

# UR018000

## Transurethral Catheter Safety Valve - TUCSV® Adult Type\*



INSTRUCTION FOR USE

### DESCRIPTION

The Transurethral Catheter Safety Valve (TUCSV®) is a single-use medical device designed to prevent accidental inflation of a Foley catheter retaining balloon in the urethra.

The TUCSV® are supplied individually packaged in a sterile pouch and consist of a proximal female Luer lock, a flow restrictor, a pressure release valve, and a distal male Luer slip.

**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

- \* Not intended for use in patients under 16 years of age.
- For Urological use only.
- Single use only. Reusing the device may compromise its effectiveness and increase the risk of infection.
- DO NOT re-sterilise.
- DO NOT store at extreme temperatures and humidity, avoid direct sunlight. Handle with care.
- STERILE (Radiation E-Beam ), 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. Remove the TUCSV® from its sterile packaging using aseptic technique and visually inspect it for any damage.
2. Remove red pull tab.
3. Connect the female Luer lock/slip of the TUCSV® to the syringe and the male Luer slip of the TUCSV® to the balloon inflation port.
4. Insert the Foley catheter as per local policy and procedure.
5. Slowly inject the amount of solution for a volume suitable to the balloon for the Foley catheter.
6. Remember that balloon inflation with the TUCSV® is slower due to the restriction channel, and will take 10-15 seconds longer than usual.
7. **"STOP, IF YOU SEE A DROP!"** If fluid leaks from the exhaust port of the valve, the catheter anchoring balloon is not in the bladder. In this event, stop depressing the syringe, note the remaining fluid volume in the syringe and aspirate the balloon fluid back into the syringe. Reposition the catheter, ensuring the retaining balloon is placed in the bladder, and attempt inflation again. Ensure the balloon is ultimately filled with a volume in accordance with the catheter manufacturer's guidelines. If the valve exhausts again, call for expert urological assistance.
8. Upon completion of inflation immediately disconnect the TUCSV® and syringe assembly together from the balloon inflation port. Failure to remove the TUCSV® from the catheter may cause deflation of the retaining balloon and subsequent catheter balloon migration into the urethra or complete loss of the catheter.
9. Dispose of the TUCSV® in accordance with local regulations.

## PRECAUTIONS

- Before use, visually inspect the TUCSV® for any signs of damage.
- Ensure that the Luer-lock connections between the syringe, TUCSV®, and catheter are secure to prevent leaks and false positives.

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- If fluid leaks from the exhaust port of the valve, stop inflation, reposition the catheter, and attempt inflation again. If the valve activates again, seek immediate medical attention.
- Remember that balloon inflation with the TUCSV® in place may take longer than usual.
- The TUCSV® is not intended for use during catheter removal.
- Never block the exhaust ports. There is a risk of inflation of balloon in urethra causing trauma.
- Potential TUCSV® blockage: If the syringe is hard to push, the TUCSV® may be blocked. Remove it and check for flow. If no fluid flows, discard the valve.
- m|devices catheters, along with many other popular brands, are validated and tested for use with the TUCSV®. Pre-inflation is not required for m|devices catheters. Some other latex-based brands may require pre-inflation to overcome some balloon "stickiness" and hence avoid false positives.

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