ENGINEERING

McMaster University

Design Project 1: GI Joe – The Endoscopy Unit

Ostonite

IBEHS 1P10 – Health Solutions Design Projects

Tutorial T05

Team 38

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AHMAD DIAA ALTARABISHI (altaraba)

Submitted: October 30, 2021

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1.0 Academic Integrity Statement

The student is responsible for performing the required work in an honest manner, without plagiarism and cheating. Submitting this work with my name and student number is a statement and understanding that this work is my own and adheres to the Academic Integrity Policy of McMaster University.

Elias Taylor 400388518

X 

The student is responsible for performing the required work in an honest manner, without plagiarism and cheating. Submitting this work with my name and student number is a statement and understanding that this work is my own and adheres to the Academic Integrity Policy of McMaster University.

Ahmad Diaa Altarabishi 400385321

X 

The student is responsible for performing the required work in an honest manner, without plagiarism and cheating. Submitting this work with my name and student number is a statement and understanding that this work is my own and adheres to the Academic Integrity Policy of McMaster University.

Samih Dalvi 400387262

X 

2.0 Executive Summary

As all who study science know, every system is destined for obsoletion including innately human mechanisms such as cellular division, making cancer an inevitable fact of life. Tens of millions [1] will develop cancer each year with cancers involving the digestive and excretory systems being particularly widespread [A1]. What is truly startling is that this represents just one of the numerous potential causes behind 13,000 Canadians becoming ostomates annually [2]. This event is life changing and it is for this reason that the Ostonite, a product designed to increase the quality of life of those suffering from what they can't control, is so important.

The importance is felt by patients that work during the day, who are unable to eat until the late evening. This contributes to overnight digestive activity and ultimately leads to high output of gas and loose stool, greatly disturbing circadian rhythms. Patients like Leiko, who prefer a one-piece drainable mini-pouch, often suffer from a lack of sleep as they are forced to wake up at constant intervals to empty out the waste. Traditional appliances are often too small and insufficient in collecting and storing output overnight. In general, 37.3% of colostomy patients get less than six hours of sleep, leading to major health repercussions [3]. It has also caused major concerns among people, who are constantly optimistic in finding solutions.

The solution is Ostonite, a waste drainage and storage system that collects and stores output overnight. The lock and twist adaptor attaches to the closure of the colostomy to facilitate the flow of stool from the ostomy and into a flexible PVC pipe. The pipe is situated inside a belt designed around comfort, discreteness, and pipe stability. The other end of the pipe attaches to a bottle that functions as a vacuum to store and aid with the flow of stool. Before going to bed, patients must attach the adaptor to the colostomy. Then, connect the pipe onto the adaptor and slide it through the belt, making sure to fix the other end of the pipe on to the bottle. From there, patients must fit the colostomy bag around their stoma, put on the belt, and squeeze the air out of the bottle and recap it. All that is left is to place the bottle on the floor next to the bed and enjoy a night of restful sleep.

To bring Ostonite to fruition, the adaptor, pipe, and bottle must be made from High Density Polyethylene to be able to resist the high acidity of stool [4]. The pipe should be properly sealed from either end by using self-fusing anti-leak silicon tape to prevent stool from leaking [5]. In addition, hydrogel ostomy adhesive should also be used to secure the colostomy onto the stoma [6].

Every component from adaptor to belt is crucial to the design and critical to the quality of life for people such as Leiko. It is imperative to the health of these people that the design behind the Ostonite is the one thing that never becomes obsolete.

3.0 Main Body

3.1 Project Schedule

3.1.1 Preliminary Gantt Chart

Design Project 1: The Endoscopy Unit

Group 38

Project Start: Tue, 9-21-2021

Display Week: 1

Sep 20, 2021 | Sep 27, 2021 | Oct 4, 2021 | Oct 11, 2021 | Oct 18, 2021 | Oct 25, 2021

20 21 22 23 24 25 26 27 28 29 30 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31

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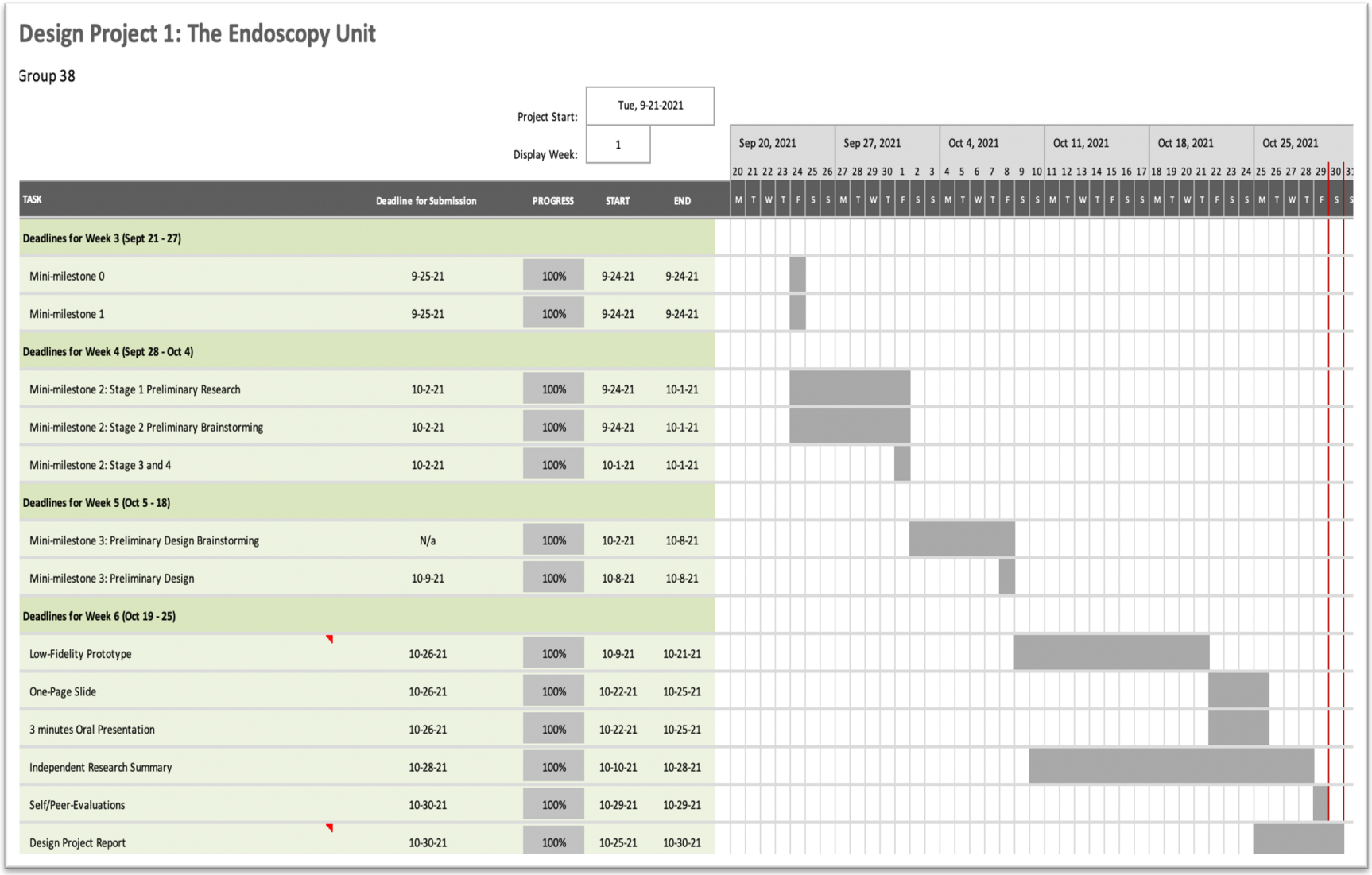
TASK	Deadline for Submission	PROGRESS	START	END
Deadlines for Week 3 (Sept 21 - 27)				
Mini-milestone 0	9-25-21	100%	9-24-21	9-24-21
Mini-milestone 1	9-25-21	100%	9-24-21	9-24-21
Deadlines for Week 4 (Sept 28 - Oct 4)				
Mini-milestone 2: Stage 1 Preliminary Research	10-2-21	0%	9-24-21	10-1-21
Mini-milestone 2: Stage 2 Preliminary Brainstorming	10-2-21	0%	9-24-21	10-1-21
Mini-milestone 2: Stage 3 and 4	10-2-21	0%	10-1-21	10-1-21
Deadlines for Week 5 (Oct 5 - 18)				
Mini-milestone 3: Preliminary Design Brainstorming	N/a	0%	10-2-21	10-8-21
Mini-milestone 3: Preliminary Design	10-9-21	0%	10-8-21	10-8-21
Deadlines for Week 6 (Oct 19 - 25)				
Low-Fidelity Prototype	10-26-21	0%	10-9-21	10-22-21
One-Page Slide	10-26-21	0%	10-22-21	10-25-21
3 minutes Oral Presentation	10-26-21	0%	10-22-21	10-25-21
Independent Research Summary	10-28-21	0%	10-25-21	10-28-21
Self/Peer-Evaluations	10-30-21	0%	10-25-21	10-30-21
Design Project Report	10-30-21	0%	9-24-21	10-30-21

3.1.2 Final Gantt Chart



Design Project 1: The Endoscopy Unit

Group 38

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One-Page Slide	10-26-21	100%	10-22-21	10-25-21
3 minutes Oral Presentation	10-26-21	100%	10-22-21	10-25-21
Independent Research Summary	10-28-21	100%	10-10-21	10-28-21
Self/Peer-Evaluations	10-30-21	100%	10-29-21	10-29-21
Design Project Report	10-30-21	100%	10-25-21	10-30-21

3.1.3 Logbook of Additional Meetings and Discussions

Wk-3 (Sept 21-27) Milestone 0&1

→ Saturday Sept 25th: Our group met today to discuss our patient's problem.
- In-depth analysis of patient's summary (highlighting crucial details in regards to our patient's case) to ensure that our solution encompasses all the needs, objectives, and constraints
- Discussed the possibility of meeting every week on Saturday (the day after our design studio sessions)
  - To go over the milestones before submissions
  - Discuss any new ideas for our solution
  - Assess the progress of our project

Wk-4 (Sept 28-Oct 4) Milestone 2

→ Thursday Sep 30th: We met today to work on our preliminary sketches prior to tomorrow's design studio
- Up until now, we came up with 4 different ideas for our solution. Hopefully by tomorrow's design studio, we can narrow down our ideas to two sketches.
- We plan on meeting this Saturday to discuss our plans going forward and to finalize Milestone 2.

→ Saturday Oct 2nd: We met today to discuss the two sketches we came up with during the design studio session.
- Narrowed down our ideas into one sketch by incorporating what we liked from each preliminary sketch
- We made a list of everything that we think would be useful for us in our final design:
  - Adapter to facilitate the flow of stool from the ostomy and into the pipe
  - A waste container to store the stool over night
  - A pipe to allow for the flow of stool from the ostomy and to the waste container.
- Made a quick sketch to reference it in the upcoming design studio session

Wk-5 (Oct5-8&18) Milestone 3/ Reading Week

→ Saturday Oct 9th: We quickly meet today to complete our milestone 3.
- We finalized the design for our solution.
- We identified all the materials that are available to us in the design studio to build our low-fidelity prototype.
- We plan to work on the low-fidelity prototype during reading week, so that we can start working on the final deliverables by week 6.
- We've also decided on 3-D printing the adaptor, so that we could customize it to the colostomy bag given to us.

→ Saturday Oct 16th:
- By now, the model for the adaptor is almost done. Diaa is facing some issues in modelling the knobs extruding off the inner component and the slots made on the outer component.
  - We are hoping to seek help from the virtual help desk once it opens after reading week.

Wk-6 (Oct 19-25) Dedicated project time (no Milestone)

→ Tuesday Oct 19th:
- Finished modelling the 3D adaptor
- Booked the design studio for Thursday Oct 21st:
  - To print the two-piece adaptor
  - Assemble the prototype
  - Discuss any concerns regarding our design

→ Thursday Oct 21st:
- Final product modifications
  - Discussed changing from zip-loc style plastic bag to PET water bottle to form the vacuum sealed container
    - Done to create a better vacuum seal at the point where the tubing meets the container and to allow for increased ease of emptying
  - Discussed the way to make modifications made to the colostomy bag itself to better fit the ostomate's needs
    - Involved the removal of the seals on both bags and the reapplication of the single-piece seal onto the drainable bag through hot glue
  - Discussed the merits of changing to a different size of plastic tubing that better fits the adaptor
    - Allows for improved flow of waste and security at connection points
  - Discussed the creation of a belt to aid the design by supporting the tubing while providing additional comfort and discreteness
    - Helps meet our ostomate's desires regarding the design of the system rather than function
  - Discussed the creation of a tunnel for the tubing within the belt
    - Decreases visibility and the chance of malfunctions, thereby increasing covertness and mental relief (comfortability)
- Additional Topics:
  - Discussed how to properly allocate the remaining tasks (3MT, One-page slide deck, executive summary, etc.)
  - Discussed how to properly schedule our remaining time until each deadline
    - Start working on the one slide deck by Friday Oct 22nd.
    - Film the video for our prototype by Sunday October 24th.
    - Start working on the final report after the 3MT presentations (Wednesday Oct 27th).

