



**INSTRUCTION FOR USE**

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**Instructions for use**

**Foley-Catheter**

**Product description**

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

**Intended Purpose**

Sterile, Latex Urethral Foley Balloon Catheters are intended for the drainage and/ or flushing of the bladder. It is to be used by trained medical professional.

**Indications**

- acute and chronic urinary disorders including urinary incontinence and urinary retention
- intra- and postoperative urinary drainage
- urinary drainage for measurement of urine excretion e.g. during intensive care and infusion therapy

**Clinical Benefits**

Relieve discomfort due to bladder dysfunction

**Patient Target Group**

Children, Adults, Both genders

**Directions for use**

- 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 technique 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 aspirate the syringe gently to remove the inflation fluid. Do not use excessive aspiration on the syringe during deflation as this may cause a vacuum collapse of the inflation lumen which may impair normal drainage.
- Maximum recommended indwelling times will vary due to patient specific factors.
- To obtain safe combination with urine bags, urine bags with nominal taper 20% connector is recommended.

**Potential complications**

If difficulty is encountered aspirating the balloon with the syringe, a rare and infrequently reported event, the limb of the catheter with the valve should be cut with sharp scissors at the bifurcation, or the balloon ruptured according to established procedures reported in medical literature. Should it necessary to rupture the balloon, care must be taken to remove all fragment 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.
- The siliconised catheter should be changed after an appropriate time usually not more than 7 days or as specified by a medical practitioner.
- The silicone elastomer coated catheters should be replaced every 28 days or as specified by a medical practitioner.

**Warnings and Precautions**

- 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.
- 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. Do not use if pouch is opened or damaged.
- Do not use lubricants or preparations with a petroleum base on products which contain latex.
- Always inflate the balloon with sterile water.
- Never clamp the catheter.
- 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.
- Excessive aspiration can collapse inflation lumen, preventing balloon deflation.
- Visually inspect the package for any breach of the packaging integrity.
- 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.


**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.

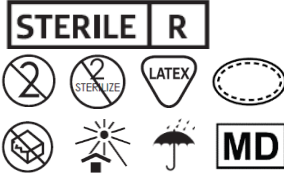
**Storage and Disposal**

These products should be stored in their original box, preferable 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.


















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**URO TECHNOLOGY SDN. BHD.**  
Lot 2491, Batu 39 1/2,  
Pontian Besar,  
82000 Pontian,  
Johor, Malaysia.



**Advena Ltd.**  
Tower Business Centre,  
2nd Flr. Tower Street,  
Swatar, BKR 4013, Malta

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

Master reference information: U-IFU-01 (v.4)

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