


URETHRAL CATHETERISATION DEVICE (UCD®)

Warning: Do not use ointments or lubricants having a petroleum base. They will damage Silicone. Visually inspect the product for any imperfections or surface deterioration prior to use.

Storage: The UCD® should be stored in the original box and at room temperature. Do not store in extreme temperatures and humidity. Store away from direct exposure to light. Do not use if the sterile packaging is damaged or opened.

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 blue stripe, a silicone balloon and polyvinyl-chloride 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 the bladder after guidewire removal.

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 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).

Product Specifications

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

SIZE	L.D.	O.D.	Effective Length
16F	UCD-0035-090-0016	5.3mm	90cm

Contraindications

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

Warning

Ensure the guidewire irrigation luer-lock is firmly pushed into the guidewire side arm. Do not pull on the guidewire luerlock or dismantle any component of the UCD® until the catheterization procedure is completed. Discard the introducer guidewire after use. After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable laws and regulations. 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. Do not inflate the balloon beyond the maximum value indicated on the label. Do not use silicone oils or iodine-based irrigation with silicone catheters. Do not 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 expose 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 catheterization 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.

Disclaimer of Warranty and Limitation of Remedy

There is no 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.

 Single use only.  Do not re-sterilize.  Do Not Use if Package is Damaged.

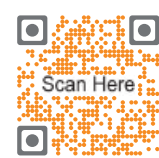
This is a single use device. Do not re-sterilize any portion of this device. Reuse and/or repackaging may create a risk of patient or user infection, compromise the structural integrity and/or essential material and design characteristics of the device, which may lead to device failure, and/or lead to injury, illness or death of the patient.

LOT Lot Number **REF** Reorder Number  Use by Date.  Units
 Caution, consult accompanying documents.  Consult instructions for use. **STERILE EO** Sterilized by Ethylene Oxide  Prescription Only

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

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URETHROtech®
 Urethrotech Ltd
 24 Garth Road
 Kingston Upon Thames
 Surrey KT2 5NY UK
 Tel (US): 1800 474 0180
 Tel (UK): 0800 051 7219
 www.urethrotech.com



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 Scan QR Code or visit <https://scnv.io/dVOC>
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Preparation of UCD®

Confirm the patient meets the CDC Guidelines for appropriate indications for an indwelling urethral catheter use:

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

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

- Sterile drape for device preparation surface
- Sterile fenestrated drape for patient
- Antiseptic solution or castile soap wipes to cleanse the patient's periurethral and genital area
- Sterile gloves
- Syringe of water-based urethral lubrication gel
- 2 x 10cc syringes of sterile water, preferably luer tip syringes
- Urine drainage bag (catheter bag/urine collection container)

Preparation of the UCD® using aseptic technique:

- Place all necessary catheterization materials on a sterile surface and adhere to sterility whilst removing the packaging
- Open the outer UCD® peel pouch and place the sterile inner sleeve pouch containing the UCD® onto a sterile surface and adhere to sterility whilst removing the packaging (Fig.1+2)



Fig.1



Fig.2

- Open inner sleeve pouch to the first horizontal perforation so that the guidewire luer-lock of the UCD® is exposed (Fig.3)
- Attach a 10cc sterile water syringe to the luer-lock and lubricate the guidewire (Fig.4). Ensure the guidewire luer-lock stays attached after removal of the syringe.



Fig.3



Fig.4

Procedure: 1. Insertion of UCD®

- Explain the procedure to the patient and ensure privacy
- Wash hands including hand hygiene sanitizer gel and don sterile gloves
- Cleanse the patient's penis and peri-urethral area starting at the urethral meatus and work outwards according to hospital protocol
- Position the sterile fenestrated catheterization drape on the patient
- Lubricate the urethra with lubricating gel keeping the penis straight
- Insert the guidewire into the straightened urethra with even and steady advancing movements, thereby automatically dragging the catheter behind towards the urethral meatus (Fig.5)
- Once the catheter tip reaches the urethral meatus, advance the entire catheter into the bladder until the Y-junction hub of the catheter (Fig.6)



Fig.5



Fig.6

- Inflate the catheter balloon using 10cc of sterile water only after urine is seen to drain from the end of the catheter (Fig.7+8).

Warning: Abandon the procedure, if resistance is felt whilst advancing the guidewire, or if the guidewire turns back repeatedly to exit the urethral meatus, or if resistance is felt whilst advancing the catheter into the bladder

Warning: Don't inflate the balloon unless urine is draining from the end of the catheter! If necessary, use a bladder syringe to aspirate urine to confirm correct catheter position in the bladder!



Fig.7



Fig.8

Procedure: 2. Removal of UCD® guidewire

- Remove the guidewire after balloon inflation and attach the plug to close the guidewire channel (Fig 9+10), or use the channel for bladder irrigation
- Pull the catheter back until the balloon is felt bouncing at the bladder neck



Fig.9



Fig.10

- Attach a urine drainage bag (catheter bag/urine collection container)
- Discard all materials in accordance with hospital protocol
- Perform hand hygiene
- Document the procedure according to hospital policy
- Patients should observe that urine is present in the catheter bag tubing
- Instruct patient to perform daily genital hygiene and contact their doctor immediately if any signs of urinary tract infection are present.

Procedure: Removal of catheter

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, gently insert a luer slip tip syringe in the catheter valve. Never use more force than is required to make the syringe "stick" in the valve. Allow the pressure within the balloon to force the plunger back. If you notice slow or no deflation, re-seal the syringe gently. Use only gentle aspiration to encourage deflation if needed. Vigorous aspiration may collapse the inflation lumen, preventing balloon deflation. Be aware that the aspirated fluid amount can vary. If in doubt, repeated aspirations will confirm that no further fluid can be aspirated. If necessary, contact adequately trained professional for assistance, as directed by hospital protocol. The catheter slides out with slow and gentle traction once the balloon is completely deflated and the patient is instructed to relax.

Discard the catheter according to hospital policy.
Document the procedure according to hospital policy.

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