

## Sterile, Latex Urethral Foley Balloon Catheters

### FRONT

### Instructions For Use

#### Latex Foley Balloon Catheter

##### Product description

Flexible shaft made of multiple-cleansed latex with siliconised or silicone elastomer coated surface.

##### Intended Purpose

- 2-Way Catheter: Intended for drainage of the urinary bladder.
- 3-Way Catheter: Intended for drainage and flushing/irrigation of the urinary bladder.

##### Intended User

The device is intended to be used by trained medical professionals in the insertion and management of the device.

##### Indications

- Acute and chronic urinary disorders (e.g., retention).
- Intra- and postoperative urinary drainage
- Urinary drainage for measurement of urine excretion e.g. during intensive care and infusion therapy.

##### Clinical Benefits

- Relieve pain or discomfort due to bladder dysfunction (e.g., acute or chronic urinary retention).
- Prevention of Post-operative Urinary Retention (POUR).

##### Patient Target Group

Children and adults of both genders.

##### Directions For Use

###### Insertion and Removal of 2-way and 3-way Catheters

- The product is sterile as long as the packaging is sealed and undamaged.
- Remove the catheter from its sterile packaging using aseptic technique.
- Using sterile techniques as indicated in published literature, insert the catheter fully into the urethra, ensuring that the balloon is beyond the bladder neck.
- Inflate the balloon with sterile water. Use sterile water only.
- The capacity of the balloon is indicated on the funnel of the catheter or on the label of the packaging. Do not overinflate.
- To deflate the balloon prior to removal, attach a luer-compatible syringe to the inflation valve and withdraw the inflation fluid.
- If deflation is slow or no deflation is noticed, reposition the syringe and repeat. Apply gentle aspiration only if required.
- Maximum recommended indwelling times vary due to patient specific factors.
- To obtain safe combination with urine bags, urine bags with nominal taper 20% connector is recommended.

###### Flushing/ Irrigation with 3-way Catheter

- Use only sterile irrigation solutions and maintain aseptic techniques at all times.
- Assemble the sterile irrigation set and ensure the catheter is unobstructed before starting irrigation.
- Introduce the prescribed irrigation slowly through the irrigation lumen. Do not force instillation as this may cause bladder trauma or catheter dislodgement.
- Monitor patient comfort and bladder distension. Stop irrigation if resistance or pain occurs.
- Check that drainage lumen is unobstructed before and after irrigation to prevent over-distension.

##### Potential complications

If difficulty is encountered when aspirating the balloon with the syringe (a rare and infrequently reported event), the limb of the catheter with the valve should be cut at the bifurcation using sharp scissors, or the balloon may be ruptured following established procedures reported in medical literature. Should it be necessary to rupture the balloon, care must be taken to remove all fragments from the patient. Irritation of the urethral mucosa, blockage of the catheter due to encrustation and catheter induced infections are documented complications with some catheter materials and patients.

- The patient should be routinely monitored in accordance with accepted procedures.
- Siliconised catheters should be changed after an appropriate period, usually not more than 7 days or as directed by a medical practitioner.
- Silicone elastomer coated catheters should be replaced every 28 days or as directed by a medical practitioner.

##### Warnings and Precautions

- For urological use only.
- Latex Urethral Catheter is packaged for single use.
- Do not re-use or re-sterilise as there is a risk of transmission of body fluids or contaminated tissue between patients.
- Visually inspect the packaging for any breach of the packaging integrity. Do not use if the pouch is opened or damaged.
- Visually inspect the catheter prior to use. Do not use if any damage, deformation, kinking or other surface defects are observed.
- Do not use lubricants or preparations with a petroleum base on latex catheters.
- Do not use excessive force during insertion or removal of the catheter, as this may cause patient injury.
- Monitor urine flow regularly. If reduced or no flow is observed, assess for possible blockage, or incorrect catheter placement.
- Do not clamp the catheter.
- Inflate the balloon with sterile water only.
- Do not overinflate the balloon beyond the recommended volume, as this may result in balloon rupture.
- Ensure the balloon is fully deflated prior to removal. Apply gentle aspiration, if necessary.
- Avoid excessive aspiration when deflating the balloon, as this may collapse the inflation lumen, preventing complete deflation.
- Do not attempt to remove the catheter if resistance is encountered. Seek assistance from a trained medical professional.
- Never use a syringe to puncture the catheter shaft for urine sampling. There is a danger of needle-stick injury, and the catheter may be compromised.
- In the event of balloon rupture, ensure that all balloon fragments are removed from the patient.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/ or patient is established.

##### Contraindication

- Product contains natural rubber latex which may elicit allergic responses in latex sensitized individuals.
- Catheters are contraindicated in patients with abnormalities of urethra, including false passages, severe strictures, bleeding or injury.
- Catheters are also contraindicated for patients who undergo urethral surgery and gender reassignment surgery.

**BACK**

**Paediatric Catheters**

Paediatric catheters include a stylet/stillette to facilitate insertion. Make sure stillette end is properly positioned in the catheter tip and not protruding from the catheter eye during insertion. Remove the stillette once the catheter is positioned correctly before inflating the balloon.

**Storage and Disposal**

These products should be stored in their original box, preferably away from direct and indirect sources of light and heat. After use, this product may be a potential biohazard. Handle and dispose off in accordance with accepted medical practice and applicable laws and regulations.

“Manufacturer”  
OR





















**URO TECHNOLOGY SDN. BHD.**  
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**CE mark**

“EU Authorized  
Representative”  
OR



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Symbol	Definition	Symbol	Definition
	Manufacturer		European authorized representative
	Sterilized using irradiation		Do not reuse
	Do not use if the package is damaged		Do not resterilize
	Keep away from sunlight		Contains natural rubber latex
	Store in a cool dry place		Consult instruction for use
	Batch code		Date of Manufacture
	Use by date		Catalogue number
	Medical device		Single sterile barrier system with protective packaging inside
	Unique Device Identifier		Importer