BOBBY™ Balloon Guide Catheter

Instructions for Use

DEVICE DESCRIPTION

The BOBBY Balloon Guide Catheter is a dual lumen catheter with an external hydrophilic coating on the distal 25 cm of the catheter shaft. The balloon guide catheter incorporates radiopaque markers to facilitate fluoroscopic visualization and indication of the balloon position. The balloon incorporates a distal air-purging system to purge air from the inflation lumen prior to use.

CONTENTS

One Balloon Guide Catheter
One Peel Away Sheath
One Compliance Card

INDICATIONS FOR USE

The BOBBY Balloon Guide Catheter is intended:

For use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel in the peripheral and neuro vascular systems. The balloon provides temporary vascular occlusion during these and other angiographic procedures. The Balloon Guide Catheter is also indicated for use as a conduit for retrieval devices.

CAUTION

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

Do not use if pouch is opened or damaged.
This device is intended for single use only. Do not resterilize or reuse.
After use, dispose in accordance with hospital, administrative and/or local government policy.

WARNINGS

Verify the size of the vessel under fluoroscopy. Ensure that the balloon guide catheter is appropriate for the size of the vessel.

Do not exceed the maximum recommended inflation volume as balloon rupture may occur.

The balloon guide catheter is provided sterile and non-pyrogenic. Do not use if the packaging is breached or damaged.

Viscosity and concentration of contrast may affect balloon inflation and deflation times.

During preparation, do not deflate the balloon unless the distal tip is submerged in saline or contrast to prevent air from entering balloon.

Attaching devices other than a syringe to the balloon inflation port may rupture the balloon.

Do not inflate the balloon with air or any other gas while in the body.

Improper preparation may introduce air into the system. The presence of air may inhibit proper fluoroscopic visualization.

For working lumen, do not exceed 300 psi (2068 kPa) maximum recommended infusion pressure. Excess pressure may result in catheter rupture.

When air-purging the balloon guide catheter, inject fluid slowly otherwise balloon rupture may occur.

Do not advance the balloon guide catheter or guidewire against resistance. If resistance is felt, assess the source of resistance using fluoroscopic means.

Always inflate and deflate the balloon while visualizing under fluoroscopy to ensure patient safety.

Failure to abide by the warnings in this labeling might result in damage to the device coating, which may necessitate intervention or result in serious adverse events.

PRECAUTIONS

After balloon preparation for use and prior to use, re-inflate to nominal volume and inspect for any irregularities or damage. Do not use if any inconsistencies are observed.

Verify balloon guide catheter compatibility when using other ancillary devices commonly used in intravascular procedures.

The balloon guide catheter has a lubricious surface and should be hydrated in saline solution for at least 10 seconds prior to use. Once the balloon guide catheter is hydrated, do not allow it to dry.

Exercise care in handling the balloon catheter to reduce the chance of accidental damage.

Take precaution when navigating the balloon guide catheter in tortuous vasculature to avoid damage. Avoid advancement or withdrawal against resistance until the cause of resistance is determined.

Presence of calcifications, irregularities or existing devices may damage the balloon guide catheter and potentially affect its insertion or removal.

Excessive torque applied with a syringe might result in damage to the hub assembly.

Exposure to angiographic and fluoroscopic X-ray presents potential risks of alopecia, burns ranging in severity from skin reddening to ulcers, cataracts, and delayed neoplasia that increase in probability as procedure time and number of procedures increase.

Exercise necessary precautions to limit X-ray doses to patients and operators by using sufficient shielding, reducing fluoroscopy times, and modifying X-ray technical factors where possible.

POTENTIAL COMPLICATIONS

Potential complications include but are not limited to: vessel or aneurysm perforation, vasospasm, hematoma at the site of entry, embolism, ischemia, intracerebral/intracranial hemorrhage, pseudoaneurysm, seizure, stroke, infection, vessel dissection, thrombus formation, and death.

Physician must be familiar with percutaneous, intravascular techniques and possible complications associated with the procedure.

COMPATIBILITY

The BOBBY Balloon Guide Catheter was tested with 6Fr OD compatible devices (2.13mm / 0.084in).

Note: Guidewire not required for inflation of balloon

Note: Choose 8F (2.92mm / 0.115in) ID introducer sheath or larger.

