

The Aspiration Containment System (ACS)

A Novel Device Design for Large Ovarian Cyst Removal

Team 12: Atiya Anwar, Emily Graba, Christabel Ekeocha, Kayla Whatley, and Mary William

Advisors: Jordan Mattson and Joram Slager

BME 4002W

April 11th, 2022

Testing

Test Methods

Throughout the testing of the Aspiration Containment System (ACS), the requirements outlined in Deliverable 4 were further researched and test methods were developed based on various factors. Table 1 below shows the different requirement categories, the ISO requirements and/or test methods used to evaluate the device, and the justification associated with testing category. Additionally, the requirements that were not met are also listed in this table with the justification as to why they were not met. More detail on the requirements that were not met will be provided in the Conclusion section.

Table 1: Requirements and Testing Summary

Requirements Met	Test Method	Justification
Size Requirements	ISO 10012 -or - Sizing Test Method	Due to the lack of access to equipment, a Sizing Test Method was designed and performed to ensure ACS was within requirements/standards.
Strength/Leak Requirements	ISO 20484 -or- Bubble Leak Test Method	A base-line Bubble Leak test was performed using a test method written by the team.
Tensile Testing	ISO 572-2 Tensile Test -or- Tensile Test Method	Due to the lack of access to equipment, a Tensile Test Method was designed and performed to ensure ACS was within requirements/standards.
Usability ranges	Functionality Tests	Tests were run on the ACS to determine how effective it is at the minimal pressure on which it works
Physical Compatibility Requirements	Visual Analysis and Physical Examination	These consisted of requirements that could feasibly be tested by examining the device. Methods were developed to standardize these tests for the ACS.
Human Factors	VOC Test Method	These are requirements for the ACS that were necessary, but focus on the user's handling of the device. A VOC test method was developed and used for these

		requirements.
Requirements Not Met		
Sterilization	Autoclave Test Method	The material used for the most current prototype is not autoclavable and thus this test was unable to be performed.
Cytotoxicity	ISO 10993-10:2013, 1-5:2000	The material used for the most current prototype is not rated for use inside the body and thus this test was unable to be performed.
Mesh Requirements	ISO 19403-6, ISO 4783-2	The mesh was not implemented into the device and thus no test method was designed to cover these ISO requirements
IFU	21 CFR Part 801	As the design for the ACS has not yet been finalized, the IFU has not been written yet, and thus these requirements cannot be measured or met.

Sizing Test Method

Materials: Caliper (IQed if possible), ACS system, and Vacuum Tubing

1. Set Up:
 - 1.1. Ensure the Caliper is measuring in mm - check the units the caliper is measuring in. If the units are not in mm, click the mm, inch, cm, etc button until the units read mm.
 - 1.2. Zero the Caliper - place the two measurement tips together and hit the zero button.
2. Measurements:
 - 2.1. Using Figure 1 in the results section, identify the desired measurement to be taken.
 - 2.2. Before taking any measurements, zero the caliper, following the steps mentioned in 1.2.
 - 2.3. Take the desired measurement by placing the two tips of the caliper around that location.
 - 2.4. Record measurement shown in the data table (results section, Table 3)
 - 2.5. Repeat steps 2.2 - 2.4 two more times to collect three measurements total for each of the desired components. This is to ensure the measurement is repeatable

- 2.6. Take the average of the three measurements to get the final measurement of each desired component.
- 2.7. Compare the final measurement to the requirements to assess if the component meets the specifications.
- 2.8. Repeat the steps 2.1-2.7 for each of the desired components.
 - 2.8.1. If time and resources allow, have other operators complete steps 2.1-2.81 to ensure the test is reproducible by other operators.

The data collected by the group is collated in the results section, in Table 3.

Please note that some of the requirements were updated after Deliverable 4 was completed as the group continued to iterate on the prototypes and the device.

