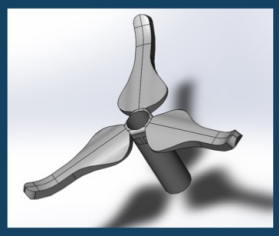
Belltower Medical

Urinary Catheter Solutions



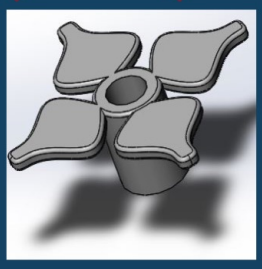
Need

Urinary catheters are responsible for **40% of all hospital acquired infections.** Catheter associated urinary tract infections (CAUTIs) often lead to sepsis, a disease known to kill over a quarter of a million people annually. In addition, the design of the Foley catheter has remained unchanged for nearly 100 years. It is our goal to improve patient outcomes by reducing the incidence of CAUTIs.

Multidiscipline Participation

The continuous and frequent input of stakeholders guided our project from the onset. The current redesign of the urinary catheter involves a variety of engineering disciplines, mainly **biomedical, material, and mechanical engineering**, as well as **multiple clinical inputs**. Feedback from stakeholders created continuous design iterations, and allowed us to generate our final solutions. We worked closely with the hospital's clinical staff, local urinary catheter manufactures, local urologists, medical device engineers and regulatory experts, rapid prototyping engineers, and a local law firm.

Slim-Cath



Sani-Cath

Our Solutions

Sani-Cath is a small catheter insertion device that is designed to reduce the procedural steps for catheter insertion and to create a mechanism to clean the catheter tube once inserted. The insertion tip prevents the catheter from contacting surrounding contaminated tissues and ease the insertion by automatically applying lubricant during insertion. In addition, Sani-Cath has cleaning rings that attach to the catheter tubing and can be drawn down the length of the catheter by the patient or clinician to clean the catheter after insertion. **By preventing bacterial exposure, we can limit the number of infections and improve patient health.**

Our second solution is **Slim-Cath**, a novel fixation tip for a urinary catheter that replaces the 100-year-old balloon design of Foley catheters. Slim-Cath is designed to allow full evacuation of the bladder and our initial testing has shown a **96% reduction in residual urine volume**. The smaller profile and improved drainage will prevent bacterial growth, reduce the number of infections, and help patients recover more quickly.

Knowledge and Skills Gained:

Utilizing a network of **75 professional connections**, our team has learned the importance of leveraging input from multiple disciplines. In addition, our team entered into multiple pitch competitions, raised $13,000 in funding and dramatically improved our communication and presentation skills. We have been exposed to real world engineering, discovered the value of defining a problem, utilizing a network of research and mentors to create solutions, and producing physical, iterative, and testable results.

Protection of the Public

The primary focus and motivation for our design was the improvement of health outcomes for patients that are being treated with urinary catheters. **15-25% of all hospitalized patients receive urinary catheters during their stay, and their chance of a CAUTI increases by almost 8% per day.** Our solutions will benefit the healthcare system by reducing rates of dangerous and costly CAUTIs. In addition, it will influence the treatments and interventions within hospitals, long-term nursing homes, and at home for patients

Abstract

Belltower Medical originated from a year long senior design project. We were tasked with shadowing clinicians in the hospital and identifying **an unmet medical need.** We then took the rest of the year developing a product that filled that need, taking into consideration our end user, FDA Regulations, and market considerations like intellectual property and price points. Our team collaborated extensively with local companies to evaluate our design and manufacturability while simultaneously revisiting our clinical mentors to determine the value and effectiveness of our product. We have entered in many local and national design competitions, submitted a provisional patent, and made plans to eventually turn our solution into a commercial product that can improve patient's lives.

Our focus area is sepsis, a systemic response to infection that **kills a quarter of a million people annually in the US alone** [1]. Through our stakeholder analysis, we identified one of the primary sources of infection as urinary catheters, which are responsible for **40% of all hospital acquired infections** [2]. Working closely with our clinical mentors, we developed a two-part solution to reduce infections. Preventing bacterial introduction into the urinary tract during and after catheter insertion and limiting the post-voidal residual urine volume within the bladder. The first component to our solution is **Sani-Cath,** a small catheter insertion device designed to reduce the procedural steps for catheter insertion and allow cleaning after insertion. Our design includes an insertion tip that prevents the catheter from contacting any potentially contaminated tissues and applies lubrication during insertion to simplify the process. Additionally, Sani-Cath has cleaning rings that attach to the catheter tubing and can be drawn down the length of the catheter, by the patient or clinician, to clean the catheter during use. **By preventing bacterial exposure, we can limit the number of infections and improve patient health.**

Our second solution is **Slim-Cath**, a novel fixation tip for a urinary catheter which replaces the nearly 100-year-old Foley catheter balloon design. Slim-Cath allows full evacuation of the bladder and compared to the Foley balloon our initial testing has shown a **nearly 95% reduction in residual urine volume.** This improvement will prevent bacteria proliferation, reduce infections, and help patients recover more quickly.

