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Foley Catheter Priming Device

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Foley Catheter Priming Device

Melissa Boswell, Landon Davis, Jason Green, Tyler Grubb, Renee Horn


Department of Biomedical Engineering

Honors Research Project


Submitted to

The Honors College

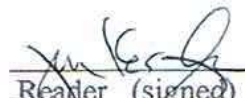
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FLOW, LLC

Foley Catheter Project

Melissa Boswell, Landon Davis, Jason Green, Tyler Grubb, Renee Horn
Senior Design Final Project
Customer: Rob Shardy
October 2014 – May 2015

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Abstract

A lack of a pressure gradient throughout the catheter prevents urine flow from the bladder and through catheter system in a condition referred to as “air-lock.” The purpose of this project was to design a device that could be utilized by person with a catheter faced with the problem of air-lock to restore urine flow and normal functioning of the catheter system. After a prototype was created, the device was put through a series of tests to insure proper functioning, absence of leakage, and durability. The device created can be added in-line with the catheter system, inconspicuously under the user’s clothing, as a primer that the catheter user can push to create a pressure gradient in the system and initiate urine flow. Overall, the device functions as its intended design and has the potential to solve the problem of air-lock for many catheter users.

Introduction

Every year, approximately 30 million patients require Foley catheter insertion in the United States alone. A Foley catheter is an indwelling system that drains urine from the bladder for patients that cannot empty it themselves. In a Foley, a thin rubber lumen is inserted into the urethra that drains urine from the bladder into a collection bag. Most often these systems are seen in sedated surgeries, after one undergoes certain surgeries (cesarean sections, ureterectomy, etc.), and in lower-limb paraplegics. Although it is the most effective draining method, there are many issues that can arise. Bladder stones, blood infections, kidney damage, urethral injury, bladder spasms, back pain, and the most common complication, urinary tract infections (UTI's) can be very damaging if not treated properly. [3] Fortunately, many procedures are in place in case one of these issues does occur. One type of catheter issue, however, that does not have a solution can occur after urine is drained from the receptacle bag and a lack of a pressure gradient throughout the catheter prevents urine from flowing from the bladder through the Foley catheter, extension tube, and into the collection bag; a condition described as "air-lock." During air-lock urine builds up in the bladder until it is forced to bypass the catheter balloon to flow out of the urethra causing extreme discomfort for the patient. Currently a patient is suggested to disconnect the receptacle bag or tube from the catheter to get the urine to start flowing again. Unfortunately, if the urine does then begin to flow with the bag no longer connected, the urine will start leaking out, causing discomfort both physically and emotionally for the person. The goal of this project was to create a device that encourages urine to flow freely from the bladder without disconnecting the urine drainage system,

eliminating air-lock and allowing for frequent drainage and repeated use of the receptacle bag.

This project was initiated by Mr. Rob Shardy, a Foley catheter user experiences the problem of air-lock within his system. Not only does he have this issue, but he has first-hand experience with many others who have this same issue with catheters. Our customer for this project was not solely Rob, but all people who use a Foley catheter and experience the complicated issue of air-lock.

Background Information

One of the first steps to help find a solution for air-lock was to first research what ideas or technologies already exist. A patent search was conducted using Google Patents to help with this research. It was hypothesized that the solution to air-lock will need to somehow control or dictate the pressure gradient within the Foley catheter in order to prevent air-lock. To narrow the search, methods of controlling pressure within Foley catheters was the main focus of the research.

Several technologies exist, but most were not intended to solve the problem of air-lock. One similar technology was called *Pressure Controlled Magnetic Valve for a Catheter - US 20140200558 A1*. The technology uses a magnetic valve and two chambers designed specifically to help change pressure. The technology seems promising to control the pressure gradient within the Foley catheter, but it did not specifically target the issues that occur during air-lock. The reason for this is that the magnetic valve creates lower pressure once urine passes through the first chamber into the second. With air-lock, the urine does not even flow through the catheter due to the

pressure gradient, therefore the release that occurs when liquid flows from the first to the second chamber does not exist. In order for it to solve the issue at hand, lower pressure would have to be created downstream, which does not occur with the Pressure Controlled Magnetic Valve.

Since few technologies related to air-lock were found in the patent search, the next step was an attempt at crowdsourcing (the process of looking up how other Foley catheter users were solving their issue of air-lock in non-technical ways). During that search a few hospital-grade, bedside Foley catheters were found that offered a potential solution. The tubing was longer for this system in order to accommodate patients lying down and the drainage bag being stationed away from the bed (typical Foley catheters attach to the user's leg, which requires less tubing). The hospital-grade catheter system also incorporates an attachment piece that has a vent to allow air to enter the system. This air helps create lower pressure in the tubing to allow for easier flow of urine. The reason this specific catheter system needs lower pressure is because some areas of the tubing are parallel to the ground and cannot use gravity to aid in urine flow. Urine flow is needed to avoid backup and the formation of urine pools within the catheter system.

It is believed the hospital-grade Foley catheter system with the vent would solve the issue of air-lock. However, the hospital-grade catheter tubing is too long for daily use and may not create sufficiently low pressure downstream to change the gradient enough to release the flow. Furthermore, these hospital-grade catheters are not available for purchase or daily domestic use. Keeping this in mind, it is possible to create a Foley catheter accessory that meets these requirements, and all customer requirements (see

Appendix A) while still keeping within the constraints and limitations that the situation provides (see Appendix B).

Project Objectives and Goals

As mentioned previously, the goal of this project was to alleviate the problem of air-lock for those persons using a catheter system by creating a device that encourages urine to flow freely from the bladder through the catheter, extension tube, and into the receptacle bag. There were many project objectives that needed to be taken into consideration with the design of this device. The operational objectives closely followed the goal of the project; the device should allow for free-flow of urine throughout the system after drainage which would prevent spilling due to air-lock. The device cannot leak or allow for any back-flow within the system.

In terms of design objectives, the device could function as either an in-line or stand-alone product, but with the device being misplaced as a potential concern, an in-line device was decided as the best choice. In order to limit opportunities for failure, keeping a simple design was also an important constraint.

Considering the project objectives from a consumer viewpoint, the device should be easily added or removed from the urine drainage system. It should also remain both discreet and comfortable for the user. In addition, the design should be clear and easy for the consumer to understand how it functions. Realistically, the device should be able to be mass produced and should cost equivalent or lesser than current Foley catheter system products. Overall, the device needs to operate safely, effectively, and simply, and be available to all Foley catheter users experiencing the problem of air-lock.