→ Friday Oct 22nd – Monday 25th:
- Completion of the 3MT slideshow

→ Saturday Oct 23rd- Sunday 24th:
- Completion of the low-fidelity prototype video

3.2 Design Studio Documents

3.2.1 Weekly Design Studio Agenda's

1) Week 4 Meeting Agenda and Meeting Minutes

Date and Time: Friday, Oct 1st, 2021

Team: Team 38

1.0 Attendance

Role	Name	Mac ID	Attendance (Yes/No)
Manager	Ahmad Diaa Altarabishi	altaraba	Yes
Administrator	Elias Taylor	tayloe26	Yes
Coordinator	Samih Dalvi	dalvis3	Yes
Guest	Abbas		

2.0 Agenda Items

- Quick recap of Design Challenge/ Need Statement/ Objectives and Constraints
- Quick summary of the research/brainstorming each team member did for the preliminary stage of the meeting minutes 2
    - Diaa, Form and Function
    - Elias, Materials
    - Samih, Device and User interaction
- Let team members address the TA with any questions regarding their research
- Check with the TA regarding the Gantt Chart
    - When exactly are we going to present the DP-1 project? On Tuesday Oct 26th or Friday Oct 29th?
    - Are we allowed to use the DS during reading week?
    - When will the Design project report template be available?
- Questions regarding final deliverables
    - Clarification Question regarding the Design project report. Do we include all the documents we worked on in that report from the milestones to the agendas and meeting minutes?
    - When researching do we include the sources/citations on the same document or in the source materials database document?
- Questions/instructions/feedback from the TA

3.0 Meeting Minutes

- The seal would be extruding
- First prototype should be made from cardboard and other materials to prevent mistakes
- Be prepared for a likely Friday (Oct 29th) presentation
- No design studio during reading week
- Template of final report and additional information will be posted soon
- Design report consists of a collage of information from multiple mini milestones
- Final bibliography in the last report

- Keep individual works cited documents
- Keep in mind both short and long-term solutions (e.g., consider feasibility)

4.0 Post-Meeting Action Items

- Diaa Altarabishi
    - Research a method to attach the adaptor on to the closure of the colostomy
    - Figure out away to facilitate the flow of stool from the colostomy and into the waste container.
    - Continue researching ways to improve our preliminary design before next week's design studio (before we start building the pre-prototype).
    - Think of a way to make our design more discrete.
- Elias Taylor
    - Research currently developing ostomy technology to find potential long-term and short-term solutions
    - Begin to turn ideas into designs that use simple materials found in design studio
- Samih Dalvi
    - Start planning about what materials can be used to make our prototype (preliminary design)
    - Continue thinking about what we can add to our design and what we may have to remove (if it doesn't work properly)
    - Research how we can make our solution "easy to use" for our potential patients

2) Week 5 Meeting Agenda and Meeting Minutes

Date and Time: Friday, Oct 8th, 2021

Team: Team 38

1.0 Attendance

Role	Name	Mac ID	Attendance (Yes/No)
Manager	Ahmad Diaa Altarabishi	altaraba	Yes
Administrator	Elias Taylor	tayloe26	Yes
Coordinator	Samih Dalvi	dalbis3	Yes
Guest	Abbas		

2.0 Agenda Items

- Quick recap of the two designs we've came up with in the last meeting.
  - Concerns:
    - The position of the ostomy bag relative to the draining system (D1)
    - Movement during sleep (D1)
    - How are we going to attach the adaptor like component onto the ostomy (D1)
    - How to prevent blockage in the system (D1)
    - How could we solve the weight problem (D2)
  - Questions:
    - When designing the attachment for the ostomy bag, how could we maximize the flow of stool from the ostomy bag to the smaller pipe? (D1)
    - What would you recommend regarding the design of the attachment? (D1)
    - Should we be concerned about the materials used while designing the device? Or just put it down in writing? (D1 and D2)
- General Questions:
  - **Follow up from last week:** When exactly are we going to present the DP-1 project? On Tuesday Oct 26th or Friday Oct 29th?
  - We were not given the skin attachment of the convex Flextend barrier. Are there any issues with that?
  - After reading week, the design studio session for week 6 is going to be online. Could we still use the design studio throughout the week?
- Questions/instructions/feedback from the TA

3.0 Meeting Minutes

- Since the output is not solid, we have more freedom in nozzle shape
- Make sure three are no blockages in the tube
- Suction mechanism in the box
- Don't have to demonstrate all functionality ion low fidelity prototype
- Demonstrate features in final prototype
- Individually presenting
- One slide, 3 minutes

- Use the prototype in the presentation
- Book the design studio to 3D print after reading week

4.0 Post-Meeting Action Items

- Diaa Altarabishi
    - Figure out a way to design the adaptor on Inventor
        - Inner Component:
            - Figure out a way to create the knobs on the inner component and how to distance them equally from each other.
            - The inner component should be able to fit into the colostomy closure.
        - Outer Component:
            - Figure out a way to create the slots onto the outer component and how to distance them equally so that the knobs could easily slide through them.
            - The size of the outer component must be relative to the size of inner component so that the inner component could fit inside the outer component.
    - Start assembling the low-fidelity prototype
    - Finish the independent research summary
- Elias Taylor
    - Write independent research summary during reading week
    - Take opportunity to do more digging into long-term solutions
    - Begin a preliminary design for group-submitted final deliverables
- Samih Dalvi
    - Start collecting materials that we can use to build the prototype
        - Pipe for waste transportation
        - Bag/box to act as a storage
        - Preliminary 3-d adapter using play-do (Diaa will work on making the 3-d component using AutoCAD)
    - Finish the IRH over the reading week

3) Week 6 Meeting Agenda and Meeting Minutes

Date and Time: Friday, Oct 22nd, 2021

Team: Team 38

1.0 Attendance

Role	Name	Mac ID	Attendance (Yes/No)
Manager	Ahmad Diaa Altarabishi	altaraba	Yes
Administrator	Elias Taylor	tayloe26	Yes
Coordinator	Samih Dalvi		Yes
Guest	Abbas		

2.0 Agenda Items

- Quick progress report on our prototype
  - Adaptor-like-component
    - Post-processing: File a bit from the inside to allow the ostomy bag to fit.
  - Alterations to the ostomy bag
    - Changed the two-piece barrier to the convex Flex tend barrier.
  - Belt (New Addition)
    - Added for comfort during sleep and to make the flexible plastic pipe more stable.
  - Vacuum
    - We've decided to replace the bag with a 4L water bottle to use as our vacuum.
    - A hole is going to be made at the bottom of the bottle.
    - Waste can be removed through the other end of the bottle (remove cap).
    - Negative pressure could be created by squeezing the bottle and putting the cap back on
- For today's design studio, we will be focusing on writing the executive summary and creating the slide deck, so we could start preparing for the 3MT.
- Questions:
  - For the video, should we demonstrate the function of our prototype only or explain the function of each component, how it would be assembled and then demonstrate its function?
  - Any tips for the 3MT?
    - Is it to late to ask to switch your time slot?
  - For the final report, are we allowed use the feedback for each of the milestone to fix them up before compiling all of them into the Final report?
  - What exactly are we supposed to do with the collaborative working document?
  - Where are we supposed to document the iteration to our prototype?
  - Where are we supposed to discuss the short term and long-term implications of our solution?
- Questions/instructions/feedback from the TA

3.0 Meeting Minutes

- Include both an explanation of the overall prototype as well as each component
- Mention criteria in video

- 3MT only briefly touches upon issue (20-25s)
- Only change things that are reused (need statement) but not unnecessary things (sketches)
- Whatever can be demonstrated about the porotype is what should be discussed in 3MT (e.g. Here is our bottle system it works as so)
- Only use the 3MT slide as a background
- Write the executive summary on the peer work document
- Only have personal time to finish everything

4.0 Post-Meeting Action Items

- Diaa Altarabishi
  - Finish the 3MT slide deck
  - Practice for the 3MT Presentation
  - Film the low-fidelity video
    - Discuss function of each component
    - Demonstrate the assembly of the prototype
    - Demonstrate the functionality of the prototype
  - Start working on the Final report
- Elias Taylor
  - Finish the 3MT slide deck
  - Create a script for the 3MT presentation
  - Finish final deliverables
    - Finishing touches on IRH
    - Begin finding articles for use in the executive summary
- Samih Dalvi
  - Finish the 3MT slide deck
  - Finish the 3MT presentation
  - Start assembling the design report
    - Formatting all the milestones
    - Including all the citations
    - Start the executive summary

3.2.2 Milestones

1) Milestone Zero (week 3)

MILESTONE 0 – COVER PAGE

Full Name	MacID
Elias Taylor	tayoe26 Eli
Ahmad Diaa Altarabishi	altaraba
Samih Dalvi	dalvis3

Figure 1. Group Photo

MILESTONE 0 – TEAM CHARTER

Project Leads:

As a team, come to an agreement on who will take the lead on each administrative task. Each role can only have one team member. In the event there are 3 students in a team, there will be no Subject Matter Expert.

Role	Team Member Name	MacID & Signature
Manager	Diaa Altarabishi	altaraba, Diaa
Administrator	Samih Dalvi	Dalvis3, SamihD
Coordinator	Elias Taylor	Tayloe26, Eli
Subject Matter Expert	All members	

2) Milestone One (Week 3)

MILESTONE 1 – COVER PAGE

Please list full names and MacID's of all *present* Team Members.

Full Name	MacID
Samih Dalvi	dalvis3
Ahmad Diaa Altarabishi	altaraba
Elias Taylor	tayloe26

MILESTONE 1 – GATHERING INFORMATION

Document all pertinent information related to the management of the assigned medical device in general and in reference to your unique design challenge in the space provided.