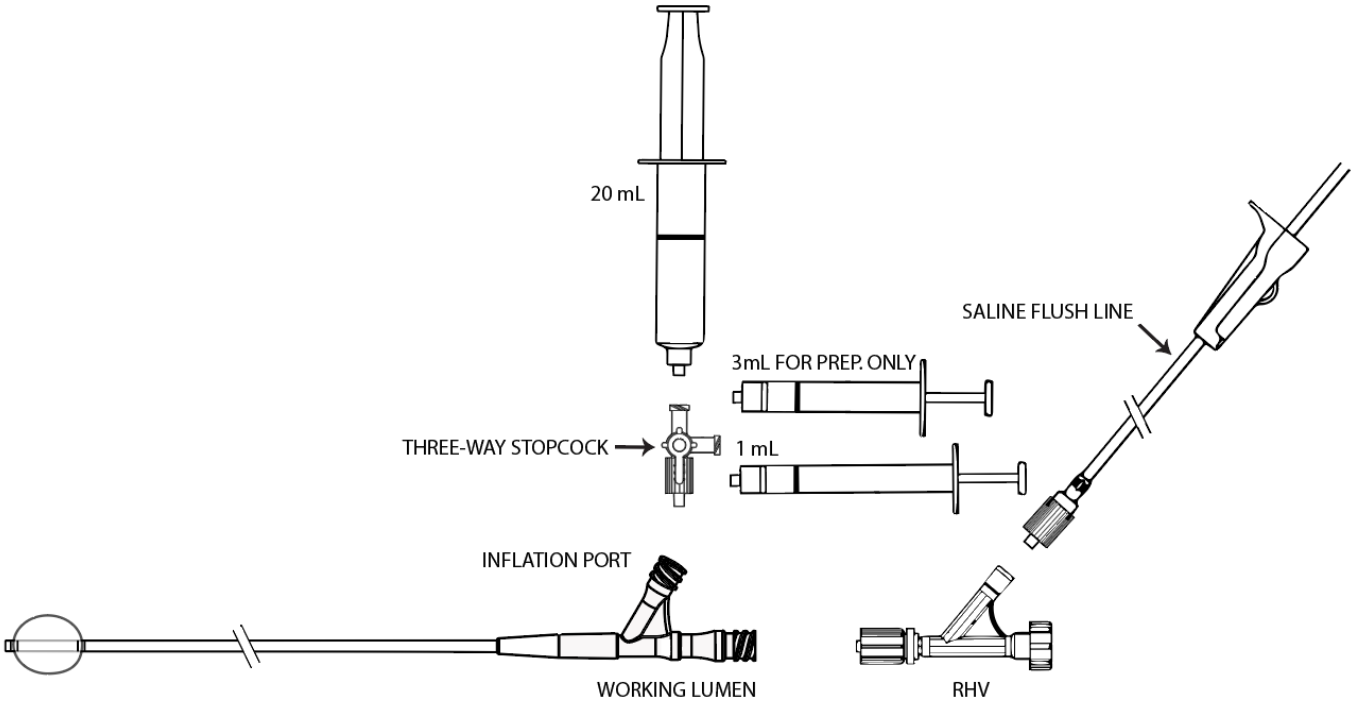


DIAGRAM OF BALLOON GUIDE CATHETER SETUP

BALLOON PREPARATION

1. Remove the balloon guide catheter by pulling it straight out from the dispenser tube without bending shaft. If resistance is observed, inspect the balloon guide catheter upon removal to ensure it is not damaged.

Submerge distal balloon portion in saline solution. Do not reinsert a hydrated balloon guide catheter into its packaging.

2. Use a syringe with saline solution to flush the working lumen. After flush is completed, detach the syringe.

3. Prepare a 50-50% contrast solution.
   WARNING: Viscosity and concentration of contrast may affect balloon inflation and deflation times.

4. Fill a 3cc syringe with contrast solution and carefully attach directly to a 3-way stopcock. Purge the 3-way stopcock and syringe of air. Connect the 3-way stopcock directly to inflation port without injecting contrast into hub. Ensure there are no bubble(s) in the syringe and stopcock prior to attaching to the hub.

5. Hold balloon upright with one hand.

6. Hold the attached syringe upright (pointing up) with the other hand and apply pressure on syringe plunger using thumb.

7. If the balloon is initially inflated with air, then maintain constant syringe pressure.

8. Maintain pressure and DO NOT TILT the balloon until the contrast reaches the distal purge hole and the contrast has completely filled the balloon.

9. Once the balloon has fully purged air out with contrast, inspect balloon for any damages, bubbles, irregularities, or leaks. Do not use if any inconsistencies are observed.

10. Inspect the balloon guide catheter distal tip for any contrast leakage from air purge hole. If contrast leakage is observed, then discard unit.

11. Deflate with 3cc syringe while distal tip is submerged in saline and let the pressure within the catheter equalize.
    WARNING: Attaching devices other than a syringe to the balloon inflation port may rupture the balloon.
    WARNING: Do not inflate the balloon with air or any other gas while in the body.
    WARNING: Improper preparation may introduce air into the system. This may inhibit proper fluoroscopic visualization.

