MODIFIED VASCULAR Tourniquet Sets (TS-2XXXX)

DIRECTIONS FOR USE

Single Use Only.
Do not reuse. Do not resterilize.
Do not use if package is damaged or open.
Ethylene Oxide Sterilized. Non-pyrogenic.
Store in a cool, dry place.

WARNING: Read directions carefully before using this device.

DESCRIPTION

Modified Vascular Tourniquet Set
California Medical Laboratories, Inc., Modified Vascular Tourniquet Set consists of flexible silicone or PVC tubing provided with a malleable stainless steel snare. The Tourniquet Sets are available with varying quantities of tubes.

1. Tourniquet Tube
2. Stainless Steel Snare

INDICATIONS FOR USE

California Medical Laboratories, Inc., Modified Vascular Tourniquet Set is indicated for use in securing cardiopulmonary bypass cannulae used during cardiopulmonary bypass surgery.

CONTRAINDICATIONS

California Medical Laboratories, Inc., Modified Vascular Tourniquet Set is not designed, sold or intended for use other than indicated.

DIRECTIONS FOR USE

1. Remove the Tourniquet Set from the packaging using aseptic technique.
2. After removing the Tourniquet Set from the packaging, inspect the packaging and product for damage.

WARNING: If the packaging is damaged, do not use as sterility of the device may have been compromised.

WARNING: Inspect the product thoroughly for damage prior to use. Damage to the product (i.e., kink, crimps, distortions or cuts) may affect product performance. Do not use damaged product.

WARNING: Proper surgical procedure and technique is the responsibility of the attending medical professional (physician). This guideline is furnished for informational purposes only. Each surgeon must evaluate the appropriate use of this device, case by case, based upon medical training, experience, and the type of surgical procedure employed.
3. To shorten the tube, remove the snare and aseptically cut the tourniquet tube to desired length. Reinstate snare into the tube.

4. Slide the snare through a tourniquet tube. Place the purse string suture ends through the hook of the snare. Pull the snare with the suture strands in the hook of the snare back through the tourniquet tube.

5. Pull the suture taut to adequate tension with one hand, slide the tube down. Once desired tension has been applied, secure the suture by clamping the tourniquet tube with a hemostat.

6. Tie a holding suture around the tourniquet tube and the cannula to keep the cannula in place.

7. To remove the cannula, cut the holding suture from around the tourniquet tube and cannula, unclamp the tourniquet and pull the tourniquet tube off the purse string suture strands. Discard the tourniquet tubes properly.

**WARNING:** Do not use Modified Vascular Tourniquet Sets in an MRI environment.

**WARNING:** This device is designed for single use only. Do not reuse product.

**CAUTION:** Federal (USA) law restricts this device to sale by or on the order of a physician.

**Symbology**

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<thead>
<tr>
<th>Symbol</th>
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<tbody>
<tr>
<td><strong>LOT</strong></td>
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<tr>
<td><strong>REF</strong></td>
<td>Catalogue Number</td>
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<td><strong>△</strong></td>
<td>Use Before Date.</td>
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<tr>
<td><strong>2X STERILE</strong></td>
<td>Do not resterilize.</td>
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<td><strong>STERILE</strong></td>
<td>Sterile. Do not use if package is damaged or open.</td>
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<td><strong>STERILE EO</strong></td>
<td>Ethylene oxide sterilized</td>
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<td><strong>⚠ ATTENTION</strong></td>
<td>Read instruction prior to use.</td>
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<tr>
<td><strong>USA</strong></td>
<td>CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.</td>
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