Aesculap
XS clip applying forceps

Legend
1 Jaw piece with pulling rod
2 Sheath outer tube
3 Sheath
4 Rotary element
5 Lock pushbutton
6 Locking button
7 Branches left/right
8 Lock
9 XS clip applying forceps

Symbols on product and packages
CAUTION: general warning symbol. CAUTION: see documentation supplied with the product

Applicable to
For item-specific instructions for use and information on material compatibility, see also the Aesculap Extraneat at www.extranet.bbraun.com.

Intended use
The XS clip applicator forceps is used for opening and closing Aesculap Yasargil Phynox and titanium aneurysm clips.
The clip applicators are MR Unsafe.

Note
In the following text, Aesculap YASARGIL aneurysm clips are referred to as aneurysm clips.

Available sizes
XS clip applying forceps are available in various working lengths (see brochure for Yasargil Aneurysm clips).

All XS clip applying forceps are marked according to size (Mini or Standard) and clip material (Phynox or titanium) so that their correct application with aneurysm clips of the respective size and material can be ensured.

Safe handling and preparation
CAUTION
Federal law restricts this device to purchase by, or on instruction by 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 in accordance with its intended use; see Intended use.

Remove the transport packaging and 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.

Safe operation

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

Damage to, imprecise functioning and incorrect closing force of the aneurysm clips caused by use of inappropriate clip applying forceps
Use aneurysm clips only with the appropriate Aesculap clip applying forceps; note the relevant markings.

The aneurysm clips must be used in the following combinations:
- Phynox aneurysm clips must be applied with the XS clip applying forceps for Phynox aneurysm clips.
- Titanium aneurysm clips must be applied with the XS clip applying forceps for titanium aneurysm clips.
- Mini and Standard aneurysm clips must be applied with the XS clip applying forceps of the appropriate size (Mini or Standard, respectively).

Inserting the aneurysm clip and engaging the lock (Fig. 1)
- Make certain that jaw piece 1 cannot be pulled out of sheath 3.
- Insert the aneurysm clip into jaw piece 1.
- Push the lock pushbutton 5 while simultaneously compressing the branches left/right 7.

Lock 8 is engaged now. With lock 8 engaged, jaw piece 1 is adjusted so that the aneurysm clip is tightly clamped between jaws 1.

Releasing the lock (Fig. 2)

WARNING
Injury to the patient caused by aneurysm clips snapping out of the applying forceps!
- Never turn the locking button while an aneurysm clip is held in the XS clip applying forceps.

Turn rotary element 4 until the aneurysm clip is in the desired position.
Compress branches left/right 7.
Jaw piece 1 of XS clip applying forceps 9 closes and the aneurysm clip opens.
Lock 8 and lock pushbutton 5 automatically click back to the unlocked position.

Detaching the XS clip applying forceps from the aneurysm clip (Fig. 3)
- Release the pressure on branches left/right 7.
- Jaw piece 1 opens and the aneurysm clip closes.
- Detaching the XS clip applying forceps 9 from the aneurysm clip.

Disassembling

WARNING
Reduced functionality of the XS clip applying forceps due to bending of, or damage to, a component!
- Apply proper care when disassembling the XS clip applying forceps.
- Observe the sequential order of disassembly.

Turn locking button 6 to its initial position, see Fig. 5.
Extract jaw piece with pulling rod 1 from sheath outer tube 2.

Assembling

WARNING
Reduced functionality of the XS clip applying forceps due to bending of, or damage to, a component!
- Apply proper care when assembling the XS clip applying forceps.
- Observe the sequential order of assembly.

Turn locking button 6 to its initial position, see Fig. 5.

WARNING
Excessive load on the aneurysm clips caused by using a wrong combination of jaw piece/pulling rod and sheath outer tube!
- Verify that the code numbers and text on the jaw piece with pulling rod tally with those on the sheath outer tube, see Fig. 5.
- Insert jaw piece with pulling rod 1 until it engages in the sheath outer tube 2, ensuring that the correct assembly position of the jaw piece with pulling rod 1 is maintained, see Fig. 7.
- Inspect the XS clip applying forceps for proper functioning, see Safe operation.

Validated reproprocessing procedure

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

Note
Since no reproprocessing methods have been validated for removal of transmissible spongiform encephalopathy (TSE) agents from medical devices, this device should not be used for patients with known or suspected TSE agent disease, including CJD and vCJD.

Note
Mechanical reproprocessing 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 operator/sterile processing technician is responsible for this. The recommended chemistry was used for validation.
General information

Dried or affixed 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 hours, after which floating pre-cleaning and temperatures >45 °C for roof disinfector in a tray that is suitable for disinfecting (avoiding rinsing blind spots). Connect components with ultrasonic energy directly to the rinsing port of the injector handle. Keep working ends open for cleaning. Place instruments in the tray with their handles open.

Disassembling the product before carrying out the reprocessing procedure

Prior to manual disinfecting, allow water to drip off for a sufficient length of time to prevent dilution of the disinfectant solution. After manual cleaning/disinfection, check visible surfaces visually for residues. Repeat the cleaning/disinfection process if necessary.

Manual cleaning with immersion disinfection

<table>
<thead>
<tr>
<th>Phase</th>
<th>Step</th>
<th>T [°C]</th>
<th>t [min]</th>
<th>Conc. [vol %]</th>
<th>Water</th>
<th>Chemical</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Disinfecting cleaning</td>
<td>RT (cold)</td>
<td>&gt;15</td>
<td>2</td>
<td>D-W</td>
<td>Aldehyde-free, phenol-free, and QUT-10 concentrate, pH 9–10</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>Aldehyde-free, phenol-free, and QUT-10 concentrate, pH 9–10</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 deionized water (deionized, low microbiological contamination: drinking water quality at least)
RT: Room temperature

Recommended: Blieau Stabilized

Manually cleaned/disinfected at least 5 times, using a disposable syringe.

