TUC SAFETY VALVE

BROCHURE

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Introduction

During the placement of a urology catheter (used to empty a patient's bladder) the anchoring balloon can be misplaced and inadvertently over inflated in the patient's urethra rather than in the correct location in the bladder. It is a blind medical procedure and balloon inflation in the urethra is associated with serious patient injury. Approximately 130 million catheters are placed annually and an incidence of injury of 1.3% leads to more than 1,560,000 injuries worldwide. Our clinical trial shows the instances to be significantly higher.

Class Medical's product offering is the patent protected TUC Safety Valve (Trans Urethral Catheterisation Safety Valve), an innovative technology aimed at eliminating the problem of inadvertent inflation of the urology catheter anchoring balloon in the urethra. The unique selling point of the TUC Safety Valve is that it will prevent inadvertent inflation of the anchoring balloon in the urethra. It uses an innovative safety pressure relief valve to indicate misplacement of the anchoring balloon, eliminating urethral damage. The TUC Safety Valve can be used with any brand of catheter as it standardises the inflation speeds of the various branded catheters allowing the balloons to open in a more controlled manner.

BENEFITS OF TUC SAFETY VALVE

- Eliminates the risk of inflating the catheter's anchoring balloon in the urethra.
- Decreased patient morbidity.
- Safe, effective and reliable procedure.
- The safety valve is simple in it's design and low in cost.
- Proven to interest to urologists, clinicians and health practitioners on a worldwide basis
- Can significantly reduce unnecessary costs of hospitalisations and restorative treatments.

Milestones

2015

- Ex-vivo human study of urethral damage in collaboration with Dr. Joachim Hess, University Hospital Essen, Germany

2016

- Completed positive Cost Benefit Analysis of Catheterisation in 2 Irish Hospitals
- Editors choice from Journal of Urology

2017

- Won Best Paper in Trauma, Reconstruction and Diversion at AUA
- 'First in Man' study of 100 patients using the TUC Safety Valve during catheterisation

2018

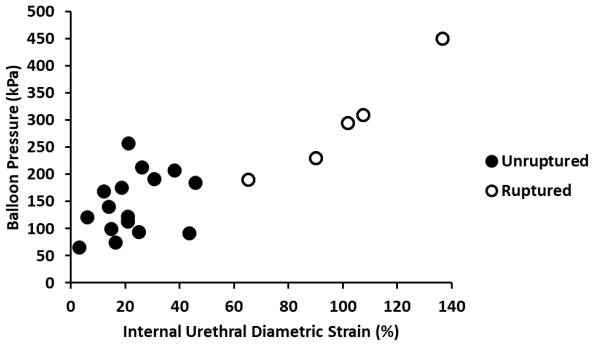
- Seed Round Funding of €550,000 Completed.
- CE and FDA approval processes initiated.
- Finalist in the Intertrade Ireland Seedcorn Competition

2019

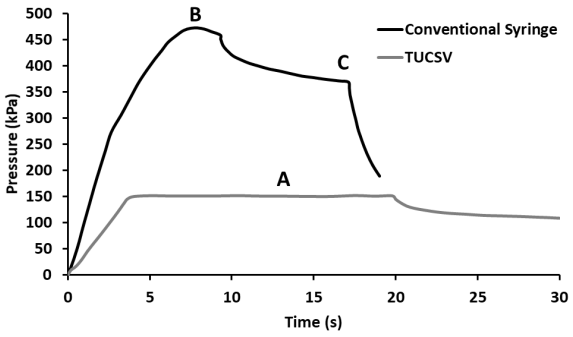
- Product Ready for Commercial Sale
- Large Clinical Trial

Publications

2015 – Evaluated the safety device (TUC Safety Valve) concept in porcine urethras and in cadavers highlighting that porcine urethral rupture did not occur below 150kPa and that the safety device did not permit pressures in excess of 150kPa in cadavers which would eliminate damage to the urethra if the catheter balloon is misplaced.



Maximum catheter balloon pressure and internal urethral diametric strain recorded for each of 21 urethral samples tested. Figure clearly demonstrates safety cut off of 40% internal urethral diametric strain and/or maximum balloon pressure cut-off of 150kPa before urethral rupture. Open circles indicate ruptured urethral samples. Filled circles indicate unruptured samples.



