

# SaniCath: Improving the Female Self-Catheterization Experience

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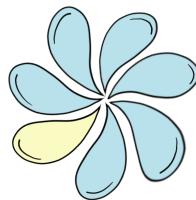
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## Table of Contents

<b>Executive Summary.....</b>	<b>7</b>
<b>I. User Needs.....</b>	<b>8</b>
Problem Definition and Needs.....	8
Disease State Background	8
Diagnosis	10
Treatment	11
Root Cause Analysis	11
Task Analysis	13
Clean Intermittent Catheterization	13
Needs Statement	15
Market Analysis.....	15
Market Overview	15
Total Addressable Market	15
Service Accessible Market	15
Service Obtainable Market	15
Existing Products and Solutions	17
Clean Intermittent Catheters	17
Indwelling Catheters	17
Anticholinergic Drugs	18
Sacral Nerve Stimulation	18
Botulinum Toxin	19
Bladder Augmentation	20
<i>Product Comparison Chart</i>	21
<b>II. Design Inputs .....</b>	<b>23</b>
Main Design Categories.....	23
User Needs	23
Safety	23
Durability	23
Biocompatibility	23
Sterility	23
Function	23
Usability	23
Cost	24
Understanding Key Stakeholders	24
Patient	24
Caregivers	24
Regulatory Bodies/FDA	24
Critical Design Requirements.....	24
Prioritization	28
Requirements and Specifications	28
Solution does not damage tissues	28
Solution does not fracture at any time during internal use	29
Solution will not break under normal application forces	29
Solution should not experience displacement during use	30
Solution can be sterilized with common methods	31
Sterile packaging that maintains an appropriate...	31
Must adequately lower PVR volume	31

Solution is removable	32
Material chemical composition of the solution is not toxic	32
Leachables are present in safe concentrations	33
Material chemical composition does not cause skin or inner mucosal irritation	33
Solution does not cause a long-term inflammatory response	34
Non-Critical Design Requirements .....	34
Prioritization	36
Solution must allow for self application	36
Solution must be portable	36
Solution can be used in a reasonable timeframe	37
Lifetime cost for patients must be less than current standards	37
Typical urine flow must be maintained	37
<b>III. Design Process.....</b>	<b>38</b>
Ideation.....	38
Morphological Chart	38
The external guide was designed...	46
The internal gated voiding prosthesis...	46
The portable suction catheter was designed...	46
Stakeholder Feedback	46
Stakeholders stressed the importance of flexible design	46
Stakeholders emphasized the importance of decreasing the UTI risk in women	46
Dr. Ashton Miller highlighted the benefits of a labia spreader concept	47
The interview with Stacey highlighted patient preferences in a solution	47
Patent Searches	47
Catheter placement assist device	47
Devices for assisting self-catheterization and methods for using such devices	48
Urine collection device	49
Female voiding prosthesis	50
Design Concepts.....	50
External Guide for Catheter Insertion	50
Insertion Guide	50
Catheter Strain Sensor	51
Labia Spreader	51
Visualization Mirror	52
Internal Gated Voiding Prosthesis	52
Device Insertion and Removal	54
Location of Device	54
Gate Mechanism	54
Bluetooth Control for Users	54
Portable Suction External Catheter	55
Suction Unit	56
Wearable Belts	56
Urine Collection Container	56
Absorbent/Suction Interface	56
Similar Existing Solution	57
Design Evaluation and Consensus.....	58
Pugh Matrix	58
Scoring Scale	58
Weight Scale .....	58
Solution does not damage tissues	60

Solution does not fracture at any time during internal use	60
Solution will not break under normal application forces	60
Insertion force analysis of insertion guide through mockup studies	60
Solution should not experience displacement during use	61
Solution can be sterilized with common methods	61
Sterile packaging that maintains an appropriate sterile shelf life is used for our solution	62
Must adequately lower post-void residual	62
Solution is removable	62
Solution does not cause long-term inflammatory response	62
Solution must allow for self-application	63
Self application analysis of insertion guide through mockup studies	63
Solution must be portable	64
Solution can be used in a reasonable timeframe	64
Lifetime cost for patients must be less than current standards	65
Typical urine flow must be maintained	66
Final concept scores	67
Lead Concept Discussion	67
<b>IV. Design Outputs.....</b>	<b>67</b>
Device Design.....	67
Device Purpose	67
Device Overview	67
User Operation.....	70
Steps of User Operation	70
Alterations in original flow of tasks caused by our design implementation.	73
Detailed Design Choices.....	75
Dimensions	75
Labia spreader.	75
Catheter guide tube	77
Support Walls	79
Optimization Model	80
Grip	84
Mirror Design	86
Grip Design	88
Material Selection	89
Principles of Operation.....	90
Failure-Mode Estimate Analysis.....	90
Severity Scoring	90
Frequency Scoring	90
Failure Modes	91
Puncture of the urethra	91
Dislodging of the catheter	92
Incorporation of EDR1 Feedback.....	92
Power, Privilege, & Identity in Design.....	93
<b>V. Verification &amp; Validation .....</b>	<b>93</b>
Actual Testing.....	93
Pressure Analysis	94
Purpose	94
Experimental Setup	94
Results	101

Compression Test	102
Purpose	102
Experimental Setup	102
Results	105
Testing Plans.....	106
Urine Flow Analysis: Verification	107
Purpose	107
Experimental Setup	107
Statistical Analysis	109
Results	110
Catheter Size Test: Verification	111
Purpose	111
Experimental Setup	112
Statistical Analysis	117
Results	117
Test Limitations	118
Sanitation Test Plan: Verification	118
Purpose	118
Experimental Setup	119
Results	121
Test Limitations	121
UTI Research Study: Validation	122
Purpose	122
Timeline Overview	122
Sample Size	122
Recruitment	122
Group Allocation	123
Procedure	124
Statistical Analysis	126
Results	127
Correct Device Placement Data Collection: Validation	128
Purpose	128
Experimental Setup	129
Statistical Analysis	130
Results	130
Catheterization Time Data Collection: Validation	131
Purpose	131
Experimental Setup	132
Statistical Analysis	133
Results	134
Design Recommendations after Testing	135
<b>IV. Design Recommendations &amp; Conclusion.....</b>	<b>135</b>
Final Design Recommendations and Future Directions.....	135
External Design Review Feedback	135
Support Wall Reinforcement	135
Grip Design	136
User Operation Feedback	136
Additional Design Modifications	136
Design Considerations After 3D Printing	136
Future Directions	138

Advice to a New BME 450 Team	138
Social Impact and Professional Responsibilities.....	138
Conclusions.....	140
<b>References.....</b>	<b>141</b>
<b>Appendices.....</b>	<b>156</b>
Appendix A: Evaluation Criteria for Skin and Mucosal Irritation Design Requirement.....	156
Appendix B: Evaluation Criteria for Long-Term Inflammation Design Requirement.....	157

## **Executive Summary**

For Spinal-Cord Injury (SCI) patients, neurogenic bladder is a prevalent condition with many associated risks. Current treatments for bladder management in these patients, most notably females, introduce additional complications such as infection. The current gold-standard treatment for incontinence management, clean intermittent catheterization (CIC), in female SCI patients is inadequate due to urinary tract infection (UTI) risk and inaccessibility during use. Additionally, CIC users have been shown to experience higher rates of UTI compared to the general population and can be inaccessible to use for those with physical disabilities that prevent them from being able to self-catheterize [1]. For females specifically, this UTI risk is elevated due to difficulties in visualizations of female urethral anatomy during insertion and difficulty in preventing contact between CIC and external surfaces prior to insertion [2]. Seeing as 80% of SCI patients experience some degree of bladder management issues, and CIC introduces infection risks for female SCI patients that use it for treatment, we have determined that there is a need to improve incontinence management resulting from SCI in female patients who use clean intermittent catheterization to decrease the risk of urinary tract infections.

Our team aims to generate a design that directly addresses this need. As such, we incorporated specific design requirements aimed at reducing the risk of urinary tract infections while ensuring that the solution meets key criteria such as functionality, safety, and biocompatibility [3]. Additional requirements for cost and usability were incorporated to generate an accessible solution. Approximately 63% of SCI patients use CIC for neurogenic bladder management, focusing our design on addressing safety and functionality gaps while meeting unmet patient needs [4].

These requirements guided a design process utilizing a morphological chart and Pugh matrix analysis. Three final concepts emerged: an external insertion guide, an internal gated voiding prosthesis, and a portable suction external catheter, all aimed at improving CIC to treat incontinence in female Spinal-Cord Injury patients. These concepts were designed to empower patients by prioritizing their perspectives and minimizing our biases. After careful evaluation of this process, an External Guide concept was chosen as the final concept due to its innovation, user benefits, and practicality. This concept served as the foundation for our final device, the SaniCath.

The SaniCath comprises various components, including a hand grip and a labia spreader for insertion between the labia minora. This device incorporates a mirror for easy urethral visualization during self-application. To ensure it meets all design requirements and is user-friendly, the SaniCath will undergo comprehensive verification and validation testing. Our testing plan encompasses verification tests such as pressure analysis and compression benchtop tests, along with additional assessments with more time and resources. These include a urine flow benchtop analysis, a research study studying UTI risk and device placement, a sanitation test to validate at-home cleaning efficacy, and a catheter sizing test to confirm the SaniCath accommodates various catheter sizes.

This report outlines the progression of the SaniCath through the design process, from researching user needs and background issues to refining our solution space, exploring design concepts, finalizing the device concept, and outlining verification and validation testing procedures. The emphasis is on ensuring the device effectively addresses user needs and design requirements.

## I. User Needs

This section delves into the fundamentals of the disease state, analyzing gaps in the current treatment landscape for female SCI patients experiencing incontinence. Additionally, it encompasses a market analysis and provides background information on existing products.

### Problem Definition and Needs

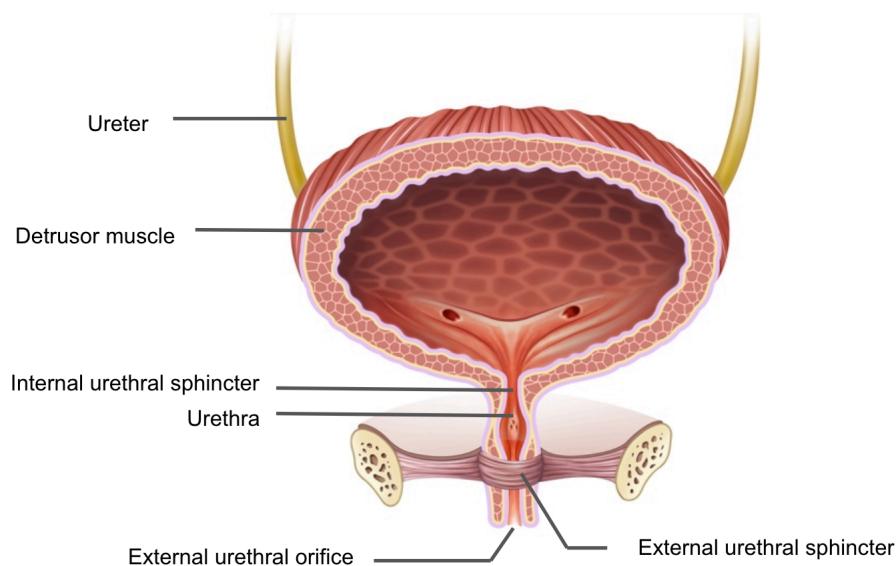
Below, we will discuss the disease state fundamentals relevant to our project and analyze gaps in current treatment methods for our target population.

#### Disease State Background

Spinal cord Injury (SCI) is a condition in which spinal cord axons of nerves are disrupted due to major trauma, and impacts over 20.6 million people globally [5]. Injuries are commonly caused by direct trauma to the spinal cord, compression from fractured vertebrae, or compression due to the growth of masses near the spinal cord [2]. SCI leads to a loss of motor and sensory function below the area of injury.

Bladder function is also regulated by the nerves in the spinal cord; therefore, SCI can lead to incontinence ranging in severity. Urinary incontinence, or the loss of bladder control and the resulting leakage of urine, is a condition affecting over 25 million people in the United States and 200 million people globally [6], [7]. This condition can range from infrequent, minor leakage to a complete lack of bladder control and significantly impacts quality of life. Incontinence resulting from SCI is a type of neurogenic bladder, which is a lack of bladder control resulting from issues in the brain, nerves, or spinal cord [8]. In fact, 80% of SCI patients experience bladder management issues [3].

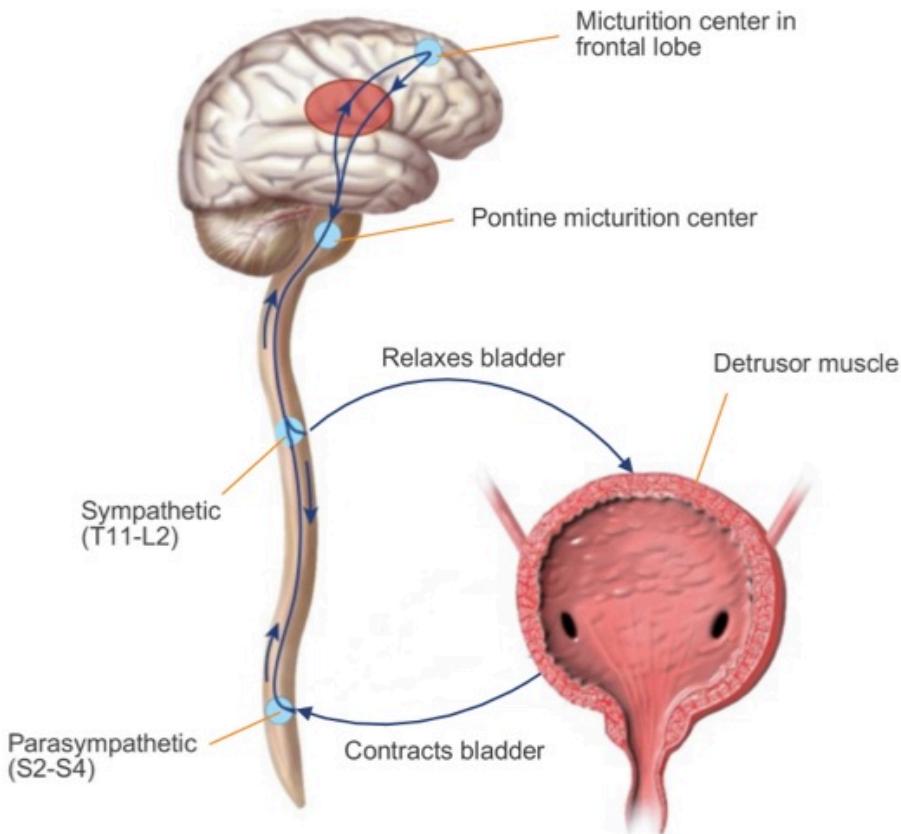
Urinary incontinence as a condition in general falls under the excretory system, which removes waste products via the kidneys, ureters, bladder, and urethra [9], [10]. Normal continence relies on intact detrusor muscle and internal and external urethral sphincter function. The detrusor muscle, made of smooth muscle, is the main component of the bladder wall, and either relaxes to hold urine or contracts to expel it. The internal urethral sphincter is a loop at the inferior end of the bladder and is a continuation of this muscle [11]. Relaxation of this sphincter allows urine to leave the bladder [12]. Both the detrusor muscle and internal sphincter are under involuntary control [13]. The external urethral sphincter is distal to the internal sphincter, consists of striated muscle, and is under voluntary control. Figure 1 shows the anatomy described above.



**Figure 1.** Continence is dependent on the coordination of muscle control among the urethra, sphincter, and detrusor to allow for urine to leave the bladder [14].

Coordination of proper voiding is handled by a neuronal circuit connecting the brain, spinal cord, bladder, and urethra. The Pontine micturition center (PMC) is located in the brain and provides parasympathetic stimulation through the S2-S4 nerves innervating the bladder from the sacral vertebrae to contract the detrusor muscle and relax the urinary sphincter during voiding; these nerves also send signals from the detrusor muscle to the PMC that the bladder is filling [15], [16]. Additionally, the PMC provides sympathetic stimulation through the T11-L2 nerves innervating the bladder to inhibit detrusor contraction and contract the urinary sphincter while the bladder fills to prevent voiding, as shown in Figure 2. Further, the guarding reflex is activated during this storage phase, which involves a higher pressure being exerted in the urethra than in the bladder [15], and the frontal cortex inhibits the PMC for storage until an appropriate time for voiding. When this time occurs, the frontal cortex stops inhibiting the PMC, which consequently does the same for the voiding and guarding reflexes.

SCIs that affect either of these spinal regions of the spine lead to loss of bladder control, leading to urinary incontinence. Injury to the T11-L2 vertebrae can lead to incontinence resulting from an inability to properly store urine, whereas injuries to the S2-S4 vertebrae can cause incontinence resulting from an underactive bladder, or an inability to void properly when the bladder fills [3]. In SCI above the sacral vertebrae, symptoms are often a hyperactive detrusor muscle and external sphincter, leading to bladder outlet obstruction and high pressures in the bladder, leading to issues in the upper urinary tract. In SCI to or below the sacral vertebrae, the detrusor muscle is acontractile and the external sphincter does not contract as it should. Both can result in incontinence. A mixed SCI with a mixture of symptoms is also possible [15].



**Figure 2.** The T11-L2 nerves stimulate urine storage by relaxing the bladder, while the S2-S4 nerves provide stimulation for voiding by contracting it [3].

Many risks are associated with neurogenic bladder, most affecting the urinary tract. This is because many neurogenic bladder patients experience a high Post-Void Residual (PVR) volume, referring to the amount of urine remaining in the bladder, due to inadequate bladder emptying while voiding. This urine that remains post-void contains uropathogenic bacteria, which can internalize into apical urothelial cells along the lower and upper urinary tract. When PVR volume is elevated, more of this urine remains in storage which allows for more bacteria to adhere to these urinary tract cells and elicit an immune response, leading to infection [17]. As such, UTI risk in neurogenic bladder patients is high, with these patients averaging about 2.5 UTI episodes per year [17]. Long-term UTI incidence can also be a risk factor for chronic conditions, such as bladder cancer, which affects SCI patients at a rate 20 times higher than the general population [3].

#### *Diagnosis*

Patients with suspected neurogenic bladder undergo an evaluation process consisting of several steps. Due to the knowledge that patients are at high risk for urinary tract issues, SCI patients are monitored early, even without symptoms. The testing includes a physical examination, urine analysis, voiding diary, test of their bladder emptying ability to evaluate PVR volume by ultrasonography or catheterization, and a scan of the upper urinary tract. The “overall health, mobility, cognitive ability, hand function, and social support network” are also assessed to inform treatment options [18]. It should be noted that physical examinations for women include pelvic examinations, which can often be associated with many negative emotions such as anxiety and fear. This examination standard has historically negated the needs and feelings of female patients receiving the exam and can be inaccessible for SCI patients due to a lack of lower body mobility [19]. Urodynamic tests, including cystometry, electromyography (EMG),

uroflowmetry, and pressure-flow studies are useful in addition to the clinical assessment to understand the patient's function [20].

#### *Treatment*

The gold standard treatment for the neurogenic bladder is clean-intermittent catheterization (CIC). This involves the insertion of a catheter into the urethra to drain urine regularly throughout the day. Other commonly used treatments include suprapubic catheters and indwelling catheters. Medications such as alpha-blockers, anticholinergics, and botulinum toxin are also commonly prescribed along with these catheterization methods.

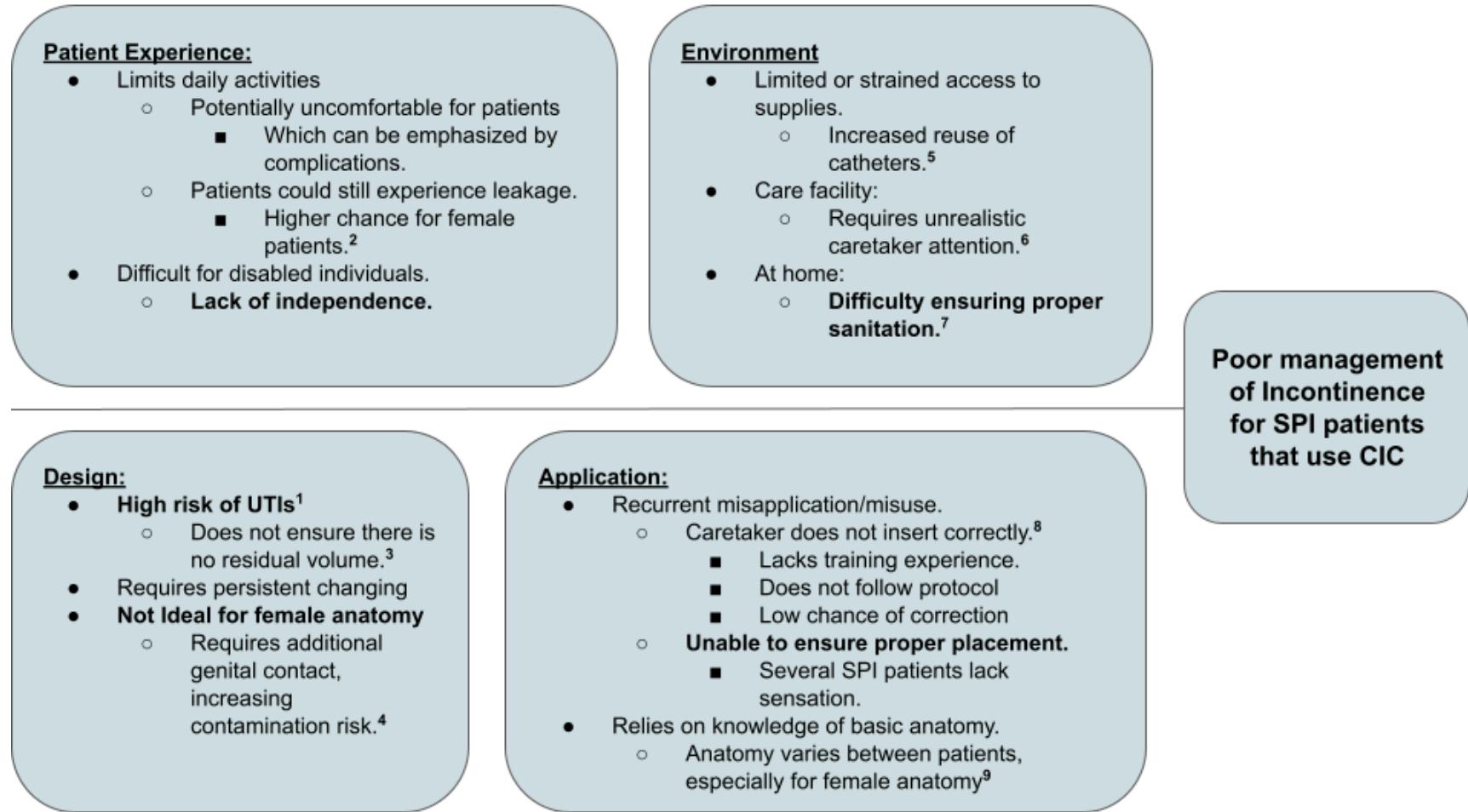
CIC is preferred by clinicians because it carries a lower risk of UTIs compared to other catheterization methods and has fewer long-term complications, such as infection, bladder stones, and urethral issues [21], [22], [23]. However, it still has limitations. The risk of UTIs is higher than in the general population, and it may not be accessible for individuals with limited manual dexterity or those who cannot self-catheterize. Additional risks include urethral strictures, hematuria, bladder overdistension, incontinence, urolithiasis, and autonomic dysreflexia [18].

Due to the differences in male and female anatomy, it is also more likely for women to sustain UTIs during CIC as visualization of the urethra and placement of the catheter without touching it to external surfaces is much more difficult [24]. Further, up to 70% of SCI patients initially advised to use CIC eventually transition to indwelling catheters despite the increased risks listed above. The most common reasons for this are inconvenience, urinary leakage, and number of urinary infections [25]. Given these significant gaps, we have focused on addressing UTI risk associated with female SCI patients who use CIC.

#### *Root Cause Analysis*

To gain a comprehensive understanding and succinctly summarize how CIC is a non-ideal form of treatment for SCI patients with incontinence, we have conducted a root cause analysis (RCA). RCA is a systematic approach to identifying the fundamental reasons behind a particular issue or problem. By conducting this analysis, we can pinpoint the primary flaws with CIC and develop more effective strategies to ensure lower risk and higher comfortability. Figure 3 shows the few main takeaways from the root cause analysis, as there are many factors to consider. The design, application, environment and patient's experience all contribute to the stress of using CIC. The main factors we thought were important to note are the inability to ensure sterilization or cleanliness of the catheter at home between uses, the high risk of UTIs, the difficulty of applying the CIC, especially for women, and the lack of confirmation for proper placement. Ensuring accurate placement is crucial to avoiding serious complications, such as creating a false passage [26].

It's important to note that our RCA was completed based on the average physique of female SCI patients. Our stakeholder interview with Dr. Ashton-Miller, Director of a Biomechanics Research Lab and a Professor for Mechanical Engineering, confirmed that additional patient health factors such as weight, labia length, previous injury, and genetic predispositions make use of CIC more difficult [24]. We recognize that our future solution may not cater to these specific deviations from the average physique, but we hope that the future versions of this device will. Furthermore, we did not consider outside patient-specific factors that could influence their experience using CIC. Factors such as education level or socioeconomic class, etc., could contribute to a less efficient management of incontinence using CIC. An example would be an individual who is more inclined to reuse a catheter past the recommended amount of use because they might not understand the associated risks or are trying to reduce replacement costs.



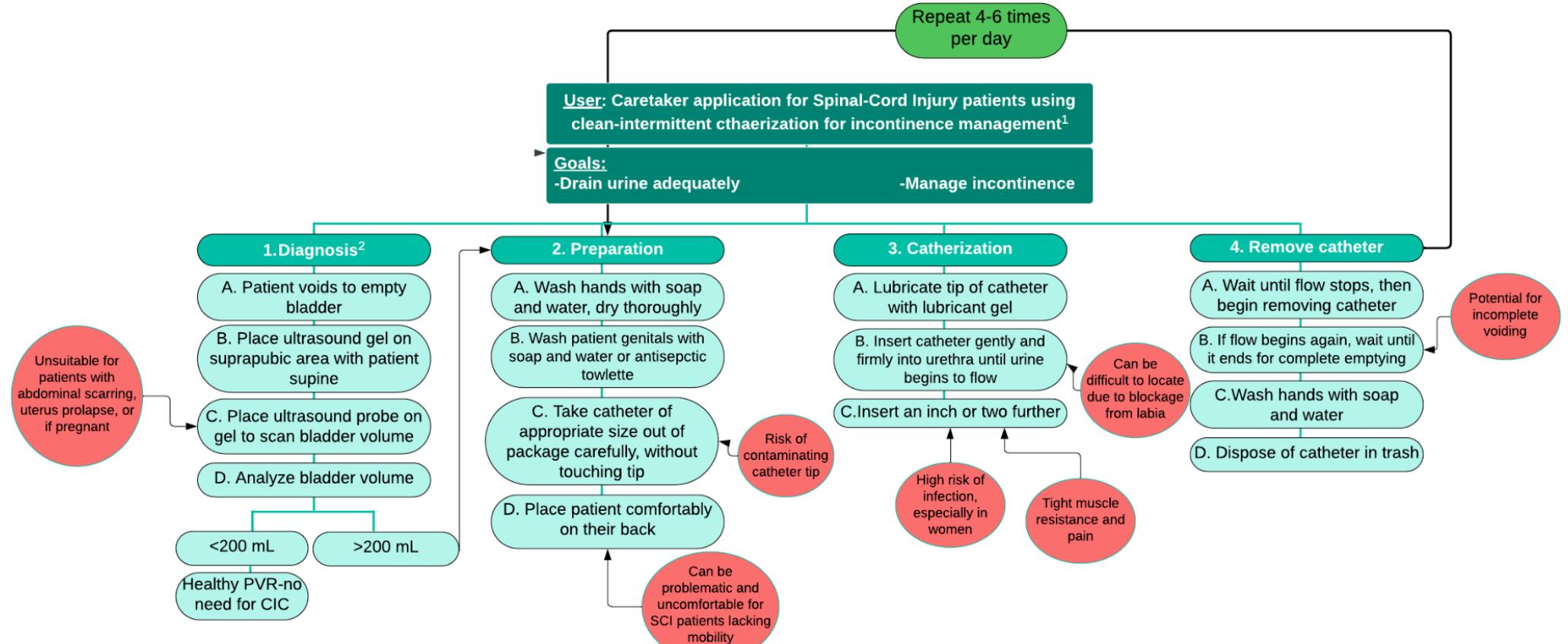
**Figure 3.** Factors from the environment, design, patient experience, and applications are the main contributors as to why CIC is not the ideal solution to incontinence for SPI patients. After conducting our RCA, the main causes we are looking to focus on are the high risks for UTIs, the patient's lack of independence, the difficulty of accurate placement, and at-home sanitation.

Sources for figure: <sup>1</sup> [17], <sup>2</sup> {[11], [12], [27]}, <sup>3</sup> [17], <sup>4</sup> [24], <sup>5</sup> [28], <sup>6</sup> [29], <sup>7</sup> [29], <sup>8</sup> [30], <sup>9</sup> [31],

### *Task Analysis*

The existing gaps in the most commonly utilized device for incontinence management in SCI patients, CIC, is presented in the task analysis below [25].

*Clean Intermittent Catheterization.* Clean intermittent catheterization (CIC) is the first-line treatment for SCI patients. This is the current market gold standard due to the relatively cheap cost, ease of use, and low complication rate relative to other solutions [25]. CIC is generally recommended after a bladder scan of an adult patient reveals a PVR volume of over 200 mL, which indicates inadequate emptying [32]. This process involves the insertion of a reusable or disposable catheter into the urethra 4-6 times a day to empty the bladder and is the standard of care for patients who “cannot effectively empty their bladders”, according to the European Association of Urology [33]. Figure 4 shows the steps involved in this process for caretaker application and some of the most prevalent challenge points encountered. Some of these include the stress and discomfort involved and the potential for introducing bacteria into the body or causing bleeding and labial erosion [34]. 81% of patients develop a UTI during CIC use [35]. As shown in Figure 4, the CIC process involves multiple inaccessible steps. For diagnosis, bladder scans can be unfeasible for many patients with health conditions separate from neurogenic bladder, such as abdominal scarring, uterus prolapse, or pregnancy [32]. For preparation, patients lacking mobility can be put in uncomfortable positions that do not address their positioning needs. Finally, insertion can be problematic for any individuals who lack clear visualizations of their labia. Many of these issues directly affect women and individuals with physical disabilities, and as we approach improving this procedure, we must keep in mind that this procedure may have been designed in a way to support able-bodied male individuals, and our solution should directly seek to empower those whose needs are currently not being addressed by this procedure, most notably women and those with physical disabilities.



**Figure 4.** The clean-intermittent catheterization process, while common, carries a high risk of infection, and discomfort, and is inaccessible for many women<sup>1</sup>[36], <sup>2</sup>[32].

### *Needs Statement*

There is a need to improve incontinence management resulting from SCI in female patients who use clean intermittent catheterization to decrease the risk of urinary tract infections.

### **Market Analysis**

To better understand the market space of our patient population, we have conducted a comprehensive market analysis that will be further explored below.

#### *Market Overview*

For our team's needs statement, we have scoped within patients with incontinence to find a specific population of patients, specifically those who have SCI and use CIC to manage their incontinence. This scoping down presents a natural segmentation of the market our solution will address. Our total addressable market (TAM) will be patients with incontinence globally, the service addressable market (SAM) will be patients with incontinence using CIC globally, and finally, the service obtainable market (SOM) will be patients with spinal cord injuries who have incontinence and use CIC globally.

The global incontinence market is rapidly growing due to an increase in the prevalence of urological disorders with an aging population and a rise in demand for minimally invasive solutions. Market growth is hampered by the lack of awareness in improvement with incontinence devices and post-operative difficulties linked with the devices [37]. Urinary incontinence is also more common in females than males [6].

*Total Addressable Market.* Because our incontinence solution for SCI patients using CIC could potentially be used by anyone diagnosed with incontinence, we take our TAM to be all individuals globally who have incontinence. There are around 200 million people globally who have incontinence. The global incontinence market in 2023 is currently valued at \$15.69 billion and will grow to \$21.1 billion in 2028 with a compound annual growth rate (CAGR) of 8.12% [6].

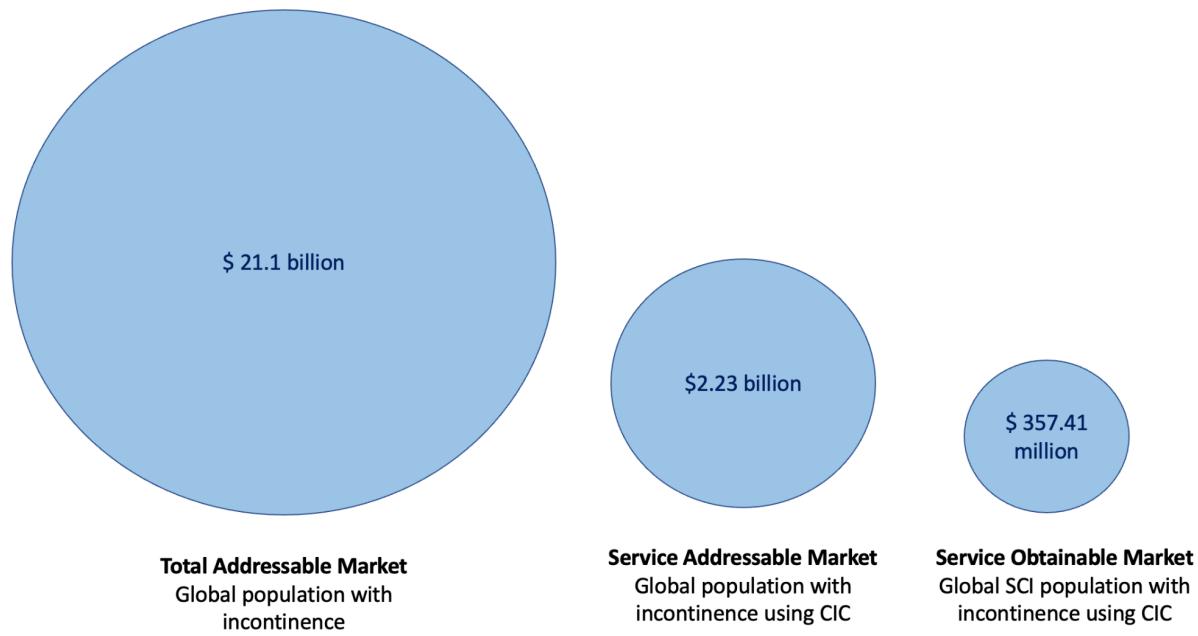
*Service Accessible Market.* Segmenting further into our market, we want to focus on patients who use CIC to manage their incontinence as our SAM. Theoretically, if our solution improves upon CIC for SCI injury patients, anyone using CIC could become part of our larger market. There is not enough data available on the number of patients with incontinence who use CIC globally. To estimate this, we can use the percent market share that CIC occupies within the incontinence market and multiply it to the number of people globally who have incontinence. This assumes that the same percentage of the population would use the products in that market share. We find that the urinary catheter market occupies a 28.76% share of the incontinence market, and CIC occupies 57.5% of the urinary catheter market [38]. Multiplying 200 million people globally with incontinence by 57.5% and 28.76% gets us approximately 33,074,000 million people who use CIC for incontinence. The global intermittent catheters market was valued at \$2031.87 million in 2020, and is projected to reach \$3038.41 million by 2030, with a CAGR of 4.1% from 2021 to 2030 [39]. The SAM for 2023 can be estimated using the CAGR formula (1), and we get \$2293.46 million.

$$CAGR = \left( \frac{\text{final value} (\$)}{\text{beginning value} (\$)} \right)^{1/\text{time in years}} - 1 \quad (1)[40]$$

*Service Obtainable Market.* Finally, our solution aims to focus on the population of patients who have SCI. Thus, we can segment our SOM to SCI patients with incontinence who use CIC. The prevalence of SCI patients globally is an estimated range of 236 to 1298 cases per million of population – these are heavily dependent on region [41]. For the purposes of this market analysis, we estimate the prevalence by taking an average of these numbers, giving us an estimated global prevalence of 767 cases per million of population. There are approximately 8 billion people in the world [42]. Applying the 767 cases per

million onto a population of 8 billion gives us an approximate 6,136,000 cases of SCI globally. Studies have shown that at around 84% of SCI patients have a neurogenic bladder, which leads to incontinence in these patients [43]. So, multiplying 84% by 6,136,000 SCI cases, gives us a total of 5,154,240 SCI patients who have incontinence. Going further, we know that about 63.4% of SCI patients with incontinence are prescribed CIC for management [44]. Multiplying 63.4% by 5,154,240 SCI patients with incontinence gives us approximately 3,267,788, which represents SCI patients with incontinence using CIC. To get the market valuation for SOM, we can use proportions between the SAM population (33,074,000) and valuation (\$2293.46 million) and the SOM population (5,154,240). Using proportional math, we get a SOM valuation of \$357.41 million.

For our final solution, we will be focusing on creating an incontinence solution for female SCI patients using CIC. Thus, we can take a sub-segment of the SOM that addresses the market for female patients. We find from literature that approximately 20% of SCI patients are female [45]. By multiplying the 6,136,000 global SCI cases by 20%, we get 1,227,200 which represents the number of female SCI patients globally. Applying the same analysis above, with 84% of SCI patients having incontinence, and 63.4% using CIC, we get a population of about 653,557 female SCI patients with incontinence using CIC. For the solution we will create for females, this will end up addressing a sub-section of the SOM. The associated market for this will be 20% of the SOM, which will be a valuation of \$71.48 million. A summarized view of the market space can be found below in Figure 5.

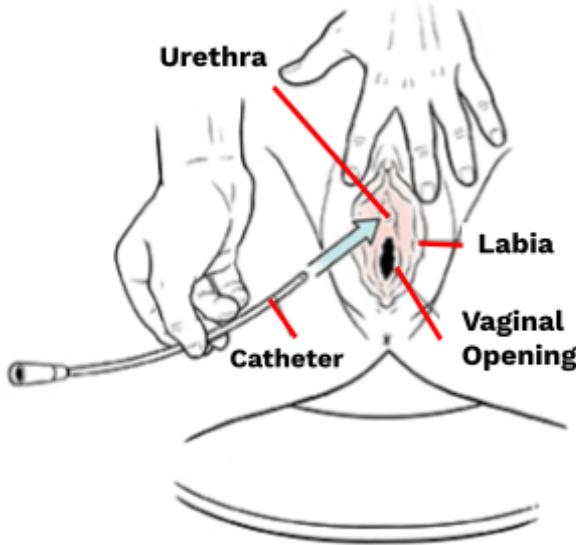


**Figure 5.** Our solution has the potential to be used by all SCI patients using CIC for incontinence management, with potential for growth into markets comprising all patients with incontinence globally.

### *Existing Devices and Solutions*

In this section, we will explore some of the most prevalent and less common devices and treatments for incontinence management in SCI patients, shedding light on their effectiveness and areas where improvement is needed. A comprehensive analysis of these solutions will help us better understand the existing landscape and identify opportunities for innovation.

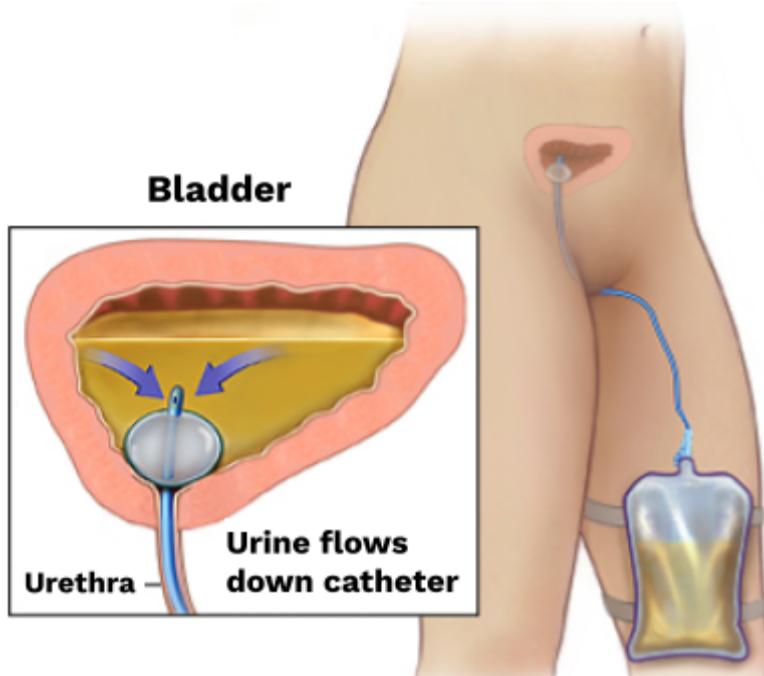
*Clean Intermittent Catheters.* As previously discussed, clean intermittent catheterization is the primary method for managing urinary incontinence in SCI patients. CIC involves periodically inserting a sterile catheter into the bladder to empty it when normal voiding function is compromised due to the SCI. The insertion of CICs for the female anatomy is seen in Figure 6 below.



**Figure 6.** Clean intermittent catheterization allows users to independently manage their incontinence by self-catheterization through the urethral opening. Most users perform this procedure four to six times a day [46].

While CIC is most commonly used, CIC usage still presents several challenges for these individuals, such as elevated urinary tract infection (UTI) rates due to frequent catheterization, limited accessibility concerns stemming from the effort required for correct insertion, and the necessity of substantial arm strength and dexterity, making them less user-friendly for those with reduced grip strength and arm mobility.

*Indwelling Catheters.* Indwelling catheters, also known as Foley catheters, are a specific form of catheterization that entails the prolonged placement of a catheter through the urethra, typically requiring monthly catheter changes. During this process, urine is continuously drained into a collection bag. The setup of this process can be seen in the Figure 7 below.

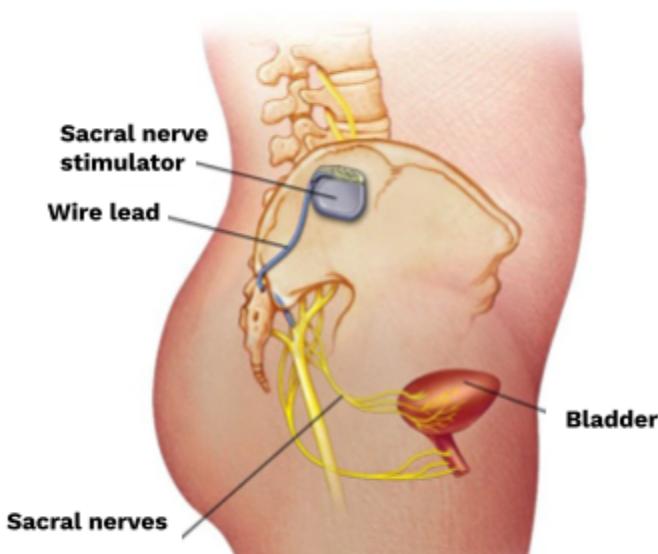


**Figure 7.** Indwelling catheters are a permanent catheterization method that collects urine in a bag attached to the individual. This device is especially helpful to individuals with limited mobility or dexterity to perform self catheterization [47].

Indwelling catheters are generally not the first choice for managing urinary issues in individuals with Spinal Cord Injuries (SCI), unless self-catheterization is impossible or impractical. This preference stems from the heightened risks associated with their use in SCI patients. One of the primary concerns when employing indwelling catheters in SCI patients is the increased susceptibility to urinary tract infections (UTIs). Additionally, prolonged catheterization can lead to complications such as renal impairment, the formation of bladder stones, urethral strictures (narrowing of the urethra), urethral erosion, and, in rare cases, an elevated risk of developing bladder cancer [3].

*Anticholinergic Drugs.* Cholinesterase inhibitors represent a class of medications designed to target benign muscarinic receptors, effectively initiating the downregulation of bladder activity. This pharmacological approach serves as the primary method for addressing detrusor overactivity, a common condition associated with urinary dysfunction in SCI patients. Among the cholinesterase inhibitors, Distigmine is the most frequently utilized, with BioSynth being a prominent manufacturer of this medication. A comprehensive study aimed at assessing the effects of Distigmine, conducted over a duration of 4 to 8 weeks, revealed a notable decrease in both the quality of life and post-void residual volume [15]. However, this promising intervention was not without its limitations. The study unveiled several drawbacks associated with distigmine use, including an increase in bowel movements, instances of fecal incontinence, and heightened urinary frequency. These side effects raised concerns about the practicality and tolerability of the treatment. Recent literature suggests that these approaches may have been applied to the wrong patient population, and they could be highly effective when used correctly [33].

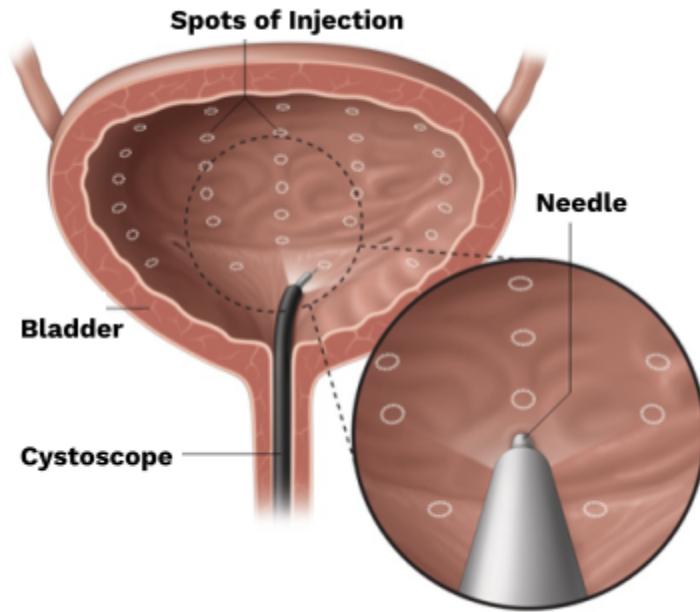
*Sacral Nerve Stimulation.* Sacral nerve stimulation, also known as sacral neuromodulation (SNM), represents a relatively recent advancement in the field of managing urinary dysfunction, specifically in SCI patients. Sacral nerve stimulation places the stimulator under the skin in the upper buttock area near the sacral nerves as seen in Figure 8. This stimulator uses constant electrical stimulation to prevent spasms and over contraction in the bladder [48].



