Tubular shaft instruments

Legend
1. Star wheel
2. Handle
3. Button
4. Movable handle part
5. Shaft, complete (outer tube, inner tube, working insert)
6. Jaw part
7. Working insert
8. Leaf springs
9. Inner tube
10. Outer tube
11. Spring elements [tactile feedback]

Symbols on product and packages

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>!</td>
<td>Caution, general warning symbol</td>
</tr>
<tr>
<td></td>
<td>Caution, see documentation supplied with the product</td>
</tr>
</tbody>
</table>

Intended use
Dismountable tubular shaft instruments are used for cutting, dissection, grasping, or biopsy, with different working tips for each intended use. They are introduced into the body by means of access instruments (e.g. trocar).

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 for its intended purpose, see intended use.

- Remove the transport packaging and thoroughly 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.
- To avoid damage to the working tip: Exercise caution when passing products through the working channel (e.g. trocar).
- If using in combination with a HF instrument within a trocar, insert the tubular shaft instrument first, where possible, to prevent compromising the HF insulation. When removing the instruments, remove the HF instrument first, if possible.

Safe operation

WARNING
Risk of injury and/or malfunction!

- Always carry out a function check prior to using the product.

WARNING
Risk of injury when using the product beyond the field of view!

- Apply the product only under visual control.

Note:
The spring elements give the user some tactile feedback just before the instrument emerges from trocar FF399R into the operating site. The functionality of this tactile feedback mechanism is only ensured when using the product with trocar FF399R.
Disassembly
The tubular shaft instruments are disassembled into the following components:
- Handle 2
- Outer tube 10
- Inner tube 9
- Working insert 7

Fig. 1
➢ To separate handle 2 and working insert 7, see Fig. 1:
  - Fully open moveable handle part 4.
  - Push and hold down button 3.
  - At the same time, pull down moveable handle part 4.

Fig. 2
➢ Separate shaft 5 from handle 2, see Fig. 2:
  - Pull back star wheel 1 towards handle 2 to the positive stop.
  - Hold star wheel 1 at its positive stop and extract shaft 5.

Fig. 3
➢ To disassemble shaft 5, see Fig. 3:
  - Remove the outer tube 10 and the inner tube 9 from the working insert 7.
  - Remove inner tube 9 from working insert 7, see Fig. 4.
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Assembly

➢ To assemble shaft 5, see Fig. 5:
  - Slide inner tube 9 with leaf springs 8 towards the working tip onto working insert 7 until leaf springs 8 engage.
  - Slide outer tube 10 over inner tube 9 onto working insert 7 as far as it will go, see Fig. 6.

➢ To connect shaft 5 and handle 2:
  - Ensure that outer tube 10 is pushed over inner tube 9 with working insert 7 to the positive stop, see Fig. 7.
  - Slide back and hold star wheel 1 at its positive stop, see Fig. 8.
  - Hold the shaft 5 at its closed working tip.
  - Slightly turn shaft 5 and handle 2 during insertion until they connect to each other.
  - Allow star wheel 1 to slide forward, see Fig. 9.
  - Ensure that shaft 5 is securely locked in handle 2 and cannot be removed even by pulling.
Validated reprocessing procedure

**Note**

National laws, national and international standards and directives, and product-specific hygiene regulations for reprocessing must be observed.

**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**

It should be noted that successful reprocessing of this medical device can only be guaranteed following prior validation of the reprocessing method. The operator/sterile processing technician is responsible for this.

**Note**

Up-to-date information on reprocessing can be found on the Aesculap Extranet at www.aesculap-extra.net

**General information**

To prevent increased contamination of loaded instrument trays during use, please ensure that contaminated instruments are collected separately and not returned to the instrument tray.

Dried or affixed surgical residues can make cleaning more difficult or ineffective and lead to corrosion of stainless steel. Consequently, the time interval between application and processing should not exceed 6 hours, pre-cleaning fixing temperatures >45 °C should not be used, and no fixing disinfectants (containing 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 chloride – e.g. in surgical residues, drugs, saline solutions and water for cleaning, disinfection and sterilization – may cause corrosion damage to stainless steel (pinholing, stress corrosion), thus rendering the products unusable. These must be removed by rinsing thoroughly with demineralized water and then drying.

