the "Cutting" operating mode.
  - Press the blue key: activation of the "Coagulating" operating mode.

**Validated processing procedure**

**Note**

Adhere to national statutory regulations, 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 the products.

**Note**

Mechanical processing should be preferred over manual cleaning because of the better and more reliable cleaning results of mechanical processing.

**Note**

Successful processing of this medical product can only be ensured if processing is performed through a validated processing procedure. The user/processor is responsible for the validation.

Due to process tolerances, the manufacturer’s specifications can only serve as an approximate guide for assessing the processing procedures applied by the individual operator/processors.

**Note**

Up-to-date information on processing can be found on the Aesculap Extranet at [www.aesculap-extra.net](http://www.aesculap-extra.net)

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**Fig. 6** e.g. inserting the coax plug in the monopolar output socket (GN640)

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Note

- For correct functioning of the HF device, configure the device for handle activation according to the instructions for use of the HF device.

When using a handle without keys, the HF output of the HF device is controlled by a foot switch connected to the HF device.
Reusable electrode handles (monopolar)

General notes
To avoid unnecessary, excessive contamination of the complete instrument tray during operations, take care that contaminated instruments are collected separately and not put back into the instrument tray. Encrusted or fixed residues from surgery can make the cleaning process more difficult or ineffective, and can cause corrosion of stainless steels. To avoid this, the time interval between application and processing should not exceed 2 h, and neither fixating pre-cleaning temperatures >45 °C nor any fixating disinfecting agents (active ingredient: aldehyde, alcohol) be used. Excessive doses of neutralizers or basic detergents can cause chemical degradation and/or fading and obliteration of laser inscriptions on stainless steel surfaces, regarding visual reading and machine-readability of the inscriptions. 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. To remove such residues, the products must be rinsed sufficiently with fully desalinated water and dried thoroughly. Only process chemicals that have been tested and approved (e.g. VAH/DGWH 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 process parameters specified by the chemical’s manufacturer, such as temperatures, concentrations and exposure times, must be strictly observed. Failure to do so can result in the following problems:

- Optical deterioration, e.g. fading or discoloration of titanium or aluminum surfaces.
- Material damage, e.g. corrosion, cracks, fracturing, premature aging or swelling.
- Do not use process chemicals that cause stress cracking or brittleness of plastics.

Preparations at the place of use

- Clean the product immediately after use. Encrustations on HF instruments are broken up most gently and effectively by immersing the product in fluid for approx. 5 minutes. The debris can be removed manually with a medium-hard brush. After this pre-treatment, continue through the normal steps of the processing procedure.
- Do not clean the product in an ultrasound bath.
- Further detailed advice on hygienically safe and material-value-preserving reprocessing can be found at www.a-k-l.org, Publications Red Brochure – Proper maintenance of instruments.
- Use suitable cleaning/disinfecting agents if the product is put away in wet condition. To prevent foam formation and reduced effectiveness of the process chemicals: Prior to mechanical cleaning and disinfecting, rinse the product thoroughly with running water.

- Remove the working electrodes from the handle.
- Rinse surfaces inaccessible to visual inspection, e.g. on products with hidden crevices or lumens or products with complex geometries, preferably with distilled water, using e.g. a disposable syringe.
- Remove visible surgical residues as completely as possible, using a lint-free wet wipe.
- Put the wet product into a closed disposal container and have it transferred to cleaning and disinfecting within 2 h.
Cleaning/Disinfecting

⚠️ CAUTION

- Use a cleaning and disinfecting agent according to the manufacturer's instructions. The cleaning and disinfecting agent must be approved for the product materials (e.g. aluminum, plastics, high-grade steel).
- Must not attack softeners (e.g. silicone).
- Do not exceed the maximum allowable cleaning temperature of 93 °C.

Mechanical cleaning/disinfecting

Note
The disinfecter must be of tested and approved effectiveness (e.g. DGHM or FDA approval or CE mark according to DIN EN ISO 15883).

Note
For thermal disinfection, always use fully desalinated (demineralized) water. Ensure that Ao is >3 000 for the process.

Note
The disinfecter used for processing must be serviced and checked at regular intervals.

