

m|devices®

UR012000-UR012007

2-Way Foley Catheter

Tiemann Tip

100% Silicone

i INSTRUCTION FOR USE

DESCRIPTION

m|devices 2-Way Foley Catheter Tiemann Tip, 100% silicone, is intended for urethral catheterisation. The symmetrical balloon expands equally in all directions to ensure reliable and correct positioning in the bladder. The Tiemann Tip supports the more demanding insertion. After deflation, the balloon minimises potential ridging. The catheter length is suitable for both females and males.

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

- Used for Indwelling Urine Catheterisation
- 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 smallest catheter size that will allow adequate access and drainage for the clinical indication.
2. Remove the catheter from the outer packaging using an aseptic technique. 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. When advancing the catheter, the plastic sleeve can be gradually peeled back as the catheter is progressed into the desired position. Dispose of the inner plastic sleeve.
3. Lubricate the distal tip with a water based lubricant and insert 2-Way Foley Catheter as per facility/hospital protocol using aseptic technique.
4. 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.
5. Gently withdraw the catheter until resistance is felt.
6. 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.
- When deflating the balloon, once the syringe is connected to the non-return valve, allow the syringe to fill independently until the balloon volume is contained in the syringe.

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

m|devices

27 Llewellyn Avenue
Villawood NSW 2163
Australia
T +61(0)2 8718 2800
F +61(0)2 8718 2801

C CONTINENCE CARE Silicone Foley Catheters

M Multigate Co., Ltd.
7 Lanjiang Road 312000
Shaoxing China

EC REP RFX+Care International A/S
Bakkegaardsvej 408
3050 Humlebaek
Denmark

STERILE EO   MD     CE 0123