Methods, Procedures, and Manufacturing

After consulting with Mr. Shardy about his experience with “air-lock” and conducting preliminary testing to try to recreate the scenario, the team met to discuss possible solutions to the problem. During one meeting in December, the team gathered in the Auburn Science and Engineering Center’s library to brainstorm. The first idea proposed utilized a vent which would allow air into the system passively. Air would flow through the vent opening and through a porous membrane into the catheter tubing (the porous membrane would only allow air to flow into the system and not out of it). However due to limited time and resources, the idea of engineering a porous membrane did not appeal to the group. Furthermore as previously stated in the background information section of this paper, the medical device manufacturing company Covidien Limited already produces a hospital-grade Foley catheter with such a vent. Creating a new vent would ultimately create unnecessary problems with patent infringement, so the idea of the passive vent was ultimately opted against.

The second solution involved utilizing materials that were already available to a Foley catheter user. The team proposed that the syringe that is normally used to fill the catheter balloon (that keeps the catheter in place within the bladder) could just as easily inject air as it could water. Since that piece is usually carried by users at all times, the idea to create a separate component (see Appendix E) that could connect inline with any Foley catheter system (between the catheter and the extension tubing) and utilize the syringe as a means of injecting water to relieve a vacuum was designed. The component would have an opening that would allow the syringe to be introduced. The user could then use the syringe to force air into the system and ideally create flow. Problems did

arise when attempting to translate this idea into a realistic situation. In order for a user to actually inject air with the syringe, any sort of bottom layer of clothing that covers the legs would have to be removed. This would be an inconvenience, and for many, not a possibility if faced with “air-lock” in a public setting. Ideas were then created on how to inject air without a customer having to remove their clothes. After extensive brainstorming, the option of creating a “primer” bulb that could be pumped was created. The same inline component from the second design would be utilized, but instead of inserting the syringe into the component, a narrow tube would be inserted and run up to the waistline of the user’s pants. A flexible ball similar to the bulb found on a pressure cuff would be placed on the proximal (nearest to the body’s center) end of the tube. The user could then squeeze the ball if air-lock occurred and force air into the system. Though this was a step in the right direction, problems still persisted in regards to the discreetness of a bulb hanging out of one’s clothes and any discomfort that would result from that weight hanging from the catheter.

Upon reflecting on the newest design idea, the team proposed a modification that would eliminate any discomfort caused by the pressure cuff bulb while also creating a more subtle profile. By simply removing the tube and placing a smaller version of the pressure cuff bulb, such as a primer bulb found on a lawnmower, directly onto the inline component the team could introduce air into the system. The design would remain discreet enough to permit the user to wear the component under his or her clothing. All the patient would have to do would be to press the primer bulb several times to relieve any vacuum that was causing air-lock to occur. After discussing the advantages and

disadvantages of each proposed idea, this design was ultimately selected as the one that would be carried out to fruition.

The team then began to implement the design by first consulting the Biomedical Engineering Department's workshop technician, Steve Paterson. Mr. Paterson understood the complexities of fabricating and testing such components so he was invaluable to talk to. He recommended two one-way valves be incorporated into the system: one directly below the primer bulb and one in the main chamber of the device proximal to the opening underneath the primer bulb. This would ensure that air only flows into the system and distally towards the collection bag (airflow towards the bladder could promote urinary tract infection). In addition, it was recommended that the initial design should be a basic block structure so that the primer bulb could sit flush on top of the component. (See Figure 1) Instead of simply creating one prototype, the idea of creating two was followed in order to initially have a model to determine function, then to have one that was sleeker and more discreet for a customer to actually use.

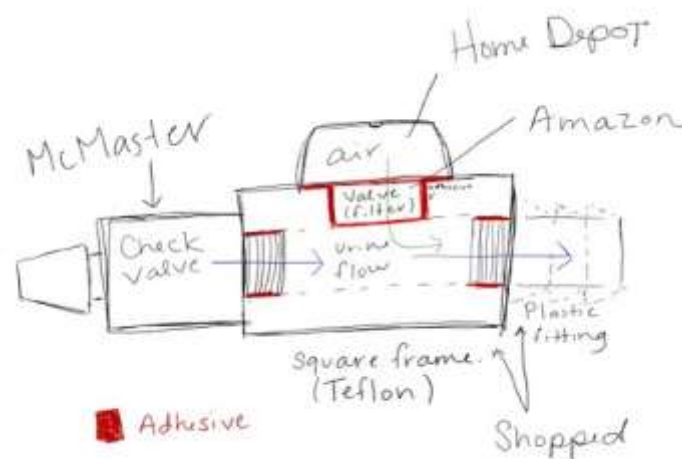


Figure 1: Sketch of anticipated first prototype. The sketch includes both one-way valves and possible sources for each component.

With all this in mind, the team began to search for different types of one-way valves to incorporate into the design. After extensive research, a one-way valve used in coffee bags was found that not only could be used to control air-flow through the primer bulb but also fit perfectly underneath the bulb that was purchased. While useful for air (since pressure was not as much of a concern), another type of valve was needed to prevent liquid backflow within the chamber itself. Fortunately, a type of medical grade one-way valve called a “duckbill valve” that was compatible for liquid flow at low pressures was discovered through Vernay Laboratories. A valve was selected that required minimal pressure for release and had a comparable diameter to that of the extension tubing used in the pre-existing Foley catheter. Fortunately for budget’s sake, the team was able to obtain a free sample of ten valves.

Once the valves were acquired, the first functional prototype was modeled utilizing SolidWorks. The model was exported to Case Western University’s Think Tank to be 3D printed using higher quality plastics. Within a few days, the prototype was completed and the team began testing the design to demonstrate proof of concept (refer to “Performance Testing” and Appendices E and F for test details, experimental results, and experimental photographs). While the first prototype did introduce air into the system and was able to induce flow, the design was not without its faults. First, the duckbill valve could not be embedded in the main chamber due to its size. Second, the design lacked a male end similar to that found on the extension tubing that could be attached to the female end of the catheter. And finally, the plastic casing was simply large and bulky.

Once proof of concept was demonstrated with the first prototype, the team began to refine the design. First and foremost the second prototype specifically incorporated

both the duckbill valve and a male end to connect to the catheter. By splitting the second prototype into two separate pieces (see Figure 2), the duckbill valve could be embedded into the device. The piece that acted as the male component was designed to have the same dimensions of those found on the male end of the extension tubing given to the team. Furthermore, the design was converted from a rectangular to cylindrical shape, thus reducing the amount of access material (and therefore cost) while providing a sleeker and more comfortable feel to the user. The second design was drafted in SolidWorks, then 3D printed utilizing The University of Akron's 3D printing service (in order to reduce costs further). The final prototype was then assembled as shown in Figure 2. In order to close the system, medical grade glue and silicone was used to affix the one-way air valve, primer bulb, duckbill valve, and male connection.

