PRODUCT INFORMATION

Aesculap’s Alpha and Alpha-mini Vascular Clamps are indicated for use in vascular surgery. They are designed for temporary occlusion of vessels. The Alpha and Alpha-mini Vascular Clamps have a closed mouth box to provide precise guidance of the jaws. A plateau mounted on both sides of the clip for secure application and removal of the clip. Closing pressure is marked upon the plateau for quick reference. The Alpha Mini Vascular Clamps are provided with a pyramid jaw profile and the Alpha Vascular Clamps are offered with the DeBakey jaw profile.

1. The Alpha Mini Vascular Clamps (FE010K – FE024K) are available in 5 different patterns with two different closing forces (50g, 80g).
   - Clamps with a closing force of **50g** are intended for **venous vessels**.
   - Clamps with a closing force of **80g** are intended for **arterial vessels**.

2. The Alpha Vascular Clamps (FE030S – FE044S) are also available in 5 different patterns with two different closing forces (250g, 350g).
   - Clamps with a closing force of **250g** are intended for **venous vessels**;
   - Clamps with a closing force of **350g** are intended for **arterial vessels**.

Read the entire insert to ensure safe and correct handling of these specialized clamps.

Proper cleaning, handling, and sterilization will ensure that the Alpha Mini Vascular Clamps and Alpha Vascular Clamps perform as intended and extend their useful life.

PRODUCT DESCRIPTION

A. Alpha Mini Vascular Clamps

   **Catalog numbers:**  
   - FE010K, FE011K, FE012K, FE013K & FE014K = **50G**
   - FE020K, FE021K, FE022K, FE023K & FE024K=**80G**

   These Alpha Mini Vascular Clamps are clearly marked with the appropriate closing force and catalog identification number.
B. Alpha Vascular Clamps

Catalog numbers: FE030S, FE031S, FE032S, FE033S & FE034S=250G
FE040S, FE041S, FE042S, FE043S & FE044S=350G

These Alpha Vascular Clamps are clearly marked with the appropriate closing force and catalog identification number.

HOW SUPPLIED

Aesculap’s Alpha Mini Vascular Clamps and Alpha Vascular Clamps are supplied non-sterile and packaged one (1) per box. Each clamp must be cleaned and sterilized prior to use according to the procedures outlined in this document.

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 Alpha Mini Vascular Clamps and Alpha 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. Alpha Mini Vascular Clamps and Alpha 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.

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 Alpha Mini Vascular Clamps and Alpha 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. Alpha Mini Vascular Clamps and Alpha 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 the drying process.
STERILIZATION

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

Sterilization of the Alpha Mini Vascular Clamps and Alpha 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>Temperature</th>
<th>Minimum Exposure Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wrapped</td>
<td>In a STERILCONTAINER™</td>
<td></td>
</tr>
<tr>
<td>STEAM PRE-VACUUM</td>
<td>270°F / 134°C</td>
<td>4 minutes</td>
</tr>
<tr>
<td>GRAVITY</td>
<td>270°F / 134°C</td>
<td>10-25 minutes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>30 minutes</td>
</tr>
</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 Alpha Mini Vascular Clamps and Alpha Vascular Clamps must be completely dry before storing and must be handled with care to prevent damage.
2. Store the Alpha Mini Vascular Clamps and Alpha Vascular Clamps in sterilization trays to prevent damage to the clamp.
3. Keep the stored Alpha Mini Vascular Clamps and Alpha Vascular Clamps on carts or shelving in a storage area free of dust, insects, chemical vapors and extreme changes in temperature and humidity.

MAINTENANCE and REPAIR

WARNING: Instruments returned to Aesculap for repair must have a statement which testifies that each instrument has been thoroughly cleaned and disinfected. Failure to supply evidence of cleaning and disinfection will result in a cleaning charge and delayed processing of your instrument repair.

1. Repair of the instruments by parties other than Aesculap will void the above warranty.
2. If the instruments require repair or maintenance, return them in the Aesculap Instrument Repair (A.I.R.) box or other sturdy box with adequate foam, bubbles or other packaging material to protect the instruments.
3. Send the packaged instruments to:

   Aesculap, Inc.
   Attn.: Aesculap Technical Services
   615 Lambert Pointe Dr.
   Hazelwood, MO 63042
   Tel.: 1 (800) 214-3392 or 1 (650) 876-7000
   FAX: 1 (650) 876-7041

WARRANTY

Every product bearing the Aesculap name is guaranteed to be free of defects in workmanship and materials when used normally for its intended surgical purpose. Any Aesculap product delivered from Aesculap, Inc. proving to be defective will be replaced or repaired at Aesculap's discretion, with no charge to the customer.

These warranties shall not apply to conditions or defects resulting from, but not limited to: negligence, improper use, improper cleaning and handling, improper opening techniques, unauthorized repair work, caustic or abrasive cleaners, or items modified or customized by the customer at the customer's request.