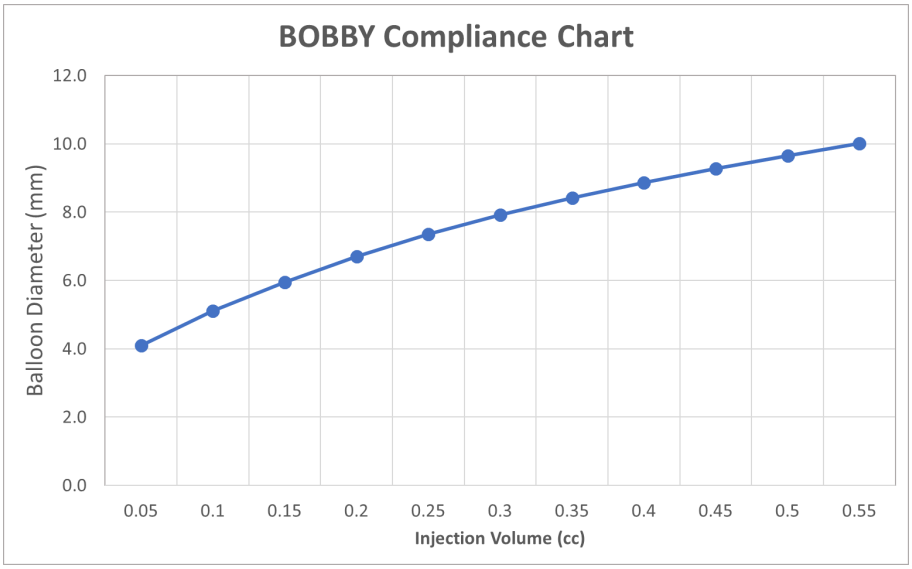
12. Inspect shaft for any kinks. Do not use if any damages are observed.

13. Remove the 3cc syringe.

14. Prime a 1cc syringe filled with recommended 50/50 contrast solution and attach to 3-way stopcock.

15. Attach a 20cc syringe pre-filled with approximately 2cc of recommended 50/50 contrast solution to the other port of the 3-way stopcock.

16. With the catheter hydrated and balloon completely prepped the balloon guide catheter is ready for use.



Balloon Inflation Compliance	
Inflation Volume* (cc)	BOBBY Diameter (mm)
0.05	4.1
0.10	5.1
0.15	6.0
0.20	6.7
0.25	7.4
0.30	7.9
0.35	8.4
0.40	8.9
0.45	9.3
0.50	9.7
0.55**	10.0

* After Priming Catheter
**Maximum Injection Volume

DIRECTIONS FOR USE (Refer to diagram for reference)

1. Attach a rotating hemostatic valve (RHV) to the working lumen of the balloon guide catheter. Set up a continuous saline flush line and connect it to the sidearm of the RHV.
2. Insert a select catheter with guidewire into the working lumen of the balloon guide catheter.
3. Ensure the balloon is fully deflated and advance a peel-away sheath over the balloon portion of the balloon guide catheter.
4. Insert the guidewire/select catheter/balloon guide catheter system into the introducer sheath using the peel-away sheath. Insert peel-away sheath into the introducer sheath until it meets resistance.
5. Advance the guidewire/select catheter/balloon guide catheter system to the desired location in the vasculature using fluoroscopic visualization.

   WARNING: Do not advance the balloon guide catheter or guidewire against resistance. If resistance is felt, assess the source of resistance using fluoroscopic means.
6. Retract peel-away sheath from introducer hub and peel off of the balloon guide catheter.

7. If using a clot retrieval device,
   - Remove any loading acquired during tracking of balloon guide catheter if needed.
   - Slowly inflate the balloon until the desired diameter is achieved. Turn off the stopcock towards balloon guiding catheter hub.
   - Follow the clot retrieval device Instructions for Use to apply aspiration using a syringe as required.

   WARNING: Do not exceed the maximum recommended inflation volume as balloon rupture may occur.

   WARNING: Always inflate and deflate the balloon while visualizing under fluoroscopy to ensure patient safety.

   WARNING: Do not exceed -28 inHg during aspiration

   Note: If withdrawal of clot retrieval device and microcatheter into balloon guide catheter is difficult, deflate balloon and under aspiration of balloon guide catheter working lumen, simultaneously

withdraw balloon guide catheter, microcatheter and clot retrieval device as a unit through introducer sheath. Remove introducer sheath if necessary.

STORAGE

Avoid exposure to water, sunlight, extreme temperatures and high humidity during storage. Store the balloon guide catheter under controlled room temperature. See the product label for the device shelf life. Do not use the device beyond the labeled shelf life.

MATERIALS

The balloon guide catheter is not made with latex or PVC materials.

SYMBOLS

LOT	Lot Number		Caution
REF	Catalog Number		Use-by Date
CONTENTS	Contents		Date of Manufacture
STERILE EO	Sterilized Using Ethylene Oxide		Manufacturer
	Do Not Reuse		Non-pyrogenic
	MicroVention, Inc. Ischemic Stroke and Carotid Artery Disease Solutions	Rx ONLY	For Prescription Use Only
	Consult Instructions for Use		

WARRANTY

MicroVention, Inc. warrants that reasonable care has been used in the design and manufacture of this device. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness. Handling, storage, cleaning and sterilization of the device as well as factors relating to the patient, diagnosis, treatment, surgical procedure and other matters beyond MicroVention's control directly affect the device and the results obtained from its use. MicroVention's obligation under this warranty is limited to the repair or replacement of this device through its expiration date. MicroVention Inc. shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this device. MicroVention neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. MicroVention assumes no liability with respect to devices reused, reprocessed or resterilized and makes no warranties, expressed or implied, including, but not limited to, merchantability or fitness for intended use, with respect to such device.

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