Edwards Lifesciences

Fogarty Dilation Atrioseptostomy Catheter

1. Stylet
2. Inflation Hub with Gate Valve
3. Catheter Shaft
4. Latex Balloon

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

For Single Use Only

1.0 Introduction

The Fogarty dilation atrioseptostomy catheter is designed for enlarging interatrial openings. In most pediatric cardiology centers, balloon atrioseptostomy is an accepted technique for palliation of several congenital cardiac defects.

2.0 Description of Use

Balloon atrioseptostomy can be performed in conjunction with diagnostic cardiac catheterization or under echocardiographic guidance and has been carried out after the diagnosis of several congenital cardiac defects including but not limited to: transposition of the great arteries, total anomalous pulmonary venous drainage without pulmonary obstruction, tricuspid atresia, and pulmonary atresia with intact ventricular septum.

3.0 Description of the Device

The Fogarty balloon atrioseptostomy catheter is a single-lumen catheter with a wire-wound shaft that may be visualized using fluoroscopy. A removable stylet is included and may be used to facilitate insertion. The catheter contains a gate valve in order to capture and release the inflation volume within the balloon and catheter body. The catheter shaft has depth markings in 10 cm spacing.

4.0 Indications for Use

Fogarty dilation atrioseptostomy catheter is indicated for enlarging interatrial openings for palliation of several congenital cardiac defects to increase mixing at atrial level or to decompress a hypertensive atrial chamber.

5.0 Contraindications

There are no known contraindications for the Fogarty dilation atrioseptostomy catheter.

6.0 Setup

6.1 Inflation Material

Inflate the balloon with a sterile, blood-compatible fluid that may include nonparticulate, radiopaque solutions only if they are highly diluted. The use of viscous or highly particulate contrast medium is not recommended for balloon inflation as this may occlude the catheter lumen and prevent deflation of the balloon before catheter withdrawal.

CAUTION: Air should never be used in ANY instance because balloon rupture could produce a dangerous air embolus.

6.2 Balloon Testing and Preparation

Standard de-airing techniques should be used to remove air from the balloon shaft. Prior to insertion, test the balloon by inflating the balloon with a syringe filled with 0.9 ml of saline.

Note: Do not use more than 0.9 ml of saline for testing. Large volumes will stretch the balloon and make insertion more difficult.

7.0 Instructions for Use

7.1 Catheter Insertion

The catheter may be introduced either by venous cutdown or percutaneous technique.

CAUTION: Care must be exercised to avoid damage to the balloon during insertion of the catheter.

Note: Use of the stylet in the catheter to facilitate introduction may reduce catheter flexibility and decrease the sensitivity for recognizing obstructions.

Note: Use of the stylet in the catheter increases uninflated balloon outer diameter.

7.2 Septostomy Procedure

All steps should be carried out with echocardiographic +/- fluoroscopic guidance.

1. Place catheter tip in the center of the left atrial cavity.
2. Inflate balloon under either continuous echocardiographic or fluoroscopic imaging. Use 0.9 ml of fluid for the first septostomy.
3. While the balloon is inflated, close the gate valve, gently retract the balloon against the septum, then pull the balloon rapidly across the atrial septum into the right atrium using a short firm motion.

   Note: This pullback must be as rapid as possible. Stop the pullback at the inferior vena cava-right atrial junction and allow the balloon to rebound into the right atrium. If necessary, advance the inflated balloon into the mid right atrium.

   CAUTION: When pulling the balloon back into the right atrium, ensure that it is positioned such that it does not impede blood flow into the heart prior to deflation of the balloon.
4. Open the gate valve and actively deflate the balloon by applying negative pressure, reposition the catheter in the left atrium and repeat the septostomy using incremental balloon inflation volumes as needed to a maximum of 1.8 ml.

CAUTION: The number of repeated pulls through the septal wall with a single catheter shall be limited to 3 to prevent balloon from detaching from the catheter or premature deflation.

