

Group 1: Gloria Cimpu, Shelby Tse, Max Fang, Yousif Fadhel

Design Project 1 - Ostomy Bag on F-leak

IBEHS IP10 – Health Solutions Design Projects

Tutorial 4

Team 1

COLIN MCDONALD (cmcdona)

KYLA SASK (ksask)

MARIA-JULIANA RIVERA-MADRINAN (riveramm)

PARMVEER BOLA (bolap1)

Submitted:

Course Instructors: Dr. McDonald and Dr. Sask

Group Members:

Max Fang - fangm16 400449164

Gloria Cimpu – cimpug 400434657

Shelby Tse – tses8 400435008

Yousif Fadhel – fadhely 4004347478

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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.

Max Fang

400449164

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(Student Signature) *

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Yousif Fadhel400434747

A handwritten signature in blue ink, appearing to be 'Yousif Fadhel', written over a horizontal line.

(Student Signature) *

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Gloria Cimpu

A handwritten signature in blue ink, appearing to be 'Gloria Cimpu', written over a horizontal line.

(Student Signature) *

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.

Shelby Tse

400435008

A handwritten signature in black ink, appearing to read 'Shelby Tse', written in a cursive style.

(Student Signature) *

Executive Summary

For every 500 Americans, one has an ostomy, according to census data from 2020 [1]. Ostomies allow stool to pass through the body via the stoma, a surgically-created opening, into an ostomy bag. Ostomies are incredibly common, though its ability to remain discrete under clothing allows ostomates to keep their condition private or unknown unless they decide to share it with others.

However, ostomy bags are not without their disadvantages. Leakages are one of the most common challenges faced by ostomates on a regular basis. These leakages between the skin and the adhesive barrier of the ostomy bag not only irritate surrounding skin and render the bag unusable. There are numerous potential causes for leakages, some being prolonged usage and wear of the bag and the stress on the adhesive, insufficient emptying of the bag, or friction caused from rigorous physical activity.

Carla is young ostomate, has an active lifestyle, and prefers more fitted clothing, thus opting for the one-piece ostomy bag. Her main challenge is frequent leakage, and despite them occurring more often after two to three days of use, her financial situation is unable to accommodate such often ostomy bag changes. As a result, she decides to change her bag every 7-8 days instead. Since Carla has an ileostomy, the stool from the end of the small intestine is more corrosive, making her leaks more irritating to the surrounding skin. As such, the design places emphasis on leak management and improving the discreteness of her bag, while prioritizing reusability to accommodate her financial situation.

Our design consists of two components. The first product is the ostosticker, a secondary sticker made from pressure sensitive silicone adhesive that attaches to the original flange of the bag, covering a larger surface area of skin to prevent leakages and provide additional security to accommodate her active lifestyle. When this Osto-sticker has been compromised, it can be easily removed to reveal the original adhesive on the flange, ensuring Carla does not need to change the entire bag every time she leaks. The second product is the Osto-pouch, made from a breathable silicone material which works well with tighter fitting clothing. It allows discrete monitoring of fluid volume since leaks can be prevented when the bag is emptied more frequently.

The Osto-sticker and the Osto-pouch can be used in tandem and do not interfere with each other. These two devices are able to prevent leaks and the need to change the entire bag upon each leakage. It is low profile and can be easily assembled. This is a great short term solution for Carla given her financial situation, and the reusability of the ostopouch makes it a sustainable long term option. The next steps would be to evaluate the effectiveness of the Osto-sticker with Carla's active lifestyle, and aim to develop a more reusable version as a long-term solution.

Statement of Problem and Goals

Ostomy bags use pressure sensitive adhesives to attach to the skin surrounding a patient's stoma and create a strong seal to effectively contain stool secreting from the stomach. Leaks can often occur between the skin and adhesive barrier allowing stool to spill onto the skin, where 88 to 90% of those with a stoma were found to have experienced effluent leaking onto their skin [2]. This is especially relevant for those with an ileostomy, where the stomach content is often liquid, as opposed to a colostomy where the output is solid. Not only can these leaks cause emotional distress for the ostomy patient, where a study found that on average 65% of employed ostomy patients reported that worrying about leakage influenced their ability to work, but leakage of stomal effluent onto skin has also been linked to experiencing peristomal skin complications (PSCs) [3,4].

