Balloon in Balloon (BIB®)

Dilatation Catheter

INSTRUCTIONS FOR USE

CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Read all instructions prior to use.

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B BRAUN

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INDICATIONS

Recommended for Percutaneous Transluminal Angioplasty (PTA) of the femoral, iliac and renal arteries. **These catheters are not designed to be used in the coronary arteries.**

DESCRIPTION

The NuMED Balloon in Balloon (BIB) Catheter is a triaxial design catheter. Two lumens are used to inflate the balloons while one lumen is for tracking over a guidewire. The radiopaque platinum marker(s) are placed beneath the 'working area' of the balloon. The inner balloon is ½ of the outer balloon diameter and 1 cm shorter. Each balloon inflates to the stated diameter and length at a specific pressure. The balloon size is ± 10% at rated burst pressure (RBP). The RBP is different for each size. Check the package label for the RBP. It is important that the balloon not be inflated beyond the RBP.

The purpose of the double balloon catheter is to apply an incremental inflation for the purpose of opening an artery. The inner balloon provides initial expansion of the artery and also acts as a tool to hold the catheter in place while the outer balloon is inflated. The outer balloon is then inflated providing the remainder of the expansion.

HOW SUPPLIED

Supplied sterilized by ethylene oxide gas. Sterile and non-pyrogenic if package is unopened or undamaged. Do not use the product if there is doubt as to whether the product is sterile. Avoid extended exposure to light. Upon removal from package, inspect the product to ensure no damage has occurred.

WARNING

- Do not exceed the RBP. An inflation device with pressure gauge is recommended to monitor pressure. Pressure in excess of the RBP can cause balloon rupture and potential inability to withdraw the catheter through the introducer sheath.
- Confirm that the distal end of the introducing sheath is at least 2.5cm back from the most proximal image band before inflating the outer balloon. Failure to do so may stretch the outer tubing and severely hinder balloon deflation.
- In PTA, the dilated balloon should not markedly exceed the diameter of the artery lying just proximal to the stenosis.
- Use only appropriate balloon inflation medium. Do not use air or gaseous medium to inflate the balloon.
- Use two appropriate size inflation devices with pressure gauges for inflation.

- Do not advance the guidewire, balloon dilatation catheter, or any other component if resistance is met, without first determining the cause and taking remedial action.
- This catheter is not recommended for pressure measurement or fluid injection.
- Do not remove the guidewire from the catheter at any time during the procedure except when the procedure has been completed.
- This device is intended for single use only. Do not resterilize and/or reuse it, as this can potentially result in compromised device performance and increased risk of cross-contamination.

PRECAUTIONS

- Dilatation procedures should be conducted under fluoroscopic guidance with appropriate x-ray equipment.
- Guidewires are delicate devices. Care should be exercised while handling to help prevent the possibility of breakage.
- Careful attention must be paid to the maintenance of tight catheter connections and by aspiration before proceeding to avoid air introduction into the system.
- Under no circumstances should any portion of the catheter system be advanced against resistance. The cause of the resistance should be identified with fluoroscopy and action taken to remedy the problem.
- If resistance is felt upon removal, the balloon, guidewire, and sheath should be removed as a unit, particularly if balloon rupture or leakage is known or suspected. This may be accomplished by firmly grasping the balloon catheter and sheath as a unit and withdrawing both together, using a gentle twisting motion combined with traction.
- Before removing the catheter from the sheath, it is very important that the balloon is completely deflated.
- Proper functioning of the catheter depends on its integrity. Care should be used when handling the catheter. Damage may result from kinking, stretching, or forceful wiping of the catheter.