Bubble Leak Test Method

Materials: Schuco-Vac 430 Suction Machine, Ballistic gel cyst model, vacuum tubing with inner diameter of 6 mm, ACS, water filled bowl large enough to fit the hand or the cyst model.

1. Set Up:
 - 1.1. Place the water-filled bowl on a stable surface that is large enough to accommodate the Schuco-Vac 430 Suction Machine.
 - 1.2. Ensure that the bowl is filled with enough water to completely submerge the ACS and the hand/cyst model.
 - 1.3. Connect one end of the vacuum tubing with an inner diameter of 6 mm to the suction inlet of the machine.
 - 1.4. Connect the other end of the vacuum tubing to the ACS, making sure that it is securely attached.
 - 1.5. Set the pressure to 520 mmHg and test that suction is being created.
2. Experiment 1: Bubble Leak Test - ACS and Hand Submersion
 - 2.1. Turn on the suction function of the Schuco-Vac 430 Suction Machine.
 - 2.2. Place the bottom of the ACS device onto the palm of the hand.
 - 2.3. Submerge the palm of the hand and ACS into the water-filled bowl while making sure that the opening of the device is not submerged.
 - 2.4. Observe the area around the bottom of the ACS device for the presence of bubbles.
 - 2.5. Record any observations of bubbles or the absence thereof.
3. Experiment 2: Bubble Leak Test - ACS and Cyst Model Submersion
 - 3.1. Turn on the suction function of the Schuco-Vac 430 Suction Machine.
 - 3.2. Place the bottom of the ACS device onto the ballistic gel cyst model.
 - 3.3. Submerge the cyst model and ACS into the water-filled bowl while making sure that the opening of the device is not submerged.
 - 3.4. Observe the area around the bottom of the ACS device for the presence of bubbles.

- 3.5. Record any observations of bubbles or the absence thereof.

Tensile Test Method

Materials: Tensile Testing Machine, Basic Compression Loading Script, ACS device, Flash Drive, Clamp, Computer with Excel/Sheets Software

1. Set Up:
 - 1.1. Prepare the tensile tester for testing
 - 1.1.1. Ensure proper load cell is in place - 500 N load cell was used
 - 1.1.2. Remove any previous fixturing
 - 1.1.3. Turn on the machine and start running computer program
 - 1.1.4. Pick out correct Compression Loading Script
 - 1.1.5. Zero the load using the computer or machine buttons
 - 1.2. Place sample into tensile testing machine (there are two possible configurations
 - 1.2.1. Configuration 1: Place Cylindrical body of ACS into the tensile testing machine and lower the crosshead to just touch the top of the cylinder enough to hold it in place (see figure 2).
 - 1.2.1.1. To lower the crosshead, unlock the crosshead by pressing the unlock button.
 - 1.2.1.2. Once unlocked, use the downward button and the scrolling wheel to lower the crosshead slowly, avoiding hitting the sample and overloading the load cell.
 - 1.2.2. Configuration 2: Place Vacuum Tube Connection Point into the tensile tester, using a clamp to hold the body of the device in place during the testing (see figure 3). Lower the crosshead to just touch the connection point to help hold the device in place during testing
 2. Data Collection:
 - 2.1. Once the sample is placed inside the tensile tester, begin the test
 - 2.2. Pay close attention to the test, and ensure the load cell is not maxed out or overloaded.
 - 2.2.1. Overloading occurs when the tensile tester applies more force to the sample than the load cell. It is important to avoid overloading, as it can damage the machine and the sample.
 - 2.2.2. If the sample is about to overload the tester, abort the test by hitting the stop button either on the machine or on the computer and return the crosshead to its initial starting position.
 - 2.3. In a compressive test, the tester will apply a load to the sample until the machine detects the breakage of the sample, or until the load cell overloads. Once either breakage or the cell has overloaded, ensure the test is stopped
 - 2.4. Return the crosshead to its original position