Only use process chemicals that have been tested and approved (with VAH, DGHM or FDA approval, for instance, or a CE mark) and are recommended by the chemical manufacturer as being compatible with the materials. All the chemical manufacturer's application specifications regarding temperature, concentration and contact time should be strictly observed. Failure to do so can result in the following problems:

- Visible changes to materials e.g. fading or changes in the color of titanium or aluminum. As regards aluminum, visible changes to the surface may already occur at a pH level of >8 in the application/working solution.
- Material damage such as corrosion, cracks, fractures, premature deterioration or swelling.
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- Do not use oxidizing chemicals (e.g. H₂O₂) for mechanical cleaning, as these can cause bleaching or layer loss.
- Do not use process chemicals that cause stress cracks or brittleness in plastics.
- Clean the product immediately after use.
- Please see www.a-k-l.org for more detailed information on hygienically safe reprocessing which is protective of materials and retains their value.
- Use appropriate 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 disinfection, rinse the product thoroughly with running water.

Preparations at the place of use

- Disassemble the product immediately after use, as described in the respective instructions for use.
- Open up instruments with hinges.
- Rinse non-visible surfaces such as those in instruments with concealed crevices, lumens or complex geometries, preferably with distilled water, using a disposable syringe for instance.
- 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

- Disassemble the product prior to cleaning, see Disassembly.

Cleaning/disinfection

- Damage to the product due to inappropriate cleaning/disinfecting agents and/or excessive temperatures!
- Use cleaning and disinfecting agents approved for aluminum, plastics, and high-grade steel, for example, according to the manufacturer's instructions.
- Observe specifications regarding concentration, temperature and exposure time.

- Carry out ultrasound cleaning:
  - as an effective mechanical supplement to manual cleaning/disinfection.
  - as a pre-cleaning procedure for products with encrusted residues, in preparation for mechanical cleaning/disinfection.
  - as an integrated mechanical support measure for mechanical cleaning/disinfection.
  - for additional cleaning of products with residues left after mechanical cleaning/disinfection.
- Clean and disinfect microsurgical products mechanically if they can be placed securely in the machine or on the positioning aids.

Manual cleaning/disinfection

- Keep working tips open for cleaning.
- When cleaning instruments with movable hinges, ensure that these are in an open position and, if applicable, move the joint while cleaning.
- 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.
- Where necessary, repeat the cleaning process.
# 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>Cleaning</td>
<td>RT (cold)</td>
<td>&gt;15</td>
<td>2</td>
<td>D-W</td>
<td>BBraun Stabimed; phenol-free, aldehyde-free and QUAT-free</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>BBraun Stabimed; phenol-free, aldehyde-free and QUAT-free</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

### Phase I
- Fully immerse the product in the cleaning/disinfecting solution for at least 15 minutes. Ensure that all accessible surfaces are moistened.
- Clean the instrument under running tap water with a suitable cleaning brush where necessary for as long as it takes to remove all discernable residues.
- Use a suitable cleaning brush (e.g. TA012889) to clean all surfaces that are not visible, e.g. in instruments with concealed crevices, lumens or complex geometries, for at least 1 min or until no further residues can be removed.
- Maneuver non-rigid components, such as adjustable screws, hinges etc during cleaning.
- Then flush these areas thoroughly at least five times with the cleaning solution using a disposable syringe (20 ml).
- Do not use metal cleaning brushes or other abrasives that would damage the product surfaces and could cause corrosion.