**Figure 8.** Sacral nerve stimulation places the stimulator under the skin in the upper buttock area near the sacral nerves. This stimulator uses constant electrical stimulation to control spasms [48].

This innovative therapy has shown overall success, particularly in clinical trials involving individuals with overactive bladders. Despite its potential benefits, SNM is not yet widely adopted due to the invasive nature of the treatment. While small-scale studies have demonstrated the safety and effectiveness of SNM in patients with spinal cord injuries, its utilization remains limited [49]. This is partly due to the restricted scope and potential biases in the studies conducted thus far. Additionally, clinicians are actively researching the long-term success and durability of this therapeutic device. One previous study, in particular, noted a decline in efficacy and observed urinary retention in approximately 30% of patients during follow-up visits [50]. These findings underscore the need for further investigation and a more comprehensive understanding of SNM's outcomes and potential challenges in order to optimize its use in the management of urinary issues, particularly in SCI patients.

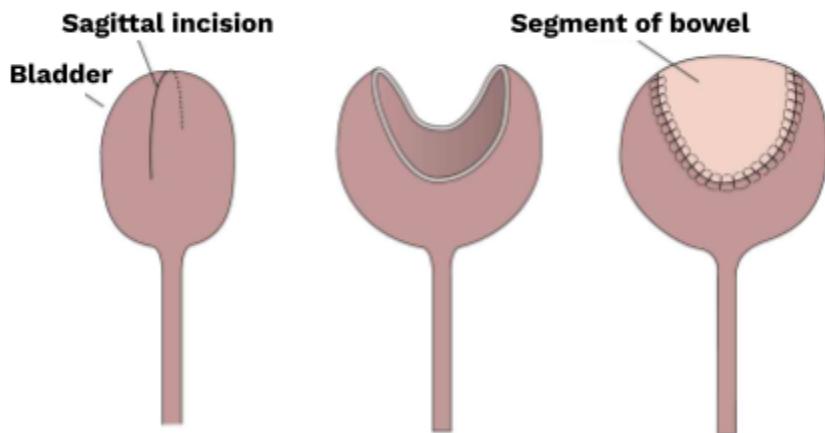
**Botulinum Toxin.** Botulinum toxin (BTX) is a neurotoxin typically administered via peripheral injection. BTX is employed to manage bladder spasticity by inhibiting the release of acetylcholine, leading to muscle relaxation [51]. It is often chosen as an alternative to anticholinergic drugs when patients seek a more lasting solution or relief from side effects. Botulinum toxin injections are administered using a cystoscope, precisely targeting multiple injection points within the bladder wall, seen in Figure 9. This procedure is designed to alleviate spasms and incontinence issues frequently experienced by SCI patients who do not use external or internal devices.



**Figure 9.** Botulinum toxin injections target the bladder wall attempting to alleviate spasms and incontinence issues frequently experienced by SCI patients who do not use external or internal devices [52].

In initial studies, BTX has shown an increase in maximum bladder capacity and a decrease in maximum detrusor pressure. One study observed restored continence in 73% of patients within three months of treatment [53]. However, like many incontinence treatments for SCI patients, effects can vary, with some individuals experiencing increased urinary tract infections and reduced post-void residual volume. Future research aims to identify predictors of BTX success in individual patients.

*Bladder Augmentation.* Bladder augmentation is one surgical treatment for incontinence that involves increasing bladder capacity and lowering bladder pressure by implanting a segment of the bowel as seen below in Figure 10.



**Figure 10.** Bladder augmentation involves taking a segment of the bowel and sewing it into the bladder in an attempt to increase bladder capacity and control [54].

This intervention is not typically the initial course of action and is generally recommended for patients who exhibit reduced responsiveness or intolerance to alternative treatments. While these procedures can significantly increase bladder capacity by up to 500 mL, it's noteworthy that 65% of patients still experience recurrent urinary tract infections (UTIs), and there is a notable 14-15 fold increase in the risk of cancer associated with this approach [3].

*Product Comparison Chart.* The following table summarizes the benefits and limitations of the treatment options for UAB described above. All of the devices below are evaluated against important criteria defined by the comprehensive review of incontinence in SCI patients contained in the above report.

These criteria were identified through an extensive literature review aimed at gaining a comprehensive understanding of the specific requirements of SCI patients and their experiences with various treatments, particularly CIC. These needs and information sources were all drawn from peer-reviewed papers, some examples including review articles of the treatments available to SCI patients and studies on the success and failures rates of different treatments approaches for incontinence in SCI patients. Within this context, the following criteria are being used to evaluate the current landscape of products:

1. Can be Independently Managed: Does the device allow for independent use by patients?
2. Lowers Risk of Infection: Does the product reduce the risk of UTIs?
3. Lowers Post-Void Residual volume: Does the product reduce post-void residual volume?
4. Detects Bladder Volume: Does the product have the capacity to detect bladder volume effectively?
5. Low Maintenance: How much maintenance does the product require?
6. Minimally Invasive: Is the product minimally invasive?
7. Long-Term Success: Is the device seen to be successful for long term use?
8. Accessibility: Is the device accessible to individuals with varying levels of mobility and strength, addressing the needs of those with limited mobility due to spinal cord injuries.

These criteria were determined based on the fundamental requirements of CIC, given its status as the most commonly used method. Additional criteria were established to address issues specific to SCI patients that may not be adequately addressed by CIC alone, taking into account common reasons why individuals discontinue CIC treatment. Our team also acknowledges that our backgrounds and identities may have influenced the criteria we deemed as essential to address the entire market.

**Table 1.** This comparison chart displays the gaps in the current solutions available for treating NBs. We see that the largest gaps in criteria in current solutions include detecting bladder volume, lowering risk of infection, and lowering post-void residual volume. These set the stage for large gaps that are team can work to improve upon.

Criteria	Ideal Solution	Commonly Adopted Solutions for SCI Patients			Less Prevalent Solutions for SCI Patients			Score out of 7
		Clean Intermittent Catheters	InDwelling Catheters	Anticholinergic drugs	Sacral Nerve Stimulation	Botulinum toxin	Bladder augmentation	
Can Be Independently Managed	✓	✓	✗	✓	✓	✓	✓	7
Lowers Risk of Infection	✓	✗	✗	✗	✓	✓	✗	3
Lowers Post-Void Residual	✓	✓	✓	✗	✓	✗	✗	4
Detects Bladder Volume	✓	✗	✗	✗	✗	✗	✗	1
Low Maintenance	✓	✗	✓	✓	✓	✓	✓	6
Minimally Invasive	✓	✓	✓	✓	✗	✓	✗	5
Long Term Success	✓	✗	✗	✗	✗	✓	✗	2
Accessible	✓	✗	✓	✓	✓	✓	✓	6
Score out of 7	8	3	4	4	5	6	3	

## **II. Design Inputs**

This section provides a comprehensive exploration of the design requirements and specifications essential for our solution, accompanied by justifications for each input."

### **Main Design Categories**

To ensure our device fits the needs of our stakeholders, we have developed a list of design requirements that our design must entail. Each of these requirements falls into a larger user needs category, allowing us to systematically address and meet the expectations of our end-users

#### *User Needs*

Each requirement falls into a main user needs category. The main need of each of these categories is defined below.

*Safety.* Safety is defined as the prevention of any physical injury to the biological structures or tissues in question. Ensuring safety ranks among our top priorities to minimize unnecessary risks, making most design requirements critical. However, certain design requirements will only apply if our solution is intended for internal use.

*Durability.* Durability, defined as the ability to withstand wear or damage, is a fundamental aspect of our design considerations. Ensuring that our solution exhibits high durability is essential to guarantee its long-lasting performance, even in challenging conditions or under frequent use.

*Biocompatibility.* Regardless of the final solution, biocompatibility will be a crucial consideration, as the solution will interact with the human body. The specifications for the design requirements in this section may have broad ranges to prevent any bias towards a particular solution. Our potential solution could be either internal or external, leading to significant variations in biocompatibility specifications. It's important to highlight that if these tests involve animals, the sex of the animal must correspond with the sex of the human for whom the solution is intended.

*Sterility.* Sterility is defined as the absence of microorganisms, a crucial factor in infection prevention. Our solution must possess the capability to undergo sterilization to ensure that patients can use it in the most sterile conditions possible.

*Function.* These requirements specify how our solution should operate during use or application. Ensuring that our solution functions in line with the needs of female SCI patients experiencing incontinence is crucial to creating a practical solution that addresses incontinence issues and reduces the associated risks of urinary tract infections resulting from clean intermittent catheterization.

It is important to note that current treatment methods do not fully address the needs of SCI patients, and as such, their personal identities and power in the medical field are limited. By highlighting function requirements, we aim to counteract this subjugation of these stakeholders by providing them with an equitable design that operates with their perspectives and needs in mind. This empowers them and allows them access to medical treatment and an enhanced quality of life that is not currently possible due to limitations in CIC.

*Usability.* Usability assesses how easily users can use and interact with the solution and complete the necessary tasks. This is especially relevant to CIC, as up to 70% of SCI patients initially advised to use CIC eventually transition to indwelling catheters despite increased risks such as infection, upper tract stones, bladder stones, urethral stricture and periurethral abscess[55]. The most common reasons for this

change are inconvenience, urinary leakage, and number of urinary infections[56]. Ensuring that barriers to use are minimized, such that CIC can be continued and UTI risk is kept lower, is key.

*Cost.* Cost requirements specify the prices associated with our solution. CIC can often be costly for SCI patients with chronic neurogenic bladder, as it requires daily use over the course of a lifetime. As such, it is important to limit these costs to prevent treatment barriers for low-income individuals and increase overall accessibility.

#### *Understanding Key Stakeholders*

Design requirements were grouped by stakeholders who may affect or be affected the most by the given specification. Descriptions of these stakeholders are listed below.

*Patient.* Patients are defined as our target population, female SCI patients using CIC for incontinence management. These are our primary stakeholders as they directly utilize our solution for bladder management. This group has a variety of identities, many of them completely independent of their injury. Our solution aims to allow them to become more independent of their “identity” in terms of their SCI and free of that lack of privilege. Our most important requirements serve the patients.

*Caregivers.* Caregivers are defined as any individual that directly assists patients in their incontinence management. This is especially pertinent to our target population, as some of them rely on a caregiver for bladder management.

It is important to note that some requirements were mapped to both the patient and caregiver as stakeholders. These decisions were made based on whether the requirement would alleviate specific caregiver expectations and also if the patient requires a caregiver, whether the requirement would impact their responsibilities or the manner in which they are carried out.

*Regulatory bodies/FDA.* Regulatory bodies are any federally regulated organization that has established legal standards for the development or testing of medical devices. These standards are regulated and established by the FDA.

#### **Critical Design Requirements**

Critical requirements were defined as any requirement that has the potential to adversely affect the health or safety of our primary stakeholders, female SCI patients using CIC. This includes requirements addressing injury, infection, and immune response. Furthermore, our rankings are influenced by the hierarchy of ergonomics and hedonomics adopted by the FDA, reinforcing our rationale that safety requirements take precedence over those of lesser importance [57].

**Table 2.** The critical design requirement summary delineates the essential prerequisites for our design process and their corresponding significance for our team's design efforts.

Critical Design Requirements				
Design Input	Requirement	Specification	Stakeholder	Team Priority
Safety	Solution does not damage the urethra or bladder.	Solution will not apply greater than 700 psig of pressure[58]	Patient	✗
		Solution facilitates and is designed for a 30-degree angle upwards from vertical [59]		
		Fits females using 12-18 Fr catheters [60]		
		The solution does not apply forces greater than 5 N on the surrounding tissue [61]		
Durability	Solution does not fracture at any time during internal use.	An internal design would need to have tensile strength of $4.61 \pm 1.112$ kPa and a Young's Modulus of $2.388 \pm 1.30$ kPa [62].	Patient and Caregiver	✗
Durability	Solution will not break under normal application forces.	Withstand $> 5$ N of force, with a safety factor of 3, to ensure design can withstand at least 15N of application force [61].	Patient and Caregiver	✓
Function	Solution should not experience significant displacement during use.	3 mm or less displacement in the X and Z planes from 3-4 cm of insertion into the urethral opening [63], [64]	Patient	✗

Critical Design Requirements				
Design Input	Requirement	Specification	Stakeholder	Team Priority
Sterility	Solution can be sterilized with common methods.	Ethylene oxide “gas” sterilization: design needs to withstand the four parameters needed; gas concentration of 450 to 1200 mg/I, temperatures 37 to 63°C, relative humidity of 40-80%, and exposure time of 1-6 hours [65].	Patient and Caregiver	✓
		Steam/Autoclave sterilization: the solution would need to withstand 121°C for ~30 minutes, in a gravity displacement sterilizer. With dryness factor of steam $\geq 97\%$ [66].		
		Dry Heat: withstand one time-temperature dependent relationship. Either 170°C for 60 minutes, 160°C for 120 minutes, and 150°C for 150 minutes [67].		
		Microwave Sterilization: withstand a 2.45GHz microwave for 60 seconds to 5 minutes [67].		
Sterility	Sterile packaging that maintains an appropriate sterile shelf life is used for our solution.	Packaging remains sterile and viable for 2-5 years [68].	Regulatory Bodies/FDA	✗
		Packaging includes explicit instructions for removing device from packaging aseptically [79], [70].		
		Packaging withstands common methods of sterilization, refer to previous requirement [79], [70].		
		Packaging maintains sterility throughout shelf life [79], [70].		
Function	Must adequately lower post-void residual volume.	PVR volume is less than 50 mL [71].	Patient	✗
Function	Solution is removable.	Able to pass through diameter of range 2-5.94 mm and length 3-4 cm [63], [72], [73]	Patient and Caregiver	✗

Critical Design Requirements				
Design Input	Requirement	Specification	Stakeholder	Team Priority
Biocompatibility	Material chemical composition of the solution is not toxic.	Reduction of cell viability is less than 30% after quantitative cytotoxic testing [10].	Regulatory Bodies/FDA	✓
Biocompatibility	Leachables are present in safe concentrations.	Calculated leachable substances will be under the allowable limit (in mg/day, cannot be determined until material is chosen) for duration of exposure (range: less than 24hrs to 25,000 days) [75].	Regulatory Bodies/FDA	✗
Biocompatibility	Material chemical composition does not cause skin or inner mucosal irritation.	For skin irritation: Magnusson and Kligman's score is <1 after 24±2 and 48±2 hours. Time may be extended based on the intended time-use of the solution [76].  For mucosal irritation: macroscopic evaluation should have grading of 1 or less. Microscopic histological evaluation scores should total 9 or less [77].	Regulatory Bodies/FDA	✓
Biocompatibility	Solution does not cause long-term inflammatory response.	Testing is between a minimum of 12 and a maximum of 104 weeks. Macroscopic inspection of the implant site does not reveal alterations of normal structure. Animals do not show signs of ill health. Histology slices are scored based on criteria involving immune cell types and responses, but this score specification will only be decided after the solution is chosen [78].	Regulatory Bodies/FDA	✗

### *Prioritization*

We prioritized critical requirements based on their potential to cause immediate harm to our primary stakeholders, female Spinal-Cord Injury (SCI) patients. Our top priority was given to requirements aimed at preventing direct injury, particularly tissue damage to the patient, which is significant in preventing severe bleeding or even sepsis during the application of our solution. Following this, we chose requirements that are crucial in preventing infections. Since urinary tract infections (UTIs) pose a significant risk to our target population, it was necessary to prioritize them to enhance patient safety. However, it's worth noting that UTIs do not present as immediate a health risk as direct injury to the patient. Requirements addressing immune responses were next in our prioritization. While it's essential to limit the immune response triggered by our solution, health risks associated with the host response do not present as immediate a risk as direct injury or UTI development. Our prioritization approach closely aligns with the FDA's hierarchy of importance in human factors [79]. According to this ranking, the primary consideration is user safety, followed by functionality, usability, the quality of the user experience, and lastly, individuation. We have adhered to this order, starting with user safety and systematically progressing through each criterion. Detailed prioritizations within these user need categories will be further discussed in each individual design requirement below.

Team priorities were determined based on three key criteria: feasibility, team interests, and our perception of user preferences. Feasibility encompasses what is both achievable and necessary for our group to verify within the time and resource constraints of this course. For instance, since we are mandated to select an FDA-approved material, any biocompatibility requirements that have already undergone thorough testing and received FDA approval will be assigned a high rank due to their strong feasibility.

As none of the current team members have SCI or experience with incontinence, it's crucial that we refine these prioritizations further as we conduct stakeholder interviews with individuals who have firsthand experience of living with SCI. Our initial considerations regarding what the user might value stem from a position of privilege. Therefore, we must leverage our expertise as informed engineers to gather insights, comprehend the perspectives, and address the needs of our target population, making informed and empathetic design decisions. These user perspectives will also heavily guide our future design concepts.

### *Requirements and Specifications*

Described below are the critical design requirements and specifications that our eventual design solution would need to possess to be adopted by female SCI patients using CIC, listed in order of decreasing priority.

*Solution does not damage tissues.* Any solution designed must have physical dimensions and properties that minimize risk to the tissues it comes in contact with. This applies to an external solution, which might contact skin or mucous membranes, or internal solutions, which might contact the urethra or bladder.

The first specification related to this requirement relates to the pressure applied and the radius of the material, which combines with velocity to ultimately determine whether the tissue is cut. Here, skin was used as an estimate for urethral or bladder tissues [58]. In this paper, a smooth-bladed pocket knife and serrated knife attached to a cart were passed over skin to determine the energy necessary to cut through skin. For the pocket knife, whose smooth surface is more accurate for our application, “if low pressure (under 1000g) is exerted on the knives, the probability of inflicting a grade 2 or higher cut is very small” [69]. A grade 0 cut does not damage the skin, whereas a grade 1 cut only damages the epidermis. Given that the knife is metal and our device will likely be plastic, this is an inherent safety factor. The ideal radius will be significantly larger than that of the swiss army knife used in the study, which is another factor to take into consideration. We would aim for a grade 0 cut, which only occurred on average at a 700 g pressure. Thus our solution will not apply greater than this pressure. Continued research will be done to find a suitable safety factor.

The solution must not have any sharp edges or apply forces that the tissues of the urethra and bladder cannot withstand. A smooth edge is also preferable to a sharp, jagged edge because a smooth edge will have a lower energy density, leading to less focused pressure at the tip of the device, meaning more force is required for puncture [58].

To ensure our solution conforms to urethral geometry easily without undue force to the urethra, our potential internal solution facilitates and is designed for a 30° angle upwards from vertical [59].

Additionally, our potential design would need to allow for customization or selection of length and diameter since urethra length and diameter change from patient to patient [80], [81]. Most female patients use CIC french catheter sizes 14 or 16. To allow for variation in anatomy, we will assume our solution should fit females using 12-18 french catheters [60]. This ensures that a catheter that is not too large is not inserted into a small urethra, which could cause bleeding or tearing.

Another specification is set so that the solution must be inserted at maximally 5 N of force; thus, the solution does not apply forces greater than 5 N on the surrounding tissues and it is not too difficult for the user to insert [60]. We need to discuss with physician and patient stakeholders to determine if this issue needs to be addressed. For example, reducing insertion forces could decrease mucosal damage and bleeding and prevent the worst-case scenario of urethral puncture, and could make it more accessible for patients to insert catheters.

*Solution does not fracture at any time during internal use.* A potential internal design must withstand any physiological forces it might endure during use. The design needs to have strong mechanical properties to avoid cracking, breaking or detaching during use.

An internal potential solution based on a urethral catheter, needs to have tensile strength of  $4.61 \pm 1.112$  kPa, and a Young's Modulus of  $2.388 \pm 1.30$  kPa [62].

This requirement was ranked after the first one since it has the potential to cause an immediate risk to the patient. However, it is also possible to break without causing immediate severe damage to the patient which is why it is ranked second. Lastly, we are basing our prioritizations off of the FDA's prioritizations which entails ranking safety specifications higher than non-safety specifications.

*Solution will not break under normal application forces.* With a potential internal solution, we need to ensure the solution can withstand the application forces of the caretaker or the user. Since at times more force is required during application than when the solution is in use. Breakage would include any cracks, deformation leading to loss of functionality and/or not allowing for repeated application of force for removal and/or reinsertion.

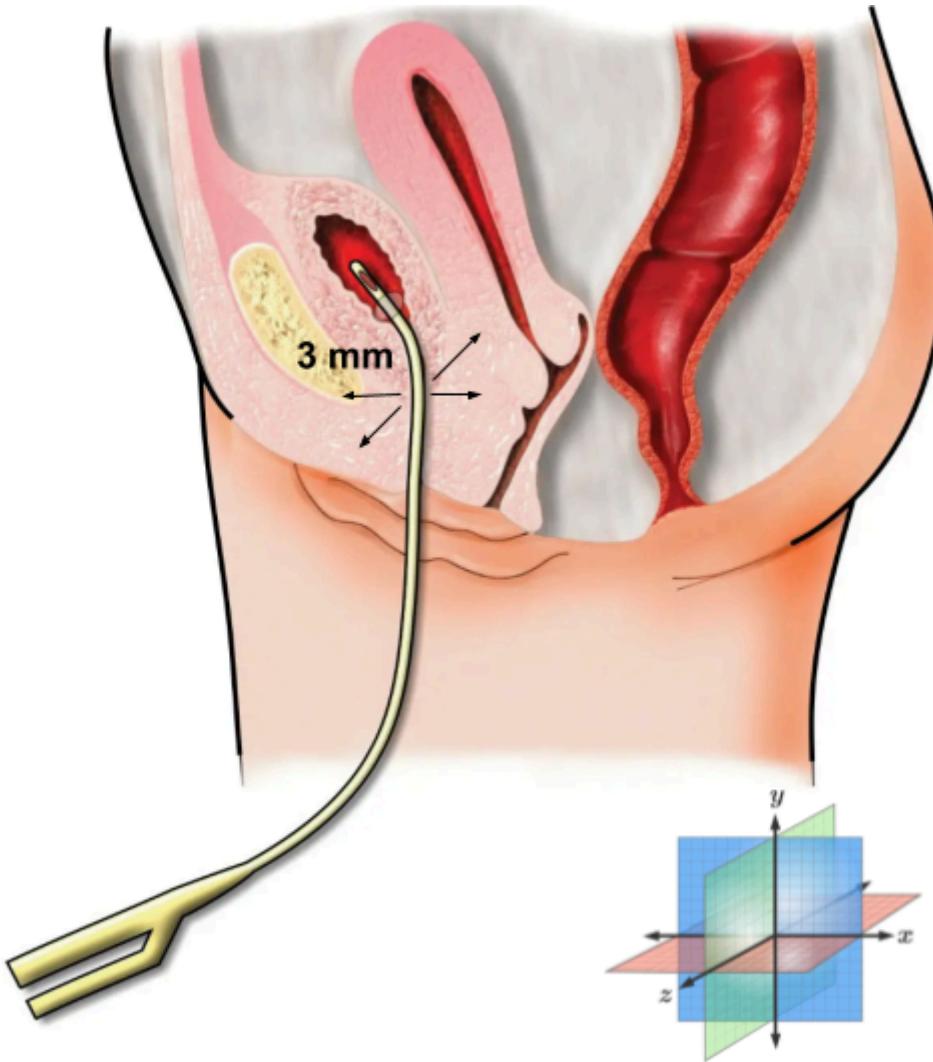
To ensure our solution does not fail under normal application forces, our solution will need to withstand  $>5$  N of force, since 5N is the optimal amount of force that should be used when inserting a CIC [61]. Additionally, we propose a safety factor of 3, to ensure our device is able to withstand even the strongest of application forces. Since the highest force insertion average is about  $10.1 \pm 3.7$ N [61]. With a safety factor of 3 our device would be able to withstand at least 15N of application forces.

This requirement has a higher priority since we are using the prioritization given by the FDA. The FDA ranks safety first, and we consider this requirement to be a part of safety. The reason we ranked this requirement as number 3, lower than the does not fracture during internal use requirement, since this requirement does not involve as much interface with the urethra. Meaning usage of the device takes longer, has longer contact with the body, then the process of application. Additionally, breakage during

insertion is more noticeable, so the user has a higher chance of noticing the damage and being able to replace the device sooner.

*Solution should not experience displacement during use.* Due to the relatively small volume available within the urethra and interfacing with the bladder, any solution must not experience displacement during use to allow for proper function. Movement of catheters inside the urethra can cause discomfort and pain in patients and even lead to urethral tract injury and bleeding [82].

Since our solution would be in use when urine flows from the bladder to the urethra and urine flow encompasses the full length of the urethra, our solution shall be inserted along the entire length of the urethra. For females, this urethral length is about 3-4 cm [83]. Significant displacement is defined as 3 mm or more in the X and Z planes shown below in Figure 11 [64]. Therefore, our solution shall exhibit less than 3 mm displacement in the X and Z planes along 3-4 cm of insertion into the urethral opening.



**Figure 11.** To ensure patient safety, the maximum displacement of our solution during insertion in the X and Z planes shall be less than 3 mm [56].

This requirement provides protection against risk for immediate injury to the patient's urethra. However,

displacement outside of these dimensions does not guarantee injury, and as such, it is given lower prioritization than requirements that specify more immediate injury above.

*Solution can be sterilized with common methods.* Common sterilization methods include ethylene oxide, autoclave/steam, microwave, and dry heat.

To utilize ethylene oxide “gas” sterilization technique, our design would need to withstand the four parameters. Which are a gas concentration of 450 to 1200 mg/l, temperatures of 37 to 63°C, relative humidity of 40-80%, and an exposure time of 1 to 6 hours [65]. Steam sterilization is accomplished in an autoclave which will expose direct steam at a required temperature and pressure for a specific amount of time. The temperature required is 121°C for about 30 minutes while supplies are already wrapped and in a gravity displacement sterilizer. With steam/autoclave sterilization the ideal steam should have a dryness fraction of  $\geq 97\%$  [66]. In order for our design to allow for sterilization by dry heat it would need to pass one of the time-temperature relationships for sterilization with hot air. The most common time-temperature relationships are 170°C for 60 minutes, 160°C for 120 minutes, and 150°C for 150 minutes [67].

A design that would allow for sterilization by microwave would need to withstand using a 2.45GHz microwave for 60 seconds to 5 minutes. This has shown to completely inactivate viruses and bacterial cultures [67].

*Sterile packaging that maintains an appropriate sterile shelf life is used for our solution.* It is important for our solution to be sterile when it is packaged and maintain sterility until the time of use with the patient. To avoid unnecessary exposure to potentially harmful microorganisms.

Sterile packaging should have low permeability to water vapor and air. Sterile medical devices that remain in their original packaging should remain sterile and viable to use for 2-5 years [68]. To test the sterility of our packaging, we will put our packaging through a series of tests and make sure it passes the requirements described by the ISO 11607-1:2019 - Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems, and packaging systems [79]. In order to do that there are a few things our packaging needs to accomplish. First it needs to allow the device to maintain sterility until it is opened for usage, maintain a sterile barrier. The packaging must also include explicit instructions on how to remove the device from the sterile barrier in the most aseptic way possible. Third, the packaging must be able to withstand the process of sterilization, such as ethylene oxide gas sterilization. Refer to requirements on utilizing sterilization techniques. Lastly, manufacturers need to ensure sterility throughout shelf life [70].

*Must adequately lower PVR volume.* Our solution must effectively lower the PVR volume of urine in the bladder. High PVR volume is a significant risk factor for urinary dysfunction and UTIs, as shown in Table 3, and is a common symptom of detrusor dysfunction resulting from SCI [84]. Our solution is expected to lower PVR volume to normal, healthy physiological levels.

For non-elderly patients ( $\leq 65$  years), typical healthy PVR volume is below 50 mL, whereas for elderly patients ( $> 65$  years), this volume is between 50-100 mL [71]. This difference in expected values can be explained by diminishing detrusor function due to aging, which limits the ability of the bladder to fully contract and empty during voiding [85]. However, we would like all patients to experience optimal PVR volume levels regardless of age, in order to minimize UTI risk as much as possible. As such, our solution shall lower PVR volume to 50 mL or below.

**Table 3.** Elevated PVR volume is strongly linked with the incidence of UTIs in females [86].

<b>Variable</b>	<b>UTI (N = 74)</b>	<b>Non-UTI (N = 74)</b>
<b>Female</b>	<b>33 (44.6%)</b>	<b>50(43.9%)</b>
<b>PVR (mL)*</b>		
<b>Mean +/- SD</b>	<b>106.5 (+/-102.0)</b>	<b>62.7(+/-88.9)</b>

Because PVR volume is significant in increasing UTI risk, this requirement is given relatively high priority. However, it does not introduce as much UTI risk as directly introducing bacteria into the patient's anatomy, which is introduced in the sterilization requirements listed above. Hence, this requirement was prioritized less.

*Solution is removable.* For a solution directly interfacing with a patient's urethra and bladder, it is desired that this solution is removable. Any outlet obstruction within the urethra increases the risk of UTI due to urine backflow, resulting in an ideal growth environment for bacteria [87]. The first stakeholder we met with, Dr. Ashton-Miller, emphasized this importance, as anything that stays in the body longer carries an increased risk of infection [88]. However, this requirement would depend on the eventual solution design and whether it is internal or external.

As such, our solution shall fit within the typical adult female urethral dimensions. The adult female urethra is 2-8 mm in diameter and 3-4 cm in length [73] [83]. Additionally, using established catheter sizing standards, it has been found that catheters of size larger than 18 Fr, equivalent to 5.94 mm, cause resistance to urine flow[72]. Using this and our desire for the solution to not encompass the full diameter of the urethral opening and block insertion, it is expected that our solution shall fit with cylindrical dimensions of 2-5.94 mm and 3-4 cm in length.

While this design requirement does include risk of immediate injury to the patient, displacement outside of these dimensions does not guarantee immediate injury and as such, this requirement is given lower priority than the requirements addressing immediate injury above.

*Material chemical composition of the solution is not toxic.* Regardless of the duration of contact between our solution and the patient, the chemical composition of the solution must remain non-toxic to the individual. We introduce this design requirement with the understanding that the effectiveness of our solution for addressing incontinence hinges on ensuring it does not inadvertently introduce harmful substances to the patient's body.

To ensure that our solution does not introduce toxins, we will perform cytotoxicity testing following the guidelines outlined in ISO 10993-5:2009. This testing involves the assessment of medical device materials in in vitro settings to evaluate their potential toxicity. Various parameters can be monitored, but the most commonly employed measure is the analysis of cell viability. Within this standard, it specifies that, after a test involving the incubation of the medical device material with relevant cell cultures, we shall observe cell viability within 48 and 72 hours. The material is deemed safe and non-toxic if the reduction in cell viability remains below 30% [74]. If the reduction in cell viability rate exceeds this threshold, the material will no longer be considered biocompatible. It is important to note that if cytotoxicity studies have already been conducted for our material, we will adhere to the ISO standard's

provisions, thus eliminating the need for additional testing. This requirement has a high priority as material toxicity could pose an immediate health risk to a patient. Furthermore, our team has selected this as a priority because we can easily confirm the material's non-toxicity by choosing an FDA-approved material, which simplifies the compliance process.

*Leachables are present in safe concentrations.* Leachables are defined as chemical species that can come off from the device under its normal clinical use. If our solution is made to be worn externally on the body, then contact with the skin could produce leachables. Similarly, if our solution is placed internally, then the contact with local bacteria, inner mucosal lining, and urine could produce leachables. Leachables have the potential to be harmful for the body depending on their reactivity, thus their safety must be evaluated.

The specification of this requirement is that leachables will be under the allowable limit (in mg per day) after the duration of exposure of the solution. The allowable limit will be calculated as per instructions in ISO 10993-17 (Biological evaluation of medical devices — Part 17: Toxicological risk assessment of medical device constituents). The calculation of allowable limits is complicated and rests on observations seen during assessment of the material with the body and the duration exposure. The duration of exposure will be altered depending on our final solution and could range anywhere from less than 24hrs to 25,000 days, as specified in the standard. At this time, we have not chosen a material nor do we know how long our solution will be in contact with the body; thus we cannot calculate the allowable limit. It is important to note that if we choose a material for our final solution that has already been tested to be biocompatible and safe, then we need not reconduct the following tests again but cite other sources where the data has been shown that the material meets the standard for our specifications [75].

This design requirement is prioritized after the toxicity requirement because it is more important to first ensure the material of the device is not inherently toxic, then we can ensure it doesn't produce leachables that are toxic. This design requirement is also a team priority because it is feasible for us to achieve, as we can easily confirm if a material's leachables are not toxic by choosing an FDA-approved and tested material.

*Material chemical composition does not cause skin or inner mucosal irritation.* If there is too much irritation from our solution, then patients may not be able to tolerate using the solution, rendering it ineffective. To avoid this, we must ensure the chemical composition of our device doesn't cause irritation. If our solution is external or internal to the body, we must address skin irritation or inner mucosal lining of the urethral tract irritation, respectively.

Our skin irritation specification will be that the solution has a 0 on the Magnusson and Kligman scale. This scale (0-3) indicates how much erythema has developed, where 0 indicates no visible change and grades of 1 or higher indicate erythema. We will follow the Closed-patch test (Buehler Test) as explained within the ISO 10993-10 standard, where pieces of pulverized material from our solution are made into a patch, placed on guinea pig skin, and observed for  $24\pm 2$  and  $48\pm 2$  hours. Depending on how long our final solution remains in or on the body, the testing range could be adapted to longer than  $48\pm 2$  hours [76].

We recognize that the inner mucosal lining has different properties than the skin, so we will use a different specification for irritation. Following evaluation scales in ISO 10993-23, macroscopic evaluation of dissected urethral mucosal lining should receive a numerical grading of 1 or less. For microscopic histological evaluation, scores should total 9 or less. The full scoring scheme that will adapt to test our solution can be found in Appendix A. We will follow an adaptation of the mucosal tests in this standard, where a 1 mL syringe of our test sample is delivered into the urethra of a rabbit. The procedure is repeated

at  $24\pm2$  hour intervals for a minimum of 5 consecutive days. Depending on how long our final solution remains in or on the body, the testing range could be adapted to longer than 5 days [77].

It is important to note that if we choose a material for our final solution that has already been tested to be biocompatible and safe, then we need not reconduct the following tests again but cite other sources where the data has been shown that the material meets the standard for our specifications.

This design requirement is prioritized after the toxicity and leachables requirements because it poses a relatively less immediate health risk. However, it can still cause discomfort and inflammation for the patient, which leads to scarring. This design requirement is also a team priority because it is feasible for us to achieve, as we can easily confirm the material's irritation levels by choosing an FDA-approved and tested material.

*Solution does not cause a long-term inflammatory response.* It is possible that our solution is implanted inside the body or simply sits within the urethra for a longer period of time. In either of these cases, we must ensure that the solution does not cause a long-term inflammatory response on the surrounding tissue and body. Long-term inflammatory responses can hinder bladder function, cause pain, and result in other undesirable symptoms [89].

This specification for this requirement will need to be altered depending on the material properties used in the solution and will be taken from ISO 10993-6 (Biological evaluation of medical devices – Part 6: Tests for local effects after implantation). If the solution is absorbable, meaning the material degrades on a known time-course after implantation in the body, then long-term inflammatory response will be tested for the duration of that degradation time. Per the standard, this could mean a minimum of 12 weeks to a maximum of 104 weeks. If the solution is non-absorbable, implying no degradation, then the test period duration will be at a maximum of 104 weeks. At any evaluation point during the testing period, the animal should show no signs of ill health and no alterations to the normal structure of the implant site. Histology samples taken at evaluation points can be scored by assigning quantitative values (1-4) to the amount of immune cells or cell responses that appear. For example, the quantity of macrophages, lymphocytes, fibrosis, and neovascularization could be scored. The full scoring scheme that will adapt to test our solution can be found in Appendix B [78]. Currently, a targeted score cannot be specified because it depends on our solution's intended impact.

### **Non-Critical Design Requirements**

Non-critical requirements were defined as requirements that did not directly address female SCI patients' safety or health, but rather their accessibility needs. This includes any requirements related to usability, function, or cost. These requirements were deemed non-critical because even if they are not met, they do not pose a direct risk or hazard to our primary stakeholders, female SCI patients.

**Table 3.** The summary of non-critical requirements outlines additional specifications that contribute to but are not paramount in guiding our team's design process. The requirements associated with priority with our team also display the requirements we will take into the highest consideration when designing.

Non-Critical Design Requirements				
Design Input	Requirement	Specification	Stakeholder	Team Priority
Usability	Solution must allow for self-application.	Maximum error rate of 5% for urethra and labia visualization [90].	Patient	✓
		Maximum error rate of 5% for correct device placement on first try [90].	Patient and Caregiver	
Usability	Solution must be portable.	Any solution will have the longest dimension as 17 cm, with other dimensions being smaller [91].	Patient	✓
		Solution should weigh less than 375 grams [92].		
Usability	Solution can be used in a reasonable timeframe.	Female users can independently use our device in less than 15 minutes [93].	Patient and Caregiver	✓
Cost	Lifetime Cost for patients must be less than current standards.	Less than \$1,395 USD/QALY [94].	Patient	✗
Function	Typical urine flow must be maintained.	Solution is expected to maintain a urine flow rate of at least 20 mL/sec using uroflowmetry analysis [95].	Patient	✗

### *Prioritization*

Non-critical design requirements were prioritized based on their effect on a patient's quality of life. Based on literature review and feedback, we assigned highest priority to usability design requirements, as these requirements we deemed to have the greatest direct impact on a patient's daily well-being and improve accessibility issues they may have from currently using CIC. From here, priority was given to requirements that also could benefit a patient's daily well-being, but may not directly address accessibility needs arising from CIC use. Prioritizations within these user need categories will be further discussed in each design requirement below. Below, we provide design requirements and specifications that our eventual design solution will need to address in order to be adopted by SCI patients using CIC.

Team priorities were again determined based on three criteria: feasibility, team interests, and our perception of user preferences. Feasibility, meaning what is both achievable and necessary for our group to verify within the time and resource constraints of this course.

*Solution must allow for self-application.* Post-injury, SCI patients desire to maintain their autonomy as much as possible. It is a driving factor behind their decision to choose incontinence solutions, which is why up to 70% of patients with SCI using CIC transition to indwelling catheters despite the increased risk of UTI and lower quality of life. Thus, our solution must allow for self-application to maintain patient autonomy and ultimately increase their quality of life [96].

We will utilize multiple specifications to ensure the solution allows for self-application. During our stakeholder interview with Dr. Ashton-Miller, we learned that it is very difficult for providers and patients to ensure that catheters are placed appropriately in female anatomy. This is due to the difficulty in visualizing the urethra and it being covered by the labia, which can worsen with obesity, limited mobility, and dexterity [88]. As a result, UTI rates are high in females because the catheter touches other body parts – breaking sterility. Thus, one of our specifications will be to stay under a certain number of errors in self-catheter positioning. We have not been able to find this data, but we will speak with patient stakeholders and meet with the BME librarian to give us more insight into how this specification can be quantified. Another specification can be drawn for visualization of urethra and labia, but again, we are not sure how to quantify this. One potential route could be to follow the FDA's guidance that Type-I error for clinical trial testing should be less than 5% for independent subgroups [90]. The importance of this specification depends on the kind of solution we create, so it will be adjusted accordingly.

*Solution must be portable.* Portability is important in making the design accessible to patients. Some patients cite the inability to access an appropriate catheter when needed to justify not continuing CIC [82]. Wellspect is a company that makes single-use discreet intermittent catheters for women that look similar to tampons in their shape and packaging and can be carried in a purse [97]. Their LoFric® Sense™ hydrophilic CIC catheter is listed to be 15 cm long [91]. Estimates from the figures available on the datasheet given this measurement result in a packaging length and width of about 17 and 3.5 cm. Bard is an industry leader in catheters; their Magic3 GO® Female Catheter is also 15 cm long [98]. If an individual is on vacation and using single-use catheters, they would need to take 4-6 of these daily; if they were out all day, they might need to take four. Thus, any solution will have the longest dimension be 17 cm, with the other dimensions being smaller for easy portability.

In terms of weight, CIC weights range from 8 to 71 grams [99]. Given this very small weight, a potentially more reasonable comparison for a solution we may design is another common device - foley catheter bags. These bags are connected to indwelling catheters and are often attached to the leg for ease of mobility. We don't know what our final solution will look like; however, this weight is an approximation for what may be reasonably expected for a patient to be willing to carry. These typically hold 350 - 750 mL of urine, and should be emptied when they are about half full [100] [92]. This

corresponds to about 375 g of liquid maximally. Therefore, we will estimate that our product should weigh less than 375 g at the very most; this is a general estimate [92].

This is an accessible method to ensure the solution is always available and makes the product more agreeable for many patients. Most people don't need to plan and worry about the accessibility of toilets and ensuring they can use the bathroom. We must ensure that our solution contributes to minimizing this barrier for our population and lowering stigmas. Portability was therefore ranked highly in our group rankings to increase accessibility. In terms of overall rankings, it is ranked at this point in the list because it also allows for independence for CIC and provides individuals with more control over where they can spend their time. It is ranked lower than self-application because, from our research, independence is a very important factor for these patients [96]. This needs to be further investigated using stakeholder interviews.

*Solution can be used in a reasonable timeframe.* The time patients catheterize themselves is important in their quality of life and affects their treatment decisions. A reasonable amount of time is defined as the amount of time the average person would be willing to spend without major inconvenience to their life. Urethral catheterization time for independent females was found to be 2-15 minutes [101]. Therefore, our solution should take less than 15 minutes to use. Other relevant findings were that the time was significantly longer for obese females than for normal weight females and CIC than for indwelling catheters. We want to ensure that our product does not only consider the "average" patient as many products do, which can exclude patients and take power away from them. As a usability requirement, the FDA ranks timing to be less important than effectiveness or safety. It is important for the patient's quality of life to be able to use the bathroom within a reasonable amount of time, therefore this was ranked as a high team priority. However, within usability, this is ranked lower than portability because it does not limit where they can spend their time but rather focuses on disruptions to this time.

*Lifetime Cost for patients must be less than current standards.* Due to the chronic nature of neurogenic bladders and the need for daily repeated use of CIC, there are high accumulated costs associated with CIC for these patients. This is especially significant for SCI patients, as low income and lack of health insurance to cover these costs are shown to be critical risk factors in mortality [102]. Thus, our design will lower the lifetime costs of using CIC for SCI patients. By limiting these costs, we aim to specifically empower low socioeconomic SCI patients and allow them access to medical treatments that they might not otherwise have access to due to systemic subjugations.

Currently, CIC has an average cost of \$29,161 for 20.91 Quality Adjusted Life Years (QALY), or the number of years a patient has in perfect health, resulting in an average cost of \$1,395 USD/QALY [94]. Thus, we will ensure our solution is less than \$1,395 USD/QALY to increase the equity of bladder management access.

It should be noted that QALY calculations and analysis can raise some ethical dilemmas, such as what constitutes a good quality of life and the assumption that the elderly have "less value" than those younger than them [103]. Considering this standard was established by a medical system that has historically served to benefit certain identity groups while preventing the entry of others, it will be important that any consideration undergone this QALY value is supported by people of a variety of backgrounds and age groups to ensure we are not using our potential positions of socio-economic privilege to perpetuate discriminatory standards.

*Typical urine flow must be maintained.* Our solution is expected to maintain minimum typical physiological urine flow for proper bladder emptying. This flow must be maintained throughout the duration of voiding so that the bladder is emptied properly in a timely manner to prevent any excessive PVR volume, which can increase the risk for UTI [104]. This requirement is deemed non-critical, as PVR

volume can still be fully emptied below or above typical physiological flow rates, even if a patient requires a longer voiding time.

Flow rates can be measured using uroflowmetry testing, where typical female physiological lower limit results are 20 mL/sec [105]. Therefore, our solution is expected to maintain a urine flow rate of at least 20 mL/s. While quality of life can be improved through improved flow rates, this design requirement only addresses time spent by the patient during voiding and doesn't account for any removal or preparation time needed for our solution. As such, it is given lower prioritization than the requirement addressing a reasonable timeframe of use above.

Our critical and non-critical design requirements will be further explored to generate design concepts in Design Process.

### **III. Design Process**

This section provides a detailed explanation of the team's brainstorming process and how final design concepts were generated and evaluated.

#### **Ideation**

A discussion of our brainstorming process and design space exploration is detailed below.

##### *Morphological Chart*

To begin brainstorming, our team used a morphological chart to transform design requirements into concepts. This method was used to ensure that we addressed each need for our primary stakeholder, female spinal cord injury patients using clean-intermittent catheterization, during brainstorming and that we were not limited to certain designs because of the identities and experiences of our team. Our team brings strong clinical experience, which was highlighted during the ideation of a portable suction device. This is similar to existing clinical devices our members have seen, allowing us to analyze pain points in these devices. An important caveat here is the bias that our experiences, such as being a medical assistant, only give us snapshots into the device implementation.

To create this chart, every design requirement was given its own row, with different cells representing separate design ideas to address the design requirement. Each cell represented a separate design idea to address the requirement. These concepts were generated via literature review, stakeholder feedback, and general problem-solving skills, listed in Table 4.

To generate comprehensive design ideas, we systematically assessed our morph chart. Initially, we reviewed each design requirement row and identified ideas that piqued our team's interest, were identified as feasible, or presented a realistic solution. These were highlighted in blue, as shown in the table. Feasible concepts were determined to have aspects proven to work in the medical field and are estimated to be achievable within the course timeline. For example, "detrusor stimulator via electrical signal" would be a very complex project for which we may not have the research background, making it infeasible. Concepts that were left unhighlighted did not meet the criteria to be highlighted in blue. For example, if the solution does not damage tissues, the "insertion end of the catheter is a soft material" was not chosen because there are a lot of catheter-specific solutions that already exist.

Subsequently, we combined different ideas, integrating various elements to create final design prototypes that addressed our needs. An example of this idea integration is highlighted in green for our external guide.

**Table 4.** Green squares in the displayed morphological chart shows ideas that could be combined to create a specific design concept. Blue squares represent our team's initial evaluation of concepts that were interesting, feasible, and solves the problem. Unhighlighted squares represent concepts that did not meet the criteria to be highlighted blue.