Throughout this design process, we have learned the value of iterative design and consistently refer back to the end user's needs. Our long-term goal is to turn these design solutions and proof of concepts into **a real healthcare commercial product**. To accomplish this, we have focused on the next steps to get to market. We have recruited graduate and undergraduate students to our team to help achieve this undertaking. With a focus on FDA design controls and raising funds, we aim to file for a full utility patent within the next year and begin the necessary testing for a FDA 510(k) pathway. We are working closely with our engineering mentors, company partners, and clinical experts to ensure the solution will be manufacturable and will translate value in the hospital. **We are Belltower Medical, and we aim to improve health outcomes for patients with urinary catheters.**

I. Project Description

Belltower Medical was formed through a Biomedical Engineering senior design class at a prestigious four-year engineering college. Our team consists of five students in three different biomedical focus areas. Our design course incorporates elements of the Stanford Biodesign Process, the Wallace Coulter Commercialization Process, and FDA Quality System Regulations. This process includes identifying unmet medical needs in the clinical setting, minimizing technical and business risks through the development process, and maintaining design controlled documentation. Initially, our team focused on reducing rates of sepsis in hospitals. At a local hospital our team shadowed clinicians, documented observations, conducted interviews and performed extensive research. To combat hospital infection and sepsis, our team systematically narrowed the scope of our work to **catheter associated urinary tract infections (CAUTIs)**. CAUTIs are the second leading cause of sepsis, which is known to kill a quarter of a million people annually [1]. CAUTIs are caused by bacterial contamination of the urinary tract by the standard insertion and use of a urinary catheter [2].

After identifying hundreds of needs from our clinical immersion, our team filtered these needs according to market size, patient impact, clinical impact, team strengths, and our constrained timeline. We narrowed the scope of our work to CAUTIs and built a database of information surrounding the problem. As a team, we continued to reach out to clinical mentors and local engineers to understand project feasibility, the urinary catheter patent landscape, and product specifications based on clinical feedback. Once the problem was well understood our team transitioned to brainstorming a solution.

Our team focused on the engineered design of the urinary catheter as the source of the bacterial contamination and infection. Our process included **multiple ideation sessions** that translated into solution concepts and two dimensional sketches. Our ideation was facilitated by **constant communication with our stakeholders,** which included clinicians, local engineers, faculty, and urinary catheter manufacturers. Our team concurrently developed manufacturing plans and product specifications to help facilitate our solution designs. As we continued our product development timeline, we pitched in several competitions and were awarded funding to push our project forward. The funding provided us physiological models, prototyping materials, and a greater network to pull expertise from.

Our latest solutions tackle two major causes of catheter associated urinary tract infections: **residual urine volume** and **bacterial contamination** [3,4,5]**.** Our first solution reduces CAUTIs by reducing the residual urine volume retained in the bladder after urination and preventing bacterial growth from the excess urine volume. This involves redesigning the inflatable indwelling urinary catheter away from the traditional balloon and replacing it with lower profile arms.

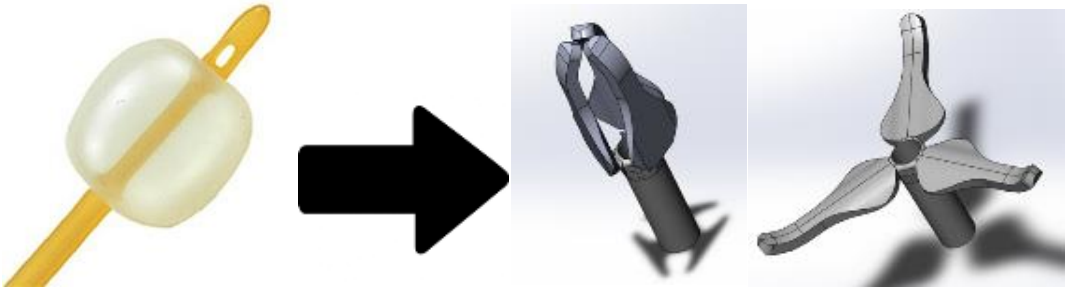


Figure 1: The transition in design of the Foley catheter balloon to the Belltower arm design (closed and open).

