Endo clips and forceps
Legend
1 Jaw piece
2 Luer lock connector for cleaning channel
3 Handle
4 Nibs
5 Holes clip
6 Lubrication points

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

Note
The clips may only be used temporarily during the operative procedure and must only be used with the original Aesculap clip applying/removal forceps PLS50R and PLS51R.

The clip applying/removal forceps and clips have been designed for endoscopic use.

The atraumatic clip applying/removal forceps are intended for applying and removing the clips PLS445-PLS495, as well as PLS504R and PLS54R.

The vascular clips PLS425-PLS495 are used to clamp vessels:
- Arterial vascular clips
  - without gold-plated spring area and with high closing force
- Venous vascular clips
  - with gold-plated spring area

The intestinal clip PLS415 is used to clamp the intestine. The roughened surface of the inner side of the clamp prevents the intestine from slipping out.

The clips PLS50R and PLS54R are used in combination with the intraepithelial retractor PLS985U.

Overview:

<table>
<thead>
<tr>
<th>Arterial vascular clip</th>
<th>Venous vascular clip</th>
<th>Intestinal clip</th>
<th>Atraumatic clip</th>
</tr>
</thead>
</table>

Safe handling and preparation

CAUTION

Ensure that the product and its accessories are operated and used only by persons with the requisite knowledge, 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 used 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.

Clip applying/removal forceps PLS50R
- Pick up the clips with the nobs 4 of the clip applying/removal forceps in the holes 5, see Fig. 1.

Clip applying/removal forceps PLS51R
- Insert the clips into the jaw pieces 1 of the clip applying/removal forceps as far as they will go, see Fig. 2.

Validated reprocessing procedure

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

Note
For patients with Creactive protein (CRP) suspected CRP or possible variants of CRP, observe the relevant national regulations concerning the reprocessing of the products.

Mechanical processing should be favored over manual cleaning as it gives better and more reliable results.

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

Note
Up-to-date information on processing can be found on the Aesculap Excellent at www.aesculap-excellent.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 air-dried surgical residues can make cleaning more difficult or ineffective and lead to corrosion of stainless steel. You should therefore leave no more than 6 hours between use and cleaning, not use pre-clean filling temperatures >85°C, and ensure that non-fouling disinfectants (pH-balanced-free alcohol-free) are used.

Excessive measures of neutralizing agents or basic cleaners may result in a chemical attack and/or fading and the laser marking becoming unreadable visually or by machine for stainless steel.

Residues containing chloride 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 (fading, stress corrosion) and result in the destruction of stainless steel products. These must be removed by rinsing thoroughly with demineralized water and then drying.

Only process chemicals that have been tested and approved (e.g. U handing/BDGMA 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 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 occur at a pH level of >3 in the application/washing solution.
- Material damage such as corrosion, cracks, fractures, premature deterioration or swelling.

Clean the product immediately after use

Please see www.aesculap.com for more detailed information on hygienically safe reprocessing which is protective of materials and retains their value.

Use suitable cleaning/desinfecting agents if the product is put away in a wet condition. To prevent formation and reduced effectiveness of the processes chemical: Prior to mechanical cleaning and disinfection, rinse the product thoroughly with running water.

Preparations at the place of use

- Remove the sealing cap from the Luer lock connector of both clip applying/removal forceps.
- Rinse surfaces inaccessible to visual inspection, e.g. in products with hidden gaps or lumens or products with complex geometries, preferably with distilled water, using e.g. a disposable syringe.
- 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

Damage to the product due to inappropiate cleaning/disinfecting agents and/or excessive temperatures:
- Use cleaning and disinfecting agents approved for plastics and high-grade steel according to manufacturer’s instructions.
- Observe specifications regarding concentration, temperature and exposure time.
- Do not exceed the maximum permitted cleaning temperature of 55 °C.

- 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.

