INSTRUCTIONS FOR USE
DS Titanium Ligature Clips and Endoscopic Clip Appliers

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

INDICATIONS FOR USE
Endoscopic and/or open surgery for ligating and marking vessels and tubular structures whenever clips are used/indicated.

CONTRAINDICATIONS
DS Titanium ligature clips (clips sizes SMALL to EXTRA LARGE)
Do not use:
- On the central circulatory system (in the aorta, truncus, brachiocephalicus, carotid artery, cerebral arteries, coronary arteries and veins, pulmonary arteries and veins, vena cava)
- On the central nervous system
- In case of foreign-body sensitivity for Titanium
- For contraceptive procedures such as tubal ligation, vasectomy
- For the closure of the renal artery or renal vein during nephrectomies in living donor patients
- DS EXTRA LARGE Clip only: with highly inflammatory appendix with inclusion of the appendix base
- Additional contraindications include, but are not limited to, medical and/or surgical conditions that could prevent the safe use of the product, e.g. disorders of the connective tissue (Marfan Syndrome) or active infections

GENERAL WARNINGS AND PRECAUTIONS
- 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 for future reference.
- Use the product only for its intended purpose.

Endoscopic Clip Appliers
- 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.
- 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
- Store implant components in their original packaging. Remove them from their original protective packaging just prior to use.
- 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.
- Do not, under any circumstances, use damaged or surgically excised clips.
- Clip cartridges and clips that have been used before must not be reused.

DEVICE DESCRIPTION
DS Titanium Ligature Clip
- 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)
- The product is gamma-sterilized and supplied in sterile packaging
## Available Sizes

### Endoscopic Clip Appliers

<table>
<thead>
<tr>
<th>Description</th>
<th>Item Number</th>
<th>Color code</th>
</tr>
</thead>
<tbody>
<tr>
<td>SMALL DS Clip Applier 5mm 31cm</td>
<td>PL801R</td>
<td>Yellow</td>
</tr>
<tr>
<td>SMALL-MEDIUM DS Clip Applier 5mm 31cm</td>
<td>PL802R</td>
<td>Purple</td>
</tr>
<tr>
<td>SMALL-MEDIUM DS Clip Applier 5mm 42cm</td>
<td>PL822R</td>
<td>Purple</td>
</tr>
<tr>
<td>MEDIUM DS Clip Applier 10mm 31cm</td>
<td>PL806R</td>
<td>Blue</td>
</tr>
<tr>
<td>MEDIUM DS Clip Applier 10mm 42cm</td>
<td>PL826R</td>
<td>Blue</td>
</tr>
<tr>
<td>MEDIUM-LARGE DS Clip Applier 10mm 31cm</td>
<td>PL807R</td>
<td>Green</td>
</tr>
<tr>
<td>MEDIUM-LARGE DS Clip Applier 10mm 42cm</td>
<td>PL827R</td>
<td>Green</td>
</tr>
<tr>
<td>LARGE DS Clip Applier 12mm 31cm</td>
<td>PL808R</td>
<td>Orange</td>
</tr>
<tr>
<td>LARGE DS Clip Applier 12mm 42cm</td>
<td>PL828R</td>
<td>Orange</td>
</tr>
<tr>
<td>EXTRA LARGE DS Clip Applier 12mm 31cm</td>
<td>PL809R</td>
<td>Light Gray</td>
</tr>
</tbody>
</table>

### DS Titanium Clips

<table>
<thead>
<tr>
<th>Description</th>
<th>Item Number</th>
<th>Color code</th>
</tr>
</thead>
<tbody>
<tr>
<td>SMALL DS Clip cartridges (15 individually packaged sterile clips each containing 6 DS Clips)</td>
<td>PL450SU</td>
<td>Yellow</td>
</tr>
<tr>
<td>SMALL DS Clip cartridges (24 individually packaged sterile clips each containing 6 DS Clips)</td>
<td>PL452SU</td>
<td>Yellow</td>
</tr>
<tr>
<td>SMALL-MEDIUM DS Clip cartridges (15 individually packaged sterile clips each containing 6 DS Clips)</td>
<td>PL453SU</td>
<td>Purple</td>
</tr>
<tr>
<td>MEDIUM DS Clip cartridges (15 individually packaged sterile clips each containing 6 DS Clips)</td>
<td>PL459SU</td>
<td>Blue</td>
</tr>
<tr>
<td>MEDIUM-LARGE DS Clip cartridges (15 individually packaged sterile clips each containing 6 DS Clips)</td>
<td>PL462SU</td>
<td>Green</td>
</tr>
<tr>
<td>MEDIUM-LARGE DS Clip Cartridges with latch (15 individually packaged sterile clips each containing 6 DS Clips)</td>
<td>PL465SU</td>
<td>Green</td>
</tr>
<tr>
<td>LARGE DS Clip cartridges (12 individually packaged sterile clips 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 clips each containing 6 DS Clips)</td>
<td>PL471SU</td>
<td>Orange</td>
</tr>
<tr>
<td>EXTRA LARGE DS Clip cartridges with latch (12 individually packaged sterile clips each containing 4 DS Clips)</td>
<td>PL475SU</td>
<td>Light Gray</td>
</tr>
</tbody>
</table>
Symbols on product and packaging

