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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LESS FREQUENT CATHETERIZATION

FULLY INTERNAL

ACTIVE BLADDER EMPTYING

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