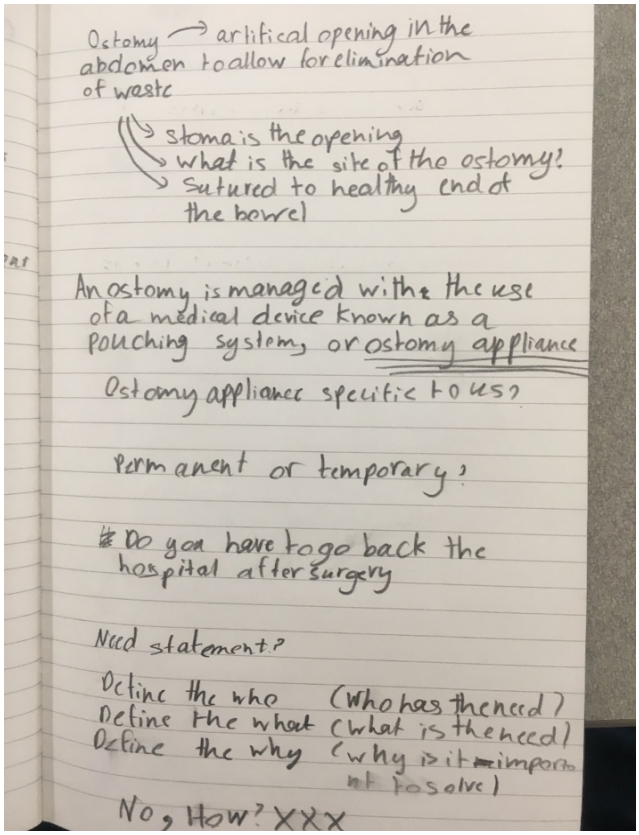

Figure 1. Notes from discussion with voluntary speakers

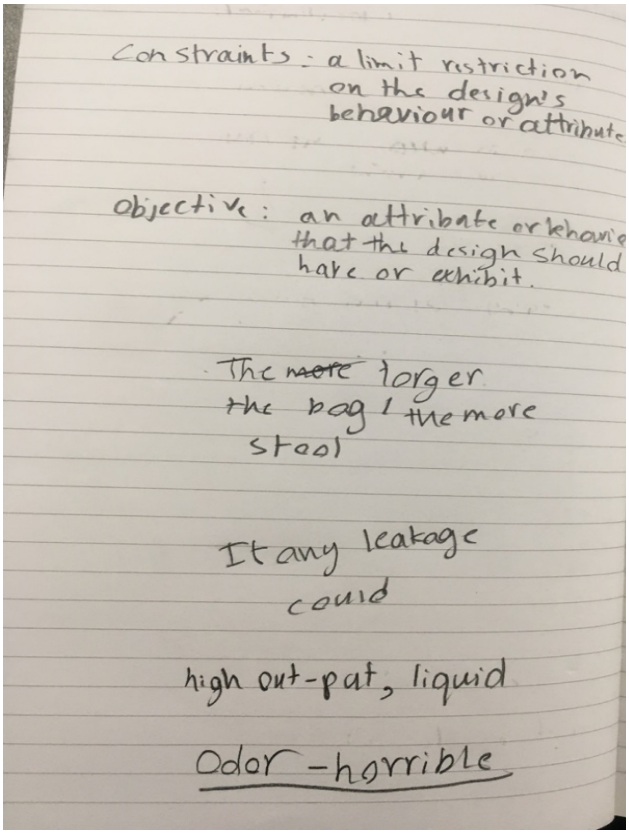

Figure 2. Notes from discussion with voluntary speakers

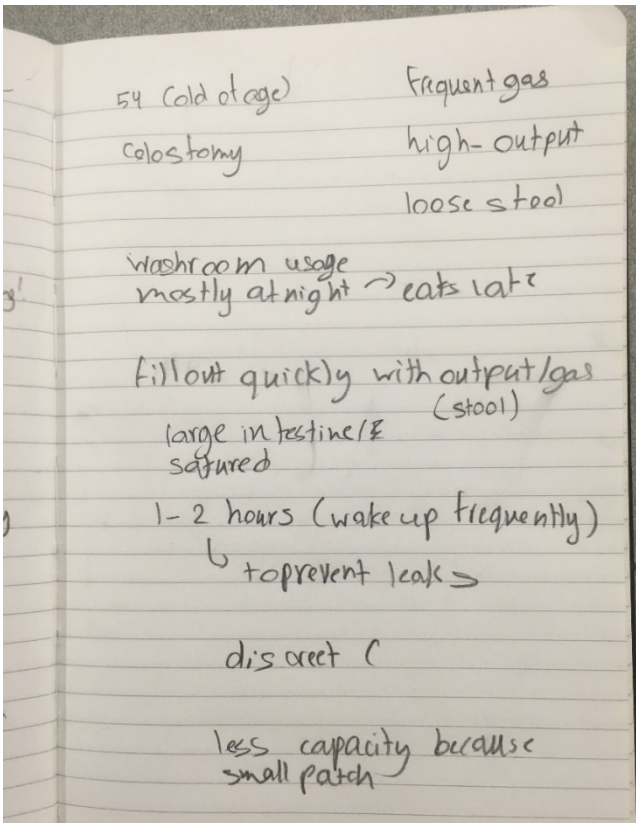

Figure 3. Notes from discussion with voluntary speakers

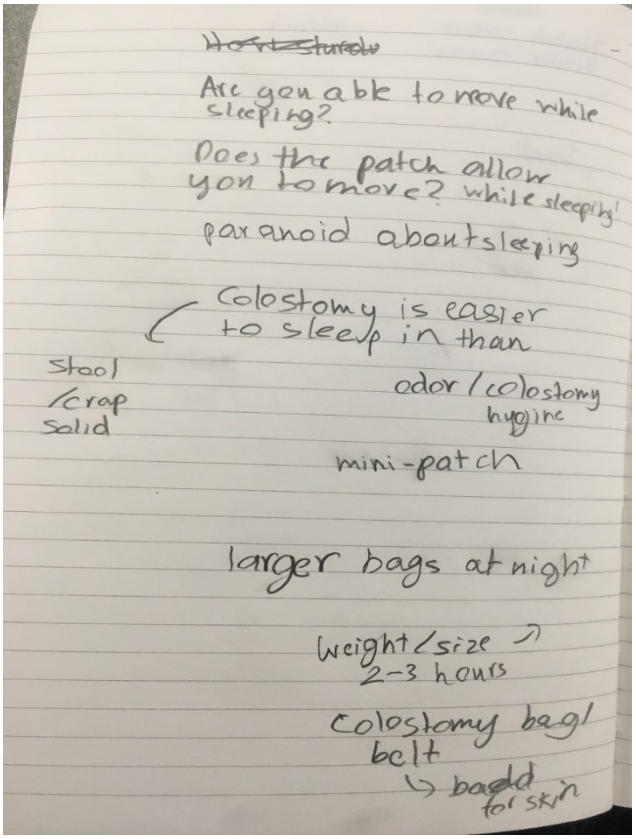

Figure 4. Notes from discussion with voluntary speakers

MILESTONE 1 – NEED STATEMENT

Need Statement

Write your *Need Statement* in the space below, based on the information you have gathered and your assigned design challenge. Recall that your need statement should:

- Have a clearly defined problem (*what* is the need?)
- Indicate your end-user (*who* has the need?)
- Have a clearly defined outcome (*what* do you hope to solve and *why* is it important?)

NEED STATEMENT:	Modify a discrete one-piece drainable mini-pouch for use by colostomy patients with high nighttime output of stool and gas in order to increase their intervals of restful sleep.

MILESTONE 1 – OBJECTIVES AND CONSTRAINTS

As a team, identify a list of objectives, constraints, and functions for a proposed design solution. Your list should:

→ Focus on your assigned design challenge
→ Be comprehensive enough to fully define the given problem

OBJECTIVES	List each objective as a separate bullet, add more if needed – Discreteness – Comfortability while sleeping – Odorless/ limiting smell (filter)

CONSTRAINTS	List each constraint as a separate bullet, add more if needed – Size/capacity o High output o Gas – Weight (sustainable/cannot be heavy) – Must be standardized/approved for use

3) Milestone 2 (Week 4)

MILESTONE 2 – COVER PAGE

Please list full names and MacID's of all *present* Team Members.

Full Name	MacID
Samih Dalvi	dalvis3
Ahmad Diaa Altarabishi	altaraba
Elias Taylor	tayloe26

MILESTONE 2 (STAGE 1) – PRELIMINARY RESEARCH

Student 1:

Name: Ahmad Diaa Altarabishi	**MacID: altaraba**
Selected Design Dimension	Form and Function

The physical form (i.e., size and shape) of the device and any sub-component	▪ One-piece, Mini-Pouch (single time use) o Beige odour-barrier pouch film o **Length:** 18 cm o **Volume:** 400 – 500ml capacity ▪ Flat SoftFlex Barrier o One Time use o Cut-to-fit and pre-sized skin barriers o **Opening:** 15 - 55 mm o Durable and offers high resistance to erosion  ▪ One-piece, Drainable Mini-Pouch o Beige odour-barrier pouch film o **Length:** 22 cm o **Volume:** 400 – 500ml capacity ▪ Lock 'n Roll microseal closure (opening through which stool is emptied) o **Opening:** 5.5 cm

- Convex FlexTend Barrier
  - Frequent pouch removal
  - **Opening:** 40 mm

- Hollister AF300 filter

Device/sub-component functionality (i.e. how components attach to each other, how components are manipulated, etc)	▪ **<u>One-piece, Drainable Mini-Pouch:</u>** From its name, this type of mini-pouch is drainable. At the bottom of a drainable ostomy, there is closure through which stool could be emptied. The closure is usually sealed with a lock ‘n roll microseal. Just after use, patients will have to open the seal and empty out the contents of the ostomy. Nonetheless, there is a limit to how many times a patient can reuse this mini-pouch (3 Days) [7]. ▪ **<u>One-piece, Mini-Pouch (single time use):</u>** From its name, this type of mini-pouch is for single time use. It doesn’t have a closure through which stool could be emptied. Just after use, patients will have to throw it out and put on a new pouch. However, it would still have the charcoal filter and skin barrier. It’s usually used by colostomy patients during the night for nightly activities [8]. ▪ **<u>Lock ‘n Roll microseal closure:</u>** Stool is usually emptied out through the closure. However, to prevent the stool from leaking out of the closure throughout the day, ostomies utilize a lock ‘n roll microseal to seal the closure. It is only found on drainable ostomies. Single time use ostomies don’t require it as there’s no openings to drain the stool [8]. ▪ **<u>Flat SoftFlex Barrier:</u>** From its name, the Flat SoftFlex Barrier is a flat skin barrier with an even surface that connects on to the stoma [9].

	▪ **Convex Flextend Barrier:** The Convex Flextend Barrier is the standard skin wear barrier. It's known to provide the most comfort and allows patients to remove to easily remove it and re-attach it frequently. From its name, the barrier curves away from the peristomal skin increasing barrier depth [9]. ▪ **Filter:** The black portion at the back of the colostomy bag is charcoal. It eliminates odor as gas passes through it [10].

Sources	List all your sources (e.g., journal articles, book chapters, websites, etc.)

[7] A. Maria and B. Lieske, "Colostomy Care," MEDSURG Nursing, vol. 28, no. 2, pp. 125–126, Sep. 2021, Accessed: Oct. 29, 2021. [Online]. Available: https://www.ncbi.nlm.nih.gov/books/NBK560503/

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[9] B. Cengiz and Z. Bahar, "Perceived Barriers and Home Care Needs When Adapting to a Fecal Ostomy," Journal of Wound, Ostomy & Continence Nursing, vol. 44, no. 1, Jan. 2017, doi: 10.1097/WON.0000000000000271.

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Student 2*:*

Name: Samih Dalvi	**MacID: dalvis3**
Selected Design Dimension	Device and user interaction

Preliminary Research	Document your preliminary research in the space below – An individual usually selects colostomy bags that suits their individual needs (i.e odor resistance, bag that is easy to put on, a bag that is gentle to the skin etc.) [11]. – They are usually easy to put on and remove, but some patients have minor difficulties as they may have a very small/large stoma (so finding the right size becomes difficult). – When wearing the bag, patients have certain limitations (i.e contact sports/activities). – Depending on the size of the bag and the patient's output, they usually last a few hours before they must be changed [11]. – Maintenance is usually tedious because patients must repeat a long cleaning process multiple times a day (it takes quite some time!) [11]. – Cleaning is also difficult (depending on circumstances-output) it requires emptying the debris and then rinsing the bag thoroughly [12].

	– If the bag is not attached properly, there could be leakage, which may lead to skin issues [13]. – Patients need to be very careful while using pouches; observe how the skin/body reacts to it (i.e material, fitting, etc.), and go to a doctor for any abnormalities [13].

Sources	List all your sources (e.g., journal articles, book chapters, websites, etc.)
	[11] "Colostomy bag: Types, uses, and living with one." https://www.medicalnewstoday.com/articles/326353#how-long-do-they-last (accessed Sep. 29, 2021). [12] "Emptying An Ostomy Bag: Tips & Tricks for Avoiding a Mess." https://farmoderm.it/en/emptying-an-ostomy-bag/ (accessed Sep. 29, 2021). [13] "Stoma Bleeding and Irritation | Ostomy Bag Leaking - UChicago Medicine." https://www.uchicagomedicine.org/conditions-services/colon-rectal-surgery/ostomy/guide-to-pouching-systems/leakage-bleeding-irritation-and-other-common-ostomy-pouch-issues (accessed Sep. 29, 2021).

Student 3*:*

Name: Elias Taylor	**MacID: tayloe26**
Selected Design Dimension	Materials

Preliminary Research	Document your preliminary research in the space below
	• Bags are made of polyvinyl chloride (PVC) and designed around a balance of disposability, cost, and efficacy [14]. • Filters contain charcoal for neutralization, they can either be disposable or integrated [15]. • Fluid-tight seal is held to body using pressure sensitive adhesives (PSAs) to maximize tack while maintaining high peel and shear [16]. • New hydrogel ostomy adhesives (HOAs) could be an improvement over the current technology [17].

Sources	List all your sources (e.g., journal articles, book chapters, websites, etc.
	[14] M. Arthur A. Gladstone, "Disposable ileostomy and Colostomy Bag," Journal of the American Medical Association, 08-Jul-1950. [Online]. Available: https://jamanetwork.com/journals/jama/article-abstract/293423 .[Accessed: 30-Sep-2021]. [15] M. Annells, "The experience of flatus incontinence from a bowel ostomy:... : Journal of Wound Ostomy & Continence Nursing," LWW. [Online]. Available: https://journals.lww.com/jwocnonline/fulltext/2006/09000/the_experience_of_flatus_incontinence_from_a_bowel.10.aspx. [Accessed: 01-Oct-2021].