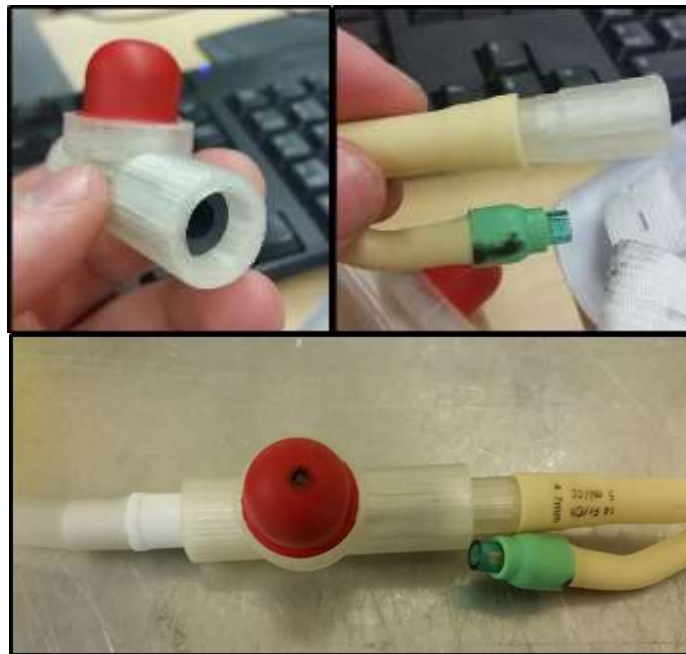


Figure 2: Final assembled catheter primer. Design includes fitting for duckbill valve, male connector, and cylindrical design.

Performance Testing

In order to ensure that the device actually worked and did not create new problems, a series of tests were performed to check properties such as proof of concept, water-tightness, and connection strength. When creating a universal connecting accessory for a catheter system, the biggest questions that should be asked are: Does this hinder the flow of liquid through the system? Will there be leakage caused by the addition of this piece? When beginning the process of analyzing both of the prototypes, these were the two ideas that the team focused on. After assuring that there were no issues in those areas, testing was expanded to create more quantitative results. The equipment required to do pressure testing on the minute scale being worked with was not available, however tensile connection strength between the primer and the catheter system was examined. If positive results are produced for all tests, it is safe to say that the catheter primer that was created could actually be a potential solutions to issues such as airlock. It can be noted that all experimental photographs can be found in Appendix F.

The first test completed on both prototypes was to check whether the primer bulb was properly injecting air while also testing if the one-way air valve properly impeded backflow. In order to do so, the catheter primer was attached to the collection bag (using the female side of the primer), and the opposite end was sealed off with electrical tape. From there, the bulb was pressed repeatedly until the bag began to fill up, then pressure was applied in order to test whether there was any air leakage from the primer bulb or the connection. For both prototypes, the process of completely inflating the bag with air (which is a gross exaggeration of the use the primer will actually experience) took approximately ten minutes of pumping. Although it was a slow and steady process, it was

successful. The primer did inject air into the system, which would in turn release any sort of vacuum that was occurring within the bag. When pressure was applied to the bag, neither prototypes experienced air leaks. For Prototype I and II, the air tests were a success.

The next series of experiments incorporated water flow through the catheter while also including the primer. Utilizing a balloon to simulate the bladder, a small hole was cut in the bottom, then taped to the catheter with electrical tape (in order to prevent leakage). The neck of the balloon was then attached to a faucet in order to easily refill the “bladder” while still keeping a closed system. From here, the primer was placed in line, then water was run through the system to see if any leaks occurred superficially. After verifying that the system was leak-free, several other scenarios were analyzed. The first was to create a pinch in the catheter above the primer to see if stagnant water could be forced down. When the problem was initially simulated, a common occurrence that was observed was a column of water building up when “air-lock” occurred. It was believed that if the primer could push down the column of water, the vacuum would release and drainage would continue as usual. The second test was to create a pinch below the catheter (in the opening of the collection bag). It is believed that a block lower down the system is creating the “air-lock” phenomena, so by creating a pinch at the end, the primer’s effectiveness can be observed.

For these water tests, Prototype I and II had different reactions, mostly resulting from design differences. When Prototype I was printed, a male connection piece was not included in the design, which has to be compensated for with alterations to placement. Prototype I was placed directly above the collection bag because it had two

male connections present. However, one was not the standard connection size, causing a leakage issue while pushing the water column down. This was a critical design alteration that was incorporated into the drawings for Prototype II. During the lower blockage, the connections were sealed shut with electrical tape in order to prevent excessive amounts of leakage (since it was already shown that there was a leak occurring due to the connection design). For this, the success of the primer depended on the strength of the pinch being created. When held tightly, the primer did not break through, but a significant amount of pressure did build in the tubing. When a looser pinch was applied, however, the system drained as expected, allowing for flow once again. The team incorporated the problems and successes observed into a new design that included a tighter fit on the female side, a recess for the duckbill valve, and a male adaptor that fit proximal to the duckbill valve. When this was placed through the same testing, it showed the same results as Prototype I without any of the leakage problems. This allowed the team to confidently move forward with proof of concept and a design that could practically be used in a real world situation.

The final test that was performed not only provided quantitative results, but also proved that the addition of the universal catheter primer would not be detrimental to the connection strength. In order to prove this, a tensile test was performed on the entire system (including Prototype II) utilizing a universal testing machine in order to show the weak point in the connection and to see how much force must be present to break the connection. The results of each test's breaking point are shown in Figure 3.

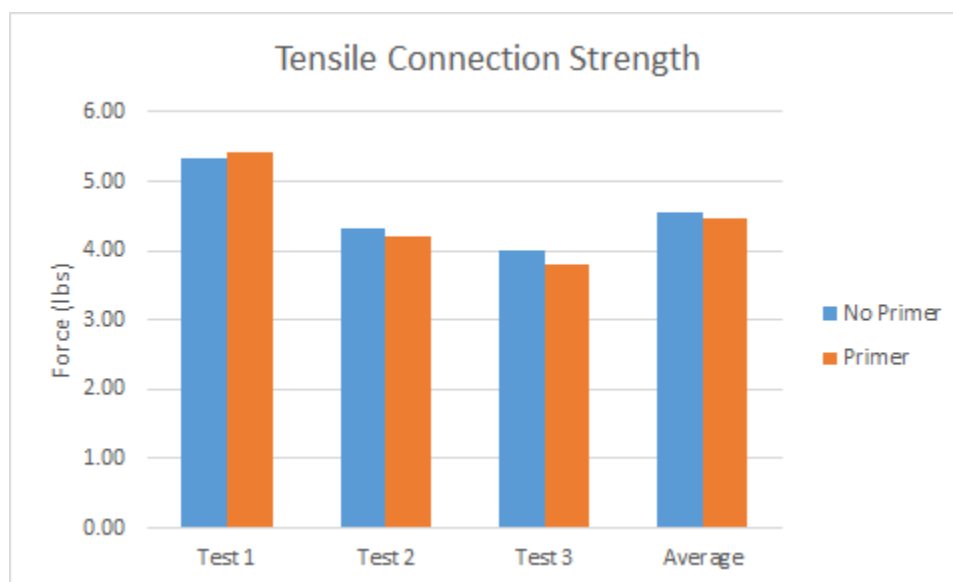


Figure 3: Connection separation points for Foley catheter systems with and without the universal catheter primer. Average shown in last column.