A one-piece ostomy bag is one collective piece where the adhesive seal is directly connected to the bag, whereas a two-piece ostomy bag separates the adhesive from the bag, allowing the seal to be changed in case of leaks without having to discard the bag as well [5]. While the two-piece ostomy bag may seem like an easy solution to solve leakage, the design can be bulky. For ostomy patients who prefer a low-profile look, such as those who wear tight clothing, the single piece ostomy bag is a better option to make the user look and feel their best. Although one piece ostomy bags are less expensive than two pieces, the issue with them is that the entire bag must be removed and discarded when a leak does occur, which can quickly add up in cost [6].

The adhesive to an ostomy bag can wear away for many reasons causing leaks, including a prolonged wear-time, not emptying out the ostomy bag in a timely manner, where the fuller the bag gets the heavier it is and the more it pulls down on the seal, and finally rigorous physical activity where the seal may be stretched and pulled and sweat can erode the adhesive [7].

Considering all these factors, ostomy bag users that are active, low-budget, and wanting a low-profile look, are the most at risk for leaks, given that they may choose to wear their one-piece ostomy bags for longer than the ideal wear-time in order to save money.

The goal is to provide a low-cost device that can easily be added onto an original one-piece ostomy bag in order to maximize its wear time. The device will prevent leaks and provide an alternative to discarding the entire bag once a leak does occur. It is engineered specifically to account for the factors of an active lifestyle, such as bending and twisting and needing a low-profile look to fit under tighter athletic style clothing. The design will give ostomy patients peace of mind during their day to day lives, lessening both the financial and social anxiety of a leaking ostomy bag.

Description of Proposed Solution

The proposed solution is in the form of two products, the Osto-sticker and Osto-pouch. Carla Tortelli suffers mainly from frequent leaks, and wants to continue her active lifestyle while wearing more fitted clothing. The final design of the osto-sticker will share some characteristics of the original ostomy bag's skin adhesive so patients will already be used to the bag. The connection between the skin and the adhesive was designed to feel just like an ostomy bag, and the patients using osto-sticker should not be able to tell a difference in its feel. To achieve a high level in comfort and function between the skin to adhesive connection, osto-sticker will use a special pressure sensitive adhesive composition. This composition is specially designed for skin adhesion and appeals to ostomy patients. The patented pressure sensitive adhesive is comprised of an elastomeric base and uses water soluble or swellable hydrocolloids [9]. The inventors of this compound had the specific interest of designing an adhesive for ostomy care, as the hydrocolloids provide an environment for the surrounding area to heal in the case of a leak. The sticker itself is made up of this special compound, while the outer protective stickers are going to be made of a skin safe acrylic polymer. The protective sticker is the outer layer that prevents the adhesive to be damaged, and this outer layer is made of the same material the used to make the plastic protective parts of band aids. This material is waterproof and does not affect the adhesive. To assemble the sticker, Carla attaches the osto-sticker to the ostomy bag's skin adhesive, and peels off the outer layer. Then she wears the bag like she usually would. This is a cheap, long-term solution that aims to solve both Carla's leakage issue and financial issues by increasing the lifespan of each bag and increasing adhesion.

The osto-pouch is an addition to help Carla feel more comfortable with her ostomy bag. She prefers a more fitted style, and the osto-pouch will allow her to personalize the ostomy bag. The osto-pouch is made of a breathable silicon material that holds its shape but is still slightly stretchy. This material will be opaque to ensure that the contents of the bag are hidden, and that there will be a thin transparent line on the side to allow the user to monitor water level. The osto-pouch will attach to the ostomy bag by wrapping around the exterior, the same way a shower cap does. The assembly is very simple and only requires the user to stretch the pouch around the bag, once the bag has been placed on the body.