- 2.5. Remove the sample from the tensile tester and examine it. Look for cracks or breakage.
 - 2.5.1. It is possible for the sample to slip in the tensile tester, so be sure to examine and make sure the sample broke
 - 2.5.2. If the sample did not break, it or another sample may need to be tested again, as the test did not work as intended.
 - 2.5.3. If the machine had to be stopped manually before it overloaded, make sure to note the sample is strong enough to withstand that amount of force.
 - 2.6. Repeat steps 1.1-2.5.3 as needed to test other configurations. If time and resources allow, repeat each configuration test 3 times and with different operators to ensure the test is repeatable and reproducible.
3. Data Processing:
- 3.1. Once the test has been completed and the sample has been removed and inspected for damage, the data must be saved.
 - 3.2. Place a flash drive into the computer
 - 3.3. Save the data points and graph collected as a comma separated file (.csv) so that it can be easily imported into Excel or Google Sheets
 - 3.4. Once the data has been saved, import to Excel/Google Sheets
 - 3.5. Open the file and using the load and time columns, create a graph of the data to determine the force at which the different components of the device broke at.
 - 3.5.1. The load can be converted from Newtons to pounds by dividing Newtons by 4.448 to get lbs.
 - 3.5.2. This may be graphed against time as well for better visualization and understanding of the data.

The team was able to collect one data set of each configuration and the resulting graphs can be found in the results section of this deliverable.

Visual Analysis Tests

The physical aspects of our device are crucial to it being a favorable inclusion to the Ovarian Cyst removal surgery. We performed visual analysis tests to confirm that our device meets some of such requirements. Table 2 below contains an overview of the tests

Table 2: Visual Analysis Tests

Requirement	Section in Design Input Document	Analysis Procedure
Cordless	8.1.2	Check that there is no need for electric cord attachment to the device

Clear Visualization	8.2.3	Check that fluid levels can be easily seen through the device
Ability to cause mechanical damage to adjacent tissue	9.1.2	Run finger across side of device body to ensure smoothness. Examine point of device contact with cyst after functionality tests
Externally powered	10.1.1	Check that all powered features of the operational setup are located away from the device and any of its components that may come in contact with fluid

Functionality Tests

Our device is intended to be used with the Neptune 3 suction machines in the OR to keep the deviation from normal OR protocol minimal. With this, the device must perform functionally on the range of pressures that the Neptune 3 provides. This range is 50-520mmHg and is detailed in section 7.1.1 of the design input document. We tested our device's function multiple times in a model of the scenario in which it is to be used. In this model, a ballistics gel model filled with water mixed with red food dye served as a cyst, a bowl partially filled with water served as a patient's abdominal cavity and a Schuco-Vac 430 Suction Machine delivered measurable and adjustable negative pressure in place of the Neptune 3.

Materials: Schuco-Vac 430 Suction Machine, cyst model, vacuum tubing with inner diameter of 6 mm, ACS, bowl large enough to fit cyst model, turkey baster, scalpel, sutures, Babcock Tissue Forceps

1. Set up:
 - a. Fill the bowl up with clean room temperature water
 - b. Place the cyst model into the bowl
 - c. Plug the Schuco-Vac 430 Suction Machine into a wall plug
 - d. Place the 6 mm tubing into the tubing attachment on the suction machine
 - e. Place the other end of the 6 mm tubing onto the tubing connection on the ACS, ensuring the tubing is over and past the tubing bump
2. Procedure
 - a. Turn the suction machine on
 - b. Place the bottom of the ACS onto the cyst
 - c. Increase the pressure of the suction machine until there is a seal created
 - d. Record the pressure at which a seal is created
 - e. In the opening of the device create approximately a 2 mm incision through the cyst wall
 - f. In the incision of the cyst insert the turkey baster
 - g. Suck out as much "cyst fluid" as possible

- h. Repeat until the fluid from the cyst is removed
- i. Enter the device through the opening with a Babcock Tissue Forcep
- j. Use the forceps to break the suction seal and pinch the incision closed
- k. Turn off the suction machine
- l. Suture the incision site shut
- m. Remove the cyst model
- n. Examine the water in the bowl for red discoloration

VOC Test Method

It was determined that certain requirements could not be tested through quantitative data but rather required the input of our clinical advisor; a representative of the population who would be utilizing the device.

