Pruitt® Occlusion Catheter

Concept
To temporarily occlude a blood vessel without using a clamp or ties. The balloon conforms to the diseased interior wall of the vessel providing occlusion with less chance of damage to the vessel wall and lining.

Description
Balloon-tipped catheters have been used to occlude vessels for years. The catheters used have not been specifically designed for this application. The catheters used were too long, have too large a catheter body, and have openings for blood flow that must be clamped off.

Dr. Pruitt’s ideas was to design a catheter to temporarily occlude vessels which had dimensions that would make it more useful and less trouble to work around.

Storage
The Occlusion Catheters should be stored in a cool dark area away from fluorescent lights and sunlight to prevent premature deterioration of the latex balloon. The recommended maximum shelf life (use by date) is shown on the label.

Catheter Inspection And Testing
The Pruitt Occlusion Catheter is supplied in sterile peel-open packages. Inspect the package and do not use the catheter if there is any evidence that the package has been punctured or that the catheter has been damaged.

Inflate the balloon to the recommended capacity with air and immerse the balloon in sterile water. If there is any evidence of air bubbles escaping around the balloon or if the balloon will not remain inflated, do not use the catheter. Federal law (U.S.A.) restricts this product to sale by or on the order of a physician.

Indications
The occlusion of vessels both arterial and venous for the control of bleeding.

Contraindications
Not for use as a dilation catheter.

Precautions
1. This catheter is a temporary device and can not be implanted.
2. The occlusion catheter is recommended for a single use only.
3. Check the balloon integrity by using sterile saline for injection before use.
4. DO NOT EXCEED RECOMMENDED INFLATION CAPACITIES.
5. Air or gas should not be used to inflate the balloon if there is a possibility of embolization with balloon rupture.
6. Make secure connection between the syringe and hub to avoid the introduction of air.
7. To avoid damage, do not grasp the balloon with instruments during insertion.
8. Do not inflate the balloon to any greater volume than necessary to obstruct blood flow.
9. Deflate the balloon prior to withdrawing the catheter.
10. The possibility of balloon rupture must be taken into account when considering the risk involved in a balloon catherization procedure.
11. Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.
### Specifications

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum Liquid Capacity</td>
<td>0.5 mL</td>
<td>0.5 mL</td>
<td>1.0 mL</td>
</tr>
<tr>
<td>Usable Length</td>
<td>27 cm</td>
<td>27 cm</td>
<td>27 cm</td>
</tr>
<tr>
<td>Contents</td>
<td>One Catheter, One Syringe, 3 mL</td>
<td>One Catheter, One Syringe, 3 mL</td>
<td>One Catheter, One Syringe, 3 mL</td>
</tr>
</tbody>
</table>

### Re-sterilization/Repackaging

This device is single-use only. Do not reuse, reprocess, or re-sterilize. The cleanliness and sterility of the re-processed device cannot be assured. Reuse of the device may lead to cross contamination, infection, or patient death. The performance characteristics of the device may be compromised due to reprocessing or re-sterilization since the device was only designed and tested for single use. The shelf life of the device is based on single use only. If for any reason this device must be returned to LeMaitre Vascular, place it in its original packaging and return it to the address listed on the box.

### Limited Product Warranty; Limitation of Remedies

LeMaitre Vascular, Inc. warrants that reasonable care has been used in the manufacture of this device. Except as explicitly provided herein, LEMAITRE VASCULAR (AS USED IN THIS SECTION, SUCH TERM INCLUDES LEMAITRE VASCULAR, INC., ITS AFFILIATES, AND THEIR RESPECTIVE EMPLOYEES, OFFICERS, DIRECTORS, MANAGERS, AND AGENTS) MAKES NO EXPRESS OR IMPLIED WARRANTIES WITH RESPECT TO THIS DEVICE, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE (INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE) AND HEREBY DISCLAIMS THE SAME. LeMaitre Vascular makes no representation regarding the suitability for any particular treatment in which this device is used, which determination is the sole responsibility of the purchaser. This limited warranty does not apply to the extent of any abuse or misuse of, or failure to properly store, this device by the purchaser or any third party. The sole remedy for a breach of this limited warranty shall be replacement of, or refund of the purchase price for, this device (at LeMaitre Vascular’s sole option) following the purchaser’s return of the device to LeMaitre Vascular. This warranty shall terminate on the expiration date for this device.

IN NO EVENT SHALL LEMAITRE VASCULAR BE LIABLE FOR ANY DIRECT, INDIRECT, CONSEQUENTIAL, SPECIAL, PUNITIVE, OR EXEMPLARY DAMAGES. IN NO EVENT WILL THE AGGREGATE LIABILITY OF LEMAITRE VASCULAR WITH RESPECT TO THIS DEVICE, HOWEVER ARISING, UNDER ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, TORT, STRICT LIABILITY, OR OTHERWISE, EXCEED ONE THOUSAND DOLLARS (US$1,000), REGARDLESS OF WHETHER LEMAITRE VASCULAR HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH LOSS, AND NOTWITHSTANDING THE FAILURE OF THE ESSENTIAL PURPOSE OF ANY REMEDY. THESE LIMITATIONS APPLY TO ANY THIRD-PARTY CLAIMS.

A revision or issue date for these instructions is included on the back page of these Instructions for Use for the user’s information. If twenty-four (24) months has elapsed between this date and product use, the user should contact LeMaitre Vascular to see if additional product information is available.

### References

| English Symbol Legend | Distributed By | Quantity | Outer Diameter |
|-----------------------|----------------|----------|----------------|----------------|
|                       |                |          |                |                |

Symbol Legend
<table>
<thead>
<tr>
<th>cm</th>
<th>Rx only</th>
<th></th>
<th>www</th>
</tr>
</thead>
<tbody>
<tr>
<td>English</td>
<td>Usable Length</td>
<td>Caution: U.S. Federal and other law restricts this device to sale by or on the order of a physician.</td>
<td>Do Not Use if Package is Opened or Damaged</td>
</tr>
</tbody>
</table>