



A New Urethral Catheterisation Device to Solve Difficult Urethral Catheterisation in Men Undergoing Cardiac Surgery

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Objectives: Pre-operative difficult urethral catheterisation (DUC) leading to Urethral Catheterisation Injury (UCI) is thought to be an infrequent event in Cardiac Surgery, but risks significant patient harm due to required peri-operative anticoagulation. DUC can delay planned patient care. Immediate Urology input may not be available in Specialist Surgical Services. This study investigates the incidence of DUC and UCI in one Cardiac Centre and evaluates the safety&efficacy of a new NICE-approved Urethral Catheterisation Device (Urethrotech UCD®) specifically designed to solve DUC.

Methods: A retrospective (150 men) and prospective (74 men) non-comparative cohort study was performed documenting catheterisation adverse events using a standard Foley-catheter for urethral catheterisation. After Hospital CESC board approval, 100 consecutive men were catheterised with the new UCD to evaluate safety and effectiveness of the new device and to compare the incidence of DUC and UCI.

Results: 127 of 150 men reviewed retrospectively had complete documentation in their clinical notes. None had documented consent about potential urethral catheterisation complications. In the retrospective cohort 3%(4/150) men required insertion of a suprapubic catheter (SPC) to solve pre-operative DUC. In the prospective cohort, 9%(7/74) men sustained DUC/UCI with urethral bleeding and pain, of which 3%(2/74) required SPC. No DUC/UCI events were encountered using the UCD. All 100 UCD's were inserted without problems by staff who normally perform the urethral catheterisation.

Conclusions: Pre-operative DUC leading to UCI is not infrequent in Cardiac Surgery. UCI not only is avoidable, but also a reportable incident. We propose that DUC should be managed with the new UCD® according to the NICE-approved catheterisation algorithm to avoid patient harm.

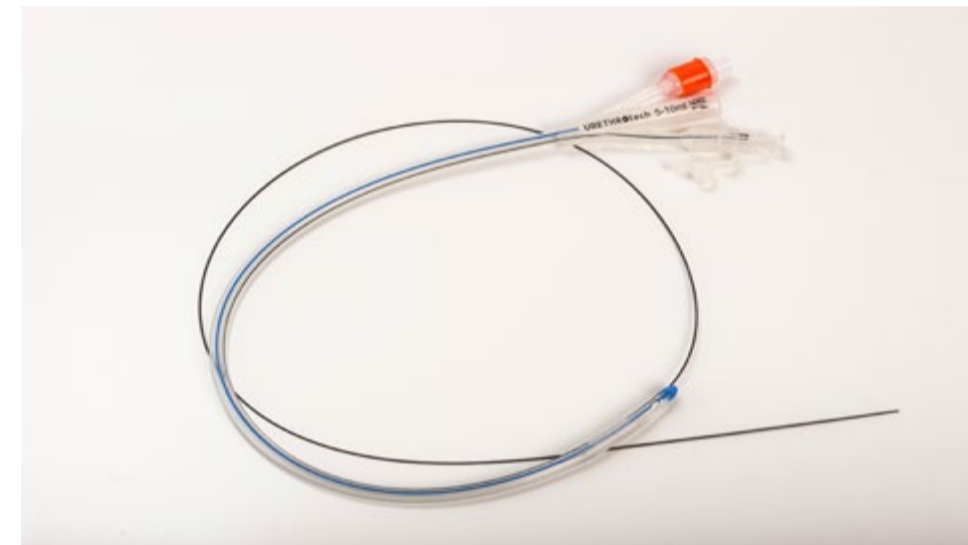


Figure 1: The UCD® consists of a 16F 3-way Silicone urethral catheter with integrated guidewire to manage difficult catheterisation safely.



Figure 2: The UCD-guidewire is glued to a luer lock which fits securely into the catheter guidewire side arm to form one secure Medical Device Unit. A syringe is attached to the luer lock to prime and lubricate the guidewire with sterile water or saline. After UCD-guidewire removal, the guidewire channel could be used for irrigation.