Manual cleaning/disinfection

Prior to manual disinfecting, allow water to drip off for a sufficient length of time to prevent dilution of the disinfectant solution. After manual cleaning/disinfection, check visible surfaces visually for residues. Repeat the cleaning/disinfection process if necessary.

Cleaning/disinfection

Product-specific safety notes on the reprocessing procedure

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.

Cleaning/disinfection

Prior to manual disinfecting, allow water to drip off for a sufficient length of time to prevent dilution of the disinfectant solution. After manual cleaning/disinfection, check visible surfaces visually for residues. Repeat the cleaning/disinfection process if necessary.

Manual cleaning/disinfection

Use manual pre-cleaning with brush and subsequent cleaning and thermal disinfection

Cleaning brush: e.g. FM232800
20 ml disposable syringe
Place the instrument in a tray that is suitable for cleaning (avoiding rinsing blind spots).
Connect components with ultrasonic energy directly to the rinsing port of the injector handle. Keep working ends open for cleaning. Place instruments in the tray with their handles open.

Chapter Manual cleaning/disinfection

Manual pre-cleaning with manual pre-cleaning and sub-chapter

Chapter Manual pre-cleaning with brush

Chapter Mechanical alkaline cleaning and thermal disinfecting
Mechanical cleaning/disinfection with manual pre-cleaning

Note
The cleaning and disinfection device must be of tested and approved effectiveness (e.g. FDA approval or CE mark according to DIN EN ISO 11140).

The cleaning and 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/°F)</th>
<th>t (min)</th>
<th>Conc. (vol%)</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>Aldehydes-free, phenols-free, and Quat free concentrate, pH = 9*</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>

Water: \( \leq 45°C \)
RT: Room temperature

*Recommended: B Braun Statimed

- Note the information on appropriate cleaning brushes and disposable syringes, see Validated cleaning and disinfection procedure.

Phase 1
- Fully immerse the product in the cleaning/disinfectant for at least 15 min. Ensure that all accessible surfaces are moistened.
- Clean the product with a suitable cleaning brush in the solution until all discernible residues have been removed from the surface.
- If applicable, brush through non-visible surfaces with an appropriate cleaning brush for at least 3 min.
- Mobilize non-rigid 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 flush the product thoroughly with clean running water.
- Mobilize non-rigid components, such as set screws, joints, etc. during rinsing.

Mechanical alkaline cleaning and thermal disinfecting

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

<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>Pre-rinse</td>
<td>&lt;25/77</td>
<td>3</td>
<td>D-W</td>
<td>-</td>
</tr>
<tr>
<td>II</td>
<td>Cleaning</td>
<td>92/191</td>
<td>10</td>
<td>FD-W</td>
<td>- Concentrate, alkaline:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- pH = 13</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- 6% w/w sodium citrate</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- 0.5% w/w working solution</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- pH = 11*</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 disinfecting</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 the program for cleaning and disinfection device</td>
</tr>
</tbody>
</table>

D-W: Drinking water
FD-W: Fully deionized water (sterile, low microbological contamination; drinking water quality at least)

*Recommended: B Braun Helimatik Cleaner alkaline

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

Inspection, maintenance and checks

- Prior to function checks, lubricate moving parts (e.g. gears, pointer components and threaded nuts) with maintenance oil suitable for the respective sterilization process (e.g. for steam sterilization: Aesculap STERILIT+® oil spray JG660 or STERILIT+® 1 lrip lubricant J5698).
- 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, crushed, worn, or fractured components).
- Dry the product if it is wet or damp.
- Repeat cleaning and disinfection of products that show insufficiencies or contamination.
- Check that the product functions correctly.
- Immediately put aside damaged or reprocessable products and send them to Aesculap Technical Service, see Technical Service.
- Assemble insufficiency products, see Assembling.
- Check for compatibility with associated products.

Packaging
- Appropriate protect products with fine working tips.
- Store products with ratchet locks fully opened or locked no further than in the first notch.
- Close the locks so that the jaws tips just touch each other.
- Place the product in its holder on or in a suitable tray. Ensure that all cutting edges are protected.
- Pack trays appropriately for the intended sterilization process (e.g. in sterile Aesculap containers).
- Ensure that the packaging provides sufficient protection against recontamination of the product during storage.

Steam sterilization

The product can be sterilized either in disassembled or in assembled condition.
- 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).
- Validate sterilization process based on the manufacturer's recommendation.
- Steam sterilization using saturated vapor process.
- Steam sterilizer according to DIN EN 285 and validated according to DIN EN ISO 17665
- Steam sterilization using saturated vapor process at 124 °C (holding time 6 min)
- When sterilizing several instruments 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 prevacuum cycle in a steam autoclave. To achieve a sterility assurance level of 10^{-6}, Aesculap recommends the following parameters:

<table>
<thead>
<tr>
<th>Autoclave Oven Tray/Steer container (gasketed 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 (132 °C)</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 cleared accessory to maintain sterility after processing, such as a wrap, pouch, etc.

WARNING for the US market
- If this device is 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 crosscontamination.

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

Technical Service

- 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/validity rights and forfeit of applicable licenses.
Service addresses
Aesculap Technischer Service
Am Aesculap-Platz
76522 Tuttingen / Germany
Phone: +49 (7461) 211-1602
Fax: +49 (7461) 16-5621
E-Mail: ats@aesculap.de
Or in the US:
Aesculap Technical Services
615 Lambert Pkwy Drive
Hazelwood
MO, 63042
Aesculap Repair Hotline
Phone: +1 (800) 214-3382
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
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Center Valley, PA, 18034,
USA
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09/14