Materials: Schuco-Vac 430 Suction Machine, cyst model, vacuum tubing with inner diameter of 6 mm, ACS, bowl large enough to fit cyst model, turkey baster, scalpel, sutures, Babcock Tissue Forcep

Entering through the device opening and pinching the incision closed with a Babcock Tissue Forcep. We can then break the suction seal and slide the device onto the forceps. Next the incision site will be sutured shut to prevent further leakage.

1. Set up:
 - 1.1. Fill the bowl up with clean room temperature water
 - 1.2. Place the cyst model into the bowl
 - 1.3. Plug the Schuco-Vac 430 Suction Machine into a wall plug
 - 1.4. Place the 6 mm tubing into the tubing attachment on the suction machine
 - 1.5. Place the other end of the 6 mm tubing onto the tubing connection on the ACS, ensuring the tubing is over and past the tubing bump
2. Procedure
 - 2.1. Turn the suction machine on
 - 2.2. Place the bottom of the ACS onto the cyst
 - 2.3. Increase the pressure of the suction machine until there is a seal created
 - 2.4. In the opening of the device create approximately a 2 mm incision through the cyst wall
 - 2.5. In the incision of the cyst insert the turkey baster
 - 2.6. Suck out as much "cyst fluid" as possible
 - 2.6.1. Repeat until the fluid from the cyst is removed
 - 2.7. Enter the device through the opening with a Babcock Tissue Forcep
 - 2.7.1. Use the forceps to break the suction seal and pinch the incision closed
 - 2.7.2. Turn off the suction machine
 - 2.8. Suture the incision site shut

Results

Sizing Test Results

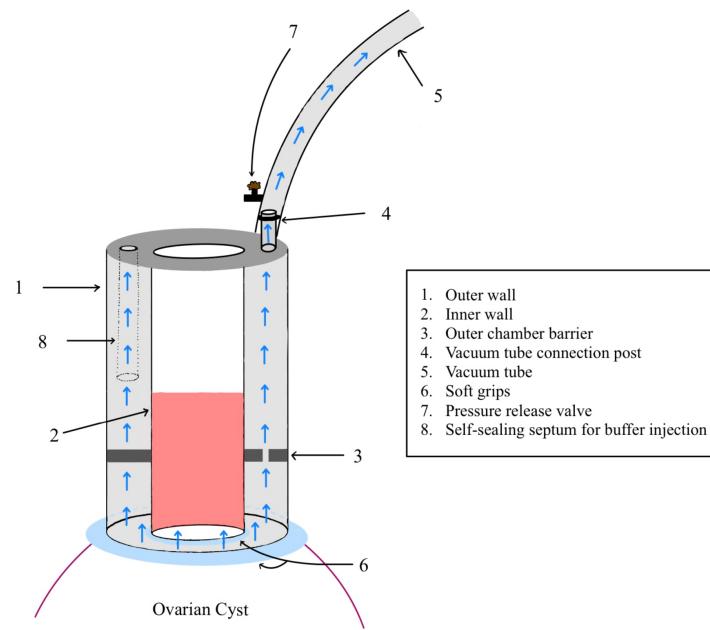


Figure 1: Labeled Diagram of the ACS device and its components

Table 3: Critical Dimension Testing Results

Measurement	Original Requirement	New Requirement	1	2	3	Average
Vacuum tubing diameter	0.8 cm. \pm tolerance of inner diameter of suction tubing	0.6 cm. \pm tolerance of inner diameter of suction tubing	0.615	0.600	0.596	0.603
Containment System Diameter (Outer wall Diameter)	$< 4.8^{+0.2}_{-0.2}$ cm	$< 4.5^{+0.2}_{-0.2}$ cm	4.499	4.500	4.485	4.494
Inner Wall Diameter	2.8 ± 0.1 cm	2.8 ± 0.1 cm	2.790	2.798	2.808	2.798
Vacuum Tube Connection Thickness	0.2 cm +/- 0.0635 cm	0.1 cm +/- 0.0635 cm	0.106	0.108	0.101	0.105