Design Requirements	1	2	3	4	5	6	7	8	9
<b>Solution does not damage tissues.</b>	Applicator that pushes the catheter in at a certain force level - similar to a tampon applicator	Sensor in catheter that senses how hard the user is pushing the catheter in	Solution has built in appropriate anatomical angle and orientation	Insertion end of catheter is a soft material	Sizing guide for solution	Smooth edges	Lubricant during insertion	External solution	Insertion Guide
<b>Solution does not fracture at any time during internal use.</b>	Increased temperature during processing, producing a grain-hardened material	Highly ductile materials	Placement guide along sides of solution, preventing fracture from internal movement						

<b>Solution will not break under normal application forces.</b>	External contraption that controls the insertion force of the device as it is inserted and removed	Solution is only applied once	Material is strong enough to withstand normal application force	Solution does not require an application force (external device)	Ductile material				
<b>Design Requirements</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>	<b>9</b>
<b>Solution should not experience displacement during use.</b>	Balloon at the end of the catheter , securing placement	Adhesive layer to position device	Solution has small, protruding grippers , enhancing friction	Device where placement does not matter (external device)	Magnet placement	Permanently attach device to bladder			
<b>Solution can be sterilized with common methods.</b>	Microwavable material	Solution include sterilizable,	Solution allows for autoclava	Solution can be boiled	Solution can be baked in the oven -				

		portable packaging	ve sterilization, potentially take into doctors offices and have it sterilized between appointments		"home autoclave"				
<b>Sterile packaging that maintains appropriate sterile shelf life is used for our solution.</b>	Manufacturing process that sterilizes and packages at the same time	Packaging material is antimicrobial	Packing routinely applies disinfectant to device	Reusable packaging					
<b>Design Requirements</b>	1	2	3	4	5	6	7	8	9

<b>Must adequately lower post-void residual volume.</b>	Solution modulates bladder pressure	Detrusor stimulator via electrical signal	Urine syringe to draw urine out of urinary tract	Filtration system that lowers the amount of urine entering the bladder	Bladder volume monitor in addition to normal catheter use	Gate controlled release of urine in bladder	Bladder pressure and volume monitors		
<b>Solution is removable.</b>	Solution is collapsable upon removal	Solution can be pulled from outside while in use	Solution can be visualized outside of the body	Self-Lubricant	Velcro for external solution				
<b>Material chemical composition of the solution is not toxic.</b>	Polyvinyl Chloride (PVC)	Rubber	Latex	Silicone					
<b>Leachables are present in safe concentrations.</b>	Use FDA approved material	Polyvinyl Chloride (PVC)	Rubber	Latex	Silicone				

Design Requirements	1	2	3	4	5	6	7	8	9
<b>Material chemical composition does not cause skin or inner mucosal irritation.</b>	Polyvinyl Chloride (PVC)	Rubber	Latex	Silicone					
<b>Solution does not cause long-term inflammatory response.</b>	Use FDA approved material	Rubber	Polyvinyl Chloride (PVC)	Latex	Silicone				
<b>Solution must allow for self-application.</b>	Urethral placement guide, allowing easy location	Solution fits within a purse and has quiet packaging	Solution notifies applicator of proper placement	Easily removable	Solution has anatomically appropriate angle and	Instructions do not allow for much user interpretation	Solution includes packaging to store before and	Solution has mirror to help visualize anatomical	Solution size can be personalized to user

					guide with an accessible grip	tation	after use	placement	
Design Requirements	1	2	3	4	5	6	7	8	9
<b>Solution must be portable.</b>	Foldable solution	Solution telescopes inside itself	Parts that disconnect	Solution is flexible and can be bent	Solution can be attached or worn on the body	Solution can be attached to a wheelchair	Solution can fit in purse or bag		
<b>Solution can be used in a reasonable timeframe.</b>	Permanent implant that does not require maintenance after placement	Permanent catheter that has external port to drain, eliminating need for complete catheterization	Solution monitors volume and pressure and regulates that pressure and volume automatically	Assist device for catheter insertion, aiding in urethra visualization	Device is accessible and minimal grip strength is required	Logical design, preventing user confusion	Bladder monitoring is connected to phone app		

<b>Lifetime Cost for patients must be less than current standards.</b>	Permanent implant	Reusable device	Device made of inexpensive material						
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We meticulously evaluated and refined our options through this process, ultimately narrowing our selection to the following three designs.

1. External guide for catheter insertion
2. Internal Gated Voiding Prosthesis
3. Portable Suction External Catheter.

*The external guide was designed by selecting concepts addressing insertion safety.* Since improper catheter insertion can cause discomfort, pain, and trauma to the urethra, this design concept is intended to improve the CIC insertion process to minimize these risks [30]. As such, top morphological concepts relating to patient safety during CIC were combined to address as many critical design requirements as possible.

*The internal gated voiding prosthesis was designed by selecting concepts addressing post-void residual.* When a patient is incontinent, they may have too high of a post-void residual or volume of urine left in the bladder, resulting in increased inflammation in the bladder and subsequent UTIs. This design concept was born from combining multiple ideas in our morphological chart that worked to lower post-void residual and address critical design requirements.

*The portable suction external catheter was designed by selecting concepts that could be worn externally on the body.* When researching why patients typically stop doing CIC over time, it is because of inconvenience and discomfort involving the procedure. Thus, we combined morphological concepts to create a concept that could be worn externally, with minimal effort required on the user's part to manage their bladder.

#### *Stakeholder Feedback*

We conducted stakeholder interviews with Dr. Harper, a family physician and researcher on HPV-associated diseases; Anastasia Biddix, a Veterans Affairs Registered Nurse; Dr. DeLancey, a urogynecologist specializing in pelvic organ prolapse and incontinence; Dr. Ashton-Miller, the director of the Biomechanics Research Laboratory at Michigan with research experience in incontinence, and Stacy, the mother of a patient with spina bifida. These interviews guided our concept generation as follows.

*Stakeholders stressed the importance of flexible design.* Across our stakeholder interviews, a common theme was the significance of generating a design that met the range of needs of our primary stakeholders, female SCI patients using CIC. Dr. Ashton Miller, Anastasia Biddix, and Stacy all addressed this theme by detailing how urethral visualization and subsequent catheterization is difficult in females and can be more difficult depending on body weight or labia anatomy. Dr. Harper highlighted that SCI includes a range of injuries with varying effects on bladder control and mobility, which we must address in our design.

*Stakeholders emphasized the importance of decreasing the UTI risk in women.* Stakeholders we interviewed stressed that due to differences in female and male anatomy, women are at a higher risk of acquiring a urinary tract infection than men. Dr. Harper said that women get infections because the urethra doesn't stay closed, and bacteria can get back up into it more easily and grow. Dr. DeLancey mentioned that patients who catheterize have colonized bacteria in the bladder due to the constant introduction of bacteria and that these can multiply and lead to a UTI if the immune defenses are broken down, and too many bacteria are present. This feedback was the core concept behind our gate device, as it allowed for proper urethral closing. Finally, Dr. Ashton-Miller built on this topic by mentioning a study performed at the University of Michigan in which the catheter touched a non-sterile location before being inserted into the urethra in 48 of the 81 placements [106]. He highlighted that patients with higher BMI can have difficulty in labia visualization due to increased labia length, which can decrease urethral

accessibility during self-catheterization. This raises improper catheterization risk, and as such, we propose a design that combines exposing the urethra, allowing for visualization, and guiding the catheter into the urethra.

Finally, Dr. Ashton-Miller built on this topic by mentioning that the difficult visualization of the urethra in women makes it challenging for nurses to perform sterile catheterization. He emphasized that if we could design something for women specifically, that would be ideal.

*Dr. Ashton-Miller highlighted the benefits of a labia spreader concept.* The stakeholder Dr. Ashton-Miller mentioned a study performed at the University of Michigan in which the catheter touched a non-sterile location before being inserted into the urethra in 48 of the 81 placements [106]. He mentioned that catheter placement is especially difficult with obese patients as labia length increases with BMI, resulting in a less accessible urethra. Dr. Ashton-Miller patented an idea based on this gap that will be discussed below. Our team built off this idea in the following manner: while nurses have the challenge of clean or sterile catheter placement, they can position themselves to visualize the urethra. Visualization is much more difficult in self-catheterizing, increasing the risk of improper catheterization. Thus, we propose a design that combines exposing the urethra, allowing for visualization, and guiding the catheter into the urethra.

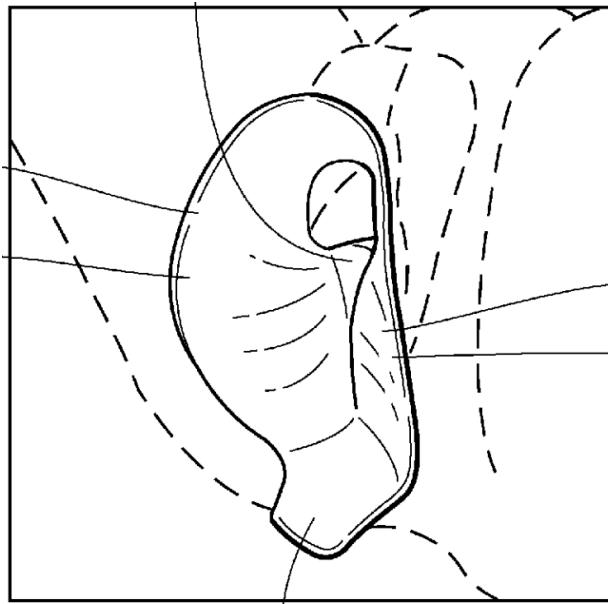
It should be noted that some of our stakeholders have valuable clinical experience that guided us in concept generation. However, they lack the experience of having SCI or working with SCI patients. As such, we acknowledge our concepts need to address experiences that they were not as familiar with.

*The interview with Stacy highlighted patient preferences in a solution.* Stacy mentioned many struggles with recurrent UTIs and her family's mitigation strategies, such as pre-lubricated, enclosed catheters. One important note here is that this is one perspective and it is important to reference studies as well when considering decisions. Further, she noted that learning how to self-catheterize was intimidating for her son, and that it is especially nerve-wracking for girls due to visualization issues or lack of feeling. She also called attention to the fact that many young adults want to be independent and live as normally as possible. Therefore, she noted that making the catheterization process simpler, faster and with discrete items would be preferable. Many of these points lined up well with our previously outlined team priorities and provided guidance in ensuring our concepts met these requirements.

#### *Patent Searches*

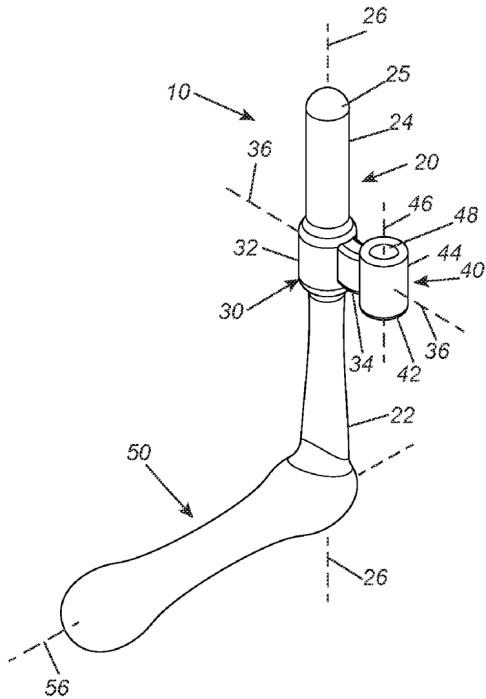
Patent searches were conducted in the scope of our brainstormed concepts and in the realm of adjacent solutions to determine what current patents exist and what potential there is for our concepts in the current design space.

*Catheter placement assist device.* As discussed above, this was invented by Dr. Jennifer Meddings, Dr. John DeLancey, and Dr. Ashton-Miller, among others. It was published internationally in November 2017. The device, seen in Figure 12 below, separates the labia to help ensure sterile catheter placement via better visualization and access. It also includes a shield that covers the perineal area to avoid cross-contamination and could include a spout into the vagina, a light, handle, or other accessories [107]. This patent describes clinicians' sterile catheter placement; however, we want to address independent clean catheter placement outside the clinic. Self-catheterization introduces a few new challenges, including visualization of one's own urethral opening and potentially having fewer hands available for maneuvering devices and separating the labia. Other patents exist to spread the labia as well; we will need to be aware of their claims as we consider our external guide concept to ensure that the design is different from the prior art [108], [109].



**Figure 12.** This catheter placement assist device helps to ensure that external tissues are displaced so that catheterization can be performed steriley [107].

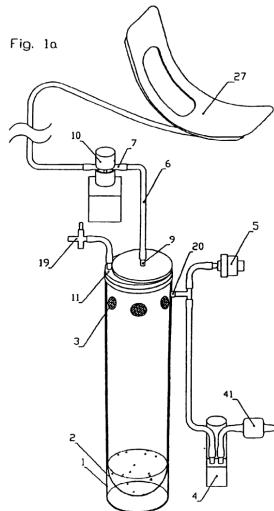
*Devices for assisting self-catheterization and methods for using such devices.* This patent was published in February of 2021 by inventors from Stanford University. This device, depicted in Figure 13 below, aims to help females catheterize without reliance on caretakers, lower the risk of infection, and fill a market gap for locating the urethra in women. It aims to make catheterization easier and thus more frequent, lowering the amount of stagnant urine and, thus, the risk of UTI. The device places an anchor into the vagina, then has a bridge towards the urethra with a guide attached, through which a catheter is placed into the urethra. This patent is one of a couple of placement assist devices that exist.



**Figure 13.** This assisted self-catheter device guides the catheter into the urethra, minimizing misses [110].

One of our concepts, the catheter guide, aims to incorporate a placement mechanism and a labia spreader as two of its components. To be granted a patent, we need to ensure that our device is novel, useful, and non-obvious [111]. In terms of novelty, we are limited in that some methods for catheter placement and spreading the labia exist as shown above, so our design needs to be substantially different. Of note, the catheter guide above anchors in the vagina to place the urethral guide, which seems to potentially pose problems with the device fitting all patients. Therefore, we aim to use a handle to keep the device in place without anchoring into the vagina as a potential aspect of our concept, which is quite different. The guide above uses the distance from the vagina to the urethra to place the catheter; however, we are considering simply adding a mirror to the design to allow placement via visualization. Further, our concept combines spreading the labia, improving visualization, and guiding the catheter into the urethra. Such prior art was not found. Importantly, a common way that patents are rejected due to obviousness is that they combine prior art elements that together are not a unique invention due to keeping each of their properties after combination. Our concept could be patented if this is kept in mind.

*Urine collection device.* This patent was published in May of 2004. The invention collects urine from the urethral opening, as seen in Figure 14 below. It includes a rigid container connected by a tube to a pump that pulls air out of the container to maintain a vacuum. The device connects to the patient either via a portable urinal or in the same position as a pad would be placed. The device can either be manually operated, or operated via a urine sensor. The patent document mentions that the device is suitable for patients “whose limited mobility makes the transfer to the toilet extremely difficult”. This might apply to our patient population - this would require talking to patients and discussing their needs, however.



**Figure 14.** This urine collection device utilizes suction and a sensor to keep a patient dry over time [112].

A popular device on the market with similar technology includes the BD Purewick Urinary Collection System [112]. However, a shortcoming of this device is that it significantly limits mobility because it is a large, rigid container. This shortcoming was the basis of one of our brainstorming sessions and led to our portable suction concept. However, as we carefully conducted our patent search, we found that this patent also describes a smaller container of 300-600 mL and a lighter pump that can be worn in a bag around the waist. Given the similarity, our concept could likely not be patented due to the novelty requirement. Of note is that we have not seen mention of this portable device being used in our research. If we choose to pursue this concept, we could continue researching whether it has been commercialized, why it is not used, and address these shortcomings, but we would need to read the claims carefully and design a device that is substantially different.

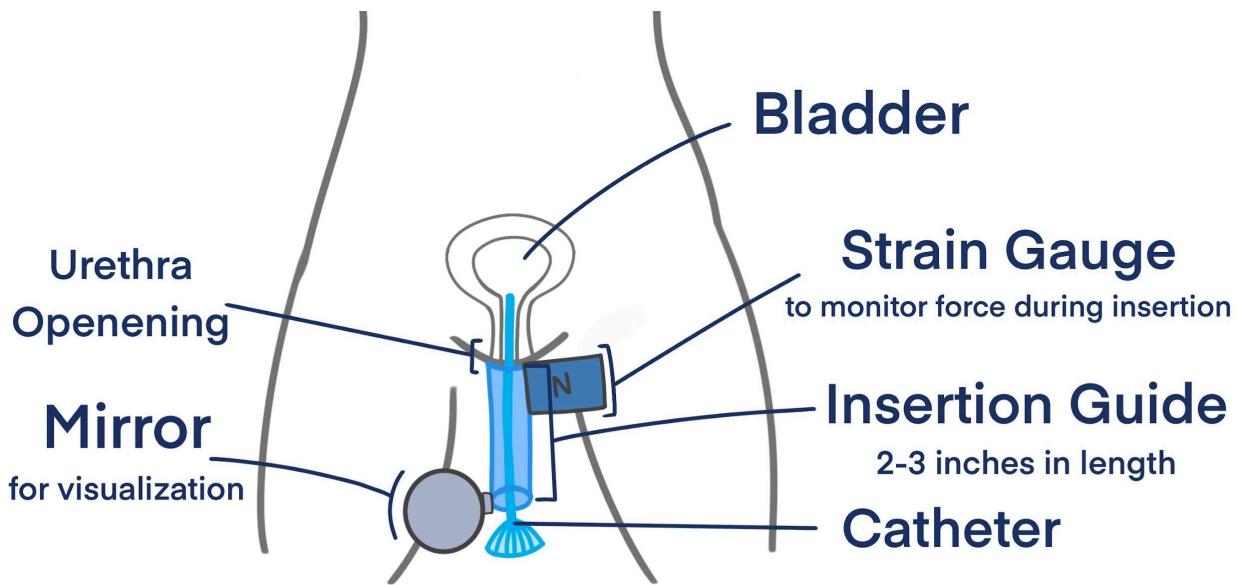
*Female voiding prosthesis.* The inFlow Urinary Prosthesis, a device placed into the urethra and replaced every 29 days, is an alternative to urinary catheters that is more similar to normal urination. It uses an activated magnetic mechanism to pump urine out of the bladder at a physiological flow rate [113]. Two patents were referenced in an FDA de novo approval presentation from the company that makes inFlow: one for a system and method for collecting clinical data associated with a medical apparatus, including an implantable device, and one for magnetically coupled implantable magnetic devices [114]. One of our concepts, a gate in the urethra that could be activated for urine flow, is similar in some aspects to this invention. However, the concept looks different, and the opening mechanism is different - battery-operated rather than via magnets. This concept could be patented because this is useful, novel, and not obvious.

### Design Concepts

Descriptions of the components and functionality of our three design concepts will be explored below. These concepts were the final results of the morphological analysis and patent searching done during concept ideation and will be evaluated to focus on a specific final design.

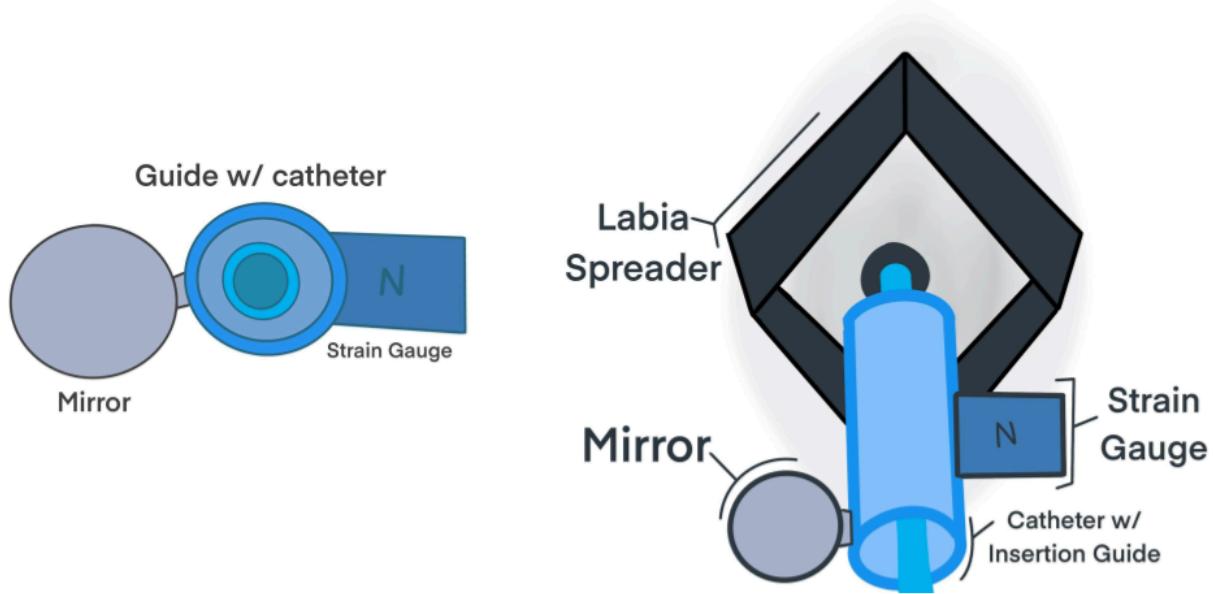
#### *External Guide for Catheter Insertion*

The external guide contains 4 major components: an insertion guide, a visualization mirror, a strain gauge, and a labia spreader, as shown in Figures 15 and 16. Detailed descriptions of each component are noted below.



**Figure 15.** The external insertion guide aims to improve the existing CIC insertion process using various unique components.

*Insertion Guide.* The insertion guide will be a hollow tube placed on the urethral opening that extends 2-3 inches, as shown in Figure 16. The diameter will ideally be fitted to the diameter of the patient's urethral opening, which addresses our design requirement for self-application. Extending this guide will help prevent the catheter from touching any skin before insertion, which was stressed by Dr. Ashton-Miller as a major source of infection. The design evaluations below will further explore this effect on preventing catheter external contact with skin. When inserting the catheter into the guide, the patient or caretaker will simply apply small pressure to push the catheter through and into the urethral opening.

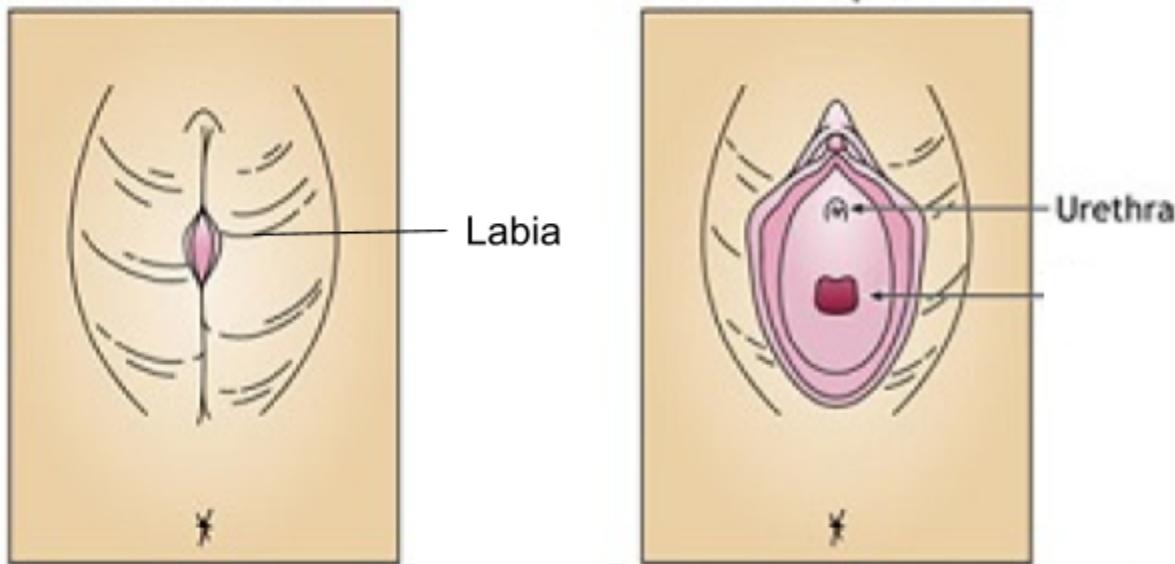


**Figure 16.** The labia spreader and mirror allow for urethral visualization. The strain gauge provides an indication of application force.

*Catheter Strain Sensor.* During insertion, excessive force can cause perforation at several layers of the urethra and damage tissue in the urethra and bladder if this force continues throughout the duration of insertion [30]. As such, this device would be fitted with a strain gauge that notifies the user of the force they are utilizing upon entry. This gauge takes the amount of force, weight, and pressure upon insertion to influence change in electrical resistance [115]. If this force exceeds the maximum force recommended for catheter insertion, 5 N, this gauge will alert the user to limit their applied force [116]. As such, this concept addresses our requirements that our solution should not break under application forces and does not damage tissues.

This also provides knowledge to the user on how to properly insert a catheter, which may not be knowledge that was previously accessible to the user based on their socio-economic status and its subsequent effect on their access to proper medical education. This status was a significant factor for us when considering the importance of this design aspect.

*Labia Spreader.* Our stakeholder interview with Dr. Ashton-Miller emphasized that catheter insertion can be difficult for certain female patients due to troubles in visualizing the urethral opening if it is blocked by the labia, as shown in Figure 17 [24]. As such, this design concept is fitted with a labia spreader that uses small mechanical force to spread the labia open and allow for proper urethral visualization during insertion, addressing self-application requirements.

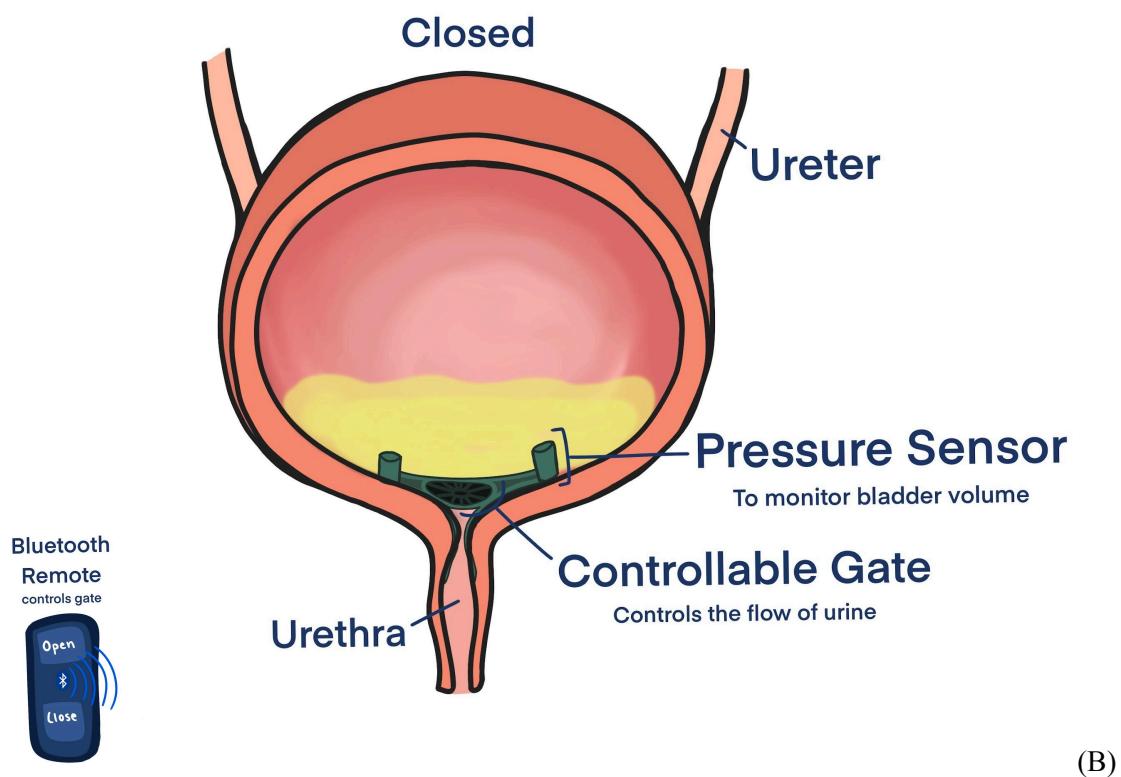
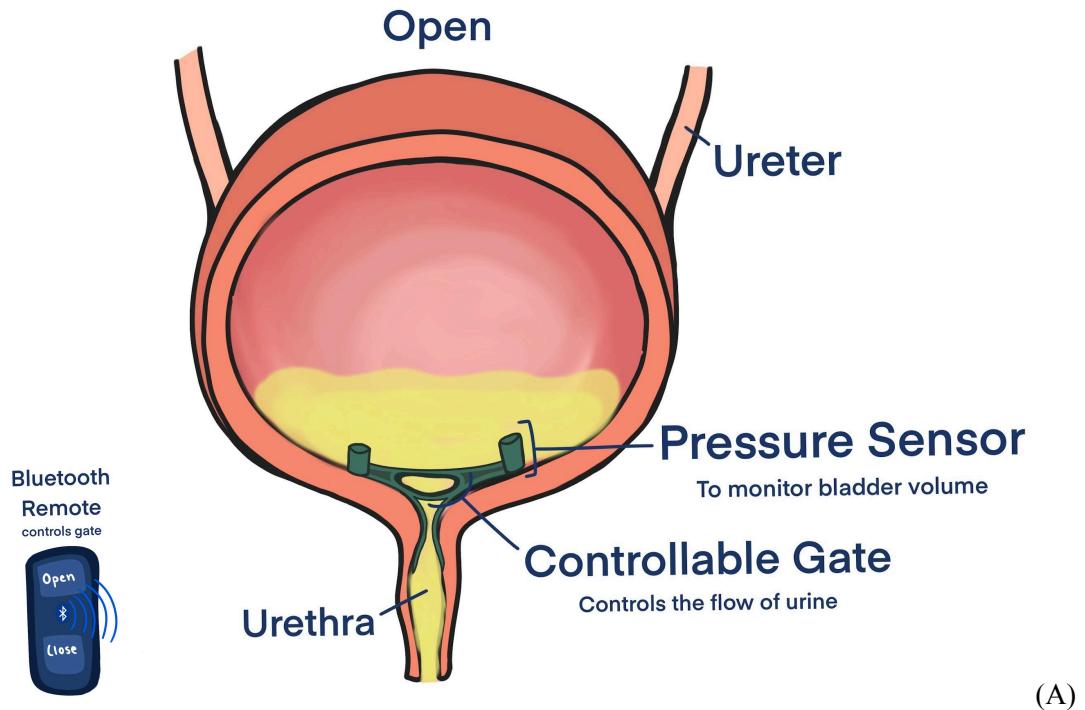


**Figure 17.** In some female patients, urethral visualization can be difficult due to the location and size of the labia [117].

*Visualization Mirror.* To allow for greater accessibility during self-application, the guide will be fitted with a mirror at the insertion end to allow a patient to fully see the catheter as they insert it into their urethra. When performing usability studies, users commonly expressed a desire to see the insertion point during self-application, and this specific concept aims to alleviate those concerns and allow for smoother insertion.

#### *Internal Gated Voiding Prosthesis*

Another important way to reduce UTIs is to lower the post-void residual. This design concept was born out of combining multiple ideas in our morphological chart – the gate-controlled release of urine and a way to monitor the volume of urine in the bladder – which work together to adequately lower post-void residual. This design concept aims to mimic health bladder function and will allow users to go about their daily routines more independently. After implantation, it is intended to stay in the body long-term, on the order of months. Stacy, one of our stakeholders, who is the mother of a son with an SCI and incontinence, stated that a solution with the most minimal things to do would be ideal. This design concept allows patients to forgo bringing catheters and other medical supplies wherever they go. Figure 18 illustrates the design concept in action inside the body.



**Figure 18.** The Female bladder with internal gated voiding prosthesis has open (A) and closed (B) states, controlled wirelessly by remote, to allow urine to flow or not.

*Device Insertion and Removal.* Ideally, this device would be inserted and removed in a non-invasive manner. The deployment mechanism would be such that it mimics placing an indwelling catheter inside a patient. The device would be folded up so that after it is placed in the appropriate location, the deployment system could be removed and the device would be left in place. This mechanism could be similar to other deployment based medical devices, such as stents. A physician would perform this placement and ensure function before sending the patient home. From there, the patient could manage the device themselves and it would remain inside their body.

*Location of Device.* This device would sit in between the bladder and the end of the urethra going into the bladder. The main concern with the location of the device had to do with comfortability. One of the existing products on the market, the InFlow, is also a voiding prosthesis; however, it spans the length of the entire urethra [113]. Clinical trials of the device reveal a very high dropout rate because patients found it uncomfortable [118]. Understandably, our team believes that a hard medical device spanning the entire length of the urethra would definitely be uncomfortable. As a result, our device would be much smaller, and situated right at the junction of the urethra and the bladder. Theoretically, this would minimize discomfort because there is less material and located further into the body so that when a user moves around they wouldn't feel it as much.

*Gate Mechanism.* The device itself would feature a gate mechanism that would open and close to allow the urine to flow. To maintain the seal around the gate, we would utilize a biomaterial that would have the properties of rubber or caulk, but it would prevent protein fouling. This could be molded around the gate portion, such that when it closes it maintains a tight seal. To ensure that the gate itself opens, it will be a battery operated technology. The battery will be enclosed around biocompatible, anti-fouling material which will not pose harm to the body. Additionally, the ideal battery is chosen such that its life lasts for many years. However, rechargeability is something we can consider further as we begin to understand exactly how long this device would realistically be inside the body. Another option for the gate mechanism would be to use magnets. While this likely poses a lower safety risk than batteries, there is a danger that by going this route we infringe upon the patent for the Inflow Device which uses magnetic coupling technology. So, for now, we have decided to go with the battery technology.

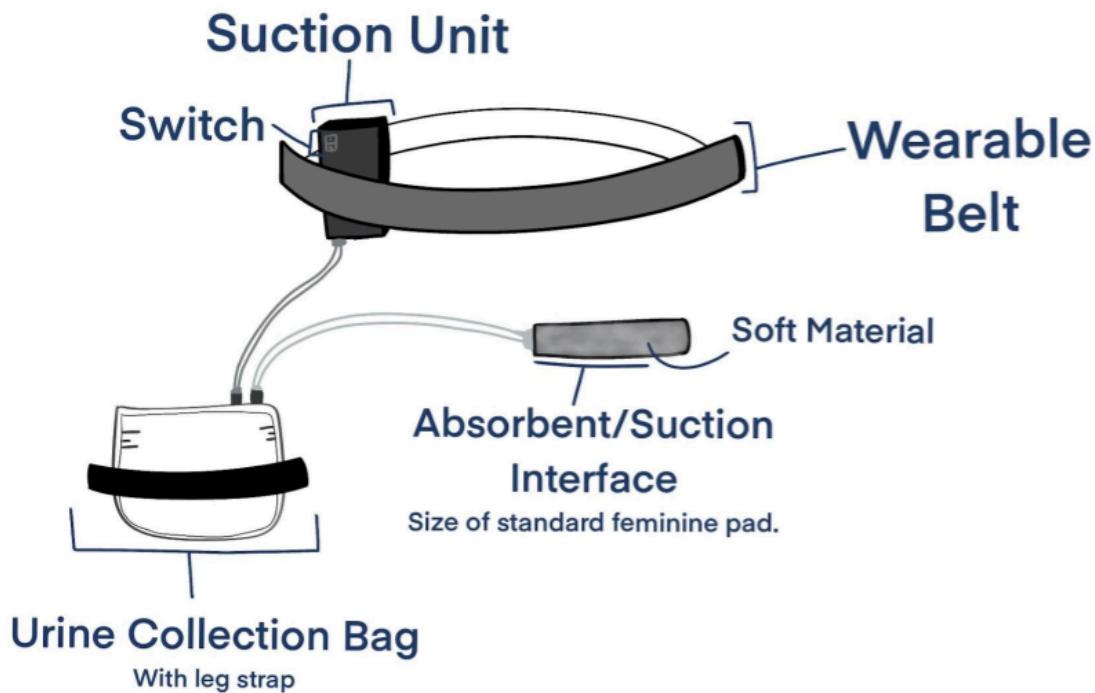
*Bluetooth Control for Users.* To ensure that this design allows for user control, we have decided to implement bluetooth control. The sensor on the device that would detect whether the bladder is full will send a signal to a bluetooth remote. There would be a sensor on this device that would calculate how much urine is in the bladder and subsequently alert the user through bluetooth that it is time to use the restroom. Once the user found themselves on a toilet, they would be able to press a button on a remote or their phone that would wirelessly open the gate on the device. When the gate is open, urine will be allowed to pass. Once the bladder is empty, the sensor will sense that and automatically close the gate while alerting the user that is closed. With any wireless technology, there is a risk that the frequency signal is attenuated by the tissues of the body and then does not allow the connection to be established. Research shows that the deeper the sensor is placed in the body, the further the signal is attenuated; therefore it is important to optimize the depth of the device within the body [119]. In females, the urethra is closer to the surface of the body, and if the signal would be sent through along the urethra, it would be approximately 40 mm deep for the average person [63]. At this depth level, Bluetooth signal attenuation will not hinder a signal from being received [120]. While conceptualizing this idea, we recognize that it is natural for us to envision its application from our own perspective. However, that may lead to us not considering other common perspectives, such as perspectives of individuals who struggle with obesity. Considering, this concept's Bluetooth signal might be attenuated more and not work for that population group as well.

### *Portable Suction External Catheter*

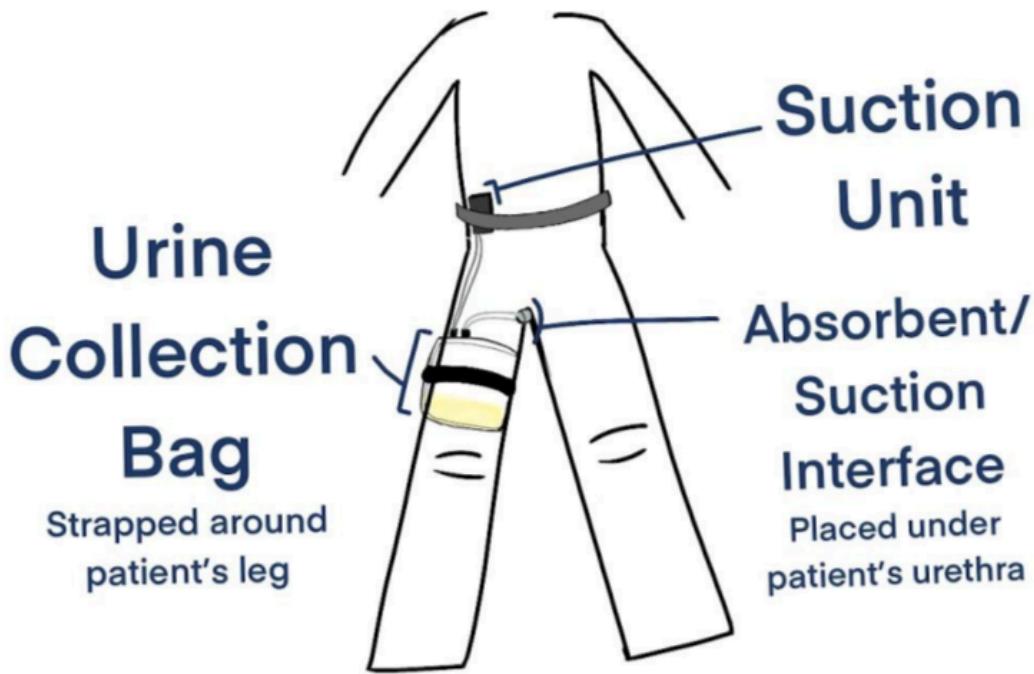
When it comes to the options for treating incontinence, the majority of them involve inserting some device into the urethra. This can not only be uncomfortable and risky but also awkward and embarrassing for some individuals. Especially if they must rely on a family member or caretaker to insert. The options for incontinence management greatly lack options that are easily self-applicable, especially for female patients, and that are non-invasive. After producing and analyzing our morphological chart, we devised the idea to potentially design an external portable suction device.

The goals of this device would be to improve comfort while managing incontinence, offering a non-invasive treatment method, and increasing independence in female patients with SCIs. This device's purpose would be to absorb and remove any liquid or moisture released throughout the day. Storing the urine in the collection bag until the user could empty or replace the bag. Removing excess moisture and liquid would increase user comfort while reducing the risk of UTIs. Additionally, since the device will sit on the outside of the body, the device could be easily placed without exposing the patient. This potential design would solve many of our design challenges but also pose a higher risk for others when compared to CIC.

Figure 19 shows the various components of the portable suction catheter. Components such as the suction unit, urine collection container, absorbent/suction interface, and the wearable belt. Figure 20 shows the relative size and placement of the device on a female patient.



**Figure 19.** Portable suction external catheter consists of a urine collection bag, a suction unit that is worn on a belt, and an absorbent pad which is placed on top of the urethra.



**Figure 20.** Diagram of suction device on female patient, with intended placement for use.

*Suction Unit.* A battery operated suction unit, potentially fastened around the waist of the patient. The suction unit would be connected to the suction end and the collection bag through plastic tubing. We would aim for our suction unit to weigh less than 3.69 kg, since that is the average weight of existing powered suction devices on the market [121]. We would want it to weigh as little as possible to remove any physical strain it may cause to the user. Additionally, we would aim for the suction unit to maintain a suction water flow rate of at least 3.93 L/min to ensure it provides adequate suction timing [121].

*Wearable belts.* The device would include two kinds of wearable straps/belts. One for the suction unit, to be placed on the patient's waist and allow for customizable placement of the suction unit. The second strap/belt for the urine collection container to be strapped to one of the patient's upper thigh. The purpose of the second belt would be to ensure that the urine collection container would be secure during daily activities.

*Urine Collection Container.* Ideally, the collection container would be a bag, and could be strapped to the user's upper thigh. This would hopefully allow for smooth and comfortable placement, when compared to a hard plastic container. Which is what is common for many kinds of suction devices [122]. The urine collection container would be connected to the suction unit to collect all waste. The collection container would also be easily replaceable.

*Absorbent/Suction Interface.* The absorptive suction end would be designed to be placed in the patient's undergarments directly beneath their urethra, roughly equivalent in size to a standard feminine pad. This would diminish the patient's need for clear and precise visualization of their urethra. The absorbent/suction interface would also be replaceable, with either reusable interfaces or disposable ones. It's worth noting that if our team was to pursue this concept idea, we would want to prioritize making the interface reusable or low cost, low environmental impact disposable ones. This objective stems from an

examination of existing solutions involving expensive disposable absorbent suction ends. With each absorbent end requiring replacement every 8-10 hours and costing \$6-\$7 each [123], it could impose a significant financial burden on patients. It's important to recognize that this may not be feasible for all individuals.

*Similar Existing Solution*

There are similar devices to this idea, such as the PureWick external urinary catheter; however, they are not portable and are usually used for minimal incontinence management. The PureWick has an initial cost of upwards of \$500, with a high routine maintenance cost for disposable components, as we discussed in the previous paragraph. The PureWick has a 2000cc hard canister with a lid and the standard unit requires connection to a power supply [124].

## **Design Evaluation & Consensus**

A Pugh Matrix was generated to evaluate the validity and efficacy of each concept. Further discussion of the Pugh Matrix framework and concept scoring will be described in detail below.

### *Pugh Matrix*

All design requirements were scored except those relating to biocompatibility. This is because we are not far along enough in the design process to make decisions regarding material selections for each design concept. These scores will be entirely dependent on the materials that we choose, due to the varying biological responses to different biomaterials that we would need to consider to justify a score. As such, each concept was given a 0 for these requirements, and these scores will be refined as we continue through the design stage and make material selections. The requirements affected are as follows: Material chemical composition of the solution is not toxic; Leachables are present in safe concentrations; Material chemical composition does not cause skin or inner mucosal irritation.

*Scoring Scale.* For our Pugh matrix, we decided on a scoring scale between -2 and +2. All of our scores represent the concept's ability to meet the design requirements and their specifications. 0 will represent the baseline comparison device, which is the gold standard treatment CIC. If any concept is assigned a score of 0 in a design requirement, it is because we expect it to perform similarly to CIC. A score of +1 is given to a design concept when it improves upon CIC in that design requirement, but there is still room for improvement. A score of +2 is given to a design concept when it completely fixes the issue and eliminates most of the risk associated with the design requirement. A score of -1 is given to a design concept when it performs worse than CIC and increases the risk associated with that design requirement. Finally, a score of -2 is given to a design concept when it performs worse than CIC and introduces additional risks not associated with CIC.

*Weight Scale.* For the weights that are used in our Pugh Matrix, we justified them similarly to the way we prioritize our design requirements. Our scale is from 1 to 5, where 5 is the highest weight and 1 is the lowest weight. Number 5 on the scale represents design requirements that provide the most immediate safety risk to the patient. 4 represents design requirements that involve a level of risk to the patient, though this risk is not as pressing or substantial as the ones assigned a weight of 5. 3 represents requirements that have the potential to result in long-term health effects. Weights of 3 to 5 essentially represent our critical design requirements. 2 represents non-critical design requirements, but plays a significant role in promoting patient independence and accessibility. Finally, 1 represents design requirements that are desired by the patient, but they are not critical for the functionality or usability of the device. Table 5 shows the final constructed Pugh Matrix with the applied scoring and weighting scheme for design requirements and 3 distinct concepts.

**Table 5.** Pugh Matrix displays the overall rankings of each requirement for each design.

	<b>Weight</b>	<b>Baseline (CIC)</b>	<b>Design Idea 1 - Insertion Guide</b>	<b>Design Idea 2 - Gate Device</b>	<b>Design Idea 3 - Portable Suction</b>
Solution does not damage tissues.	5	0	1	-1	2
Solution does not fracture at any time during internal use.	5	0	0	-1	2

	Weight	Baseline (CIC)	Design Idea 1 - Insertion Guide	Design Idea 2 - Gate Device	Design Idea 3 - Portable Suction
Solution will not break under normal application forces.	5	0	0	0	2
Solution should not experience displacement during use.	5	0	0	-1	-2
Solution can be sterilized with common methods.	4	0	0	1	0
Sterile packaging that maintains appropriate sterile shelf life is used for our solution.	4	0	0	0	0
Must adequately lower post-void residual.	4	0	0	2	-2
Solution is removable.	4	0	0	-1	2
Material chemical composition of the solution is not toxic.	3	0	0	0	0
Leachables are present in safe concentrations.	3	0	0	0	0
Material chemical composition does not cause skin or inner mucosal irritation.	3	0	0	0	0
Solution does not cause long-term inflammatory response.	3	0	0	-1	1
Solution must allow for self-application.	2	0	2	2	2
Solution must be portable.	2	0	1	1	2
Solution can be used in a reasonable timeframe.	2	0	1	1	1
Lifetime Cost for patients must be less than current standards.	1	0	1	1	-2
Typical urine flow must be maintained.	1	0	0	2	0
<hr/>					
<b>Net Score</b>			14	0	14
<b>Rank</b>			1	3	1

*Solution does not damage tissues*

By striving to minimize the risk of erroneous insertion, the external guide not only reduces the likelihood of tissue damage but also contributes to enhancing the overall safety of CIC, earning it a score of +1.