Pressure profile of catheter inflated in cadaveric urethra using a syringe pump at an infusion rate of 30ml per minute. Testing was performed with standard (black curve) and prototype (gray curve) syringes. Prototype curve clearly shows safety of novel prototype safety device (TUCSV) as maximum inflation pressure was limited to safe plateau pressure of 150kPa up to 20 seconds (s), when inflation process was completed (A). In contrast, the standard syringe achieved inflation pressure of 450kPa (B). Inflation pressure decreased at approximately 8 seconds, indicating that urethral threshold pressure was breached. Pressure continued to decrease until inflation was discontinued at approximately 16 seconds (C).

PAPER

NF Davis, RO'C Mooney, CV Cunnane, EM Cunnane, JA Thornhill, MT Walsh. Preventing Urethral Trauma from Inadvertent Inflation of Catheter Balloon in the Urethra during Catheterisation: Evaluation of a Novel Safety Syringe after Correlating Trauma with Urethral Disten- sion and Catheter Balloon Pressure. Journal of Urology. 2015, 194(4), 1138–1145. https://doi.org/10.1016/j.juro.2015.02.083

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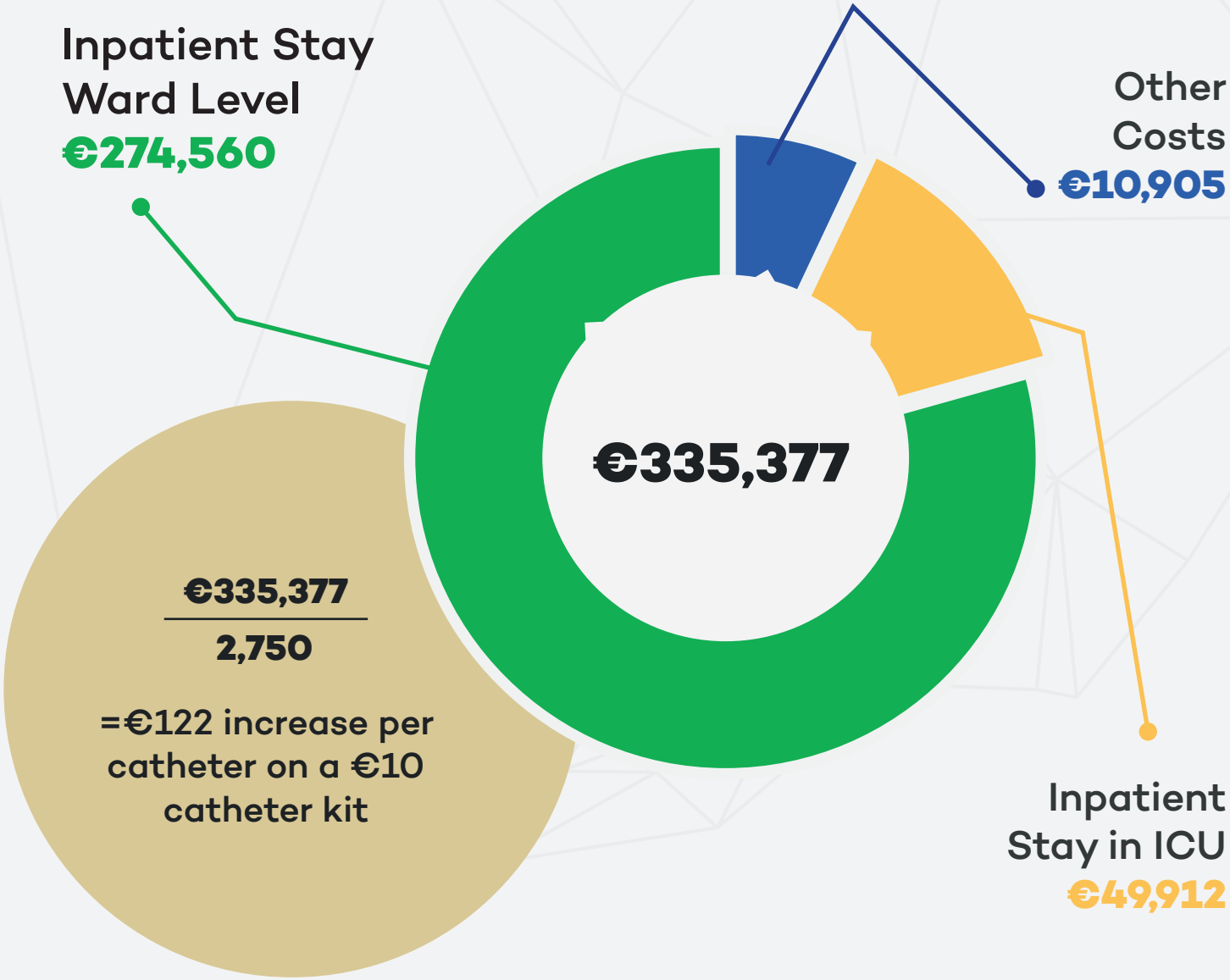
Publications

2016 – A prospective study in two hospitals over 6 months highlighted that 37 urethral injuries occurred across the two hospitals during the placement of 2,750 catheters and resulting in a healthcare cost of €335,377 exclusive of long-term complications, out-patient care and medicolegal costs. This results in a cost in excess of €122 per catheter placed in these hospitals to cover the costs of iatrogenic injuries caused during the procedures.



