Innovative Catheter Design to enable Safe Urinary Management of Warfighters with Neurogenic Bladder

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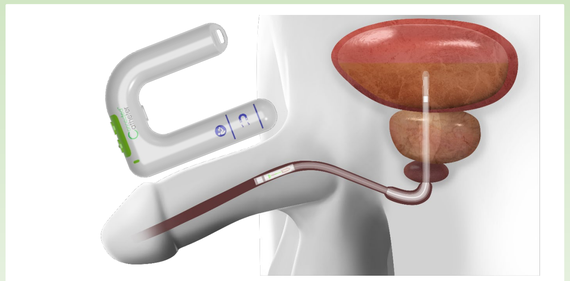
INTRODUCTION

The loss of bladder sensation and/or control – known collectively as Neurogenic Bladder (NB) – is a major challenge many of our warfighters face after traumatic injuries. The current standard of care for NB is to empty the bladder using some form of urinary catheter. All current forms of catheterization are burdensome and have a high risk of urinary tract infections (UTIs), which often leads to re-hospitalization.



THE SOLUTION

The Connected Catheter is the first fully internal, extended-use catheter that:

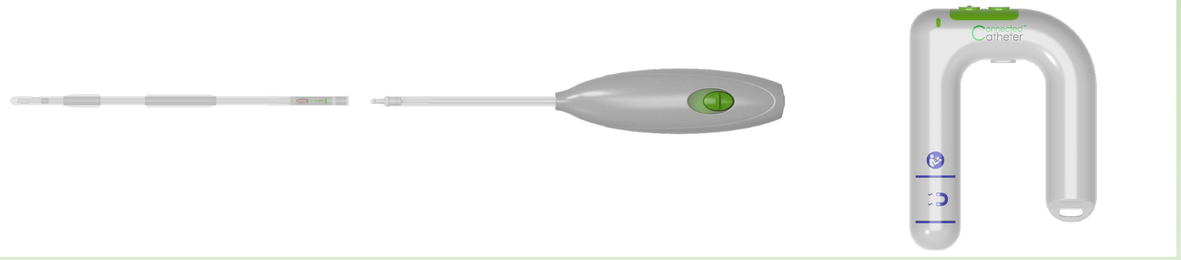
- Is fully internal to the male anatomy
- Aims to reduce the risk of complications
- Lasts for one week and replaces roughly 50 disposable catheters
- Enables users to wirelessly control a valve that actively empties the bladder
- Can be inserted/removed by the user (or clinician) in minutes with a simple sterile tool

Our goal is to offer a new way to empty the bladder that leverages the strengths, while minimizing the drawbacks, of both Foley/Intermittent Catheters.

DESIGN

The Connected Catheter resides fully internal to the male lower urinary tract (LUT), with its distal end in the mid-penile urethra, for an extended service life of up to 7 days. The distal Catheter tip incorporates a magnetic valve-pump that enables the bladder to fill naturally and the user to control voiding using a hand-held wireless controller.

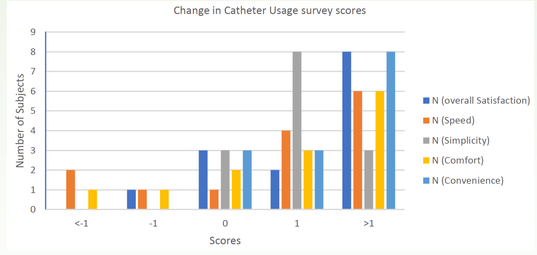
Catheter | **Insertion/Removal (IR) Tool** | **Wireless Controller**



CLINICAL RESULTS

During a clinical study under an IRB approved protocol, patients were permitted to use the Connected Catheter at home for extended periods. Patients who left the clinic with the device used the Connected Catheter for as many as 30 days (per device) as their only means of bladder management. In addition to recording any clinically significant events, these patients also completed QoL surveys to compare their current method of bladder management to that of the Connected Catheter.

Spinal Singularity designed a survey and asked participants to rate their satisfaction with five aspects of their current method of catheterization. Responses included a 1-5 scale with 1 being very dissatisfied and 5 being very satisfied. After enrolling in the study they were asked the same questions regarding their experience using the Connected Catheter.



71.4% (10/14) found using the Connected Catheter to be more satisfying (Overall Satisfaction)
64.3% (9/14) found using the Connected Catheter to be quicker (Speed)
78.6% (11/14) found using the Connected Catheter to be simpler (Simplicity)
71.4% (10/14) found using the Connected Catheter to be more comfortable (Comfort)
78.6% (11/14) found using the Connected Catheter to be more convenient (Convenience)

STUDY CENTERS

The Connected Catheter is currently recruiting and screening patients to be evaluated in a multi-site clinical study that aims to enroll up to 80 adult males with NB. Each patient will receive up to 5 Connected Catheters, in consecutive weeks, for up to 35 days of device use to evaluate the clinical performance of the device.

REGULATORY APPROVAL

The data from this study will be used to support the subsequent regulatory submission of the Connected Catheter System for market clearance in the US, thus making a potentially superior bladder management technology available to thousands of warfighters and veterans who rely on long-term urinary catheterization.

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