Justification of Proposed Solution

Group one's innovations were carefully created to cater to Carla Tortelli and patients in similar situations' exact needs. The osto-sticker gives users who experience leaks that hinder the adhesive capacity of their wafer a specific solution that allows them to replace their compromised adhesive with a fresh new one. This additional adhesive layer will permit Carla to fully optimize the length she is able to use a single

bag and no longer require her to endure the inconveniences and disturbances that accompany using a wet, leaky bag. She will be able to perform more effective workouts with the removal of these hindrances. Additionally, the user-interaction of this product will simply require the patient to layer on the accessory over the ordinary ostomy bag and attach the three intermediary components that are placed between the skin and flange. This low-stress process will take an estimated application time of only around five to ten minutes allowing Carla to remain dedicated to her active lifestyle. When she needs to remove the ostosticker she can be sure that the original sticker will exhibit no signs of wear or damage from the leaks of urine, stool and sweat to the secondary sticker as it is sealed under the secondary-sticker. Furthermore, as it is specifically stated that Carla is financially challenged, the materials used to manufacture the ostosticker make purchasing / manufacturing one drastically more cost-effective than it would be for Carla to purchase an entirely new ostomy bag. The ostosticker will be a solid circular piece composed of hydrocolloid material that directly mimics the primary adhesive and according to research gathered from, [10], this material is relatively waterproof, flexible and non-irritating towards the skin. Long term, this innovation will save Carla a lot of money and decrease the overall effect that having an ostomy has on Carla's life.

The ostopouch also directly addresses Carla's preference to wear tight-fitting clothing. This product provides the user a discrete design while simultaneously giving Carla a quantitative reading of the volume of the bag. The ostopouch encases the ostomy bag in a sleek latex material that keeps the bag low profile with a tightening mechanism that is extremely user friendly and intuitive (comparable to putting on a shower cap). This information will allow Carla to make accurate decisions regarding when she should drain her bag allowing for increased convenience and overall quality of life. The design will give Carla the confidence she needs to carry out her everyday activities without the constant fear of how others perceive her physical appearance intruding on her.

Summary of Contributions

Task	Contributors
Executive Summary	Shelby Tse
Statement of Problem and Goals	Gloria Cimpu
Description of Proposed Solution	Max Fang

Justification of Proposed Solution	Yousif Fadhel
One Page Slide Deck	Shelby, Gloria, Yousif, Max
Preliminary Prototype	Shelby, Gloria, Yousif, Max

Reference List

- [1] UOAA, “Mythbusters! facts and truth to fight ostomy stigma.” [Online]. Available: https://www.ostomy.org/wp-content/uploads/2020/08/UOAA_Mythbusters_Infographic_2020-08a.pdf. [Accessed: 31-Oct-2022].
- [2] B. Cancaster, “Choosing an ostomy pouch made easy,” *Vitality Medical*, 24-Jun-2022. [Online]. Available: <https://www.vitalitymedical.com/blog/choosing-an-ostomy-bag.html>. [Accessed: 30-Oct-2022].
- [3] D. M. Smith, G. Loewenstein, P. Rozin, R. L. Sherriff, and P. A. Ubel, “Sensitivity to disgust, stigma, and adjustment to life with a colostomy,” *Journal of Research in Personality*, 02-Nov-2006. [Online]. Available: <https://www.sciencedirect.com/science/article/abs/pii/S0092656606001164>. [Accessed: 30-Oct-2022].
- [4] G. Down, M. Vestergaard, T. A. Ajslev, E. B. Boisen, and L. F. Nielsen, “Perception of leakage: Data from the Ostomy Life Study 2019,” *British journal of nursing (Mark Allen Publishing)*, 09-Dec-2021. [Online]. Available: <https://pubmed.ncbi.nlm.nih.gov/34889680/>. [Accessed: 30-Oct-2022].
- [5] British Journal Of Nursing, “Impact of stoma leakage in everyday life: Data from the Ostomy Life Study 2019,” *British Journal of Nursing*, 24-Mar-2022. [Online]. Available: <https://www.britishjournalofnursing.com/content/patient-experience/impact-of-stoma-leakage-in-everyday-life-data-from-the-ostomy-life-study-2019#B23>. [Accessed: 30-Oct-2022].
- [6] N. Rolls, C. Yssing, M. Bogelund, J. H. Bloch, and L. Jensen, “Utilities associated with stoma-related complications: Peristomal skin complications and leakages,” *Journal of medical economics*, 25-Jan-2022. [Online]. Available: <https://pubmed.ncbi.nlm.nih.gov/35833520/>. [Accessed: 30-Oct-2022].
- [7] “Product guide: How to choose an ostomy bag,” *How to Choose an Ostomy Bag / Express Medical Supply / Medical Supply Company*. [Online]. Available:

- <https://www.exmed.net/product-guide-how-to-choose-an-ostomy-bag>. [Accessed: 30-Oct-2022].
- [8] G. Down, M. Vestergaard, T. A. Ajslev, E. B. Boisen, and L. F. Nielsen, "Perception of leakage: Data from the Ostomy Life Study 2019," *British journal of nursing (Mark Allen Publishing)*, 09-Dec-2021. [Online]. Available: <https://pubmed.ncbi.nlm.nih.gov/34889680/>. [Accessed: 30-Oct-2022].
- [9] "EP2221067A1 - pressure sensitive adhesive composition for medical use," *Google Patents*. [Online]. Available: <https://patents.google.com/patent/EP2221067A1>. [Accessed: 30-Oct-2022].
- [10] L. Cox, "Key Ostomy Products You should know about," *Shield HealthCare*, 07-Dec-2019. [Online]. Available: <http://www.shieldhealthcare.com/community/ostomylife/2019/07/12/key-ostomy-products-you-should-know-about/>. [Accessed: 30-Oct-2022].

Appendices

*** Add relevant Appendices as instructed. A sample Appendix is shown below.**

Appendix A: Project Schedule

Project Planner

Select a period to highlight at right. A legend describing the charting follows.

Period Highlight: 1

Plan Duration

Actual Start

% Complete

Actual (beyond plan)

% Complete (beyond plan)

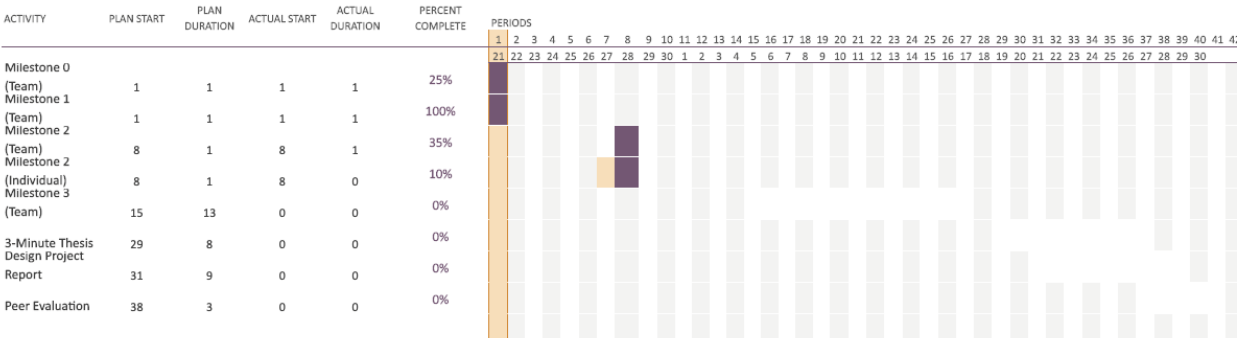


Figure 1.1 Preliminary Gantt Chart

Project Planner

Select a period to highlight at right. A legend describing the charting follows.

Period Highlight: 1

Plan Duration

Actual Start

% Complete

Actual (beyond plan)

% Complete (beyond plan)