For just the Foley catheter itself, the average breaking strength was 4.55lbs of force. With the addition of the universal primer, the breaking strength was 4.48lbs. (Individual testing results can be found in Appendix E) Overall, these two strengths are comparable and are much higher than the everyday force that would be applied to a Foley catheter when in use. It was observed that over time, the connection strength began to decrease (from continuous stretching with the universal testing machine) which could also explain the difference between the two (the connection without a primer was tested first and also had slightly higher tensile strength). It was also observed that the breaking point occurred on the male side where the actual catheter met plastic. Though it would seem that the female connection would be weaker, it proved to not be a concern. In order to verify that the addition of the device did not compromise the strength of the catheter-tubing interface, a t-test was performed. It was found that with 95% confidence the difference between failure loads (lbs) with and without the primer was between -1.69 and 1.82 lbs. The mean for these values is .065, proving that there was no significant difference in connection

strength. After completing these air, water, and tensile tests and obtaining positive results, the team feels confident in the design and function of the universal catheter primer. This device does solve the issue of “air-lock” in Foley catheters.

Future Directions

The universal catheter priming pump is a novel idea that could revolutionize the catheter industry. Although the two part system is functional, there are many ways in which it can be improved. Improvements with the device can help lower production cost, be more aesthetically pleasing, and lower the risk of infection. The first future improvement that will be made is making the device smaller. One of the great features of the Foley catheter is that they are virtually inconspicuous when worn under clothes. The last thing users want is to draw attention to the fact that they are wearing a catheter. The goal would be to make our device similar in size and proportions in order to maintain the image that they are not wearing a catheter. In order to do this, the team would have to find a new material that is stronger, lighter, and able to maintain its shape at very small dimensions. Also, since the current method of 3-D printing will not be able to handle such small details, a different means of fabrication, such as producing a mold, would need to be utilized.

Another improvement that will be made is making the device completely in line with the catheter system. As of right now, the tubing and the bag must be separated to connect the primer, which introduces non-sterile air into the system. In order to prevent this from happening and keep the system sterile, this small device could be incorporated into a full catheter system. It would be small and inconspicuous but still functional and easy to use. This will also make it easier for patients to purchase the device; if it is included in the

Foley catheter it will most likely be covered by insurance and made affordable to the masses that may experience air-lock. This essentially makes a more powerful version of the hospital-grade catheters available to anyone.

The last change to be made in the future is to have different types of air pumps available for patients of different capabilities. Some patients may not be able to reach down to their leg and press a button on the catheter. Therefore, an electrical and mechanical component could be added for those less able. A button can be placed conveniently on a wheelchair or on a hip, and at the press of a button a mechanical pump can force clean, sterile air into the catheter system. Our air pump idea has the potential to be very useful to millions of people using catheters and can be innovated in ways to accommodate any type of patient. With innovations such as this, the problem of air-lock will be a thing of the past for future generations of Foley catheter users.

APPENDIX A

Functional Requirements

1. Continuous flow of urine from catheter to collection bag at all times
 - a. Goal of the project: relieve problem of air-lock
2. No blockages or kinks in the catheter tube and device
 - . Most susceptible to blockages at catheter opening inside bladder
3. Easy to insert and remove
 - . Decreases risk of complication
4. Catheter should remain in place
 - . Device should not allow for disconnection of any parts in catheter line including the connection point of the device itself
 - a. It should allow for normal placement of all components
5. Device should be inconspicuous and have a low profile
6. Device must remain in operating condition for at least as long as catheter and components
 - . Failure of the device can cause serious problems for consumer
7. The device must not cause skin irritation
8. Device must not be easily damaged; robust in design
9. Device should be universal; can fit both male and female catheters
10. The device must not allow for any backflow through the system
 - . Backflow can cause devastating infections

APPENDIX B

Constraints and Limitations

1. The cost of production to create the device must be feasible for the product budget.
2. A lack of experience for the design team could cause limitations in the design process.
3. This project must be completed in a limited amount of time. This could limit the amount that can be completed.
4. The team will be working with a limited number of resources which could limit what can be accomplished with prototypes, etc.
5. Another design constraint is to keep in mind the customer base that will be utilizing the product. Not all catheter users run into the “air-lock” problem, so that needs to be the central design aspect.
6. All designs must be within FDA regulations and follow all government codes.
7. The final product should be able to be manufactured.
8. Designs must consider the safety of workers, consumers, and the public.
9. Materials that cause adverse reactions should not be utilized in the manufacturing of the device.
10. Products should not use patent protected design aspects.
11. The design should be sustainable. After the scope of this project is completed, if the device proves to be effective it should be able to be continued by another design team.

12. Not all individuals who will be utilizing this device will have the ability in their hands to connect the device to the tubing or catheter. Dexterity could be limiting based on the customer's physical abilities.
13. The device can be sterilized by the user. There should be an in-home process for sterilization that is simple enough for the general populace to complete.
14. The device must be cost-efficient for the user. If the device is disposable, the amount that must be purchased needs to be sustainable. If reusable, sterilization procedures must be in place.
15. In the case of an accident, there should be fail-safes in place to close the valve.
16. The device must be light enough to avoid disturbance of the system. Weight should not cause discomfort of the user from pulling.
17. If the device requires outside air to function it cannot be blocked by skin or fabric.
18. The device must be easily accessible. A user should not have to remove their pants, etc. in order to operate the device.

APPENDIX C

Timeline

Original and current Gantt Charts turned in as separate documents.

