Aesculap Orthopaedics

GB USA Instructions for use/Technical description
Orthopedic and traumatology instrument sets

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Aesculap – a B. Braun company
TA-Nr. 013850 10/13 V6 Änd.-Nr. 47145

GB USA

Aesculap Orthopedic and traumatology instrument sets

Symbols on product and packages

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

Scope
These instructions for use apply to instruments with lumens or indentations, as well as collapsible instruments that are composed entirely or in part of sensitive materials (e.g. aluminium or POM).

Intended use
The orthopedic/trumatology instrument set is used in orthopedic or trauma surgery, e.g. for procedures involving implantations of endoprostheses or fracture implants.

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

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 ensured if the processing method is first validated. The operating medical processing technician is responsible for this.

The recommended chemistry was used for validation.

Note
If there is no 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 afflued surgical residues can make cleaning more difficult and ineffective and lead to corrosion. Therefore the time interval between application and processing should not exceed 6 h. Also, neither freezing nor pre-cleaning temperatures above 45°C nor fixation of dissecting agents (active ingredient: alcoholdehyde/alkohol) should be used.

Excessive measures of neutralizing agents or basic cleaners may result in a chemical attack and to foaming and the laser marking becoming unrecognizable. Thus, machines 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 cleaning thoroughly with demineralized water and then drying.

Additional drying, if necessary.

Only those chemicals that have been tested and approved (e.g. VAW 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 5.5 to 8.5 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-specific-preparing reprocessing can be found at www.a-k-long.it, link to Publications, Red Brochure – Proper maintenance of instruments.

Preparations at the place of use

- If applicable, rinse non-visible surfaces preferably with demineralized 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

![CAUTION]

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, e.g. 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 90°C.
- 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.
- Mount jaws protection on the product.

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 immersion disinfection</td>
<td>Suitable cleaning brush</td>
<td>Chapter Manual cleaning/disinfection and sub-chapter:</td>
</tr>
<tr>
<td></td>
<td>20 ml disposable syringe</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Drying phase: Use a lint-free cloth or medical compressed air</td>
<td></td>
</tr>
</tbody>
</table>

| Manual pre-cleaning with brush and subsequent mechanical neutral or mild alkaline cleaning and thermal disinfection | Suitable cleaning brush | Chapter Mechanical cleaning/disinfection with manual pre-cleaning and sub-chapter: |
| | 20 ml disposable syringe | | |
| | Place the instrument in a tray that is suitable for cleaning (avoiding rinsing blind spots) | | |
| | Connect components with laminae and channels directly to the rinsing port of the injector carriage | | |
| | | | |

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/E]</th>
<th>t [min]</th>
<th>Conc. [%]</th>
<th>Water</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-VI</td>
<td>Alcohol-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-VI</td>
<td>-</td>
</tr>
<tr>
<td>III</td>
<td>Disinfection</td>
<td>RT (cold)</td>
<td>15</td>
<td>2</td>
<td>D-VI</td>
<td>Alcohol-free, phenol-free, and QUAT-free concentrate, pH ~ 9</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
D-I: Fully demineralized water (deionized, 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 wetted.
- 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, joints, 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 elements 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 elements 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/disinfection with manual pre-cleaning

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 14988).

Note
The cleaning and disinfection device used for processing must be serviced and checked at regular intervals.

Manual pre-cleaning with a brush

<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>Disinfectant cleaning</td>
<td>RT (cold)</td>
<td>&gt;15</td>
<td>2</td>
<td>D-W</td>
<td>Alcohol-free, phenol-free, and QUAT-free concentrate, pH = 9*</td>
</tr>
<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>

D-W: Drinking water
RT: Room temperature
*Recommended: B.Braun Stabilized

▼ 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 maintained.
► Clean the product with a suitable cleaning brush in the solution until all discernible residues have been removed from the surfaces.
► 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
► Rinsing: Thoroughly (all accessible surfaces) under running water.
► Mobilize non-rigid components, such as set screws, joints etc. during rinsing.

Mechanical neutral or mild 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</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Pre-rinse</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>Concentrate:</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>- &lt;5% amionic surfactant</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.5% 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>Concentrate:</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>- &lt;5% amionic 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;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 the program for cleaning and disinfection device</td>
</tr>
</tbody>
</table>

D-W: Drinking water
FD-W: Fully demineralized water (demineralized, low microbiological contamination; drinking water quality at least)
*Recommended: B.Braun Helimatic Cleaner neutral

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

Inspection, maintenance and checks
► Allow the product to cool down to room temperature.
► After each complete cleaning, disinfecting and drying cycle, check that the instrument is dry, clean, aporaphial, 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 non-operating products and send them to Aesculap Technical Service, see Technical Service.
► Check for compatibility with associated products.

Packaging
► 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 using fractionated vacuum process
  - Steam sterilizer according to DIN EN 285 and validated according to DIN EN ISO 17665
  - Sterilization using fractionated vacuum process at 124 °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.

Sterilization for the US market
► Aesculap advises against sterilizing the device by flash sterilization or chemical sterilization.
► Sterilization may be accomplished by a standard precycle vacuum 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/Sterile container (perforated bottom)</th>
<th>Minimum cycle parameters*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterilization method</td>
<td>Temp.</td>
</tr>
<tr>
<td>Pre-vacuum</td>
<td>270 °F/135 °C</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.

Storage
► Store sterile products in germ-proof packaging, protected from dust, in a dry, dark, temperature-controlled area.

Technical Service

⚠️ WARNING
► 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@aesculap.de
Or in the US:
Aesculap Implant Systems LLC
Attn: Aesculap Technical Services
615 Lambert Pointe Drive
Hazelwood
MO, 63042
Aesculap Repair Hotline
Phone: +1 (314) 214-3392
Fax: +1 (314) 995-4420
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
Aesculap Implant Systems LLC
3773 Corporate Parkway
Center Valley, PA, 18034,
USA

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