The armed design allows for less residual urine volume after evacuation of the bladder. Less residual urine in the bladder eliminates the growth medium for bacterial proliferation [3,4]. In addition, the contouring arms reduce the pressure on the bladder walls, increasing patient comfort and presenting a smaller surface area for bacterial attachment.

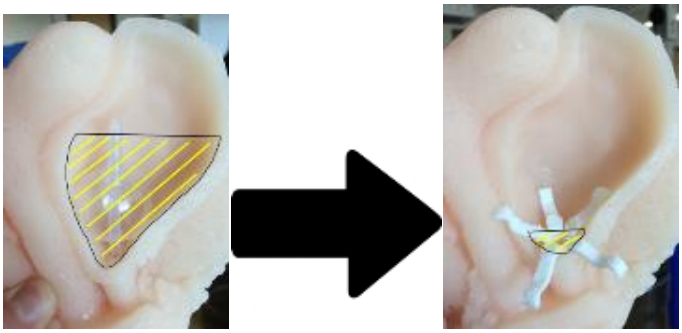


Figure 2: The reduction of residual urine volume seen from the Foley urinary catheter design to the Belltower arm design.

For deploying the arms in the bladder and securing the catheter in patients, our team designed two deployment mechanisms. The first deployment mechanism requires custom arm shaped balloons that inflate in the bladder. Our second deployment mechanism depends on a guide wire that allows the silicone arms to expand and retract within the bladder by pulling the guide wire through an additional lumen in the tube. In addition, both mechanisms have safety features designed to reduce urethral damage if the catheter is unexpectedly removed from the patient. Both mechanisms are currently being designed and tested to investigate feasibility.

Our second solution is an improved insertion device for the urinary catheter based on the urinary catheter introducer tip currently on the market. The current introducer tip is used exclusively for intermittent catheterization (catheterization without balloon fixation) and only provides lubrication. Our product enhancements improve ease of use for clinicians, reduce bacterial entry into the urethra during insertion, and create a novel cleaning mechanism for the catheter.

Figure 3: The Belltower insertion aid device (left). Insertion aid proof concept (right).

Our device is comprised of a soft tip that enters the patient's urethra prior to insertion, a chamber filled with antiseptic lubricant, and a series of ring devices used to clean the catheter after insertion as seen in Figure 3. The soft insertion tip is designed to reduce the trauma of the initial insertion and prevent the catheter from contacting any of the bacteria that builds up in the entrance of the urethra, reducing bacterial introduction into the bladder. The lubricant chamber passively applies the appropriate amount of lubricant necessary for insertion, and the antiseptic element reduces any bacterial presence in the urethra prior to catheter insertion. Finally, our cleaning rings are designed to be drawn along the length of the catheter at incremental times according to nursing protocol after the catheter has been inserted into the patient as seen in Figure 3. As 70% of bacteria that cause infections climb up the outer lumen, this process will continually reduce bacterial introduction to the bladder and reduce the incidence of CAUTIs [5].

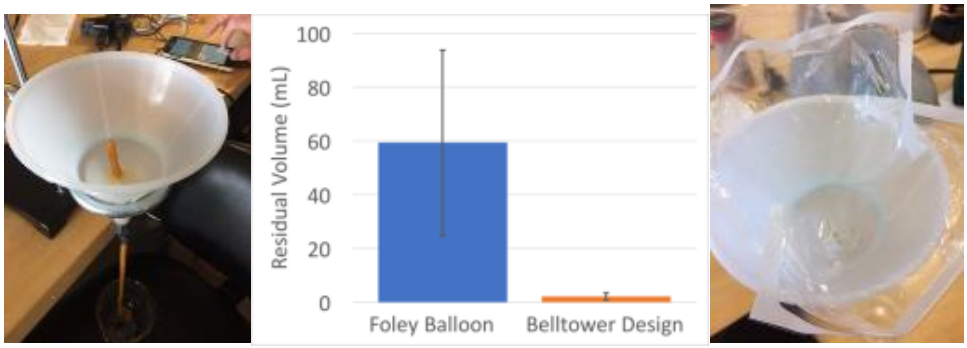


Figure 4: The testing apparatus for passive bladder evacuation. The Foley balloon is on the far left, our plot of results is in the middle (with standard deviation shown), and our armed design is on the right.

Our initial testing results show significant improvement in reducing residual volume in our table top experiments. While the testing cannot fully model the muscle activity used in bladder contractions, we have shown a reduction of nearly 95% in residual urine volume. Moving forward, we plan to collaborate with research professionals to determine a more effective way to model active bladder contraction. Additionally, our insertion aid has been shown to adequately lubricate the catheter and the cleaning rings completely coat the outer lumen of the catheter with a cleaning substance.