<i>Vacuum Tube Connection Hole</i>	0.8 cm. \pm 0.127 cm	0.4 cm. \pm 0.127 cm	0.399	0.397	0.393	0.396
<i>Outer Wall Thickness</i>	0.6 cm +/- 0.05 cm	0.12 cm +/- 0.05 cm	0.128	0.121	0.129	0.126
<i>Inner Wall Thickness</i>	0.6 cm +/- 0.05 cm	0.12 cm +/- 0.05 cm	0.125	0.129	0.131	0.128

Bubble Leak Test Results

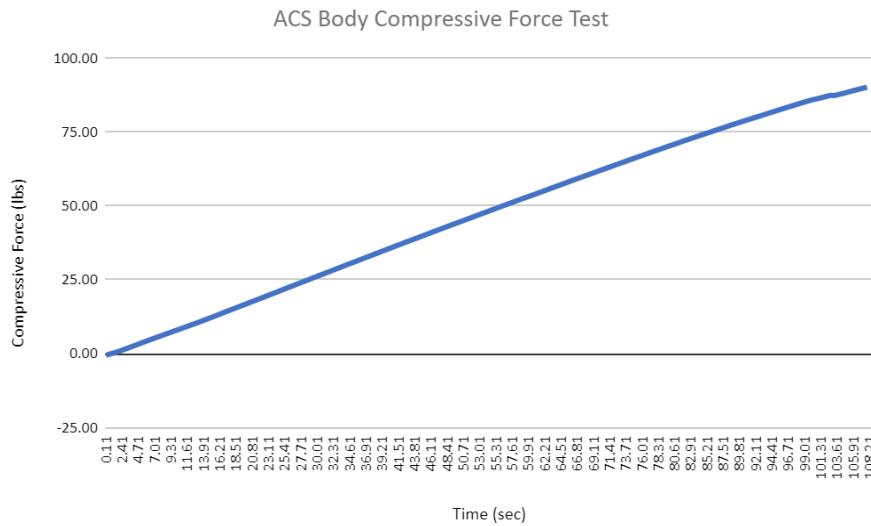
Based on the absence of bubbles observed during the bubble leak tests performed using the Schuco-Vac 430 Suction Machine at 520 mmHg, it was concluded that there were no leaks.

Table 4: Bubble Leak Test Results

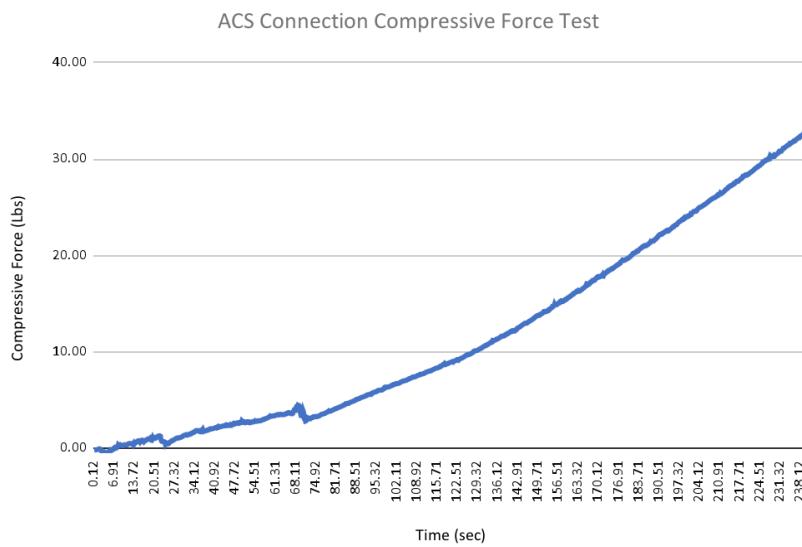
Experiment	Indicator	Result
ACS and Hand Submersion	The hand and device were submerged under water while applying suction at 520 mmHg, and upon observation, no bubbles were noticed.	No leak was detected.
ACS and Cyst Model Submersion	The device and cyst model were partially submerged in water while applying suction at 520 mmHg, and upon observation, no bubbles were noticed.	No leak was detected. At 520 mmHg, the cyst model ruptured at the ACS - cyst wall attachment point. All the cyst fluid was contained in the ACS and no bubbles were observed.