Endoscopic clip appliers:

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

DS Titanium Ligature Clips:

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>🔇</td>
<td>Sterilization using irradiation</td>
</tr>
<tr>
<td>🕒</td>
<td>Not for reuse in intended application as defined by the manufacturer</td>
</tr>
<tr>
<td>⏰</td>
<td>Use by</td>
</tr>
</tbody>
</table>
| ⚠️     | Caution, general warning symbol  
Caution, see documentation supplied with the product |
| 📅      | Date of manufacture |

Endoscopic Clip Appliers and DS Titanium Ligature Clips

Legend for Figures Below
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
Safe Operation
- Always carry out a function check prior to using the product.
- Ensure the appropriate clip size is chosen for the intended application.
- Only use the clip applier with the appropriate clip cartridge.
- Ensure there is appropriate visualization during use to avoid potential patient injury.
- When removing clips from the clip cartridge, hold the endoscopic clip applier at the shaft.
- Insert the clip applier carefully, in a straight line and centrally through the trocar.
  - **CAUTION:** Do not close jaw parts when inserting through the trocar to avoid inadvertent clip closure. Leave at least the width of the clip. Ensure the structure is not under tension when cutting.
  - **CAUTION:** Do not cut tissue close to clips to avoid dislocation.

Note
The sizes of the clip appliers and clip cartridges 8 can be identified by their color codes see clip applier 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 applier vertically into the clip cartridge 8 slot down to the positive stop, see Fig 3.
  - The support arms unlatch when the clip applier is inserted into the clip cartridge 8, see Fig. 5.
- Remove the clip applier, 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 applier:
  - 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 applier (positive stop), see Fig. 7.
- Ensure that all of the tissue to be ligated is situated within the clip.
- To close the clip correctly, squeeze together the clip applier as far as it will go. Make sure the clip 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.

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.
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.

EXTRA LARGE

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 demineralized water and then drying.
- Only use process chemicals which have been tested and approved (e.g. VAH/DGHM 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.
- 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 recommended for high-grade steel, and
  - 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.
  - As a pre-cleaning procedure for products with encrusted residues, in preparation for mechanical cleaning.
  - As an integrated supplementary mechanical measure for mechanical cleaning.
  - For additional cleaning of products with residues left after mechanical cleaning.

Manual cleaning

- 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, check visible surfaces for residues.
- Where necessary, repeat the cleaning process.

### Manual Cleaning

<table>
<thead>
<tr>
<th>Stage</th>
<th>Step</th>
<th>Temp. [°F]</th>
<th>Min. Conc.</th>
<th>Water Quality</th>
<th>Chemical Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Manual Cleaning</td>
<td>unheated</td>
<td>1/8 oz. per gallon</td>
<td>Util.-W</td>
<td>Steris Protystica 2X Concentrate Enzymatic Cleaner</td>
</tr>
<tr>
<td>II</td>
<td>Final Rinse</td>
<td>cold</td>
<td>-</td>
<td>Crit.-W</td>
<td>-</td>
</tr>
<tr>
<td>III</td>
<td>Drying</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>IV</td>
<td>Inspection</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

Util.-W: Utility water
Crit.-W: Critical water
Stage I
- Prepare washing solution following instructions on solution label using unheated utility water.
- Open or disassemble instrument/s so solution can reach all instrument surfaces and submerge instrument/s in solution.
- Brush all surfaces until visibly clean with a soft or medium bristle brush brushing hard to clean areas such as lumens, special rotating areas and hidden surfaces 4 times (back and forth = 1 time).
- Move moving parts during washing to reach all surfaces and flush lumens 4 times with at least 20cc washing solution using a syringe.

Stage II
- Rinse by placing instruments under critical water and expose all surfaces of the device under the water flow for 3 times.
- Move parts during the rinsing to rinse all surfaces and flush lumens 4 times with at least 20cc washing solution using a syringe.