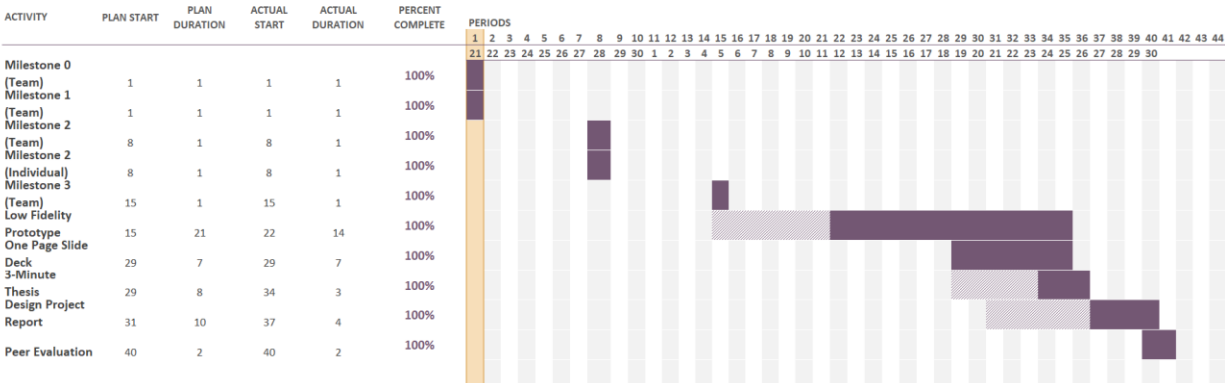


Figure 1.2 Final Gantt Chart

Figure 1.3 Logbook

Team Meeting #4

Thursday, October 20, 2022

Attendance

Role	Name	Mac ID	Attendance
Manager	Shelby Tse	tses8	present
Administrator	Max Fang	fangm16	present
Coordinator	Gloria Cimpu	<u>cimpug</u>	present
Subject Matter Expert	Yousif Fadhel	<u>fadhely</u>	present

Summary

- Team met in design studio
- Began work on prototypes
- Began working on slide deck

Team Meeting #5

Friday, October 21, 2022

Attendance

Role	Name	Mac ID	Attendance
Manager	Shelby Tse	tses8	present
Administrator	Max Fang	fangm16	present
Coordinator	Gloria Cimpu	<u>cimpug</u>	
Subject Matter Expert	Yousif Fadhel	<u>fadhely</u>	

Summary

- Team met in design studio
- Worked on Prototypes

Team Meeting #6

Tuesday, October 25, 2022

Attendance

Role	Name	Mac ID	Attendance
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Manager	Shelby Tse	tses8	present
Administrator	Max Fang	fangm16	present
Coordinator	Gloria Cimpu	<u>cimpug</u>	present
Subject Matter Expert	Yousif Fadhel	<u>fadhely</u>	present

Summary

- Team met in design studio
- Finished up the two prototypes
- Filmed the 60 second prototype video
- Divided up the slide making responsibilities

Appendix B: Scheduled Weekly Meetings

Team Meeting #1

Wednesday, September 28, 2022

Attendance

Role	Name	Mac ID	Attendance
Manager	Shelby Tse	tses8	present
Administrator	Max Fang	fangm16	present
Coordinator	Gloria Cimpu	cimpug	present
Subject Matter Expert	Yousif Fadhel	fadhely	present

Agenda Items

1. Check-in
 - a. How's everyone doing?
 - i. Good, no one needs specific help
 - b. Are needs met?
 - i. Yup!
 - c. General reminders/inquiries
 - i. No one can stay late today, we all have labs
2. Identify work expectations (eg. deadlines, communication)
 - a. Working on milestone 3
 - b. Shelby has to submit the ghant chart
 - c. Max will submit the work
 - d. Yousif has prepared the big doc for all work
 - e. Put all work on teams when doing it
 - f. Communication has been good
 - g. Ensure transparency between group members when deadlines cannot be met
 - h. Have understanding towards others and adjusting to university life
3. Issues from past week
 - a. Hasn't really been any issues, everyone completed their work
4. Finalize Gantt chart timeline

Post-meeting Action Items

1. Everyone submit individual work
2. Continue with milestone 3

Additional questions/concerns

Feedback

- Very detailed
- Give idea of where you are at
- What everyone did before today/will do during today
- How you felt about your parts/work
- Mention questions/ difficulties with work done to the TA
 - Take advantage of TA presence
- Mention need statement and how the prototype meets needs in the thesis presentation (around october 30th)

Figure 2.1 Team Meeting #1 Weekly Agenda and Meeting Minutes

Team Meeting #2

Wednesday, October 5, 2022

Attendance

Role	Name	Mac ID	Attendance
Manager	Shelby Tse	tse8	present
Administrator	Max Fang	fangm16	present
Coordinator	Gloria Cimpu	cimpug	present
Subject Matter Expert	Yousif Fadhel	fadhely	present