CAUTION: Do not exceed maximum recommended capacity per Table 1 as over-inflation increases the possibility of balloon rupture. Inflation of the balloon is associated with a feeling of resistance so that on release of

pressure the plunger of the syringe should slip back. If no resistance is encountered, it should be assumed that the balloon has ruptured. Inflation should be discontinued at once, and the catheter withdrawn.

CAUTION: *In vitro* laboratory tests indicated that there is a potential risk of balloon fragmentation with balloon inflation above 1.8 ml.

7.3 Catheter Removal

Always deflate the balloon before withdrawal of the catheter to prevent patient injury. When withdrawing through a sheath, always remove the balloon under negative pressure in order to maintain balloon integrity. If a significant increase in resistance occurs when withdrawing the catheter, stop withdrawal and investigate the cause of resistance before proceeding.

8.0 Potential Adverse Events

Potential risks associated with the device and procedure include:

- Allergic/immunologic reaction to the device
- Arrhythmia/Conduction system injury
- Bleeding
- Cardiogenic shock
- Cardiovascular injury including perforation or dissection of vessels, ventricle, atrium, septum, myocardium, valvular structures, arteriovenous (AV) fistula, or pseudoaneurysm that may require intervention
- Death
- Device failure or separation that may require intervention
- Embolism (air and device fragment)
- Emergency surgery
- Fever
- Hematoma
- Infection
- Inflammation
- Stroke
- Thromboembolic event

9.0 MRI Information

This product has not been tested for MRI compatibility.

10.0 How Supplied

Fogarty dilation atrioseptostomy catheters are supplied sterilized with ethylene oxide gas and non-pyrogenic. Do not use if the package has been opened or damaged.

11.0 Storage

Store in a cool, dry place.

12.0 Shelf Life

The recommended shelf life is marked on each package. Storage beyond recommended time may result in balloon deterioration.

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

WARNING: This device is designed, intended, and distributed for single use only. Do not resterilize or reuse the device. There are no data to support the sterility, nonpyrogenicity, and functionality of the device after reprocessing.

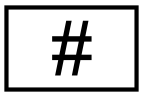
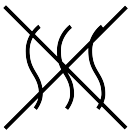
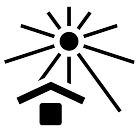
13.0 Specifications

Table 1

Model	**830705F**
French Size	5 F (1.67 mm)
Uninflated Balloon OD	8 F (2.7 mm)
Body Length 50 cm, single-lumen, wire-wound body	
Maximum Balloon Inflation Capacity (liquid)	1.8 ml
Maximum Inflation Diameter	15 mm
Recommended Inflation Volume	
First septostomy	0.9 ml
Maximum septostomy	1.8 ml
Tip Angle	35 °
Percutaneous Introducer Size	8 F (2.7 mm)

Symbol Glossary

The following symbols used in the product labels are established in ISO 15223-1:2021 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.

	Title of symbol	Meaning of the symbol
	Model number	Indicates the model number or type number of the product
	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure
	Contains or presence of natural rubber latex	Indicates the presence of natural rubber or dry natural rubber latex as a material of construction within the medical device or the packaging of a medical device.
	Non-pyrogenic	Indicates a medical device that is non-pyrogenic.
	Do not resterilize	Indicates a medical device that is not to be resterilized.
	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been opened or damaged.
 eifu.edwards.com + 1 888 570 4016	Consult instructions for use on the website	Indicates the need for the user to consult the instructions for use (IFU). Note: when accompanied by a URL or phone number, the IFU with symbol glossary may be located at the URL or via the phone number.
	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified
	Use-by date	Indicates the date after which the medical device is not to be used.
	Date of manufacture	Indicates the date the medical device was manufactured
	Manufacturer	Indicates the medical device manufacturer
	Keep away from heat	Indicates a medical device that needs to be protected from heat.

	Title of symbol	Meaning of the symbol
	Keep dry	Indicates a medical device that needs to be protected from moisture.

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