URETHRAL CATHETERISATION DEVICE® (UCD®)

STERILE. Sterilized with ethylene oxide gas. For single use only. Do not resterilize.

Caution: Federal (USA) Law restricted this device to sales by or on the order of a physician.

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

Device Description

The Urethrotech® UCD® (Urethral Catheterization Device®) is a urethral catheter with an integrated non-traumatic introducer guide wire. The introducer guide wire is to assist with the correct positioning of the catheter and is withdrawn once the urethral catheter is successfully positioned in the bladder. The catheter is intended to remain in situ for up to 30 days.

Indications

The UCD® is intended for use for bladder management including urine drainage, collection and measurement. The single unit of integrated guide wire and catheter is passed through the urethra during catheterization and into the bladder to drain urine as a 2nd-line device in difficult or failed standard urethral catheterisation.

Product Specifications

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

Contraindictions

Don't use the UCD® in patients with known obliterative (blocked) lower urinary tract conditions.

Warnings

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

Precautions

Do not use open or damaged packages.
Use prior to the "Use By" date.
Do not resterilize.
Do not exposed to organic solvents.
Inspect the UCD® before use to verify that its size, shape and condition are suitable for the specific procedure.

If the guide wire 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 guide wire, discontinue the procedure and determine the cause of the resistance before proceeding.
If the cause of the resistance cannot be determined, withdraw the UCD® guide-wire-catheter unit.
Torquing the UCD® excessively may cause urethral damage. Should the UCD® catheter shaft become severely bent, withdraw the entire UCD® device (guide-wire-catheter unit). If there is any urethral bleeding before or after urethral catheterization, please seek specialist help.

Complications

Although significiantly lower when using the UCD®, there is still a very small risk of urethral trauma and bleeding, especially if the manufacturer's instructions for use are not followed closely.
The risk of urine infection is related to the length of catheter indwelling time and bacterial biofilm formation on the catheter.

Caution for Storage

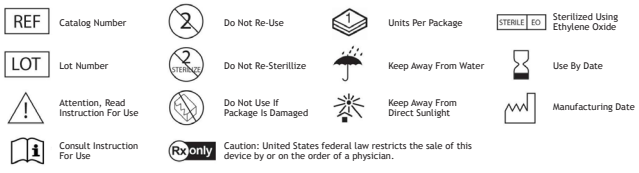
Do not store in extreme temperatures and humidity.
Store in a dry, dark, and cool place.
Avoid exposure to direct sunlight and water.

Disclaimer of Warranty & Limitation of Remedy

THERE IS NOT EXPRESS OR IMPLIED WARRANTY, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRNTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, ON THE URETHROTECH PRODUCT(S) DESCRIBED IN THIS PUBLICATION UNDER NO CIRCUNSTANCES SHALL URETHROTECH BE LIABLE FOR ANY DIRECT, INCIDENTAL OR CONSEQUINTAL DAMAGES OTHER THAN AS EXPRESSELY PROVIDED BY SPECIFIC LAW, NO PERSON HAS THE AUTORITY TO BIND SEISA TO ANY REPRESENTATION OR WARRANTY EXCEPT AS SPECIFICALLY SET FORTH HEREIN.

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 guide wire.



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Recommended Procedure

1. Confirm the patient meets the CDC Guidelines for Appropriate Indications for Indwelling Urethral Catheter Use

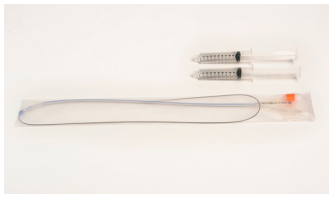
a. Patient has acute urinary retention or bladder outlet obstruction
b. Need for accurate urine output measurements
c. Use for selected surgical procedures
d. To assist in healing of open sacral or perineal wounds
e. Patient requires prolonged immobilization
f. To improve comfort of end of life care

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

a. Sterile drape for catheterization trolley
b. Sterile fenestrated catheterization drape for patient
c. Antiseptic solution or castile soap wipes to cleanse the patient's peri-urethral area
d. Sterile gloves
e. Syringe of water-based urethral lubrication gel
f. 2 x 10mL syringes of sterile water
g. Urine drainage bag

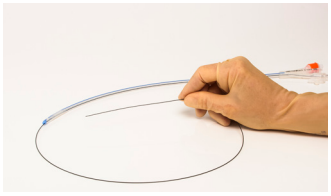
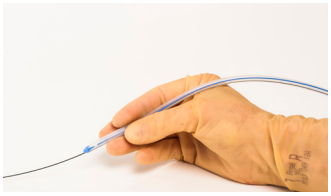
3. Insert the UCD® using aseptic technique and sterile equipment

a. Explain the procedure to the patient and ensure privacy
b. Drape catheterization trolley with sterile drapes and place all necessary catheterization materials on it and adhere to sterility whilst removing the packaging
c. Open UCD® box and take out the UCD®
d. Open outer UCD® pouch and place the sterile inner sleeve pouch, containing the UCD®, on the catheterization trolley without touching it

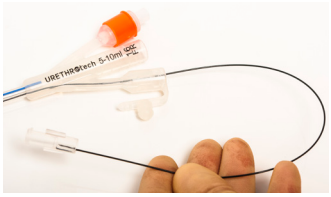
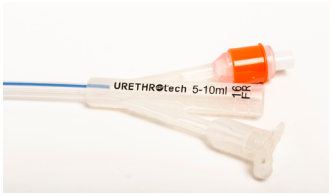
e. Wash hands and perform hand hygiene with hand sanitizer gel and don clean sterile gloves
f. Prepare patient by cleansing the patient's penis and peri-urethral area in a circular motion starting at the urethral meatus and working outwards using antiseptic solution or castile soap wipes and position fenestrated catheterization drape on patient appropriately
g. Open inner sleeve pouch to the first horizontal perforation so that the guide wire Female Luer Lock of the UCD® is exposed
h. Lubricate the guide wire by attaching and flushing a 10mL sterile water syringe into Female Luer Lock of the UCD®


i. Slowly inject one Syringe of water based urethral lubrication gel into the urethral meatus with the penis straightened
j. Insert the UCD® guide wire in to the urethra and advance into the bladder with even movements of about 5cm at a time
k. Once the catheter tip reaches the glans, insert the catheter (over the guide wire) into the bladder until the entire length of the catheter shaft is inserted up to the Y-junction of the catheter end

l. Inflate the catheter balloon using the entire Syringe of 10mL of sterile water only when 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 is felt reaching the bladder neck.


n. Remove the guide wire and attach the plug to close the guide wire channel

o. Attach the urine drainage bag to the main catheter urine drainage lumen
p. Discard all materials in accordance with hospital protocol and remove contaminated gloves
q. Perform hand hygiene
r. Document the procedure according to hospital policy

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: Push a 10mL empty syringe firmly into the orange balloon inflation port and aspirate the entire fluid of the balloon. Ensure all balloon fluid is truly aspirated, but be aware that the aspirated fluid amount can vary, therefore it is important to ensure the syringe is properly pushed into the inflation port during the aspiration. If in doubt, several repeated aspirations will confirm that no more fluid can be aspirated. Use gentle but consistent aspiration to allow steady balloon deflation because too quick and vigorous aspiration may collapse the inflation lumen, preventing 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, and if in doubt, the patient should be referred to adequately trained professionals for further investigation.
Remove the catheter gently and discard it according to hospital policy. Document procedure according to hospital policy.