The proposed internal gated voiding prosthesis is designed to be strategically positioned between the urethra and the bladder opening, facilitated by a specialized deployment mechanism, and its placement requires the expertise of a trained physician. Once positioned, the device is designed to remain stationary, minimizing the risk of damaging tissues. Its replacement frequency, measured in months, contrasts significantly with the more frequent CIC insertions (occurring 4-6 times a day), reducing the overall impact on tissue health by limiting the frequency of insertions and removals from the urethra. It is crucial to acknowledge that, unlike CIC, where tissues are intermittently in contact with the device, the proposed design entails prolonged contact on the order of months. However, this extended contact duration introduces potential risks, as movements from the patient or external forces could dislodge the device, potentially causing damage to internal tissues—a risk not associated with CIC due to its non-implanted nature. Considering these advantages and drawbacks, the proposed prosthesis earns an overall score of -1.

Because the portable suction device would be entirely external, the risk of potentially damaging a patient's tissues is significantly reduced compared to CIC, earning the portable suction device a score of +2.

*Solution does not fracture at any time during internal use*

The insertion guide does not affect the mechanical properties of the CIC, meaning it does not affect the CIC's tendency to fracture during internal use, resulting in a score of 0.

The gate device will experience forces from the pressure of the urine and the urethral muscle while being held in place, meaning it must withstand a higher range of potential conditions for a longer period of time. We anticipate the device's mechanical properties to be stronger than that of CIC. The design components are intricate, making the task of ensuring its mechanical integrity more challenging. Consequently, we assign it a score of -1.

The portable suction device, intended for external use, eliminates the risk of fracture during internal use, resulting in a score of +2 for this design idea.

*Solution will not break under normal application forces*

Mockup day studies were instrumental in evaluating the insertion guide for this requirement. However, the gate device and the portable suction device lacked relevant studies for this aspect and were assessed using methodologies similar to previous requirements.

*Insertion force analysis of insertion guide through mockup studies.* Mockup studies consistently demonstrated a higher catheter application force when utilizing the guide, suggesting a potential elevated risk of fracture during insertion. Participants, in subsequent mockup testing, rated their resistance level for insertion using the guide compared to CIC on a 0-3 scale (see Table 6). The average responses during self and caretaker application were 1.4 and 1.75, respectively, indicating a moderate to sufficient insertion resistance with the guide. This heightened resistance may prompt patients to exert slightly more force during catheter insertion, amplifying the risk of fracture. It is crucial to acknowledge that prototyping with an attached strain gauge has not been undertaken yet. There is a possibility that individuals could be more conscious of their insertion force if provided with an indication of acceptable force ranges. Consequently, a preliminary rating of 0 was assigned due to inconclusive results regarding the potential benefits of a strain gauge during insertion. Future mockup studies are imperative to analyze this user effect, and the rating will be refined upon the acquisition of relevant data.

**Table 6.** Study participants utilized a quantitative rating scale to summarize resistance to catheter insertion using an external insertion guide. On average, it was reported that this guide added moderate to sufficient resistance to the overall insertion process

<b>0</b>	No resistance to insertion, took no added force other than force needed to grip catheter to guide insertion
<b>1</b>	Some resistance to insertion, but took minimal effort to guide insertion
<b>2</b>	Resistance to insertion, took significant added force to guide catheter through the insertion
<b>3</b>	Significant resistance to insertion, took strenuous effort to guide catheter through insertion/was not able to insert catheter due to resistance

The gate device is designed to be inserted and removed using a deployment mechanism similar to CIC. Therefore, it is important that it possesses comparable mechanical properties to endure these actions. Consequently, we have assigned it a score of 0.

The portable suction device received a score of +2 for this design requirement. This evaluation is based on the minimal physiological forces applied to the solution and the fact that no application force is needed to utilize the potential device.

*Solution should not experience displacement during use*

The insertion guide will not affect the movement of the catheter inside the patient's body during use, earning it a score 0.

The gate device's effectiveness during its presence in the patient's body relies significantly on minimizing displacement. Any displacement could lead to urine leakage even with the gate closed—a concern not present in CIC, where user-controlled displacement is intended, and removal follows use. Unlike CIC, our proposed device introduces an additional risk of preventing displacement. In CIC, uncontrolled catheter movement poses safety hazards, such as urethral lining puncture, bladder damage, and inadequate urine removal. Our device aims to remain fixed between the bladder and urethra, reducing the risk of repeated tissue damage seen in CIC. While slight movement remains possible, it represents an improvement over CIC. Considering both positive and negative aspects compared to CIC, with the negative improvements posing a higher risk, we assign a score of -1.

The suction device, designed for easy removal and adjustment by the patient, poses a notable risk of displacement during use. As it is intended for continuous use throughout the day in various situations, the potential for suboptimal placement is heightened. Consequently, the design earned a score of -2. In the event of significant displacement, the patient could experience unfortunate accidents.

*Solution can be sterilized with common methods*

Considerations for concept material selection are not yet incomplete, preventing the ability to assess sterilization options at this stage of the design process. This encompasses sterilization methods such as ethylene oxide "gas," steam/autoclave, dry heat, and microwave sterilization, each yielding varied effects depending on the material in question. Consequently, the insertion guide is assigned a score of 0.

The gate device, similar to CIC, requires pre-insertion sterilization. Given that patients won't handle the device's removal and insertion at home, considerations for home sterilization methods like boiling or

washing with soap and water are unnecessary. With fewer sterilization methods to account for compared to CIC, we assign it a score of +1.

Since the material for our portable suction device has not yet been finalized, its compatibility with sterilization methods remains uncertain. Consequently, we have assigned it a score of 0. Ideally, we aim to choose a material compatible with common sterilization methods, and we will reassess this criterion after material selection.

*Sterile packaging that maintains an appropriate sterile shelf life is used for our solution.*

Considerations for concept packaging dimensions and material selection are incomplete for all devices, meaning the sterile shelf life cannot be calculated at this point in the design process. As such, the insertion guide, gate device, and suction device all score 0.

*Must adequately lower post-void residual*

The insertion guide does not alter the mechanism at which the CIC induces urine flow from the bladder for emptying to lower post-void residual (PVR), resulting in a score of 0.

Similar to CIC, the gate device contributes to reducing post-void residual. However, it achieves this in a controlled manner through the gating mechanism. Real-time monitoring of post-void residual is facilitated by the sensor, providing timely alerts to the user for restroom use. Consequently, our device presents additional enhancements for effectively lowering post-void residual compared to CIC, thereby decreasing the risk of developing a UTI. Based on this rationale, we assign a score of +2.

The portable suction device is a completely external device, it will not enter the urethra or bladder. Due to this reason, the device will not be able to reduce PVR volume, earning a score of -2 when compared to CIC.

*Solution is removable*

The insertion guide does not modify the dimensions of the CIC, thereby having no impact on its removability. As a result, it is assigned a score of 0.

The proposed gate device is not intended to be removed from the body for long periods of time on the order of months. With such a design, this imposes an increased risk of long term inflammation that could lead to damage of the surrounding tissue. On the contrary, CIC is meant to be removed after each use, which leads to a lower risk of inflammation and subsequent UTI. Because of the increased risk with this device, it is given a score of -1.

With the potential suction device being external and easily moveable. It earned a score of +2 since it will 100% be removable without any additional risk.

*Solution does not cause long-term inflammatory response*

Long-term inflammatory response has the potential to be affected by the material choice and the time the material is in contact with the body. Since material choice has not been finalized for any of the devices, we will instead focus on the time that the concepts are in contact with the body.

The external catheter insertion guide device will not change how often CIC is in contact with the body and thus earns a score of 0.

The gate device is intended to be a long term solution that is implanted within the body. This introduces a greater risk of inflammation and subsequent UTI as opposed to CIC; however, since the device is fully

within the body it will have a lower risk of UTI compared to indwelling catheters. As such, it is scored a -1. Scoring can be subject to change once more design details are finalized.

For the suction device, it will be in contact with the external genital tissue for hours at a time. While this may cause some external skin irritation, it will not cause any inflammation to the internal urinary structures. CIC, on the other hand, will be inserted into the urethra and may cause more inflammation. Therefore, we do not expect the suction device to produce a long-term inflammatory infection and will potentially perform better than CIC, so it scores a +1.

*Solution must allow for self-application*

Mockup day studies were instrumental in evaluating the insertion guide for this requirement. However, the gate device and the portable suction device lacked relevant studies for this aspect and were assessed using methodologies similar to previous requirements.

*Self application analysis of insertion guide through mockup studies.* The insertion guide dramatically shows an increase in the ability of an individual to apply CIC to themselves while also eliminating nearly all external contact during insertion, which can be a major risk for UTI, as explained in our stakeholder interview with Dr. Ashton-Miller [24]. When performing mockup studies, observations were made of how often participants made contact with an external skin surface on an anatomical model prior to self-catheterization using both CIC and the insertion guide. On average, subjects made contact with the external surface about 7.667 times prior to insertion performing CIC without the insertion guide as shown in Table 7, while no subject made contact with an external surface while performing CIC using the insertion guide. By removing this external contact, the guide eliminates the majority of the infection risk that comes with CIC. By eliminating the majority of UTI risk during self-application, this concept was given a score of +2.

**Table 7.** Individuals contacted an external surface with a catheter over 7 times on average prior to insertion, greatly increasing the risk of infection upon insertion.

Number of times catheter touched external surface prior to insertion	
Individual	Touches
A	6
B	9
C	16
D	6
E	5
F	6
G	8
H	7
I	6
Average	7.666666667

Following the insertion of the gate device by a medical professional, control is handed over to the patient via a wireless remote, enabling them to open and close the gate, regulating the passage of urine. Unlike CIC, which may be challenging for spinal cord injury patients with paralyzed hands, our solution offers

programmability for exclusive user operation. Whether through manual control or voice commands via a phone app, our solution addresses the limitations of CIC, earning it a score of +2.

The suction device facilitates convenient incontinence management, providing a less invasive option. Consequently, the design is awarded a score of +2 when compared to the challenging aspects of self-applying a CIC. The suction device reduces the demands on time, knowledge, practice, and discomfort associated with CIC self-application.

*Solution must be portable*

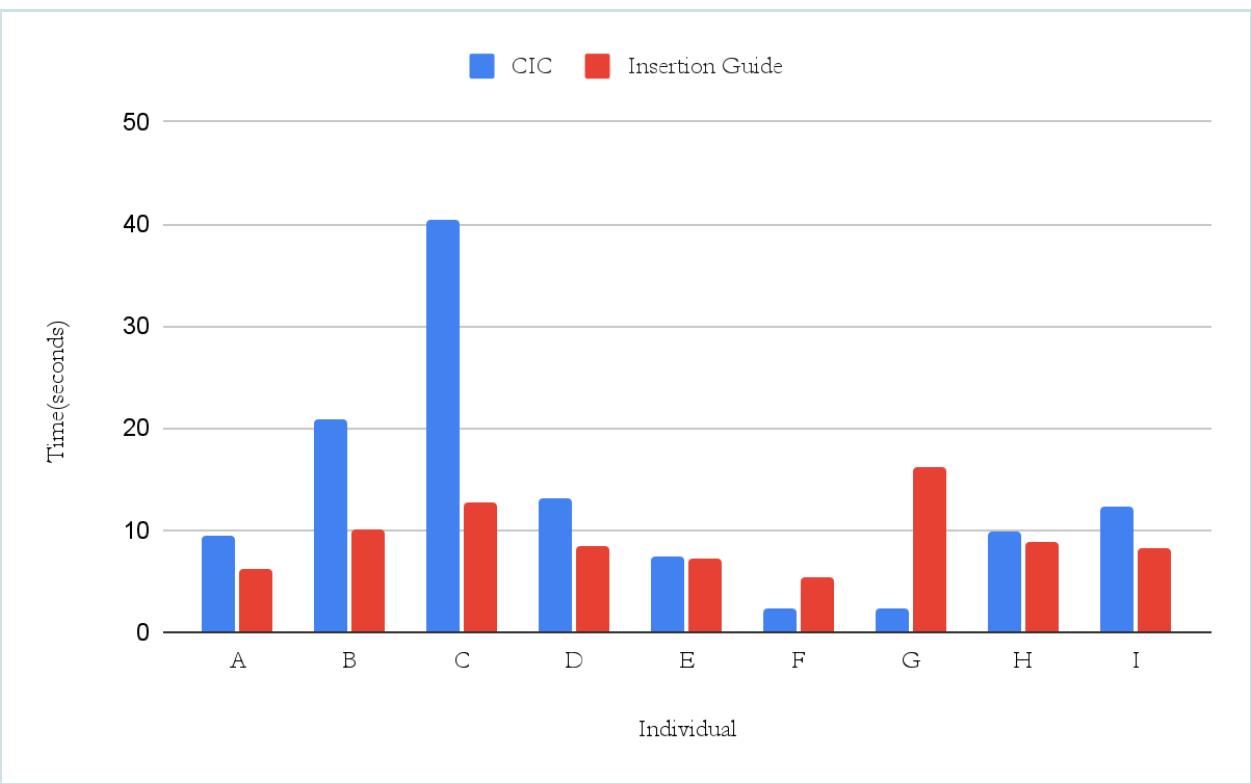
The insertion guide would allow for individuals to have more accessibility in performing CIC outside of their home, as individuals would be more readily able to perform CIC without the need for a caretaker. As such, this concept increases user accessibility and improves upon CIC portability, earning a score of +1.

With the gate device, users only need a remote to operate the device, eliminating the need to carry catheters everywhere. Many individuals find carrying catheters for CIC inconvenient, with frequent insertions being tedious and posing infection risks in public places due to potential breaches in aseptic technique. The remote can also function as a phone app, a commonly carried item. In usability testing, users expressed that this feature "increased their independence" and "normalized bathroom visits." The improved portability compared to CIC results in a score of +1.

The suction device earns a score of +2, because the device focuses on improving upon a current solution that has similar function but is not portable. The solution is designed with the intention of optimal portability.

*Solution can be used in a reasonable timeframe*

The insertion guide demonstrated a notable improvement in the time patients needed for the CIC insertion process during self-application. In mockup testing, participants, on average, spent 13.133 seconds on CIC insertion without the guide, compared to 9.25 seconds with the guide. Among the 10 individuals measured, 9 experienced faster insertion times using the guide, as depicted in Figure 21. While this concept enhances insertion times, its impact on preparation, usage, and disposal times remains uncertain, prompting a score of +1 instead of 2. Future mockup studies will delve into the time considerations for these processes.



**Figure 21.** When using an insertion guide, the majority of individuals reported faster insertion times when self-catheterizing.

The gate device mimics healthy physiologic bladder control. Users will be alerted as their bladder begins to fill up as healthy bladders do, and they will know when to use the restroom. During urination, the users simply have to press a button to open the gate, and the urine will flow. There is no need to perform an aseptic technique and locate the urethra, which you have to do with CIC, which will add additional time to urinate. As such, this is scored +1.

The portable suction device would be made with the intention to be wearable throughout the day, through a patient's daily activities. Since it will be continuously available, it would efficiently manage incontinence symptoms without requiring very much time dedication, thus earning the device a score of +1. Since we are unsure of how much time a user might dedicate to setting up the device, or any potential daily maintenance, we are unsure of what would be considered a reasonable timeframe. However, further into the design process, we will reevaluate this requirement in further detail.

#### *Lifetime cost for patients must be less than current standards*

Seeing as the insertion guide concept has no effect on the frequency of use of CICs and will induce some additional costs for our primary stakeholders, it will be more expensive than CIC. However, we believe this guide will lower UTI rates resulting from improper insertion, limiting costs for UTI treatment. SCI patients using CIC experience about 10.3 UTI cases/10,000 days of use [125]. Assuming patients would utilize CIC for a time frame of about 40 years, we can estimate this total UTI incidence rate to be about 15 over the course of a patient's lifetime. Utilizing a mean cost of conservative antibiotic therapy of approximately \$50 and estimating that we are able to limit the 40% of UTI cases that occur in catheterized patients due to improper insertion, the total cost savings for UTI prevention from our device can be estimated to be \$300 [126]. We aim for the lifetime cost of this concept to be less than \$300, earning this concept a score of +1. Several assumptions, including the device's lifetime effectiveness in limiting UTI incidence, overall UTI rates for patients, and varying costs of UTI treatments, were

considered in this calculation. This cost estimate will require refinement through validation and verification testing to assess the concept's effectiveness. Further refinement will also occur during stakeholder interviews with SCI patients using catheters. As socially engaged engineers, our goal is to make this concept universally accessible, independent of an individual's socio-economic status. This approach empowers those with limited influence in incontinence management by providing access to treatments that might otherwise be unavailable.

To estimate the lifetime cost of the gate device, we can compare it to the InFlow device. This is because it is also a long term use device to help with incontinence, similar to our proposed gate device. To start, the cost per self-catheter is \$1.70 [127]. Assuming patients would utilize CIC for a rough time frame of about 40 years, with CIC being done at most 6 times a day, this would amount to 87,600 catheters in a lifetime. This equates to a lifetime cost of \$156,804. From the InFlow device's company page, we see that 12 InFlow devices replace 2400 self-catheters [128]. This would amount to approximately Total of 36.5 InFlow devices that a patient goes through. While our team was unable to find the exact cost of the InFlow device, from this statistic we see that significantly less devices are needed when compared to the CIC and will likely cost less than the CIC lifetime cost of \$156,804. Even though our gate device is more complex than CIC, including batteries and bluetooth remote control, it is like the InFlow device and does not need constant replacement. Therefore, we hypothesize that the lifetime cost for the gate device will be significantly less than purchasing all those catheters for CIC and it scores a +1.

To estimate the lifetime cost of the Portable Suction device we are able to look at the PureWick female external catheter device that is a stationary suction device. The initial cost of the PureWick is about \$500 [124]. It has a couple components, the canister, the tubing, the power supply/battery component, and the disposable external catheter. The external catheter should be replaced every 8-12 hours and replacements for these external catheters are about \$6-\$7 [123]. The canister and tubing should be replaced every 60 days, and costs about \$50 each time [129]. Assuming that the device is being worn throughout the day, the external catheter should be replaced at least twice a day costing around \$14 per day. Assuming a user is using this device for about 40 years, it would cost about \$204,400 for a lifetime supply of just the external catheters. With the canister and tubing needing to be replaced every 60 days, a user would need to replace it 6.1 times for one year. Leading to a lifetime cost of about \$12,200 just to have an up to date canister and tubing. Combining the lifetime costs of the external catheter and the replacement costs of the tubing and canister with the initial PureWick purchase, a user is looking at a lifetime cost of about \$217,100. Which is considerably larger than the lifetime cost of CIC, which is \$156,804. Since it is significantly more expensive than CIC, it earns the portable suction device a score of -2.

#### *Typical urine flow must be maintained*

The insertion guide does not affect the functionality of the catheter while inside the patient; therefore, it has no effect on the maintenance of urine flow during catheterization and is scored a 0.

The gate device will be sized appropriately to the average diameter of the female urethra, similar to how CIC catheters are sized. There will be no leakage or hindered flow with our device. However, our device will be analogous to healthy bladder control, such that urine will only flow when the bladder is full, and the patient will be alerted when the bladder is full. This is an additional benefit when compared to CIC, with which you cannot tell when the bladder is full and there may be leakage. Thus, this will be scored a +2.

The suction device will not be inserted into the urethra or bladder, it will not have influence over the rate of urine flow. Since the device will not increase or decrease the risk of altering typical urine flow, it earned a score of 0.

### *Final Concept Scores*

The pugh matrix scoring led to final scores of +14 for the insertion guide, 0 for the gate, and +14 for the portable suction device. Based on these scores, the insertion guide and portable suction device showed clear improvements over the CIC gold standard and will be highly considered when converging to a final design solution.

### *Lead Concept Discussion*

To narrow down our final design concept, we excluded any concepts scoring less than or equal to 0, indicating they wouldn't surpass the current standard, CIC. Consequently, the gate device was eliminated. The ultimate design selection considered uniqueness, benefits to primary stakeholders, and feasibility, leading us to choose the external insertion guide.

After consulting with stakeholders, it became evident that discreetly implementing the portable suction device might pose challenges, potentially complicating incontinence management. Additionally, we concluded that it might be more suitable for treating lower levels of incontinence, as displacement during use could result in uncomfortable complications for the patient. We also deemed the external insertion guide as more innovative compared to the suction device, which resembles an existing device on the market, the PureWick.

Our Insertion Guide boasts four distinctive features—the guide, force gauge, labia spreader, and visualization tool—offering unique benefits not currently replicated by devices on the market. Moreover, we believe the aspects required to build and test this device are achievable within the course's timeframe. Initial testing results highlight a significant risk of the catheter touching an external surface without a guide, directly addressing our needs statement of reducing the risk of UTIs. Finally, this concept aligns with high-priority team goals, such as enabling self-application and decreasing usage time. The design details for our Insertion Guide will be outlined in Design Outputs.

## **IV. Design Outputs**

This section outlines how the SaniCath model was created. Detailed justifications for various design choices will be described below.

### **Device Design**

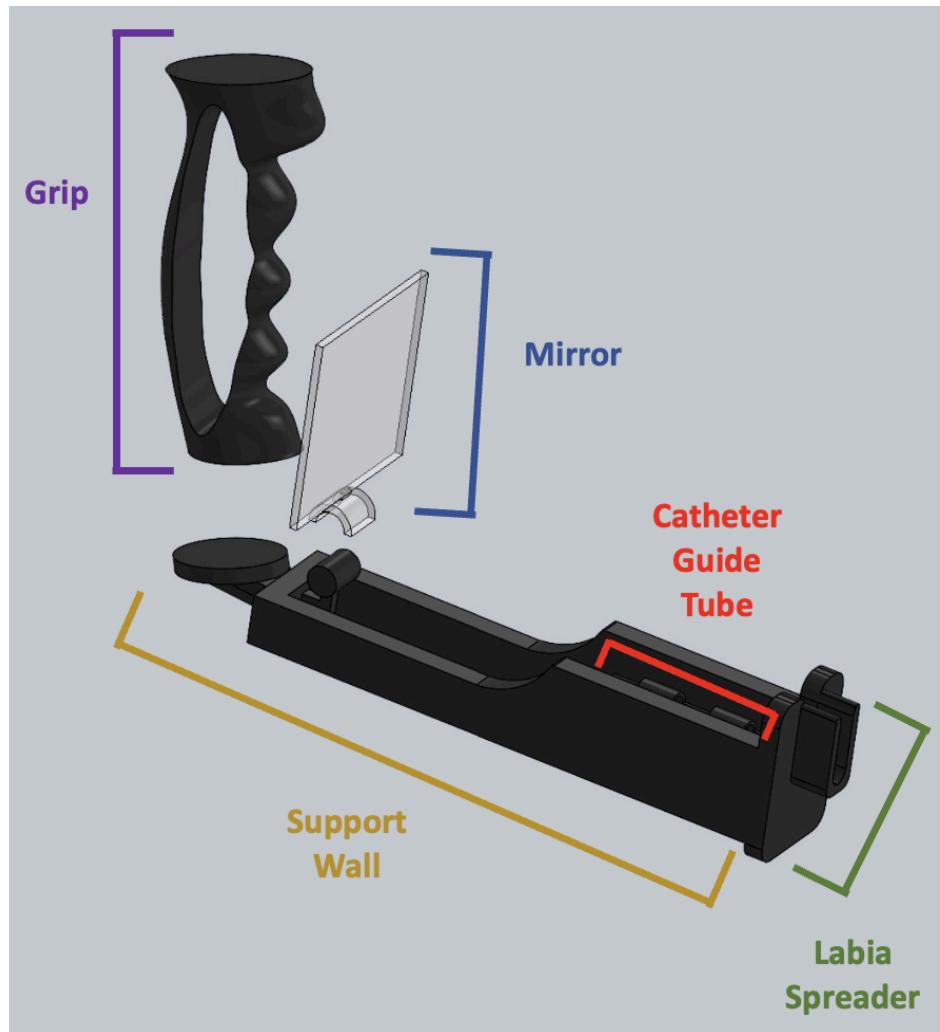
The following section details the device design including purpose of the device and a device overview.

#### *Device Purpose*

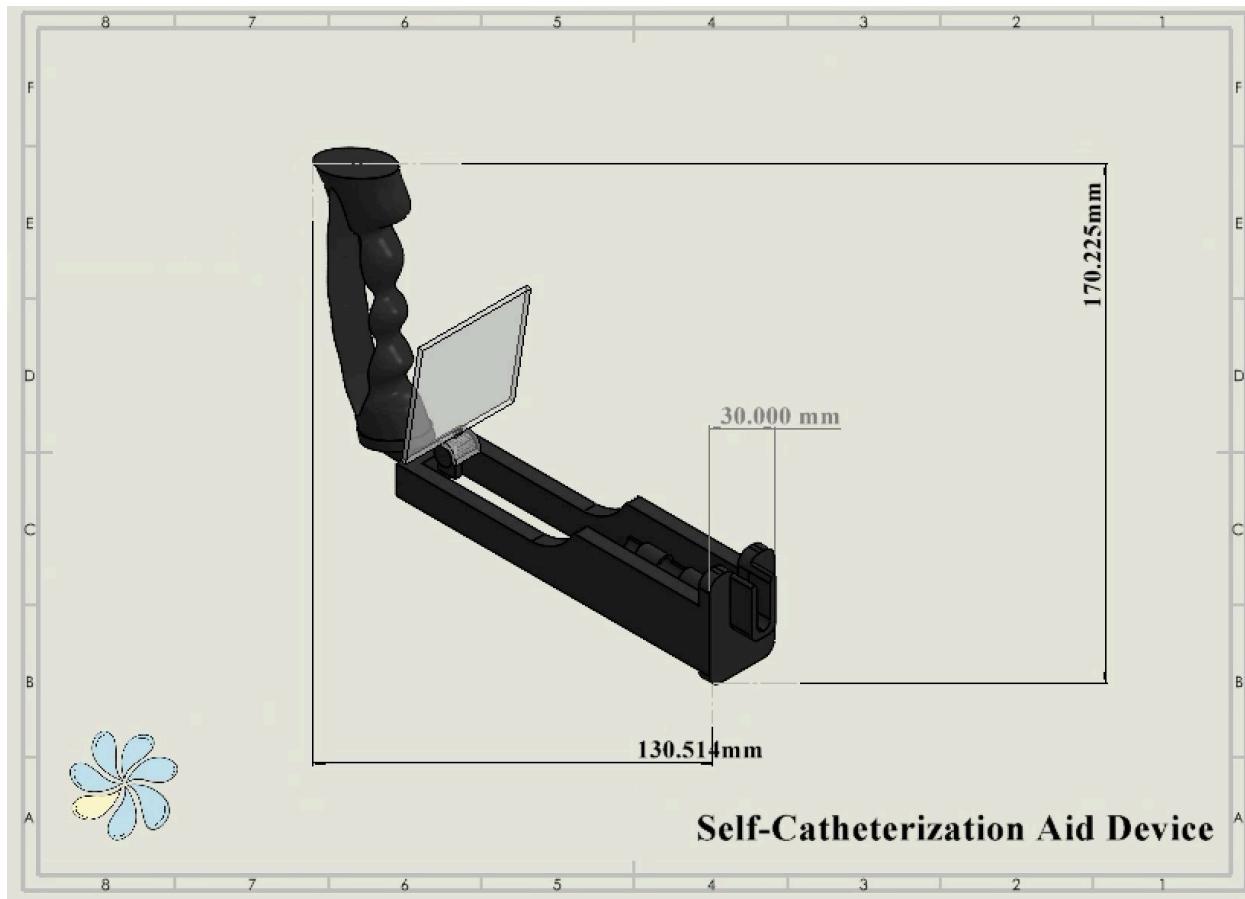
This device was created to improve incontinence management resulting from SCI in female patients who use clean intermittent catheterization (CIC) to decrease the risk of urinary tract infections.

#### *Device Overview*

This device can be used by female SCI patients or their caregivers to aid in CIC by improving visualization, sterility, and independence. It is intended to be used as one piece; however, there are multiple sections of the device that we will refer to with their own names. The following design concept and naming scheme for the SaniCath is shown in Figure 22. Figure 23 shows a drawing of the device's overall dimensions. Further details on how and when the device can be used, its specific components and composition, and justifications for the design will be detailed below.



**Figure 22.** SaniCath contains a hand grip, mirror, catheter guide tube and labia spreader to facilitate ease of self-catheterization in female SCI patients and caregivers.



**Figure 23.** SaniCath has dimensions that allow it to be handheld and portable.

## User Operation

An overview of how users will interact with the proposed device as well as how its implementation improves the current CIC standard is described below.

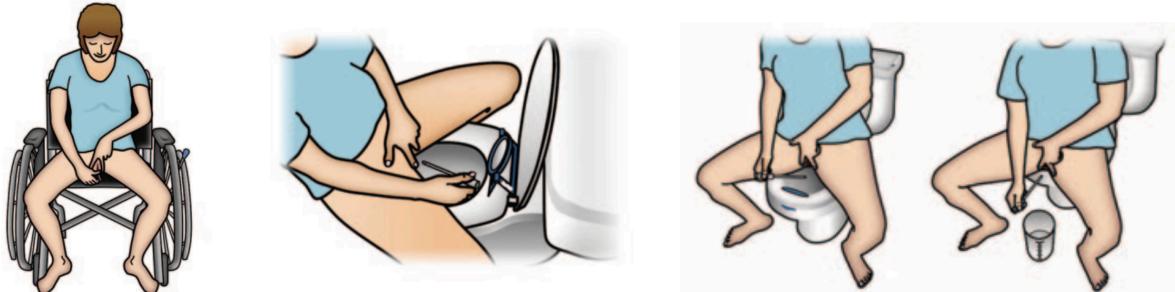
### *Steps of User Operation*

User operation steps are adapted from methods for the typical process for CIC. These steps are performed by the intended user: females with SCI. The steps are repeated 4-6 times a day or at the frequency of CIC as directed by the user's physician.

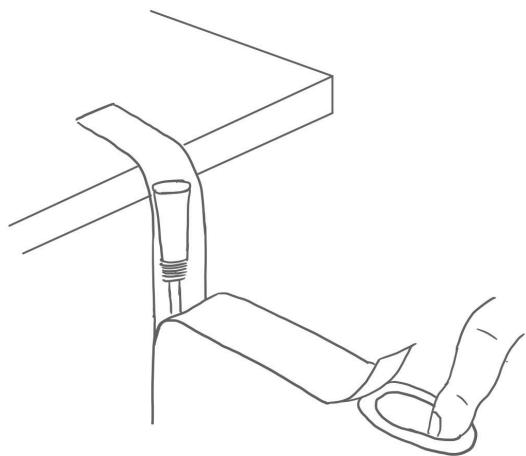
Depending on the user's preference, mobility, and flexibility, CIC can be performed in a few different positions and places. The user can sit on a toilet, facing forward or backwards, on a bed, in a chair, or in a wheelchair. It is commonly performed in a bathroom with access to a sink; however, it can be adapted as long as the user can clean their hands. For this user operation description, we will assume that the patient is catheterizing where they normally would.

Various catheter options are possible depending on user preference and physician direction. The user will choose the catheter they already use for CIC. First, the user gathers the necessary equipment, including the catheter in its packaging, the catheter insertion device in its packaging, a cloth, soap, and water or moist towelettes, and any other aids as necessary. If not catheterizing within reach of a toilet, they prepare a basin.

Then, the user thoroughly washes their hands with soap and water and positions themselves on the toilet, edge of their wheelchair, or other position as necessary with the legs spread apart, as seen in Figure 24. They open the catheter packaging carefully without touching the catheter, as seen in Figure 25, and then clean the genital area from front to back with soap and water or a moist towelette.



**Figure 24.** SaniCath is designed so that users can position themselves as normal when performing CIC [130].



**Figure 25.** Opening the catheter package ensures that the catheter is ready to be picked up with one hand when needed.

The user should eventually insert the catheter with the same hand as they usually do: the dominant hand. First, the user picks up the SaniCath grip with the dominant hand by placing four fingers into the slot and optionally wrapping the fingers around the grip. This is detailed further in the Grip Design section. Then they spread the labia minora with the non-dominant hand as seen in Figure 26 below.

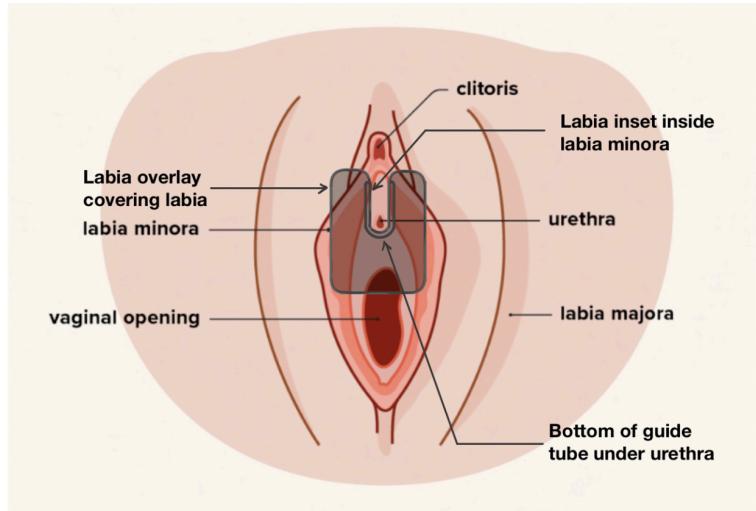


**Figure 26.** Spreading the labia allows easier access to the urethral opening for initial device placement.

The user then uses the mirror to place the labia inset on the inside of the labia minora, with the bottom of the catheter guide tube aimed underneath the urethral opening, as seen in Figure 27. This will result in the labia overlay covering the labia minora and some of the labia majora, decreasing the risk of catheter contact with external tissues. The user then transfers the device handle to the non-dominant hand, which ensures that the user does not touch the catheter with the hand that spreads the labia, thereby introducing bacteria. They continue holding the device in place with the handle.



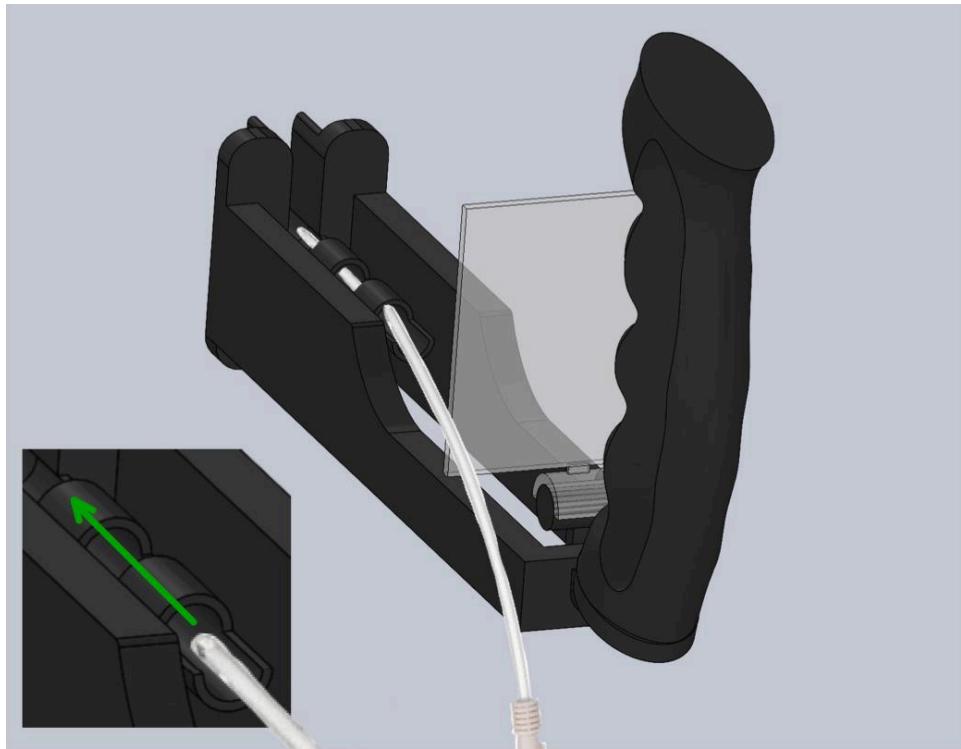
(A)



(B)

**Figure 27.** The device is placed after spreading the labia (A), with the final placement of the device ensuring that the opening of the catheter guide tube is aligned with the urethral opening (B) [131].

The user removes the catheter from its packaging with the clean dominant hand, being careful not to touch the tip. They place the tip of the catheter into the guide, then advance the catheter into the urethra slowly. The user must ensure that the end of the catheter is pointed into the toilet over the wall of the device, then continues advancing the catheter until urine begins to flow. They finally insert it another inch or two. This insertion process should be performed just as it is without the insertion device, following the same safety precautions as instructed by the user's healthcare team. At no point should the user touch the catheter guide tube. These steps are shown in Figure 28.



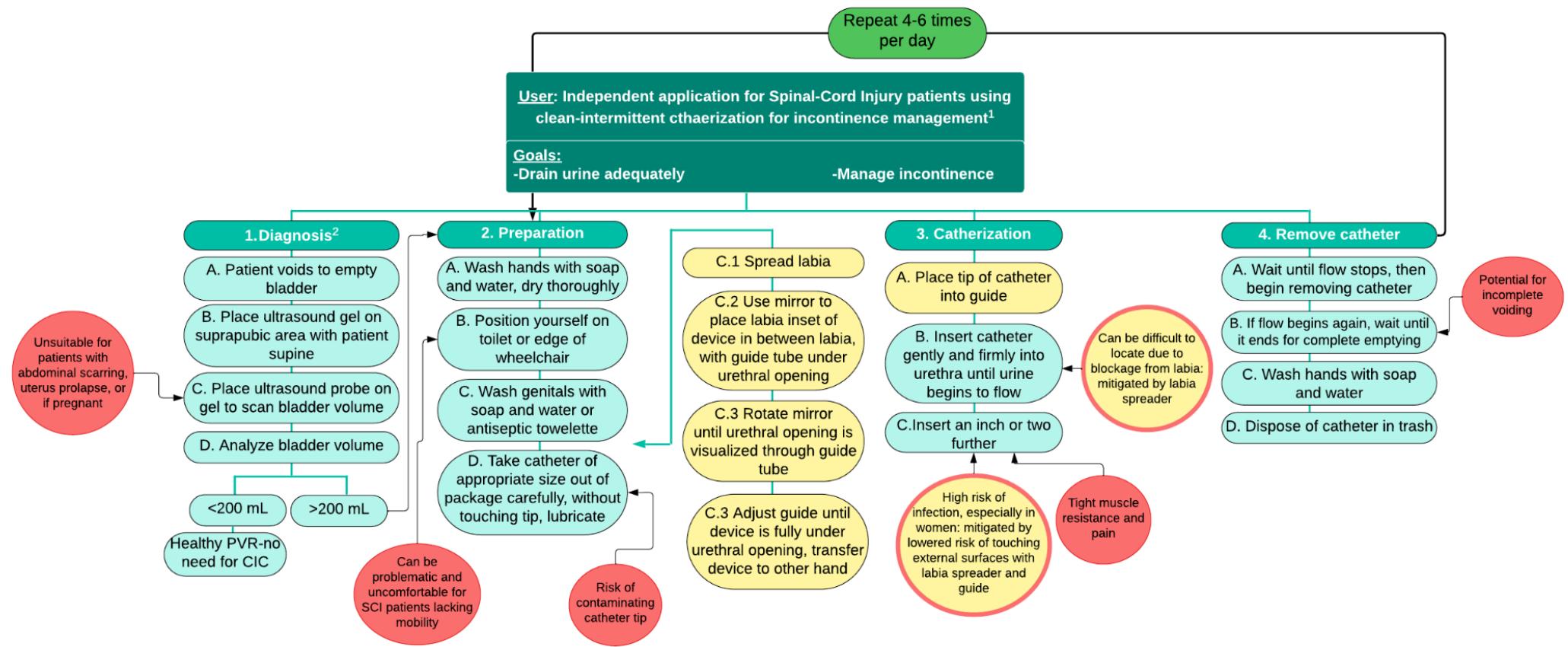
**Figure 28.** Insertion of the catheter through the guide tube allows for a controlled advancement.

Once the urine stops flowing, the user slowly begins removing the catheter. If flow begins again, they wait until it ends to allow for complete emptying. Once flow stops, they remove the catheter first and SaniCath second, then dispose of the catheter. They wash the SaniCath with soap and water and dry. If not at home, they spray it with disinfectant spray.

*Alterations in original flow of tasks caused by our design implementation.* Our SaniCath device adds an extra step to CIC, however it improves many issues associated with CIC. Although more stakeholders will need to be interviewed to determine the current difficulty of CIC, use of SaniCath will remove the step of holding the labia apart from patients; instead, they will only have to hold a handle, which will require a lower level of dexterity and improves accessibility of CIC to all individuals who can self-catheterize. Ensuring the spread of labia improves visualization, which will make the procedure easier and faster. This will increase patient compliance with CIC at the frequency recommended by the doctor, ultimately decreasing the risk of infection.

We acknowledge that our engineering team does not have limited hand dexterity or mobility whereas our target population might. Having to switch hands while using the device might be difficult, so it is imperative that we get patient feedback to understand if the device steps are simple enough to implement. This will be an important part of our verification and validation testing.

Holding or anchoring a mirror is an added challenge while performing CIC that we foresee – mirror integration into SaniCath mitigates this. However, it is important to note that we are considering this from the perspective of not having done the procedure ourselves, having only watched instructional videos. Our future validation testing will promote user perspectives in further refinements of our design. The original task analysis for CIC has been edited to show the improvements made by SaniCath and is seen in Figure 29 below.



**Figure 29.** The flow of tasks for CIC has been improved after implementation of SaniCath by improving visualization and decreasing the risk of touching the catheter to external anatomy, decreasing the risk of infection. Steps added to the CIC process with use of the device are shown as yellow rectangles, and mitigations to risks are shown as yellow circles with red borders.

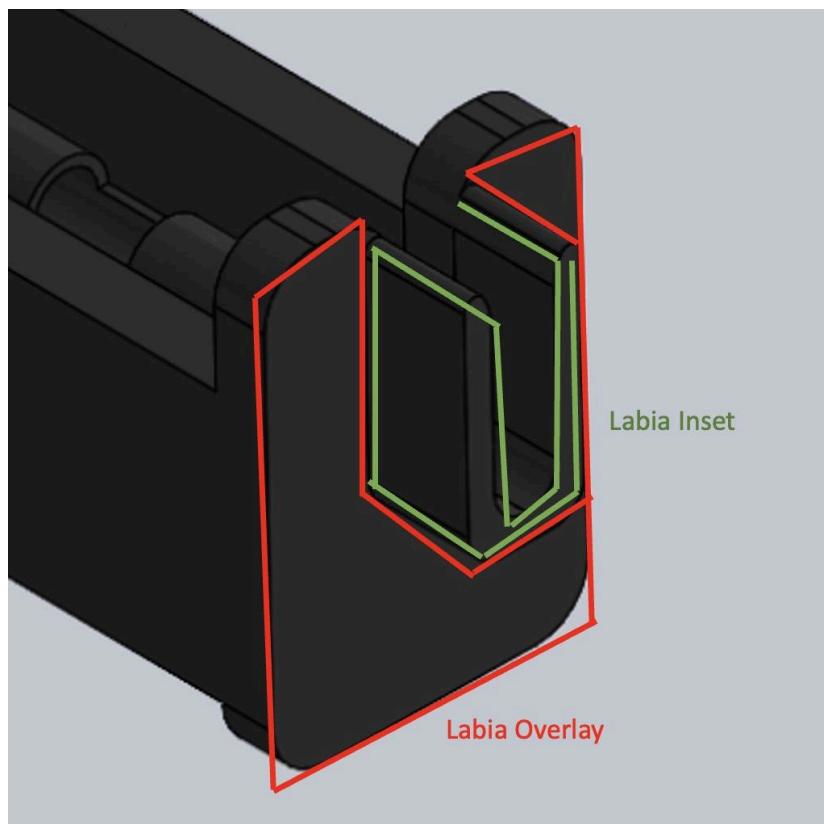
## Detailed Design Choices

The three critically evaluated design choices in this report were the device's dimensions, grip design, and material choice. These choices, along with the principle of operation, will be detailed in the following text.

### Dimensions

Our team determined and justified the dimensions for SaniCath. The diameter of the catheter guide tube and support wall thickness have been critically evaluated for their ability to meet design specifications. The support wall thickness was determined by an optimization process described below. All dimensions are stated in millimeters. The dimensions are organized by the portion of the device they belong to: labia spreader, catheter guide tube, support wall, grip, and mirror.

*Labia spreader:* There are a few sections within the labia spreader portion of the device: the labia overlay and labia inset. These names will be referred to throughout this section and are shown in Figure 30.

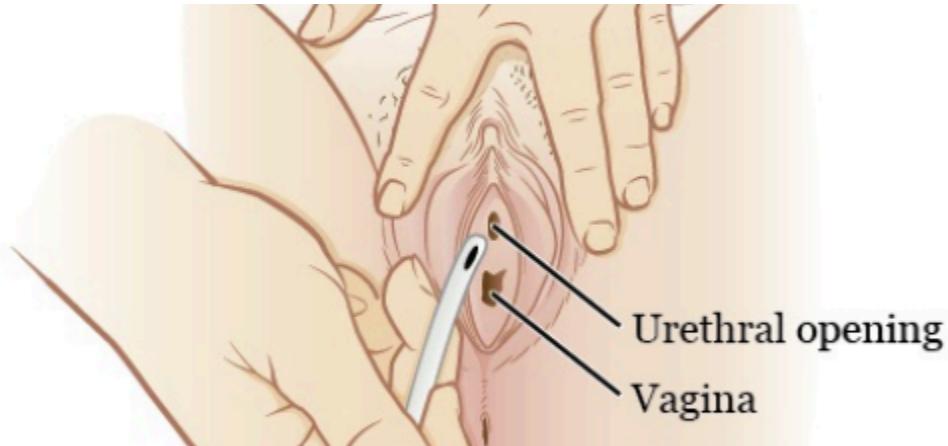


**Figure 30.** The labia spreader consists of the labia overlay and the labia inset components.

The total length of the labia overlay will be 43.14 mm. This will cover the upper portion of the vaginal opening so that users don't touch the catheter there and break aseptic technique, as shown in Figure 27. The top of our labia spreader would end up touching the end of the genitals, which we consider to be the clitoris in females. So, the total length of the labia overlay of the device will cover the average distance from the clitoris to the vagina, which is 43.14 mm [132].

