URETHRAL BALLOON CATHETER

Guides & instruction for use

CAUTION: Federal law (USA) restricts this device to sale by or on the order of physician.

INDENTED USE:
For drainage of urine from the bladder through urethral.

Common indications include the following:
- Drainage of the bladder in case of acute urinary retention.
- Drainage of the bladder in some cases of chronic retention.
- Stenting of the urethra in some urethral surgery.
- Drainage of the bladder after bladder surgery.
- Drainage of the bladder after major operation in some selected cases.

CONTRAINDICATION:
Acute Urinary Retention due to clot retention caused by undiagnosed bladder mass to avoid malignant fistula. Previous Supra-pubic Surgery.

WARNING:
- For single product and patient use only.
- Do not use catheter if any sign of product damage is visible.
- Do not re-use, reprocess or re-sterilize. Reuse may lead to infection. Reprocessing or Re-sterilization may damage the catheter and affect its integrity which when re-used may lead to possible deterioration in health and safety of patients.

PRECAUTIONS:
- The procedure must be carried during complete aseptic technique.
- The catheter is for single use.
- Damage of the pack indicates lost sterility guarantee.
- The silicon type should be used for 30 days or less while the latex is not used for more than 3 days.

DEVICE DESCRIPTION:
It is a 2 ends branched catheter and has two lumens with inflatable balloon at the upper end one of the two lumens is big in size for drainage and funneled to be connected with urine bag. The other is small for balloon inflation and is connected to one way valve to allow injection of fluid to inflate the balloon and prevent flow back. The material is either latex (silicon coated surface) or completely silicon.

The aim of this catheter is to drain urine from inside the bladder.

Product code key: F-MM-XX-L
F : Urethral balloon catheter (Foley catheter).
MM: Material.
   (TS) For total silicon.
   (SC) For latex silicon coated.
XX : Size in Fr.
L : Number of lumens. (2 or 3)

METHOD OF APPLICATION:
- Explain the procedure to the patient. Especially if they have never had a catheter before.
- Assist the patient into supine (Laying on their back) position with legs spread.
- Place a sterile drape over the procedure area.
- Apply the sterile gloves. (Be careful not to touch the catheter tube) and squirt a lubricating jelly onto the catheter. Once that is done.
- Test to make sure that the balloon inflates and deflates properly. Attach the pre-filled syringe in the kit to the "Y" pigtail port and insert all of the water from the syringe. Next, deflate the balloon. Do not remove the syringe, as it will need to be in inflated after catheter insertion.
• Clean the urinary opening. If the patient is female, separate labia using the non-dominant hand. The non-dominant hand will become the "dirty hand." This hand should not touch any of the sterile items in the kit. If male, hold the penis with the non-dominant hand. Using the dominant hand, cleanse peri-urethral mucosa with cleansing solution. Cleanse anterior to posterior, inner to outer, one swipe per swab, discard swab away from sterile field.
• Pick up catheter with gloved (and still sterile) dominant hand. Hold end of catheter loosely coiled in palm of dominant hand. Insert into urethral opening (female). In the male, lift the penis to a position perpendicular to patient’s body and apply light upward traction (with non-dominant hand). Identify the urinary meatus and gently insert until 1 to 2 inches beyond where urine is noted.
• Inflate balloon, using correct amount of sterile liquid (usually 10 cc but check actual balloon size). Once inflated, gently pull catheter until the inflated balloon is snug against bladder neck. Next, connect catheter to drainage system. Place drainage bag below level of bladder, but not on the floor. Evaluate catheter function and amount, color, odor and quality of urine.
• Remove gloves, dispose of equipment appropriately, wash hands. Document size of catheter inserted, Amount of water in balloon, patient’s response to procedure, and assessment of urine.

COMPLICATIONS:
•Incomplete urethral injury during introduction.
•Haematuria.
•Infection.
•Long term complication: Stricture of the urethra.

HOW SUPPLIED:
The devices are sterilized by ethylene oxide. Contents are sterile in unopened or undamaged package. Do not use catheter if package has been damaged or has been opened.

STORAGE:
Store at room controlled temperature. Do not expose to organic solvents, ionizing radiation or ultraviolet light. Rotate inventory so that catheters are used prior to expiration date on the package label.

PRODUCT SAFE DISPOSAL:
Used Catheter should be disposed in sanitary container to prevent possible contamination and cross infection.