Aesculap  Endoscopic  Technology

USA  Instructions for use
Endoscopic Clip Applicators and OS Titanium Ligature Clips
Endoscopic Clip Appliers and DS Titanium Ligature Clips

Legend

1. Jaw parts
2. Guide tips
3. Lubrication points
4. Sealing cap for Luer lock irrigation connector
5. Luer lock connector for cleaning the applier
6. Handle
7. Clip applier color coding
8. Clip cartridge
9. Latch position marking (marking only for product with latch)
10. DS clip
11. Adhesive strip
12. Slot (in DS clip)
13. Latch

Symbols on product and packaging

Endoscopic clip appliers:

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

DS Titanium Ligature Clips:

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Symbol]</td>
<td>Sterilization using irradiation</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>Not for reuse in intended applications as defined by the manufacturer</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>Use by</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>Caution, general warning symbol Caution, see documentation supplied with the product</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>Date of manufacture</td>
</tr>
</tbody>
</table>

Intended use

Indications for use
Endoscopic and/or open surgery for ligating and marking vessels and tubular structures whenever clips are used/indicated.

DS Titanium Ligature Clip material
- Pure titanium acc. to ISO 5832-2
- Not transparent to X-rays
- Non-ferromagnetic; suitable for use under NMR tomography with fields of up to 3.0 Tesla (no risks or hazards caused by magnetic fields, but possible artifacts)
Available sizes

### Endoscopic clip applier

<table>
<thead>
<tr>
<th>Designation</th>
<th>Art. no.</th>
<th>Color code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endoscopic clip applier for SMALL DS clips (0 5/310mm)</td>
<td>PL801R</td>
<td>Yellow</td>
</tr>
<tr>
<td>Endoscopic clip applier for SMALL-MEDIUM DS clips (0 5/310mm)</td>
<td>PL802R</td>
<td>Purple</td>
</tr>
<tr>
<td>Endoscopic clip applier for SMALL-MEDIUM (0 5/420mm)</td>
<td>PL822R</td>
<td>Purple</td>
</tr>
<tr>
<td>Endoscopic clip applier for MEDIUM (0 10/310mm)</td>
<td>PL806R</td>
<td>Blue</td>
</tr>
<tr>
<td>Endoscopic clip applier for MEDIUM (0 10/420mm)</td>
<td>PL826R</td>
<td>Blue</td>
</tr>
<tr>
<td>Endoscopic clip applier for MEDIUM-LARGE DS clips (0 10/310mm)</td>
<td>PL807R</td>
<td>Green</td>
</tr>
<tr>
<td>Endoscopic clip applier for MEDIUM-LARGE (0 10/420mm)</td>
<td>PL827R</td>
<td>Green</td>
</tr>
<tr>
<td>Endoscopic clip applier for LARGE (0 12/310mm)</td>
<td>PL808R</td>
<td>Orange</td>
</tr>
<tr>
<td>Endoscopic clip applier for LARGE (0 12/420mm)</td>
<td>PL828R</td>
<td>Orange</td>
</tr>
<tr>
<td>Endoscopic clip applier for X-LARGE DS clips (0 12/310mm)</td>
<td>PL809R</td>
<td>Light Gray</td>
</tr>
</tbody>
</table>

### DS Titanium Ligature Clips

<table>
<thead>
<tr>
<th>Designation</th>
<th>Art. no.</th>
<th>Color code</th>
</tr>
</thead>
<tbody>
<tr>
<td>SMALL DS clip cartridges (15 individually packaged sterile cartridges each containing 6 DS clips)</td>
<td>PL450SU</td>
<td>Yellow</td>
</tr>
<tr>
<td>SMALL DS clip cartridges (24 individually packaged sterile cartridges each containing 6 DS clips)</td>
<td>PL452SU</td>
<td>Yellow</td>
</tr>
<tr>
<td>SMALL-MEDIUM DS clip cartridges (15 individually packaged sterile cartridges each containing 6 DS clips)</td>
<td>PL453SU</td>
<td>Purple</td>
</tr>
<tr>
<td>MEDIUM DS clip cartridges (15 individually packaged sterile cartridges each containing 6 DS clips)</td>
<td>PL459SU</td>
<td>Blue</td>
</tr>
<tr>
<td>MEDIUM-LARGEDS clip cartridges (15 individually packaged sterile cartridges each containing 6 DS clips)</td>
<td>PL462SU</td>
<td>Green</td>
</tr>
<tr>
<td>MEDIUM-LARGEDS clip cartridges with latch (15 individually packaged sterile cartridges each containing 6 DS clips)</td>
<td>PL465SU</td>
<td>Green</td>
</tr>
<tr>
<td>LARGE DS clip cartridges (12 individually packaged sterile cartridges each containing 6 DS clips)</td>
<td>PL468SU</td>
<td>Orange</td>
</tr>
<tr>
<td>LARGE DS clip cartridges w/ latch (12 individually packaged sterile cartridges each containing 6 DS clips)</td>
<td>PL471SU</td>
<td>Orange</td>
</tr>
<tr>
<td>X-LARGE DS clip cartridges with latch (12 individually packaged sterile cartridges each containing 4 DS clips)</td>
<td>PL475SU</td>
<td>Light Gray</td>
</tr>
</tbody>
</table>
Side effects and interactions

