Aesculap
Cholangiography clamp

Legend
1 Jam parts
2 Lever lock connector (for cleaning channel)
3 Working channel
4 Handle
5 Lock Bracket
6 Lubrication points

Symbols on product and packages

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

Date of manufacture

Intended use
The cholangiography clamp is intended for performing cholangiography during laparoscopic cholecystectomy. The instrument serves to insert the cholangiography catheter in the bile duct and seal it against the escape of contrast solution.

Safe handling and preparation
CAUTION
Federal law restricts this device to sale by, or on order of a physician.

Note
The present instructions for use only apply to cholangiography clamp PT VL480 with cleaning channel.

► 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 all transport packaging and clean and prepare 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 end: Carefully insert the product through the working channel (e.g. trocar).

Safe operation

Risk of injury and/or malfunction
► Always carry out a function check prior to using the product.

Risk of injury when using the product beyond the field of view
► Apply the product only under visual control.

► Press down lock bracket 5 and open handle 4.
► Open jaw part 1 open.
► Insert the cholangiography catheter through working channel 3 into the bile duct.
► Close jaw part 1 and release lock bracket 5 to activate the locking mechanism.
► The cholangiography catheter is fixed, and the bile duct sealed.
► To open the locking mechanism, press down lock bracket 5 again.

Validated reprocessing procedure

General safety notes

Note
Adhere to national statutory regulations, national and international standards and directives, and local clinical hygiene instructions for steril processing.

Note
For patients with Cystic Fibrosis (CF), 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 operational processing technician is responsible for this.
The recommended chemistry was used for validation.

Note
If there is no final sterilization, then a suitable disinfectant must be used.

Note
For the latest information on reprocessing and material compatibility see also the Aesculap testkit at www.aesculap-dolcos.com

The validated steam sterilization procedure was controlled in the Aesculap sterile container system.
General information

Dried or arched 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 flashing pre-cleaning temperatures >60 °C nor flashing disinfector gases (detrimental ingredient: chlorinated hydrocarbons) should be used. Effective measures of neutralizing agents (basic cleaners) may result in a chemical attack on the laser marking becoming unsuitable visually or by machine for stainless steel.

Residues containing chlorine or chlorinated e.g. in surgical residues, medicines, saline solutions and in the nerve 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 cleaning thoroughly with demineralized water and then drying.

Additional drying, if necessary.

Only process chemicals that have been tested and approved (e.g. VWR or OSI 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 material, e.g. fading or dissolution of titanium or aluminium. For aluminium, the application temperature limits vary according to the surface finish and thickness, 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 hygiene-related and material-related processing concerning can be found at www.s-k-l.com, link to: Publications, Info Brochure: Fitting maintenance of instruments.

Disassembling the product before carrying out the reprocessing procedure

- Open up products with hinges.
- Remove the sealing cap from the Leer lock connector.

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 in 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

[Image of caution sign]

Damage to the product due to inappropriate cleaning/disinfector agents and/or inappropriate temperature

- Carry out ultrasound cleaning:
  - as an effective mechanical supplement to manual cleaning/disinfector.
  - as an additional pre-cleaning procedure for products with excrusted residues, in preparation for mechanical cleaning/disinfector.
  - as an integrated mechanical support measure for mechanical cleaning/disinfector.

- For additional cleaning of products with residues left after mechanical cleaning/disinfector.

Manual cleaning/disinfector

<table>
<thead>
<tr>
<th>Validated procedure</th>
<th>Specific requirements</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manual cleaning with ultrasound and immersion disinfection</td>
<td>- Cleaning brush, e.g. 74012089</td>
<td>Chapter Manual cleaning/disinfector and immersion disinfection</td>
</tr>
<tr>
<td>- 20 ml disposable syringe</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Keep working ends open for cleaning.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- When cleaning products with movable tips, ensure that these are in an open position and, if applicable, move the joint while cleaning.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Drying phase: Use a lint-free cloth or microfiber/paper towel.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Manual cleaning with brush and subsequent mechanical immersion cleaning and thermal disinfection | - Cleaning brush, e.g. 14012089 | Chapter Mechanical cleaning/disinfector with manual pre-cleaning and sub-chamber |
| - 20 ml disposable syringe | | |
| - Place the product in a tray that is suitable for cleaning (including mini-bin system). | | |
| - Connect components with lumen and channels directly to the cleaning port of the injector cartage. | | |
| - Keep working ends open for cleaning. | | |
| - Place products in the tray with their hinges open. | | |

Manual cleaning/disinfector

Risk to patients!

- The product must only be cleaned mechanically.

- Prior to manual disinfection, allow water to drip for a sufficient length of time to prevent dilution of the disinfecting solution.

- After manual cleaning/disinfector, check visible surfaces visually for residues.

