Atraumatic Vascular Clamps
Instructions for Use

PRODUCT INFORMATION

Aesculap's Atraumatic Vascular Clamps are indicated for use in vascular surgery for temporary occlusion of arterial or venous vessels. The Atraumatic Vascular Clamps have a closed mouth shape to provide precise guidance of the jaws. Closing pressure is marked upon the clamp for quick reference. The Atraumatic Vascular Clamps are available in straight and curved jaw shapes.

- For endoscopic use, use only the Aesculap Endoscopic Vascular Clamp Applying Forceps or Clamp Removal Forceps.

**CONTRAINDICATIONS**

The use of vascular clamps is contraindicated when, in the judgment of the physician, their use would be contrary to the best interest of the patient.

**INSPECTION**

Before use, inspect the Atraumatic Vascular Clamps for possible damage, wear or non-functioning of the product. Carefully inspect the jaws. Damaged or defective clamps should not be used or processed. Contact your local sales representative or Aesculap Inc. for repair or replacement.

**PRECAUTIONS**

1. Atraumatic Vascular Clamps are delicate surgical devices. Do not apply excessive stress or strain at jaws or joints; misuse will result in misalignment. Use caution during cleaning and sterilization.

2. The vascular clamps should not be mechanically altered. Modification may result in changes in closing force and malfunction.

**CAUTION:** FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

**CARE AND HANDLING**

The procedures outlined below must be followed to ensure safe handling of biologically contaminated clamps.

**PRE-CLEANING**

1. Keep clamps moist and do not allow blood and/or body fluids to dry on the clamps. The decontamination process should begin immediately after completion of the surgical procedure.

2. Using a steady stream of lukewarm / cool water (below 110°F), rinse each clamp thoroughly to remove debris.

3. Open jaws of clamps for cleaning. Give special attention to joints and serrations.

**CLEANING**

1. Hand wash the Atraumatic Vascular Clamps using a low-sudsing, neutral pH (7-9), protein dissolving detergent. Follow manufacturer’s directions regarding concentration, temperature, and contact time.

2. Totally, immerse clamps during cleaning to prevent aerosolization. Do not exceed two hours soaking in ANY solution.

3. Do not use steel wool, wire brushes, pipe cleaners or abrasive detergents. Use of anything other than high quality brushes or lint free cloths designed for clamp cleaning may result in damage to the clamp.

4. Atraumatic Vascular Clamps can be cleaned manually, mechanically or in an ultrasonic cleaner.

**DECONTAMINATION / DISINFECTION**

**Note:** The decontamination procedure does not sterilize the clamps. Refer to and process the clamps as outlined in the STERILIZATION section.

Select a high-level disinfectant. Follow the cleaning agent’s recommended directions regarding concentration, temperature, contact time, and solution re-use. Do not use high acid (pH 4 or lower) or high alkaline (pH 10 or higher) products for disinfectants, such as bleach and bi-chloride of mercury.

**RINSING**

Thoroughly rinse the clamps with distilled water to remove all traces of the disinfecting solution. USE STERILE WATER ON THE FINAL RINSE.

**DRYING**

1. Clamps must be thoroughly dried to remove residual moisture before they can be stored. Moisture that is not removed may cause clamp corrosion.

2. Use a soft, absorbent towel, cloth, filtered compressed air, or a 70% alcohol rinse to aid in the drying process.

**STERILIZATION**

Aesculap does not recommend the Atraumatic Vascular Clamps to be sterilized by “Flash” or Chemical sterilization.

Sterilization of the Atraumatic Vascular Clamps may be accomplished by steam. To achieve a sterility assurance level of 10^-6, Aesculap recommends the sterilization parameters listed below:

<table>
<thead>
<tr>
<th>Sterilization Method</th>
<th>Minimum Exposure Time</th>
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<tbody>
<tr>
<td>STEAM: Pre-Vacuum</td>
<td>270°F / 134°C 4 minutes 4 minutes</td>
</tr>
<tr>
<td>Gas sterilizer</td>
<td>250°F / 121°C 15-30 minutes 40 minutes</td>
</tr>
<tr>
<td></td>
<td>270°F / 134°C 10-25 minutes 30 minutes</td>
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</tbody>
</table>

Other sterilization cycles may also be suitable. However, individuals or hospitals not using the recommended methods are advised to validate any alternative methods using appropriate laboratory techniques.

**STORAGE**

1. Aesculap Atraumatic Vascular Clamps must be completely dry before storing and must be handled with care to prevent damage.

2. Store the Atraumatic Vascular Clamps in sterilization trays to prevent damage to the clamp.

3. Keep the stored Atraumatic Vascular Clamps on carts or shelving in a storage area free of dust, insects, chemical vapors and extreme changes in temperature and humidity.