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Transurethral Catheter Safety System – Instructions for Use

Product	Features	Manufacturer
Transurethral Catheter Safety Valve (TUCSV®) – Adult type	Adult Type	Class Medical Ltd
AMSure® 100% Silicone Foley Catheter	Radiopaque	Amsino
D.B.M AQUAFLUSH® - 5ml Sterile water Prefilled Syringe D.B.M AQUAFLUSH®	Sterile – Latex-free – Disposable	D.B.M. S.r.l. Italia
Syringe w/o needle 10ml – Central	Luer Slip	Pic Solution

PLEASE READ ALL INSTRUCTIONS CAREFULLY BEFORE USE!

Warning/Cautions:

"Adult type" Transurethral Catheter Safety Valves are not intended for patients aged under 16 years.

AMSure® 100% Silicone Foley Catheter contains or presence of Phthalate (DEHP)

Packaging

1. PCG01MA1: 5 mL disposable pre-filled syringe, filled to 5 mL, with Luer Lock adapter, individually packaged in a PET/PP Paper Pouch.
2. The volume reported on the label refers to the filling volume of the syringe. The graduated scale reported on the label of the primary packaging (syringe) has no measuring function.
3. Only the contents and the outside of the components are sterile with all types of packaging.

Indications

1. The TUC SAFETY SYSTEM (TUCSS™), and its components, is indicated for single use Foley catheterisation to prevent accidental inflation of the balloon in the urethra. All components are for Urological use only

Contraindications

1. The Adult type TUCSV® is not intended for patients aged under 16 years of age.
2. The TUCSV® is not intended for use as part of the removal of the catheter procedure.

Preparations for Use

1. Remove TUCSS™ Components from their sterile packaging using aseptic technique.
2. Visually inspect the TUCSS™ Components for any mechanical damage.
3. Check the validity of the expiry date reported on the various pouches.
4. Remove red pull tab of the TUCSV® prior to inflation of catheter retaining balloon.
5. Check the correct position of the pre-filled syringe cap and the transparency of the solution. If necessary, place the syringe on the sterile field.

Special Instructions and Precautionary Measures

1. Do not use the product for purposes other than its intended use.
2. Do not administer D.B.M. AQUAFLUSH® intravenously directly.
3. Do not use the product if the packaging is open or damaged, if the syringe is not perfectly intact or if the cap is so damaged that the syringe leaks.
4. Do not use the product if the solution is not colourless or if it contains particulate matter.
5. Once opened, the devices must be used immediately and disposed of after use.
6. Do not re-sterilize.
7. For the AMSure® 100% silicone Foley Catheter do not inflate exceeding recommended capacities.
8. Never block the TUCSV® exhaust ports. There is a risk of inflation of the retention balloon in the urethra causing urethral trauma.

Instructions for Use

The health-care worker must use an aseptic technique throughout, per the procedures of the healthcare institution.

1. Remove the protective cap, making sure that no contact contamination of the syringe Luer cone occurs.
2. Connect the syringe to the female Luer lock of the TUCSV® on the catheter, taking care to avoid any contamination through contact with the Luer cone of the syringe.
3. Continuing the use of a sterile technique, insert Foley catheter as per standard procedure/instructions.
4. Slowly inject the amount of solution for a volume suitable to the correct and effective anchoring of the balloon in the Foley catheter, according to the procedure adopted by your institution.
5. Remember that balloon inflation with the TUCSV® in place is slower (due to the restriction channel) and will take 10-15 seconds longer than usual.
6. 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.

Warning:

"One Drop Stop!"

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 pre-filled syringe, aspirate the balloon fluid back into the pre-filled syringe, reposition the catheter, ensuring the retaining balloon is placed in the bladder, and attempt inflation again. If the valve exhausts again call for expert urological assistance.

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Warning:
In the event of valve activation, it is important to note how much fluid remains in the pre-filled syringe to ensure that the balloon is ultimately filled with a volume in accordance with the catheter manufacturers guidelines

Warning:
Ensure that the Luer-lock connection between the pre-filled syringe and the TUCSV® and the push-in connection between the TUCSV® and the balloon inflation port are sufficiently tight to prevent leaks and/or false positives, as per a normal catheterisation procedure.

7. **To deflate catheter balloon:** Gently insert an empty syringe in the catheter valve. Never use more force than is required to make the syringe "stick" in the valve. If you notice slow or no deflation, re-seat the syringe gently. Allow the balloon to deflate slowly on its own. Do not aspirate or manually accelerate the deflation of the balloon

The TUCSV® is not to be used for the removal or deflation of transurethral catheters.

Potential Complications
The restriction orifice of the TUCSV® may become blocked preventing the depression of the syringe plunger. If difficulty is encountered depressing the syringe, remove the TUCSV® from the catheter and test flow through it. If no fluid passes through the TUCSV® the restrictor orifice is blocked. Dispose of the TUCSV®.

Do not Reuse
Re-processing of medical devices intended for single use only may result in degraded performance or a loss of functionality. Reuse of single use only medical devices may expose patient or user to viral, bacterial, fungal, or prionic pathogens. Validated cleaning and sterilisation methods and instructions for reprocessing to original specifications are not available for these medical devices. These products are not designed to be cleaned, disinfected, or resterilised.

Disposal
After use, dispose of the individual components and any unused solution volumes in accordance with accepted medical practice and the applicable laws and regulations.

Storage
Store the components tightly sealed, away from direct light and heat sources, at a temperature between + 5°C and + 30°C.
Do not freeze.
The expiration date refers to the product in its intact packaging and correctly stored. Do not use the Medical Devices after the expiration date.

Incident reporting
Serious Adverse Events (such as the possibility of death or serious injury) should be reported immediately to the relevant Manufacturer, or Distributor, and relevant Competent Authority. Other Adverse Events associated with the TUCSV® should be reported to the Manufacturer or Distributor without undue delay.