Balloon in Balloon

(BIB®)

Stent Placement 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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INDICATIONS

Indicated for CP Stent / Covered CP Stent placement in vessels over 8mm in diameter.

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 a vascular channel using a balloon expandable intravascular stent. The inner balloon provides initial expansion of the stent and also acts as a tool to hold the stent in place while the outer balloon is inflated. The outer balloon is then inflated securing the stent against the vessel wall.

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.
- Use two appropriate size inflation devices with pressure gauges for inflation.
- Do not advance the guidewire, balloon 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.
- 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

- Use of an inflation device with pressure gauge is highly recommended during this procedure.
- The stent is rigid and may make negotiation through vessels difficult.
- 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.
- The inflation diameter of the balloon used during stent delivery should approximate the diameter of the obstructive vessel and the intended implant site.
- 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.
- 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

NOTE: Circumferential tear of the delivery balloon catheter prior to complete expansion of the stent may cause the balloon to become tethered to the stent, requiring surgical removal. In case of rupture of an adequately sized balloon after stent expansion, it can be withdrawn and a new balloon catheter exchanged over a guidewire to complete expansion of the stent.

Cardiac catheterization carries certain risks. In addition, potential complications and related adverse effects associated with stent placement include, but are not limited to:

- Sepsis/infection

- Stent migration
- Minor hematoma
- Intraluminal thrombosis
- Pseudoaneurysm
- AV fistula formation
- Bleeding
- Distal thromboemboli
- Death
- Vessel rupture
- Cerebrovascular incident
- Hematoma

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 stent placement, carefully examine all equipment to be used during the procedure. Verify that the catheter and sterile packaging have not been damaged in shipment and that the catheter size is suitable for the specific procedure for which it is intended.

1. Always place an appropriate sized guidewire through the balloon catheter lumen while prepping the balloon and crimping the stent.
2. Visually inspect the balloon catheter being used to insure that it is properly folded to its lowest profile. "Dry Prepping" the balloon delivery catheter by using negative pressure is highly recommended.
3. Slide the stent over the distal end of the balloon, maintaining the balloon fold, until the radiopaque markers are equal distance from the ends of the stent.
4. Gently crimp the stent on the balloon using the stent manufacturer's recommendation.
5. Visually inspect the balloon/stent assembly to assure proper placement of the stent.
6. The assembly is advanced through the long delivery sheath and over the stiff guidewire into the desired location for implant. Sometimes covering the balloon mounted stent with a protective plastic covering while introducing through the bleed-back valve of the delivery sheath will decrease the incidence of stent movement on the BIB catheter during deployment.
7. After correct positioning of the stent, pull back on the sheath to expose the stent. Confirm proper stent position by a small injection of contrast through the sidearm of sheath or through a second catheter.
8. Expand the stent initially by inflating the inner balloon until it is fully expanded. One may "reposition" the stent at this point by moving the BIB catheter. The unexpanded outer balloon and expanded inner balloon hold the stent tightly against the BIB catheter. DO NOT deflate the inner balloon before expansion of the outer balloon. This could cause the stent to slip off the balloon catheter.
9. Confirm positioning and inflate the outer balloon to rated diameter. Do not exceed the rated burst pressure.
10. Once the stent is expanded, deflate both balloons completely. If there is a residual waist in the stent, expand only the outer balloon again, making sure not to exceed RBP. Deflate the balloon and rotate the BIB catheter to insure the stent is free and properly deployed.
11. Remove the balloon catheter and confirm the result with angiography.

BIB® Balloon Sizing Chart

Applied Press.	Inner Balloon 6.0 (mm)	Outer Balloon 12.0 (mm)	Inner Balloon 7.0 (mm)	Outer Balloon 14.0 (mm)	Inner Balloon 7.0 (mm)	Outer Balloon 15.0 (mm)	Inner Balloon 8.0 (mm)	Outer Balloon 16.0 (mm)
1.0 ATM	5.11	10.17	6.17	12.14	6.17	13.25	6.16	14.17
2.0 ATM	5.32	10.54	6.36	12.49	6.41	13.71	6.84	14.87
3.0 ATM	5.51	11.01	6.54	13.00	6.59	14.33	7.24	15.60
4.0 ATM	5.74	11.51	6.71	13.51	6.79	14.75	7.71	16.21
5.0 ATM	**5.97**	11.81	**6.97**	13.88	**6.96**	**15.15**	**7.96**	**16.58**
6.0 ATM		12.06		**14.15**				
7.0 ATM		**12.24**						

Applied Press.	Inner Balloon 9.0 (mm)	Outer Balloon 18.0 (mm)	Inner Balloon 10.0 (mm)	Outer Balloon 20.0 (mm)	Inner Balloon 11.0 (mm)	Outer Balloon 22.0 (mm)	Inner Balloon 12.0 (mm)	Outer Balloon 24.0 (mm)
1.0 ATM	7.78	15.33	8.88	17.66	9.77	19.55	10.08	22.09
2.0 ATM	8.08	16.59	9.17	18.63	10.09	20.70	10.50	23.09
3.0 ATM	8.41	17.45	9.43	19.64	10.36	**21.98**	11.09	**24.11**
4.0 ATM	8.69	**18.11**	9.63	**20.46**	10.78		11.62	
4.5 ATM					**11.00**		**11.96**	
5.0 ATM	**8.98**		**9.93**					

Applied Press.	Inner Balloon 13.0 (mm)	Outer Balloon 26.0 (mm)	Inner Balloon 14.0 (mm)	Outer Balloon 28.0 (mm)	Inner Balloon 15.0 (mm)	Outer Balloon 30.0 (mm)
1.0 ATM	5.13	22.61	5.29	24.40	5.47	27.50
2.0 ATM	11.02	23.98	11.78	**27.95**	13.07	**30.09**
3.0 ATM	11.86	**26.16**	12.87		14.10	
4.0 ATM	**12.47**		**13.90**		**14.85**	

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.

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.

Description of Graphical Symbols:

USE BY

CONSULT INSTRUCTIONS FOR USE

CATALOG NUMBER

MANUFACTURER

MODEL NUMBER

BATCH CODE

STERILIZED USING ETHYLENE OXIDE

DO NOT REUSE

KEEP AWAY FROM SUNLIGHT

TEMPERATURE LIMITATION

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