PAPER

N.F. Davis, M.R. Quinlan, N.R. Bhatt, et al. Incidence, cost, complications and clinical outcomes of iatrogenic urethral catheterisation injuries: a prospective multi-institutional study J Urol, 196 (2016), pp. 1473-1477

Publications

2017 – Published a paper highlighting how different hand strengths produce different pressure inflation profiles for the same urology catheter (see figure 1). The lightest hand force inflated the urology catheter without exceeding 75kPa whereas the heaviest hand force created pressures in the urology catheter approaching 350kPa. Consequently, user variability required consideration in the TUC Safety Valve design. To use the TUC Safety Valve with any catheter brand, manufacturing variability also requires consideration. The design approach for the TUC Safety Valve reduces the manufacturer variably across 3 brands of catheters at 3 different hand forces (see figure 2). This demonstrates that the TUC Safety Valve can be used with any type of catheter. The paper also demonstrates that by applying a flow resistance using a small orifice and setting the TUC Safety Valve valve activation pressure at 150kPa it can be seen that even heavy handed users cannot apply enough pressure to the syringe to activate the valve when pushing the flow through an orifice with a cross-sectional area of 0.05mm^2 (see figure 3). This eliminates user variability effects on the functioning of the device resulting in the TUC Safety Valve being usable for all health practitioners irrespective of their hand strength.

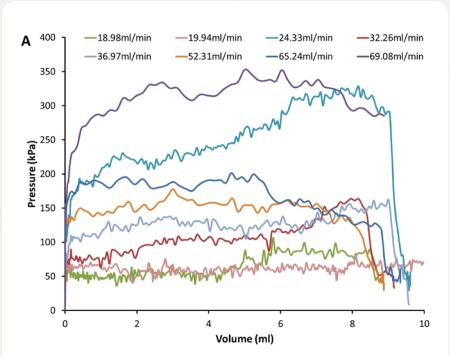


FIGURE 1.

User variability for the same urology catheter balloon inflation at atmospheric pressure mimicking the urinary bladder (n = 8)

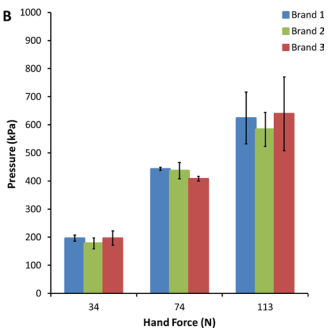


FIGURE 2.

Maximum inflation pressures for 3 brands of urinary catheter at 3 simulated hand forces. There is no significant difference in maximum inflation pressure between brands at any of the 3 simulated hand forces (P = .97)

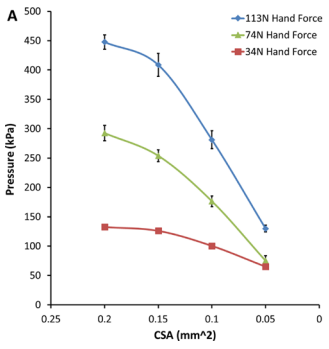


FIGURE 3.

Pressure and inflation time vs flow resistance for the (34 N), (74N), and (113N) simulated hand forces. (A) Flow restrictors were placed on the syringe outflow with CSAs ranging from 0.2 to 0.05mm^2 and constant forces were applied. Reducing the cross-sectional area (CSA) from 0.2 to 0.05mm^2 causes a significant decrease in maximum inflation pressure at each hand force (P < .001)

PAPER

NF Davis, EM Cunnane, ROC Mooney, RP Manecksha, JA Thornhill, MT Walsh. Quantification of User and Manufacturer Variabilities in Urinary Catheter Anchoring Balloon Inflation and Mitigation of Variability by Flow Resistance. 2017. Urology. Volume 102, 258-263. https://doi.org/10.1016/j.urology.2016.11.037

Publications

2017 – 'FIRST IN MAN' STUDY.

