

Uncoated Intermittent Catheters
Pre-Lubricated Intermittent Catheters
Hydrophilic Intermittent Catheters
Ready-to-Use Hydrophilic Intermittent Catheters

Instructions for Use

INDICATIONS FOR USE

The TruCath® Intermittent Catheters are indicated for intermittent urinary catheterization by inserting through the urethra to pass urine from the bladder.

CONTRAINDICATIONS

- Acute urethritis
- Acute prostatitis
- Acute epididymitis
- Patients with a PVC or Gel allergy
- Patients with calcareous urolithiasis

WARNINGS

- After removing the catheter from the packaging, do not wipe or scrub the surface of the catheter by either physical force or chemicals to avoid damaging the hydrophilic coating which may result in efficacy loss.
- This is a single use device. Do not re-sterilize any portion of this device. Reuse and/or repackaging may create a risk of patient or user infection, compromise the structural integrity and/or essential material and design characteristics of the device, which may lead to device failure, and/or lead to injury, illness or death of the patient.

PRECAUTIONS

- Federal law restricts this device to sale by or on the order of a physician.
- This product can be used in healthcare centers under supervision of appropriately qualified and trained personnel or at home by patients according to the instructions for use.
- To prevent urinary tract infection, appropriate aseptic steps should be taken to areas around the urethral opening prior to insertion.
- This product is disposable, do not reuse.
- Do not use if the package is damaged, contaminated, or expired.
- Special attention shall be taken for patients with disturbance of consciousness as involuntary pull of the catheter may lead to bladder and urethra mucosal injury or break the catheter.
- Intubation and extubation should be as gentle as possible to prevent urethral injury.
- If the catheter is applied with a guide wire, the operator shall ensure that the guide wire is at the foremost end of the catheter. Pumping action shall be avoided as the guide wire may pass through the eyelets with the risk of injuring the urethral mucosa.
- Slowly advance the catheter through the urethra into the bladder. If substantial resistance is met, do not force the catheter. Slowly pull out the catheter and look for reasons.
- If there is no urine draining into the bag, take the following steps: Check for and remove any kinks in the catheter or the drainage bag tubing. Check the position of the catheter and drainage bag. Ensure the bag is positioned below the bladder when lying, sitting or standing.
- For overfilled bladder, the urine should not be discharged too fast which may lead to shock or bladder bleeding.
- Catheter insertion should always be carried out in accordance with local and national best practice policies by appropriately qualified and trained personnel.

ADVERSE REACTIONS

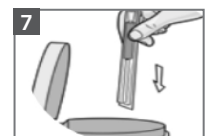
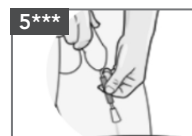
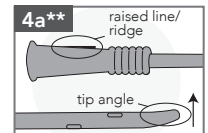
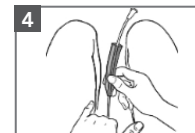
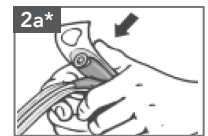
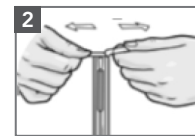
- Bleeding in the urethra
- Catheter-associated urinary tract infection
- Urethral injuries and inflammation

STEP-BY-STEP INSTRUCTIONS

1. Select an appropriate specification of catheter which is suitable for the specific procedure. For uncoated intermittent catheters, pre-treatment with water lubricant is required. Carefully inspect the package and

catheter prior to use. Discard and replace the product if it is damaged. The operator and patient shall follow the standard aseptic procedure before conducting the catheterization.

2. Open the product as specified below for each catheter type:
 - **TruCath® Uncoated Intermittent Catheter**
Open the package from the tear-away opening and expose the funnel. Remove the catheter and apply a liberal amount of lubricant to the tip and the first several inches of the catheter.
 - **TruCath Swift® Pre-Lubricated Intermittent Catheter**
Open the package using the tear-away opening and expose the funnel. Remove the catheter.
 - **TruCath® Hydrophilic Intermittent Catheter (see 2a*)**
Activate the water pouch by folding and squeezing the pouch. Allow the water to flow out. Wait 15 seconds to enable water coating activation. Affix the package to any dry, flat surface by using the self-adhesive tape on the package.
 - **TruCath Oasis® Ready-to-Use Hydrophilic Intermittent Catheter**
Open the package and expose the funnel. Remove the catheter.
3. Holding the funnel, slide the contactless sleeve/grip (if applicable) along the catheter towards the tip.
4. Carefully insert the catheter through the urethral orifice until urine starts to flow out - this occurs after the eyelets of the catheter reach the bladder cavity.
 - **Coudé tip catheters:** Before insertion, ensure the curved tip angle is facing upwards. For guidance, use the raised line/ridge on the catheter funnel and the blue line on the catheter tube to help orient the upward position. Always defer to the tip angle for positioning (see 4a**).
5. For user positioning in front of a toilet facility, the urine can drain into the toilet. If lying down, place the funnel end of the catheter into a container or connect a drainage bag by inserting the plug of the drainage bag into the catheter funnel to collect the urine. Then, hold the catheter until urine stops flowing.
6. When urine stops flowing, begin to withdraw the catheter. Slowly rotate the catheter during withdrawal, stopping each time urine begins to flow until the bladder is empty.
7. After use, remove the catheter from the urethra and dispose of it in accordance with local administrative regulations to prevent environmental pollution and potential health hazards.
8. Wash hands after catheterization.



* Step 2a is only applicable to hydrophilic intermittent catheters with a water pouch.

** Step 4a is only applicable to coudé tip catheters.

*** Steps 5 & 6 are universal for both male and female users.

RECOMMENDED STORAGE CONDITIONS

- The product is valid for three (3) years from the date of manufacture.
- For single use only, do not repeat sterilization and reuse.
- Use immediately after opening the package and destroy after use.
- Store the device in a cool, dry, and dark place. Do not store catheters where there is direct exposure to organic solvents, ionizing radiation, ultraviolet light, and high temperatures.

See reverse for additional information.