BD Bardia™

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PTFE Coated Foley Catheter

5 mL or 30 mL Balloon

Instructions for Use

The clinical benefits of Bardia™ PTFE Coated Foley Catheters are that they aid in clinical management by allowing for continuous drainage and measurement of urine, and when applicable, bladder irrigation and hemostasis.

Foley catheters can be used in patients of all ages. Up to 10 CH/Fr is generally considered pediatric sizing; however, the appropriate size should be determined by the healthcare professional.

Intended Use: For urological use only.

Intended User: This product is intended to be used by qualified Healthcare Professionals.

Indications For Use: Bardia™ PTFE Coated Foley Catheters are indicated for any clinical condition requiring drainage and/or collection and/or measurement of urine. Generally, drainage is accomplished by inserting the catheter through the urethra and into the bladder.

Contraindications: No known contraindications.

Warnings:

- On catheter, do not use ointments or lubricants having a petroleum base. They will damage catheter and may cause balloon to burst.
- After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practices and applicable local, state, and federal laws and regulations.
- This is a single use device. Do not resterilize any portion of this device. Reuse and/or repackaging may create a risk of patient or user infection, compromise the structural integrity and/or essential material and design characteristics of the device, which may lead to device failure, and/or lead to injury, illness, or death of the patient.

Users and/or patients within the European Union, should report any serious incident that has occurred in relation to the device to the manufacturer and the competent authority of the Member State in which the user and/or patient is established. Users outside of the European Union should report any serious incident that has occurred in relation to the device to the manufacturer and the regulatory authority of the country in which the user and/or patient is established.

Precautions:

- Do not use device if package is opened or damaged.
- Do not aspirate urine through drainage funnel wall. Refer to direct unit label for product content and gender specific use where applicable.
- Should balloon rupture occur, care should be taken to assure that all balloon fragments have been removed from the patient.

Cautions:

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

Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

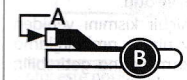
Storage: Keep away from sunlight.

Instructions for Use:

- Follow your facility protocol for all processes related to catheterisation, re-catheterisation, stabilization and urine collection.
- Follow aseptic procedures outlined by your local hospital or healthcare facility. Thoroughly wash hands, wear sterile gloves, and use aseptic technique whenever handling the catheter or catheter components during insertion.
- Visually inspect the product for any imperfections or surface deterioration prior to use. If package is opened or if any imperfection or surface deterioration is observed, do not use.

Insertion of Catheter:

1. Wash hands.
2. Use aseptic technique to prepare the patient for catheter insertion.
3. Use aseptic technique to remove the catheter from package. Connect catheter to urine collection container as needed.
4. Catheterize the patient using dominant hand.
   a. If coude tip, insert with the curve facing upwards.
5. When catheter tip has entered bladder, urine will flow through the catheter.
   a. For female anatomy, insert catheter approximately 5 cm (2 inches) more.
   b. For male anatomy, insert catheter all the way to bifurcation.
6. Inflate the balloon with pre-filled water syringe if included.
   a. If pre-filled syringe is not included, then use a slip tip/luer lock syringe to fill catheter balloon with sterile water. Do not use needle.
   b. Do not exceed recommended capacities as stated on the applicable labelling.
   c. The chart below provides additional information on inflation volume and balloon size.
   d. Inflation Volume (A) incorporates the volume required to pass through lumen and fully inflate the specific Balloon Size (B).

	Recommended Inflation Volume (A)	Balloon Size (B)
	10 mL	5 mL
	35 mL	30 mL

Note: Drawing may not display actual shape of catheter tip or presence of additional lumen(s).

7. Gently pull the catheter until the catheter balloon is snug against the bladder neck.

Removal:

1. Wash hands.
2. Gently insert a luer slip tip syringe into the catheter valve.
   a. Never use more force than is required to make the syringe "stick" in the valve.
3. Allow the pressure within the balloon to force the plunger back and fill the syringe.
   a. If you notice slow or no deflation, re-seat the syringe gently.
4. Use only gentle aspiration to encourage deflation, if needed. Vigorous aspiration may collapse the inflation lumen, preventing balloon deflation.
5. If balloon does not deflate, contact trained professional for assistance, as directed by hospital protocol.
6. After balloon is fully deflated, remove catheter, and dispose of in accordance with hospital policy.

The Becton, Dickinson and Company English symbols glossary is located at bd.com/en-us/symbols-glossary.

For U.S. patents that may apply, see **bd.com/patents.**

- Inspeccione visualmente el producto para determinar si tiene algún

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