Class medical successfully completed this trial in Beaumont Hospital, Dublin, Ireland.

01 Do you feel confident inserting a transurethral catheter independently?

YES 97% | NO 3%

02 Have you ever inflated the catheter's anchoring balloon in the urethra instead of the bladder in a male patient

YES 10% | NO 90%

03 Would a safety mechanism that prevents urethral trauma from trans-urethral catheterisation interest you?

YES 87% | NO 13%

04 Do you think a safety mechanism that prevents urethral trauma during catheterisation should be compulsory?

YES 100% | NO 0%

05 Would you use this safety device again during urethral catheterisation?

YES 100% | NO 0%

PAPER

NF Davis, EM Cunnane, RO'C Mooney, JC Forde, MT Walsh. Clinical Evaluation of a Safety device to Prevent Urinary Catheter Inflation Related Injuries. Urology. Volume 115, May 2018, Pages 179-183 https://doi.org/10.1016/j.urology.2018.02.026

Publications

‘FIRST IN MAN’ STUDY.

N=100 catheterisations with TUC Safety valve, N=7 number of safety valve activations.

AGE 68

Known history of BPH

Patient required UC for PVR >400 ml
Intern documented difficulty passing catheter

AGE 69

No past urologic history

Patient required UC for urinary output monitoring post colorectal surgery. No difficulty documented with catheterisation

AGE 72

Known history of BPH

Patient required UC for PVR >400 ml
Intern documented difficulty passing catheter

AGE 74

Known history of BPH

Patient required UC for output monitoring post orthopedic surgery Intern documented difficulty passing catheter

AGE 75

No past urologic history

Patient required UC for urinary output monitoring post colorectal surgery. No difficulty documented with catheterisation

AGE 75

No past urologic history

Patient required UC for output monitoring post orthopedic surgery. No difficulty documented with catheterisation

AGE 78

No past urologic history

Patient required UC for PVR >400 ml post inguinal hernia surgery No difficulty documented with catheterisation

BPH, benign prostatic hyperplasia, PVR, postvoid residual; UC, urethral catheterisation. Three patients had a history of prostatic enlargement and 4 patients had no previous urologic history. In 3 cases the intern documented difficulty with the catheterisation. These 3 patients had a known history of BPH explaining the difficulties. In 4 cases the safety-valve activated in patients with no known urologic history indicating a lack of experience of the intern.

PAPER

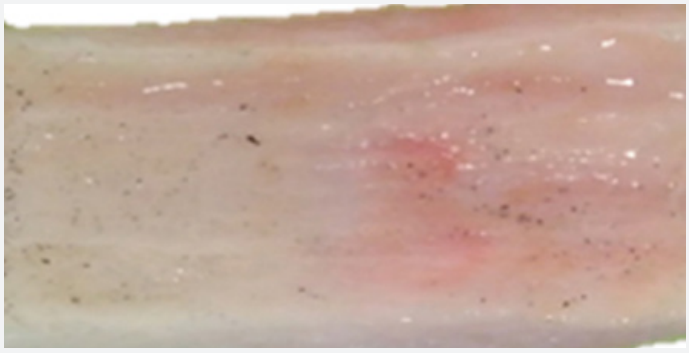
NF Davis, EM Cunnane, RO’C Mooney, JC Forde, MT Walsh. Clinical Evaluation of a Safety-device to Prevent Urinary Catheter Inflation Related Injuries. Urology. Volume 115, May 2018, Pages 179-183 https://doi.org/10.1016/j.urology.2018.02.026

Publications

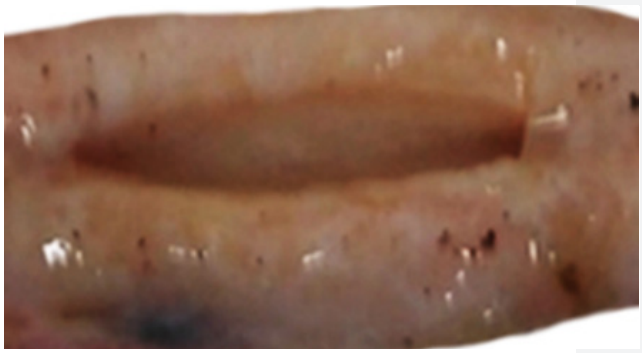
2018 – The behaviour of explanted human urethral tissue was evaluated during the inflation of the catheter balloon in the urethra. The paper highlighted human tissue behaviour following on from previous porcine tissue testing and human cadaver testing.