The labia inset will have its bottom aligned with the bottom of the urethral opening and the top of the genitals, or the clitoris. Thus, the length of the labia inset will be the distance from the clitoris to the urethral opening bottom: 22.27 mm [132].

The total width of the labia overlay of the device will be 30 mm, such that it is covering approximately 1.5 cm of the labia majora on each side. To determine this value, we considered how females typically spread their labia during CIC to access the urethral opening, as shown in Figure 31.



**Figure 31** Patients use two fingers to spread the labia minora so the urethral opening can be visualized [133].

When physicians show their patients how to do CIC properly, the labia minora is spread so that it lies over approximately half of the labia majora, which is how users of our device will perform CIC. In literature we find that the average width of the labia majora is 3 cm [134]. Since we want our labia overlay to cover half of the labia majora on each side, it must be configured to 3 cm in width. This will allow the device to be placed such that 1.5 cm of the labia majora are covered on each side. All these dimensions together will ensure the urethral opening can be accessed and the labia are properly spread.

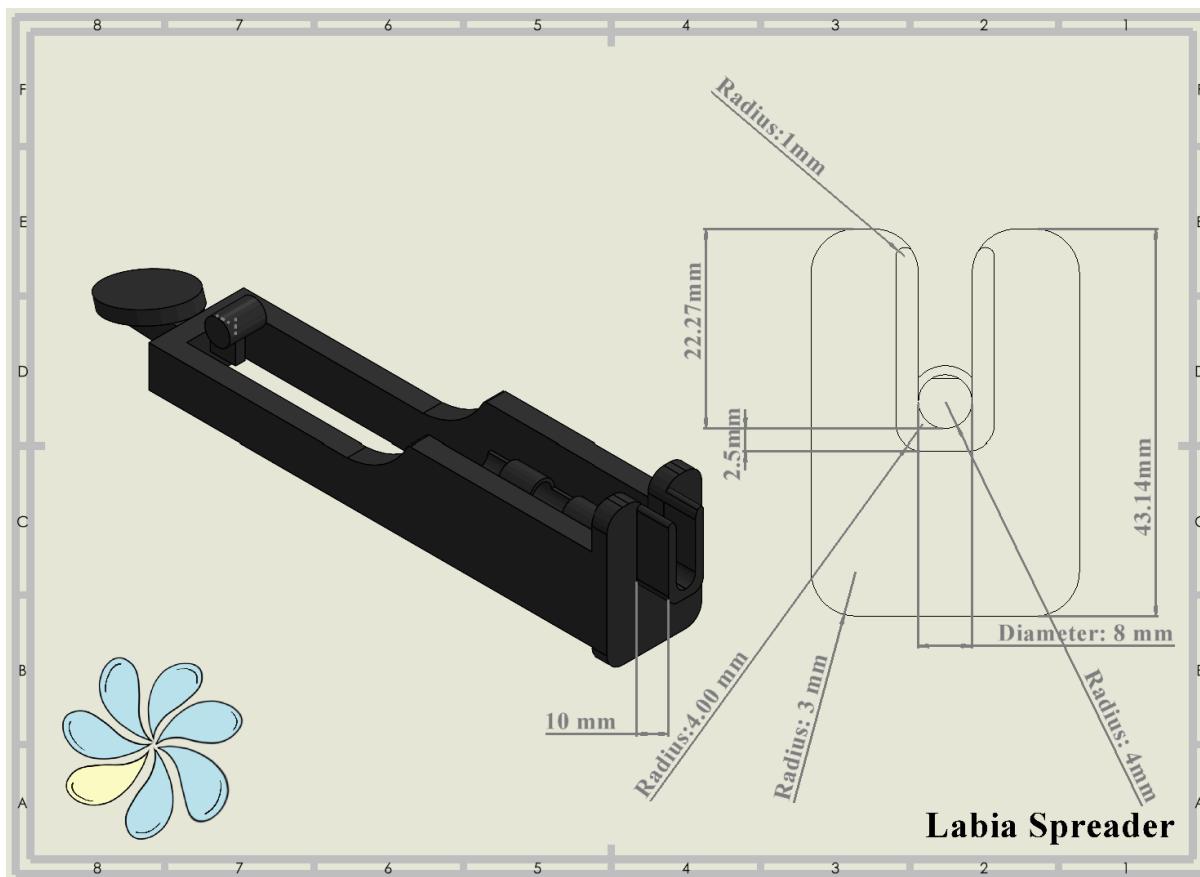
The labia inset will have a depth of 10 mm. We don't want the labia inset to dig too deep into the patients genitals, thus we will only have an insertion depth of half the labia minora width. To approximate this depth value, we used the average width of the labia minora, which is 2 cm [72]. This would make the labia inset have a depth of 1 cm. The rest of the labia minora will spread out over the labia majora and be covered by the labia overlay. This depth will also minimize the distance between the urethral opening and the catheter guide tube, facilitating smooth insertion.

The thickness of the pieces of the labia inset are 2.5mm. We acknowledge that this value needs to be adjusted according to usability testing for user comfort. With any future adjustments, we will verify that it continues to meet our specification for no more than 700 psi applied to the genital areas.

We decided to make the external edges of the labia spreader filleted by 3mm for sterility and comfort. Sharp edges, especially on the labia spreader, that dig into the patient's body can cause pain, discomfort, and in extreme cases bleeding. While we will choose a material which is softer, to minimize bacterial growth and maximize comfortability we will still smooth out any corners.

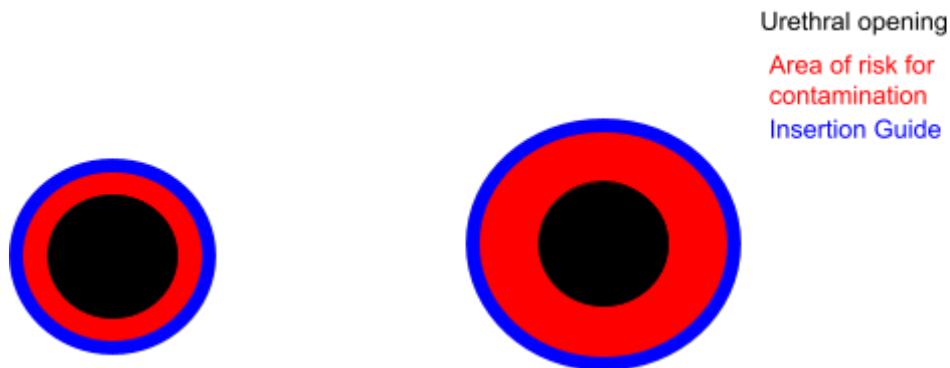
The internal edges of the labia spreader, where the urethra will sit inside, are filleted by 4mm. This was done to match up with the diameter of the guide tube, which will be 8 mm, to facilitate a seamless transition of the catheter insertion from the guide tube into the labia spreader and into the urethra.

All labia spreader dimensions are shown in a drawing in Figure 32.



**Figure 32.** The labia spreader dimensions allow for the labia not to interfere with the self-catheterization process, thereby reducing the risk of touching the catheter anywhere other than into the urethra.

*Catheter guide tube.* The diameter of the catheter guide tube will be 8 mm. This dimension was critically evaluated. This diameter must encompass the full urethral opening to allow for proper insertion and prevent any discomfort from tight insertion; however, if the diameter is much larger than the opening, this can increase the chances of the catheter touching skin external to the urethra, as shown in Figure 33.



**Figure 33.** The difference of diameter between the catheter guide tube and the urethral opening is positively correlated with the risk of contamination due to external skin contact of the catheter prior to insertion.

Seeing as typical female urethral openings are 2-5.94 mm in diameter, our catheter guide tube diameter will be above this range to ensure that the device is accessible and usable for all intended users. This directly maps to our design requirement that states our solution is removable and the specification that states the solution is able to pass through a diameter of 2-5.94 mm and length 3-4 cm in length [63], [72], [73]. To find an ideal diameter size, we built a low-fi prototype of our device and gauged resistance to insertion when a user inserted a catheter through the guide tube. We started with a guide tube diameter of 5 mm, the smallest diameter we were able to make, and increased it by 0.5 mm until a user was able to insert the largest female catheter on market, a 16 Fr catheter, into the guide tube with no resistance [135]. We used the largest catheter available to ensure all users could safely insert any-sized catheter through the guide tube with relative ease. It was found that a guide tube diameter of 8 mm was the smallest diameter that provided no resistance to insertion. Diameters from 6-7.5 mm still allowed for catheter passage, but caused significant resistance to insertion and required large user force and precision, making the device less accessible to those with dexterity limits. Our catheter guide tube will be 8 mm in diameter to ensure users can insert a catheter with minimal resistance while also limiting potential user contact with external skin.

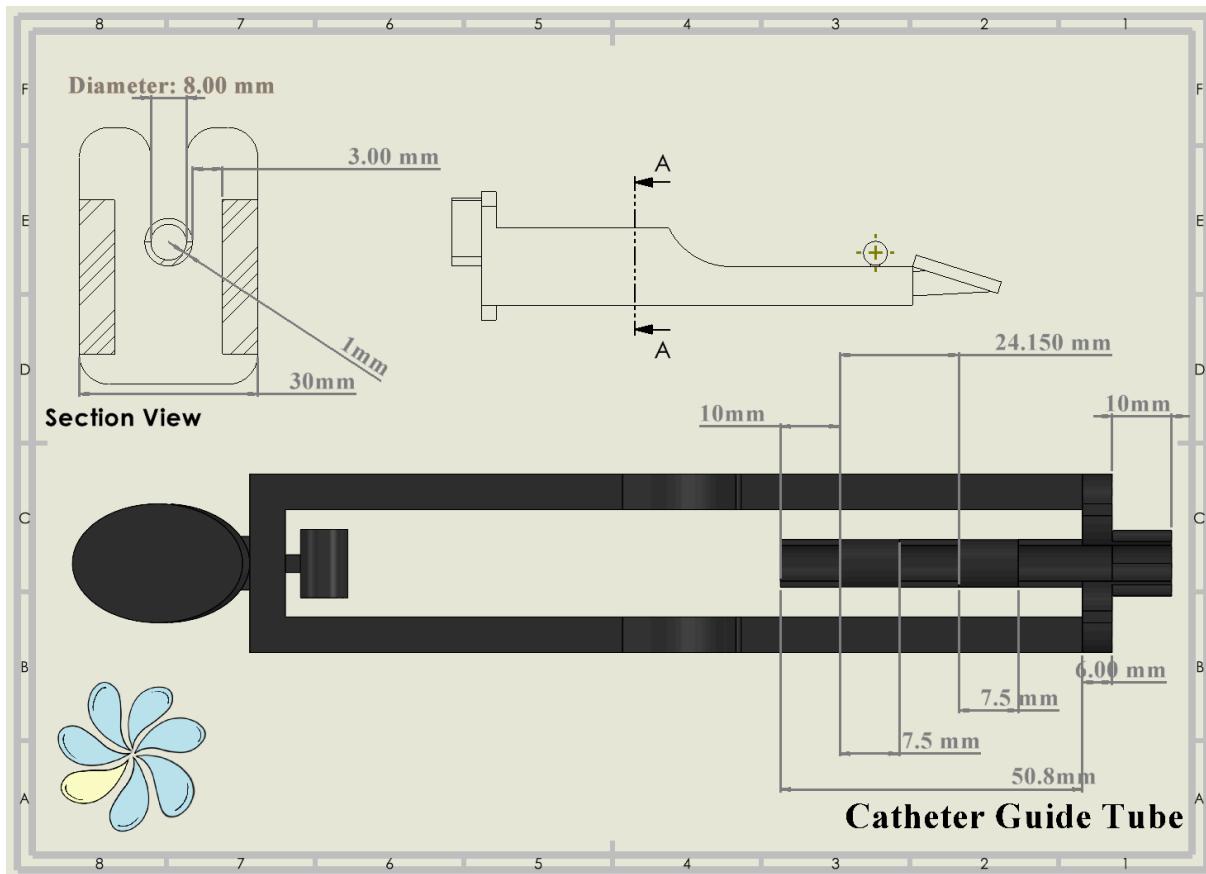
The length of the catheter guide tube will be 50.80 mm, extending out from the labia spreader portion of the device. This will be the portion of the device where users will thread their catheter through, and it will facilitate guidance into the urethra. To determine the optimal length of the catheter guide tube, we conducted usability testing with four of the female members on our team while sitting on chairs. After attempting to model the device with a ruler and the phone as a mirror, we determined that a tube 5.08 cm extending out from the urethra was easy for us to spot and thread a catheter through. However, we acknowledge that none of our team members are SCI patients with incontinence, so that perspective is justifying this length. Further usability testing with this population must be done to see if this length is optimal for our target patient population.

The thickness of the catheter guide tube is 1 mm. This thickness was somewhat arbitrarily chosen, intending to allow the tube not to be flimsy or break off. We acknowledge that this value should be justified according to material properties as well as manufacturing processes that we choose. At this time, we have not chosen a manufacturing process. Once that is done, we can optimize the thickness according to that.

The angle of the catheter guide tube is 0° relative to the urethral opening. This means that when the patient places the device and lines it up with the urethra, the catheter will go straight into the urethra collinearly. We have it this way because when a patient does CIC normally, they line up the catheter horizontally to their urethral opening [136].

To prevent the catheter from coming away from the guide tube, we will enclose two portions of the tube to facilitate guidance of the catheter, and they will be called the catheter flyaway guards. These pieces will be 7.5 mm thick each. The first one is 10 mm into the catheter guide tube and the second one is 24.15 mm away from the front of the flyaway guard. The second guard is placed such that it is an equal distance from the first guard and start of the labia spreader portion of the device. This will ensure that the catheter tube stays in place throughout the entire 5.08 cm length of the tube. The first guard is placed 1 cm in so that the user can see where to start inserting the catheter. As for the 7.5 mm length, we decided that would be an adequate length to provide enough mechanical integrity to the guard, ensuring that they don't break. However, further testing with a prototype must be done to optimize the length of these pieces.

All catheter guide tube dimensions are shown in a drawing in Figure 34.



**Figure 34.** The catheter guide tube will aid users in inserting a catheter by positioning it correctly relative to the urethra.

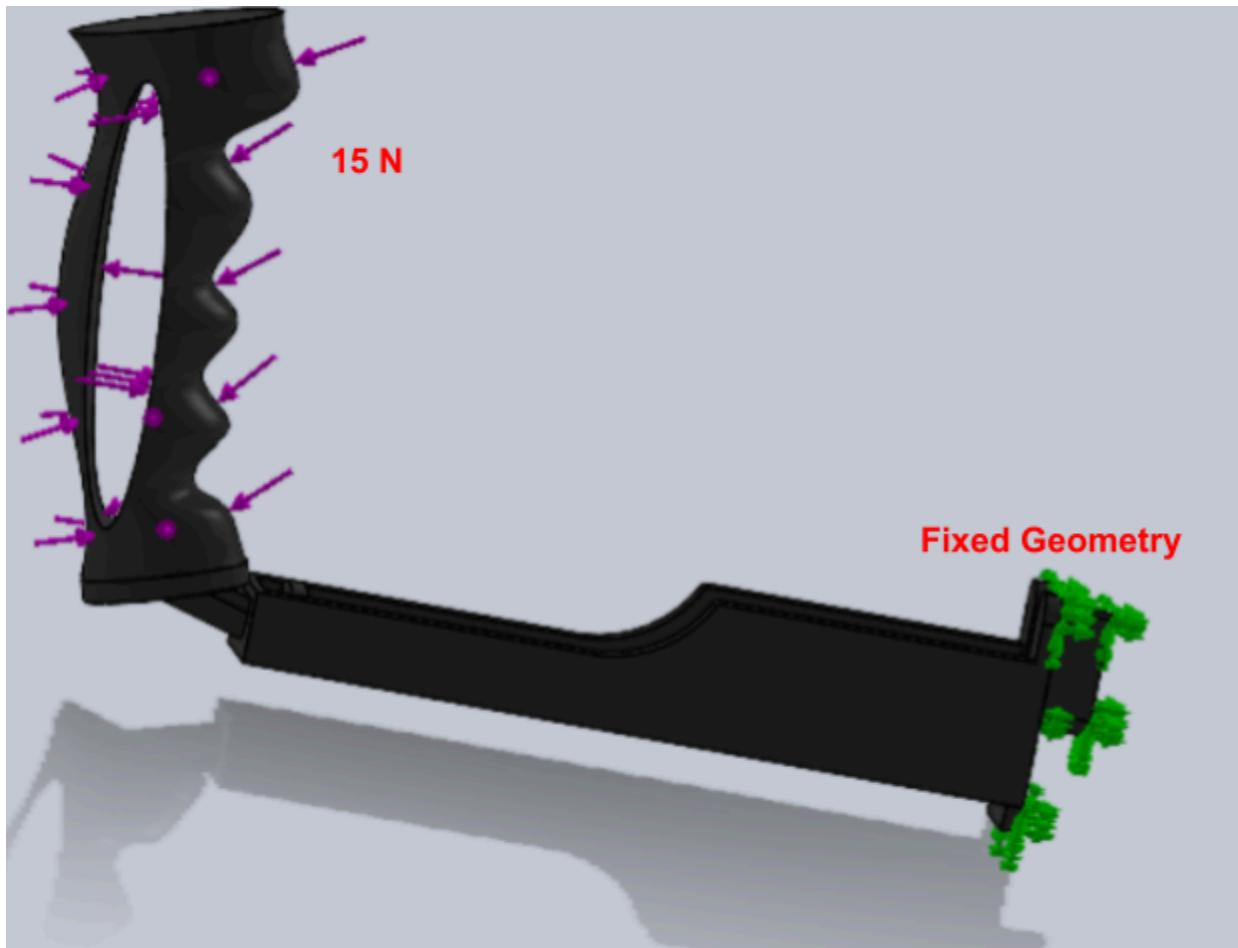
*Support Walls.* The support wall dimensions and design were determined via our team's usability testing. Cardboard versions of the support walls on the device with a straw to approximate the catheter guide tube were built.

The support wall surrounding the catheter guide tube was made to be higher than the portion near the labia spreader, with final heights of 25.9 and 12.59 mm, respectively. The 25.9 mm height was chosen to ensure that the catheter guide tube was sufficiently protected from both sides to maintain sterility, but it was not too tall to obstruct the view of the catheter guide tube. Originally, the whole support wall was at 25.9 mm height; however, after usability testing was performed, it was determined that it was cumbersome to place the catheter because the height of the walls blocked visualization and easy access to the guide tube. Furthermore, after the catheter has been inserted, we encountered difficulties with where to place the external end of the catheter due to the high walls; this required bending the catheter more to aim it downwards, which requires more dexterity than our stakeholders may not have. After considering various options, such as removing the walls and placing a "support floor" instead of walls, the combination of the most user-friendly, mechanically stable, and easy to clean device was determined to be one with shorter walls near the handle. This was chosen to be half the original height after experimenting with different options.

To determine the optimal length of the SaniCath, we conducted usability testing with four female team members while sitting on chairs. After modeling the device with a ruler and a phone as a mirror, we determined that a support wall 140 mm away from the urethra was a comfortable distance to hold the device and still be able to generate enough force to hold it against the body. After building the prototype,

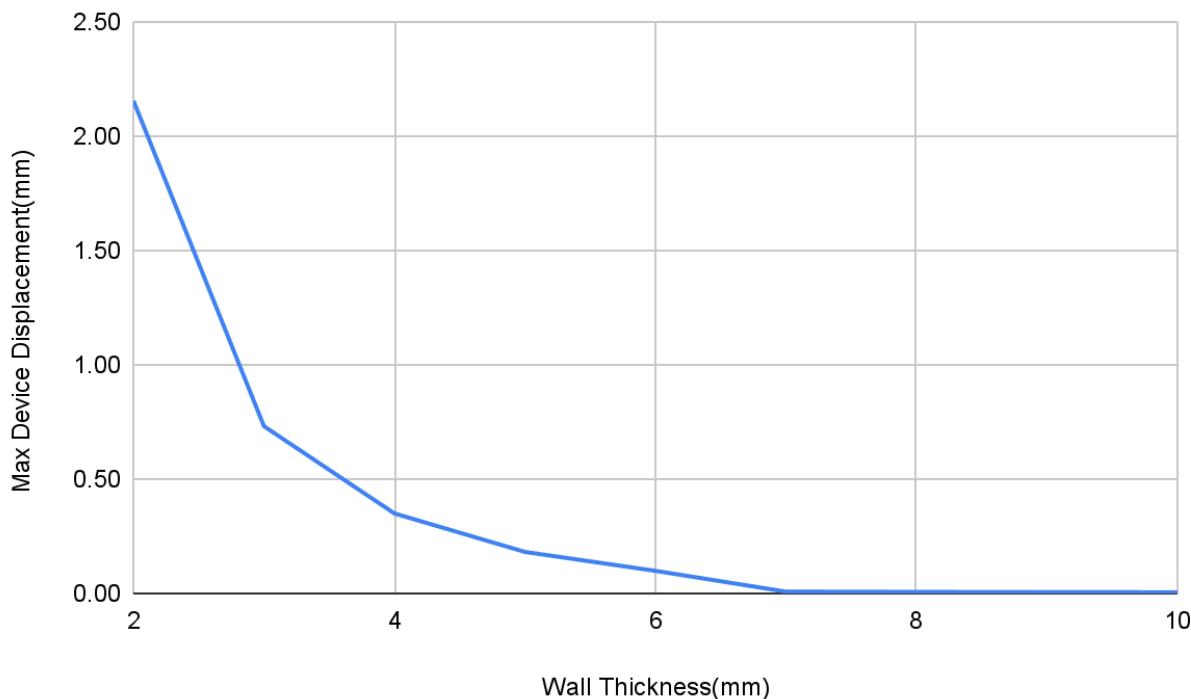
we will conduct further usability testing with SCI patients to determine if this length is optimal. Seeing as none of our team members has SCI, it is pertinent that we remove any assumptions we have regarding the length in meeting stakeholder needs; rather, we shall transfer that power to female SCI patients and ensure their perspectives are guiding the solution so that we can create an equitable solution.

*Optimization Model.* To ensure our support walls provide enough mechanical stability and fracture resistance, the support wall thickness will be 6 mm. This was determined via an optimization model in which we tested our device's response to typical loading conditions to a variety of wall thickness values and critically evaluated against our design inputs. Here, we performed static loading simulation testing in SolidWorks and measured stresses and displacements throughout our device. To simulate a user environment, a 15 N load was applied to our device handle. This takes the 5 N maximum load seen during insertion in a clinical study and applies a safety factor of 3. Using this upper limit ensures that if our device experiences minimal displacement at this load, it will be sufficiently stable at all user application forces [116]. From here, wall thickness values from 1-10 mm were used, as these represent the minimum and maximum wall thickness values that are possible for our device based on surrounding dimensions. Our labia spreader was set as a fixed geometry, as users will fix the device against their body using the labia spreader during use. The remainder of the device was established as a free boundary. Figure 35 shows the setup of the optimization model.

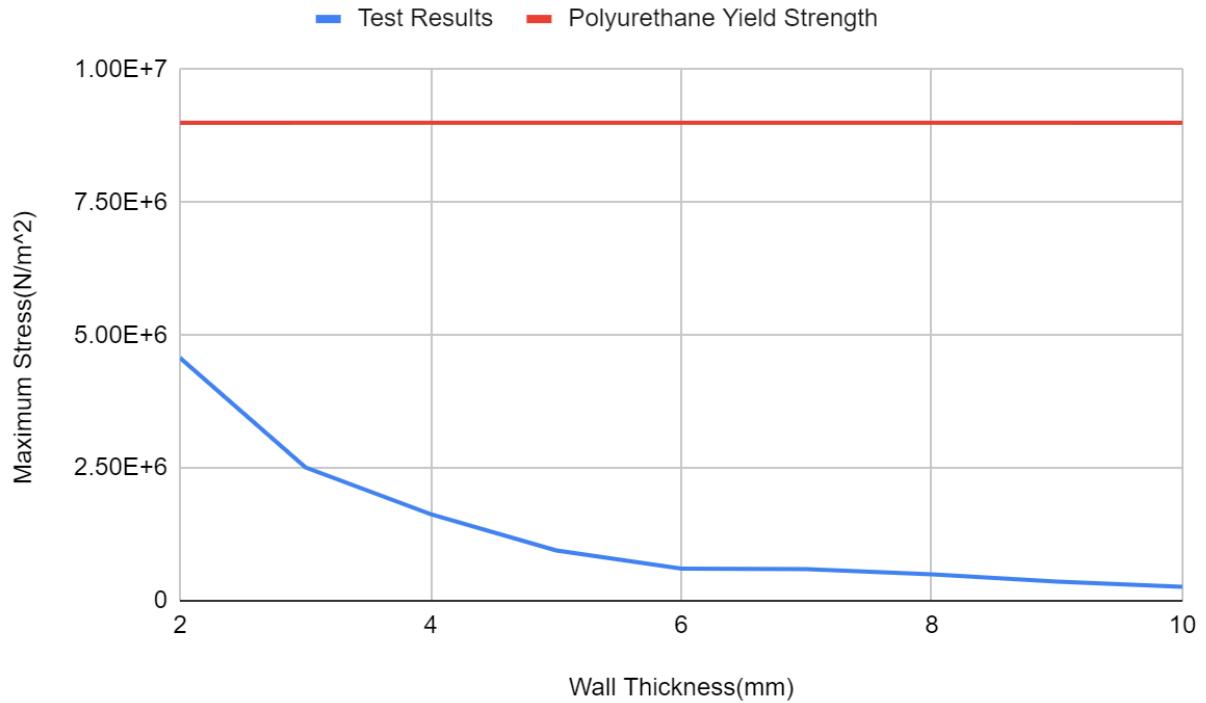


**Figure 35.** To simulate our user environment, a load of 15 N was placed on the device handle and the labia spreader was established as a fixed geometry.

Results were generated by finding the maximum displacement and maximum stress experienced by any portion of our device for each wall thickness value. These values were then graphed to display the relationship between wall thickness and device displacement and maximum device stress, as shown in Figures 36 and 37. Generally, the maximum device displacement and stress decreased when wall thickness increased. Stress values were compared to the yield strength of polyurethane, 9 MPa, which represents our device material. None of our stress values exceeded this yield strength, indicating that our device provides sufficient resistance to plastic deformation and appropriate stability with any given wall thickness.

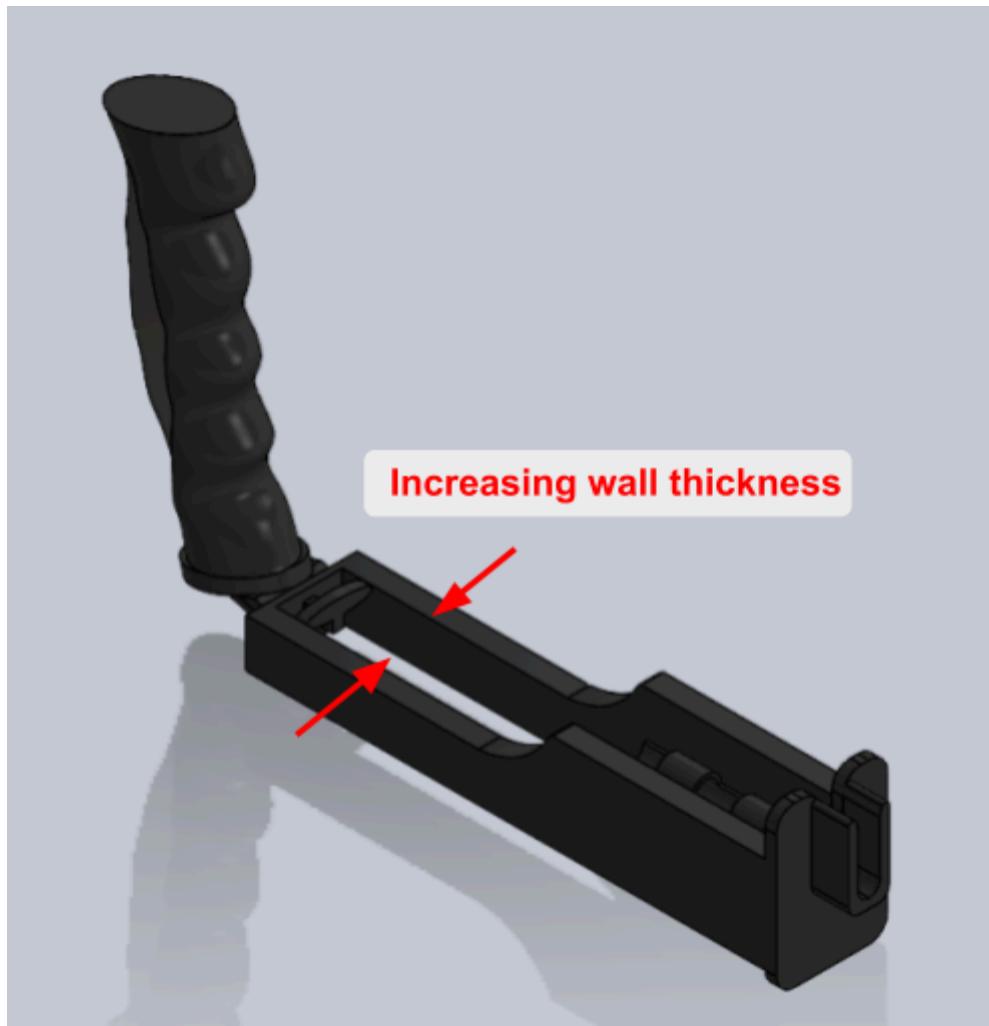


**Figure 36.** Maximum device displacement decreased exponentially with increasing wall thickness.



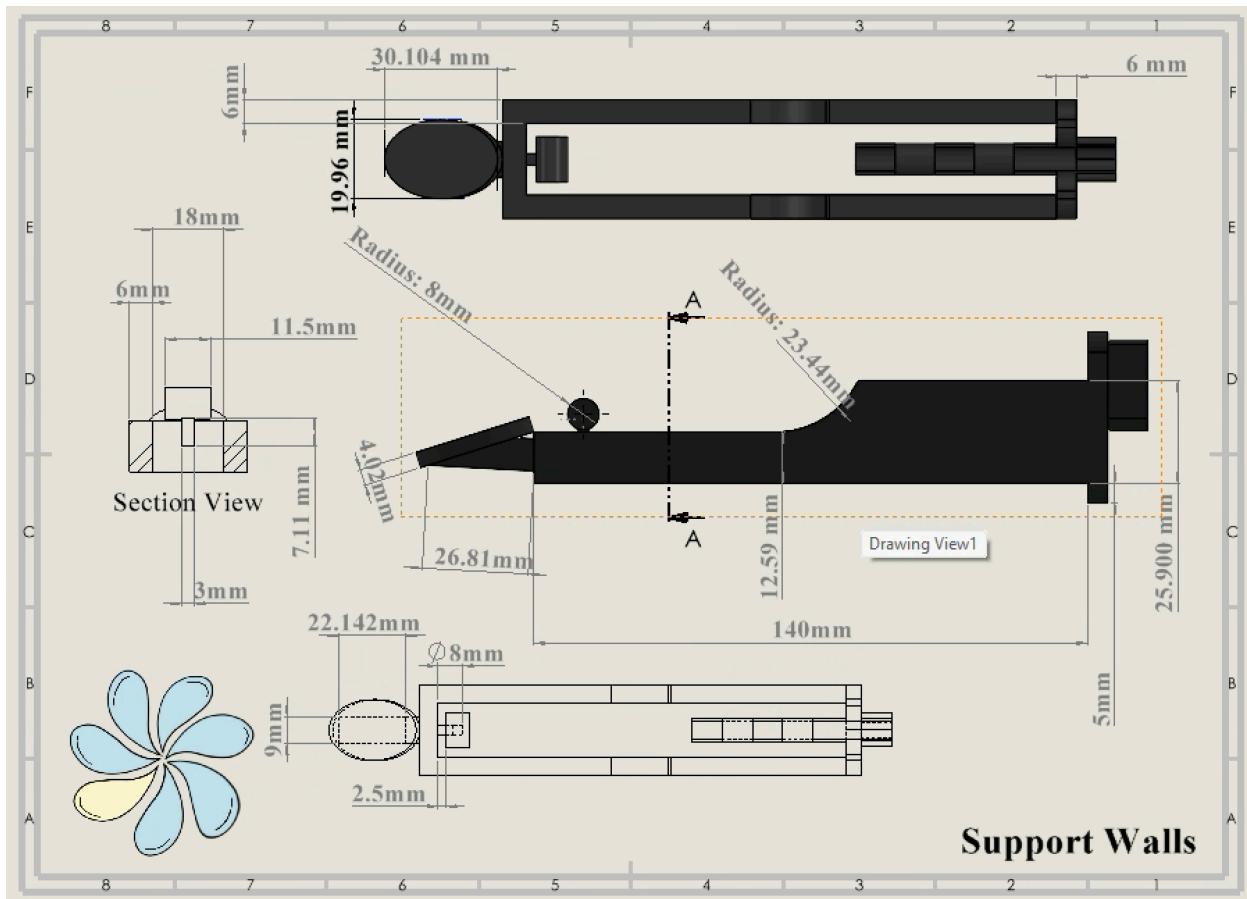
**Figure 37.** Maximum stress decreased exponentially with increasing wall thickness. Maximum stress never exceeded the yield strength threshold, indicating sufficient resistance to plastic deformation.

Based on this optimization model, we established the wall thickness to be 6 mm. We wanted this thickness to minimize device displacement and stress under load. As shown in Figures 36 and 37, both of these begin to level off at a minimum once the wall thickness reaches 6 mm. Additionally, for thickness values greater than 6 mm, these values perform similarly in these optimization results while also limiting the total space available for a user to insert the catheter, as shown below in Figure 38. Therefore, a wall thickness of 6 mm maximizes device stability and accessibility for users.



**Figure 38.** Because a user has to insert the catheter through an open space defined by the support walls, increasing wall thickness decreases this overall space and makes catheter insertion more difficult.

All support wall dimensions mentioned in this section are shown in the drawing in Figure 39.



**Figure 39.** The support wall dimensions will ensure the device does not fracture under 15N of force during use.

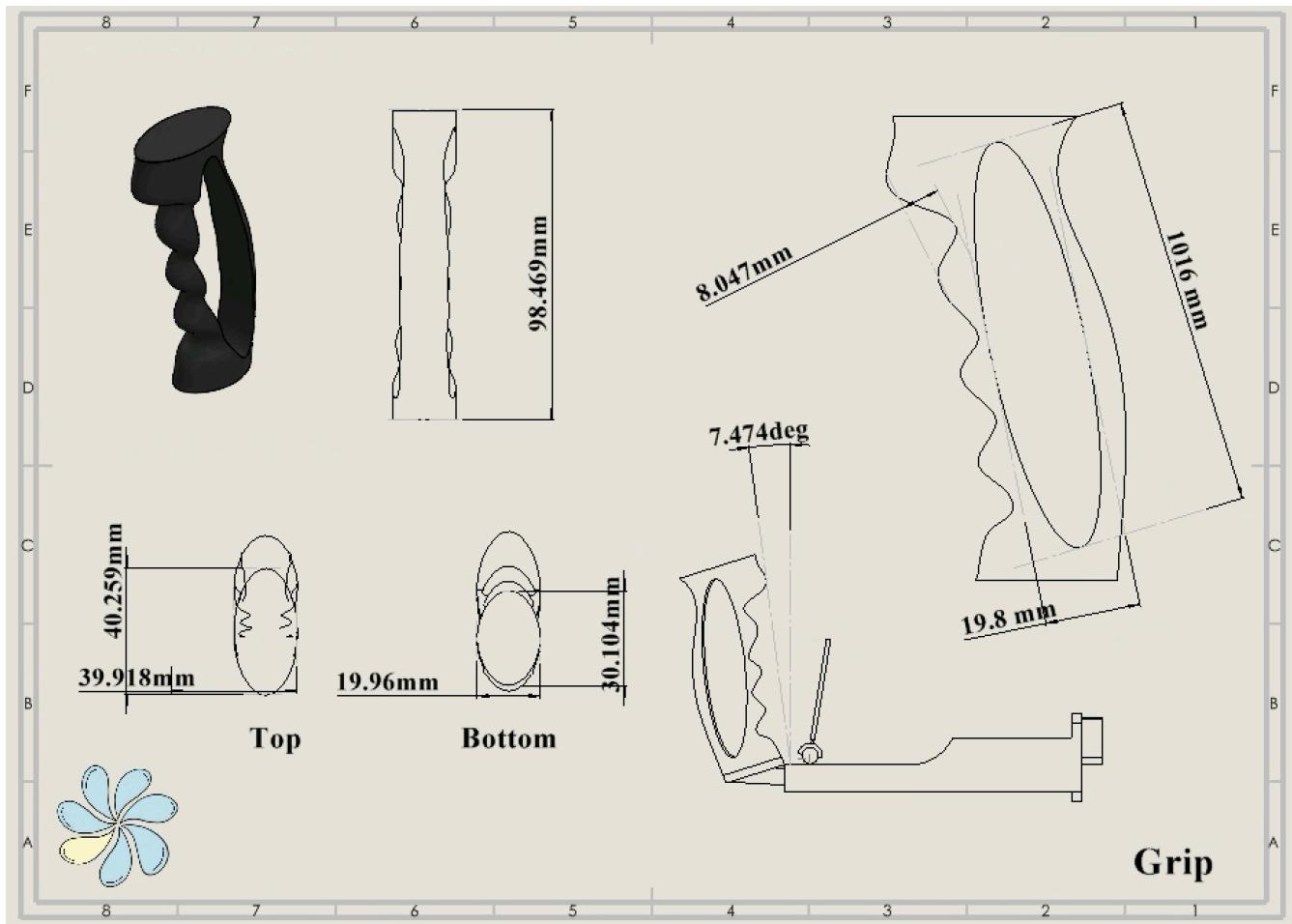
*Grip.* The length of the slot is 10.16 cm and the width is 19.8 mm. These values were determined via sizing charts for gloves (hand breadth) and rings (finger diameter). The maximum hand breadth listed for females was 3  $\frac{3}{8}$  inches, which was chosen as the slot length to ensure that it would fit most if not all users [137]. Ring size values for women were listed from size 3 to a size 9, with maximum size 9 being 19.8 mm in diameter, representing the slot width [138]. The grip design was traced based on an existing 3D hand grip model, shown in Figure 40, as this ensured proper dimensions for placing and depth of the finger grooves for hand placement during use.



**Figure 40.** By designing the grip from an existing hand grip model, we ensure the grip is fitted to typical hand anatomies [139].

The grip was angled such that the grip edge closest to the user was at  $7.474^\circ$  from vertical. This angle was determined by usability testing, where a mock device made of cardboard was created with the proper dimensions. A female anatomy diagram was printed and taped to cardboard. The catheter guide tube of the cardboard device was placed at the cardboard urethral opening to emulate how CIC users would place the device. A mirror was held at the handle end, and the device was held at chair level while a team member was sitting to reproduce the device's position while being used. The team member adjusted the mirror angle to be able to visualize the cardboard urethra through the guide tube. This angle was measured for two members and averaged to determine grip angle; this angle was assumed to be the “standard” mirror angle. As the mirror is offset from the grip, this would allow users to angle the mirror towards the grip and away, allowing flexibility given the range of people that will use the device.

All grip dimensions mentioned in this section are shown in the drawing in Figure 41.

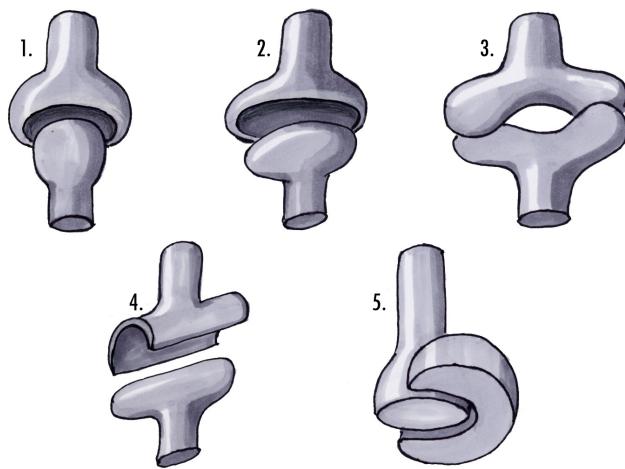


**Figure 41.** The grip design was made to accommodate users with low dexterity and mobility in their hands.

*Mirror Design*. The mirror design was determined via a combination of usability testing and brainstorming. The goal was to design a mirror mount that was simple, robust, and allowed for mirror angle adjustability. Constraints were that the mirror should only rotate front to back and not side to side and should be removable, which helped eliminate some concepts. Removability is important to allow for cleaning the parts separately and to replace the mirror. The simplicity serves three purposes - it decreases small surfaces that can collect bacteria, makes the device less likely to break, and makes it more user-friendly.

The inspiration for the final mounting mechanism decided upon was a ball and socket hinge joint similar to those found in Legos. Lego hinge joints can rotate around a socket and stay in place once positioned. This is important for the mirror design because the mirror needs to stay at the angle chosen but also be adjustable, as the user's position may vary from day to day and the device is not custom-made.

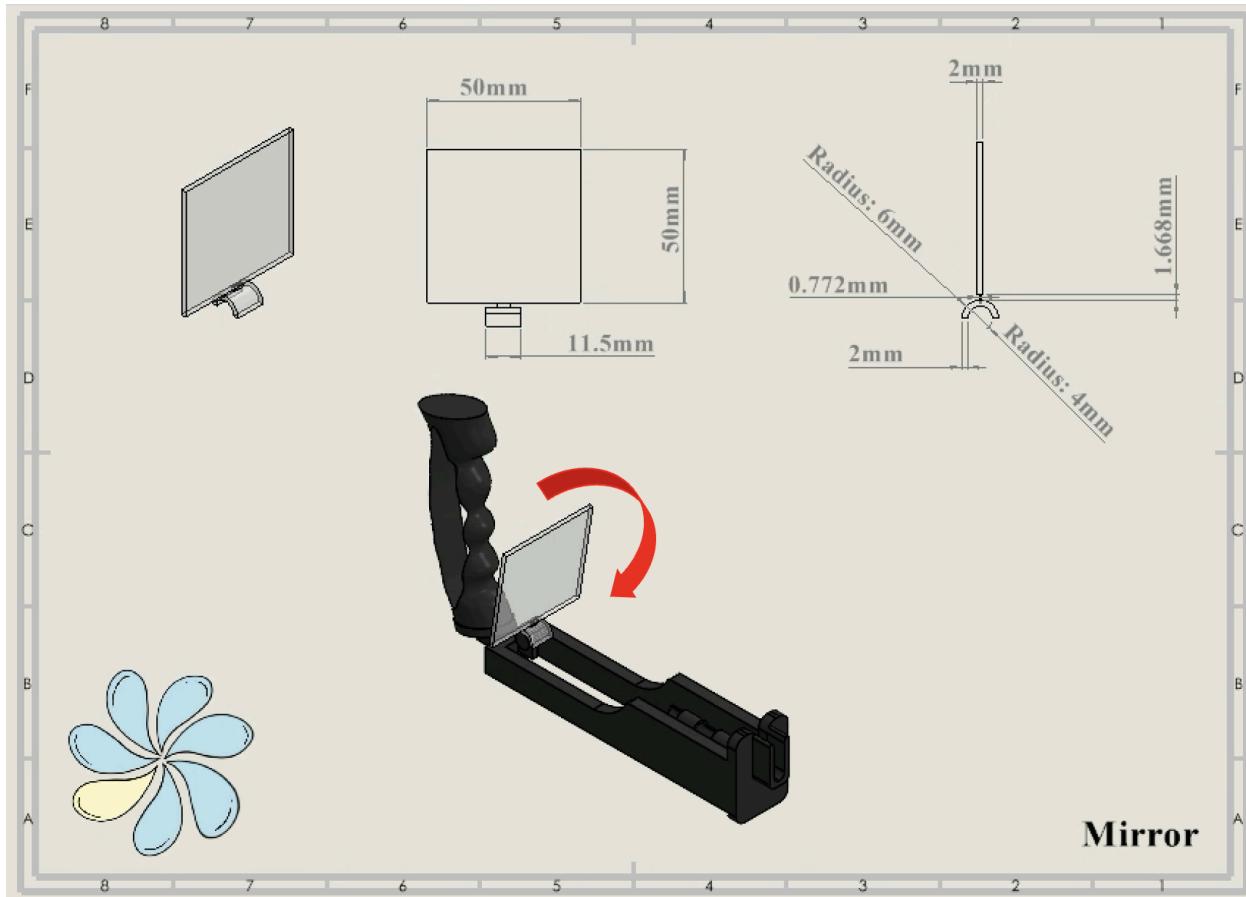
Another important aspect considered when designing the mirror mounting system was that mounting the mirror would need to be as easy as possible for users with limited dexterity, which our stakeholders might have. This simple mechanism with a longer cylindrical insert instead of a ball, as depicted in Figure 42, increases ease of use. Users also have the option to leave the mirror on if this is easier. More testing with users is required to determine whether this mechanism is easily removable.



**Figure 42.** Version 4 of the ball and socket joint was chosen to attach the mirror to the SaniCath.

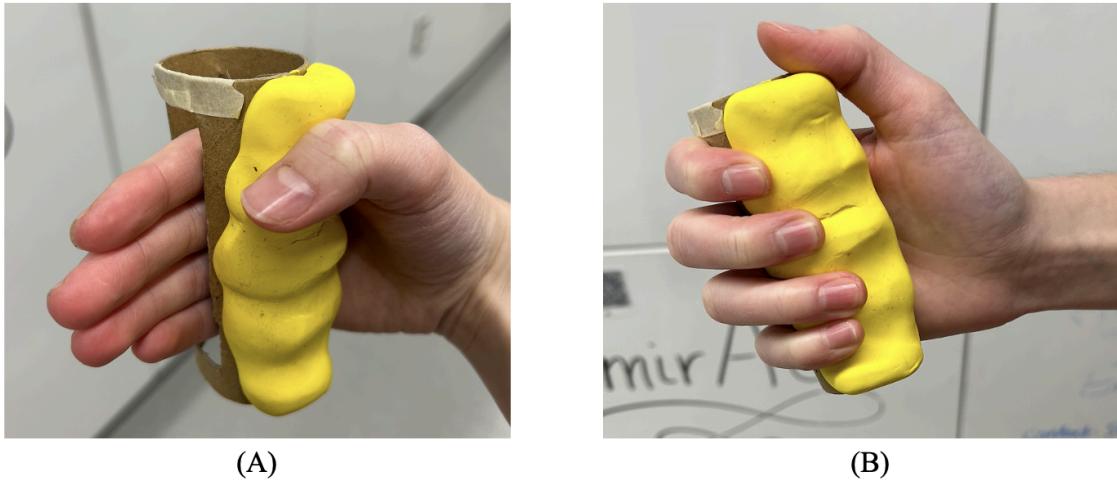
The mirror dimensions were chosen to be 5 cm by 5 cm based on usability testing, so that the mirror did not have to be perfectly angled but also was not too big to be cumbersome. The mirror was placed in line with the catheter tube for direct visualization, which is an important aspect of the solution for stakeholders due to the importance of locating the urethra for CIC.