POTENTIAL COMPLICATIONS / ADVERSE EFFECTS

- Potential complications related to the introduction of the catheter into the body include, but are not limited to, the following: infection, air embolism, and hematoma formation.
- Potential balloon separation following balloon rupture or abuse and the subsequent need to use a snare or other medical interventional techniques to retrieve the pieces.
- Complications associated with PTA include, but are not limited to: clot formation and embolism, nerve damage, vascular perforation requiring

surgical repair, damage to the vascular intima, cerebral accident, cardiac arrhythmias, myocardial infarction, or death. For specifics, refer to: Fellows, K. et al.: Acute Complications of Catheter therapy for Congenital Heart Disease, Amer Journ of Cardiol, 60;679(1987).

NOTE: There have been infrequent reports of larger diameter balloons bursting circumferentially, possibly due to a combination of tight focal strictures in large vessels. In any instance of a balloon rupture while in use, it is recommended that a sheath be placed over the ruptured balloon prior to withdrawal through the entry site. This can be accomplished by cutting off the proximal end of the catheter and slipping an appropriately sized sheath over the catheter into the entry site. For specific technique, refer to: Tegtmeyer, Charles J., M.D. & Bezirdijan Diran R., M.D. "Removing the Stuck, Ruptured Angioplasty Balloon Catheter." Radiology, Volume 139, 231-232, April 1981.

INSPECTION AND PREPARATION

1. Using proper sterile technique, open the catheter package and remove BIB® catheter. Inspect the catheter for kinks prior to use. **DO NOT REMOVE BALLOON PROTECTOR FROM BALLOON.** The catheter lumen (green hub), the inner balloon (indigo hub), and the outer balloon (orange hub) are appropriately labeled. Flush catheter lumen (green hub) with heparinized flush and insert .035 guidewire. **DO NOT ATTEMPT TO PURGE BALLOONS WITHOUT A GUIDEWIRE THROUGH THE CATHETER LUMEN.**
2. Prepare an inflation solution of 40% by volume of contrast medium (such as Renografin® 76%, Omnipaque® 300 etc.) and flush solution.
3. Fill and purge air from the inflation devices (2 needed for BIB® catheter). Rotate stopcock handle to "off" position relative to inflation device. Apply negative pressure with the inflation device and tip to remove air from manometer. Repeat as necessary. Attach one inflation device to each inflation port of the BIB catheter using a three way stopcock with rotating adapter. The indigo hub is the smaller inner balloon, the orange hub is the larger outer balloon.
4. Purging of the two balloons is done with negative pressure only. **DO NOT INFLATE EITHER BALLOON PRIOR TO USE.**
5. Attach a syringe capable of maintaining negative pressure (e.g. VacLok® syringe from Merit Medical or Becton-Dickinson Luer-Lok® syringe) to the other port of the stopcock. With the stopcock handle in the "off" position to the syringe, apply negative pressure to the syringe and lock. **ALWAYS START WITH THE INNER BALLOON (INDIGO HUB).** Turn the handle of the stopcock to apply negative pressure to the balloon. Tap the catheter shaft to facilitate movement of bubbles, and then shut off the negative pressure. Some contrast will passively move from inflation

device into the balloon. Repeat, alternating negative pressure and passive contrast, until you no longer have bubbles when applying negative pressure. It will be necessary to repeat this process several times. Repeat process with the outer balloon.

6. Leave both balloons on continuous negative pressure for insertion. Remove balloon protector prior to removing the guidewire. Flush catheter lumen with heparinized flush.

INSTRUCTIONS FOR USE

Prior to angioplasty, carefully examine all equipment to be used during the procedure, including the catheter, to verify proper function and that the catheter size is suitable for the specific procedure for which it is intended. Also, inflate the dilatation catheter to the appropriate RBP and deflate to verify proper function.

