
INNOVATIVE CATHETER DESIGN TO REDUCE CAUTI

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NON-CONFIDENTIAL





Disclosures

- Spinal Singularity – Founder
- Johnson & Johnson – PrimeUC
 - \$150k – Dec 2015
- NSF I-Corps – Team Customer Discovery Grant
 - \$3k - June 2015
- NIH Phase I SBIR - 1R43DK120262-01A1
 - \$225k - June 2017
- NIH Phase II SBIR - 2R44DK109865-02A1
 - \$1.5M - Jun 2020



Connected Catheter Animation Video

https://www.youtube.com/watch?v=C_nMogem9k0



Bottom Line Up Front (BLUF)

- We have continued to develop and refine a fully-internal, extended-use, wirelessly-controlled, urinary catheter for adult males with Chronic Urinary Retention (CUR).
- We are optimistic that this could reduce CAUTI for both Indwelling and Intermittent Catheter users and offer a new option for adult males who are chronic catheter users.

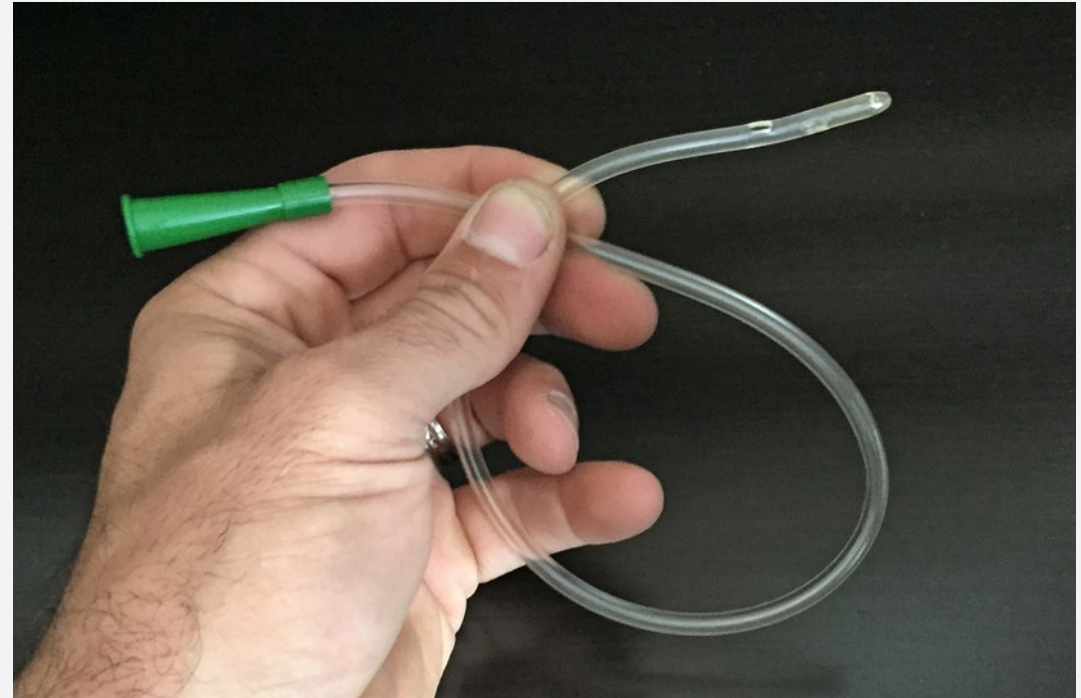
CHALLENGES WITH EXISTING METHODS OF BLADDER MANAGEMENT



Intermittent Catheters (IC)

Preferred method of care

- Does frequency of use increase likelihood of CAUTI?
- Does frequency of use increase likelihood of other complications?
- **Less Frequent Catheterization**



Foley Catheters

Alternative Option to IC

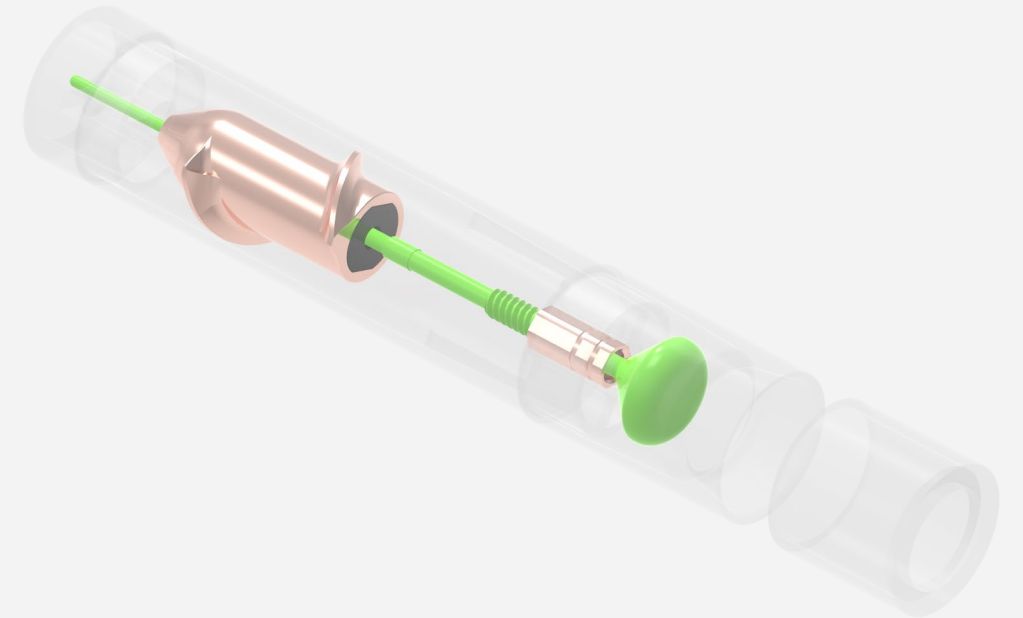
- Does Foley use increase likelihood of CAUTI?
- Does Foley use increase likelihood of other complications?
- **Fully Internal**