All mirror dimensions mentioned in this section are shown in the drawing in Figure 43.



**Figure 43.** The mirror is placed directly in line with the catheter guide tube and is adjustable to a range of angles.

*Grip Design.* Another major portion of the device was the grip that users will use to hold the device to their body. The goal was to make holding the handle as easy as possible, as some stakeholders will have limited hand dexterity and strength due to the nature of SCI injuries. This included not requiring the users to grip with the ends of their fingers and requiring as little arm muscle activation as possible. Team members determined that the easiest position to hold the arm and hand was with the arm straight out, the palm of the hand facing the body, and the fingers pointed to the side. Usability testing using the non-dominant hand also showed that pulling a device towards the body with the base of the fingers as leverage instead of gripping, as shown in Figure 44, required the least amount of dexterity. Placing ridges on the grip for comfortable finger placement gives users the option for more control. We cut a grip out of cardboard with model magic grooves to test this grip option.



**Figure 44.** A cardboard model of the proposed design allows users to slide their hand into the grip (A) or wrap their hands around the grip (B) depending on their dexterity.

One of our team members is left handed. It has traditionally been more difficult to use certain devices, such as scissors, with this identity. Therefore, we were aware of the importance of making the design symmetrical and equally accessible to both left and right-handed users. Further, some users might have much weaker left or right hands, necessitating the use of one hand or the other. Our final grip design is shown in the drawing in Figure 41.

#### *Material Selection*

For our design, we will use a combination of polyurethane and silicone rubber. The whole device will be made out of polyurethane. However, the handle and the labia spreader will be covered with silicone for user comfort.

Polyurethane (PU) is a well known biostable biomaterial. PU has strong mechanical properties with an average Rockwell Hardness score of 66.3 and a Modulus of Elasticity of 0.621 GPa [140], allowing for increased stability during device use. PU also passes our biocompatibility specifications as leachables were found to be non-toxic during in vitro use and the chemical composition does not cause skin or inner mucosal irritation when used externally [141]. However, one possible disadvantage to using PU is that it could potentially favor bacterial adherence [142], contributing to an increased risk of UTI. UTI occurrence will be tested in clinical trials for validation. Seeing as our device is external, all sterility design requirements will have to be altered to address sanitation rather than sterility, and PU is able to be sanitized. Silicone rubber is biocompatible, flexible, can withstand a wide range of temperatures, bioinert, hemocompatible, chemically stable, and provides antimicrobial properties. It also does not cause skin or inner mucosal irritation when used externally [142]. Silicone meets many of the same specifications that PU does, and it also provides a softer interface between the SaniCath and the genital area or hands. Together, these materials can give the SaniCath a strong physical structure while also having a soft, comfortable, and antimicrobial surface. However, it is possible these materials might change as we finalize manufacturing processes and run verification tests.

The mirror will be a Glass First Surface Mirror (FSM) since this is a widely recognized kind of mirror designed for science and engineering. FSMs prevent a ghosting effect, which is when a faint secondary

projection is created allowing for a true clear reflection. FSMs also offer a protective laminate over coating and are 96% reflective. Ensuring that the mirror we use is clear and accurate is important for us to meet our less than 5% error rate in visualization of the urethra.

#### *Principles of Operation*

The principles that govern the operation of this device are those that revolve around mechanical stability under externally applied forces. Aside from user error, this device can fail if it breaks from the forces applied by the patient to hold it against the body. Thus, we will consider the stress and strain applied to the portions of our device in order to determine if the thickness, design, and material selection will withstand multiple patient uses of the device.

Secondary principles governing the operating of this device relate to light. Mirrors are highly reflective surfaces from which light reflects off in an orderly fashion, producing a clean image on the retina [143]. The placement relative to the patient's line of view and their anatomy is important - the urethral opening needs to be in a direct line to the mirror, and the eyes need to be as well. Adding a rotating component adjusts for varying dimensions.

#### **Failure-Mode Estimate Analysis**

A Failure-Mode Estimate Analysis (FMEA) was completed to analyze risk management principles associated with each user task on our device.

#### *Severity Scoring*

To analyze the harm of using our device for users, a severity scale was generated to score each failure mode on its potential to cause harm. This scale ranged from 1 to 5. 1 represented a minor adverse event (AE), such as a scrape or bruise, 2 represented a moderate AE that was reversible, 3 represented an irreversible moderate AE or reversible severe AE, such as major organ or functional damage, 4 represented irreversible severe AE, such as permanent loss of function, and 5 represented the potential to cause death. A summary of this scale is shown below in Table 8.

**Table 8.** Failure modes associated with user tasks for our device were scored on their potential to cause adverse effects to the user.

#### **Severity Scale**

5	Death
4	Irreversible Severe Adverse Event
3	Irreversible Moderate Adverse Event or Reversible Severe Adverse Event
2	Moderate Reversible Adverse Event
1	Minor Adverse Event

#### *Frequency Scoring*

To analyze how often a user would experience non-ideal events during use of our device, each failure mode was scored on an occurrence scale as depicted below in Table 9. This scale was inspired by recommendations in ISO: 14971:2019, FDA standards for medical device risk management [144].

**Table 9.** Failure Modes were scored based on their frequency of occurrence

Occurrences Scale	
5	Failure is inevitable
4	Failure occurs often
3	Failure occurs sometimes
2	Failure occurs occasionally
1	Failure rarely occurs

It should be noted that the occurrence scale will need to be refined as we collect data with our device in future studies. This will allow each occurrence score to be defined quantifiably. Additionally, it is important that we consult experts in the field of incontinence care, this will help reduce the influence by preconceived notions we have as engineers who have not had SCI or incontinence.

#### *Failure Modes*

Two potential failure modes were identified for our device.

*Puncture of the urethra.* One potential failure mode identified is that the catheter could puncture the urethra during insertion after the SaniCath is placed. A different, less severe failure mode includes bruising and damage to the urethra below the level of puncture. The critical design requirement our team ranked as the highest priority was “solution does not damage the urethra or bladder”. This priority was chosen because such damage poses an immediate safety risk to the patient due to the potential for bleeding, the possibility of needing surgery, and a high chance of infection. This could lead to sepsis, which can ultimately lead to irreversible organ failure or death. Due to the high risk consequences described, including and up to death, this failure is assigned a severity score of 5. Because puncture of the urethra with a catheter is possible but rare, this is assigned an occurrences score of 1 [145]. Further, use of the catheter guide tube is expected to lower the risk of puncture due to a more controlled guiding of the catheter into the urethra. Using these scores, this hazard was given a Risk Priority Number (RPN) of 5 out of 25, indicating a low priority for risk management due to the low possibility of failure. A summary of this analysis is shown below in Table 10.

**Table 10.** Catheter puncturing the urethra is identified as a top hazard with an RPN of 5.

Task	Failure Mode	Failure Mode Causes	Severity	Occurrences	RPN
Placing catheter into urethra	Catheter punctures urethra	Device placed at incorrect angle	5	1	5

This hazard is remedied by certain aspects of the device design. Urethral puncture is only possible if the catheter is inserted at an angle through which it could apply sufficient force to the urethral wall to break through the tissue. The labia overlay portion of the device is relatively large and lies flat against the user’s vulva as explained in the instructions for use, in which case the catheter is at 0° to the urethral opening. Further, angling the device at any other angle other than laying flat against the anatomy will provide tactile feedback if the user has feeling, and the mirror will display to the user that the device has been angled away from the proper position. It is also important to note that some angle change within normal use will not lead to puncture as this emulates normal self-catheterizing without the device.

For this risk, PubMed was searched using the search terms “catheter insertion urethra\* injury” and “urethral injury catheter\*”. Previously collected relevant papers on urethral puncture were also referenced.

*Dislodging of the catheter.* Another potential failure mode involves the patient dropping the device during use. If the device were to catch on to the catheter in this situation, it could dislodge the catheter quickly. This could, in the worst-case scenario, cause damage to the urethra or bladder if the catheter pulls at the tissue while being removed from the body. Repeated catheter use over time can cause scarring, leading to urethral stricture; more traumatic catheterizations can make this more likely [146]. Serious damage to the urethra, while highly unlikely, could necessitate minor surgery, which has risks, including infection and hemorrhage. This situation was scored a 4 on the severity scale because it is classified as an irreversible severe adverse event, meaning urethral stricture and surgery will have lasting effects and could possibly result in severe consequences. In terms of occurrence, this was scored a 2, as patients with SCI are more likely to have limited dexterity and to drop the device. A summary of this analysis is shown in Table 11.

**Table 11.** Dislodgement of the catheter during use poses a potential risk of injury to the patient, indicated by an RPN of 8.

Task	Failure Mode	Failure Mode Causes	Severity	Occurrences	RPN
Holding device in place	Dislodging of catheter during use	If our device secures catheter and patient drops the device during use, causing catheter to be removed from bladder and potentially urethra	4	2	8

This hazard is remedied by the fact that the catheter guide tube is designed such that all catheter sizes used by female patients will move smoothly within it. Therefore, even if the device is dropped, the chance of the catheter becoming lodged in the guide tube is very low. Safety factors have been added to the diameter of the guide tube to account for this hazard so that the device will not be pulled out of the urethra when the device falls. Additionally, cyclic compression verification testing will be performed to ensure that the device will not deform to the point of the catheters not moving smoothly within the guide.

For this risk, PubMed was searched using the search terms “catheter\* urethral stricture scarring” and “urethral injury catheter\*”. Previously collected relevant papers on the risks of urinary catheter use were also referenced.

### Incorporation of EDR1 Feedback

One suggestion we received during EDR1 was how to optimize our design for sterilization. It was pointed out that sharp edges and corners could be difficult to sterilize and may contribute to bacterial buildup that doesn’t get cleaned properly. This could especially become an issue if the device is reusable and patients are sterilizing it at home. Per this suggestion, we decided to round out as many corners on our device design.

Other suggestions we received were to make the mirror adjustable and make the device discreet. Both of these are valid ideas to consider, and we performed usability testing as described above to determine the need for adjustability and placement options. Additionally, to make the device discreet, we minimized dimensions as possible while still maintaining function. Future steps could include looking into carrying cases or packaging that can be disguised as a headphone case or other everyday use item.

Another suggestion was that we should look into what specific physiological presentation of SCI and

neurogenic bladder we are targeting because that may change how we design our final solution. Currently, it appears that our device could be used for any type of neurogenic bladder; however, we will conduct more research to ensure that truly is the case. From there, we can amend our intended use statement and indications for when to use the device.

### **Power, Privilege, & Identity in Design**

When we began the research process into understanding the needs of patients with incontinence, we initially intended to focus on patients with underactive bladder, as this is an under-researched condition with few treatment options. However, with stakeholder input, we determined that this population may be too small to feasibly design a solution for. While unfortunate, it is important to consider market size when designing. Ultimately our continued research led us to another underserved population, female SCI patients, allowing SaniCath to address needs that are currently unmet in that design space.

We decided to focus on female SCI patients since during user needs research, we identified that it was much more difficult to visualize the female urethral opening. During both caretaker catheterization and self-catheterization. Additionally since women are at a higher risk for UTIs than men. Another reason we decided to focus on female patients, and gear our design towards people with labias, is because there is a systemic bias in engineering and in medicine in which applications deemed “unisex” are investigated using only males. Such as seatbelts and medications, and there is a systemic lack of research in female-specific fields.

Throughout the process, we have also been careful to keep in mind that none of us have an SCI nor have any of us have catheterized, and therefore cannot fully understand the day to day experiences of females who do. Thus, we have emphasized stakeholder input during our research on user needs, our concept generation, and our decision-making processes, and continue to reach out to relevant individuals for more information.

When we defined our requirements and specifications, we prioritized the patient stakeholders. This meant ensuring their health and safety first in terms of critical requirements, and prioritizing group requirements based on our perception of user preferences. We emphasize that these initial prioritizations were assumptions, however we were able to confirm many of them through later stakeholder interviews, such as the importance of usability in a reasonable timeframe, portability, and self-applicability. For concept generation, our final consensus design aligns with some aspects of our initial sketches - it improves visualization, spreads the labia, and includes a catheter guide tube. However, we decided not to pursue the strain gauge as initially conceptualized because it may be costly for our patients and doesn't directly address the needs they specifically outlined.

## **V. Verification & Validation**

This section details how our team assessed the SaniCath's efficacy through verification and validation testing. This includes actual tests performed by the team this semester as well as future test plans to further evaluate the device.

### **Actual Testing**

The following sections provide detailed information on the two actual tests performed by the team to verify the functionality of our device. This includes a pressure analysis simulation and a compression benchtop test, as shown in Table 12 below.

**Table 12.** Actual tests provide a framework for evaluating the functionality of our device

Design Input	Requirement	Specification	Test type	Test name	Acceptance criteria
Safety	Solution does not damage the urethra or bladder.	Solution does not apply greater than 100 psi of pressure [147] on the genitals.	Verification	Pressure analysis	Pressure exerted on external skin is less than 100 psi
Durability	Solution does not fracture under daily use	Solution can withstand > 5N of force, with a safety factor of 3, to ensure design can withstand at least 15N of application force [#]	Verification	Compression Test	No statistically significant difference between initial and post-test dimensions after 180 compression cycles

#### *Pressure Analysis*

A pressure analysis was conducted on our device, as detailed below.

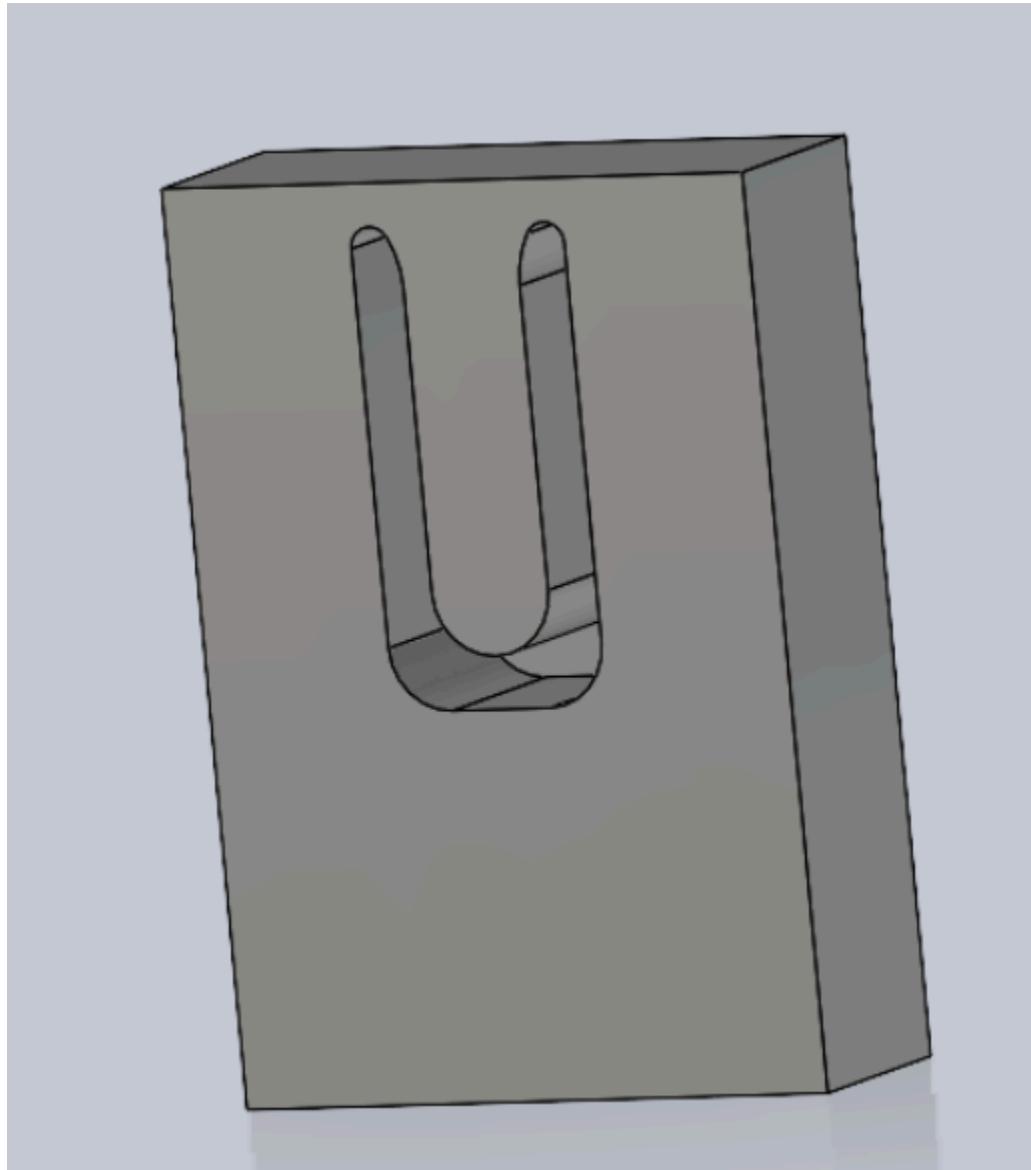
*Purpose.* This verification test aimed to analyze pressure applied to the external skin when SaniCath was in use and ensure our design requirement that our solution does not damage the urethra or bladder was met. The corresponding specification was that the solution would not apply greater than 100 psi of pressure on the genitals [147].

*Experimental Setup.* This test was performed using Finite-Element Analysis (FEA) in a SolidWorks simulation study. A boundary was established to simulate the skin that the device comes in contact with and thereby analyze the pressure induced by the device on the skin. Due to limitations in biological modeling in Solidworks, this boundary was simply an extruded rectangle encompassing the labia spreader component of the device, as shown in Figure 45. Material properties representative of human skin were applied to the boundary, as shown in Table 13. We acknowledge that this may be a limitation to our testing, as the genitals are technically mucous membranes. However, due to the widespread availability of skin material properties, they will be used as an approximation. All values were found through literature review.

**Table 13.** Material properties representative of human skin were applied to the created boundary to simulate the body's response during device use.

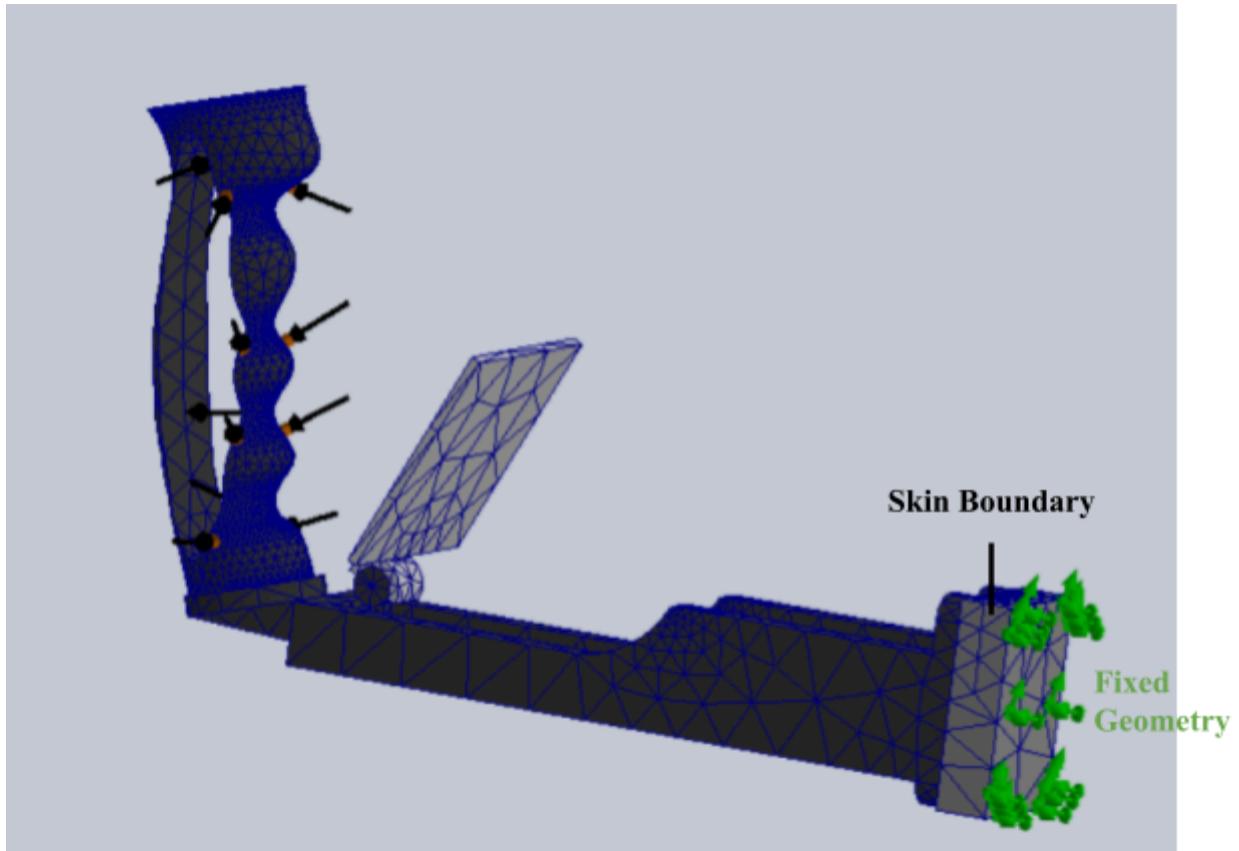
Property	Value
Elastic Modulus	9.5 kN/m <sup>2</sup> [148]
Poisson's Ratio	0.5 [149]
Shear Modulus	4 kN/m <sup>2</sup> [150]

Mass Density	1020 kg/m <sup>3</sup> [149]
Tensile Strength	27.2 MPa[151]



**Figure 45.** A skin boundary was created to simulate the response of a user's external skin that comes into contact with the SaniCath during use

The face of the boundary facing away from the device was established as a fixed boundary. This was to simulate the user's body being stationary in space while the device is inserted into the labia. This is a slight oversimplification as the user could move while the device is in use; however, we expect this movement to be minimal due to the labia needing to be stationary during catheterization to allow for proper urethral visualization and the fact that most individuals with SCI will likely be sitting while catheterizing. This resulted in no displacement and pressure being experienced along this face, indicating an experimental control. This setup is displayed in Figure 46.



**Figure 46.** To simulate a user environment, the outer face of the skin boundary was established as a fixed boundary.

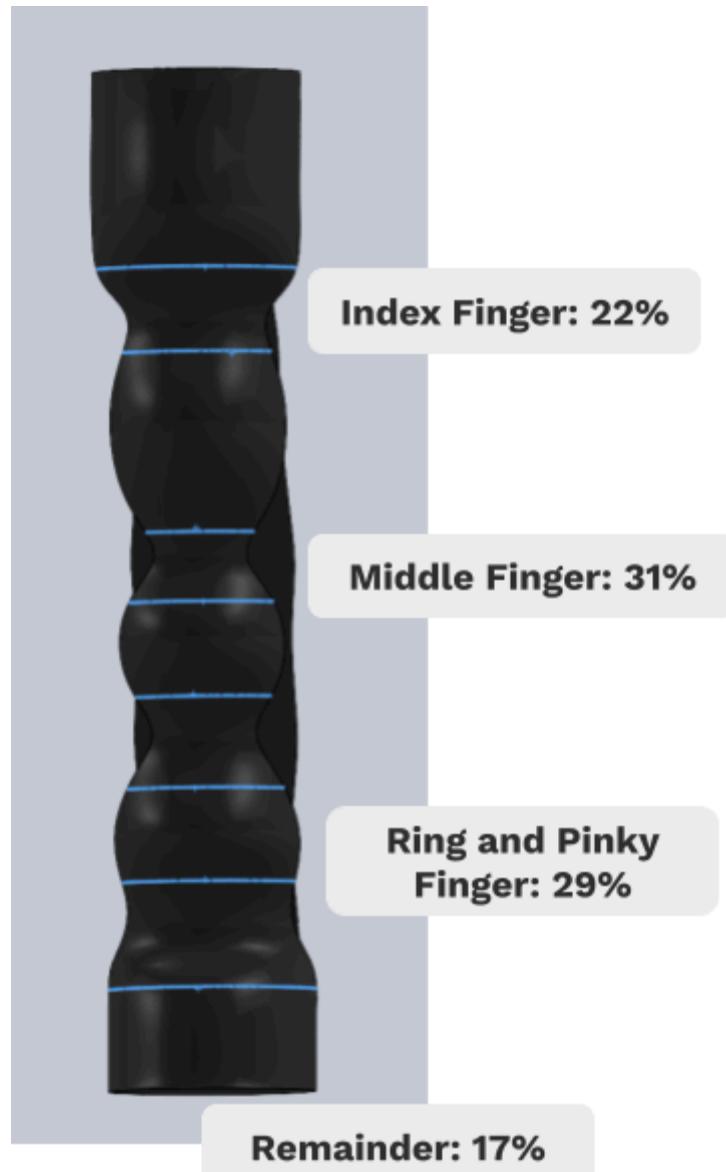
To simulate the application force, we had to understand how users would interact with our grip. To do this, we performed mockup studies with our grip design to understand how users hold the grip and distribute their application force. It was seen that users primarily distributed their application force along their fingers in the grooves of the handle, with any remaining force being applied along the inside surface of the handle where users' palms interface with the handle. This setup is shown in Figure 47.



Figure 47. Mockup Studies showed that application force was distributed primarily along the users' fingers, with the remainder of the force being applied along the inner surface of the grip by the users' palm, as indicated by the arrow

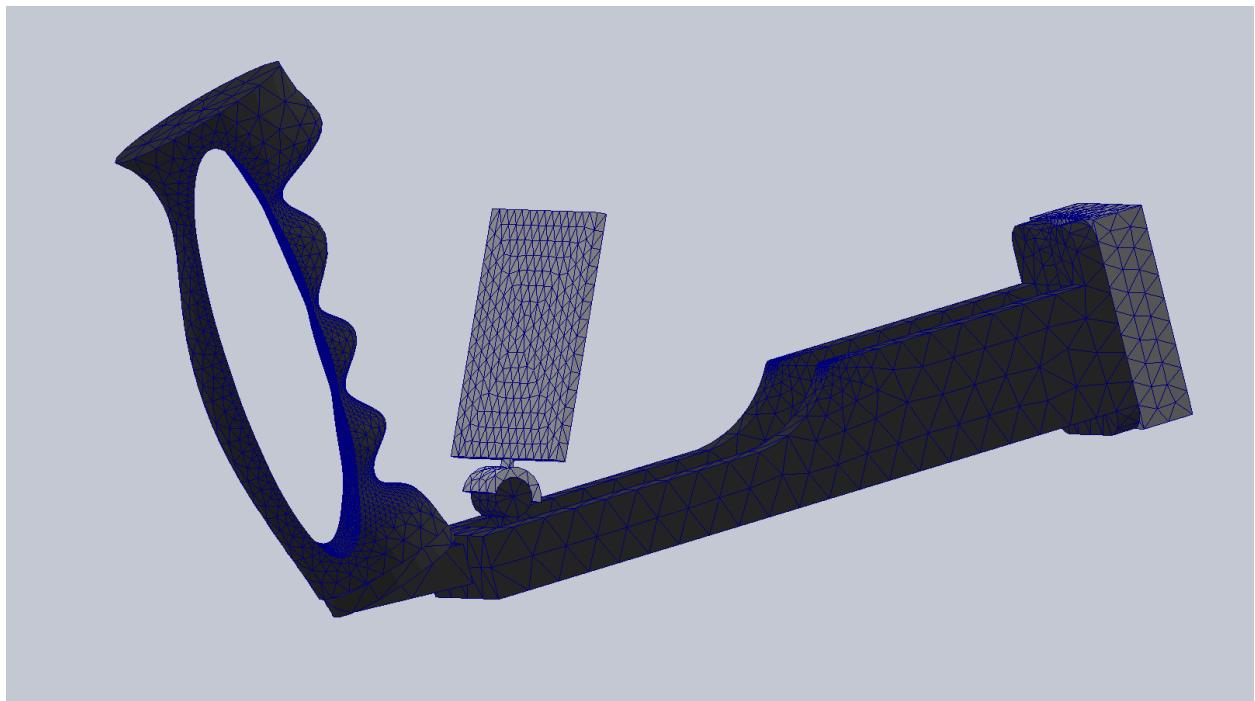
It should be noted that this form of holding the grip assumes no dexterity limitations for the user, which may not be applicable to all users. Seeing as all of our team members have full dexterity, it is pertinent that we continue performing mockup studies directly with SCI patients, especially those lacking dexterity, to further understand the variety of ways in which users interact with the grip. Doing this allows us to rerun this simulation to address each possible way to hold the grip so that all stakeholder perspectives can be included in the design of this test.

After performing these mockup studies, literature review was performed to understand exactly how much each finger contributed to the total application force. This showed that the index finger contributed 22% of total application force, the middle finger contributed 31%, and the ring and pinky finger combined contributed 29%[152]. The remaining 17% was applied across the inner surface of the grip. This setup is shown in Figure 48.

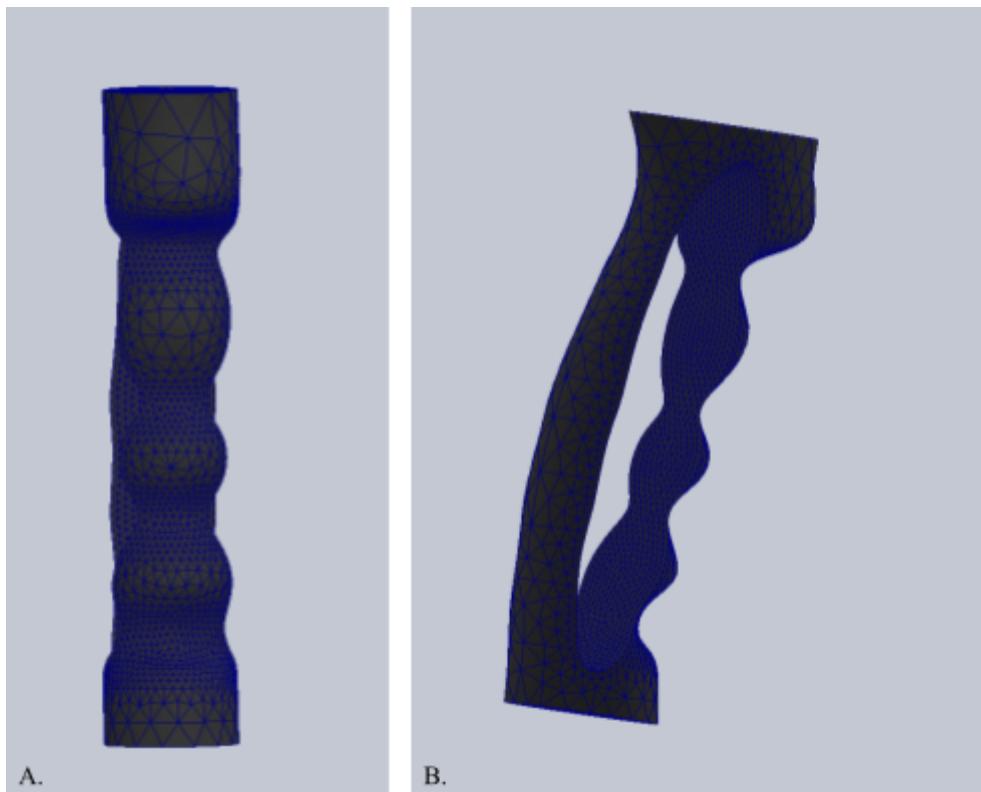


**Figure 48.** The contribution of each finger to total application force was applied along the finger grooves of the grip, with the remainder being applied along the grip inner surface

Seeing as the only parts of the device that experienced application loads were the finger grooves and inner grip surface, these device portions had finer meshes to generate the most accurate results. The remaining device mesh was coarse, as there was no application load along this portion of the device, indicating that results would not be altered by the mesh size. Making the mesh size coarse along these portions served to decrease test runtime. The overall device mesh element size was 0.576 inches, shown in Figure 49. A curvature-based mesh was applied to adapt element size to any local curvatures along the device to prevent any mesh failures. The handle portions along which force would be applied had a mesh element size of 0.05 inches, representing the smallest mesh element size at which the test could be run, shown in Figure 50.



**Figure 49.** Coarse meshing was applied along the device to reduce runtime



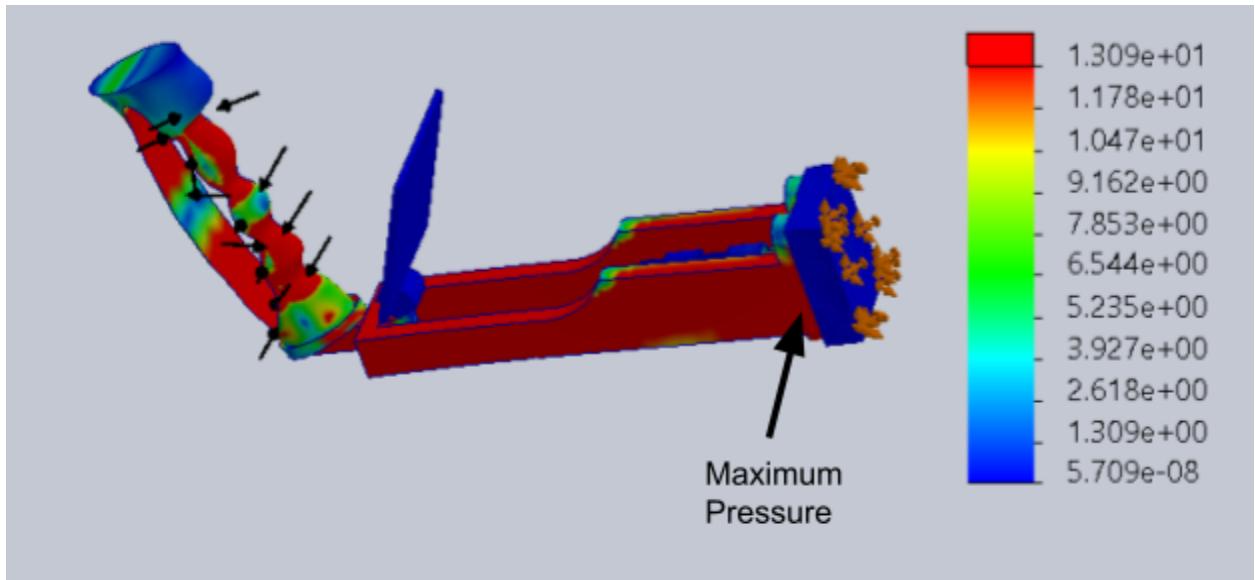
**Figure 50.** Fine meshing was applied along the finger grooves and inner grip surface to ensure accurate test results

Total application forces from 3-15 N were used, representing the range of catheter application forces seen in clinical study [116]. Each of these application forces was multiplied by the proportions of each finger contribution to total grip strength, as explained above. A summary of this application force distribution can be seen in Table 14.

**Table 14.** Total application force was multiplied by the proportion that each finger contributed to simulate force distribution

Total Force	Index Finger(N)	Middle Finger(N)	Ring and Pinky Finger(N)	Grip Inner Surface(N)
15	3.3	4.65	4.35	2.55
14	3.08	4.34	4.06	2.38
13	2.86	4.03	3.77	2.21
12	2.64	3.72	3.48	2.04
11	2.42	3.41	3.19	1.87
10	2.2	3.1	2.9	1.7
9	1.98	2.79	2.61	1.53
8	1.76	2.48	2.32	1.36
7	1.54	2.17	2.03	1.19
6	1.32	1.86	1.74	1.02
5	1.1	1.55	1.45	0.85
4	0.88	1.24	1.16	0.68
3	0.66	0.93	0.87	0.51

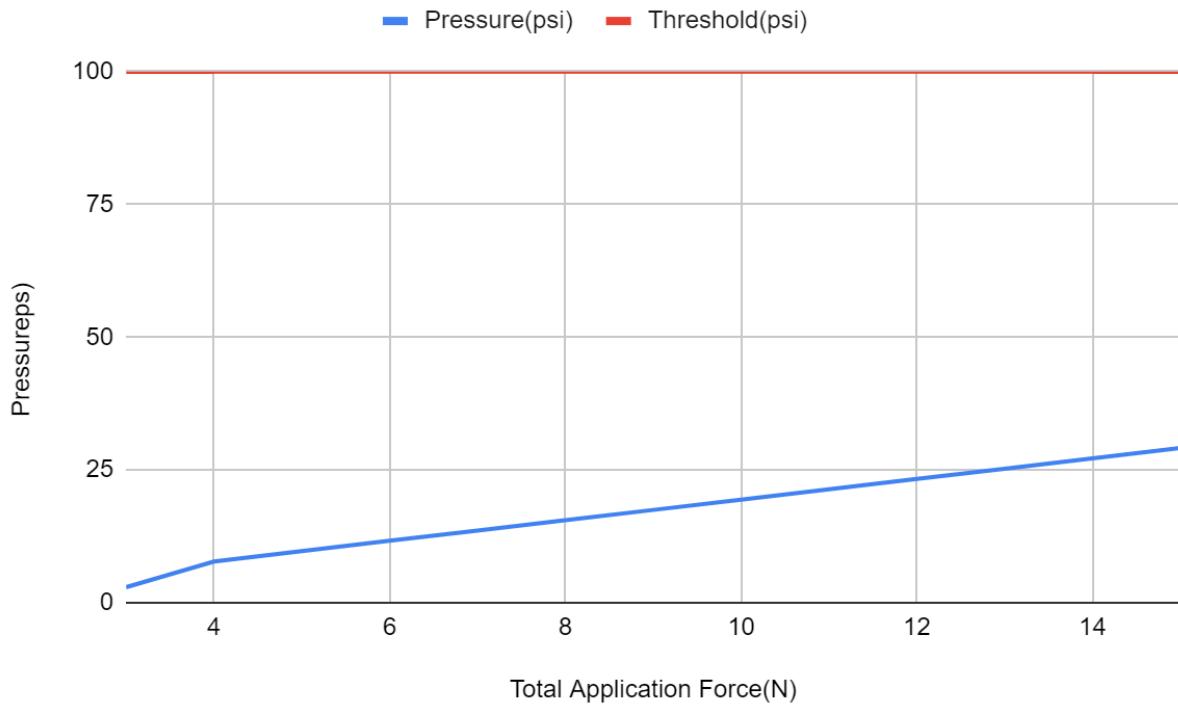
A load case manager was set up using the parameters in Table 14 to run all application forces at once. For each of these total application forces, the corresponding maximum pressure, in pounds-per-square-inch (psi), along the skin boundary face interfacing with the device was analyzed using a sensor to find the maximum induced pressure. This can be seen in Figure 51. Seeing as we were aiming to see the maximum compressive pressure experienced by the boundary, the 1st principal stress in psi was analyzed[153].



**Figure 51.** Maximum pressure, in psi, was analyzed along the face of the skin boundary interfacing with the SaniCath

Each maximum pressure was then compared to our threshold value defined in our design specification, 100 psi. If the maximum pressure was less than 100 psi, our device passed our design specification at the given application force. If it was greater than or equal to 100 psi, that indicated failure for that given application force.

*Results.* Our test results are shown below in Figure 52. As indicated in this graph, the maximum pressure induced on our skin boundary by the device at each application force was significantly less than 100 psi, indicating our device successfully passed our design requirement at all potential application forces.



**Figure 52.** At any given application force, the pressure induced by our device was less than 100 psi, indicating safety for the patient and a successful test result.

Seeing as this was a simulation test and results would not change as long as the experimental setup was constant, there was no need for formal statistical analysis, and we could simply compare our results to our threshold value without needing to collect samples.

There were no evident anomalous results or testing errors. As our device successfully passed this test, and the tested design requirement was met, we propose no redesigns based on these results.

#### *Compression Test*

Compression testing will be used to assess the durability of the SaniCath device.

*Purpose.* The compression test analyzed if the SaniCath could withstand the possible forces placed on the device when used. This test verifies that the SaniCath meets the durability design requirement: “The device does not fracture under daily use.” More specifically, this test verifies that our design can withstand 15 N of application force. This test ensured that our device will withstand its intended use periods for our patient population.

*Experimental Setup.* The testing equipment required for this test was the Test Resources 100Q Series Single Column Frame and the Test Resources Q Controller. Additionally, a ruler, a digital caliper, and clay were required.

During the test, 15 N of force was applied cyclically. 15 N was chosen from the design specification aimed at ensuring that our device can withstand 15 N of force for 15 minutes when used four to six times a day by the user [46]. This 15 N of force also includes a safety factor of 3, ensuring that our team is considering the maximum possible force [116].

The 15 N force was pre-loaded at a rate of 600 mm/min, a loading rate determined through a usability test assessing the time required for proper device positioning. Team members observed an average time of approximately 1.5 seconds for device positioning, leading to the identification of the 600 mm/min loading rate.

Each testing iteration lasted ten seconds to emulate the practical duration of the device being pressed against the skin with the full 15 N force. This timeframe was chosen due to class time constraints, and in future testing, a longer duration, up to 1 minute, would be preferable to account for users applying force for extended periods, with a maximum of 15 minutes to fully satisfy the design specification.

Each cycle comprised six tests, involving the application of a 15 N force for a 10-second period in each test. The decision to conduct six tests per cycle was informed by the average frequency of four to six self-catheterization instances per day [46]. This approach ensures that individuals with more frequent catheterization are appropriately represented in the SaniCath testing.

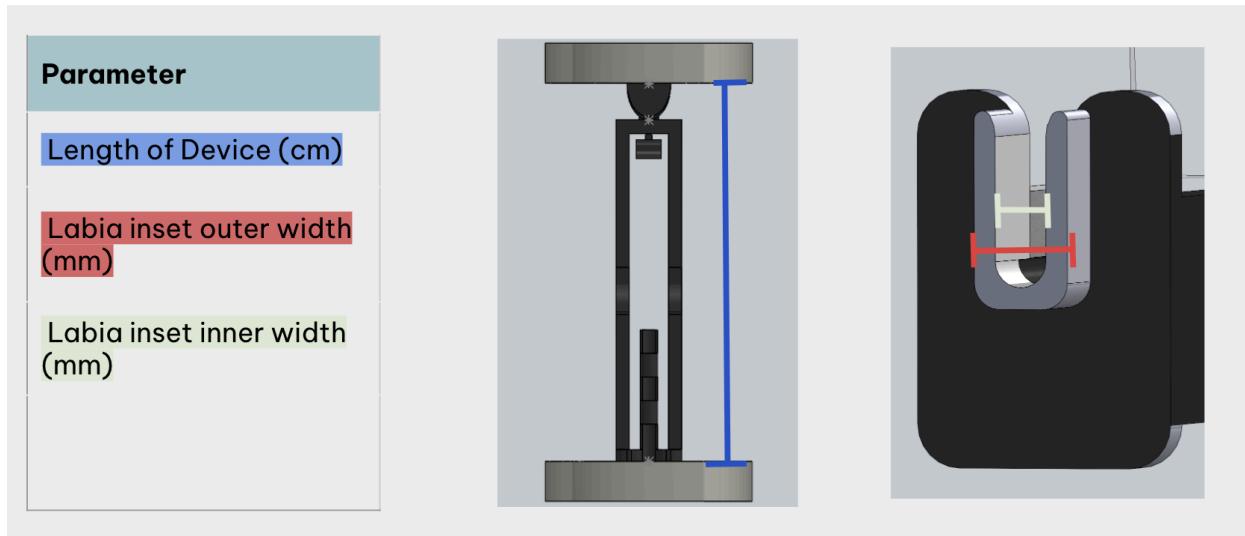
To simulate daily, repeated use of our device, 30 testing cycles were conducted. The choice of 30 cycles aimed to replicate approximately a month of consistent use of the SaniCath, involving catheter insertion six times a day. It's essential to note that, in an ideal testing scenario, a higher number of tests would be preferable to ensure the device's durability over the entire year or two of repeated use. However, this was constrained by time limitations within the class.

A summary of all relevant test parameters can be seen below in Table 15.

**Table 15.** The included test parameters are used to simulate device performance under conditions of repeated use

Parameter	Value
# Total Cycles	30
# Tests in each Cycle	6
Test Time	10 seconds
Force	15 N
Loading Rate	600 mm/min

Before starting the test, three measurements were recorded for the device: the entire device length, the labia inset inner width, and the labia inset outer width. A visual representation of these measurements is provided in Figure 53. The device's length was measured using a ruler, while the inner and outer width of the labia inset were measured with a digital caliper. Additionally, a functionality check was performed to ensure the compatibility of the 16 French catheter, chosen for its immediate availability in the simulation studio materials. In future tests, this check would encompass catheters ranging from sizes 12 to 18 French, ensuring functionality across all sizes specified in the safety design requirement of "Solution does not damage the urethra or bladder" [116]. These metrics were chosen as acceptance criteria of this test because of the impact that distortion to these dimensions would have on the patient. These parameters were also able to be reasonably measured with the resources and timeframe available to us.

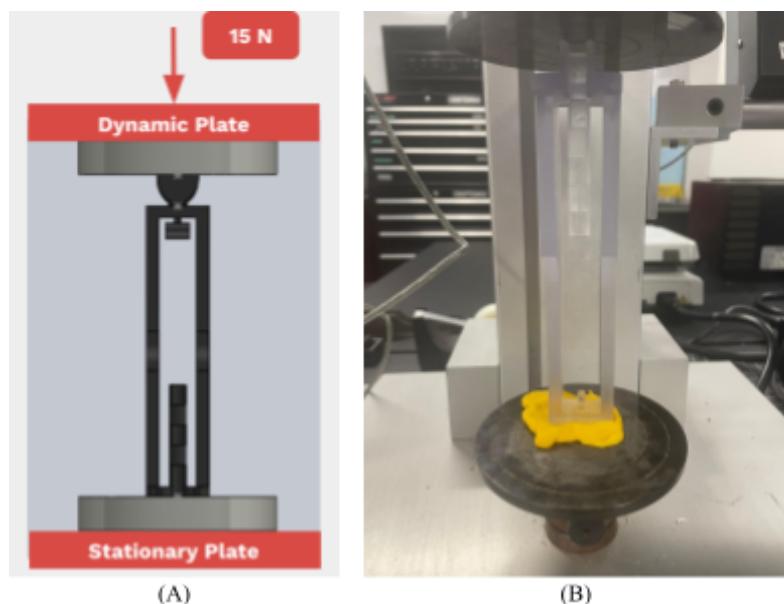


**Figure 53.** The length of the device and the inner and outer width of the labia inset were measured to test the durability of the device at 15N of repeated compression.