APPENDIX D

Full Budget	
<i>Prototype Production Costs:</i>	
Primer Bulbs (x3)	\$15.00
Duckbill Valves	\$0.00
Degassing Valve	\$6.98
3D Printing (Prototype I)	\$36.91
3D Printing (Prototype II)	\$0.00
Foley Catheter	\$0.00
Medical Grade Silicone	\$0.00
Medical Grade Adhesive	\$0.00
Total:	\$58.89
Project Budget:	\$500.00
Margin:	\$441.11

Rough Manufacturing Budget	
<i>Estimated Production Costs (per piece):</i>	
Primer Bulbs	\$0.76
Duckbill Valves	\$2.40
Degassing Valve	\$0.05
Polypropylene	\$0.40
Medical Grade Silicone	\$0.02
Dual #88 Adhesive	\$0.01
Total (per piece):	\$3.65

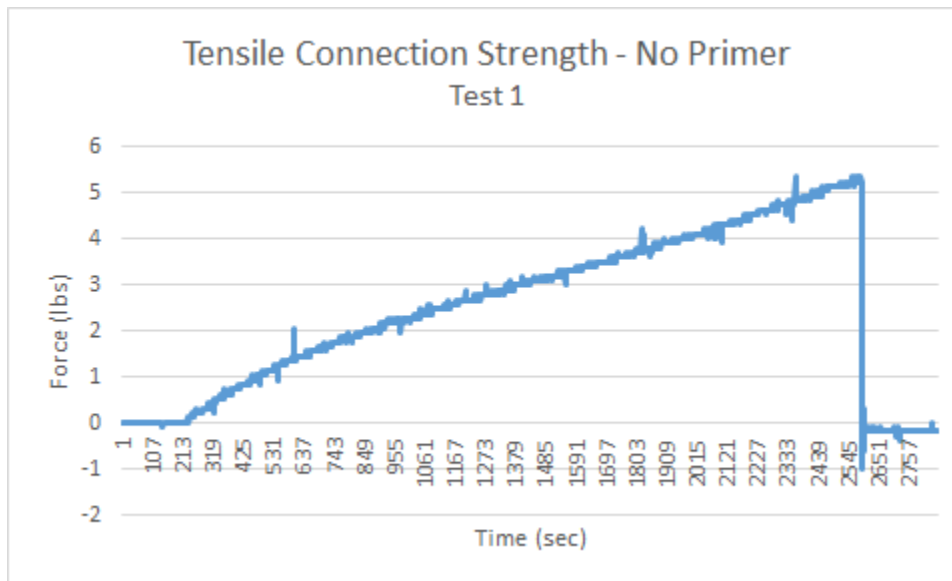
\$758.10	1000 per lot
\$1,200	500 per lot
\$1,365	25000 per lot
\$20	2" by 1' rod (50 pieces/rod)
\$4.96	per bottle (200 pieces/bottle)
\$15.00	per quart (1500 pieces/quart)

Sources:
 EC Power
 Vernay Laboratories Inc
 Pacific Bag Inc
 Professional Plastics
 Yanke Bionics
 Yanke Bionics

Upfront cost of Injection Mold Tooling: \$1,000.00 (Source: Applied Medical Technologies)

