

BALLOON URINARY CATHETERS

BRIEF STATEMENT

Physician Facing

Indications

Foley catheters: urethral urinary catheterization. Only straight 2-way Foley catheters with a maximum balloon volume of 15 ml may be used for the suprapubic approach (except for ribbed catheters).

3-way Foley catheters: urethral urinary catheterization and postoperative bladder irrigation-lavage.

Prostate catheters:

- Short-term drainage of bladder urine
- Postoperative bladder irrigation-lavage
- After prostate surgery: hemostasis of the prostatic fossa

Contraindications

Same as for urethral urinary catheterization and supra-pubic bladder drainage, and generally, known allergic reactions due to the device material (e.g. latex). Where indicated, some products contain latex, which may cause allergic reactions. The evaluation of the allergic background of a patient is the health care professional's responsibility.

Warnings and Precautions

Reuse of this single use product may create a potential risk to the user. Reprocessing, cleaning, disinfection and sterilization may compromise product characteristics which in turn create an additional risk of physical harm to or infection of the patient.

Adverse Events

Bladder irritation symptoms, pain, urinary tract infection, encrustation, stone formation, urinary tract trauma, leakage, balloon burst or deflation, hematuria, skin irritation, migration of the catheter, catheter knotting, peritoneal perforation with or without bowel perforation, and misplacement/displacement.

The risks and benefits of using balloon urinary catheters should be considered in patients.

The information provided is not comprehensive with regard to product risks. For a comprehensive listing of indications, contraindications, warnings and precautions refer to the product's Instructions for Use. Alternatively, you may contact a Coloplast representative at 1-800-258-3476 and/or visit the company Website at www.coloplast.com.

Complications from the use of this device should be brought to the attention of your Coloplast Representative and your physician.

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

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