Tensile Test Results:

Configuration 1 tested how much force would be needed to crack the body of the containment system. It was found that the average grip strength of a human was approximately 60 Lbs of force [1]. The body of the ACS went well above 60 Lbs, and actually the test needed to be stopped to ensure the load cell was not overloaded. The ACS body can withstand at least 80 Lbs of compressive force before breaking, which means the requirement for that configuration was met. This is shown below in Graph 1. The connection point of the ACS was able to withstand over 35 lbs of force before the device slipped out of the machine. This was lower than the 60 lbs goal, but overall unless someone is handling the device roughly, the connection point should not be an area of concern. The results are shown below in Graph 2.



Graph 1: A plot of the data collected of the compression tensile test done on the ACS in config. 1



Graph 2: A plot of the data collected of the compressive tensile test done on the ACS in confi. 2

Visual Analysis Test Results:

Table 5: Visual Analysis Tests

Requirement	Section in Design Input Document	Results
Cordless	8.1.2	Operating room scenario setup is only powered by the vacuum source. There are no cords in

		contact with or attached to the device during the procedure
Clear Visualization	8.2.3	Level of fluid in can clearly be seen through device wall
Ability to cause mechanical damage to adjacent tissue	9.1.2	Fingernail slides across the device without resistance. After functionality tests, cyst wall is only damaged at point of incision
Externally powered	10.1.1	Operating room scenario setup is only powered by the vacuum source which does not come in contact with any bodily fluids.

Functionality Test Results:

Minimum pressure at which ACS was functional = 110mmHg

Table 6: Leak Analysis

Direction of Leak	Indicator	Result
Leak of abdominal fluid into the device cavity.	Clear fluid starts to collect in the vacuum chamber (cavity between the inner and outer walls) of the device.	Once the suction was applied, there was no clear fluid collected in the suction tank or device cavity.
Leak of cyst fluid into the device cavity.	Red fluid leaks into the bowl causing the clear fluid to change color. 	Once the suction was applied and the incision was made, the fluid in the bowl didn't change color. Indication that there was no leak into the bowl (abdominal cavity).



VOC Test Results:

Table 7: VOC Feedback

Requirement	Section in Design Input Document	Result
Size Adaptability	8.2.2	Device is confirmed to be one-size fits all
Skill Level Required	8.2.4	Device is confirmed to require a surgeon to use it

Conclusion

Verified Requirements

From the functionality tests, we found that a pressure of 110mmHg is minimally required for the functioning of the device. This value falls within the intended range and that testing requirement is therefore met by the Aspiration Containment System. Visual inspections found that the device is indeed cordless and externally powered and is sufficiently clear and smooth to minimize mechanical damage to bodily tissue, and to allow for easy visualization during the surgery. From the bubble leak tests, we found that the ACS is strong enough to withstand the maximum pressure of 520mmHg provided by the Neptune 3 suction system, and holds a seal at this pressure without leaks. We also determined that the device is one-size-fits-all and requires a surgeon to use it.

Untested/Features not Included

There were several requirements outlined in Deliverable 4 that were not tested. This was due to either the feature the requirement was written for was not included in the design of this prototype, or because the tests did not make sense to do. Any of the requirements regarding the mesh on the inside of the vacuum chamber were not tested because the mesh was removed from the design of the prototype and thus was not untestable. The IFU requirements were also not

tested, as the design of the device is not frozen, and thus the Instructions For Use document has not been written yet. As such, those requirements were not met and cannot be tested at this point in time.