### Phase II
- Rinse/flush the instrument 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 instrument in the disinfectant solution.
- Mobilize non-rigid components, such as set screws, joints, etc. during disinfection.
- Rinse the lumens at least five times at the beginning of the contact period using a disposable syringe (20 ml) and a suitable irrigation adapter. Ensure that all accessible surfaces are moistened.
- Drain any remaining water fully.
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Phase IV
- Rinse/flush the instrument thoroughly (all accessible surfaces).
- Mobilize non-rigid components, such as set screws, joints, etc. during final rinse.
- Rinse the lumens at least five times using a disposable syringe (20 ml) and a suitable irrigation adapter.
- Drain any remaining water fully.

Phase V
- Dry the instrument with a lint-free cloth or medical compressed air.

Mechanical cleaning/disinfection with manual pre-cleaning

Note
The disinfectant 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 water (demineralized, low microbial contamination: drinking water quality at least) and ensure that Ao is >3 000 for the process.

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>BBraun Stabimed; phenol-free, aldehyde-free and QUAT-free</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
Phase I

- Fully immerse the product in the cleaning/disinfecting solution for at least 15 minutes. Ensure that all accessible surfaces are moistened.
- Clean the product with a suitable cleaning brush until all discernable residues have been removed.
- Use a suitable cleaning brush (e.g. TA012889) to clean all surfaces that are not visible, e.g. in instruments with concealed crevices, lumens or complex geometries, for at least 1 min or until no further residues can be removed.
- Maneuver non-rigid components, such as adjustable screws, hinges etc during cleaning.

- After cleaning, thoroughly rinse through these components (at least five times) with the cleaning solution, using a disposable syringe (20 ml).
- Do not use metal cleaning brushes or other abrasives that would damage the product surfaces and could cause corrosion.

Phase II

- Rinse/flush the instrument thoroughly (all accessible surfaces) under running water.
- Mobilize non-rigid components, such as set screws, joints, etc. during rinsing.

Mechanical alkaline cleaning and thermal disinfection

Machine type: Single-chamber cleaning/disinfection device without ultrasound

- Place the instrument in a tray that is suitable for cleaning (avoiding rinsing blind spots).
- Connect components with lumens and channels directly to the rinsing port of the injector carriage.
- Keep working tips open for cleaning.
- Place instruments in the tray with their hinges open.

<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>
<tr>
<td>II</td>
<td>Cleaning</td>
<td>55/131</td>
<td>10</td>
<td>FD-W</td>
<td>BBRAUN HELIMATIC CLEANER alcaline with tensides, application solution 0.5%</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 disinfection</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 disinfector program</td>
</tr>
</tbody>
</table>

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FD-W: Fully desalinated water (demineralized, low microbiological contamination: drinking water quality at least)
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Inspection, maintenance, and checks

Damage (metal seizure/friction corrosion) to the product caused by insufficient lubrication!

- Prior to function checks, lubricate moving parts (e.g. joints, pusher components and threaded rods) with maintenance oil suitable for the respective sterilization process (e.g. for steam sterilization: Aesculap STERILIT® I oil spray JG600 or STERILIT® I drip lubricator JG598).

- Allow the product to cool down to room temperature.
- After each complete cleaning, disinfecting and drying cycle, check that the instrument 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.
- Assemble dismountable instruments, see Assembly.
- Check for compatibility with associated products.

Packaging

- Appropriately protect products with fine working tips.
- Place the product in its holder or on a suitable tray. Ensure that all cutting edges are protected.
- 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).

Sterilization

Note

The product can be sterilized either in disassembled or in assembled condition.

- Ensure that the sterilant can reach all external and internal surfaces (e.g. by opening valves and stop-cocks).
- Validated sterilization process
  - Steam sterilization through fractionated vacuum process
    - Steam sterilizer specified in DIN EN 285 and validated in accordance with 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 permitted load specified by the manufacturer for the steam sterilizer is not exceeded.

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>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–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 cleared by FDA for the sterilization and storage of these instruments. 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.

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 Technical Service
Am Aesculap-Platz
78532 Tuttingen / Germany
Phone: +49 7461 95-1602
Fax: +49 7461 16-5621
E-Mail: ats@aesculap.de

Or in the US:
Aesculap Inc.
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
Aesculap Inc.
3773 Corporate Parkway
Center Valley, PA 18034
USA