

## **BALLOON CATHETER**

### **DEVICE DESCRIPTION**

The Catheter consists of radio-opaque polymeric tubing with two lumens in the main body of the catheter. An inflation lumen and an infusion lumen and a balloon.

### **INDICATIONS FOR USE**

The Catheter is indicated for infusing contrast solutions for vascular imaging and balloon occlusion. The Catheter is intended for single use only.

### **STORAGE**

**Store in a cool, dark, dry area.**

Avoid prolonged exposure to direct light.

### **DIRECTIONS FOR USE**

The procedures for using the catheter include testing the balloon before use, placing the catheter, and infusing contrast. NOTE: Do not use the syringe supplied with the balloon catheter for contrast administration.

### **CATHETER INSPECTION AND TESTING**

The Catheter is supplied in a sterile package. Do not use if there is any damage noted.

1. Inflate the balloon to the largest recommended capacity. If the balloon will not remain inflated, do not use the catheter.

CAUTION: NEVER USE LIQUID FOR BALLOON INFLATION.

2. Flush the infusion lumen with a sterile solution of heparinized saline.

3. Maximum inflation diameter 1.75cm

### **PRECAUTIONS**

1. Always deflate the balloon prior to withdrawing the catheter.

### **WARNINGS**

1. Filtered CO<sub>2</sub> must be used for balloon inflation in any situation where balloon rupture may result in air embolus entering the arterial circulation, as in right-to-left intracardiac or intrapulmonary shunts.
2. Do not inflate the balloon beyond the stated maximum inflation capacity.

## **COMPLICATIONS**

1. Vessel Trauma
2. Stroke

## **PLACING THE BALLOON CATHETER**

Place the balloon catheter with an introducer or wire into the desired vessel.

## **OBTAINING AN ANGIOGRAM**

1. After testing the catheter use fluoroscopy to check appropriate placement of the balloon.
2. Aspirate and flush through the infusion lumen to remove air and blood.
3. Fill one of the syringes supplied with the catheter, with inflation medium: air or filtered carbon dioxide
4. 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 if resistance is felt indicating that the balloon has occluded the vessel. Do not over inflate as this may cause vessel trauma or rupture. Close the stopcock.
5. Inject the contrast solution into the vessel of interest while recording a fluoroscopic image.
6. After obtaining the contrast image, open the stopcock to allow the balloon to deflate. Then, remove balloon catheter slowly.