To set up the test, the SaniCath is positioned between the machine plates, with the handle end on the stationary plate and the labia inset pointed toward the dynamic plate. The handle is excluded from the test setup due to multiple limitations. The TestResources machine has a maximum length capacity of 14 cm, and with the handle, the device length exceeds this limit. Additionally, during 3D printing, the handle was printed separately, and its attachment to the device would be inaccurate to actual manufacturing. The device was affixed to the plate using clay to address uneven parts and ensure secure placement.

Upon starting the test, 15 N of force was pre-loaded onto the device at a rate of 600 mm/min. The ten-second test period began after the full application of the 15 N force. At the test's conclusion, the TestResources machine promptly removed the force, marking the completion of one test.

The overall experimental setup can be seen below in Figure 54.



**Figure 54.** Experimental test setup allows 15 N of force to applied axially to the device. (A) Planned experimental setup. (B) Actual experimental setup.

After completing all 30 testing cycles, the same three measurements were taken for the device: the entire device length, the labia inset inner width, and the labia inset outer width. The device's overall length was measured using a ruler, while the labia inset inner and outer widths were measured using the digital caliper. Additionally, the functionality check to determine if the 16 French catheter could be inserted was repeated.

This testing procedure was replicated on three separate device samples to assess device consistency. Biomedical Grade Clear Resin was chosen for these tests due to its availability in the Design Spaces and desired properties established during initial testing.

*Results.* To analyze the outcomes of the compression testing, a two-tailed, paired t-test was used. This statistical method is well-suited for comparing the means of two related groups, allowing us to see whether there are statistically significant differences between the pre-test and post-test measurements of the SaniCath.

All statistical analyses were performed using MATLAB. Initially, the conditions for statistical testing, including normality and homogeneity of standard deviations, were checked. Normality was assumed due to the limited number of samples (three). It is acknowledged that for future testing, an increased sample size will be necessary for a more comprehensive assessment of normality. Additionally, homogeneity of standard deviations was assessed to confirm consistent variability between the paired samples.

To conduct the statistical test, the average and standard deviation of each dimension were calculated across all three samples for both the pre-test and post-test measurements. These values are presented in Table 16. Furthermore, the mean difference between pre and post-test measurements was determined, providing insights into the overall change observed in the dimensions of the SaniCath.

The t-statistics were computed using a two-tailed, paired t-test in MATLAB, using the ttest2 function. The degrees of freedom (DOF) for the statistical analysis was two, with consideration that three samples were being used. The p-values for each test were obtained, enabling the assessment of statistical significance. These results are crucial for determining whether the observed changes in the dimensions of the SaniCath after compression testing are statistically meaningful or simply due to random variability.

**Table 16.** Test statistics revealed no statistically significant differences in device dimensions before and after testing.

Parameter	Before Testing	After Testing	Mean Difference	T Statistic	P-Value
Length (cm)	15.667 ± 0.0577	15.6 ± 0.00	0.0667 ± 0.0577	2.000	0.1835
Inner Diameter (mm)	5.7967 ± 0.0971	5.8467 ± 0.0513	-0.0500 ± 0.1300	-0.6662	0.5739

Outer Diameter (mm)	11.2633 ± 0.1274	11.2533 ± 0.0493	0.0100 ± 0.0781	0.2218	0.8451
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The null hypothesis states that there is no significant difference between the pre and post-test measurements, while the alternative hypothesis suggested the presence of a significant difference. Across all three tests, encompassing device length and labia inset inner and outer width, the calculated p-values exceeded the predetermined alpha level of 0.05. This outcome implies the failure to reject the null hypothesis. In the context of our device, this indicates that, following simulated use over a month, the device demonstrates durability and can withstand the anticipated application forces.

### Testing Plans

Detailed test plans have been outlined for various design requirements and specifications, as shown in Table 17. The details are outlined below.

**Table 17.** Testing plans outline how our team aims to evaluate device functionality in the future

Requirement	Specification	Test type	Test name	Acceptance criteria
Typical urine flow must be maintained.	Solution does not decrease urine flow rate significantly when compared to CIC,	Verification	Urine Flow Analysis	Urine flow through the SaniCath does not decrease when compared to CIC using t-test analysis at $\alpha=0.05$
Solution does not damage the urethra or bladder.	Fits females using 12-18 Fr catheters [60]	Verification	Catheter Size Test	Catheter length does not change before and after testing and catheters are not damaged
Solution can be sterilized with common methods	Solution can be sanitized with boiling, microwaving, placing in dishwasher for sanitation cycle or use of weak bleach solution [154].	Verification	Sanitation Test Plan	Protein concentration swabbed on SaniCath needs to be below 6.4 $\mu\text{g}/\text{cm}^2$ after each cleaning method, which is the AAMI ST98:2022 cleaning acceptance criteria for protein end points [155].
Solution decreases the risk of UTIs	Solution decreases the number of UTIs per year significantly	Validation	UTI Research Study	Number of UTIs in device group is significantly lower, as assessed by t-test analysis at alpha value of 0.05
Solution must allow for self-application	Use of the device increases the number of times the device is inserted correctly on the first try significantly	Validation	Correct Device Placement Data Collection	Correct device placement percentage is significantly greater with the device, as assessed by a t-test analysis at an alpha value of 0.05

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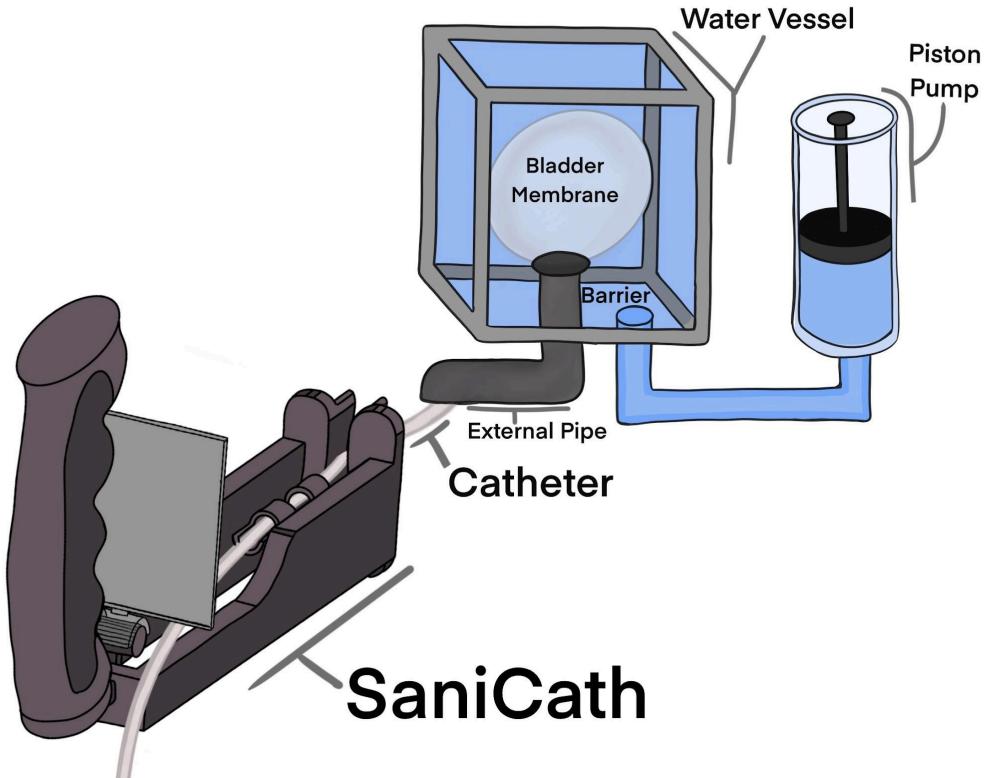
Solution can be used in a reasonable timeframe.	Use of device increases the number of times the device is inserted correctly on the first try significantly	Validation	Catheterization Time Data Collection	Catheterization time with device is significantly faster, as assessed by a t-test analysis with alpha = 0.05
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### *Urine Flow Analysis: Verification*

A urine flow analysis benchtop study is outlined below.

*Purpose.* This test is aimed to analyze whether our device allows for typical, healthy physiological urine flow rates through the catheter. The corresponding specification is that the solution does not decrease urine flow rate significantly when compared to CIC. This will serve as a verification test without any human subjects.

*Experimental Setup.* To analyze our device's impact on urine flow rate, we must first create a model bladder to allow for drainage through the catheter. To do this, we will create an elastomeric bladder membrane within a water-filled vessel, which is connected to an external piston pump. This pump controls the volume of water within the vessel, and subsequently the bladder membrane. The bladder membrane is connected to an external pipe through the vessel wall, to allow for catheter insertion. This pipe contains a barrier at the bladder membrane, keeping the volume of the membrane constant when needed. This is a mechanical barrier that can be engaged and disengaged via an attachment along the outside of the vessel. This model was heavily influenced by bladder models that were previously developed in clinical study and the overall setup is shown in Figure 55 [156].



**Figure 55.** Our bladder model allows for control of simulated bladder volume using a piston pump and water vessel and provides catheter insertion through an external pipe.

The piston pump will have designated markings that indicate the volume within the bladder membrane, which will be calibrated prior to testing.

For this test there will be 2 sets of data taken, urine flow using CIC and urine flow with CIC and the SaniCath. Each of these groups will have 30 total samples taken, as this ensures our sample size is sufficiently large to allow for statistical analysis according to the Central Limit Theorem[157].

Prior to each sample taken, the volume of the bladder membrane will be filled to 500 mL using the piston pump. This represents the upper limit of urine volume in the female bladder[158]. To take a sample, a catheter will be passed through the external pipe until it reaches the bladder membrane. At this point, the barrier will be disengaged and water will flow through the catheter until the bladder membrane is fully emptied. The time it takes for full emptying will be measured. Then, this same process will be performed using the SaniCath. This will be repeated 30 times to collect 30 samples.

Flow rate will be calculated by taking the volume of water passed through the catheter and dividing it by the time it takes for full emptying, as shown in Equation 1. Seeing as the volume emptied will always be 500 mL, this represents an experimental control.

$$\text{Flow Rate(mL/seconds)} = \frac{500 \text{ mL}}{\text{Time for full bladder emptying(seconds)}} \quad (1)$$

*Statistical Analysis.* To compare results between the groups, we will perform a two-sample, one-sided t-test. This test will be one-sided because we will simply be analyzing whether our device significantly reduces flow rates compared to CIC. Our null hypothesis will be that our device has no effect on flow rate. If we reject the null hypothesis, this indicates urine flow rate was decreased using our device, indicating test failure. Failing to reject the null hypothesis indicates our device did not significantly decrease flow rate, indicating test success. A significance level, or  $\alpha$ , of 0.05 will be used, per clinical standards [159]. We can ensure this test method is appropriate because we will take independent samples and can assume data is normally distributed due to the sample size meeting criteria for the Central Limit Theorem.

From here, we will calculate the means of each group using Equation 2:

$$\mu = \frac{\sum X}{30} \quad (2)$$

where  $\mu$  represents the group mean,  $\sum X$  represents the summation of flow rates for each group, and 30 represents the sample size of each group[160].

Degrees of freedom(DOF) for each group will be calculated using Equation 3:

$$DOF = n - 1 \quad (3)$$

where  $n$  represents the sample size. Seeing as the sample size for both groups will be 30, the DOF for each group will be 29, and the pooled DOF will be the summation of each group, equivalent to 58[160]. Standard deviation for each group will be calculated using Equation 4:

$$s = \sqrt{\frac{\sum (x_i - \mu_i)^2}{29}} \quad (4)$$

where  $s$  represents the standard deviation for each group,  $x_i$  represents the flow rate of a given sample,  $\mu_i$  represents the mean flow rate for the group, and 29 represents the DOF for one group[160].

Using the standard deviations of each group, we will calculate the pooled standard deviation using Equation 5:

$$s_p = \sqrt{\frac{(29)s_1^2 + (29)s_2^2}{58}} \quad (5)$$

where  $s_p$  represents the pooled standard variance,  $s_1$  represents the standard deviation for the CIC-only group,  $s_2$  represents the standard deviation of the SaniCath+CIC group, 29 represents the DOF for each group, and 58 represents the pooled DOF for both groups[160].

Finally, we will calculate the t-statistic using Equation 6:

$$t = \frac{\mu_1 - \mu_2}{s_p \sqrt{\frac{1}{30} + \frac{1}{30}}} \quad (6)$$

where  $\mu_1$  and  $\mu_2$  represent the sample means for the CIC-only group and CIC+SaniCath group, respectively,  $s_p$  represents the pooled standard deviation, and 30 represents the sample size for each group[160].

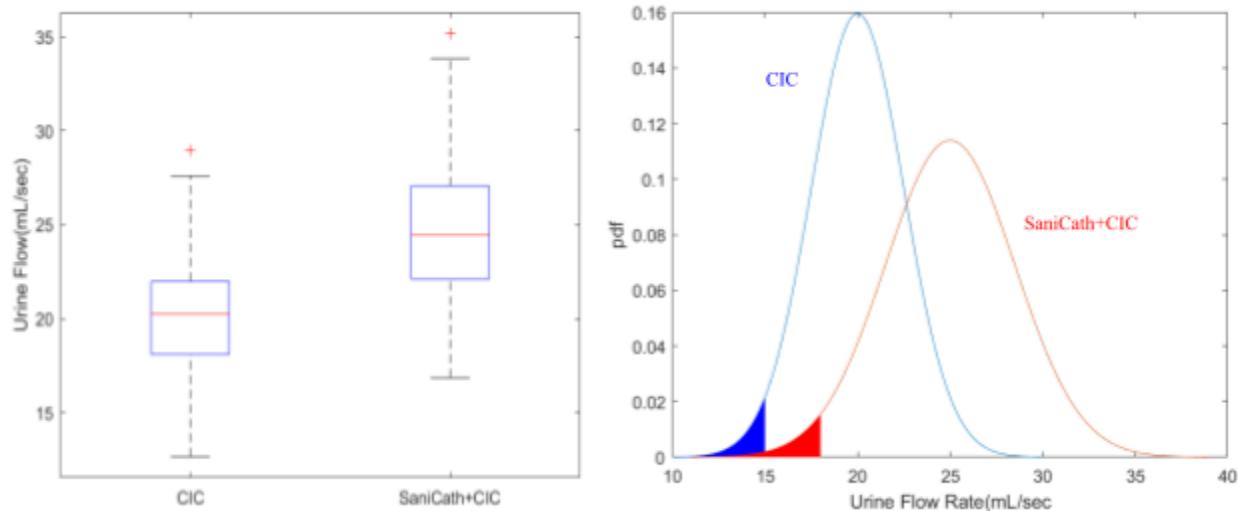
The t-value for this test with  $\alpha=0.05$  with DOF=58 is -2[161]. This value is negative because we are only analyzing the lower tail to test for a decrease in flow rate. If our t-statistic is greater than this value, we fail to reject the null hypothesis, indicating test success, and if the statistic is less than this value, we can reject the null hypothesis, indicating test failure.

*Results.* We expect to see no significant difference in urine flow rates when using the SaniCath with CIC as compared to CIC alone. These test results will first be presented in a table including the mean, standard deviation, and sample size for both groups, the calculated test statistic, and indication of whether the null hypothesis was rejected or not. Table 18 has mock data representative of results we might expect and shows how our results will be presented. These mock results are indicative of test success.

**Table 18.** Mock Results show there is no significant decrease in urine flow rate when using the SaniCath

Group	Mean $\pm$ Standard Deviation(mL/sec)	Sample Size	T-Statistic	Conclusion
SaniCath + CIC	20 $\pm$ 2.5	30	-1.022	Failed to reject null hypothesis
CIC	25 $\pm$ 3.5	30		

To compare the two groups, we will use distribution and box plots, shown using mock data in Figure 56.



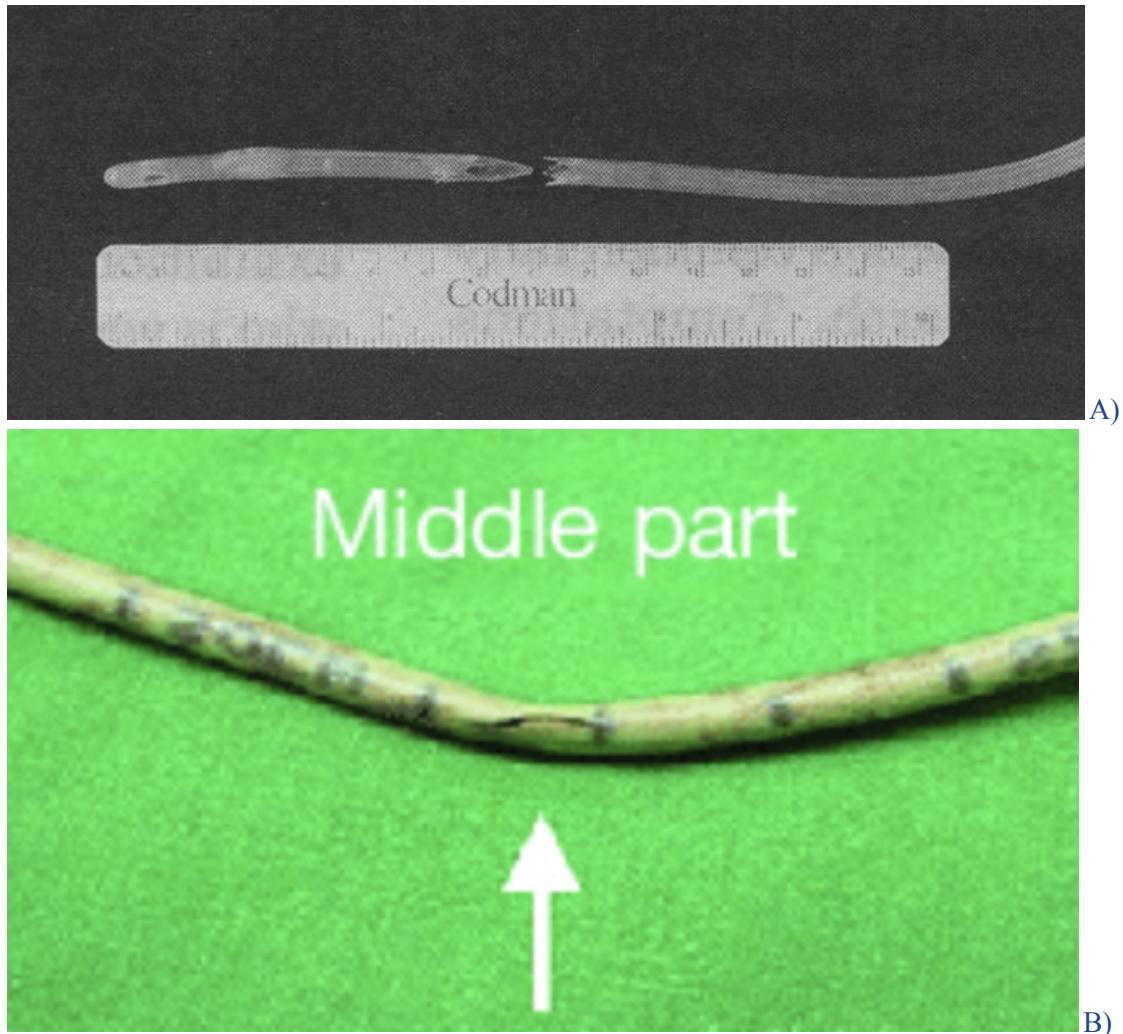
**Figure 57.** Box and distribution plots convey that the SaniCath does not decrease urine flow rates.

### *Catheter Size Test: Verification*

A catheter size test will be designed as outlined below as a verification test.

*Purpose.* In order to ensure that our device meets the specification, to allow usage of 12-18 Fr sized female catheters (diameter range 3.96-5.94 mm) [162], we propose a verification catheter sizing test.

The team member conducting this test would insert lubricated 12-18 Fr sized catheters into the SaniCath, noting difficulties with application such as excess force needed, breaks, cracks, stretching or shrinking of the catheter. Figure 58 shows examples of how catheters can break or crack.



**Figure 58.** A) Example of severe break in catheter [163]. B) Example of severe crack in catheter [164].

Amount of force required for insertion would be measured using a pressure sensor. Since 5 N is the optimal amount of force required to insert a urinary catheter [116], the hope is that our device does not require more than 5 N of insertion force to insert any sized catheter within the size range.

Catheters may experience stretching or shrinking over time, when they do they should be discarded [165]. For this reason we are testing to ensure the SaniCath does not cause any stretching or shrinking to the catheters.

*Experimental Setups.* To start the SaniCath device would be placed in a stationary position to simulate the user holding the device in place. This could be replicated by applying adhesive to the bottom of the SaniCath.

4 different sized female catheters (12 Fr, 14 Fr, 16 Fr, and 18 Fr) will be used. A packet of Surgilube Lubricating Jelly, that is a popular kind of water-based lubricant for urinary catheters [166]. Additionally, the operator would need a tape measure, to measure the length of the female sized catheters before and after testing.

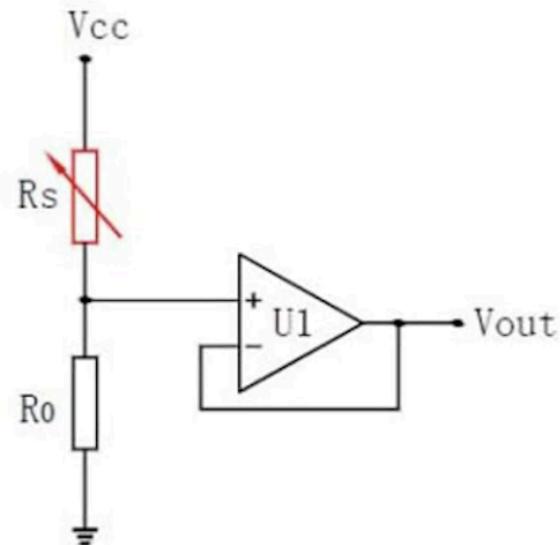
In order to measure the amount of force needed to insert each sized catheter, the pressure sensor would be placed behind the labia spreader of the SaniCath, where the urethra would normally be during usage. That way when the catheter is inserted through the SaniCath, it will press into the pressure sensor and allow us to measure how much force was used for each catheter insertion. We propose using a RP-C resistance type pressure sensor, such as the one shown in figure 59. It has a pressure sensing range of 20 g to 2 kg [167].



**Figure 59.** A RP-C resistance type pressure sensor by Walfront that would be used for the Catheter Size Test [167].

Note that this is an adequate pressure sensing range since 2 kg is over 19 N of force and we are testing to ensure that no more than 5N of force is needed to insert any of these catheters.

The pressure sensor would be connected to a fixed resistor in series to measure the output voltage ( $V_{out}$ ) at both ends of the fixed resistance. Figure 60, shows a circuit diagram of how the pressure sensor would be set up.

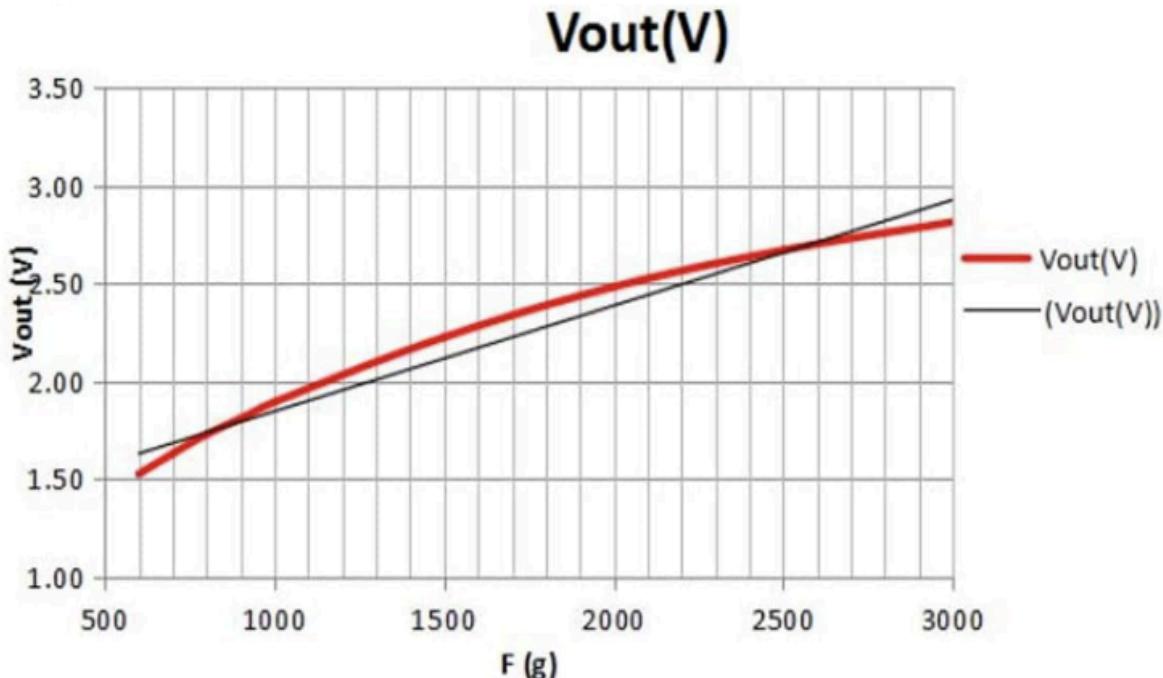


**Figure 60.** How to set up the Walfront Pressure sensor,  $R_s$  and  $R_o$  being two resistors of known value [167].

The value of  $V_{out}$  would then be measured and collected using a voltmeter. Equation 7 is the equation we would use to determine what the variable  $V_{out}$  from the pressure sensor would be.

$$V_{out} = V_{cc} * R_o / (R_o + R_s) \quad (7)$$

$V_{out}$  would then allow us to calculate force based on the graph in figure 61.



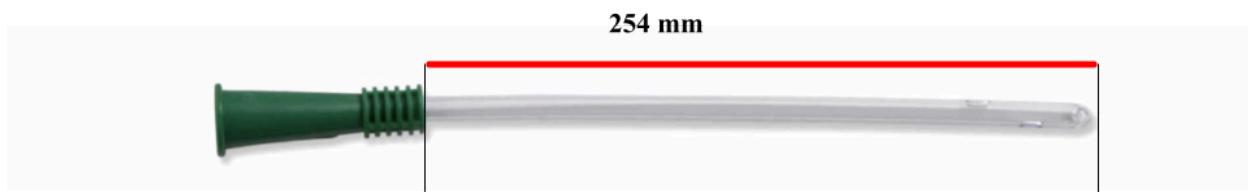
**Figure 61.** Force (g) vs  $V_{out}$  (V) for the Walfront pressure sensor [167].

Note that this test plan does not focus on a used/compressively tested SaniCath's ability to utilize female catheters 12-18 Fr, since the compression test already includes testing to determine the amount of deformation allowed before loss of function.

There are three parts to being able to determine if the SaniCath will pass the Catheter sizing test. If lubricated female 12, 14, 16, and 18 Fr sized with around 177.8 mm to 254 mm in length [165] catheters are able to be inserted into the SaniCath without; more than 5 N of application force, any change in length of catheter, any obvious physical changes to the catheter; such as obvious cracks or breaks.

If the SaniCath fails to meet any of the criteria listed above, even if it passes two out of three requirements, it will not pass this test.

The team member conducting this test will start with a 12 Fr size catheter and measure the entire length of the catheter that is to be inserted. Figure 62 shows where the measurements will be taken.



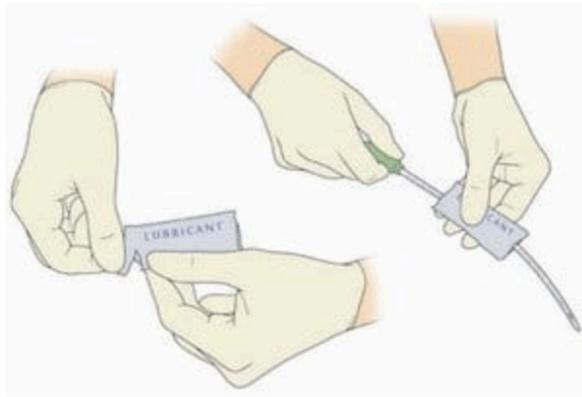
**Figure 62.** Picture of Catheter and the red line shows the entire length of the catheter to be inserted and so that is where the catheter will be measured [168].

The measurement will be noted in the “Pre-Testing Length” column of table 19.

**Table 19.** Length measurements of catheters before and after testing will be listed in this table.

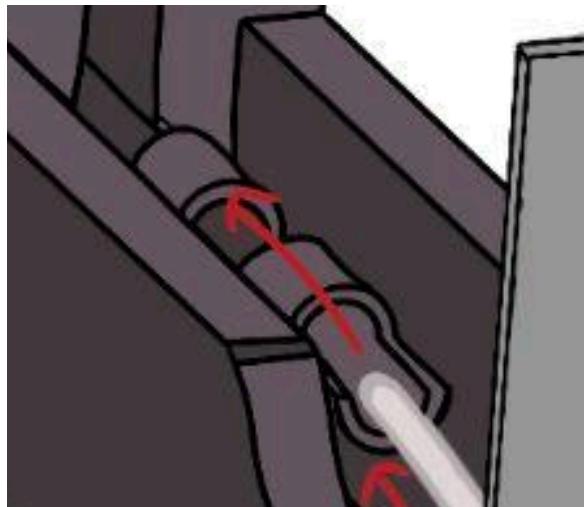
Catheter Size	Pre-Testing Length (mm)
12 Fr	
14 Fr	
16 Fr	
18 Fr	

Next, cut a sterile lubricant packet open at both ends, then slide the catheter through the packet, to apply the lubricant hygienically [169]. Figure 63 illustrates how to conduct these steps.



**Figure 63.** Illustration of how to apply lubricant to a catheter. First cut or tear open each end of the sterile lubricant packet, then slide the catheter through the packet [169].

The team member conducting this test will then insert the catheter through the SaniCath until it presses into the pressure sensor. Figure 64 for reference of the catheter being inserted into the SaniCath.



**Figure 64.** Catheter being inserted into the SaniCath.

The team member conducting this test will then record Vout from the voltmeter in table 20.

**Table 20.** For collection and organization of data from the pressure sensor.

Catheter Size	Vout from Voltmeter (V)	Amount of Force (g)	Amount of Force (N)
12 Fr			
14 Fr			
16 Fr			
18 Fr			

The team member conducting this test will then remove the catheter from the SaniCath and re-measure the entire length of the catheter. Noting measurements into the “Post-Testing Length” column of table 21.

**Table 21.** Table for collection of post testing catheter length, reference - figure 62.

Catheter Size	Post- Testing Length (mm)
12 Fr	
14 Fr	
16 Fr	
18 Fr	

Next, the team member will closely inspect the catheter for any cracks or breaks. The team member will then complete tables 22 and 23, by answering the questions in the first row of the tables for each catheter size.

**Table 22.** The team member conducting this test will complete this table while evaluating each size catheter for any cracks.

Catheter Size	Any cracks? Yes or No	If yes, describe the crack	Picture of Crack
12 Fr			
14 Fr			
16 Fr			
18 Fr			

**Table 23.** The team member conducting this test will complete this table while evaluating each size catheter for any breaks.

Catheter Size	Any breaks? Yes or No	If yes, describe the break	Picture of Breakage
12 Fr			
14 Fr			
16 Fr			
18 Fr			

The same steps will be repeated for size 14, 16 and 18 Fr catheters, then the whole test will be repeated 29 more times. Therefore, after completing this test each catheter in the size range 12-18 Fr will have been inserted through the SaniCath 30 times.

*Statistical analysis.* In order to determine if the change in length from before and after inserting each size through the SaniCath is significant we will be performing a two-sample, one-sided t-test. This test will be one-sided because we will simply be analyzing whether our device significantly changes the lengths of catheters in the size range 12-18 Fr. Our null hypothesis will be that the SaniCath does not affect the length of catheters. Our alternative hypothesis would be that the SaniCath does significantly change the length of catheters in the size range 12-18 Fr, since we are checking if the SaniCath causes the catheters to stretch or shrink, meaning increase or decrease the length of the catheters. In order to indicate success, we would have to fail to reject the null hypothesis, meaning the SaniCath did not significantly change the length of catheters.

Note that this t test will be conducted following the same procedure as in the urine flow analysis test to compare catheter lengths in millimeters pre- and post testing. Equations 2-6 will be applied, with variables modified to test catheter length instead of flow rate [159], [160], [161]. Of note,  $\mu_1$  and  $s_1$  in this case represent the baseline mean and standard deviation catheter length before being inserted through SaniCath and  $\mu_2$  and  $s_2$  represent these values after insertion through SaniCath,  $x_i$  represents the catheter length of a given sample, and  $\mu_i$  represents the mean catheter length for the group. The t-value for this test with  $\alpha=0.05$  with DOF=58 is 0 because we are analyzing both of the two tails to test if there is a significant increase or decrease in catheter length. If our t-statistic is greater or less than zero we can reject the null hypothesis, indicating test failure. However, if our t-statistic is equal to zero, we fail to reject the null hypothesis, indicating test success.

**Table 24.** Ideal Mock Results show there is no significant change in catheter length when using the SaniCath. Plots of Statistical Analysis would be similar to figure 57.

Group	Mean $\pm$ Standard Deviation (mm)	Sample Size	T-Statistic	Conclusion
Catheter Length with using SaniCath	$254 \pm 20.4$	30	0	Failed to reject null hypothesis - Success
Normal Catheter Length	$254 \pm 20$	30		

*Results.* We expect that the SaniCath will not change the length of catheters, cause any severe cracks or breaks of the catheter or require  $>5N$  of application force for catheters sized 12-18 Fr. This would ensure our device adequately allows for usage of catheters within this range since changing length or causing a crack/break would affect the integrity of the catheter. And 5 N is the optimal amount of force, we don't want our device to be the reason users need to apply more, since it could potentially be dangerous. Table 25 demonstrates how this test's results will be presented, highlighting the main requirements of this test.

**Table 25.** Final data presentation of ideal Mock Data test results from the Catheter Size Test.

Catheter	Insertion Force	Change in length	T-test	Severe Cracks or	Picture of
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Size	(N)	(mm)	Conclusion:	Breaks Present: (Yes or No)	Crack or Break
12 Fr	3.0 N	0 mm	Fail to reject Null - Success	No	n/a
14 Fr	3.5 N	0 mm	Fail to reject Null - Success	No	n/a
16 Fr	4.3 N	0 mm	Fail to reject Null - Success	No	n/a
18 Fr	4.9 N	0 mm	Fail to reject Null - Success	No	n/a

*Test Limitations.* An important limitation to consider with this test plan is the fact that we are not considering all catheter sizes. We acknowledge that there are female patients who might use catheters outside of the range of 12-18 Fr, but since this is the average range and the range we primarily used to shape our design we will not consider other sizes for this test. We hope that in the future, SaniCath would be more applicable for users who use catheter sizes outside of this range. Another limitation is the fact that we do not inspect the catheters micro or sub-microscopically. This is worth noting since the SaniCath could potentially cause damage to catheters at the micro or sub-microscopic level that could reduce the lifespan of a catheter.

#### *Sanitation Test Plan: Verification*

The SaniCath sanitation plan will be conducted following the outlined procedures, and will serve as a verification test. Note: this test was updated based on the material change from polyurethane to BioMed Resin.

*Purpose.* The purpose of this test is to determine if our device meets the newly drafted specification that our solution can be sanitized with common methods such as boiling, microwaving, placing in dishwasher for sanitation cycle, or the use of weak bleach solution. This is because we believe it is very important for users to be able to properly clean their device at home, so we will be testing these methods' abilities to clean the device. In order for SaniCath to pass this test, protein concentration needs to be below 6.4  $\mu\text{g}/\text{cm}^2$  after each cleaning method, which is the AAMI ST98:2022 cleaning acceptance criteria for protein end points [155]. See the experimental setup for an explanation on why proteins are analyzed. See Figure 65 for the table of acceptance criteria from the AAMI ST98:2022 standard.

Clinically Relevant Analyte	Acceptance Criteria
Protein	$\leq 6.4 \mu\text{g}/\text{cm}^2$
Total Organic Carbon	$\leq 12 \mu\text{g}/\text{cm}^2$
Carbohydrate	$\leq 1.8 \mu\text{g}/\text{cm}^2$
Hemoglobin	$\leq 2.2 \mu\text{g}/\text{cm}^2$
Adenosine Triphosphate (ATP)	$\leq 22 \text{ femtomoles}/\text{cm}^2$

**Figure 65.** The table of acceptance criteria for endpoints from AAMI ST98:2022 standard shows the protein acceptance criteria boxed in green to indicate which value we are focusing on for this test [155].

Note that an analyte is a chemical substance that is the subject of chemical analysis [155].

*Experimental Setup.* A soil is natural or artificial contamination on a device or surface following its use or simulated use [155]. According to the AAMI TIR12:2020/(R)2023 standard, the soil used for cleaning method testing should be as close to actual clinical use as possible and should be applied based on device usage [170]. The following steps will be performed by a team member to allow for verification.

The soil we will be using for this test is reconstituted dry milk powder because it has clinical relevance as a protein, carbohydrate, and carbon source [171]. This is important because SaniCath would potentially come in contact with biological fluids such as blood, which contains many proteins [172], and urine, which contains carbon and small amounts of carbohydrates [173]. The dry milk will be reconstituted by mixing together 1 cup of water and  $\frac{1}{3}$  cup of milk powder to make 1 cup of solution [174].

The soil will be applied by dipping the end of SaniCath into the milk solution, with the labia overlay and spreader covered. Next, a catheter within the size range of 12-18 Fr will be selected and inserted into SaniCath. Once through the guide tube, the catheter will be inserted further so that it is completely submerged in the solution, while still inserted through the SaniCath, and then removed from the device. This will simulate actual usage conditions where the catheter is inserted into the urethra and into the bladder and then removed after draining the bladder. This process of soiling will be repeated for 3 additional SaniCath devices.

Four different manual cleaning methods will be tested, each requiring their own setup elements. A new roll of paper towels and four pairs of tongs will be acquired, one for each method. A dry, well ventilated area without dust will be located for drying. One soiled SaniCath will be used for each cleaning method for a total of four SaniCath devices used to complete this test.

To set up for cleaning with a mild bleach solution, 2 teaspoons of unscented bleach and one gallon of water will be added to a sterile basin and the SaniCath will be placed into the basin, ensuring that it is completely submerged. The device will be soaked for at least two minutes, removed with tongs, and placed in the designated drying area. Note that the device should not be rinsed with water since any remaining bleach will break down quickly as the device dries and rinsing with water could potentially reintroduce germs for the device [175].

To set up for the boiling cleaning method, the mirror will be removed and set aside. Next, a large pot will be filled with water and placed on a stove top heating element. The soiled SaniCath will then be placed into the water and completely submerged. The pot and device will then be heated until the water boils and then boiled for 5 minutes [175]. The device will then be removed with tongs and placed in the designated drying area.

To set up for microwave cleaning, the soiled SaniCath will first be disassembled by removing the mirror and then washed with soap and water. It will then be placed inside of a 2.45 GHz microwave with a turntable for 60 seconds [67]. The device will then be removed with tongs and placed in the designated drying area.

Note that in order to use a microwave for disinfecting purposes it can be microwaved for 60 seconds to 5 minutes, but according to the AAMI ST98:2022 you should base your cleaning procedure on the worst case scenario or bare minimum procedure [155].

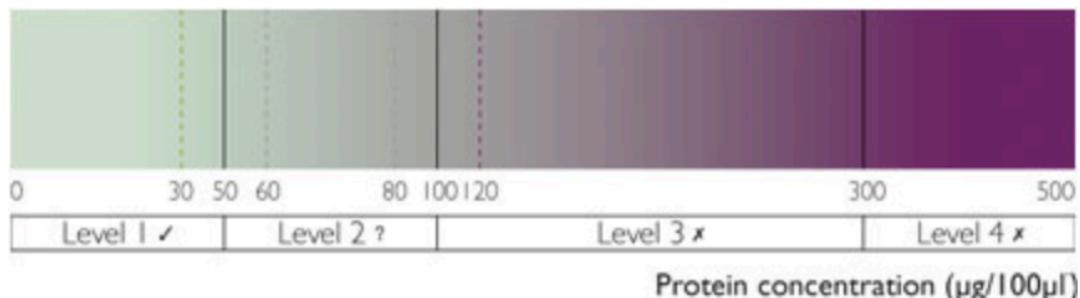
For the dishwasher sanitation method, the sanitation setting on the dishwasher will be identified and the soiled SaniCath will be disassembled by removing the mirror. Standard dishwashing soap will also be

needed. The dishwasher will be turned on for a sanitation cycle. Once the dishwashing cycle is complete, device will be removed with tongs and placed in the designated drying area.

It is worth noting that in order for a dishwasher to perform a sanitation cycle, it needs to heat the water used to over 150°F [176] and that not all dishwashers will specifically have a sanitation cycle, but the majority will have an appropriate alternative that also reaches 150°F.

Once the SaniCaths have dried a 10 Minute Result Protein Plus Surface Test Swab will be utilized to swab the labia overlay and the inside of the catheter guide tube. These surfaces were chosen because they are the most challenging areas of the SaniCath to clean due to their shape and prolonged direct contact with the body. If they are not properly cleaned, there may be a higher risk of infection.

10 Minute Result Protein Plus Surface Test Swabs are used since they will test for concentration of proteins present after cleaning. After swabbing the challenging areas, the swab will take about 10 minutes. It will turn either purple or green depending on the concentration of protein. Figure 66 shows how the test will demonstrate concentration of protein.



**Figure 66.** After the swab and solution have been combined for 10 minutes, the solution color will indicate protein concentration. Green (level 1) indicates a pass result - clean, purple indicates a fail result - re-clean and re-test [177].

Table 26 will then be filled out after swabbing the labia overlay and the inside the catheter guide tube. After 10 minutes have passed, the color will be assigned to a concentration level.

**Table 26.** The team member conducting this test will complete the table as they complete testing for each SaniCath used per method.

	Labia Overlay - Color of swab:	Labia Overlay Protein concentration level	Clean (yes or no)	Catheter guide tube - color of swab:	Catheter guide tube Protein concentration level	Clean (yes or no)
Bleach Solution						
Boiling						
Microwaving						
Dishwashing						

*Results.* We expected that the SaniCath will be cleaned with all four common methods to allow for home cleaning. The data will be presented in table 27 below as a summary of results from the test as a whole.

Note that for this test we did not conduct statistical analysis testing since for this test the data comparison was direct, did the protein concentration meet the end point concentration, yes or no.

**Table 27.** Mock Data for the SaniCath Sanitation test, comparing protein concentration to AAMI ST98:2022 standard endpoint criteria protein level of 6.4 ug/cm<sup>2</sup> [155].

Cleaning Method:	Labia Overlay Protein concentration Color	Correlating Protein concentration (ug/100 ugl)	Meets Acceptance Criteria (yes or no)	Catheter guide tube Protein concentration Color	Correlating Protein concentration (ug/100 ugl)	Meets Acceptance Criteria (yes or no)
Bleach Solution		~10 ug/100 ugl	No - reclean and retest		~60 ug/100 ugl	No - Reclean and retest
Boiling		~5.1 ug/100 ugl	Yes - clean		~5 ug/100 ugl	Yes - clean
Microwaving		~6.0 ug/100 ugl	Yes - clean		~80 ug/100 ugl	No - Reclean and retest
Dishwashing		~15.1 ug/100 ugl	No - reclean, retest		~50 ug/100 ugl	No - Reclean and retest

Based on this table, if the protein concentration meets the acceptance criteria for both the labia overlay and the catheter guide tube, it would indicate success of the sanitation test. If the protein concentration for the labia overlay or the catheter guide tube does not meet the acceptance criteria, this would indicate failure of the sanitation test.

*Test Limitations.* Since we are mainly testing for protein concentration after cleaning, this is a limitation of our test since there could be potential additional factors to consider such as total organic carbon, carbohydrate, or hemoglobin concentration that might increase risk of infection.

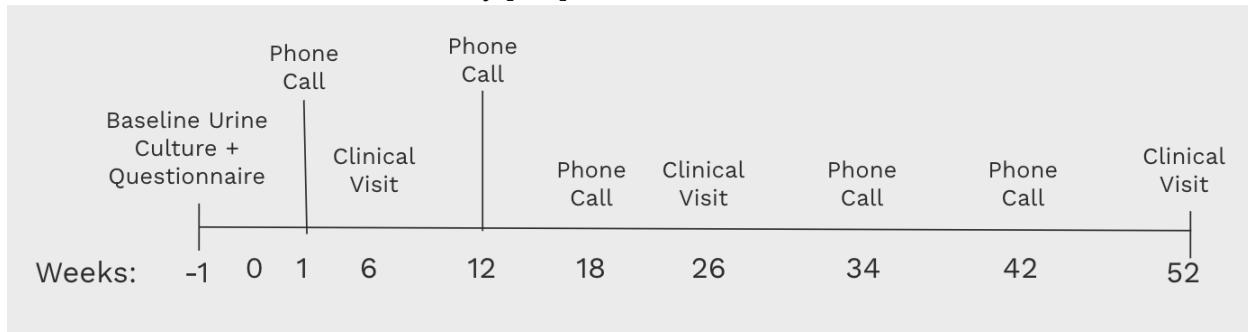
### *UTI Research Study: Validation*

A clinical trial will be designed as outlined below as a validation test. It will follow two groups, one performing CIC as normal, and one performing CIC with SaniCath.

*Purpose.* SaniCath was designed with the main goal of decreasing the risk of UTIs due to the fact that UTIs are prevalent in high rates among SCI patients using CIC, with 81% being treated for at least one UTI/year, 22% with 2-3 UTIs/year, and 12% with 4+ UTIs/year [178]. To determine whether SaniCath addresses this need, we created a new specification: “use of the SaniCath decreases the number of UTIs per year significantly, as assessed by a t-test analysis at an alpha value of 0.05”. Validating this specification will be the primary goal of this research study. This study will therefore be structured as a superiority trial and will test the null hypothesis that there is not a significant difference in the UTI rates of those catheterizing with SaniCath than those catheterizing without SaniCath. Secondary goals involve sub-tests for validating specifications relating to the success of catheterizing on the first try and catheterization time, which will be discussed in their respective test plans.

