Instructions for use/Technical description

YASARGIL aneurysm clip removal forceps
Aesculap®
YASARGIL aneurysm clip removal forceps

Legend
1. Jaw part
2. Branches left/right
3. Clip removal forceps

Symbols on product and packages

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

Intended use
Aesculap YASARGIL aneurysm clip removal forceps are used to remove Aesculap YASARGIL titanium aneurysm clips in neurosurgical procedures.

⚠️ The removal forceps are MR Unsafe.

Note
In the following, the Aesculap YASARGIL aneurysm clips will be referred to simply as “clips”.

Available sizes
Detailed information on available sizes can be found in the main Neurosurgery Catalog and in the YASARGIL Aneurysm Clips brochures.
All removal forceps are marked according to size (Mini or Standard) and clip material (titanium) so that their correct application with clips of the appropriate size and material is ensured.

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.
Safe operation

Damage, imprecise function and incorrect closing force of the clips due to incorrect choice of removal forceps!
- Only use Aesculap clip removal forceps.
- Use clips only with the appropriate Aesculap clip removal forceps (see labels).

- Use the clip removal forceps only in the following combinations:
  - Titanium Standard clips with the clip removal forceps for titanium Standard clips
  - Titanium Mini clips with the clip removal forceps for titanium Mini clips
- Adapt the applied clip in jaw piece 1.
- Actuate branches left/right 2.
- Take clip removal forceps 3 with the clip out of the operating field.

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
Since no reprocessing methods have been validated for removal of transmissible spongiform encephalopathy (TSE) agents from medical devices, this device should not be used for patients with known or suspected TSE agent disease, including CJD and vCJD.

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 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

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 fixing pre-cleaning temperatures >45 °C nor fixing 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-pH-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

- Open up products 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.

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 are approved for use, for example, on aluminum, plastic materials, and high-grade steel.
- Do not attack softeners (e.g., in silicone).
- Observe specifications regarding concentration, temperature and exposure time.
- Do not exceed the maximum permitted cleaning temperature of 55 °C.

- 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.

- Clean and disinfect microsurgical products mechanically if they can be placed securely in the machine or on the positioning aids.

Validated cleaning and disinfection procedure

<table>
<thead>
<tr>
<th>Validated procedure</th>
<th>Specific requirements</th>
<th>Reference</th>
</tr>
</thead>
</table>
| Manual cleaning with immersion disinfection | Cleaning brush  
20 ml disposable syringe  
When cleaning products 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 |
| Mechanical alkaline cleaning and thermal disinfection | Cleaning brush  
Place the product in a tray that is suitable for cleaning (avoiding rinsing blind spots).  
Place products in the tray with their hinges open. | Chapter Mechanical cleaning/disinfecting and sub-chapter:  
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

<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>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&quot;</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&quot;</td>
</tr>
<tr>
<td>IV</td>
<td>Final rinse</td>
<td>RT (cold)</td>
<td>1</td>
<td>-</td>
<td>FD-W</td>
<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 at least)
RT: Room temperature
*Recommended: B Braun Stabilmed

- 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/disinfecting

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.

Mechanical alkaline cleaning and thermal disinfecting
Machine type: single-chamber cleaning/disinfection device without ultrasound

<table>
<thead>
<tr>
<th>Phase</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>
</tbody>
</table>
| II    | Cleaning        | 55/131    | 10      | FD–W          | - Concentrate, alkaline:  
  - pH = 13  
  - <5% anionic surfactant  
  - 0.5% working solution  
  - pH = 11* |
| III   | Intermediate    | >10/50    | 1       | FD–W          | -                                                  |
|       | rinse           |           |         |               |                                                    |
| IV    | Thermal         | 90/194    | 5       | FD–W          | -                                                  |
|       | disinfecting    |           |         |               |                                                    |
| V     | Drying          | -         | -       | -             | According to the program for cleaning and disinfection device |

D–W: Drinking water
FD–W: Fully desalinated water (deionized, 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 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 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.
▶ Check for compatibility with associated products.

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 all cutting edges are protected.
▶ Pack trays appropriately for the intended sterilization process (e.g. in Aesculap sterile 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 using fractional vacuum process
  – Steam sterilizer according to DIN EN 285 and validated according to DIN EN ISO 17665
  – Sterilization using fractional vacuum process at 134 ºC; holding time 5 min
▶ When sterilizing several products 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:

<table>
<thead>
<tr>
<th>Sterilization method</th>
<th>Temp.</th>
<th>Time</th>
<th>Minimum drying time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevacuum</td>
<td>270 °F/275 °F</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 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.

**WARNING** for the US market
If this device is/was used in a patient with, or suspected of having Creutzfeldt-Jakob Disease (CJD), the device cannot be reused and must be destroyed due to the inability to reprocess or sterilize to eliminate the risk of cross-contamination.

**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.

**Service addresses**

Aesculap Technischer Service
Am Aesculap-Platz
78532 Tuttlingen / Germany
Phone: +49 (7461) 95-1602
Fax: +49 (7461) 16-5621
E-Mail: ats@aeculap.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. 013147   11/12   V6   Änd.-Nr. 45598

TA013147-US Rev. 03   09/14