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MILESTONE 2 (STAGE 2) – PRELIMINARY IDEAS

Name: Ahmad Diaa Altarabishi	MacID: altaraba

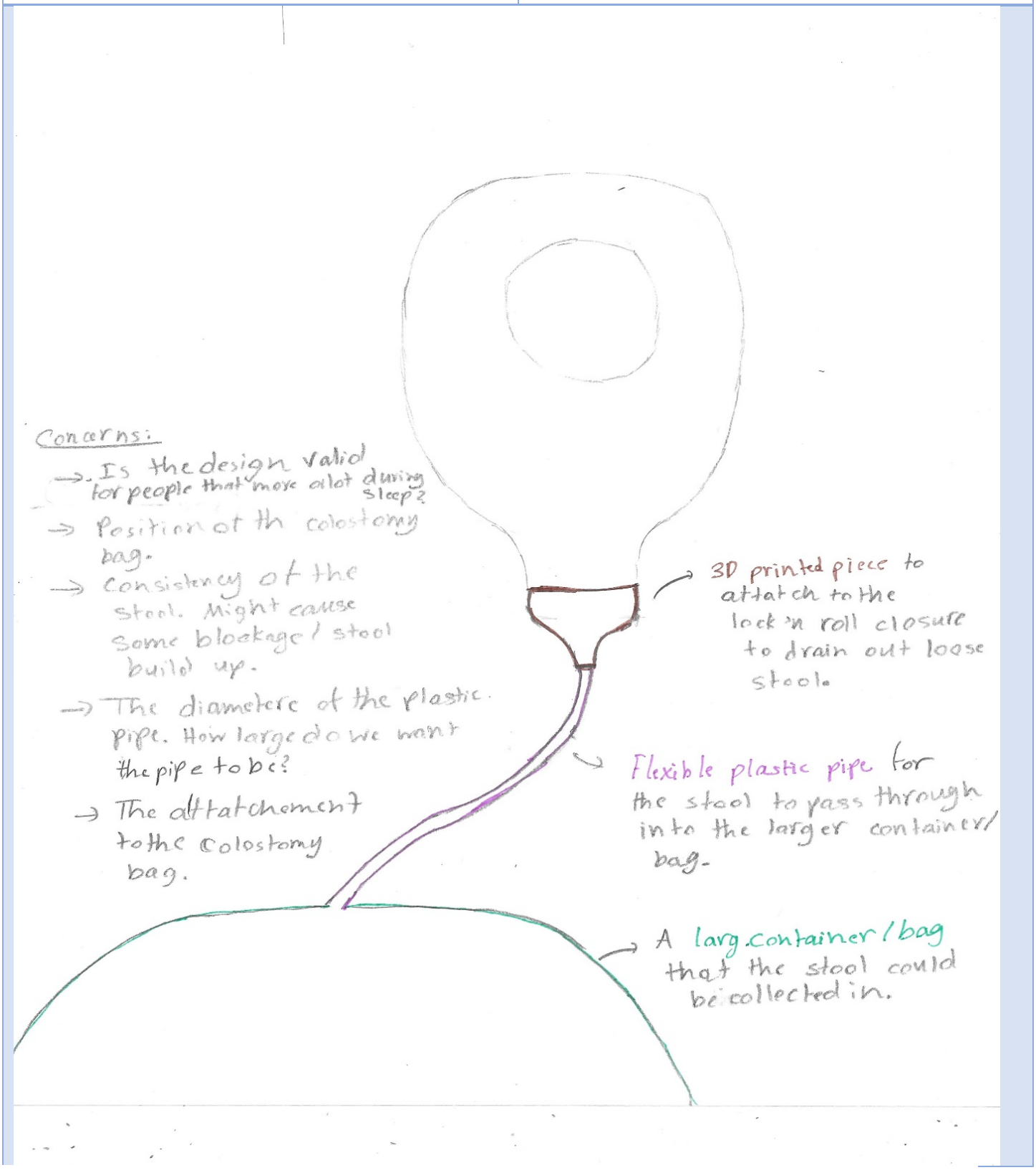


Figure 1. Preliminary sketches/ideas for possible solution (Diaa)

Name: Samih	MacID: dalvis3

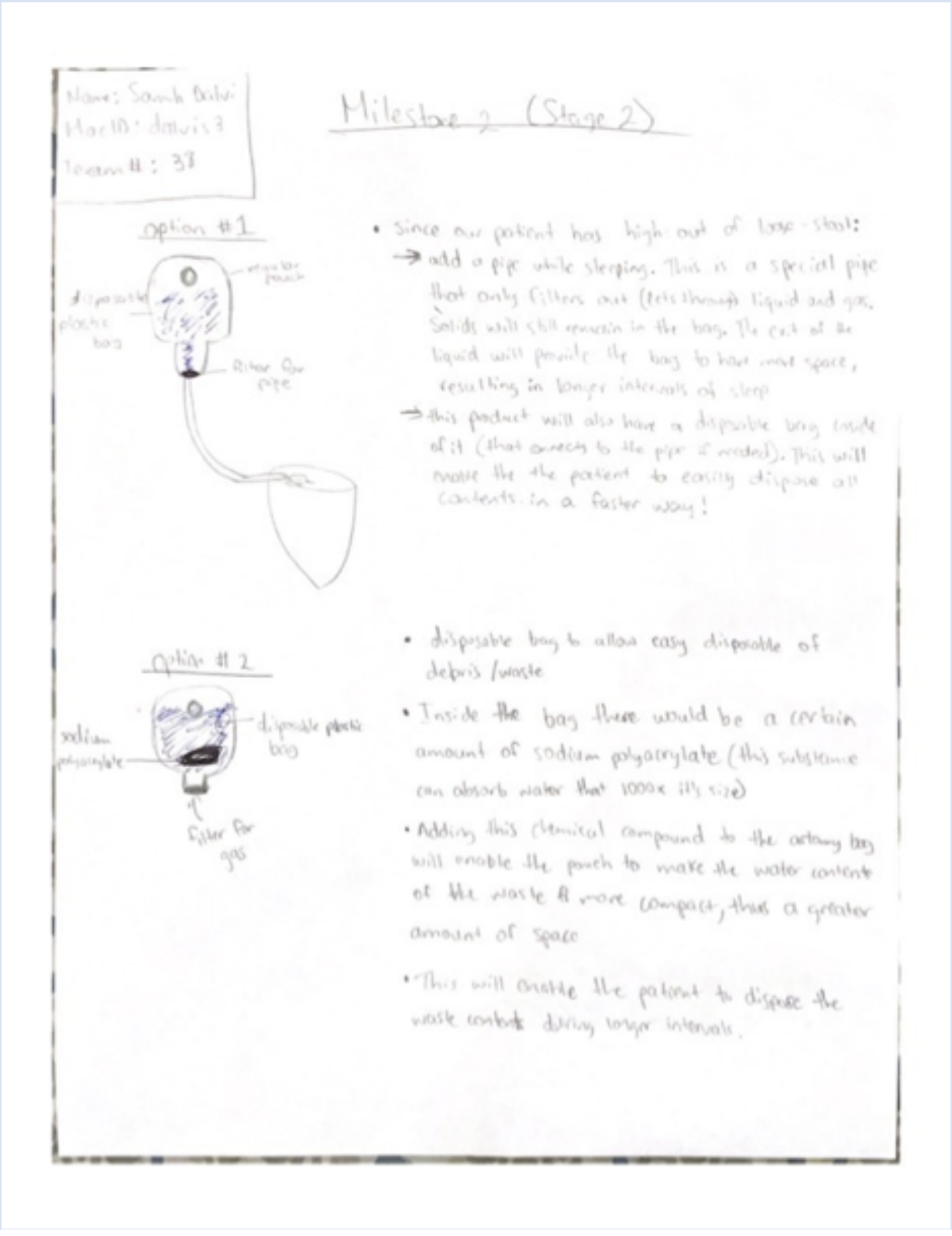


Figure 2. Preliminary sketches/ideas for possible solution (Samih)

Name: Elias Taylor	MacID: tayloe26

- Could use filters that are larger or made with a better material
- Could use more filters or multiple disposable filters with many perforations
- Could use HOAs to reduce her leak anxiety
- Drainage system solves capacity problem

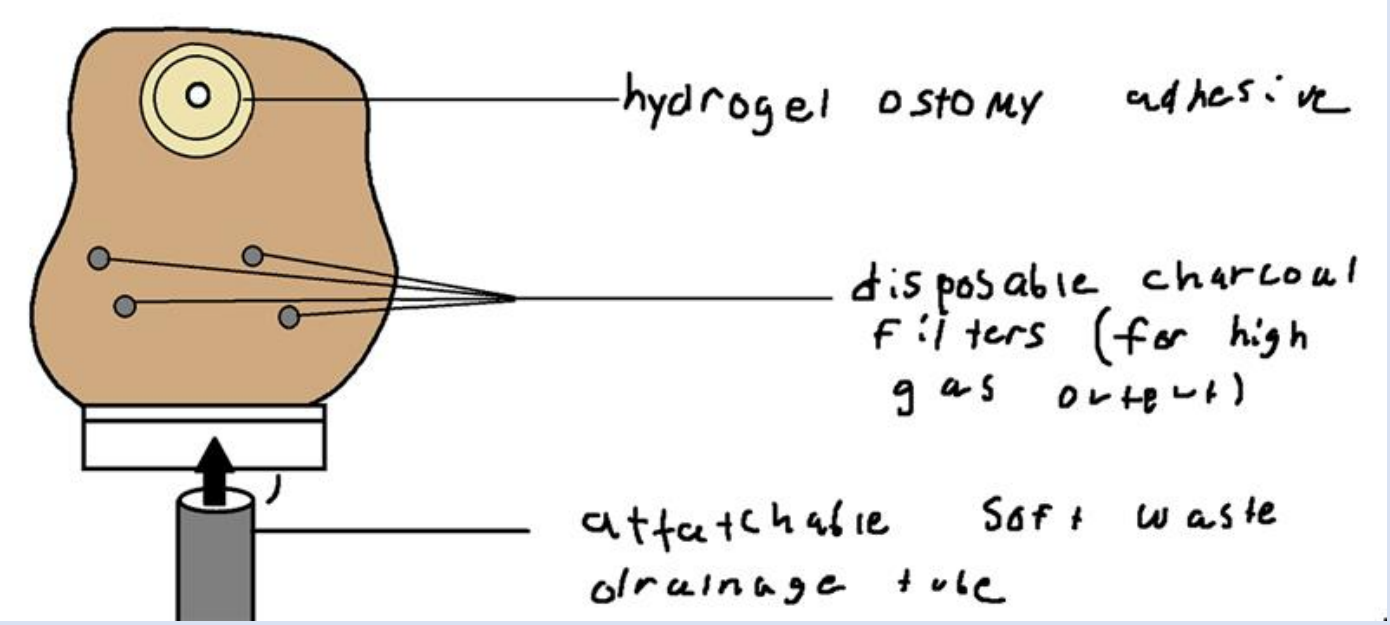


Figure 3. Preliminary sketches/ideas for possible solution (Elias)

MILESTONE 2 (STAGE 3) – CONCEPT GENERATION

As a team, generate several different means for solving your assigned design challenge.

1. Generate ideas that either includes or builds on each team members preliminary list of ideas (i.e., Stage 2)
    - You can complete this activity by any means you wish
        - e.g., sheet of paper, notepads and sticky notes, whiteboard, etc.
    - Document this process on the following pages
2. Generate a minimum of two (2) concept solutions
    - Each concept solution should be in the form of a clearly labelled sketch or schematic
    - Document this process on the following page.

