TruCath® Duo

100% Silicone Dual-Balloon Urinary Catheter

Instructions for Use

DESCRIPTION

The TruCath® Duo 100% Silicone Dual-Balloon Urinary Catheter consists of a shaft with eyelets near the tip, two (2) balloons, a drainage funnel, and two (2) inflation arms with cap and valve. The eyelets allow for drainage of urine from the tip of the catheter through the drainage lumen. When inflated, the balloons retain the catheter within the bladder. There are three (3) lumens in each catheter: one (1) for urine drainage and two (2) for individual balloon inflation/deflation.

INDICATIONS FOR USE

The TruCath Duo 100% Silicone Dual-Balloon Urinary Catheter is intended for use in the drainage/collection of urine from the urinary bladder.

CONTRAINDICATIONS

None known.

WARNINGS

- After use, this product may be a potential biohazard. Handle and dispose
 of in accordance with acceptable medical practice and applicable local,
 state, and federal laws and regulations.
- Do not use petroleum-based lubricants or ointments. They will damage the catheter and cause the balloons to deflate.

PRECAUTIONS

- Vigorous aspiration may collapse the inflation lumen and prevent balloon deflation. If no deflation occurs, the valve arm may be severed if permitted by institution protocol. If this fails, qualified personnel should be contacted for assistance.
- DO NOT aspirate urine through the drainage funnel wall. Inflate the balloons using luer slip-adapter syringes.
- DO NOT use needles. Maximum catheter inflation capacity with sterile water: 10 ml/cc per balloon.

STEP-BY-STEP INSTRUCTIONS PREPARATION:

- Visually inspect the product for any imperfections or surface deterioration prior to use. If the package is opened or if any imperfection or surface deterioration is observed, do not use.
- Gather required materials: Two 10 ml/cc syringes filled with sterile water. (See Figure 1.)



Figure 1. Installation requires two 10 ml/cc syringes.

3. Wash hands before and after the procedure.

INSERTION:

- 1. Insert the catheter according to institution guidelines.
- 2. Insert one of the 10 ml/cc syringes into the port of the French-size color-coded **Non-Black valve** (proximal/anchor balloon inflation/deflation valve). Slowly depress the syringe plunger to fill the proximal/anchor balloon with approximately **10 ml/cc** of sterile water, then remove the syringe. (See Figure 2.)



Figure 2. Use the **Non-Black valve** (18 FR/Red shown) to inflate the proximal/anchor balloon with **10 ml/cc** of sterile water

 Insert the second 10 ml/cc syringe into the port of the BLACK valve (distal/ bladder-protection balloon inflation/ deflation valve). Slowly depress the syringe plunger to fill the distal/bladderprotection balloon with approximately 5 ml/cc of sterile water, then remove the syringe. (See Figure 3.)



Figure 3. Use the **Black valve** to inflate the distal/bladder-protection balloon with **5 ml/cc** of sterile water.

REMOVAL:

- 1. Deflate the proximal/anchor balloon by gently inserting a luer slip syringe into the port of the French-size color-coded Non-BLACK valve, allowing water to flow into the syringe barrel. Never use more force than required to make the syringe "stick" in the valve. If slow or no deflation occurs, gentle aspiration may be necessary.
- Empty the syringe and then insert it into the port of the BLACK valve (distal/bladder-protection balloon inflation/deflation valve). Repeat the deflation process.
- 3. Remove the catheter according to Institution guidelines.

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