- Repeat the cleaning/disinfector process if necessary.
### Manual cleaning with ultrasound and immersion disinfection

<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>Ultrasonic cleaning</td>
<td>RT (cold)</td>
<td>&gt;15</td>
<td>2</td>
<td>D-W</td>
<td>Alddehyde-free, phenol-free, and glutaraldehyde-free concentrate, pH = 3.5</td>
</tr>
<tr>
<td>II</td>
<td>Intermediate rinsing</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>Alddehyde-free, phenol-free, and glutaraldehyde-free concentrate, pH = 3.5</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>

- **FD-W**: Fully deionized water (demineralized, low microbiological contamination; drinking water quality at least at temp of 60°C)
- **D-W**: Drinking water
- **Recommended**: Biokas Statimed

> Note the intervention on appropriate cleaning brushes and disposable syringes, see Validated cleaning and disinfection procedure.

#### Phase I

- Clean the product in an ultrasonic cleaning bath (frequency 25 kHz) for at least 15 min. Ensure that all accessible surfaces are immersed and acoustic shadows are avoided.
- Rinse the product with a sterile cleaning brush in the solution until all disposable 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-sterile 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/rinse the product thoroughly (all accessible surfaces) under running water.
- Mobilize non-sterile 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-sterile components, such as set screws, joints, etc. during rinsing.
- Rinse lumens at least five times at the beginning of the exposure time with an appropriate disposable syringe. Ensure that all accessible surfaces are mobilized.

#### Phase IV

- Rinse/rinse the product thoroughly (all accessible surfaces) under running water.
- Mobilize non-sterile 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. shelf, compressed air), see Validated cleaning and disinfection procedure.

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

**Note**

Disinfection device must be of tested and approved effectiveness (i.e. FDA approved or CE marked according to DIN EN 14476)

**Note**

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]</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>Alddehyde-free, phenol-free, and glutaraldehyde-free concentrate, pH = 3.5</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**: Biokas Statimed

> Note the intervention 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 mobilized.
- Clean the product with a suitable cleaning brush in the solution until all disposable 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-sterile 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/rinse the product thoroughly (all accessible surfaces) under running water.
- Mobilize non-sterile components, such as set screws, joints, etc. during rinsing.
Mechanical alkaline cleaning and thermal disinfecting

<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>Premise</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  
▶ ≤6 % anionic surfactant  
▶ 0.5 % working solution  
▶ pH = 11 |
| III   | Intermediate| >110/50 | 1       | FD-W         | -        |
| IV    | Thermal disinfecting| 90/194 | 5       | FD-W         | -        |
| V     | Drying | -         | -       | -            | According to the program for cleaning and disinfecting device |

D-W: Drinking water  
FD-W: Fully demineralized water (demineralized, low microbiological contamination: drinking water quality 2/F1)  
Recommended: Biocare Helmiclar Cleaner alkaline

▶ Check visible surfaces for residues after mechanical cleaning/disinfecting.

Inspection, maintenance and checks

⚠️ CAUTION

Dents (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 ends) at the marked lubrication points, using maintenance oil suitable for the respective sterilization process (e.g. for steam sterilization: Aesculap STELLIT® I oil spray J0560 or STELLIT® I drip lubricant J0558).

▶ 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 disinfecting of products that still show impurities or contamination.
▶ Check that the product functions correctly.
▶ Immediately put aside damaged or imperative products and send them to Aesculap Technical Service, see Technical Service.
▶ Check for compatibility with associated products.

Packaging

▶ Store products with a notch locked fully open or locked no further than in the first notch.
▶ Place the product in its holder or on a suitable tray.
▶ 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

Note

To avoid breakage due to steam crack corrosion, sterilize the product with the lock fully open or locked no further than in the first notch path.

▶ 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 124°C 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 peracetic acid cycle in a steam autoclave.
▶ To achieve a sterility assurance level of 10⁶, Aesculap recommends the following parameters:

<table>
<thead>
<tr>
<th>Aesculap Orca Tray/Steril container (perforated bottom)</th>
<th>Minimum cycle parameters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterilization method</td>
<td>Temp.</td>
</tr>
<tr>
<td>Peracetic acid</td>
<td>270</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 cleaned accessory to maintain sterility after processing, such as a wrap, pouch, etc.

Storage

▶ Store sterile products in airtight 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-Palz
78552 Tuttlingen (Germany)
Phone: +49 (7461) 95-1602
Fax: +49 (7461) 16-5821
E-Mail: ats@ausculap.de
Or in the US:
Aesculap Inc.
Attn. Aesculap Technical Services
615 Lambert Pointe Drive
Huntersville
NC, 28078
Aesculap Repair Hotline
Phone: +1 (800) 214-3392
Fax: +1 (704) 815-4420

Other service addresses can be obtained from the address indicated above.

Accessories/Spare parts

<table>
<thead>
<tr>
<th>Art. no.</th>
<th>Designation</th>
</tr>
</thead>
<tbody>
<tr>
<td>E7512600</td>
<td>Sealing cap</td>
</tr>
<tr>
<td>PL401230</td>
<td>Silicon cover</td>
</tr>
</tbody>
</table>

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
3775 Corporate Parkway
Center Valley, PA, 18034,
USA

TA-Nr. 012799 03/13 V6 Änd.-Nr. 46434