### *Timeline Overview.*

The timeline for the study spans one year. This timeframe was chosen as it is consistent with other well-designed UTI studies [179]. Further, if participants have an average of 1.1 UTIs a year while using CIC, a shorter study may not catch UTIs that would have happened in the longer timeframe [180]. Participants will be called five times and come into the clinic 5 times during the weeks shown in Figure 67 below, as modeled after a similar study [179]. Details will be discussed later.



**Figure 67.** The timeline for the study spans one year and includes phone calls alternating with clinical visits.

*Sample Size.* The sample size was determined via a power analysis using the SampSize app [181]. The test is two-sided because UTI prevalence with the device could theoretically be higher or lower. The power was set at 80% and the significance level at 5% per clinical standards [159]. The effect size was chosen as 0.3 based on similar literature, meaning that a 30% improvement in the data between control and treatment groups demonstrates that SaniCath has made a clinically significant difference [182]. A study that was done to determine the recurrent UTI incidence per year in females on antibiotics used an estimated standard deviation of 0.9 in their sample size calculation. Thus, we will have the same standard deviation of 0.9, keeping consistent with UTI literature. There is of course a limitation in using this standard deviation because the study does not feature catheterization; however, this is the most reliable number that we found so far [180]. These parameters were inputted into the calculator for a sample size of 143 in each group. According to related UTI studies, the expected participant dropout rate is 20% [183]. Therefore, to calculate the final sample size, 176 was divided by 0.8 and rounded up for a final sample size of 179 per group.

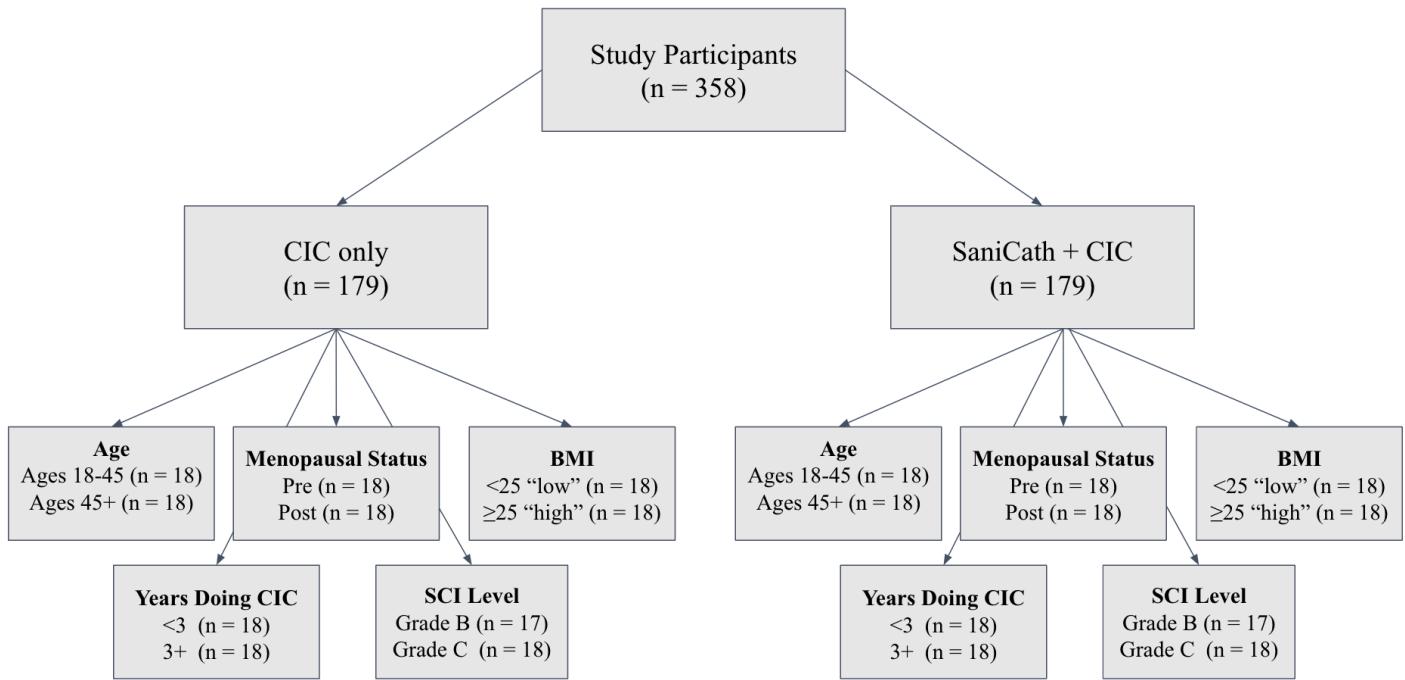
*Recruitment.* Given that the results of this research study will determine if SaniCath can be marketed to a wide range of individuals, we want to ensure that trial participants are diverse in race, socioeconomic

status, ethnicity, etc. Additionally, it is important to acknowledge that historically, clinical trials have not included marginalized groups, such as the Black American community, as participants [184]. Therefore, to build trust and ensure SaniCath's efficacy for diverse people, we will recruit for and conduct the study in many places. These places may include nursing homes or rehabilitation facilities that take predominantly Medicaid and Medicare patients and others that take private insurance. Recruitment and testing will also take place at University of Michigan clinics, other educational institutions and their clinics, and SCI Facebook groups. The study team will ensure that a financial burden is not placed on participants and that difficulties due to participant availability or family situations do not cause participants to be ruled out preemptively. Instead, to avoid implicit biases, we will actively work with participants to ensure they can participate in the trial if desired. Additionally, recruiting from diverse locations will aid us in meeting group allocation requirements.

Inclusion criteria for the study include being female and currently only self-catheterizing, as opposed to using other bladder management methods such as indwelling catheters. Exclusion criteria include a high SCI such that individuals cannot independently self-catheterize, symptomatic UTI in the last two weeks, and current or planned pregnancy. The study will be sent for approval to the University of Michigan Institutional Review Board and all participants will give written consent to participate.

*Group allocation.* Participant age, menopausal status, BMI, time since beginning CIC, injury level, and number of UTIs in the past year will be recorded. Participant age impacts physiological factors and attitudes of patients in adopting new devices. Age will be split into younger adults from 18-45 years of age and then to older adults 45+. Having 45 years of age as the middle ground is ideal because elderly individuals (70+) are less likely to be doing CIC themselves due to age-related difficulties. Furthermore, previous studies have shown a significant difference in UTI rates pre and post-menopause [185]. We included BMI as a category because stakeholders such as Dr. Ashton-Miller mentioned that high BMI results in longer labia, which increases the risk of UTIs [88]. Participants will be split into high (25+) and low BMI (<25) categories based on established BMI scale categories [186]. The design decision to include a labia spreader in the SaniCath was influenced by this group, so having this category can allow observation of trends in the data and make changes to SaniCath to better serve these individuals. Moreover, years doing CIC will be recorded because catheter placement expertise influences catheterization technique, and better technique should lead to lower UTI rates. 3 years was chosen as the cutoff for being less or more experienced. SCI level will be documented because it affects hand dexterity and body movement. Specifically, we will be using the ASIA impairment scale and only recruiting participants who have injury levels categorized at Grades B and C. These grades are the only two that have some impairment to motor but would allow a patient to continue self-catheterizing [187]. Finally, the average number of UTIs in the past year should be consistent between groups because individuals can have a higher risk of UTI for various reasons, and this should be accounted for. All of these factors can be confounding variables in our results, so it is important to segment our study groups by them so we can interpret if the significant difference in yearly UTI rates are due to the use of SaniCath.

Participants will be randomly assigned to one of the following groups – control or treated – and each group will have an equivalent distribution of the demographic variables discussed above. The control group will continue self-catheterizing as normal using Cliny brand catheters and the treated group will do the same but additionally using the SaniCath device [183]. This distribution will be performed using the ALEA software, which randomly assigns participants to groups while ensuring that the groups each contain members with similar demographics as recorded above [183]. Figure 68 shows the ideal breakdown of the number of participants and their demographics in each group. The exact participant numbers in each category will vary some from this ideal.



**Figure 68.** Participants will be equally distributed in their groups according to the demographics of age, menopausal status, BMI, years doing CIC, and SCI Level.

*Procedure.* After being screened, informed about the study, and giving consent, all participants will come in for an initial visit one week before the trial starts. During this visit, all participants will provide a baseline urine sample and be informed of best-practice CIC methods. Participants in the SaniCath group will be taught how to use the device with the same procedure as described in the User Operation section earlier in this report.

During the period of the study, participants will fill out a guided diary to record the data associated with one primary and two secondary objectives of the UTI clinical trial. These secondary diary entries will be discussed in the sub-test test plans. The primary objective relates to the main goal of the trial, which is to assess how the frequency of UTIs compares between groups. Each day, each participant will be asked whether they are experiencing any symptoms, and if yes, they will place a checkmark next to those symptoms, as shown in Figure 69 below. Secondary diary objectives relate to the time for catheterization and the number of catheterization attempts. The methods for these will be discussed in the respective test plans, “Correct Device Placement Data Collection” and “Catheterization Time Data Collection”.

**Are you experiencing any of the following symptoms?**

Yes  
 No

**If yes, check the boxes for all symptoms you are experiencing:**

Painful or difficult urination  
 Blood in urine  
 Cloudy or foul-smelling urine  
 Increase in urinary frequency or urgency  
 Increased urinary incontinence  
 Pain in pelvic/lower abdominal area  
 Flank pain  
 Fever > 38°C / 100.4°F  
 Delirium (confused thinking)  
 Chills/shivering  
 Fatigue  
 Nausea/vomiting  
 Other: \_\_\_\_\_

**If you are experiencing any of these symptoms, please see your personal physician or study physician, and call study staff to report results at (XXX) XXX – XXXX.**

**Figure 69.** Daily checklist for UTI symptoms that subjects in the clinical trial will out as part of the bladder diary.

Participants will be prompted to receive a urine culture if they are experiencing any of the following symptoms of UTI shown in Figure 69. This is based on the standard of care for diagnosing UTIs that physicians use [188]. It is possible that a patient has asymptomatic UTI; however, it is clinical understanding that these UTIs do not pose a threat to the patient and thus rarely require treatment [189]. Therefore, our study will focus specifically on symptomatic UTIs, which can be dangerous and sometimes fatal if not treated properly. Logistically, it is also more feasible to know when a patient may have a UTI if they are symptomatic. Participants will be considered to have a UTI if they meet the criteria of testing positive on a urine culture, dipslide, nitrite test, or urine sediment and having at least one of the symptoms listed in the diary above. Participants are instructed to go to their own doctors, urgent care, or contact the research staff if these symptoms are noted, so a UTI can be tested for and treated. Some participants may have less access to make such visits due to transportation issues and location, which is important to address monetarily or by making arrangements on our end. Study staff will discuss any such challenges with participants and come up with a strategy. These diagnoses can also be determined at the pre-scheduled clinical visits, as part of the research study design, if the urine sample is positive and symptoms will also be assessed over the phone. Diagnoses outside of this study at other clinics but in the timeframe of the study will also be considered in the total UTI count. Any UTIs will be treated with antibiotics.

Participants will be called over the phone at weeks 1, 12, 18, 34, and 42. During these phone calls, they will discuss their bladder diary findings and answer the following questionnaire questions (SaniCath + CIC group), which gather data to obtain feedback on device use and possible improvements. Likert-type scales will be used to standardize answers and provide quantifiable metrics to the data analysis that will be done after the study. Some examples of questionnaire statements and their scales are shown in Table

28.

**Table 28.** Statements with Likert scales will be administered to study participants to determine how well the SaniCath device functions.

Statement	Likert-type Scale			
It is easy for me to hold the SaniCath device.	Strongly Agree	Agree	Disagree	Strongly Disagree
I am able to visualize my urethra using the SaniCath device.	All the time	Some of the time	Rarely	Never
The SaniCath device was able to spread my labia.	Strongly Agree	Agree	Disagree	Strongly Disagree
I had more than one failed catheterization attempt.	All the time	Some of the time	Rarely	Never

Participants will come in for a clinical visit at weeks 6, 26, and 52 to collect the same data along with a urine sample. Figure 67 shows the timeline for patient clinical visits and phone calls. The timepoints for both of these items were determined from other literature published studying UTI rates. To stay consistent with the clinical standard demonstrated in the literature, we chose to use these timepoints as well .

*Statistical analysis.* Statistical analyses will be performed in Python. Demographics will be calculated for each group (mean  $\pm$  standard deviation). Tests for normality will be conducted using the Kolmogorov-Smirnov test [190]. To determine the significance of using our device, we will conduct a two-sided, two-sample independent equal variance superiority t-test. Performing this as a superiority test was important because the use of SaniCath + CIC should reduce UTI rates more than CIC alone; if it does not, users are unlikely to adopt our device. It is possible that SaniCath + CIC could perform worse than CIC alone; therefore, a two-sided t-test is adequate in capturing this possibility. This test requires two independent groups of the same size. Our study defined these as CIC and CIC + SaniCath, with N = 179 each. To conduct this test, we will first find the variance within each of the sample groups using Equation 8:

$$\sigma^2 = \frac{\sum_{i=1}^n (x_i - \bar{x})^2}{N} \quad (8)[191]$$

where  $x_i$  is each value in the data set,  $\bar{x}$  is the mean of all values in the data set, and N is the number of values in the data set [192]. From there, we can now use Equation 9 to perform the t-test:

$$T \text{ value} = \frac{\text{mean1} - \text{mean2}}{\frac{(n_1-1) \times \text{var1}^2 + (n_2-1) \times \text{var2}^2}{n_1 + n_2 - 2} \times \sqrt{\frac{1}{n_1} + \frac{1}{n_2}}} \quad (9)[193]$$

where *mean1* and *mean2* are the average number of UTIs across the group of participants in SaniCath + CIC or CIC only, *var1*, and *var2* are the variance of each of the groups, and *n1* and *n2* are the number of

records in each sample set. Once a t-value has been calculated, the degrees of freedom for the data will be calculated using Equation 10:

$$Degrees\ of\ Freedom = n_1 + n_2 - 2 \quad (10)[193]$$

For criteria of acceptance, we will specify a level of probability (alpha level, level of significance,  $p$ ) of 5%. This is a common level of probability set in t-test studies. Using the degrees of freedom value and the t-value, we will find the corresponding value on a t-value distribution table. Then, we will compare the calculated t-value to the one in the distribution table. If the t-value is greater than the table value, then it is safe to reject our null hypothesis that there is no difference between CIC only and the use of SaniCath with CIC. This means that the groups are significantly different, meaning that the SaniCath is effective in reducing UTI rates [193].

*Results.* An inclusion flow chart figure similar to Figure 68 will be created to show participant drop-out rates and reasons, so that accurate population values are reflected.

Another important part of this clinical trial are the demographics of participants. We plan to present these demographics (mean  $\pm$  standard deviation for numerical data and the number per category and percentage of group for categorical data), along with our treatment and control group data, in a table. Table 29 shows a possible presentation of this data, consistent with literature.

**Table 29.** This example demographics table convinces reviewers that participants were allocated evenly to each group [194].

Demographic	Value	SaniCath + CIC	CIC
Mean Age $\pm$ SD (years)	n/a	45 $\pm$ 6.4	48 $\pm$ 4.4
Menopausal status (n, %)	Premenopausal	150 (68)	140 (64)
	Postmenopausal	70 (32)	80 (36)
Mean BMI $\pm$ SD	n/a		
Mean time since beginning CIC $\pm$ SD (years)	n/a	10 $\pm$ 3.2	9.5 $\pm$ 2.5
Injury level (n, %)	Cervical	20 (9)	25 (11)
	Thoracic	80 (36)	75 (34)
	Lumbar	70 (32)	64 (29)
	Sacral	50 (23)	56 (25)
Number of UTIs in the past year $\pm$ SD	n/a	3.2	3.4

We expect that the clinical trial results will show that the use of SaniCath during CIC will reduce UTI

incidence rates by a significant difference. The results for this test will first be presented in a table that includes the mean, standard deviation, p-value from the results of t-test, range, and percent difference, similar to Table 7 with mock data below. Percent difference is calculated as the difference between means divided by the mean of the CIC only group. Together, this data can give an adequate picture of how well the SaniCath + CIC group performed against the CIC only group. Table 30 currently has mock data representative of results we might expect and shows how our results will be presented.

**Table 30.** This example table depicts the final outcome of a significantly lower UTI rate in the SaniCath group.

Group	Mean ± standard deviation (# UTIs)	Range (# UTIs)	P-value	Percent difference (%)
SaniCath + CIC	1.5 ± 0.5	0 - 4	0.04	40
CIC only	2.5 ± 0.4	0 - 7		

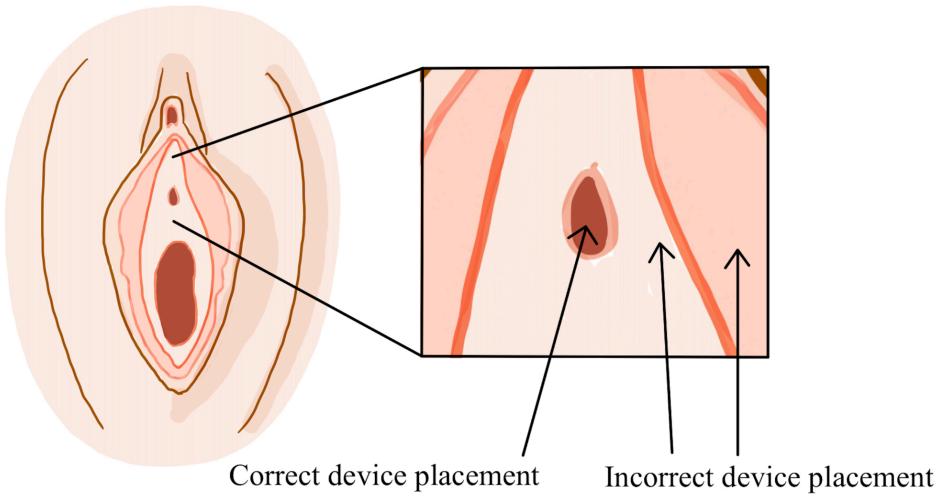
For viewer presentation, we will use a combination of the following bar and distribution graphs to show the distribution of results comparing the two groups. Results will be presented similarly to Figure 59.

#### *Correct Device Placement Data Collection: Validation*

As mentioned above, a secondary goal of the UTI clinical trial involves sub-tests for the validation of other specifications. One of these will involve validation testing for whether the final design meets the required specification for the design requirement that the solution must allow for self-application.

Originally, we had a specification of “Maximum error rate of 5% for correct device placement on the first try”; however, we think that a stronger claim can be made when the two groups already available in the trial (CIC and SaniCath + CIC) are compared to each other for a two sample t-test instead of simply comparing the device group against a set number, which would be a one sample t-test. Thus, we will test a new specification: “the use of the device increases the number of times the device is inserted correctly on the first try significantly, as assessed by a t-test analysis at an alpha value of 0.05.”

*Purpose.* The SaniCath device has been designed with the goal of spreading and covering the labia to decrease the chance of the catheter touching external surfaces and being contaminated prior to catheterization, increasing visualization of the urethral opening, and guiding the catheter into the urethra. Ultimately these all serve to decrease the risk of infection and are important components for this specification - improving visualization via a mirror and by spreading the labia will allow the user to see the urethral opening to target it and including the guide is an engineering control to position the catheter correctly. Proper placement on the first try is important because it decreases the risk of a user contaminating the catheter and either placing it anyway, increasing the risk of infection, or having to take a new catheter, which increases costs and time. Ultimately the purpose of this test is to determine whether the device improves the chance of proper catheter placement on the first try to the level required by the specification. Correct placement means that the catheter goes straight into the urethra without first touching the external tissues, as depicted in Figure 70. For a criteria of acceptance, we will specify a significance level (alpha level,  $p$ ) of 5%. If the t-test demonstrates less than 5% significance, then it is safe to reject our null hypothesis that there is no difference between CIC only and the use of SaniCath with CIC. This means that the groups are significantly different, meaning that the SaniCath is effective in reducing the number of incorrect catheter placements on the first try [193].



**Figure 70.** Correct device placement is when the catheter is inserted directly into the urethra, while incorrect placement involves the catheter touching an external surface first.

*Experimental setup.* The date collection for this test will be conducted via a home diary. During a three day period during weeks 1, 18, and 42, participants will record the number of catheterization attempts required each time they urinate. Three testing periods spaced apart were chosen so that trends over time in each group could be analyzed as participants get used to using the SaniCath. The shorter 3-day time period was chosen as opposed to the time period in the full UTI trial because recording whether or not the catheter was placed correctly on the first try for every catheterization each day is an unreasonable expectation. We chose this 3 day metric because we thought it would be a reasonable expectation if we were participating in a clinical trial. However, we acknowledge that this view is biased and based on our understanding of time spent; therefore, we would want to ask our SCI patients using CIC what their reasonable expectation could be and adjust this metric accordingly. If a catheterization attempt fails and the participant touches the end of the catheter to their external body or it is otherwise contaminated, a new catheter must be selected. The three testing periods will allow for an understanding of the trends in time as participants get used to using the SaniCath and the 3-day time period is a reasonable expectation for logging this data. The diary questions to record this information are shown below in Figure 71.

## **Week 1**

Please record the number of catheterization attempts required each time you catheterize for three days.

*Note: if the catheter is contaminated in any way, throw away the catheter and begin a new catheterization attempt*

Day 1:

Catheterization number of the day	Number of catheterization attempts required
1	
3	
4	
5	
6	
7	
8	

Day 2:

Catheterization number of the day	Number of catheterization attempts required
1	
3	
4	
5	
6	
7	
8	

Day 3:

**Figure 71.** Example page of diary for first two days of first week to record number of catheterization attempts

*Statistical analysis.* To determine if a significant difference is attained with the use of our device, we will conduct a two-sided two-sample independent equal variance t-test for each week of data collection to compare the two groups, similar to how it was done for the UTI incidence rate. Additionally, a two-sided one-sample independent equal variance t-test will be conducted for each week to compare the SaniCath + CIC group to the 5% incorrect placements value.

*Results.* We expect that the results for the test below will show that the SaniCath group experiences significantly fewer failed placements on the first try during weeks 18 and 42, thus meeting the specification. However, the participants are still learning how to use the device during week 1, so we do not expect a significant difference there. This data can give an adequate picture of how well the SaniCath

+ CIC group performed against the CIC only group in terms of number of incorrect device placements on the first try. We expect to meet our original specification that incorrect placements only occur 5% of the time once users have gotten used to the device in week 18 and week 42. Table 31 currently has mock data, but it shows how our results will be presented. Data will also be displayed visually similarly to Figure 59 above.

**Table 31.** This example table depicts a passing final outcome, with the p-value for the difference in incorrect placement rates in the two groups being less than 0.05 for week 18 and 42. The outcome when compared to the 5% incorrect placements benchmark was also a pass in weeks 18 and 42.

	Mean ± standard deviation (# incorrect placements on first try)		
Group	Week 1	Week 18	Week 42
SaniCath + CIC	0.14 ± 0.05	0.04 ± 0.04	0.03 ± 0.03
CIC only	0.15 ± 0.07	0.14 ± 0.04	0.14 ± 0.02
Two-sample t-test			
P-values	0.35	0.001	0.0005
Percent Difference between SaniCath + CIC and CIC only (%)	6.7	71	79
One-sample t-test			
P-values	0.03*	0.04	0.02
Percent Difference between SaniCath + CIC and 0.05 incorrect placements benchmark (%)	180**	20	40

\* Although these are significantly different, the SaniCath + CIC is significantly larger than the benchmark because the user is still getting used to using the device correctly.

\*\* Benchmark is less than SaniCath + CIC due to users getting used to device

#### *Catheterization Time Data Collection: Validation*

The second sub-test included as part of the clinical trial involves gathering data regarding the times it takes participants to catheterize with the SaniCath and without.

As mentioned above, another secondary goal of the UTI clinical trial involves the sub-tests for the validation of the specification associated with the design requirement that the solution can be used in a reasonable timeframe. The primary specification we will test is “female users can independently use our device in less than 15 minutes.” While this specification is critical in determining that the device is still reasonable to use, we also want to add a second specification that could strengthen our claim that the use of the SaniCath device will take less time than using CIC only, by a significant difference.

*Purpose.* Ensuring that the solution was quick to use was an important factor emphasized by stakeholders;

therefore, it is important for us to test the specifications associated with time needed to use the device. The purpose of this test plan is twofold: one is to determine whether the device meets the specification that the solution must be able to be used in 15 min or less, and the other is to see whether catheterizing with the SaniCath is faster than without it. For a criteria of acceptance, we will specify a significance level (alpha level,,  $p$ ) of 5%. The first null hypothesis for this test plan is that the time taken to use the SaniCath is not less than 15 minutes, and the second is that there is no difference between CIC only and the use of SaniCath with CIC. If the two t-tests demonstrate significance via a p-value less than 0.05, then it is safe to reject our null hypotheses [195]. This means that the specifications listed above are met, suggesting that one, the SaniCath device can be used in a reasonable timeframe and two, the device decreases catheterization time as compared to CIC alone. It is also possible to reject one null hypothesis and not the other.

*Experimental Setup.* The date collection for this test will be conducted via a home diary. During a three day period during weeks 1, 18, and 42, participants will record the time taken to self-catheterize each time they do so. The three testing periods will allow for analysis of the trends in time as participants get used to using the SaniCath and the time period of three days is a reasonable expectation for logging this data. An example template for the diary questions are shown below in Figure 70. The measurement will be taken from the time the participant enters the bathroom to when they exit, including time to gather supplies, wash hands, and dispose of supplies. Participants should use the timing method most intuitive to them. The study team will suggest options such as a cell phone, watch, or mechanical timer and will provide a timer if needed. An important limitation to this data collection method is that the data is self-reported, which comes with biases. Study staff will instruct participants when to begin and stop the timer, however all users have slightly different processes and may interpret the intended start and stop times differently.

**Week 1**

Please record the time required to catheterize each time you catheterize for three days.

*Note: Please start your timer when you enter the bathroom and stop it when you exit the bathroom. Catheterization time includes gathering supplies, washing your hands, and disposing of supplies.*

Day 1:

Catheterization number of the day	Catheterization time (minutes, seconds)
<i>Example</i>	<i>10 min, 15 sec</i>
1	
2	
3	
4	
5	
6	
7	
8	

Day 2:

Catheterization number of the day	Catheterization time (minutes, seconds)
<i>Example</i>	<i>10 min, 15 sec</i>
1	
2	
3	
4	
5	
6	
7	
8	

Day 3:

**Figure 70.** Example diary template for time collection for the first week.

*Statistical analysis.* To conduct the one sample t-test to determine if the SaniCath group meets the specification of 15 minutes or less time for usage, we will calculate the mean, standard deviation, and sample size of this group. Then, find the difference between the mean and 15, which is the value we are comparing to: this will be called *diff*. From there, we calculate the standard error of the mean with Equation 11:

$$\text{Standard Error for the mean} = \frac{s}{\sqrt{n}} \quad (11)[196]$$

where *s* is the standard deviation and *n* is the number of samples. Now, we can calculate our test statistic

(*t*) value using Equation 12.

$$t = \frac{diff}{Standard\ Error} \quad (12)[197]$$

Finally, we calculate the degrees of freedom using the following formula:  $n - 1$ , where  $n$  is the number of samples in the SaniCath group. We will specify a level of probability (alpha level, level of significance,  $p$ ) of 5%. This is a common level of probability set in t-test studies, prior to conducting the test. Using the degrees of freedom value and the *t*-value, find the corresponding value on a *t*-value distribution table. Compare the calculated *t*-value to the one found in the distribution table. If the test statistic value is greater than the table value, then it is safe to reject the null hypothesis which is that the SaniCath group performs at exactly 15 minutes of usage time [198].

To determine if a significant difference is attained with the time to use our device, we will conduct a one-sided two-sample independent equal variance t-test, similar to how it was done for the UTI incidence rate.

*Results.* We expect that the results for the one sample t-test described above will show that the SaniCath group meets the specification of 15 minutes or less time for usage. We also expect that the two-sample independent equal variance t-test will show that the usage of SaniCath + CIC is faster than CIC only, by a significant difference. The data for the two sample t-tests for each week comparing SaniCath + CIC to CIC alone will be presented in a table as shown in Table 9 below. The data for the one sample t-test comparing SaniCath to the 15 minute time limit for each week will be added to this table, with the percent difference calculated using the mean for the SaniCath + CIC group and comparing it to the 15 minute specification benchmark. Together, this data can give an adequate picture of how well the SaniCath + CIC group performed against the CIC only group in terms of catheterization time. Table 32 currently has mock data, but it shows how our results will be presented. Data will also be displayed visually similarly to Figure 57 above.

**Table 32.** This example table depicts the final outcome - the difference in catheterization time in the two groups, with the two groups being significantly different for week 18 and 42 and SaniCath + CIC being significantly different from 15 minutes during all weeks. This data thus shows a clear pass for both comparisons.

	Mean $\pm$ standard deviation (time in minutes)		
Group	Week 1	Week 18	Week 42
SaniCath + CIC	10.3 $\pm$ 2.0	7.8 $\pm$ 1.3	6.8 $\pm$ 1.0
CIC only	11.3 $\pm$ 2.5	9.4 $\pm$ 1.7	7.8 $\pm$ 1.4
Two-sample t-test			
P-values	0.6	0.1	0.3
Percent Differences between SaniCath + CIC and CIC (%)	8	17	13
One-sample t-test			

P-values	0.04	0.03	0.01
Percent Differences between SaniCath + CIC and 15 min (%)	31	48	55

### **Design Recommendations after Testing**

Based on the pressure test results, no modifications are necessary, as they indicate that the design specification of "solution will not apply greater than 100 psi of pressure to the skin" has already been met.

Based on the statistical analysis of the compression testing, no design modifications are necessary, as all tests indicate that there was no statistically significant difference between the before and after measurements of the device, indicating durability for the testing period.

While the conducted tests and outlined test plans encompass a substantial portion of the verification and validation testing necessary for FDA approval, additional tests are imperative for securing device clearance. A grip usability test is essential to ensure the device's user-friendliness for female Spinal Cord Injury (SCI) patients. This test would be a validation test conducted through users using the grip and evaluating it through a survey. Furthermore, examinations of the sterile packaging of our device are mandatory to meet the design requirement of "Sterile packaging that maintains an appropriate sterile shelf life is used for our solution."

Additionally, a comprehensive verification, cost analysis, considering the intended usage duration and manufacturing processes of our device, is indispensable to ensure compliance with the design requirement test of "Lifetime Cost for patients must be less than current standards." Lastly, material biocompatibility studies must be conducted to guarantee the safety of our device for patient use. These studies would be verification tests with in vitro studies looking at the biological reaction to our device.

Initial validation tests, ensuring the device's usability by females for its intended purpose and assessing its comfort, will be incorporated. Constructive feedback gathered during this stage will be seamlessly integrated into the design before progressing to validation testing with subjects. These supplementary assessments, among others, will collectively contribute to a comprehensive evaluation essential for regulatory approval.

## **IV. Design Recommendations & Conclusions**

### **Final Design Recommendations and Future Directions**

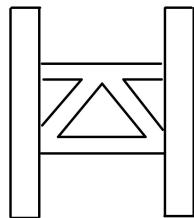
After completing preliminary testing, 3D printing our design, and outlining future test plans, the team has established various design recommendations for future implementation.

#### *External Design Review Feedback*

The team received valuable feedback after the second external design review and used it to make design recommendations.

*Support wall reinforcement.* The first piece of feedback received from a reviewer was to add connector bars between the support walls. After our compression test, we realized that the walls bending out was a major weak point of the design. While we had already started brainstorming ways to prevent this bowing motion, the reviewer suggested triangle-shaped connectors. This is very logical given that triangles are very strong. We want to avoid adding anything that will make cleaning the device harder, such as a floor.

Crossing connectors, forming triangles in a similar fashion as shown in Figure 71 below would be a valuable addition.



**Figure 71.** Adding triangles, a strong structural element often included in designs undergoing compressional forces, in between support walls is a suggested improvement to the design.

*Grip design.* Another valuable insight we received was that the grip design was not completely intuitive, and a reviewer would have held the device incorrectly without instruction. With this in mind as well as our own analysis of the grip once it was 3D printed helped us to analyze pros and cons of the current grip design. While the slot is certainly important for those with decreased hand strength, moving the ridges so they are also present on the sides of the device would allow the base of the fingers to engage with ridges instead of just the tips of the fingers, allowing for improved control and lining up more with what the reviewer would have expected.

*User operation feedback.* A third reviewer mentioned that switching hands while using the device might be cumbersome. This was a carefully considered point as the team began writing user operation steps, because we realized that there are quite a few moving parts. The key reason for switching hands was to ensure the catheter was not touched with the same hand that touched the labia. Designing an option in which the user did not have to switch hands and could place the device without first spreading the labia, for example, might be a path to consider. However, this might increase the complexity of the device or the risk of introducing bacteria because there is a higher likelihood of the labia inset touching tissues with bacteria and spreading them to the urethra. Further research needs to be performed to determine if this is a concern. Another user choice would be to have hand sanitizer available to sanitize their hand after placing the device and before touching the catheter.

#### *Additional Design Modifications*

Other feedback received include smoothing out the edges, which is an important next step for the CAD design we plan to implement, and whether this device is one size fits all. Future design iterations could include a pediatric device, and further testing should include a determination of whether all adult females can utilize the device with its current dimensions.

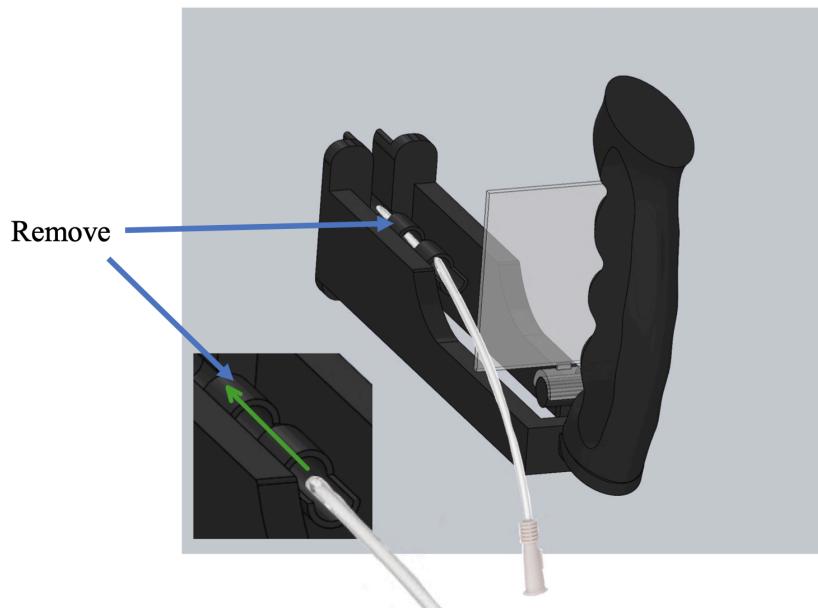
*Design considerations after 3D printing.* Although the device will not be manufactured using 3D printing, printing our device allowed the team to analyze the design physically, outside of the Solidworks design space. Although all dimensions were chosen and justified based on research, it is only possible to fully verify that the choices were suitable when an accurate prototype has been created.

The 16 French catheters we used for testing fit into the catheter guide tube smoothly. However, there was no further space, indicating that 18 French catheters, which our design must also fit according to our design specification, would likely be snug. This would require increased force to be applied to the catheter to advance it through the device. This should not be the case and could increase the risk of injury. A 16 French catheter has a diameter of 5.33 mm, while an 18 French catheter has a diameter 12.5% bigger, or 6 mm. If we assume that catheter diameters fitting well corresponds directly to the tube diameter, this would result in needing a 9 mm tube diameter to smoothly fit the 18 French catheter. To

account for imperfections in manufacturing and part to part variations, a diameter of 11 mm is proposed with a tolerance of 1 mm.

The team also noted that the guide tube was a weak point in the design due to thin walls and because it is long and only connects to the device at one point. This will be remedied through further testing and will depend on final material properties. Ultimately the only limiting factor for guide tube wall thickness is the location of the walls and that there should be sufficient space to clean. The team also suggests adding a support to the tube. This could be bars underneath the tube connecting the walls or extra material connecting the sides of the wider tube to the walls.

Further, the guide tube currently has two covering regions. The back one will be removed to allow for improved visualization as preliminary user testing with a cardboard urethra determined that the covering blocked visualization at times, as shown in Figure 72 below.



**Figure 72.** After usability testing with the 3D printed design, the team decided to recommend removing the back guide covering for improved urethral visualization.

Lastly, the labia overlay may need to be increased in size to adequately hold the tissues down and apart. This will be determined through verification testing on catheterization models and verification and ultimately validation testing with human subjects.

Fabrication will be conducted using injection molding, which is very precise and has high repeatability. These characteristics are especially critical in making the guide tube, which needs to be carefully dimensioned. Next steps related to the manufacturing process include deeper research on the limitations of this method and how they may affect design choices. For example, design changes are expensive, so design needs to be tested thoroughly before manufacturing, and hollow parts are not possible using injection molding, so the tube overlay may need to be produced separately.

Furthermore, the materials will undergo updates in the next generation design. During the initial trial testing of our device, we observed that polyurethane exhibited more flexibility and deformability than desired by our team. In subsequent iterations, we intend to select a new material that maintains its

structural integrity during testing. Additionally, we plan to conduct thorough research on how this chosen material performs after manufacturing, addressing concerns that arose from significant fluctuations observed with different printing machines during preliminary outputs and testing. Moreover, we identified limitations in the sanitation methods for polyurethane. Choosing a new material will allow us to explore alternative and potentially more accessible cleaning methods for our users.

#### *Future Directions*

Our team aims to make multiple refinements to our project as well as advise future BME 450 teams.

*Changes to previous drafts.* As discussed in the verification and validation section above, some tests were based on new or revised specifications that arose as the needs of the users became more clear and the design was chosen and refined. Future steps would include updating the original design inputs tables and adding to them as development continues.

*Advice to a new BME 450 team.* Overall, if this project were continued by another BME 450 design team, we would advise them to print even initial CAD designs early. The timeline of the course is quite tight and we were careful to optimize parts of the design based on our research. However, we determined that there is no substitute for actually printing the design and holding it, which allowed us to make many of the design recommendations outlined above. This also gives information on the material's properties and allows improved understanding of whether the material chosen is appropriate for the application. Further, we would advise continuing to search for a female with a spinal cord injury who uses CIC to interview, as this will give very valuable information on what types of devices these users might adopt and what their specific needs are without requiring assumptions by the team.

#### **Social Impact & Professional Responsibilities**

Improving public health was an important factor that team Neurosense took into consideration during the application of the engineering design process. Preventing disease is a critical aspect of public health. The main goal of our device, decreasing the prevalence of UTIs, is therefore directly related. This goal was established early on by interviewing researchers in the field and caretakers for those that do CIC. Further, the team considered social factors when deciding to focus on women. Research on those with SCI in general is lacking, and the fact that the vast majority of those with SCI are men suggests that research on women with SCI is even less common.

The environmental impact of the device was also considered. CIC can be performed with disposable and reusable catheters, however disposable catheters are much more common in the US. Therefore, this process in general is quite environmentally unfriendly. We wanted to make sure that we did not add to this burden excessively, which a disposable SaniCath would do. Therefore, we chose to develop a reusable catheterization aid device that should last at least one year. This choice also impacts economic factors as it would likely decrease the lifetime costs as compared to single use devices, even if the single use devices were cheaper, due to the sheer frequency of catheterizing each year. Choosing injection molding as the manufacturing process also lowers the price per part. Of note, CIC will be more expensive if the device is used. However, treatment of UTIs is also very expensive, and decreasing the number of UTIs should therefore balance out the cost both monetarily and in terms of quality of life. One way in which our design needs to be further tested is to ensure that it fits females of various body sizes - this continued research will help to overcome this potential barrier to adoption.

One way in which the team considered the ethical responsibilities of the engineering profession was by upholding the national society of professional engineers' fundamental canon of issuing public statements only in an objective and truthful manner. All reports written by the team contain information directly consistent with the research performed by the team, without warping those findings. In this way,

deception was avoided as well. Further, when information was not known or needed to be refined, this was clearly stated. Our reusable device upholds the principles of sustainable development, and its goal to decrease UTI rates is designed directly for the health and well-being of the community. Further, as students, the team inherently continued to develop themselves and kept current in our chosen field.

## **Conclusion**

Through this project experience, our team has gained many valuable insights. A consistent theme that emerged was the importance of incorporating user feedback into design choices. From narrowing down scope during User Needs to identifying the process of catheter insertion for users during Verification and Validation, we consistently prioritized the unique perspectives and backgrounds of our primary stakeholders in our device to ensure our solution was patient-driven. This patient-centric approach not only ensured the relevance of our solution but also mitigated biases or preconceived notions we might have held regarding Clean Intermittent Catheterization (CIC) and female SCI patients.

Additionally, our team recognized the necessity of iterative design throughout medical device development. As we progressed through the project, we systematically refined our work from previous design stages as we continued to further understand our target population and the problem at hand. This iterative process involved refining our CIC task analysis in User Needs, showcasing enhancements in Design Outputs, and adjusting design requirements and specifications in Design Inputs based on insights learned from Verification and Validation. Finally, our team noted that it is paramount to incorporate ELSE(Environmental, Legal, Social, Economic) principles in medical design. These principles manifested differently in each design stage, offering valuable insights in understanding the multitude of contexts in which our device could be applied. This holistic consideration of ELSE principles significantly contributed to a comprehensive understanding of the societal, legal, economic, and environmental factors influencing our medical device design. Collectively, these takeaways not only guided the development of an effective solution tailored to our target population's needs but also provided a foundation for navigating socially-engaged medical design.

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## Appendix A: Evaluation Criteria for Skin and Mucosal Irritation Design Requirement

**Table 1.** To test the irritation of urethral inner mucosal lining, scoring from Table D.2 for macroscopic evaluation criteria in ISO 10993-23 will be used [77].

Reaction	Numerical grading
<b>Erythema and eschar formation</b>	
No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate erythema	3
Severe erythema (beet-redness) to eschar formation preventing grading of erythema	4
Other adverse changes of the tissues should be recorded and reported.	

**Table 2.** To test the irritation of urethral inner mucosal lining, scoring from Table D.3 for microscopic histology evaluation criteria in ISO 10993-23 will be used [77].

Reaction	Numerical grading
<b>Epithelium</b>	
Normal, intact	0
Cell degeneration or flattening	1
Metaplasia	2
Focal erosion	3
Generalized erosion	4
<b>Leucocyte infiltration (per high power field)</b>	
Absent	0
Minimal (less than 25)	1
Mild (26 to 50)	2
Moderate (51 to 100)	3
Marked (greater than 100)	4
<b>Vascular congestion</b>	
Absent	0
Minimal	1
Mild	2
Moderate	3
Marked, with disruption of vessels	4
<b>Oedema</b>	
Absent	0

## Appendix B: Evaluation Criteria for Long-Term Inflammation Design Requirement

**Table 1.** To score histopathology analysis of cell types for long-term inflammation of our solution, Table E.1 from ISO 10993-6 will be used [78].

Cell type/response	Score				
	0	1	2	3	4
Polymorphonuclear cells	0				
Lymphocytes	0	Rare, 1 to 5/phf <sup>a</sup>	5 to 10/phf	Heavy infiltrate	Packed
Plasma cells	0				
Macrophages	0				
Giant cells	0	Rare, 1 to 2/phf	3 to 5/phf		Sheets
Necrosis	0	Minimal	Mild	Moderate	Severe

<sup>a</sup> phf = per high-powered (400×) field.

**Table 2.** To score histopathology analysis of cell responses for long-term inflammation of our solution, Table E.2 from ISO 10993-6 will be used [78].

Response	Score				
	0	1	2	3	4
Neovascularisation	0	Minimal capillary proliferation, focal, 1 to 3 buds	Groups of 4 to 7 capillaries with supporting fibroblastic structures	Broad band of capillaries with supporting fibroblastic structures	Extensive band of capillaries with supporting fibroblastic structures
Fibrosis	0	Narrow band	Moderately thick band	Thick band	Extensive band
Fatty infiltrate	0	Minimal amount of fat associated with fibrosis	Several layers of fat and fibrosis	Elongated and broad accumulation of fat cells about the implant site	Extensive fat completely surrounding the implant

**Table 3.** To score histopathology analysis across multiple samples for long-term inflammation, Table E.3 from ISO 10993-6 will be used [78].

<b>Test sample:</b>	Polymer XYZ					
<b>Implantation interval:</b>	2 weeks					
<b>Control sample:</b>	HDPE					
<b>Animal number</b>	<b>Test sample</b>			<b>Control sample</b>		
	<b>1001</b>	<b>1002</b>	<b>1003</b>	<b>1001</b>	<b>1002</b>	<b>1003</b>
<b>F.1 Inflammation</b>						
Polymorphonuclear cells	2	1	2	1	1	1
Lymphocytes	1	1	0	0	1	0
Plasma cells	0	0	0	0	0	0
Macrophages	2	2	2	1	1	1
Giant cells	1	1	1	0	0	0
Necrosis	0	0	0	0	0	0
<b>SUB TOTAL (x2)</b>	<b>12</b>	<b>10</b>	<b>10</b>	<b>4</b>	<b>6</b>	<b>4</b>
<b>F.2 Neovascularization</b>						
Fibrosis	1	1	1	1	1	1
Fatty infiltrate	0	0	0	0	0	0
<b>SUB TOTAL</b>	<b>1</b>	<b>1</b>	<b>1</b>	<b>1</b>	<b>1</b>	<b>1</b>
<b>TOTAL (F.1 and F.2)</b>	<b>13</b>	<b>11</b>	<b>11</b>	<b>5</b>	<b>7</b>	<b>5</b>
<b>GROUP TOTAL</b>	<b>35</b>			<b>17</b>		
<b>AVERAGE<sup>a</sup></b>	<b>11,7 (-)</b>			<b>5,7 = 6</b>		
Traumatic necrosis	0	0	0	0	0	0
Foreign debris	0	0	0	0	0	0
Number of implants examined <sup>b</sup>	<b>4</b>	<b>4</b>	<b>4</b>	<b>4</b>	<b>4</b>	<b>4</b>
<sup>a</sup> Used to determine reactivity ranking shown below as the conclusion. A negative difference is recorded as zero.						
<sup>b</sup> Histological evaluation score represents the averaged score for that animal across the number of implants examined.						
NOTE Additional observations can be needed for degradable materials, i.e. extent of degradation.						