1. Enter the vessel percutaneously using the standard Seldinger technique over the appropriate guidewire for the size catheter being used.
2. Under fluoroscopic guidance advance the guidewire to the desired position. Pass the catheter over the guidewire. An introducer should be utilized to facilitate catheter insertion.
3. Advance the catheter across the lesion with fluoroscopic guidance using accepted percutaneous transluminal angioplasty technique (see references). In most patients, the balloon should meet with minimal resistance to insertion. Do not advance the catheter unless the guidewire is in place. Place the catheter to position the mid-length of the balloon within the lesion. Radiopaque bands define both the inner and outer balloon shoulders.
4. The distal lumen is provided for guidewire tracking. An inflation device with pressure gauge is required to monitor inflation pressure (refer to package label for RBP).
5. Inflate the inner balloon to RBP or lower and close stopcock. Immediately inflate the outer balloon to RBP to achieve dilatation. DO NOT EXCEED THE RBP.
6. Immediately after dilatation, deflate both balloons. Both balloons are deflated simultaneously. Deflate the balloon by drawing a vacuum with an inflation device with pressure gauge. Note: The greater the vacuum applied and held during withdrawal, the lower the deflated balloon profile. Gently withdraw the catheter. As the balloon exits the vessel, use a smooth, gentle, steady motion. If resistance is felt upon removal, then the balloon, guidewire and the sheath should be removed together as a unit under fluoroscopic guidance, particularly if balloon rupture or leakage is known or suspected. This may be accomplished by firmly grasping the balloon catheter and sheath as a unit and withdrawing both together, using a gentle twisting motion combined with traction.

7. Apply pressure to the insertion site according to standard practice or hospital protocol for percutaneous vascular procedures.

WARNING

NuMED catheters are placed in the extremely hostile environment of the human body. Catheters may fail to function for a variety of causes including, but not limited to, medical complications or failure of catheters by breakage. In addition, despite the exercise of all due care in design, component selection, manufacture and testing prior to sale, catheters may be easily damaged before, during, or after insertion by improper handling or other intervening acts. Consequently, no representation or warranty is made that failure or cessation of function of catheters will not occur or that the body will not react adversely to the placement of catheters or that medical complications will not follow the use of catheters.

NuMED cannot warrant or guarantee NuMED accessories because the structure of the accessories may be damaged by improper handling before or during use. Therefore, no representations or warranties are made concerning them.

WARRANTY AND LIMITATIONS

Catheters and accessories are sold in an 'as is' condition. The entire risk as to the quality and performance of the catheter is with the buyer. NuMED disclaims all warranties, expressed or implied, with respect to catheters and accessories, including but not limited to, any implied warranty of merchantability or fitness for a particular purpose. NuMED shall not be liable to any person for any medical expenses or any direct or consequential damages resulting from the use of any catheter or accessory or caused by any defect, failure, or malfunction of any catheter or accessory, whether a claim for such damages is based upon warranty, contract, tort, or otherwise. No person has any authority to bind NuMED to any representation or warranty with respect to catheters and accessories.

BIB® Balloon Sizing Chart

Applied Press.	Inner Balloon 4.0 (mm)	Outer Balloon 8.0 (mm)	Inner Balloon 5.0 (mm)	Outer Balloon 10.0 (mm)
1.0 ATM	3.24	6.67	3.72	8.05
2.0 ATM	3.41	6.84	4.11	8.40
3.0 ATM	3.58	6.99	4.43	8.70
4.0 ATM	3.78	7.19	4.66	9.07
5.0 ATM	**3.98**	7.37	**4.95**	9.35
6.0 ATM		7.56		9.61
7.0 ATM		7.71		9.80
8.0 ATM		7.84		9.93
9.0 ATM		7.95		**10.09**
10.0 ATM		**8.06**		

The figures in bold face represent the balloon diameter @ Rated Burst Pressure.

FOR ALL NUMED CATHETERS AN INFLATION DEVICE WITH PRESSURE GAUGE SHOULD BE USED.

Description of Graphical Symbols:

USE BY

CONSULT INSTRUCTIONS FOR USE

REF

CATALOG NUMBER

MANUFACTURER

MODEL NUMBER

BATCH CODE

STERILIZED USING ETHYLENE OXIDE

DO NOT REUSE

KEEP AWAY FROM SUNLIGHT

TEMPERATURE LIMITATION

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Renografin® is a registered trademark of Bracco Diagnostics Inc
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