Following hospital ethical research committee approval, human urethras were obtained from 9 consenting patients undergoing male to female gender reassignment surgery at the University Hospital Essen, Essen, Germany. Representative images of urethra samples that experienced no damage (n=3), tearing (n=3) and rupture (n=3) following inflation of a urinary catheter anchoring balloon in the bulbar male urethra.

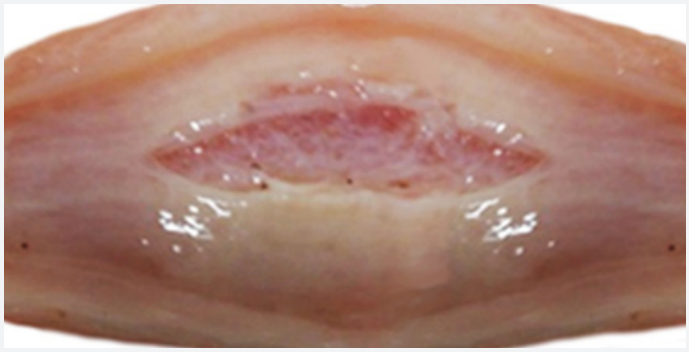
NO DAMAGE

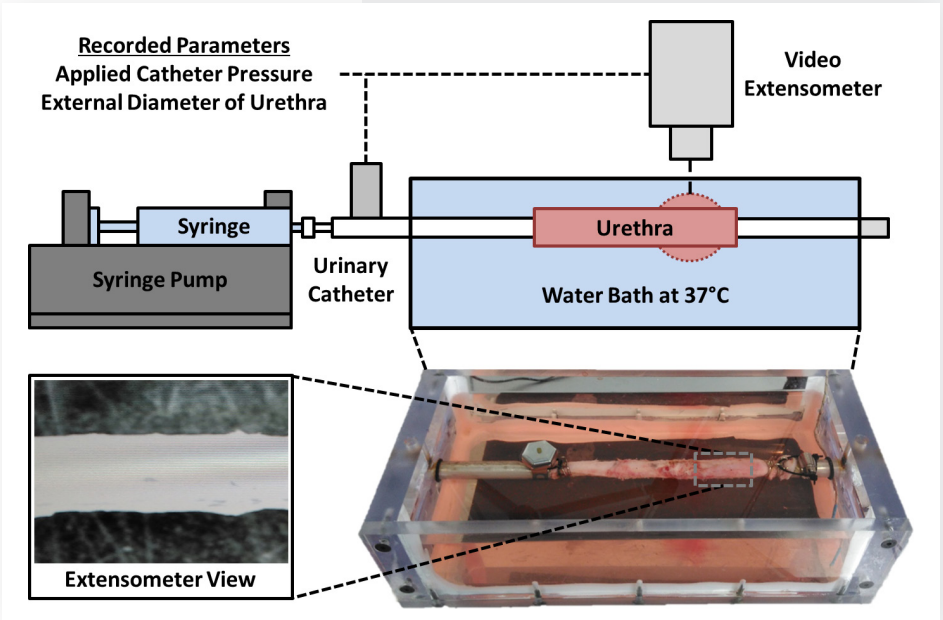


RUPTURE



TEARING





Testimonials

"I see this device as having a very important role, in both adult and paediatric practice, in limiting the risk of catheter balloon urethral injury and giving confidence to both doctors and nurses that the balloon is actually in the bladder prior to inflation."

DAVID A. BLOOM

MD, Dept. Chair, Urology and Jack Lapides Professor of Urology, University of Michigan Medical Centre, Ann Arbor, Michigan.

"This device has the potential to eliminate the near daily consults our service receives to deal with patients who have suffered urethral injury due to inadvertent catheter balloon inflation."

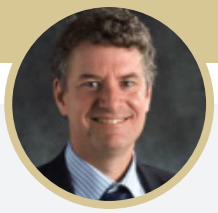
RONALD L. HREBINKO

MD, Urological Surgeon, UPMC, Pittsburgh, Pennsylvania.

"The TUC Safety Valve has undoubted clinical potential in inpatient and outpatient settings for decreasing morbidity associated with urethral catheterisation. I think it should become a compulsory component to the catheterisation process."

MR. GREG JACK

Consultant Urologist, The Austin Hospital, Melbourne, Australia.



"The beauty about this device is the simplicity in design and proven clinical benefit in preventing traumatic urethral injuries during catheterisation."

PROF DAMIEN BOLTON

Consultant Urologist and Head of Department, The Austin Hospital, Melbourne

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