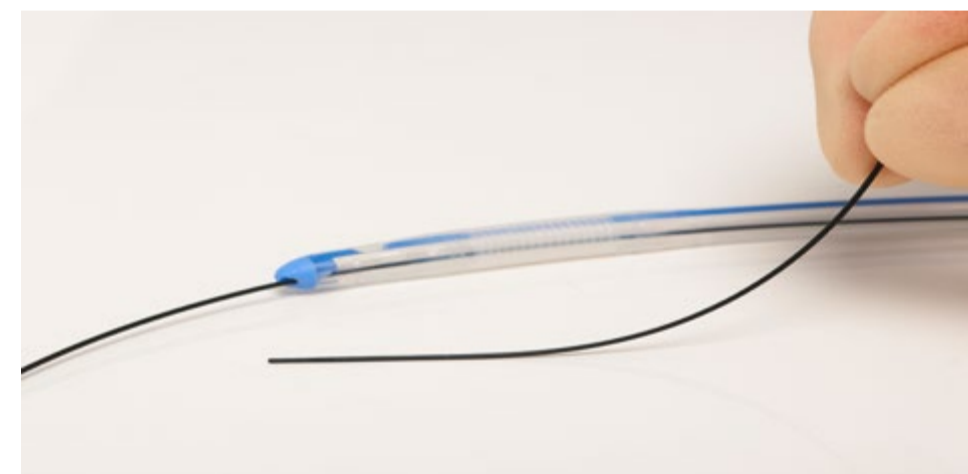


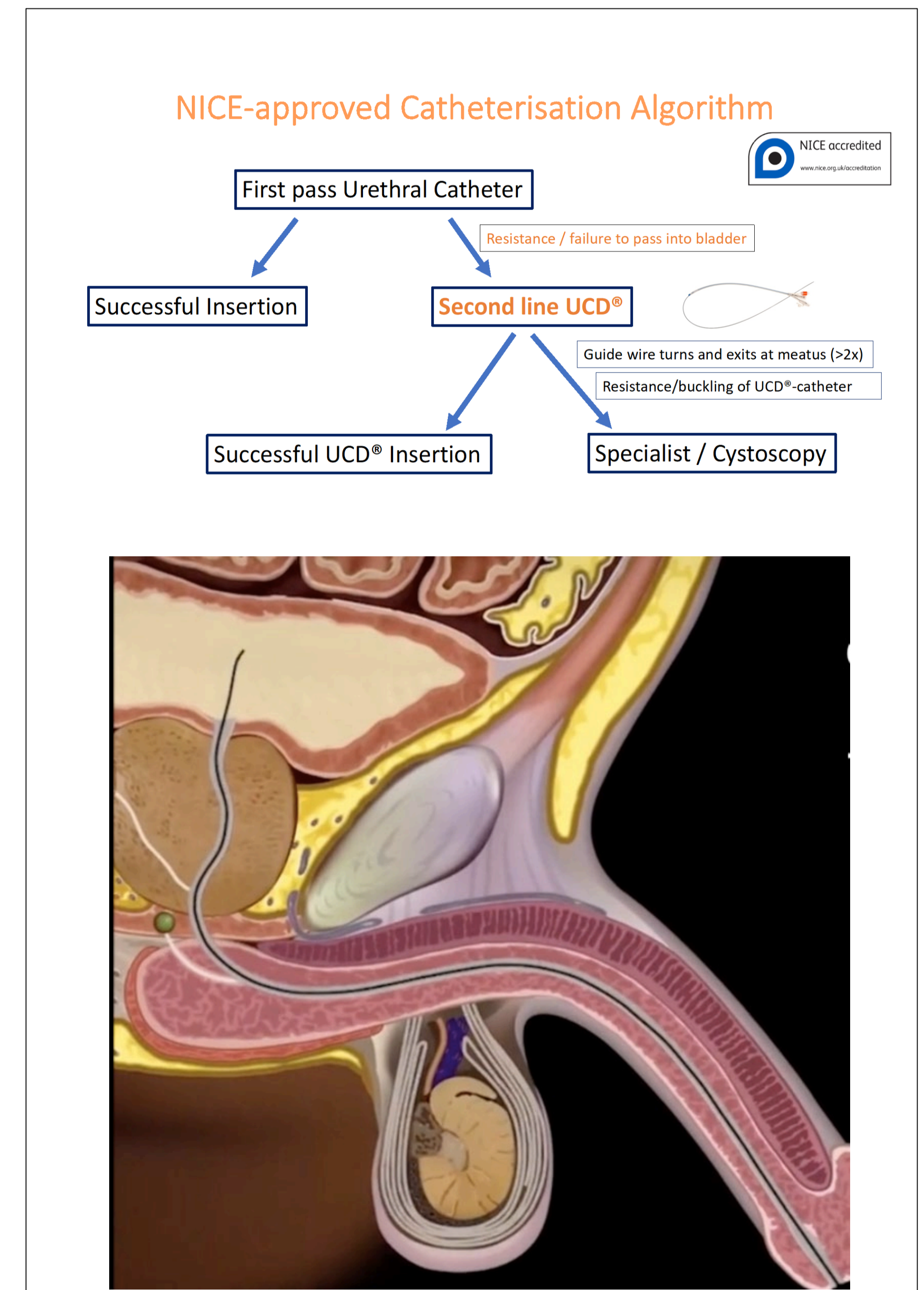
Figure 3: Non-traumatic hydrophilic Nitinol guidewire exits at the round catheter tip.



Figure 4: The UCD-guidewire is introduced into the straightened urethra and advanced with even movements into the bladder where it curls up and then drags the catheter behind.



Figure 5: The catheter is then passed over the guidewire into the bladder, bypassing any enlarged prostate lobes.





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