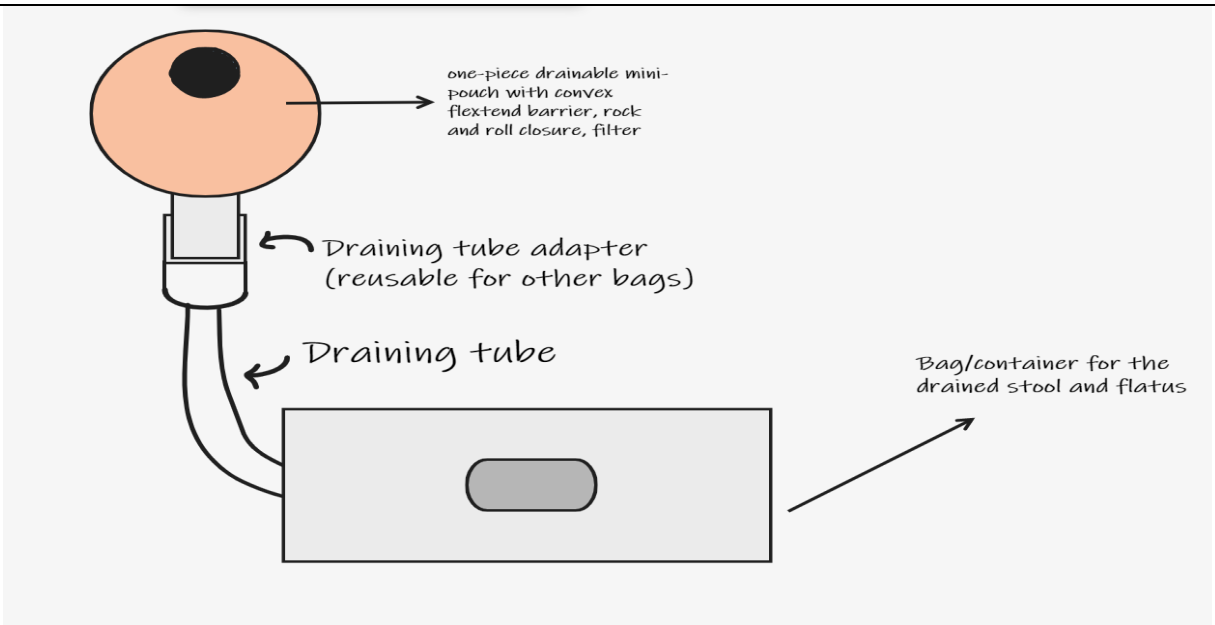


Figure 4. Cumulative sketch (incorporates all our ideas

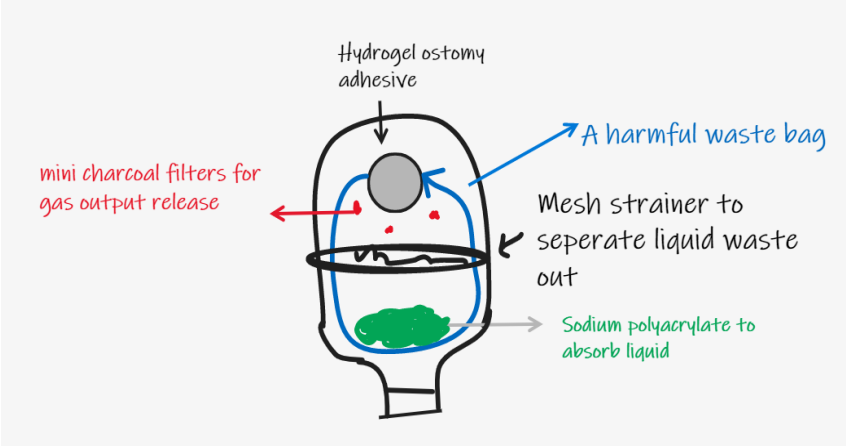


Figure 5. Cumulative sketch #2 (incorporates all our ideas)

MILESTONE 2 (STAGE 4) – GROUP DISCUSSION

As a team, discuss each concept generated in Stage 3. Document your group discussion in the space below (you are encouraged to use more than one page).

Questions to think about:

→ What are the advantages and disadvantages of each concept?
→ Do the concepts align with the objectives and constraints from Milestone One?
→ Do the concepts address the need statement?

Table 1. Advantages and Disadvantages of Preliminary Designs and Adherence to the Objectives, Constraints, and Need Statement

Concept	Advantages	Disadvantages	Objectives and constraints	Need statement
Drainage System	– Greatly increases potential volume of waste that can be released before manual intervention is required – Reusable design helps to reduce cost	– Extra piece is needed, which may affect mobility while sleeping and design time	– Adheres to some context, main issue is comfortability and discreteness, however, enables for easy release of high-output loose stool and relieves any issues related to weight	– This concept adheres to the need statement as it provides the user to sleep comfortability without having to constantly wake-up and manually empty the bag
Dual Bag System	– One piece, no need of external additions	– Accumulated weight associated with adding all the contents	– It adheres to the objectives of discreteness, comfortability while sleeping and limiting smells. Regarding constraints, it adheres to the size and capacity. However, it might be overstepping on the weight constraints.	– Generally, this concept design adheres to the need statement as it could be used by colostomy with high nighttime output to increase their intervals of sleep. The device eliminates the need to wake up every to hours to empty the ostomy.

4) Milestone 3 (Week 5)

MILESTONE 3 – COVER PAGE

Please list full names and MacID's of all *present* Team Members.

Full Name	MacID
Samih Dalvi	dalvis3
Ahmad Diaa Altarabishi	altaraba
Elias Taylor	tayloe26

MILESTONE 3 – DESIGN CONFIGURATION

As a team, document the configuration of your design in the space below, describing each of the following:

→ The form and function of your design

→ The fabrication and assembly (if applicable)

→ The device/user interaction

Your description can be in the form of detailed sketches and schematics, a list of design specifications (i.e., bullet-point descriptions) or a combination of the two.

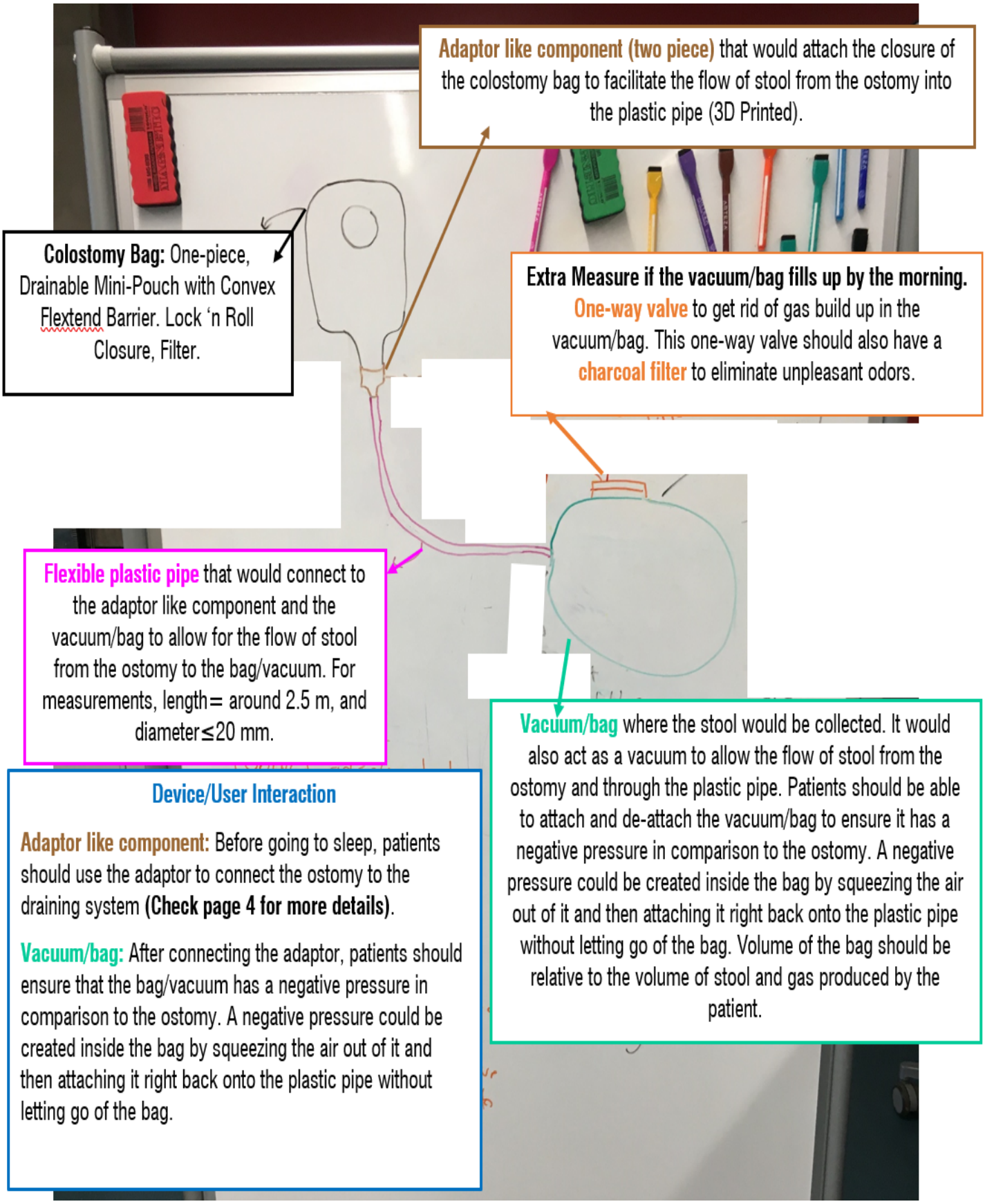
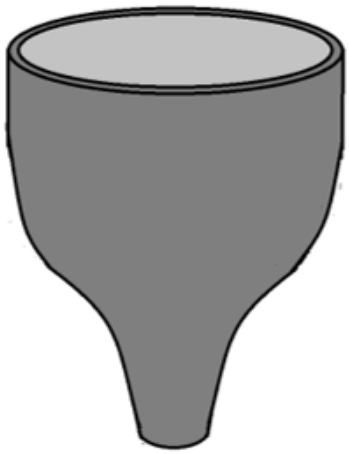


Figure 1. Final Sketch (incorporates new changes— vacuum)

Adaptor Like Component

General Design:

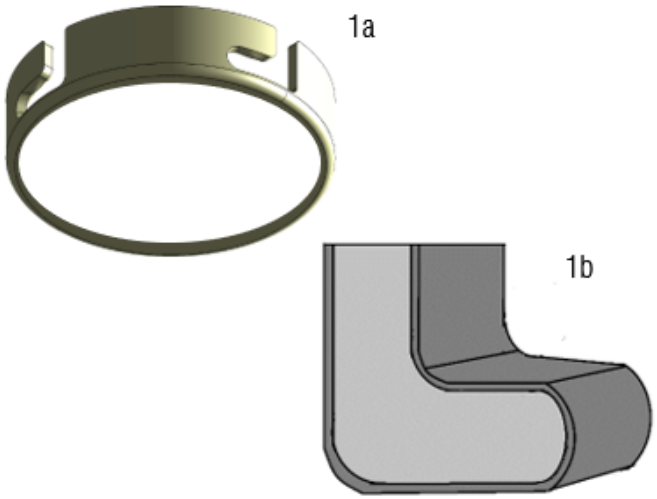
Piece 1: Outer piece of the adaptor. This part of adaptor would be located outside the colostomy around the end of the closure. The opening from the top should have a diameter of 38.5 mm, while the diameter of the bottom opening will depend on the diameter of the plastic pipe (≤20 mm). For the length, 52 mm seems reasonable.



Piece 2: Inner piece of the adaptor. This part of the adaptor would be located inside the ostomy bag at the end of the closure. It should have a length of 25 mm and a diameter of 32 mm (based on the opening of the colostomy bag given to us).

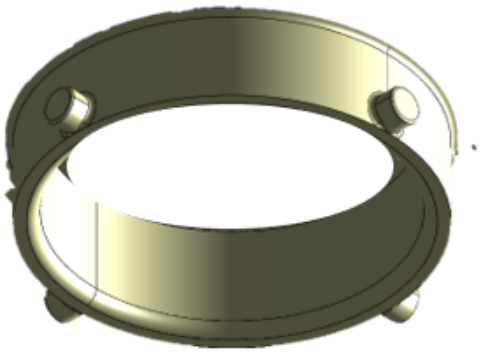
Twist-Lock Cylindrical Enclosure:

Piece 1



Piece 1: Similar layout to the mechanism in 1a but instead of cutting it out we would have it extruding off the inner wall, 1b. These extrusions should be at the top of the inner wall and should be spread out at the same distance from each other as the four cylinders on piece 2. The opening should be able to fit the 5-diameter cylinder. The walls should have thickness of 2 mm and a length of 3 mm.

Piece 2



Piece 2: The four cylinders extruding off the outer wall should have a length of 3 mm and have a diameter of 5 mm. These extruded cylinders should be at the bottom of the cylinder wall.