➢ Place the product on a tray that is suitable for cleaning (avoid rinsing blind spots).
## Reusable electrode handles (monopolar)

### Mechanical alkaline cleaning and thermal disinfecting

*Machine type: Single-chamber washer/dispenser without ultrasound*

<table>
<thead>
<tr>
<th>Stage</th>
<th>Step</th>
<th>T [^{°C/°F}]</th>
<th>t [min]</th>
<th>Water quality</th>
<th>Chemical/Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Prerinse</td>
<td>&lt;25/77</td>
<td>3</td>
<td>D-W</td>
<td>-</td>
</tr>
<tr>
<td>II</td>
<td>Cleaning</td>
<td>55/131</td>
<td>10</td>
<td>FD-W</td>
<td>neodisher® mediclean forte with neodisher® mediklar</td>
</tr>
<tr>
<td>III</td>
<td>Intermediate rinse</td>
<td>&gt;10/50</td>
<td>1</td>
<td>FD-W</td>
<td>-</td>
</tr>
<tr>
<td>IV</td>
<td>Thermal disinfecting</td>
<td>90/194</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>according to disinfecting program</td>
</tr>
</tbody>
</table>

D-W: Drinking water  
FD-W: Fully deionized water (deionized)
Inspection, maintenance and checks

- Allow the product to cool down to room temperature.
- After each complete cleaning, disinfecting and drying cycle, check that the product 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 moist.
- Repeat cleaning and disinfecting of products that still show impurities or contamination.
- Check the product for proper functioning.
- Immediately sort out damaged or inoperative products and have them sent to Aesculap Technical Service, see Technical Service.
- Check for compatibility with associated products.

Sterilization method and parameters

- Make certain that all external and internal surfaces will be exposed to the sterilizing agent (e.g. by opening all 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 through fractionated vacuum process at 134 °C (holding time 5 min)
- When sterilizing several products at the same time in one steam sterilizer: Make certain that the maximum allowable load capacity of the steam sterilizer, as specified by the manufacturer, is not exceeded.

Packaging

- Sort the product into its appropriate storage device or put it on a suitable tray.
- Package trays appropriately for the sterilization process (e.g. in Aesculap sterile containers).
- Ensure that the packaging provides sufficient protection against recontamination of the product during storage (DIN EN ISO 11607).
Reusable electrode handles (monopolar)

Sterilization for the US market
- Aesculap does not recommend the device sterilized by flash or chemical sterilization.
- Sterilization may be accomplished by steam autoclave in a standard prevacuum cycle.
To achieve a sterility assurance level of $10^{-6}$, Aesculap recommends the following parameters:

<table>
<thead>
<tr>
<th>Sterilization method</th>
<th>Temp.</th>
<th>Time</th>
<th>Minimum drying time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-vacuum</td>
<td>132 °F—270 °F</td>
<td>5 min</td>
<td>20 min</td>
</tr>
</tbody>
</table>

*Risk of injury and/or malfunction!*
- Do not modify the product.

**WARNING**
- 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
  78532 Tuttingen / Germany
  Phone: +49 7461 95-1602
  Fax: +49 7461 16-5621
  E-Mail: ats@aesculap.de

- Aesculap Repair Hotline
  Phone: +1 800 214-3382
  Fax: +1 314 895-4420

Other service addresses can be obtained from the address indicated above.
Accessories/Spare parts

Note
Information about accessories and spare/replacement parts can be found in Aesculap brochure C-304-81.

Disposal

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

Always adhere to national regulations when disposing of or recycling the product or its components!

The recycling pass can be downloaded from the Extranet as a PDF document under the respective article number. (The recycling pass contains disassembling instructions for the product, as well as information for proper disposal of components that could be harmful to the environment.) Any product carrying this symbol must be disposed of separately through dedicated electrical and electronic devices recycling. Within the EU, such disposal is taken care of by the manufacturer free of charge.

In case of any questions concerning the disposal of the product, please contact your national B. Braun/Aesculap agency, see Technical Service.

Distributor in the US/Contact in Canada for product information and complaints
Aesculap Inc.
3773 Corporate Parkway
Center Valley, PA 18034
USA

Technical specifications

Classification acc. to Directive 93/42/EEC

<table>
<thead>
<tr>
<th>Designation</th>
<th>Class</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reusable electrode handles (monopolar) without keys</td>
<td>IIa</td>
</tr>
<tr>
<td>Reusable electrode handles (monopolar) with keys</td>
<td>IIb</td>
</tr>
</tbody>
</table>

Ambient conditions

Storage and transport conditions

<table>
<thead>
<tr>
<th>Relative humidity</th>
<th>0 % to 75 %, no condensation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ambient temperature</td>
<td>-20 °C to +50 °C</td>
</tr>
<tr>
<td>Atmospheric pressure</td>
<td>500 hPa to 1 600 hPa</td>
</tr>
<tr>
<td>Direct sunlight</td>
<td>Protect against direct sunlight</td>
</tr>
<tr>
<td>Conforming to standard</td>
<td>IEC/DIN EN 60601-2-2</td>
</tr>
</tbody>
</table>