

m|devices®

UR013000 – UR013004

3-Way Foley Catheter  
100% Silicone

 INSTRUCTION FOR USE

### DESCRIPTION

m|devices 3-Way Foley Catheter, 100% silicone is used to help remove blood clots and debris from the bladder after surgery or in the treatment of haematuria. Primarily used for drainage after bladder/prostate or upper urinary tract surgery to allow continuous irrigation capabilities.

**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 that will allow adequate access and drainage for the clinical indication.
2. Check local and facility policy for IDC 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. Dispose of the inner plastic sleeve or if preferred, can be used to maintain sterility whilst advancing catheter.
4. Lubricate the distal tip with a water based lubricant and insert 3-way Foley Catheter as per facility/hospital protocol using aseptic technique.
5. Once the catheter is in the correct position in the bladder indicated by urine flow, inflate the balloon with the indicated volume of sterile water as stated on the catheter.
6. Gently withdraw the catheter slowly to the point of resistance.
7. Connect the catheter to the drainage bag, connect to irrigation if required and secure the catheter using a securement device.

### STEPS FOR IRRIGATION

1. Ensure the IV pole is at a safe accessible height and above bladder to promote gravitational flow and hang irrigation solution.
2. Insert the prongs from the irrigation set into the solution, prime tubing, and close roller clamps, maintaining asepsis
3. Insert irrigation tubing into irrigation port of 3-Way Foley Catheter.
4. Open roller regulator to start irrigation, regulate flow as required.
5. Monitor the irrigation bag and collection bag frequently.
6. If irrigation is discontinued, place a catheter spigot into the irrigation port using aseptic technique.

### STEPS FOR REMOVAL OF CATHETER

1. Using a syringe attached to the non-return valve, allow syringe to independently withdraw the sterile water to deflate the balloon completely and then carefully pull the catheter out.

### PRECAUTIONS

- Maximum indwelling time is 29 days
- Never clamp or block the catheter or drainage bag tubes whilst irrigation is flowing.
- 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 catheter is connected to drainage bag and irrigation fluid and also monitored during use to prevent disconnection.
- Ensure the catheter is stored in the box and is not coiled or folded when stored.
- Ensure the catheter is secured to the patient immediately after insertion using a dedicated urinary catheter securement device.
- Do not test inflate the balloon prior to insertion.
- 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. Patients should be routinely monitored according to facility policy.

Contraindications  
Acute urethritis  
Acute prostatitis

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