Figure 2. Components of the 3-d piece

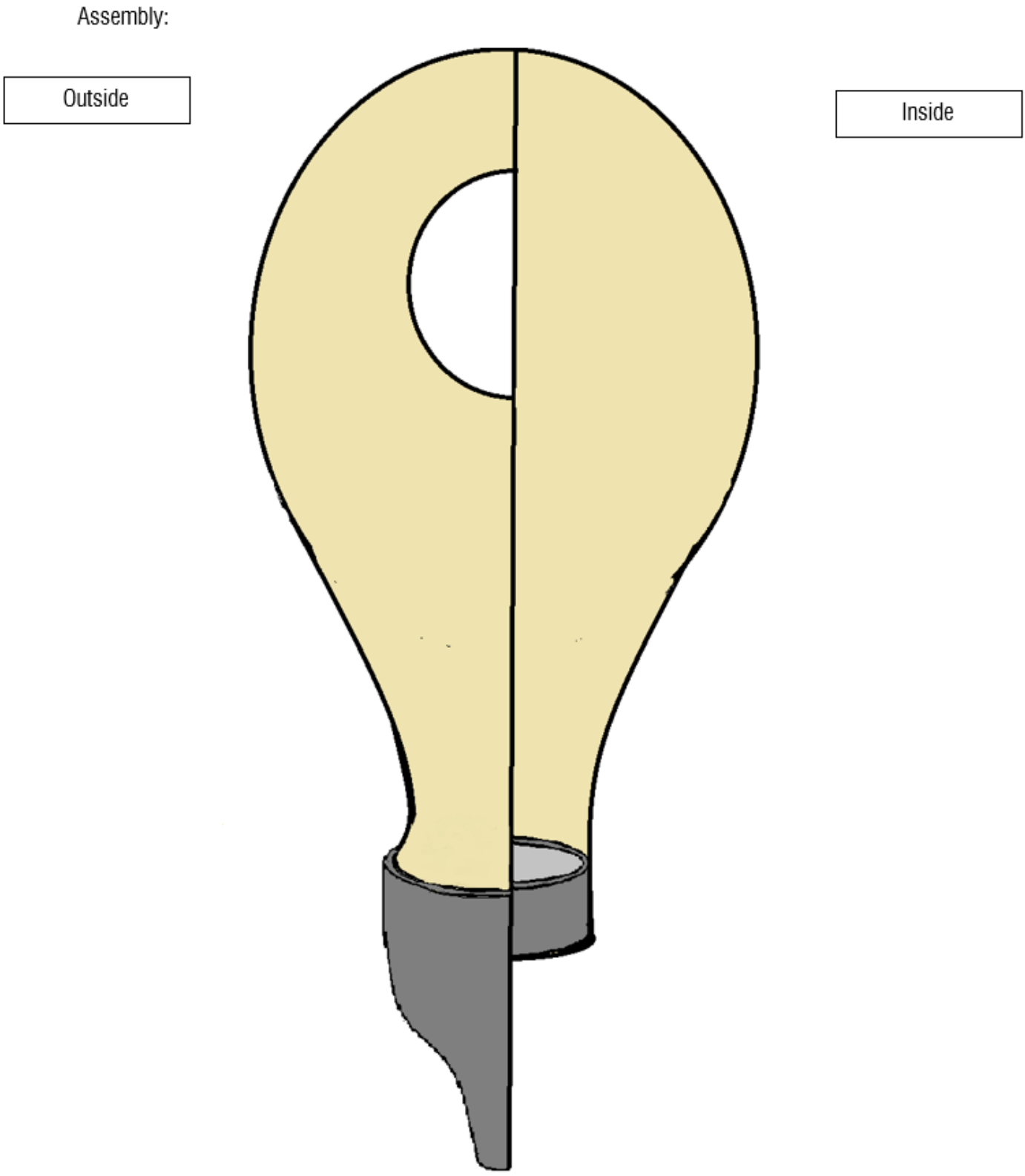


Figure 3. Assembly of the two-piece lock and twist mechanism

MILESTONE 3 – PRELIMINARY PROTOTYPING

As a team, outline the specifications for your low-fidelity prototype. You should clearly describe the following:

1. All components that need to be fabricated
2. Necessary modifications to the existing medical device (if applicable)
3. What materials would comprise your prototype
4. What tools and processes are required to fabricate your prototype?

You can use the table below as a guide but are free to document your work however you choose. There is no explicitly required format for submission

Components to be fabricated	Document your work in the space below • Adapter like Component – attaches to the ostomy bag and connects to the flexible plastic tube (3D printed). • Bag/Vacuum - a vacuum like bag where stool is going to be drained too. • Tube - to empty contents from the bag into the vacuum/ bag.

Modifications to existing medical device (if applicable)	Document your work in the space below • Change seal from a two piece to a one piece locking mechanism • Adhesive to connect skin barrier to skin (HOA) – represented in protype by scotch tape

Materials to be used	Document your work in the space below • HOA – represented in prototype by scotch tape • PVC tubing – represented in prototype by foam tube (the hole in the foam is small, but is a representation of a "bigger hole" to allow contents to easily pass through) • Waste bag/Vacuum represented by "static shielding bag (grey)" to collect all the waste

Tools and processes required to fabricate your prototype	Document your work in the space below • Design the adaptor using Inventor and then printing it out using a 3D printer. • Remove the two-piece skin barrier off the ostomy (by hand or scissors) and attach the convex Flex Tend (using glue) on the drainable ostomy. • Create a hole on the side of the bag/vaccum that would fit the plastic pipe.

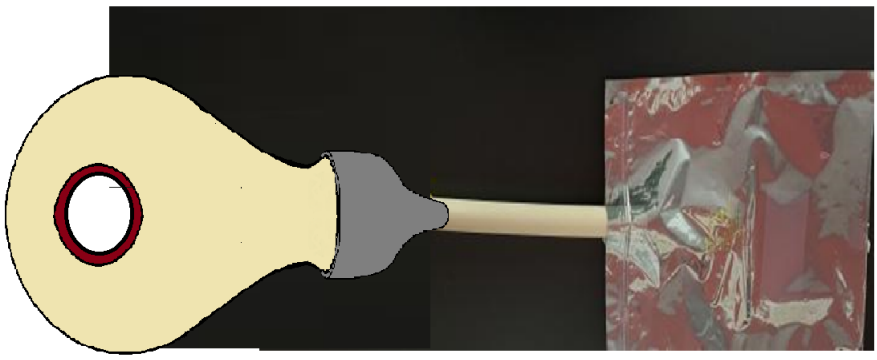


Figure 4. Preliminary Prototype

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5.0 Appendices

5.1 Appendix A: Executive Summary

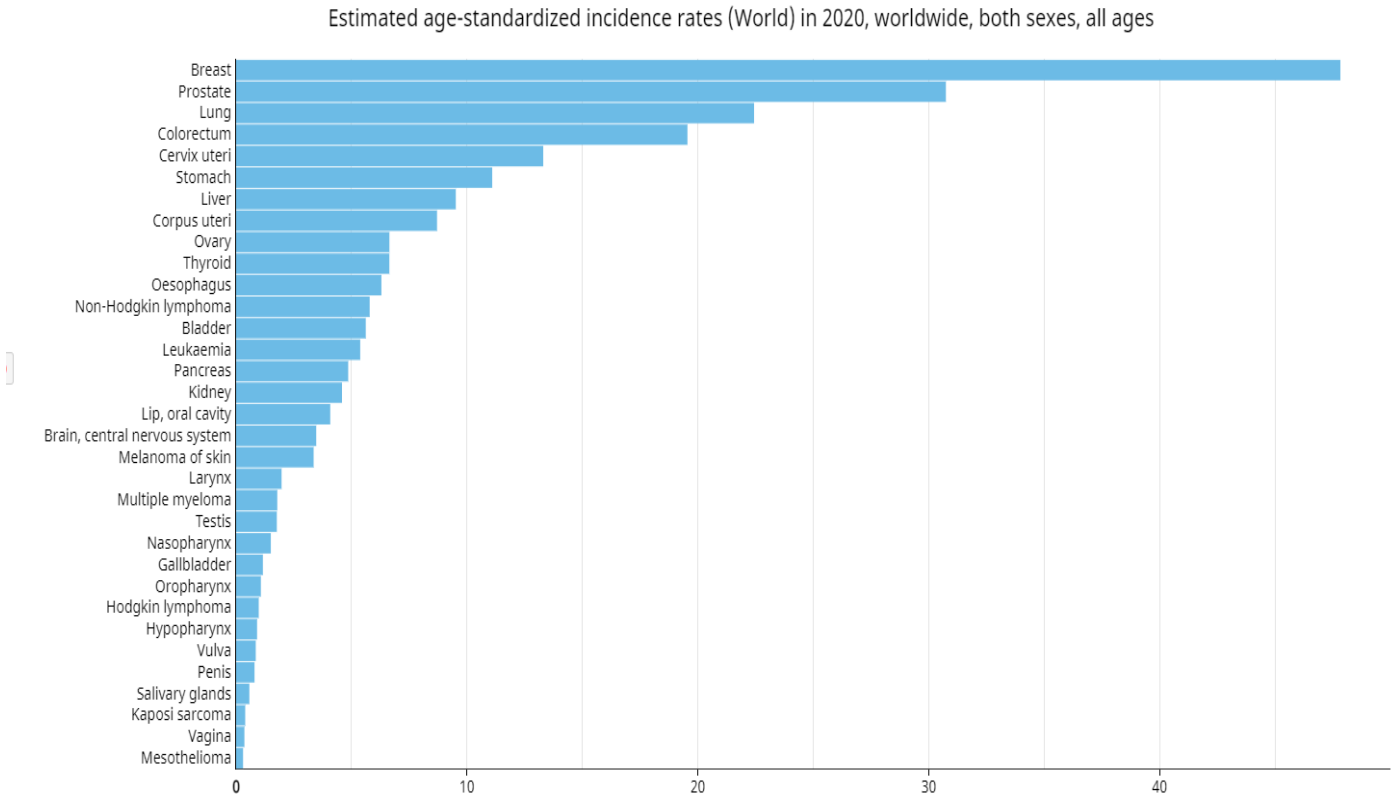

Figure A1. demonstrates the incidence rates of many cancers worldwide, note the high incidences of colorectal and bladder cancers which often result in the creation of stomas for waste management [18].

5.2 Appendix B: Materials

Figure B1. One-piece, Drainable Mini-Pouch with Convex Flextend Barrier, and a Charcoal Filter

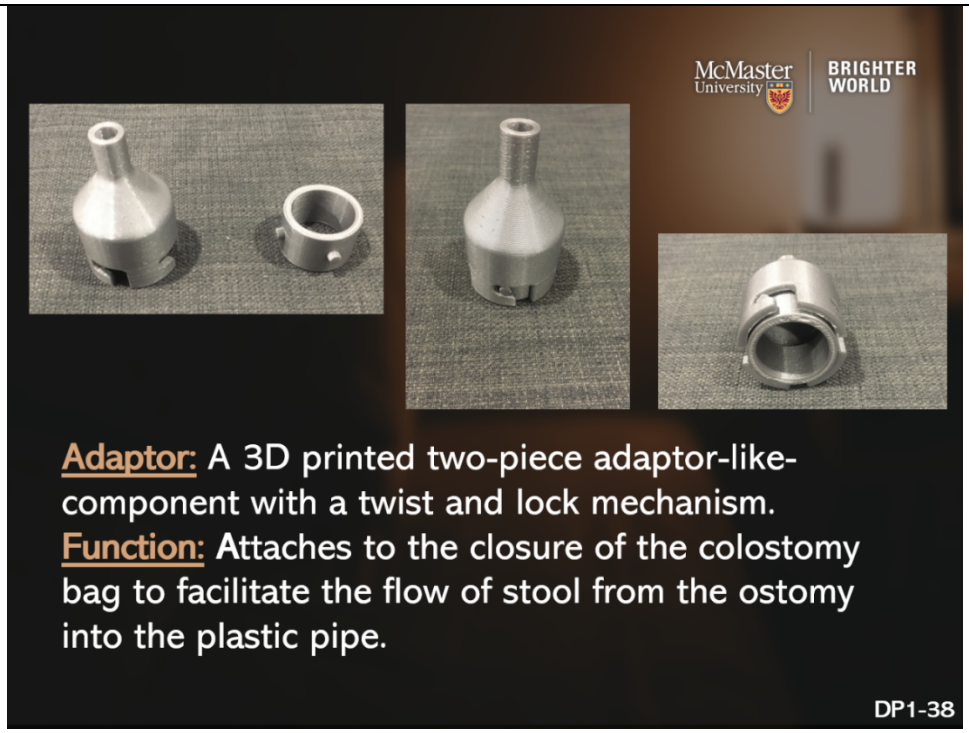

Figure B2. A 3D printed two-piece adaptor with a twist and lock mechanism.

