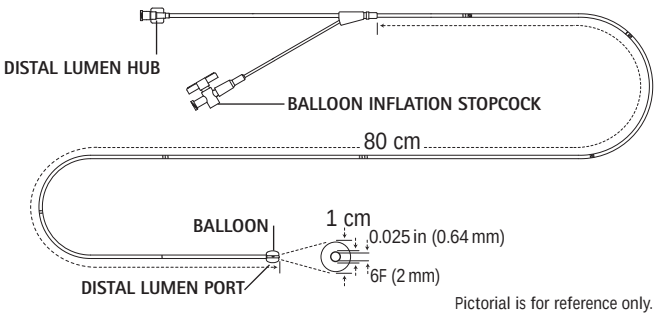
Venogram Balloon Catheter: Balloon Inflation, Distal Infusion

Detailed Device Description	
Tip Shape	J
Lumens	2
Catheter Body Outer Diameter	6 F (2 mm)
Introducer Size	6 F (2 mm) (minimum)
Usable Length	32 in. (80 cm)
Maximum Inflation Capacity	1.25 cm^3
Inflated Balloon Diameter	10 mm
Recommended Guidewire Size	0.025 in. (0.064 cm)
Materials - Catheter Body Balloon	Polyurethane Latex



Pictorial is for reference only.

DESCRIPTION
The venogram balloon catheter consists of extruded radiopaque polymeric tubing with two lumens in the main body of the catheter. The inflation lumen features a one-way stopcock at the proximal end. Its distal end opens into a latex balloon, which is located near the catheter tip. The distal lumen has an infusion lumen at its proximal end. The infusion port is at the very end of the catheter distal to the latex balloon.

INDICATION FOR USE
The venogram balloon catheter is indicated for use within the coronary sinus; it is intended for infusing contrast solutions into the coronary vasculature for venogram imaging.

CONTRAINDICATION
The venogram balloon catheter is contraindicated for patients with a known allergy to latex or contrast medium.

WARNINGS
- Do not exceed the recommended maximum balloon inflation capacity. Exceeding this volume will not appreciably increase the diameter of the balloon and will increase the probability of balloon rupture. Refer to the Detailed Device Description table for maximum inflation capacity.
- Use only filtered carbon dioxide to inflate the balloon if there is a possibility that balloon rupture would result in air embolism in the left side of the heart or systemic circulation.
- Do not use liquids as a balloon inflation media.
- Do not inject contrast solution into the infusion lumen if blood cannot be aspirated, to avoid pulmonary extravasation.
- Although diagnostic cardiac catheterization procedures have proven to be safe, certain complications can occur, and it is recommended that the user of this product becomes familiar with the guidelines established by Drs. Swan and Ganz for the safe use of the venogram balloon catheter.[1]

PRECAUTIONS
DISPOSABLE DEVICE
- The venogram balloon catheter has been sterilized in ethylene oxide prior to shipment. Do not clean or resterilize the venogram balloon catheter. Destroy the venogram balloon catheter after use.
- Inspect the sterile package before opening. If the package is damaged, do not use the product.

STORAGE
Avoid prolonged exposure to direct light in order to protect the patency of the latex balloon.

HANDLING THE CATHETER
Do not use forceps on the catheter. Perforations, arteriovenous fistula formation, and other vascular trauma have been reported with the use of vascular catheters. Complications may develop during any catheterization procedure.

POTENTIAL COMPLICATIONS
Potential complications related to the use of the venogram balloon catheter include, but are not limited to, the following patient-related conditions: air embolism, allergic reaction to contrast media, allergic reaction to latex, bleeding at the insertion site, brachial plexus injury, cardiac tamponade, dissection, endocarditis, hematoma formation, hemothorax, infection, irregular heart beat, perforation,

Avoid prolonged exposure to direct light in order to protect the integrity of the latex balloon.

PHT DEHP Contains DEHP

STERILE EO NONPYROGENIC Contents sterile in unopened, undamaged package.

Rx only

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

For single use only. Do not resterilize.

15° C – 30° C Store between 15° - 30° C (59° - 86° F), in a dry place.

Distributed by:
Pressure Products, Inc.
49 Via Alicia
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Manufactured by:
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Bethlehem, PA 18018-3524 USA
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Assembled in USA.
Components from USA and Germany.

pneumothorax, subclavian artery puncture, thrombophlebitis, thrombosis, valve damage, vascular occlusion, vessel damage. Other potential complications related to the venogram balloon catheter include, but are not limited to the following: balloon rupture, catheter knotting.

INSTRUCTIONS FOR USE

The procedures for using the venogram balloon catheter include testing the balloon before use, placing the venogram balloon catheter, and obtaining a venogram.

Some techniques vary according to physician preference and the patient's anatomy or physical condition. The following instructions suggest one or two possible techniques, additional methods may exist.

NOTE: Creating a venogram using the venogram balloon catheter requires the use of a contrast solution. A syringe containing contrast solution should be prepared prior to using the venogram balloon catheter. Do not use the syringe supplied with the balloon catheter for this purpose. Refer to the documentation packaged with the contrast medium used for the solution to determine the amount of solution required for the venogram imaging.