General cleaning instructions for clips:
- Products that need to be opened via a joint, hinge etc., must be cleaned in open position.
- Products that do not need to be opened via a joint, hinge etc., can be opened using a wire or similar object (e.g. device) for cleaning.
- Ensure that the wire or similar object is thick enough to keep the clips half open.
- Position the wire or similar object near the edge or in the non-serrated region to avoid scoring surfaces.
- Position the product in the tray in such a way that the best possible cleaning effect will be achieved.

Note
The similar object must be made of metal and if possible be of round cross-section. To avoid scoring/surface damage do not use plastic materials or elastic tubes (silicon or PVC).
The applying forceps can also be used for the manual pre-cleaning of the serrated area.

Mechanical cleaning/disinfection with manual pre-cleaning

Note
The disinfector must be of tested and approved effectiveness (e.g. DGMM or FDA approval or CE mark according to DIN EN 13883).

Note
For thermal disinfection, always use fully deionized water (demineralized, low microbial contamination; drinking water quality at least) and ensure that Ask is >3000 for the process.

Note
The disinfector used for processing must be serviced and checked at regular intervals.

Manual pre-cleaning with ultrasound and brush

<table>
<thead>
<tr>
<th>Stage</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>Ultrasonic cleaning</td>
<td>RT (cold)</td>
<td>T&gt;15</td>
<td>2</td>
<td>D-W</td>
<td>BBraun Stabilized-gluconate-free and QAV-free</td>
</tr>
<tr>
<td>II</td>
<td>Rinse</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

Stage I
- Clean the product in an ultrasonic cleaning bath (frequency 35 kHz) for at least 15 minutes. Ensure that all accessible surfaces are immersed and acoustic shadows are avoided.
- Clean the product with a suitable cleaning brush until all discernible residues have been removed.
- Use a suitable cleaning brush to clean all surfaces which 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, use a 20-ml single-use syringe to rinse thoroughly, for at least 5 times, these difficult to access parts of the product.
- Do not use metal cleaning brushes or other abrasives that would damage the product surfaces and could cause corrosion.

Stage 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/disinfecting device without ultrasound
- Place the instrument in a tray suitable for washing to ensure that all parts are cleaned.
- Connect the clip applying/removal forceps directly to the special rinsing port of the injector cart.
- Keep working ends open for cleaning.
- Place instruments in the tray with their hinged open.

<table>
<thead>
<tr>
<th>Stage</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>DM-W</td>
<td>BBraun HELIMAC CLEANER alkaline with terrosides; application solution 6.5%</td>
</tr>
<tr>
<td>III</td>
<td>Intermediate rinse</td>
<td>&gt;10/50</td>
<td>1</td>
<td>D-W</td>
<td>-</td>
</tr>
<tr>
<td>IV</td>
<td>Thermal disinfection</td>
<td>90°/194</td>
<td>5</td>
<td>DM-W</td>
<td>-</td>
</tr>
<tr>
<td>V</td>
<td>Drying</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>According to disinfect program</td>
</tr>
</tbody>
</table>

D-W: Drinking water
ID-W: Fully deionized water (demineralized, low microbial contamination; drinking water quality at least)

Control, care and inspection

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 1 oil spray J5600 or STERILIT 1 drip lubricator J5940).

- 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 frustured components).
- Dry the product if it is wet or damp.
- Repeat cleaning and disinfection of products that show impurities or contamination.
- Check that the product functions correctly.
- Immediately put aside damaged or inappropriate products and send them to Aesculap Technical Service, Siehe Technical Service.
- 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.
- Pack 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
- Make certain that all external and internal surfaces of the product will be exposed to the sterilizing agent.
- Validate sterilization process:
  - Steam sterilization through saturated vacuum process
  - Steam sterilizer according to DIN EN 205 and validated according to DIN EN ISO 17665
  - Sterilization through saturated vacuum process at 134°C heating 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, as specified by the manufacturer, 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 presaturated cycle.
To achieve a sterility assurance level of 10-6, Aesculap recommends the following parameters:

Aesculap Orga Traumatic container (perforated bottom)

<table>
<thead>
<tr>
<th>Sterilization method</th>
<th>Temp.</th>
<th>Time</th>
<th>Minimum drying time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-sterilization</td>
<td>270 °F to 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 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.

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.

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