Stage III
- Use heat or low-linting cloth to dry instruments following final rinse (not required if followed by mechanical cleaning process).

Stage IV
- Visually inspect instruments for remaining soil or washing solution.
- Repeat manual washing and/or rinsing steps until instrument is free from soil or washing solution.

Mechanical Cleaning with Manual (Pre-) Cleaning

- **Manual (Pre-) Cleaning**

<table>
<thead>
<tr>
<th>Stage</th>
<th>Step</th>
<th>Temp. [°F]</th>
<th>Min. Conc.</th>
<th>Water Quality</th>
<th>Chemical Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Manual Cleaning</td>
<td>RT (cold)</td>
<td>1/8 oz. per gallon</td>
<td>Util.-W</td>
<td>Steris Protystica 2X Concentrate</td>
</tr>
<tr>
<td>II</td>
<td>Final Rinse</td>
<td>RT (cold)</td>
<td>-</td>
<td>Crit.-W</td>
<td>Enzymatic Cleaner</td>
</tr>
</tbody>
</table>

Util.-W: Utility water
Crit.-W: Critical water

Stage I
- Prepare washing solution following instructions on solution label using unheated utility water.
- Open or disassemble instrument/s so solution can reach all instrument surfaces and submerge instrument/s in solution.
- Brush all surfaces until visibly clean with a soft or medium bristle brush brushing hard to clean areas such as lumens, special rotating areas and hidden surfaces 4 times (back and forth = 1 time).
- Move moving parts during washing to reach all surfaces and flush lumens 4 times with at least 20cc washing solution using a syringe.

Stage II
- Rinse by placing instruments under critical water and expose all surfaces of the device under the water flow for 3 times.
- Move parts during the rinsing to rinse all surfaces and flush lumens 4 times with at least 20cc washing solution using a syringe.
Mechanical Cleaning

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Pre-Rinse</td>
<td>unheated</td>
<td>1</td>
<td>Util.-W</td>
<td>-</td>
</tr>
<tr>
<td>II</td>
<td>Wash</td>
<td>unheated</td>
<td>6</td>
<td>Util.-W</td>
<td>Steris Protystica 2X Concentrate Enzymatic Cleaner (minimum concentration 1/8 oz. per gallon)</td>
</tr>
<tr>
<td>III</td>
<td>Final Rinse</td>
<td>180</td>
<td>2</td>
<td>Crit.-W</td>
<td>-</td>
</tr>
<tr>
<td>IV</td>
<td>Drying</td>
<td>194</td>
<td>10</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>V</td>
<td>Inspection</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

Util.-W: Utility water
Crit.-W: Critical water

- **Stage I**
  - Use unheated utility water rinse for at least 1 minute (may be part of automated washer program)
- **Stage II**
  - Using unheated utility water, follow washing instructions for recommended dilution in washer.
  - Open or disassemble instrument/s so washing solution can reach all instrument surfaces and wash lumens using flush attachments in washer if available or use manual method.
  - Use wash cycle for at least 6 minutes.
- **Stage III**
  - Use minimum 180° F. critical water rinse for at least 2 minutes.
- **Stage IV**
  - Dry at 194° F. for 10 minutes OR
  - Use the manual dry method
- **Stage V**
  - Visually inspect instruments for remaining soil or washing solution.
  - Repeat cleaning steps until instrument is free from soil or washing solution.
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 threaded rods) with maintenance oil suitable for the respective sterilization process (e.g. for Steam sterilization: Aesculap I Oil spray JG600 or STERILITY 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 be accomplished by Steam auto- clave in a standard prevacuum cycle.

To achieve a sterility assurance level of $10^{-6}$ Aesculap recommends the following parameters:

<table>
<thead>
<tr>
<th>Steam Sterilization Parameters</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sterilization Method</strong></td>
</tr>
<tr>
<td>Terminal Sterilization</td>
</tr>
<tr>
<td>Dynamic air removal (Pre-Vacuum)</td>
</tr>
<tr>
<td>Terminal Sterilization</td>
</tr>
<tr>
<td>Dynamic air removal (Pre-Vacuum) without dry time</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.

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.

Aesculap AG
Am Aesculap-Platz
78532 Tuttlingen Germany

Phone: + 49 7461 95-0
Fax: + 49 7461 95-2600
www.aesculap.de

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!

Distributor in the US/Contact in Canada for product information and complaints:

Aesculap Inc.
3773 Corporate Parkway
Center Valley, PA 18034
800-258-1946
www.aesculapusa.com

SOP-AIC-5001044 Rev. 5 0118