The cytotoxicity and the sterilization of the device were not tested due to the lack of access to the required equipment for testing. Additionally, it was determined through conversations with ProtoLabs that the material used in the most recent prototype prints of the device are not autoclavable and were potentially cytotoxic if ingested. The material currently being used for the prototype is ABS-like translucent/clear and non medical polyjet material. Tests were not performed as they require tools outside of our capability and the material has previously been determined to not meet these requirements. As such, neither of these requirements were met or tested. Once a final design and material have been decided upon, these will be critical tests to perform.

Partially Met Specifications

Table 3 shows that the measured size requirements of the device do not match the original requirements due to changes made based on customer feedback and testing observations. However, the new requirements have been met by the device. In terms of the tensile test, the device passed the configuration 1 testing but failed in configuration 2 testing, which measured the force that the connection point of the ACS can withstand. Although the device slipped out at 35lbs, which is lower than the expected value of 60lbs, it is not a significant concern as all device manipulations are limited to the body of the device and not the connector.

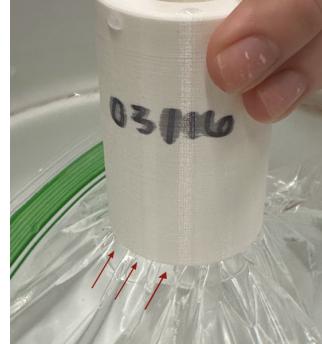
Future Prototype Changes

In the future, there are changes that can be made to the device, especially before moving to clinical testing and FDA approval. This includes determining the material to be used for the containment system. The material must be see-through, autoclavable, non-cytotoxic and not irritating to human tissue. The material currently being used only meets the first requirement. As mentioned previously, the ABS and non-medical polyjet material will not meet this requirement, but there are materials that will meet all three requirements. There are also some other human factors that need to be considered, such as ergonomics of the device, vacuum tube, and stop valve. Finally, depending on the outcomes of our final rounds of testing with the most recent prototype and last round of VOC from the doctors, there may still be a few form and functional changes that are made to the device. This may include adjusting the buffer flush system and pressure stop valve, as these were recently added.

Validation

The team's main source of validation has been surgeon feedback. Our clinical advisor and two of her attendings all provided feedback on the second to last iteration of the device. This feedback was used to guide final design decisions. A summary of the highlights and downsides provided by each surgeon is given in Table 8 below.

Table 8: Summary of VOC Feedback

Surgeon	Highlights	Downsides
Jordan Mattson (MD)	<ul style="list-style-type: none"> - Likes simplicity of design a lot– device is very intuitive to use - Translucent material is adequate for visualization - Height of the device is just right (tall enough that fluid doesn't fill fast, short enough that tools can be easily inserted/withdrawn) - No signs of leakage! 100% containment 	<ul style="list-style-type: none"> - A containment bag is unnecessary. Aspiration tools will not be moved in and out of the operation field as is being done with the turkey baster. Rather, the Neptune will provide continuous suction, thus eliminating the risk of liquid dropping into the body. - The device functions better without a mesh at its bottom. The ability of the cyst to suction into the device in the absence of a mesh allows for the seal to be best maintained after deflation. 
Dr. Peter Argenta	<ul style="list-style-type: none"> - Enjoyed compatibility with current surgical tools (e.g. scalpel, yankauer suction tips, etc.) - Prefers (translucent) material that provides basic level of visibility - No signs of leakage! 100% containment 	<ul style="list-style-type: none"> - A softer bottom is needed to maintain adequate suction if the device is bumped. Hard device w/ soft cyst does not interface well. - Future work recommendation: incorporate suction cup inside of device. Suction cup can be detached from the device, allowing for placement and drainage in other areas.

