



**Polyurethane Dual Lumen Occlusion  
Catheter**  
English — Instructions for Use

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# Polyurethane Dual Lumen Occlusion Catheter

## Polyurethane Dual Lumen Occlusion Catheter

(Model Numbers 4F-2L-40, 4F-2L-80, 5F-2L-40, 5F-2L-80, e4F-2L-40, e4F-2L-80, e5F-2L-40, e5F-2L-80)

Instructions for Use - English



### Concept

Balloon tipped catheters have been used to occlude vessels for years. Balloon occlusion can lessen the chance of damage to vessel walls and lining. Often, catheters were not specifically designed for this application. They did not have a second lumen or access to the vessel distal to the point of occlusion nor did they have a stopcock to maintain the inflation level of the balloon. Dr. Pruitt's idea was to design a line of catheters specifically for arterial occlusion and irrigation.

### Description

The Polyurethane line of balloon dual lumen occlusion catheters and kits has been specifically designed and dimensioned for use as described in the 'Indications' section. The Polyurethane line of catheters features a second lumen designed to allow access to the vessel distal to the point of occlusion. Two stopcocks with a luer-lock fitting at the proximal end of the irrigation lumen are provided to facilitate control of such procedures. The balloon thickness is designed to reduce the possibility of puncture by calcium deposits, and maintain balloon inflation levels throughout the procedure.

### Indications

The Dual Lumen Occlusion Catheters are intended for temporary occlusion of blood vessels to control bleeding and to access the vessel lumen distal to the point of occlusion.

### Contraindications

1. The Dual Lumen Occlusion Catheter is NOT to be used as a Vessel Dilatation Catheter. This Catheter is a temporary device and CANNOT BE IMPLANTED.
2. The Dual Lumen Occlusion Catheter should not be used in the venous system.
3. This catheter is NOT designed for use in cleaning AV grafts.
4. Not for the introduction of drugs other than heparin or contrast media.

### Specifications

Model Number	Catheter Size	Balloon Diameter	Useable Length	Maximum Liquid Capacity	Balloon Material
4F-2L-40, e4F-2L-40	4F	9 mm	40 cm	0.75 cc	Polyurethane
4F-2L-80, e4F-2L-80	4F	9 mm	80 cm	0.75cc	Polyurethane
5F-2L-40, e5F-2L-40	5F	11 mm	40 cm	1.5 cc	Polyurethane
5F-2L-80, e5F-2L-80	5F	11 mm	80 cm	1.5 cc	Polyurethane

### Applications

1. Occlusion: To temporarily occlude vessels during surgery, position the catheter balloon with the vessel lumen to the point requiring the occlusion. Inflate the balloon with sterile saline for injection to occlude the vessel, taking care not to overinflate the balloon (see recommended inflation capacity chart). Do not inflate the balloon to any greater volume than necessary to obstruct the blood lumen. Close the inflation stopcock to maintain balloon inflation. During positioning, the irrigation lumen should be allowed to aspirate until there is free return of fluid, to reduce the chance of air embolism.
2. Irrigation: Once the catheter is positioned, introduction or withdrawal of materials to areas distal to the point of occlusion may be accomplished through the irrigation lumen. This is facilitated through the luer-lock fitting at the base of the irrigation stopcock.

### Precautions

1. The catheter is recommended for single use only.
2. Inspect the product and package prior to use and do not use the catheter if there is any

evidence that the package has been punctured or that the catheter has been damaged.

3. Pretest the catheter before use: a) inflate the balloon to the recommended capacity with air and immerse the balloon in sterile water. If there is any evidence of air escaping around the balloon or if the balloon will not remain inflated, do not use the product. b) Also, check the balloon integrity by inflating and deflating with sterile saline for injection before use. If the balloon does not appear to function normally, do not use the product.
4. Air or gas should not be used to inflate the balloon if there is a possibility of embolization with balloon rupture.
5. Make secure connections between all syringes and hubs to avoid the introduction of air.
6. Do not inflate the balloon to any greater volume than is necessary to obstruct the blood flow. DO NOT EXCEED the recommended maximum inflation capacity. See chart for specific catheter inflation limits.
7. The irrigation lumen of the catheter should be aspirated until there is a free return of fluid during insertion. This should reduce the chance of air embolism.
8. Caution should be exercised when encountering extremely diseased vessels. Arterial rupture or balloon failure due to sharp calcified plaque, may occur.
9. Deflate the balloon prior to withdrawing the catheter.
10. The possibility of balloon rupture or failure must be taken into account when considering the risk involved in a balloon catheterization procedure..
11. Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.
12. This catheter is intended for use in the arterial system. It is not designed for use in cleaning AV grafts.

#### **Storage/Shelf Life**

Store the catheter in a dry dark area away from heat and chemicals.

#### **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.

#### **References**

1. Burdick, J.F., Williams, G.M., "A Study of the Lateral Wall Pressure Exerted by Balloon Tipped Catheters". *Surgery*, v. 87, June 1980, pages 638-644.
2. Chidi, C.C., DePalma, R.G., "Atherogenic Potential of the Embolectomy Catheter". *Surgery*, 83:549,1978.
3. Dujovny, M., Laha, R.K., Barrionuevo, P., "Endothelial Changes Secondary to Use of the Fogarty Catheter". *Neurological Surgery*, 7:39, 1977.
4. McCaughan, J.J., Young, J.M., "Intra-Arterial Occlusion in Vascular Surgery". *Annals of Surgery*, v. 71, May 1970, pages 695-703.


#### **Limited Product Warranty; Limitation of Remedies**

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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.

## Symbol Legend

			<b>Rx only</b>				 eflu.Lemaitre.com
Distributed By	Outer Diameter	Usable Length	Caution: U.S. Federal and other law restricts this device to sale by or on the order of a physician.		Do Not Use if Package is Opened or Damaged	Not made with natural rubber latex	Consult instructions for use: <a href="https://eflu.lemaitre.com">https://eflu.lemaitre.com</a>

						
Manufacturer	Do not re-use	Do not resterilize	Sterilized using ethylene oxide	Keep dry	Keep away from sunlight	Consult instructions for use

				
Catalogue Number	Batch Code	Use-by Date	Quantity	Date of Manufacture



# Polyurethane Dual Lumen Occlusion Catheter

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