NOTE: To reduce clotting, a slow infusion of heparinized saline solution or heparinized 5% dextrose solution is recommended.

TESTING THE BALLOON BEFORE USE

WARNING: Use only filtered carbon dioxide to inflate the balloon if there is a possibility that balloon rupture would result in an air embolism in the left side of the heart or systemic circulation. If carbon dioxide will be used as the inflation medium during the procedure, then carbon dioxide must be used as an inflation medium during balloon testing.

1. Using aseptic technique, remove the balloon catheter and accessories from the sterile package.
2. Fill the syringe with 1.25 cm^3 of inflation medium; air or filtered carbon dioxide.
3. Open the stopcock on the inflation lumen by moving the lever so that it is parallel with the inflation lumen.
4. **CAUTION:** Do not inflate the balloon using a syringe other than the one provided with the venogram balloon catheter. Inject the inflation medium into the inflation lumen. Then, close the stopcock.
5. Inspect the balloon.
6. Deflate the balloon using one of the following techniques:
   a. If air is the inflation medium, open the stopcock to deflate the balloon.
   b. If carbon dioxide is the inflation medium, refill the syringe with carbon dioxide. Open the stopcock to allow the balloon to deflate, and then inflate the balloon a second time. Open the stopcock to allow the balloon to deflate. Remove the syringe soon as the balloon has deflated.

PLACING THE VENOGRAM BALLOON CATHETER

The venogram balloon catheter should be introduced into the body and placed within the coronary sinus by inserting it through an appropriate guide catheter. Refer to the documentation packaged with the guide catheter for instructions on the following procedures:

- Inserting the guide catheter
- Placing the guide catheter tip within the coronary sinus
- Inserting the venogram balloon catheter into the guide catheter
- Passing the venogram balloon catheter through the guide catheter
- Removing the venogram balloon catheter

OBTAINING A VENOGRAM

1. After testing the venogram balloon catheter and passing the venogram balloon catheter through a guide catheter positioned in the coronary sinus, use fluoroscopy to check the placement of the balloon. The balloon should be in a proximal coronary sinus position, and the balloon should be completely past the distal end of the guide catheter. Use fluoroscopy to facilitate placement.
2. Prior to inflating the balloon catheter, inject a small amount of contrast solution through the infusion lumen of the venogram balloon to verify balloon catheter position and coronary sinus size.
3. Fill the syringe, supplied with the venogram balloon catheter, with 1.25 cm^3 of inflation medium; air or filtered carbon dioxide.
   WARNING: Use only filtered carbon dioxide to inflate the balloon if there is a possibility that balloon rupture would result in an air embolism in the left side of the heart or systemic circulation.
   WARNING: Do not exceed the recommended maximum balloon inflation capacity; 1.25 cm^3. Exceeding this volume will not appreciably increase the diameter of the balloon and will increase the probability of balloon rupture.
4. **CAUTION:** Do not inflate the balloon using a syringe other than the one provided with the venogram balloon catheter. Attach the inflation-medium-filled syringe to the inflation lumen; open the stopcock; slowly inject the inflation medium into the inflation lumen to inflate the balloon. Stop inflating the balloon when resistance is felt, indicating that the balloon has occluded the coronary sinus. Close the stopcock.
5. Aspirate blood through the infusion lumen to remove air from the infusion lumen.
   WARNING: Do not inject the contrast solution into the infusion lumen if blood cannot be aspirated, to avoid pulmonary extravasation.
6. With the inflated balloon occluding the coronary sinus, attach the syringe containing the contrast solution to the infusion lumen, and slowly inject the contrast solution through the infusion lumen and into the coronary vasculature.
   NOTE: If carbon dioxide is the inflation medium, the balloon may partially deflate because carbon dioxide diffuses through latex. If this happens, refill the syringe supplied with the balloon catheter with carbon dioxide; open the stopcock to deflate the balloon completely; inject the carbon dioxide into the inflation lumen and close the stopcock.
7. Create a venogram by recording a fluoroscope image of the contrast solution in the coronary vasculature.
8. After obtaining the venogram, open the stopcock to allow the balloon to deflate. Then, remove the venogram balloon catheter from the guide catheter according to the instructions in the guide catheter documentation.

WARNING

Re-use of single-use devices creates a potential risk of patient or user. It may lead to contamination and/or impairment of functional capability. Contamination and/or limited functionality of the device may lead to injury, illness or death of the patient. Animal experiments have shown DEHP to be potentially toxic to reproduction. Given the current state of scientific knowledge, a risk (in case of long-term use) especially for premature male babies cannot be completely excluded. As a precaution, the application of medical products containing DEHP should be restricted to short-term use for pregnant women, breastfeeding mothers, infants, and children.

[1]Swan HNC, Ganz W, Forrester J et al: Catheterization of the heart in man with the use of a flow directed balloon tipped catheter. N Engl J Med 283:447-451, 1970.