Agenda Items

1. Check-in
 - a. How's everyone doing? How was their individual workload?
 - i. Good
 - b. Are needs met?
 - i. Yes
 - c. General reminders/inquiries
 - i. Manager update Gantt chart
 - ii. Team go over previous grades/rubrics and upcoming Milestone 2 rubric
2. Recap last week's design studio (Milestone 2)
 - a. Go over our three ideas
 - i. Belt, narrow, comfortable, low profile
 1. TA said it's feasible, within scope of project
 2. Maybe add Velcro
 3. Think about how is it going to be secure while carla moves
 4. Hole opening stretching when carla is
 - ii. Secondary Sticker
 1. Leak affects first adhesive
 2. Start sourcing adhesives and an idea of how carla would use the product
 3. Is she going to add the sticker herself to every bag she buys
 4. Biggest issue might be user interaction, consider this in design, justify how the process would go
 - iii. Cover (maybe sticker)
 1. Maximize low profile for Carla, having little clear markings to see how full the bag is
 2. Emptying bag when 1/3 full will reduce leakage
 3. Reusable
 4. Consider how going to put on
 5. Sticker/reusable not compatible (doesn't have to be both)
 - a. Active sweating and moving, jumping and twisting
 - iv. All ideas within the scope of the project
 - v. Create projects that help carla right now, in this moment
 - vi. Quickly produce product to give a longer lifespan to the bag
 - vii. Not redesigning the actual bag
 - viii. Feel well thought out
 - ix. In final project can discuss ideal long-term goals for ostomy bag modifications
3. Discuss goals for today's design studio (personal, team)
 - a. Start making design decisions (velcro or hooks, etc) (optimizing the design)
 - b. Visualizing and iterating
4. Questions for TA/any difficulties?
 - a. We can start prototyping

Post-meeting Action Items

1. Complete design configuration worksheet
2. Complete preliminary prototyping worksheet
3. Manager update Gantt chart
4. Administrator submit DP1 Milestone 3 worksheet (team)

Figure 2.2 Team Meeting #2 Weekly Agenda and Meeting Minutes

Team Meeting #3
Wednesday, October 19, 2022

Attendance

Role	Name	Mac ID	Attendance
Manager	Shelby Tse	tseS	present
Administrator	Max Fang	fangm16	present
Coordinator	Gloria Cimpu	cimpug	present
Subject Matter Expert	Yousif Fadhel	fadhely	present

Agenda Items

1. Check-in
 - a. How's everyone doing?
 - i. Great!
 - b. General reminders/inquiries
2. Recap last week's design studio (Milestone 2/3)
3. Discuss goals for today's design/studio (personal, team)
 - a. Decide to do one product?
 - b. Group outline for 3MT
4. Questions for TA/any difficulties?

Post-meeting Action Items

1. Begin prototyping
2. 3MT slide
3. Review rubric
4. Schedule design studio
5. Manager update Gantt chart

Meeting Notes

- Maybe try to combine ideas (maybe cover and sticker, covering two objectives)
- Don't over engineer (not too long to put on)
- Sticker idea is more novel
- Think about price, one time purchase for belt vs several purchases for stickers
- Briefly touch on finances

Figure 2.3 Team Meeting #3 Weekly Agenda and Meeting Minutes

Appendix C: Comprehensive List of Sources

❖ Initial group research:

1. American Cancer Society, “What is an ileostomy?,” *American Cancer Society*, 16-Oct-2019. [Online]. Available: <https://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/surgery/ostomies/ileostomy/what-is-ileostomy.html>. [Accessed: 30-Oct-2022].

This source provided introductory insight on defining an ileostomy and explaining its functionality.

2. Byram HEALTHCARE, “Types of ostomy bags and how to choose what's best for you,” *Byram Healthcare*, 20-Jan-2020. [Online]. Available: <https://www.byramhealthcare.com/blogs/How-to-Choose-an-Ostomy-Bag>. [Accessed: 30-Oct-2022].

Information pertaining to the advantages and disadvantages of a one-piece system versus a two piece.

3. Hytape International, “Maintaining a healthy stoma & active lifestyle with an ostomy,” *HYTAPE International*, 28-Mar-2018. [Online]. Available: <https://hytape.com/latest-news/exercise-healthy-secure-ostomy/?v=920f83e594a1>. [Accessed: 30-Oct-2022].

This source outlined the mechanics of living an active lifestyle as an ostomate.

❖ Materials research from individual milestone 2:

4. M. Stepp, “Ostomy belt advantages,” *Personally Delivered Blog*, 22-Oct-2020. [Online]. Available: <https://www.personallydelivered.com/blog/ostomy-belt-advantages/#:~:text=Constructed%20of%20a%20blend%20of,supports%20the%20>. [Accessed: 30-Oct-2022].

The materials, advantages and applications of an ostomy belt that was researched during brainstorming.

