URETHRAL CATHETERISATION DEVICE (UCD®)

The Urethrotech UCD® is sterilized with ethylene oxide gas. For single use only. Do not resterilize. Do not reuse any product component provided in this packaging.

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

Read the following precautions, warnings and instructions for use carefully.

Device Description

The Urethrotech UCD® (Urethral Catheterisation Device) 3-way Silicone Foley Balloon Catheter is composed of a silicone tube with an embedded radiopaque black stripe, a silicone balloon and polyvinylchloride valve and an integrated introducer guidewire. The tube has three lumens, one lumen for urinary drainage which is to be connected to a urine collection container, one lumen with two-way valve for inflation/deflation of a Foley balloon and one lumen for the integrated removable guidewire made of Nitinol with hydrophilic coating for the introduction of the catheter through the urethra into the bladder to negotiate any prostatic curve or tight external urethral sphincter, and also for irrigation of he bladder after guidewire removal. The UCD® is intended to be used to provide safe urinary tract access through the urethra and into the bladder and to pass fluids to and from the urinary bladder and to provide continuous bladder irrigation of fluids and drainage of urine from the urinary tract. The device is provided sterile and is intended for short-term use (<=30days).

Indications for Use

The Urethrotech UCD® is intended for use for bladder management including urine drainage, collection and measurement and/or bladder fluid instillation or irrigation.

Intended Use

The Urethrotech UCD® is intended to be used to provide safe urinary tract access through the urethra and into the bladder to pass fluid to and from the urinary bladder and to provide continuous bladder irrigation of fluids and drainage of urine from the urinary tract.

Product Specifications

The UCD® is available in 16 French with 10cc balloon.

<table>
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<tr>
<th>SIZE</th>
<th>L.D.</th>
<th>O.D.</th>
<th>EFFECTIVE LENGTH</th>
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<tr>
<td>16F</td>
<td>UCD-0035-090-0016</td>
<td>5.3mm</td>
<td>90cm</td>
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Contraindications

Same as for urethral urinary catheterisation for bladder drainage. Don’t use the UCD® in patients with known urethral stricture or injury, bladder neck injury, urorectal fistula, or known allergic reactions to device materials.

Warnings

Ensure the guidewire irrigation luer-lock is firmly pushed into the guidewire side arm. Don’t pull on the guidewire luerock or dismantle any component of the UCD® until the catheterization procedure is completed. Discard the introducer guide wire after use. Structural integrity and/or function may be impaired through reuse or cleaning.

Precautions

The UCD® must be used by a healthcare professional. Any use other than stated indications is the responsibility of the healthcare professional. The choice of the balloon volume is the responsibility of the healthcare professional. A 10cc balloon volume is recommended. Don’t inflate the balloon beyond the maximum value indicated on the label. Don’t use silicone oils or iodine-based irrigation with silicone catheters. Don’t clamp the catheter. Any fixation should be applied to the connector. Inspect the UCD® before use to verify that its size, shape and condition are suitable for the specific procedure. Do not use open or damaged packages. Use prior to the “Use By” date. Do not exposed to organic solvents. Follow the manufacturer’s instruction for use.

Adverse Events

Several adverse events have been reported with the use of balloon catheters. Some are related to patient conditions, and others to the procedure or the device. If the guidewire is removed before the catheter is fully inserted into the bladder, the balloon may be inadvertently inflated in the urethra. If in doubt, the catheterisation procedure should be started from the beginning with a new UCD®. If the guidewire turns during insertion and is seen exiting at the external urethral meatus repeatedly, the procedure should be abandoned and the patient referred to a specialist for further investigation and management. Equally, if strong urethral resistance is met during catheter insertion over the guidewire, discontinue the procedure and determine the cause of the resistance before proceeding. If the cause of the resistance cannot be determined, withdraw the UCD® altogether. Torquing the UCD® excessively may cause urethral damage. Should the UCD® catheter shaft become severely bent, withdraw the entire UCD® device (guidewire-catheter unit). If there is any urethral bleeding before or after urethral catheterization, please seek specialist help. Indwelling catheter related adverse events include bladder irritation from the catheter balloon, pain, urinary tract infection, encrustation and stone formation. A leaking balloon valve can lead to balloon deflation with catheter migration.

Caution for Storage

The UCD® should be stored in the original packaging. Do not store in extreme temperatures and humidity. Store away from light in a cool and dry place. Do not use if the sterile packaging is damaged or opened.

