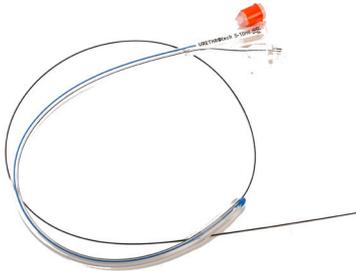


URETHRAL CATHETERISATION DEVICE® (UCD®)

“Empowering Non-Specialist Healthcare Professionals to provided safe urethral catheterisation”



- Sterile off-the-shelf Ready-to-Use NEW Urethral Catheterisation Device
- Multiple International Patents
- ISO 13485:2012
- CE-Mark Certification, FDA-Certification pending

Unique Selling Points

- 2nd-line Medial Device for failed or difficult urethral catheterisation
- Suitable for ANY clinical environment
- Suitable for un-assisted ‘One-man’ procedure
- Avoidance of more invasive specialist procedures
- Avoidance hospital admissions and specialist care
- Using natural urethral tract into bladder
- Non-traumatic integrated Nitinol hydrophilic guide wire forms One-Unit with the catheter to avoid trauma to urethra and (enlarged) prostate
- Easy insertion of catheter over guide wire into bladder, particularly in men with enlarged prostate
- Once guide wire is removed, bladder irrigation is possible

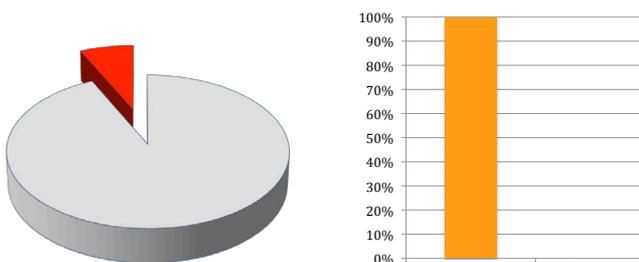
Competitors

The UCD® is a NEW and unique Medical Device. There is no competitor on the market.

Key Customer Groups

Community/Hospital Nurses, Junior Doctors, Theatre Technicians/Assistants, Continence Advisors, Urology Consultants, Procurement

Clinical Studies



■ 93% uneventful urethral catheter, n=74 ■ 100% UCD® success, n=100
 ■ 7% adverse events*/ 3% SPC ■ 0% adverse events*/ 0% SPC

Targeting Strategy

Available literature shows using a non-traumatic Nitinol hydrophilic guidewire with a urethral catheter is a well established clinical practice for difficult urethral catheterisation [1-4], but the two components are currently not available as one sterile ‘Ready-to-Use’ medical device. Instead, clinicians have to ‘bastardise’ the catheter tip with a needle [5] or knife to back-feed the guide wire into the catheter, which is a needle-stick hazard to the clinician and potentially could damage the urethral catheter design or function. Difficult male urethral catheterisation is not an infrequent problem. The incidence of difficult urethral catheterization is 4% in cardiovascular surgery [6] and 6% of all urological referrals over one year within a tertiary teaching hospitals were related to complications arising from male urethral catheterization [7]. Another prospective study calculated an incidence of 0.7 iatrogenic urethral catheter injuries per 1,000 adult male admissions in a single academic tertiary care center [8]. A prospective surveillance study showed that Foley urethral catheterisation related genitourinary trauma was as common as symptomatic urinary tract infection [9] and the additional cost of managing iatrogenic urethral injuries was €335,377 (\$371,790) during a 6 month study period at 2 tertiary referral teaching hospitals in the UK [10]. Another prospective study recorded that 32% of men sustained significant urethral injury as a result of catheterization attempts [11]. The UCD® is a purpose-built medical device, which incorporates a non-traumatic Nitinol hydrophilic guide wire into a standard urethral 3-way catheter design, to fulfill the clinical need of safe urethral catheterization in patients with difficult urethral catheterisation with reduced risk to the clinician. A clinical prospective study in high-risk cardiac surgery patients showed that the UCD® was used in 100 consecutive patients without adverse events [12].

Publications

1. Olson L et al. Blind hydrophilic guide wire for difficult urethral catheterization. Ann RCSEng. 2014; 96 (8): 629-630. 2. Villanueva C et al. The Approach to the Difficult Urethral Catheterization among Urology Residents in the United States. Int Br J Urol 2010; 36 (6): 710-717. 3. Zammit PA, German K. The difficult urethral catheterization: use of a hydrophilic guidewire. BJU Int. 2004; 93: 883-4. 4. Lachat ML et al. The Seldinger technique for difficult transurethral catheterization: a gentle alternative to suprapubic puncture. Br J Surg. 2000; 87: 1729-30. 5. Henderson J. Feeding a urethral catheter over a guidewire using an intravenous cannula. Ann RCSEng. 2012; 94: 61-65. 6. Özkan B et al. Difficult Urethral Catheterization in Cardiovascular Surgery Patients: Do you have a Road Map? J Neph Urol Res. 2014; 2: 32-36. 7. Bacsu C et al. A prospective analysis of consultation for difficult urinary catheter insertion at tertiary care centres in Northern Alberta. 8. Kashefi C et al. Incidence and Prevention of Iatrogenic Urethral Injuries. J Urol. 2008; Vol. 179: 2254-2258 CUAJ. 2013; 7: 343-7. 9. Leuck AM et al. Complications of Foley Catheters—Is Infection the Greatest Risk? J Urol. 2012; 187: 1662-1666. 10. Davis NF et al. Incidence, cost and clinical outcomes of iatrogenic urethral catheterisation injuries: A prospective multi-institutional study. J Urol 2016; 196: 1473-77. 11. Thomas AZ et al. Avoidable iatrogenic complications of urethral catheterisation and inadequate intern training in a tertiary-care teaching hospital. BJU Int, 2009; 104: 1109-1112. 12. Mundy A, Yim I, Tamini A, Roberts N. 2015. Reducing the Risks of Trauma Due to Urethral Catheterisation World J Urol (2015); 22(Suppl 1):207.