Incomplete Emptying

Active Valve-Pump

- Does incomplete emptying increase likelihood of CAUTI?
- Does incomplete emptying increase likelihood of complications?
- **Active bladder emptying**



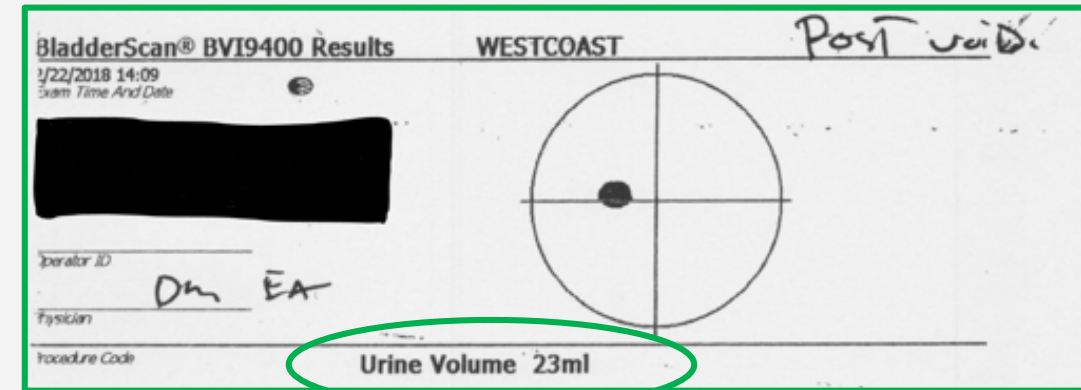
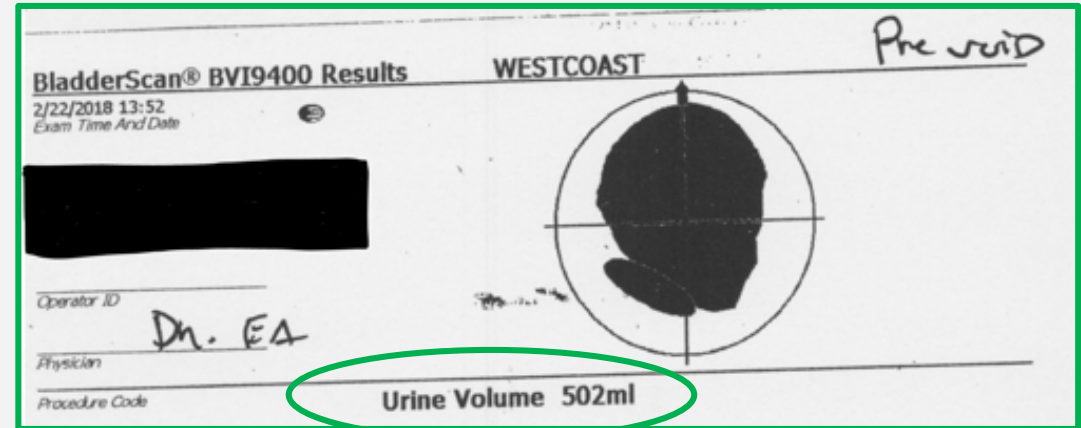
CLINICAL DATA



First in Man Study

2018

- 5 Patients
- 1 Day of use (In Clinic)
- Tested functionality of:
 - Insertion
 - Bladder Emptying
 - Removal





Feasibility Study

2018

- 21 Patients
- 1-90 days of use (Home Use)
- User Needs – Human Factors:
 - Patient Training/Support
 - Shorten duration of device use

CASE STUDY 1

- Male 34 yo
- T6 – Complete Paraplegia
- Intermittent Catheter User
- 90 days of device use
- 1 case of Asymptomatic Bacteriuria

CASE STUDY 2

- Male 82 yo
- TURP
- Failed artificial sphincter
- Foley Catheter User
- Immediate device migration

Evaluation Study

2019

- Up to 80 Users for 5 weeks of use
- Safety – Freedom from GU Injury
- Performance – Complete Bladder Emptying (PVR)
- Survey - QoL instruments

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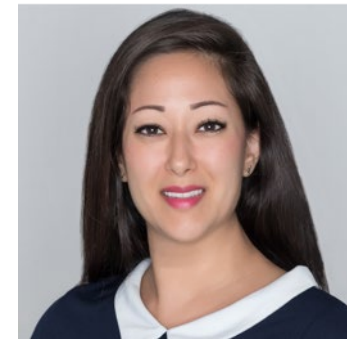
Team



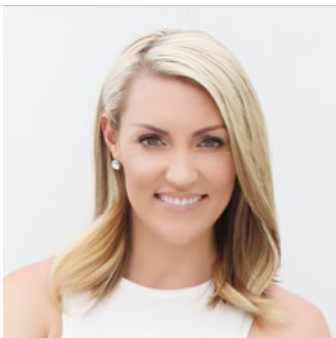
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LESS FREQUENT CATHETERIZATION

FULLY INTERNAL

ACTIVE BLADDER EMPTYING

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