



UR010000 - UR011021

2-Way Foley Catheter

100% Silicone

INSTRUCTION FOR USE

DESCRIPTION

m|devices 2-Way Foley Catheter is a soft, flexible tube and is 100% silicone. Paediatric 33cm, Female 23cm and Standard 45cm are available. Female 23cm and Standard 45cm are intended for both urethral and suprapubic catheterisation (SPC) and Paediatric 33cm is intended for urethral catheterisation only. The intended purpose of the 2-Way Foley Catheter is for urinary drainage, monitoring of renal function and treatment of appropriate therapeutic agents into the bladder. SPC may be indicated for some acute and long-term care use. The symmetrical balloon when inflated ensures reliable and correct positioning in the bladder. After deflation, the balloon minimises potential ridging.

The standard-length range has high contrast incremental markings from 6cm - 30cm to assist with SPC catheter changes.

FOR USE BY A QUALIFIED CLINICIAN. THE BELOW IS ONLY A SUGGESTION AND FACILITY PROTOCOL MUST BE FOLLOWED FOR ALL CLINICAL PROCEDURES WHERE THIS PRODUCT IS USED.

CAUTION

- DO NOT use with petroleum based ointments or lubricants.
- Use immediately after opening packaging. Discard catheter after use according to hospital protocol.
- Single use.
- DO NOT re-sterilise.
- DO NOT store at extreme temperatures and humidity, avoid direct sunlight. Handle with care.
- STERILE (EO), DO NOT use if the package or product has been damaged or contaminated.
- EU Notice: 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.

STEPS

1. Select the appropriate catheter size and length considering gender, body type and the procedure to be performed.
2. Check local and facility policy for IDC/SPC insertion to organise equipment to apply aseptic technique for the catheter insertion.
3. Remove the catheter from the outer packaging using an aseptic technique and place on sterile field. The inner plastic sleeve serves to assist with maintaining sterility of the catheter during the insertion procedure. If preferred, the sleeve can be completely removed at this stage or peeled open at the catheter tip end to allow for the lubricant to be applied. Advance the catheter with the inner plastic sleeve to maintain sterility. If the sleeve isn't used, dispose of it appropriately.
4. Lubricate the distal tip with a water-based lubricant and insert 2-Way Foley Catheter as per facility/hospital protocol using aseptic technique.
5. For suprapubic insertion the water-based lubricant can be applied directly into the suprapubic site.
6. For suprapubic catheter exchange, prior to removing current catheter, make a note of the length, as a guide for how far to insert the new catheter.
7. Once the catheter is in the correct position in the bladder, indicated by urine flow, inflate the balloon with the recommended volume of sterile water as stated on the catheter and packaging.
8. Gently withdraw the catheter slowly to the point of resistance.
9. Connect the catheter to the drainage bag and secure the catheter using a securement device.

PRECAUTIONS

- Maximum indwelling time 8 weeks*
- Ensure the drainage bag is positioned below the level of the bladder and is off the floor.
- The security of all connections should be checked once the catheter is connected to the drainage bag and monitored during use to prevent disconnection.
- Ensure the catheter is stored in the box and is not coiled or folded when stored.
- Do not test inflate the balloon prior to insertion.
- Ensure the catheter is secured to the body immediately after insertion using a dedicated securement device.
- Observe suprapubic site regularly to monitor for signs of infection.

- When deflating the balloon, once the syringe is connected to the non-return valve, allow the pressure within the inflated balloon to push the plunger back and fill the syringe with water.

- Do not inflate catheter balloon above its stated capacity.

Possible complications with indwelling catheters include irritation or injury of urethral mucosa or, encrustation leading to blockage and catheter induced infections. Catheter use should be routinely monitored according to facility policies and guidance.

Contraindications

For urethral:

Acute urethritis
Acute prostatitis
Urethral/bladder trauma

For suprapubic:

Non palpable bladder
Instable suprapubic stoma
Known or suspected carcinoma of bladder
Immature stoma track (less than 4 weeks)

* *As per laboratory-based testing results and validation against requirements ISO 20696.*

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