Our team is currently collaborating with clinicians to improve the designs and working with partners in the community including medical device designers and prototyping facilities. In addition, our team has conducted extensive testing along with patentability, manufacturability, and regulatory considerations to provide a basic outline for getting our product to market.

II. Protection of the Public

The primary focus and motivation for our design was the improvement of health outcomes for patients that are being treated with urinary catheters. **15-25% of all hospitalized patients receive urinary catheters during their stay, and their chance of a CAUTI increases by almost 8% per day** [6]**.** CAUTIs are the most prevalent hospital acquired infections and cost $3,000-$20,000 per patient [7]. Urinary catheterization and CAUTIs cause various comorbidities and a mortality rate of 2.3% [8]. Copious research identifies the Foley catheter, an outdated technology created almost 100 years ago, as the source of CAUTIs and their associated poor health outcomes. With the best interest of the patient in mind and to the bottom line, hospitals would be incentivized to prefer technology that would decrease the patient's risk of acquiring an infection.

Our products will positively influence the healthcare system by improving the health outcomes for patients that require urinary incontinence products, such as urinary catheters. Our products will positively influence treatments and interventions within hospitals, long-term nursing homes, and at home.

When designing our device and making critical engineering decisions, we strove to understand the device from the clinician and the patient perspective. When keeping the users in mind, we found that the device had to balance affordability with clinical effectiveness. To be clinically effective the device had to be easily inserted, operated, and maintained by a busy clinician who will have numerous patients and limited time. With this in mind, the operation of the device does not drastically change clinical practice; however, the design team's greatest obstacle was creating a device that could be manufactured affordably on a large-scale while meeting the standards for limiting bacterial introduction. At the same time, the team had to maintain various FDA regulations required to market the device in the US. The design team continues to face engineering challenges that range from improving clinical effectiveness, manufacturability, patient safety, and extensive regulatory processes. The team has met every challenge by relying on a diverse set of expertise and has seen first-hand how each decision can improve the quality of the device. We look forward to developing the product further and consider well educated engineering decisions to be the cornerstone for future innovation and the development of our device.

III. Collaboration of Faculty, Students, and Licensed Professional Engineers

Our team realized early on that we would need a host of collaborators to assist us and increase our chances of success. Our faculty mentor has served as a guiding hand in the entire project. His industry experience and connections have helped us find the right people to collaborate with and also given us direct feedback on our designs and design process. His

focus on “failing quickly” helped our team go through this traditionally multiyear process within 9 months. His strict adherence to FDA Quality Design Controls forced us to maintain our history file as if this was a real medical company. These experiences have proven invaluable for our team and greatly improved the overall quality of our project.

Our faculty mentor introduced us to our licensed professional engineer mentor (PE) after our first phase review. We then met with the PE a few times over the course of our project, and he offered a great deal of feedback on every aspect of our design: from the initial concepts to the exact implementations of our solutions. Additionally, our PE pointed out design details we may have overlooked and assisted our progress by constantly asking detailed questions that our team had not considered. Leveraging his and our faculty mentor’s connections, we expanded our professional network to designers with extensive 3D modeling experience. We have since collaborated with these experts to further develop and design our ideas. Without our PE’s and faculty mentor’s involvement, we would not have expanded our professional network to the degree that it is now.

IV. Multidiscipline Participation

The continuous and frequent input of stakeholders guided our project from the very beginning. Once we established a focus onto CAUTIs, our team expanded our network and reached across a variety of disciplines to move our project forward. The current redesign of the urinary catheter involves a variety of engineering disciplines, with an emphasis on biomedical, material, and mechanical engineering. As a FDA class 2 medical device inserted into the body, biomedical engineers understand the relationship between the design of the balloon mechanism and the function of the bladder anatomy and physiology. The material science engineers provide valuable insight into the material properties necessary for a functional design. In the case of our urinary catheter designs, the durometer of the silicone is crucial for our working prototypes. Lastly, the mechanical engineers help create various mechanical deployment mechanisms for our project which includes a custom balloon deployment and a wire based deployment within the lumen of the urinary catheter. Currently, our team is going beyond engineering to work with patent lawyers, marketing professionals, and business strategists to evaluate our product’s potential future in market.