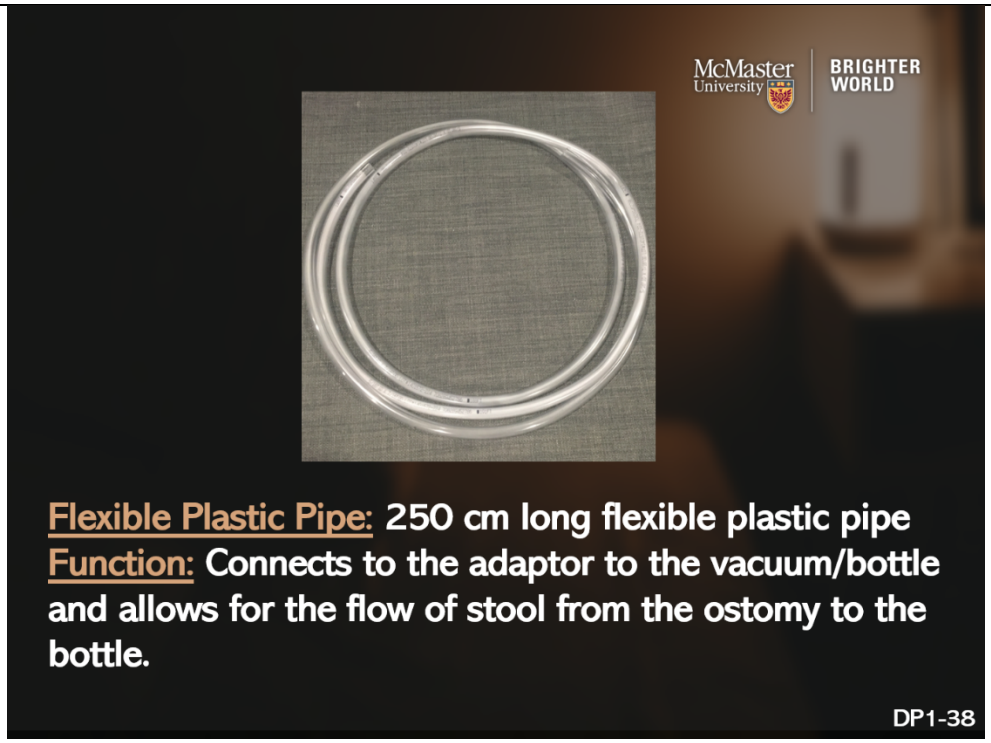

Figure B3. 250 cm long flexible plastic pipe

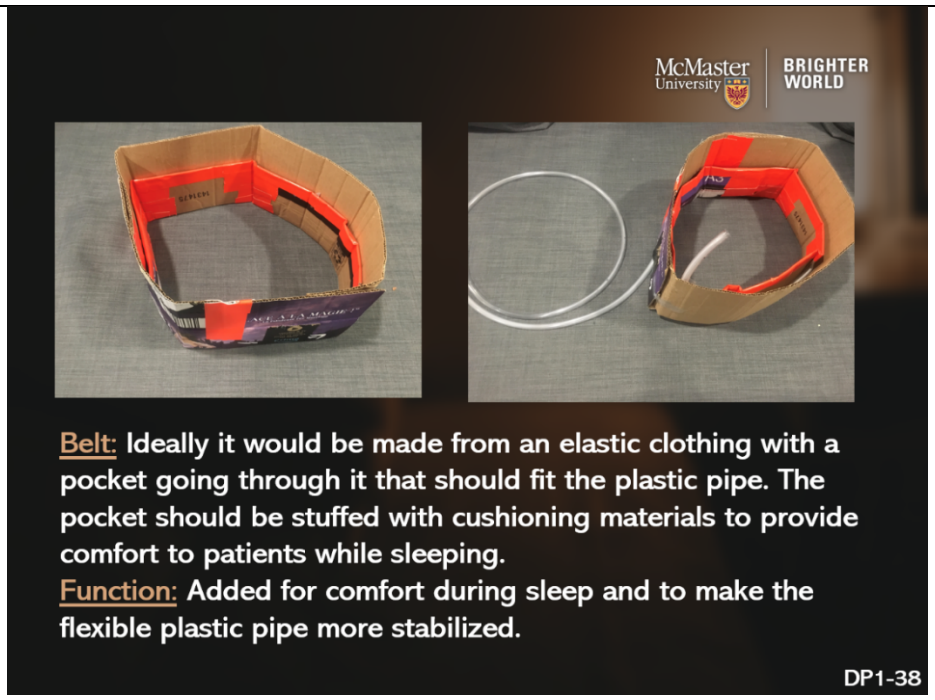

Figure B4. A belt ideally made from an elastic clothing with a pocket going through it that would fit the plastic pipe.

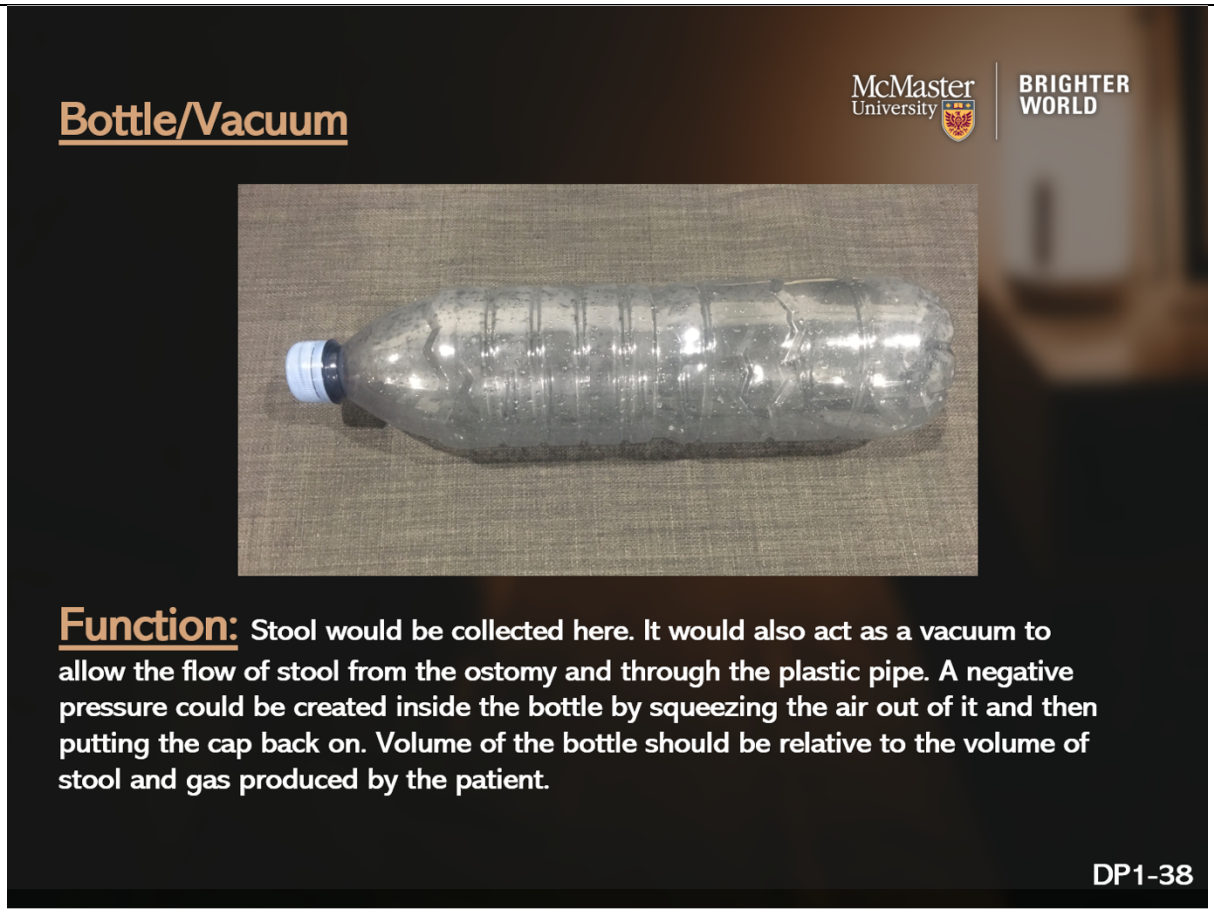

Figure B5. A bottle where stool would be collected. It would also act as a vacuum to allow the flow of stool from the ostomy and through the plastic pipe.

5.3 Appendix C: Adaptor

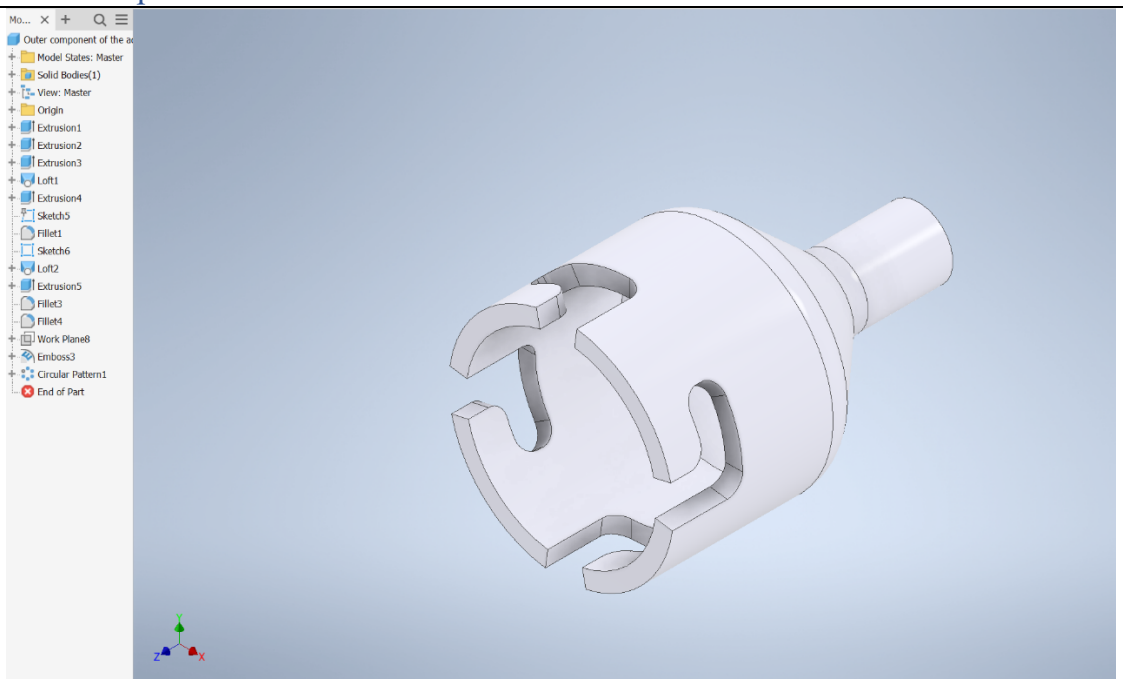

Figure C1. Outer component of adaptor sketched and modelled on inventor

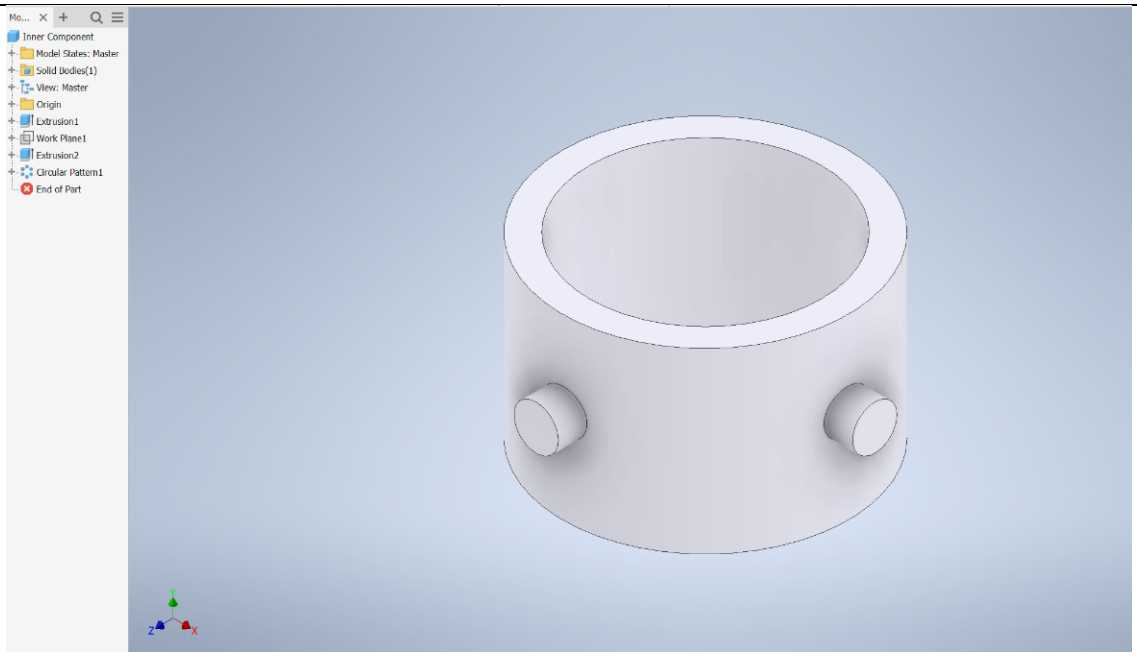

Figure C2. Inner component of adaptor sketched and modelled on inventor

Figure C3. Adaptor attaches on to the closure of the ostomy to facilitate the flow of stool.