5. Wound Management & Prevention, “The Ostomy Files: Choosing a Skin Barrier,” *Hmpgloballearningnetwork.com*, Dec-2011. [Online]. Available: <https://www.hmpgloballearningnetwork.com/site/wmp/content/choosing-skin-barrier#:~:text=Ostomy%20skin%20barriers%20are%20made,skin%20for%20lon>. [Accessed: 30-Oct-2022].

Information relating to ostomy wafer materials and applications

❖ Device and user-interaction research from individual milestone 2:

Express Medical Supply, “What is Stoma Powder?,” *What is Stoma Powder? | Express Medical Supply / Medical Supply Company*, 2022. [Online]. Available: <https://www.exmed.net/what-is-stoma-powder>. [Accessed: 30-Oct-2022].

Mayo Clinic Staff, “Feel empowered after stoma surgery,” *Mayo Clinic*, 28-Jul-2022. [Online]. Available: <https://www.mayoclinic.org/diseases-conditions/colon-cancer/in-depth/ostomy/art-20045825>. [Accessed: 30-Oct-2022].

❖ Information for specific patient study

A. Henry, “Fitness and exercise with an ostomy,” *Hpfy shopostomysupplies.com*, 09-Jul-2022. [Online]. Available: <https://www.shopostomysupplies.com/ar-fitness-and-exercise-with-an-ostomy.html>. [Accessed: 30-Oct-2022].

More information on intricacies of exercise and fitness with an ostomy (Carla’s situation)

I. Valtolina, “20 failproof tips to prevent your stoma from leaking,” *Farmoderm*, 27-May-2021. [Online]. Available: <https://farmoderm.it/en/stoma-leakage-prevention-tips/>. [Accessed: 30-Oct-2022].

Researched in pursuit of inspiration of effective strategies to prevent stoma leaks and deterioration.

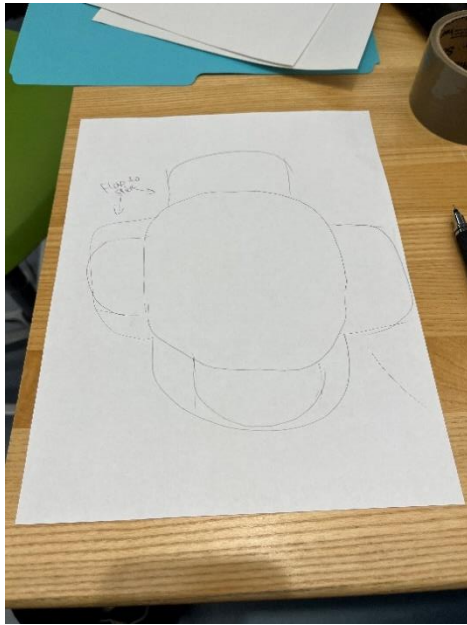
Inflammatoryboweldisease (IBD), “How do I hide an ostomy bag under clothing?: Crohnsdisease,” *InflammatoryBowelDisease.net*, 01-Jul-2016. [Online]. Available: <https://inflammatoryboweldisease.net/living/hiding-ostomy-bag>. [Accessed: 30-Oct-2022].

Information associated with remaining discrete and low profile with an ostomy bag, beneficial to tight clothing.

❖ Other general resources that furthered our general understanding of the field and lead to our solutions

M. mcNally says: I. G. T. says: K. M. D. says: T. K.-S. says: and I. G. T. says: “Are ostomy supplies covered in Canada? insurance coverage FAQ,” *Inner Good*, 04-Sep-2018. [Online]. Available: <https://innergood.ca/are-ostomy-supplies-covered-in-canada/>. [Accessed: 30-Oct-2022].