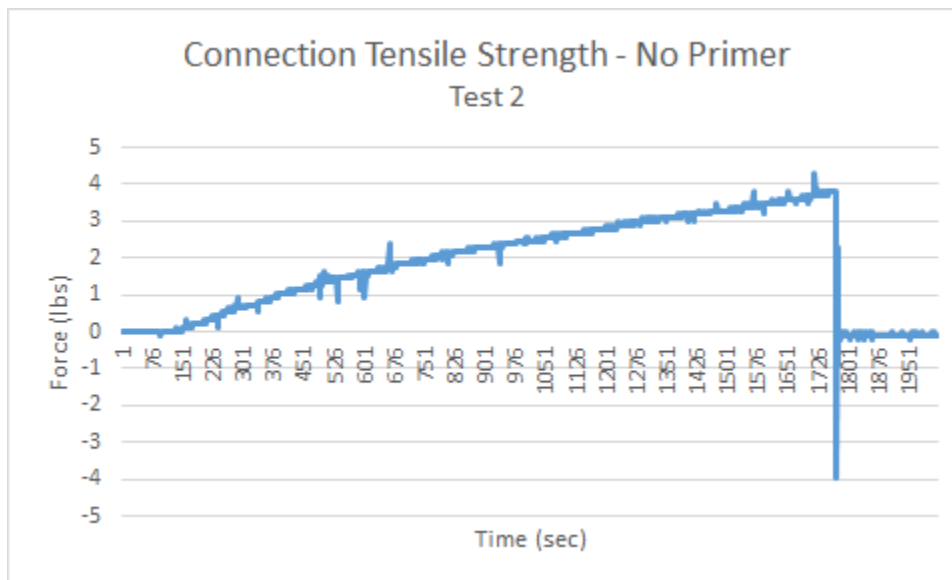
APPENDIX E

Individual Testing Results



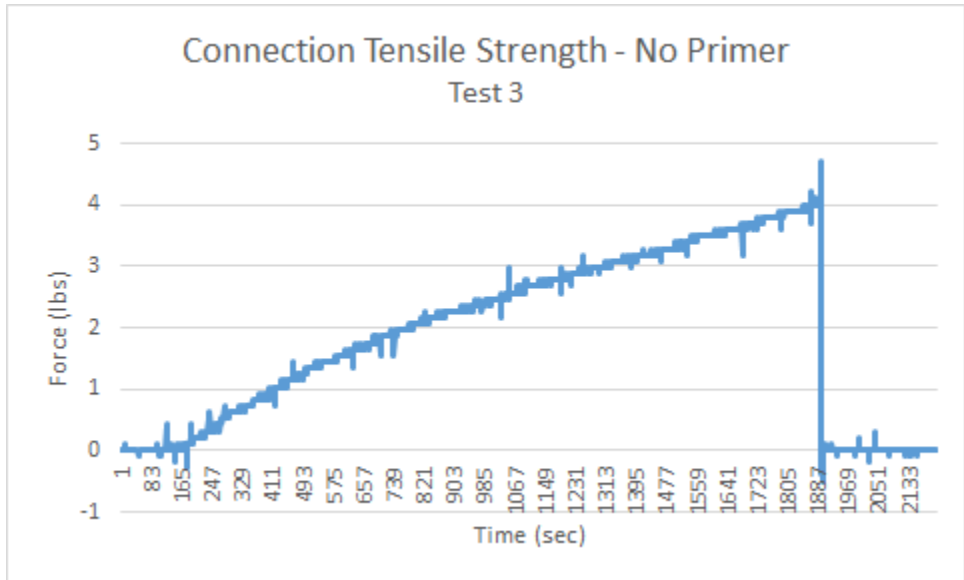
Breaking Force: 5.33

Break Location: Primer male end



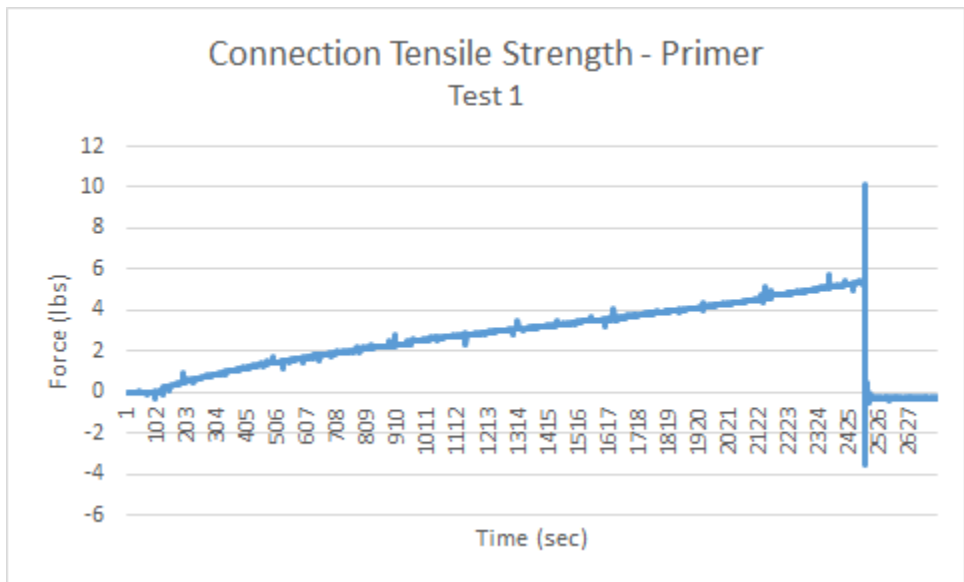
Breaking Force: 4.31

Break Location: Primer male end



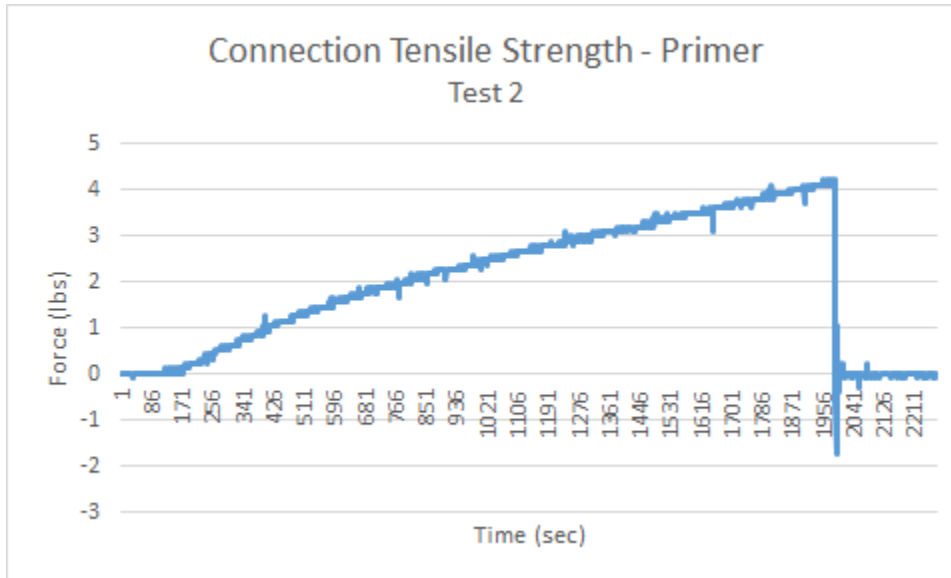
Breaking Force: 4.00

Break Location: Primer male end



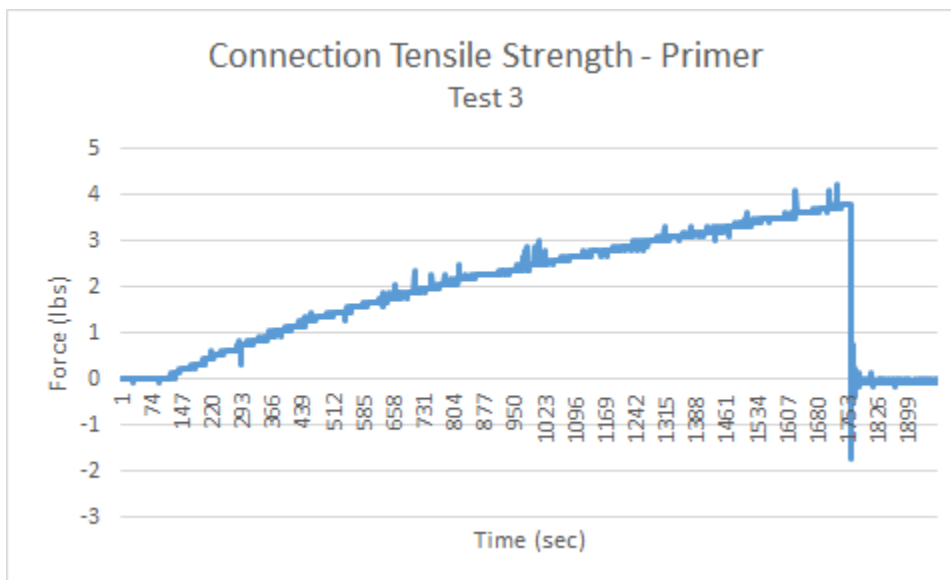
Breaking Force: 5.433 lbs

Break Location: Primer male end



Breaking Force: 4.21

Break Location: Primer male end

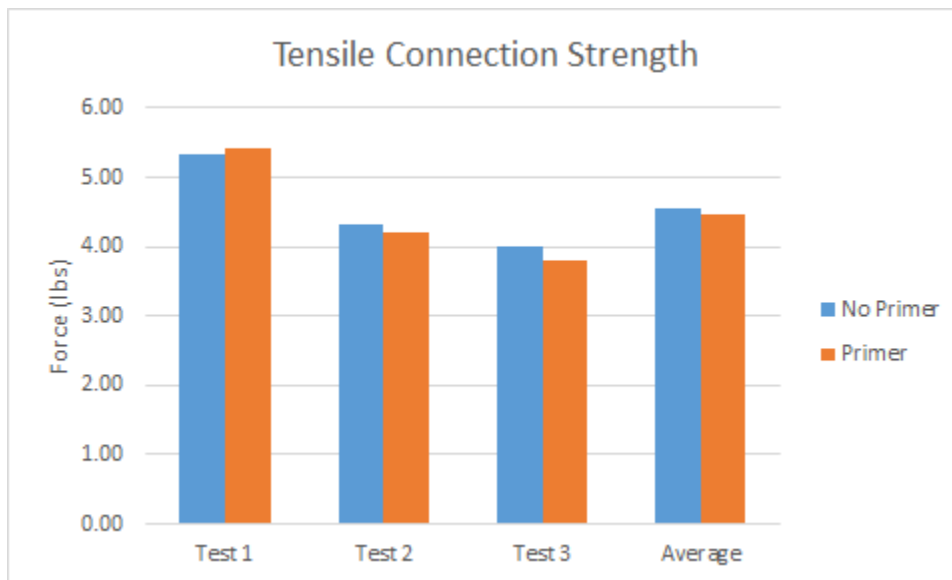


Breaking Force: 3.80

Break Location: Primer male end

Strength Comparison Table:

	No Primer	Primer
Test 1	5.33	5.43
Test 2	4.31	4.21
Test 3	4.00	3.80
Average	4.55	4.48