Disclaimer of Warranty & Limitation of Remedy

There is not express or implied warranty, including without limitation any implied warranty of merchantability or fitness for a particular purpose, on the Urethrotech product(s) described in this publication. Under no circumstances shall Urethrotech be liable for any direct, incidental or consequential damages other than as expressly provided by specific law. No person has the authority to bind these to any representation or warranty except as specifically set. Descriptions or specifications in Urethrotech printed matter, including this publication, are meant solely to generally describe the product at the time of manufacture and do not constitute any express warranties. Urethrotech will not be responsible for any direct, incidental or consequential damages resulting from reuse of the catheter or guidewire.

This is a single use device. Do not resterilize 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.
**Recommended Procedure**

1. Confirm the patient meets the CDC Guidelines for appropriate indications for an indwelling urethral catheter

   a. Patient has acute urinary retention or bladder outlet obstruction
   b. Need for accurate urine output measurements
   c. Use for selected surgical procedures
   d. To assist in healing of open sacral or perineal wounds
   e. Patient requires prolonged immobilization
   f. To improve comfort of end of life care

2. Prepare the necessary materials for urethral catheterization that meet patient needs, local protocols and guidelines, including:

   a. Sterile drape for urethral catheterization trolley
   b. Sterile fenestrated catheterization drape for patient
   c. Antiseptic solution or castile soap wipes to cleanse the patient’s periurethral and genital area
   d. Sterile gloves
   e. Syringe of water-based urethral lubrication gel
   f. 2 x 10cc syringes of sterile water
   g. Urine drainage bag (catheter bag/urine collection device)

3. Insert the UCD® using aseptic technique and sterile equipment

   a. Explain the procedure to the patient and ensure privacy
   b. Drape urethral catheterization trolley with sterile drapes and place all necessary catheterization materials on it. Adhere to sterility whilst removing the packaging
   c. Open the outer Urethrotech box and take out the UCD®
   d. Open outer UCD® peel pouch and place the sterile inner sleeve pouch containing the UCD® onto the sterile draped urethral catheterization trolley surface without touching it
   e. Wash hands and perform hand hygiene with hand sanitizer gel and don sterile gloves
   f. Prepare the patient by cleansing the patient’s penis and peri-urethral area in a circular motion starting at the urethral meatus and working outwards using antiseptic solution or other fluid according to hospital policy and position a fenestrated catheterization drape on the patient appropriately
   g. Open inner sleeve pouch to the first horizontal perforation so that the guidewire irrigation luer-lock of the UCD® is exposed
   h. Attach a 10cc sterile water syringe to the luer-lock and lubricate the guidewire. Ensure the luer-lock stays attached
   i. Slowly inject water based urethral lubrication gel into the urethra of a straightened penis
   j. Insert the guidewire into the urethra and advance it into the bladder with even steady movements, thereby automatically dragging the catheter behind towards the urethral meatus
   k. Once the catheter tip reaches the external urethral meatus, the catheter is advanced over the guidewire into the bladder until the entire length of the catheter shaft is inserted to the Y-junction hub of the catheter end
   l. Inflate the catheter balloon using 10cc of sterile water after urine is seen to drain from the catheter urine drainage lumen!
   m. Once the balloon is fully inflated, gently pull the catheter back until the inflated balloon has reached the bladder neck.
   n. Remove the guidewire and attach the silicone plug to close the guidewire channel (or use channel for bladder irrigation)
   o. Attach a urine drainage bag (catheter bag/urine collection device)
   p. Discard all materials in accordance with hospital protocol
   q. Perform hand hygiene
   r. Document the procedure according to hospital policy
   s. Patients should observe that urine is present in the catheter bag tubing, ensure genital hygiene and contact their doctor immediately if any signs of urinary tract infection are present

4. Procedure: Removal of UCD®

   Explain the procedure to the patient and ensure privacy. Remove any catheter fixation pads. Conduct a 15-30 second antiseptic hand wash. Don sterile gloves.

   To deflate the catheter balloon: Firmly but gently attach an empty 10cc syringe into the orange balloon valve and steadily aspirate the entire fluid of the balloon. Ensure all balloon fluid is truly aspirated. Be aware that the aspirated fluid amount can vary. It is important to ensure that the syringe is properly pushed into the balloon valve during the aspiration. If in doubt, repeated aspirations will confirm that no more fluid can be aspirated. Use gentle but consistent aspiration to allow steady balloon deflation. Too quick and vigorous aspiration may collapse the inflation lumen and prevent balloon deflation. If the balloon will not deflate and if permitted by hospital protocol, the valve arm may be severed. If this fails, contact adequately trained professionals for assistance, as directed by hospital protocol.

   Should balloon rupture occur, care should be taken to assure that all balloon fragments have been removed. If in doubt, the patient should be referred to adequately trained professionals for further investigation.

   The catheter slides out with simple traction once the balloon is completely deflated. Remove the catheter gently and discard it according to hospital policy. Document procedure according to hospital policy.