Edwards Lifesciences

Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.

Fogarty Arterial Embolectomy Catheter

For Single Use Only

Indications

The Fogarty Arterial Embolectomy Catheter is indicated for the removal of fresh, soft emboli and thrombi from vessels in the arterial system.

To remove fibrous or adherent material, alternative devices such as the Fogarty Adherent Clot and Graft Thrombectomy Catheter are recommended.

Contraindications

- The arterial embolectomy catheter should not be used outside the arterial system.
- The arterial embolectomy catheter is not recommended for the removal of fibrous, adherent, or calcified material (e.g. chronic clot, atherosclerotic plaque). The catheter is not designed to withstand the additional pull force needed to remove these materials.
- The arterial embolectomy catheter is not intended for use as a vessel dilator.
- The arterial embolectomy catheter should not be used in the venous system.

Warnings

- Balloon rupture and catheter separation as a result of excessive pull force applied to remove adherent material are the most frequent causes of reported failures. The possibility of balloon rupture must be taken into account when considering the risks involved in any embolectomy procedure.
- To minimize the risk of vessel damage, balloon rupture, or tip detachment, do not exceed the maximum recommended inflation volume and pull force for each size catheter (see **Specification Table**).
- Use of a highly viscous or particulate contrast medium is not recommended for balloon inflation because the inflation lumen may become occluded.
- To avoid air embolus in case of balloon rupture, air should not be used for balloon inflation. Carbon dioxide is the only recommended gas. See Instructions.

Instructions

Prepare

Using sterile technique, remove the cap or cap and stiffening stylet from the catheter hub.

Purge

Inflate the balloon with sterile fluid or gas to the maximum recommended volume. (It is recommended that the 2F (0.67 mm) catheter be inflated with carbon dioxide gas.) Pull a vacuum on the syringe. Repeat until all air is removed. **Note:** For all inflations use the smallest syringe capable of holding the stated maximum fluid capacity.

Inspect

The catheter should be inspected with the balloon inflated during purging. A balloon that does not inflate, leaks, or inflates in a grossly asymmetric (eccentric) manner should not be used.

Caution: The amount of fluid in the syringe should be checked before each inflation. Do not exceed the recommended maximum inflation volume. See the specification table.

Place

With the balloon deflated, insert the catheter into the vessel and beyond the obstructing material.

Inflate

With the catheter suitably positioned, inflate the balloon with sterile fluid or gas. Balloon inflation should be stopped when the balloon can be felt to engage the arterial wall. **Note:** The 2F (0.67 mm) catheter should be inflated with carbon dioxide gas. Gas seepage through the intact balloon will require frequent adjustment of the inflation volume.

Caution: To minimize lateral wall pressures and shear forces on the inner surface of the artery, use the smallest inflated balloon diameter that will remove the obstructing material.

Caution: Air should not be used for inflation in instances where balloon rupture could produce a dangerous air embolus.

Withdraw

Remove the occlusive material by gently withdrawing the catheter. During withdrawal, it is important to adjust the balloon diameter to the varying arterial diameters by controlling the inflation volume. **Caution:** Do not exceed the Maximum Recommended Pull Force. (See **Specification Table**).

Caution: Inflation of the balloon is associated with a feeling of resistance to the fluid or gas injection. When no resistance is encountered it should be assumed that the balloon has ruptured. Discontinue inflation and remove the catheter at once.

MRI Information

This product has not been tested for MRI compatibility.

Complications

As with all catheterization procedures, complications may occur. These may include local or systemic infection, local hematomas, intimal disruption, arterial dissection, perforation and vessel rupture, hemorrhage, arterial thrombosis, distal embolization of blood clots and atherosclerotic plaque, air embolus, aneurysm, arterial spasm, arteriovenous fistula formation, and balloon rupture with fragmentation, tip separation and distal embolization.

How Supplied

Contents sterile and nonpyrogenic if package is unopened and undamaged. Do not use if package is opened or damaged.

Storage

Store in a cool, dry place.
Temperature Limitation: 0° - 40 °C,
Humidity Limitation: 5% - 90% RH.

Shelf Life

The recommended shelf life is as marked on each package. Storage beyond the expiration date may result in product deterioration. **Note:** Reprocessing or resterilization will not extend the indicated shelf life.

Technical Assistance

For technical assistance, please call Edwards Technical Support at the following telephone numbers:
Inside the U.S. and Canada
(24 hours): 800.822.9837
Outside the U.S. and Canada
(24 hours): 949.250.2222
In the UK: ..... 0870 606 2040 - Option 4
In Ireland: ..... 01 8211012 Option 4

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

Disposal

After patient contact, treat the device as biohazardous waste. Dispose of in accordance with hospital policy and local regulations.

Warning: This device is designed, intended, and distributed for single use only. **Do not re-sterilize or reuse this device.** There are no data to support the sterility, nonpyrogenicity, and functionality of the device after reprocessing.

Prices, specifications, and model availability are subject to change without notice.

Refer to the symbol legend at the end of this document.

Sterilized Using Ethylene Oxide

Specification Table

Catheter French Size (mm)	**2F 0.67**	**3F 1.00**	**4F 1.33**	**5F 1.67**	**6F 2.0**	**7F 2.3**
Maximum Liquid Capacity (ml)	N/A	0.2	0.75	1.5	2.0	2.5
Maximum Gas Capacity (ml)	0.2	0.6	1.7	3.0	4.5	5.0
Maximum Recommended Pull Force on Inflated Balloon (lbs.)	0.5	0.7	1.5	2.0	2.5	3.5
(kg)	0.23	0.3	0.68	0.9	1.13	1.59
Diameter of Inflated Balloon (mm)	4	5	9	11	13	14
Maximum French Size of Deflated Balloon	3.4F	4.3F	5.0F	6.0F	7.0F	8.0F
(mm)	1.13	1.43	1.67	2.0	2.3	2.7

Symbol Legend

	English		English		English
cm	Usable Length		Use By	SZ	Size
GW	Recommended Guidewire Size	STERILE EO	Sterilized Using Ethylene Oxide		Consult instructions for use
REF	Catalogue Number	BC	Balloon Capacity		Store in a cool, dry place.
	Minimum Introducer Size		Do not use if package is opened or damaged.	40 °C 0 °C	Temperature Limitation
	Caution		Manufacturer	90% 5%	Humidity Limitation
	Single use		Date of Manufacture	STERILIZE	Do not resterilize
#	Quantity	LATEX	Contains or presence of natural rubber latex		Non-pyrogenic
LOT	Lot Number	Rx only	**Caution:** Federal (USA) law restricts this device to sale by or on the order of a physician.	CE 0123	CE conformity marking per European Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.
EC REP	Authorized Representative in the European Community	eifu.edwards.com + 1 888 570 4016	Consult Instructions for Use on the website eifu.edwards.com	+ 1 888 570 4016 http://eifu.edwards.com	Consult Instructions for Use on the website

Note: Not all symbols may be included in the labeling of this product.

VEM1SL8x11.7

Edwards

EC REP

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