APPENDIX F

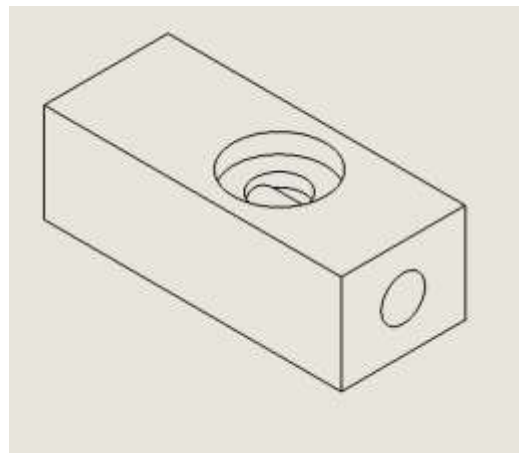
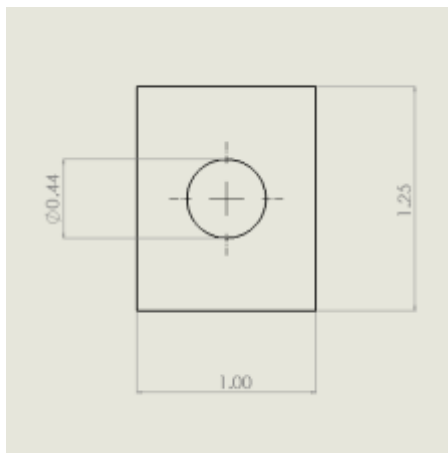
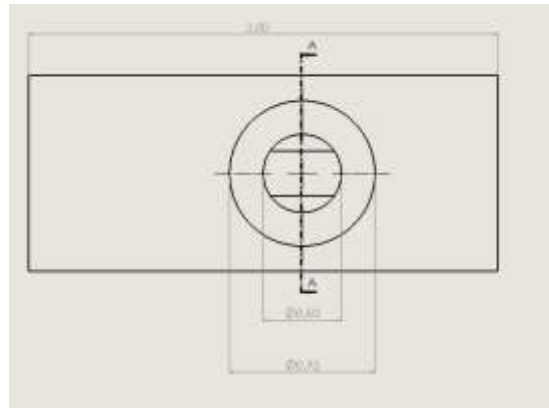
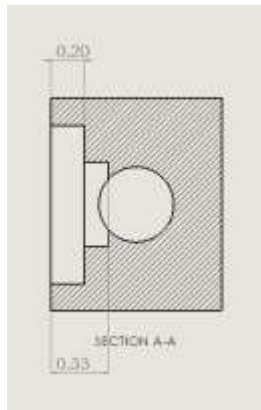
Experimental Pictures

“Air Lock” Simulation:

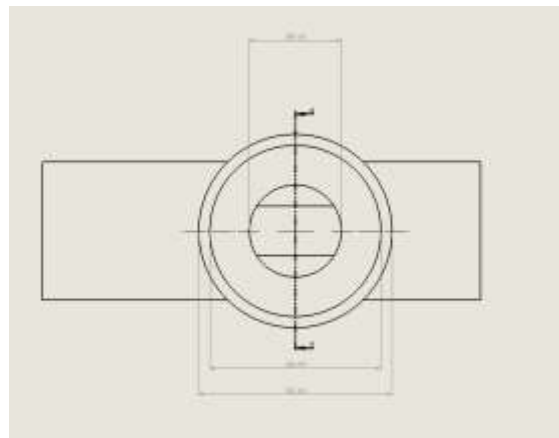
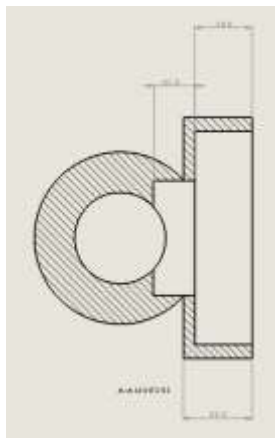


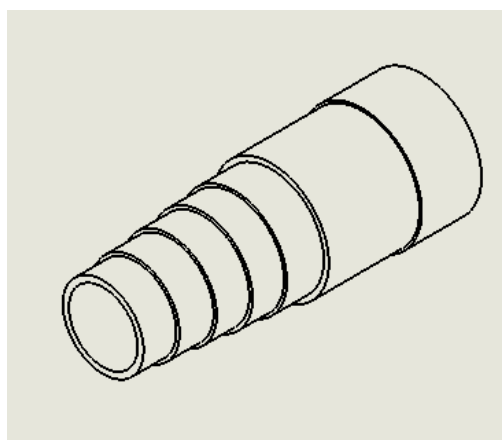
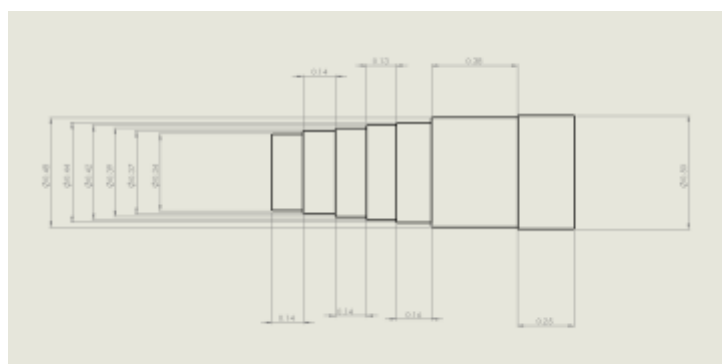
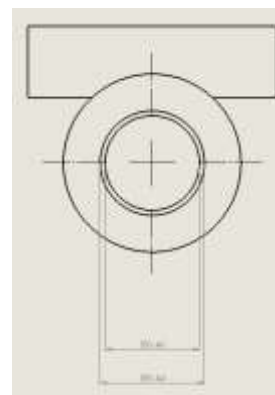
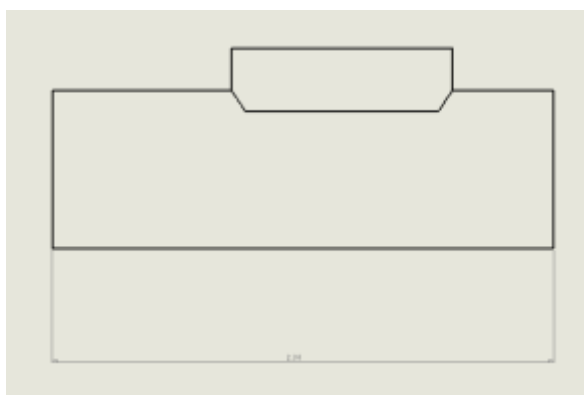
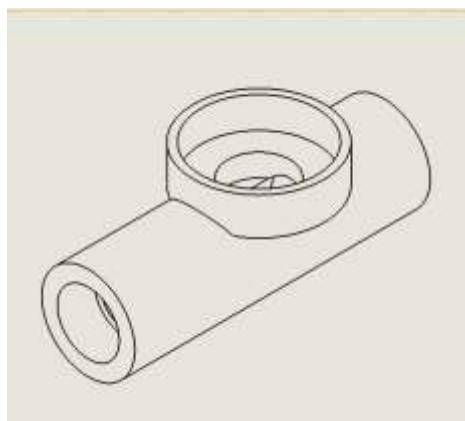
Design Drawings:

