Disassembling

- Slide the safety lock switch 5 in the direction of the arrow.
- Grasp the front of the magazine 4 and rotate the magazine in the direction of the arrow against the safety lock switch 5, see Fig. 3.
- Slide the safety lock switch 5 towards the magazine 4. When doing this, make certain that you do not press the trigger 1.

The magazine snaps into place and is now mounted.

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
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.

Single-use products

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

Reprocessable products

General information

Dried or adhered 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 foaming pre-cleaning temperature >45 °C nor fixing disinfecting agents (active ingredient: aldehydes/alcohols) should be used.

Efficient 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 (etching, 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/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:

- Chemical changes of materials, e.g. fading or discoloration of titanium or aluminium.
- Uncontrolled vapor release in the sterilizer due to reprocessing failure.

- 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 material damage such as corrosion, cracks, fracturing, premature aging or swelling.
- Further detailed advise on hygienically safe and material-value-preserving reprocessing can be found at www.a-k-lang.de, 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.

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

- Risk to patients!
  - The product must only be cleaned mechanically!
**Validated cleaning and disinfection procedure**

For mechanical cleaning:

- Use appropriate (neutral, enzymatic and mild-alkaline) detergents on this product with its aluminum components.

**Mechanical cleaning/disinfection with manual pre-cleaning**

Note

The cleaning and disinfection device must be of tested quality (e.g. in accordance with DIN EN ISO 15883).

**Manual pre-cleaning with a brush**

<table>
<thead>
<tr>
<th>Phase</th>
<th>Step</th>
<th>T [°C]</th>
<th>t [min]</th>
<th>Conc. [%]</th>
<th>Water quality</th>
<th>Chemical</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Disinfec-tant cleaning</td>
<td>RT (cold)</td>
<td>&gt;15</td>
<td>2</td>
<td>D–W</td>
<td>Aldohexyde-free, phenol-free, and QUAT-free concentrate, pH ~ 9</td>
</tr>
</tbody>
</table>

**II Rinsing**

<table>
<thead>
<tr>
<th>Phase</th>
<th>Step</th>
<th>T [°C]</th>
<th>t [min]</th>
<th>Conc. [%]</th>
<th>Water quality</th>
<th>Chemical</th>
</tr>
</thead>
<tbody>
<tr>
<td>II</td>
<td>Rinsing</td>
<td>RT (cold)</td>
<td>1</td>
<td>-</td>
<td>D–W</td>
<td>-</td>
</tr>
</tbody>
</table>

**Sterilization for the US market**

- Aesculap advises against sterilizing the device by flask 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>Aesculap Orga Tray/Sterelet container (perforated bottom)</th>
<th>Minimum cycle parameters*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterilization method</td>
<td>Temp.</td>
</tr>
<tr>
<td>Prevacuum</td>
<td>270 °F/275 °F</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 an FDA cleared accessory to maintain sterility after processing, such as a wrap, pouch, etc.

**Steam sterilization**

- Check to ensure that the sterilizing agent will come into contact with all external and internal surfaces (e.g. by moistening).
- Connect components with lumens and channels directly to the special injector carriage attachment.
- Store any products with hinges or joints on the tray in such a way that the joints are kept open.

- Do not use oxidizing chemicals (e.g. H₂O₂), which could cause bleaching/layer loss of the product.
- 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.

**Mechanical neutral or mild alkaline cleaning and thermal disinfecting**

Machine type: single-chamber cleaning/disinfecting device without ultrasound

<table>
<thead>
<tr>
<th>Phase</th>
<th>Step</th>
<th>T [°C]</th>
<th>t [min]</th>
<th>Water quality</th>
<th>Chemical</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Precious</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>Neutral:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- pH neutral</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- ≤5% anionic surfactant</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.5% w/w working solution</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Mildly alkaline:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- pH = 9.5</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- ≥5% anionic surfactant</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.5% solution</td>
</tr>
<tr>
<td>III</td>
<td>Intermediate rinse</td>
<td>&gt;1050</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>-</td>
</tr>
</tbody>
</table>

**Inspection, maintenance and checks**

- Check visible surfaces for residues after mechanical cleaning/disinfecting.
- Repeat the cleaning/disinfecting process if necessary.

**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. 010579
11/12
V6
And.-Nr. 45838