Dr. Andrea O'Shea

- Device is intuitive and easy to use
 - Would be nice to make the device thinner (i.e. so as to fit in a smaller incision). However, the large area provided in the center for inserting surgical equipment is worth the device being a little wider
 - Prefers (translucent) material that provides basic level of visibility
 - No signs of leakage! 100% containment
- A septum for flushing buffer solution throughout the outer chamber would be nice
 - Suggested use of a babcock for closing the cyst post aspiration. The babcock is inserted through the device and grasps the incision. Suction is then turned off, the device is slid up the babcock, and a purse string suture is made around the incision.



All in all, the team received very positive feedback on our device. Simplicity was identified as a design requirement early on this year and surgeon feedback indicates this requirement was satisfied. Additionally, the device's height and diameter make it easy to maneuver tools in and out of and to maneuver the device itself within the surgical incision. All surgeons indicated that the device did a phenomenal job at preventing leakage of cyst contents during aspiration, as no red dye was noted to spill into the clear water bath below during testing. This alone proves our device is advantageous over the current containment bag method. Finally, surgeons expressed it would be easy to implement this device in the OR as it is meant to attach to the Neptune 3 Waste Management System- a suction machine already used in these procedures.

The team also created a user feedback survey to gauge our peer's opinions on the device. This survey has a large focus on user-device interaction and ergonomics. As we are currently awaiting our final prototype from Protolabs, this survey has not collected any responses yet. The team expects to receive our final device by Friday, April 14th and will ask for class feedback shortly thereafter. The results of this survey will be included in our design showcase presentation, however, the questions and answer options are shown in Table 9 below.

Table 9: Peer User Feedback Survey Questionnaire

Question	Answer Options
What is your biological sex?	Male Female
On a scale of 1- 5, rate how comfortable the device is to hold in your hand.	1- Extremely uncomfortable 2 3 4 5- Extremely uncomfortable
Does the device fit well in your hand?	Too small Just right Too large
On a scale of 1-5, rate your ability to see through the device.	1- Cannot see finger 2 3 4 5- Could read text
Does the device appear to utilize any batteries or connect to an external power source other than the vacuum pump?	Yes No
Does the device appear to connect to any	Yes

cords aside from the connection to the vacuum pump?	No
Does the device feel like it would collapse if squeezed too hard?	Yes No
Does the connection post (i.e. where the vacuum tubing connects to the device) feel like it would break easily during handling? 	Yes No

If the team were to continue this project post graduation, we would certainly reach out to more than three surgeons and gather their feedback. We would love to have at least 10 male and 10 female surgeons, as ergonomic data can vary greatly with biological sex (e.g. device grip due to hand size). Additionally, the team would like to evaluate device performance within an open abdomen. This would be carried out using either the virtual reality equipment in the BMDC or pig abdomens. Such testing would be performed multiple times under surgical supervision to validate the versatility of our device. Specifically, we would aim to validate device applicability in overweight or obese patients, as we suspect device height to fall short in those with exceptionally thick adipose fat layers. Finally, the team would like to acquire surgeon feedback regarding the device's compatibility with the Neptune 3 Waste Management System. Given time and OR accessibility constraints, this is something we were unable to do. The results of such testing would validate compatibility of our device in the OR.

Table 10: Reference Documents

Document Number	Revision	Description
21 CFR Part 801	2022	This regulation set forth by the United States Food and Drug Administration (FDA) outlines the information that must be included on the label of a medical device.
ISO 14971	2019	International Standards for risk management of medical devices.

ISO 10993	2018	Document specifying general principles governing the biological evaluation of medical devices within a risk management process
ISO 20484	2017	Document specifies leak tests.
ISO 19403-6	2017	Specifies a method to measure the dynamic contact angle with an optical method
ISO 572-2	2012	Specifies the test conditions for determining the tensile properties of molding and extrusion plastics,
ISO 10012	2003	Document specifies requirements for the measurement process and measuring equipment.
ISO 4783-2	1989	Specifies preferred combinations for woven wire cloth