Prototype I:



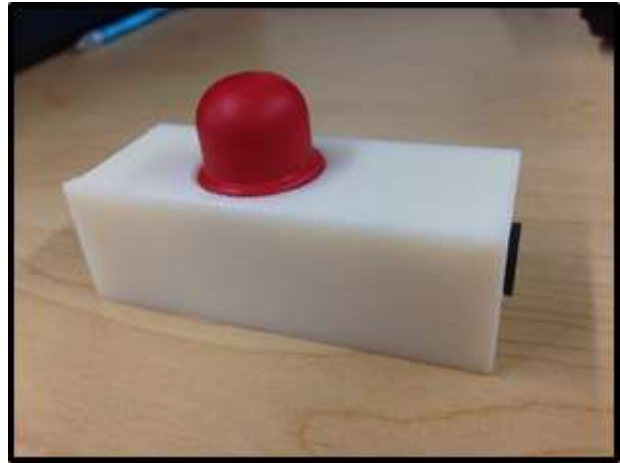
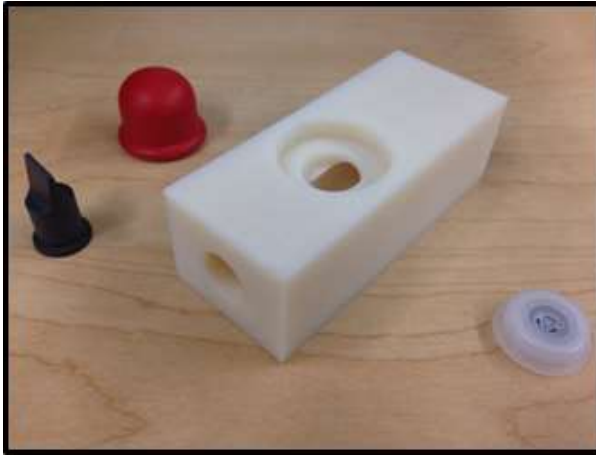
Prototype II:





Catheter Primer Components and Assembly:

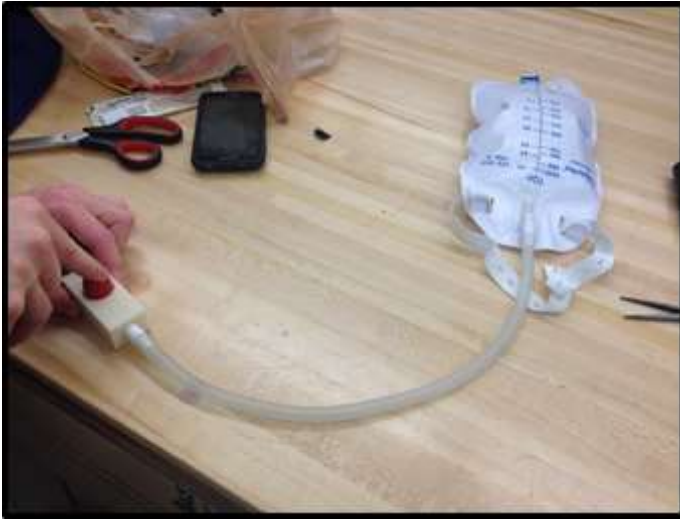
Prototype I:



Prototype II:



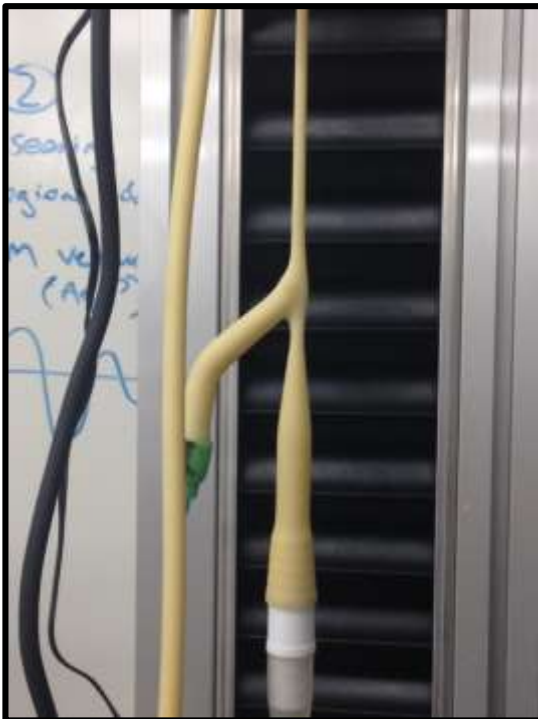
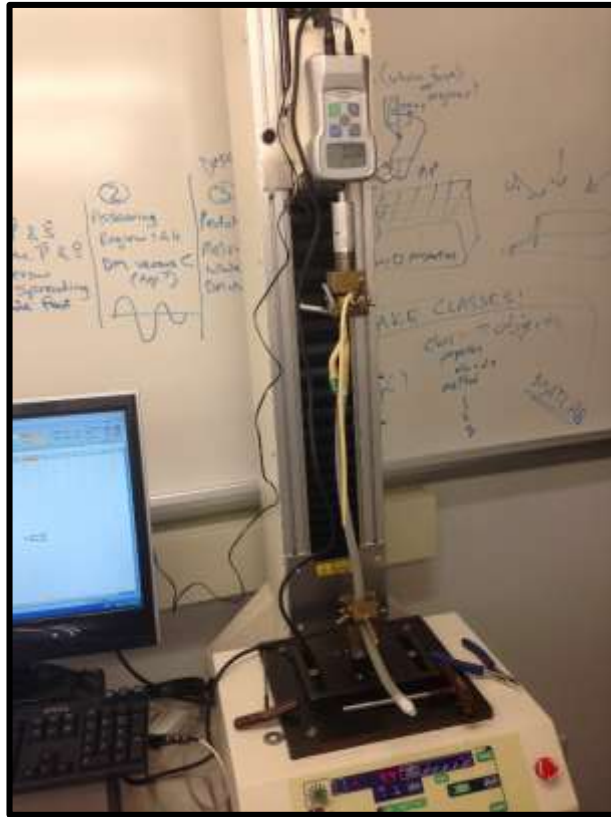
Air Testing:



Water Testing:



Prototype II Tensile Strength Tests:



Project References:

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