5.4 Appendix D: Design Process (Iteration)

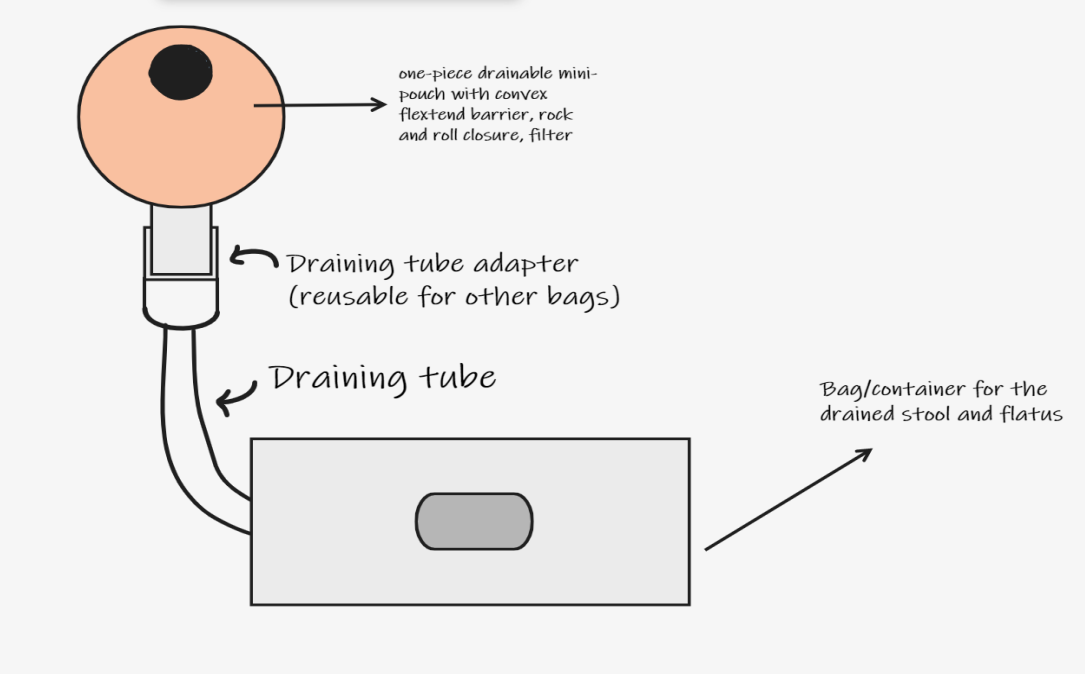

Figure D1. This is our initial design for our solution (after week 4). There are 3 major components: an adaptor, a draining tube, and a waste container.

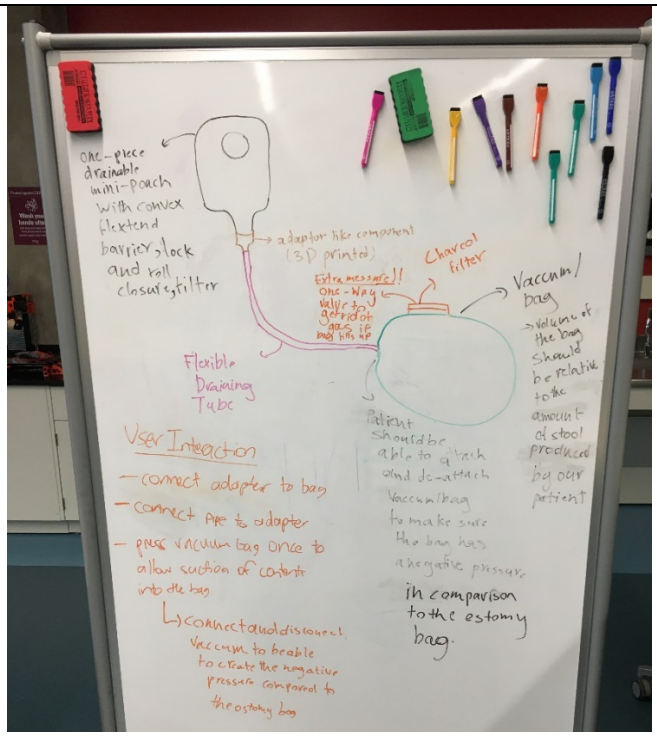

Figure D2. This is our design after week 5. We decided on modelling the adaptor on inventor and 3D printing it, and to change the waste container to a bag that acts as a vacuum to aid the flow of stool.

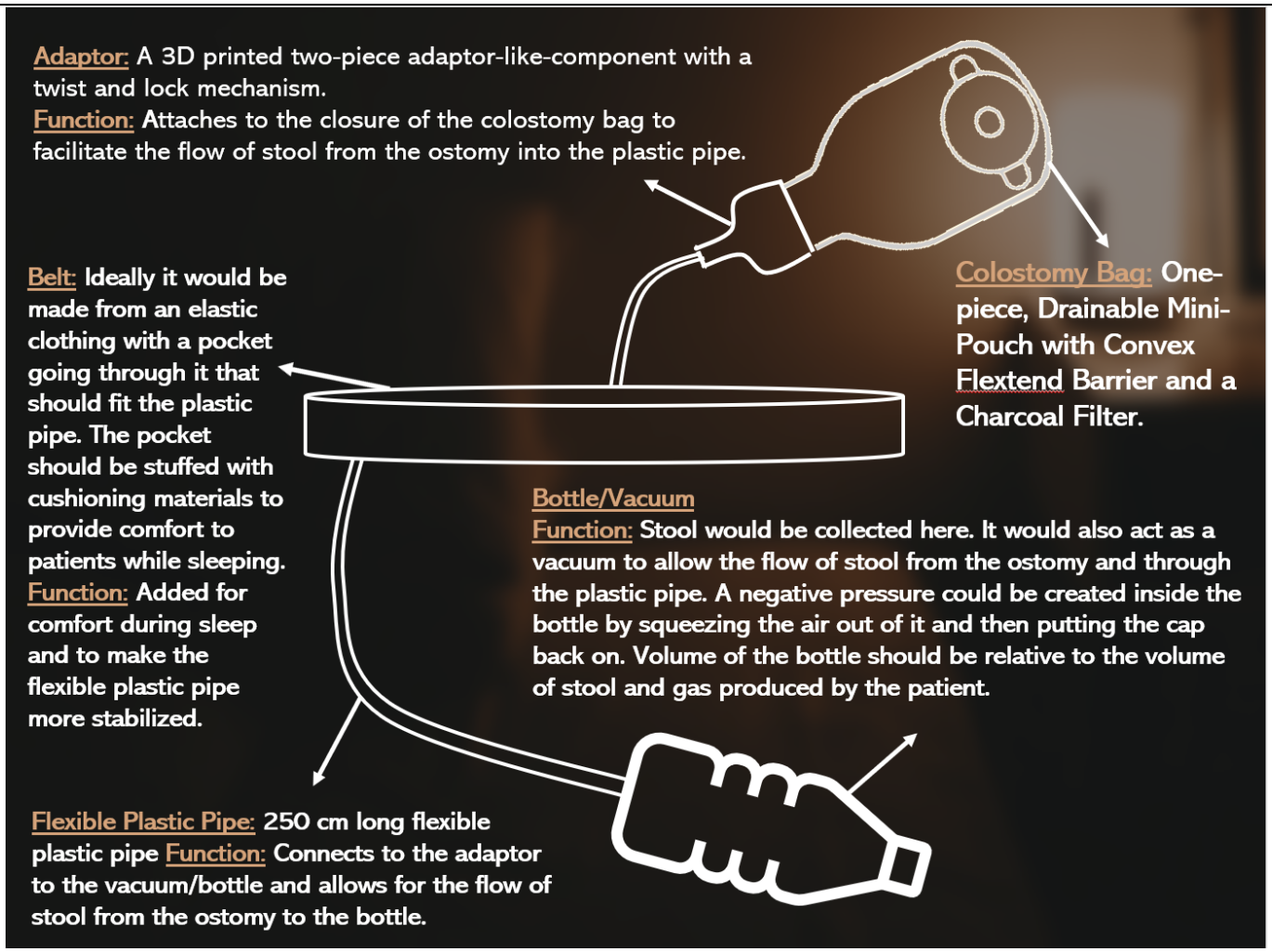

Figure D3. This is our final design (at week six). For our final design, we've decided to add a belt for comfort and pipe stability. Also, we replaced the bag with a bottle to act as the vacuum. The negative pressure facilitating the flow could be created inside the bottle by squeezing the air out and putting the cap back on

5.5 Appendix E: Solid Modelling

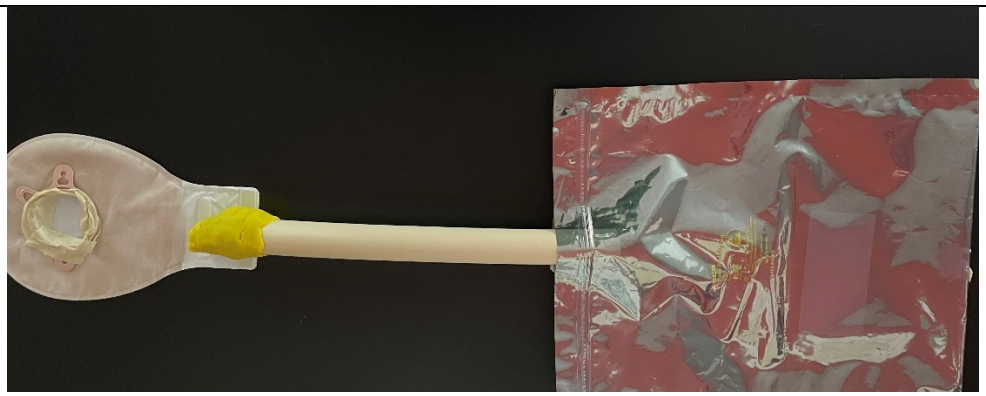

Figure E1. This is our preliminary prototype. In week 5, we got the chance to build a mock prototype of our low-fidelity solution. The play dough is supposed to represent the adaptor, the foam pipe is supposed to present the flexible PVC pipe, and the static shielding bag is supposed to represent the bag This /vacuum.

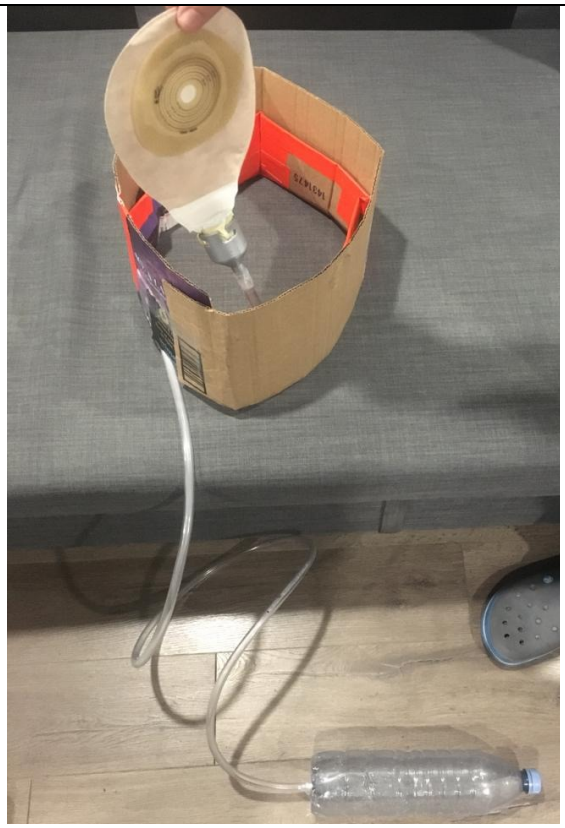

Figure E2. This is our final prototype (Week 6). The adaptor attaches to the closure of the colostomy bag to facilitate the flow of stool from the ostomy and into a flexible plastic pipe. The pipe is then run through a pocket inside an elastic cloth belt. It is then attached to the bottom side of a bottle where stool would be collected.