In approaching the CAUTI problem, our team relies heavily on the expertise of a variety of different parties. A central theme of our project and the success of our current path has been dependent upon the network of people around us. Here is a brief list of parties and experts that have assisted in our project:

- The hospital’s clinical staff have provided consistent feedback on the feasibility and designs of our project ideas. As the primary consumer of our product, nurse feedback has been critical to the designs.
- A local urinary-catheter manufacturer has provided mentorship and feedback on our project. They provided key insights into design for manufacturability.
- A group of local urologists offered extensive medical experience about the urinary system and continue to provide key information and insight into our project. Additionally, they provide a deep understanding of how our products will behave and react within the urinary tract.

- A local medical device company engineer provided design and engineering assistance. He gave feedback, ideas, and insight for our engineering approach.
- A local medical device design firm provided regulatory insight into our product and guidance on the 510(k) FDA clearance process.
- A rapid prototyping company aided with prototyping and design ideation.
- A local polymer manufacturer gave custom ballooning expertise and prototyping assistance. As experts in custom balloons, they have been critical in building prototypes for our project.
- The Office of Technology Transfer at our university worked with us to understand the terms and conditions to declare technology out of a University system.
- A law firm assisted in filing for a provisional patent and understanding the patent landscape for our product.

Several branches of the biomedical engineering department have been utilized in creating our product. The areas of study within biomedical engineering include biomechanics, bioinstrumentation, and biomaterials. All divisions are represented within our team. Two members of our team are biomechanics students, two members are bioinstrumentation students, and one is a biomaterials student. The diversity of our focuses and the team resources provide our project with a unique and creative approach to solving CAUTI.

V. Knowledge and Skills Gained

The design process used for this project created an environment of innovation and self-directed learning. Our project involved a great deal of exploratory learning. While we were guided by our faculty mentor, his philosophy on teaching was very hands off. He laid out what we needed to accomplish, but it was the team's responsibility to figure out how to accomplish each task and make sure we asked the right questions of him. We learned how to work ahead and self-motivate as a team to complete all tasks. One of the most important components of our senior design class was the focus on design controls and maintaining a design history file (DHF). Every assignment in the class was a component of our DHF. We were asked to regularly update the deliverables and to maintain well documented engineering design notebooks. This was especially important for medical device innovation, as the FDA has a significant focus on documentation, maintaining clear design controls, and always having an eye on our regulatory pathway to market.

The project and design process fostered self-reliance and cooperation among the team members as well as demonstrating how much one can learn via networking with outside mentors and experts. The course began with the "gifting" of a single mentor within a hospital system. While this mentor was invaluable in allowing the team to shadow clinicians as well as allowing clinical immersion within the health system, we soon found that we would need to go beyond this network. This empowered our team to take advantage of our own strengths and networks to meet many clinicians and medical device professionals. In all, our team has enlisted the expertise of **over 75 professionals.** Their expertise and roles range from registered nurses to industry experts, urologists, catheter engineers, and manufacturers. The project team used these connections to approach the problem from a unique multidisciplinary angle that would separate us from our market competition. The individuals of the design team were responsible for identifying a substantial unmet medical need,

creating a novel solution based on research and knowledge acquired from experts within our network, and documenting the solution based on a four-phase design process to FDA standards. The project required large amounts of cooperation as it was too large to complete individually. Each team member developed a unique role on the team according to individual skillsets. The combination of a lead communicator, a project manager, a design engineer and two prototyping engineers increased our team's ability to work well together and produce results.

We have also had the value of proper pitching instilled in us by our faculty mentor. We started off the year giving very dry, technical presentations and have evolved into attention-grabbing, need-based stories designed to inform and help others see the problems that exist in medicine. By winning pitch competitions, **we have raised $13,000** to help our project move forward. We have also made untold numbers of professional connections through our short elevator pitches we give to anyone to whom we talk.

Potentially the most valuable requirement of the project was the need to constantly request and receive feedback from mentors. We acknowledged that we can only know so much and that sometimes it is better to reach out to those that have more experience. We have asked clinical mentors about the value of individual features and discussed patient comfort and usability. We have talked to our industrial mentors about fabrication and cost while evaluating the manufacturing feasibility of our designs. One of the most important skills we have honed through this senior design process is the ability to build a network. We started off with a single clinician mentor in a local hospital and through them and our personal contacts, we have expanded our mentor list to include over 75 people who work in a diversity of fields including law, design, medicine, and manufacturing.

This project was an incredible undertaking. It helped the students mature professionally and personally. We have been exposed to real world engineering and are ready to take the next step and begin solving the world's most challenging problems. We have discovered the value of approaching a problem ethically and then developing a solution to help people. We hope that in ten years, our products can be pulled off the shelf in a hospital and patients will not have to worry about CAUTIs. Once again, we are Belltower Medical, and we aim to improve health outcomes for patients with urinary catheters.

Thank you.

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