Docket #: S19-197

Urethral-locating device to assist with female clean intermittent self-catheterization

Stanford researchers have prototyped a medical assistive device which improves efficiency of female self-catheterization by utilizing anatomical landmarks to aid accurate catheter placement in the urethra. Standard of care for patients with neurogenic bladder is clean intermittent self-catheterization where the patient inserts a single-use catheter in the urethra to void their bladder 4-6x a day. By making this process user friendly, this device can mitigate several key UTI risk factors, including bacterial contamination from missing the urethra and inadequate frequency of voiding. Importantly, the device is designed to be easily and reliably used by individuals at home without the need of physician or caregiver assistance.

Please see drawing of prototype below and video demonstrating the mechanism of action in "Related Web Links".

Figure:

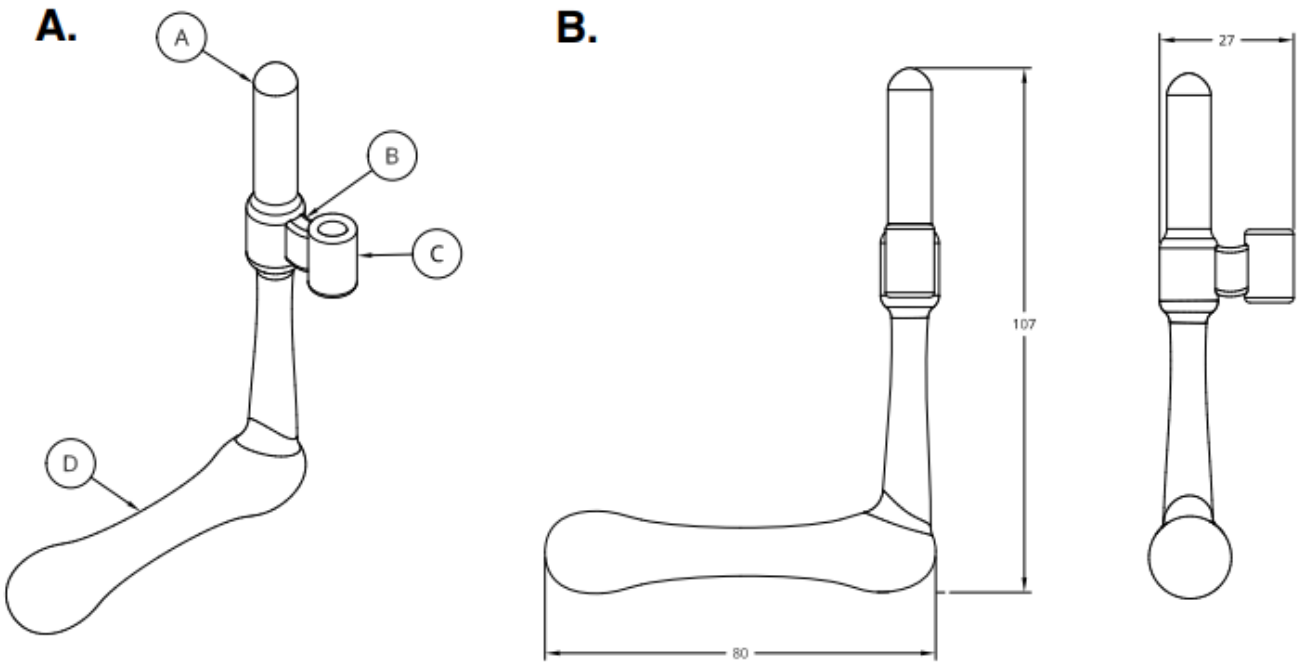


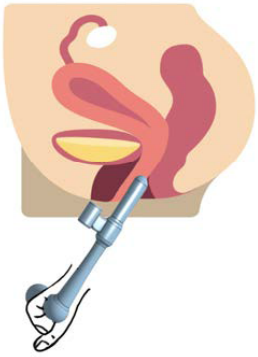
Figure Description: Device components and scale. A. Drawing of current prototype identifying the four components: vaginal insert (A), bridge (B), catheter guide (C), and handle (D). B. Current device prototype dimensions in mm are 80 x 107 x 27.

The Cath Path

For Clean & Easy Catheterization

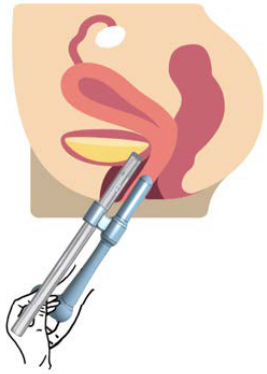
1 Insert Cath Path

Goes in like a tampon



2 Insert Catheter

Easily locate your urethra



3 Empty Bladder

*4-6 times per day**



4 Remove Catheter & Clean Cath Path

Scan for video example of use

**Infrequent catheterization increases amount of stagnant urine in the bladder at any given time and places a patient at increased risk for developing a UTI. Catheterization between 4-6x/day is thus recommended for most individuals. (Newman & Wilson, Urologic Nursing, 2011)*

Stage of Development

- Prototypes tested using a novel, non-invasive self-catheterization model.
- IRB protocol has been accepted for review to conduct a 20-patient clinical trial in the near future.
- Device manufacturing for the clinical trial is underway in collaboration with the 3DQ Lab at the Stanford School of Medicine; an autoclavable, biocompatible surgical guide resin was selected for the material.

Applications

- Self-catheterization for females with neurogenic bladder

Advantages

- Improves efficiency of female self-catheterization
- Helps locate and visualize urethra for catheter insertion
- Easier process
- Decreases infection episodes
- More user-friendly than current competitor devices
- Multiple design variations

Patents

- Published Application: 20210052852
- Published Application: WO2021041349
- Issued: 11,992,630 (USA)

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