In case of foreign-body sensitivity to titanium.

Safety notes

- It is the operating surgeon’s responsibility to ensure that the surgical procedure is performed properly.
- The implant components used, along with the article number, implant designation, patient label and batch and serial number (if applicable), must be documented in the patient records.
- General risk factors associated with surgical procedures are not described in this documentation.
- The operating surgeon must have a thorough command of both the hands-on and conceptual aspects of the established operating techniques.
- Aesculap is not responsible for any complications arising from erroneous indication, wrong choice of implant, incorrect combination of implant components and operating technique, the limitations of the treatment method, or inadequate asepsis.
- Do not, under any circumstances, use damaged or surgically excised clips.
- Clip cartridges and clips that have been used before must not be reused.

Safe handling and preparation

CAUTION

Federal law restricts this device to sale by or on order of a physician!

Endoscopic clip applicators

- 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.
Endoscopic Clip Appliers and DS Titanium Ligature Clips

- 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.
- Ensure that the sealing cap is fitted securely on the Luer lock irrigation connector to prevent gas loss during insufflation.

DS Titanium Ligature Clips

**DANGER**

Infection hazard for patients and/or users and impairment of product functionality due to reuse. Risk of injury, illness or death due to contamination and/or impaired functionality of the product!
- Do not reprocess the product.

The product is gamma-sterilized and supplied in sterile packaging.

The product must not be reused.
- Ensure that the product and its accessories are operated and used only by persons with the requisite training, knowledge, or experience.
- Read the package insert enclosed with the clips.
- Use the product only for its intended purpose, see intended use.
- Do not use products from opened or damaged sterile packaging.
- 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.
- Do not use the product after its use-by date.
- Store implant components in their original packaging. Remove them from their original protective packaging only just prior to application.

- Prior to use, check the shelf life expiration date and verify the integrity of the sterile packaging.
- Do not use implant components that are past their expiration date or whose packaging is damaged.

**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 applying the product outside the field of view!
- Apply the product only under visual control.

**WARNING**

- Risk of dislocation of clips from cutting tissue too close to clip!
- When cutting clipped structures, leave an area of tissue of at least the width of a clip between the clip and the cutting site.
- Ensure that the structure is not under tension when cutting.

**CAUTION**

- Damage to/loss of clip when removing from clip cartridge!
- When removing clips from the clip cartridge, hold the endoscopic clip applier at its shaft.
- Insert the clip applier carefully, in a straight line and centrally through the trocar.
- Do not close jaw parts when inserting through the trocar.

- Choose the appropriate clip size for the intended application.
Validated reprocessing procedure

For clip appliers only

Note
National laws, national and international standards and directives, and product-specific hygiene regulations for processing 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 the products.

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

Note
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
Clip cartridges 8 with a hollow at the top and an elevation in the handle recesses contain clips with latch 13. The latch position marking 9 indicates the position of the latch in clip cartridge 8.

➢ Ensure that all of the tissue to be ligated is situated within the clip.
➢ Only use the clip applicer with the appropriate clip cartridge.

Note
The sizes of the clip appliers and clip cartridges 8 can be identified by their color codes, see clip applicer color coding 7.

➢ Affix the clip cartridge 8 to a sterile surface using the adhesive strip 11 for stability purposes.
➢ Applying light pressure, insert the jaw parts 1 of the clip applicer vertically into the clip cartridge 8 slot down to the positive stop, see Fig. 3. The support arms unlatch when the clip applicer is inserted into the clip cartridge 8, see Fig. 5.
➢ Remove the clip applicer, which has the clip in its jaw part 1, from the clip cartridge 8, see Fig. 4.
➢ Check that the clip is positioned correctly in the clip applicer:
  - The guide tips 2 of the jaw parts 1 must be positioned in the slot 12 of the DS clips, see Fig. 6/Fig. 7.
  - The clip must be seated as far as it will go in the clip applicer (positive stop), see Fig. 7.
➢ To close the clip correctly, squeeze together the clip applicer as far as it will go. Make sure the clip is applied under visual control.
➢ Check the fit and function of the clip.
➢ Fit more clips if necessary.
➢ Dispose of the opened clip cartridge 8 after the surgical procedure.
Endoscopic Clip Appliers and DS Titanium Ligature Clips

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. You should therefore leave no more than 6 hours between use and cleaning, not use pre-clean fixing temperatures >-45°C, and ensure that non-fixing disinfectants (aldehyde) 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 deionized water and then drying.
Only use process chemicals which have been tested and approved (e.g. VAH/DGTHM or FDA-certified or CE marking) and 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:
- Optical deterioration of materials, e.g. fading or color changes
- Material damage such as corrosion, cracks, fractures, premature deterioration or swelling.
Please see www.a-k-i.org for more detailed information on hygienically safe reprocessing which is protective of materials and preserves their value.

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.

Preparations at the place of use
- Remove the sealing cap from the Luer lock connector.
- Remove star wheel.
- 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.
Cleaning/disinfection

Damage to the product due to inappropriate cleaning/disinfecting agents and/or excessive temperatures!

- Use cleaning and disinfecting agents as recommended by the manufacturer which
  - are approved for high-grade steel, for instance,
  - do not attack softeners (e.g. silicone).
- Observe specifications regarding concentration, temperature and exposure time.
- Do not exceed the maximum allowable cleaning temperature of 267.8 °F.

- 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 supplementary mechanical measure for mechanical cleaning/disinfection.
  - for additional cleaning of products with residues left after mechanical cleaning/disinfection.

Manual cleaning/disinfection

- Keep working ends 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 for residues.
- Where necessary, repeat the cleaning process.
Endoscopic Clip Appliers and DS Titanium Ligature Clips

Manual cleaning with ultrasound and immersion disinfection

<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>&gt;15</td>
<td>2</td>
<td>D-W</td>
<td>BBraun Stabimed; aldehyde-free, phenol-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; aldehyde-free, phenol-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>-</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

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 discernable residues have been removed.
- Use a suitable cleaning brush to clean all surfaces which are not visible, e.g. in products 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.

Stage II
- Rinse/flush the instrument thoroughly (all accessible surfaces) under running water.
- Maneuver non-rigid components such as set screws, joints, etc when rinsing.
- Drain any remaining water fully.

Stage III
- Fully immerse the instrument in the disinfectant solution.
- Maneuver 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.
Stage IV

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

Stage V

- Dry the instrument thoroughly 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.

Note

The disinfectant used for processing must be serviced and checked at regular intervals.
**Endoscopic Clip Appliers and DS Titanium Ligature Clips**

**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>&gt;15</td>
<td>2</td>
<td>D–W</td>
<td>BBraun Stabimed; aldehyde-free, phenol-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

**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 products 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.

**Stage II**

- Rinse/flush the instrument thoroughly (all accessible surfaces) under running water.
- Maneuver non-rigid components such as set screws, joints, etc. when rinsing.
**Mechanical alkaline cleaning and thermal disinfection**

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

- Place the instrument in a tray suitable for washing (to ensure that all parts are cleaned).
- Connect components with lumens and canals directly to the special rinsing port of the injector cart.
- Keep working ends open for cleaning.
- Place instruments in the tray with their hinges 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>FD–W</td>
<td>BBRAUN HELIMATIC CLEANER alkaline 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 disinfecter program</td>
</tr>
</tbody>
</table>

D–W: Drinking water
FD–W: Fully desalinated water (demineralized, low microbiological contamination: drinking water quality at least)
Endoscopic Clip Appliers and DS Titanium Ligature Clips

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) at the marked lubrication points.

- 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.
- Fit the star wheel and sealing cap onto the Luer lock connector.

Packaging

- Place the product in its holder or on a suitable tray.
- 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

- 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.
Storage
➢ Store sterile products in germ-proof packaging, protected from dust, in a dry, dark, temperature-controlled area.
➢ Store sterile packed single-use products dust-protected in a dry, dark and temperature-controlled area.

Distributor in the US/Contact in Canada for product information and complaints
Aesculap Inc.
3773 Corporate Parkway
Center Valley, PA 18034
USA

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 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!