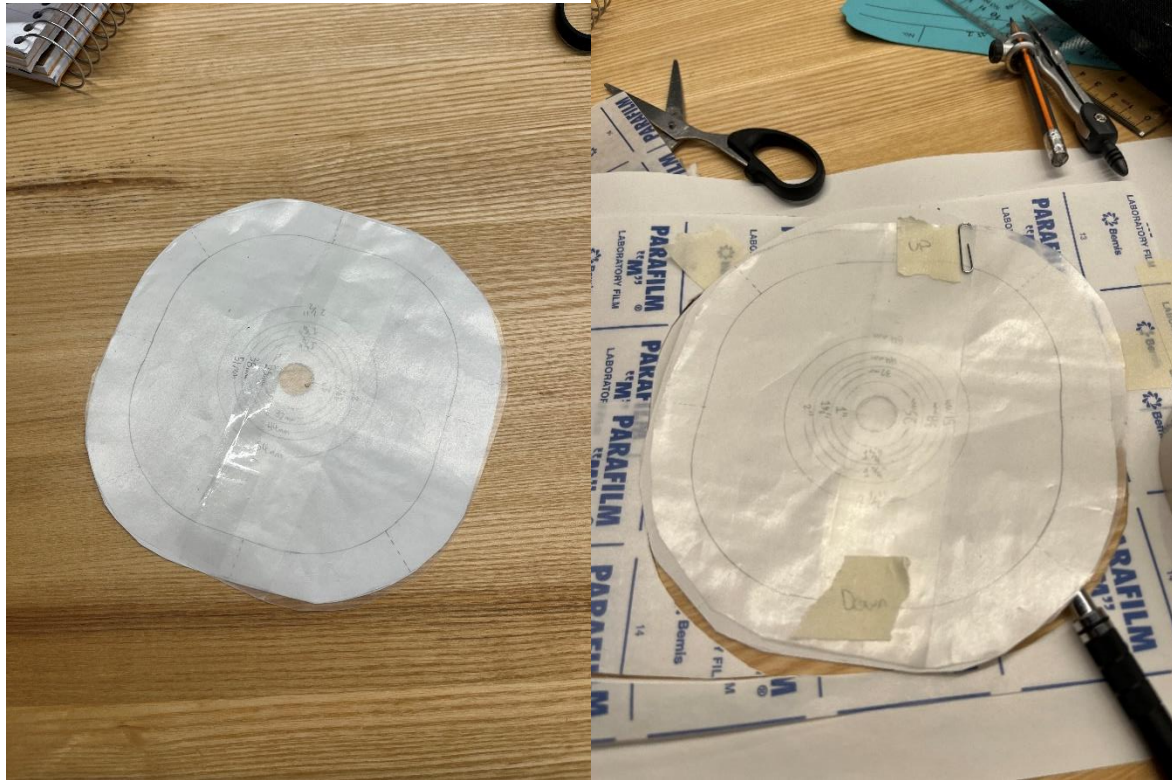
- M. Reynolds, “Dealing with ostomy leaks: Ostomy Tips,” *VeganOstomy*, 08-Feb-2022. [Online]. Available: <https://www.veganostomy.ca/ostomy-leaks-tips/>. [Accessed: 30-Oct-2022].
- S. O'Sullivan, “My stoma saved my life – but really damaged my mental health,” *My Stoma Saved Me But Damaged My Mental Health*, 07-Oct-2021. [Online]. Available: <https://www.refinery29.com/en-ca/ostomy-bag-mental-health-impact>. [Accessed: 30-Oct-2022].

Appendix D: Additional Documentation

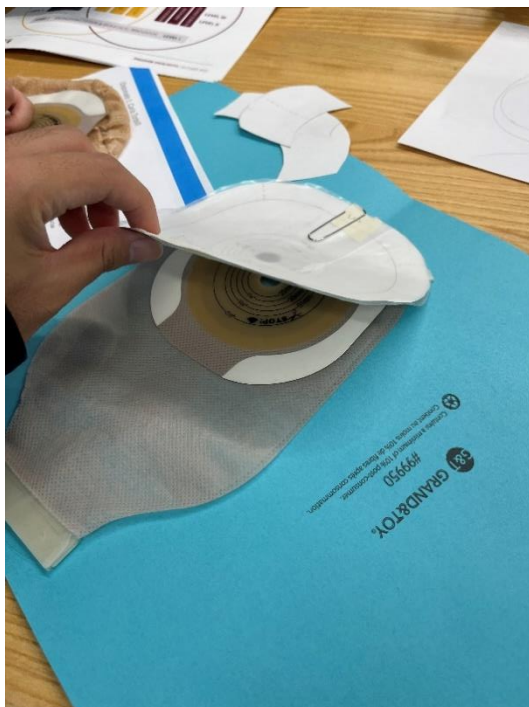
Early Sketches of Prototype



Low Fidelity Osto-Sticker with Failed Protective Layer



Low Fidelity Prototype of Skin Adhesive



Osto-Sticker Prototype connected to Ostomy Bag



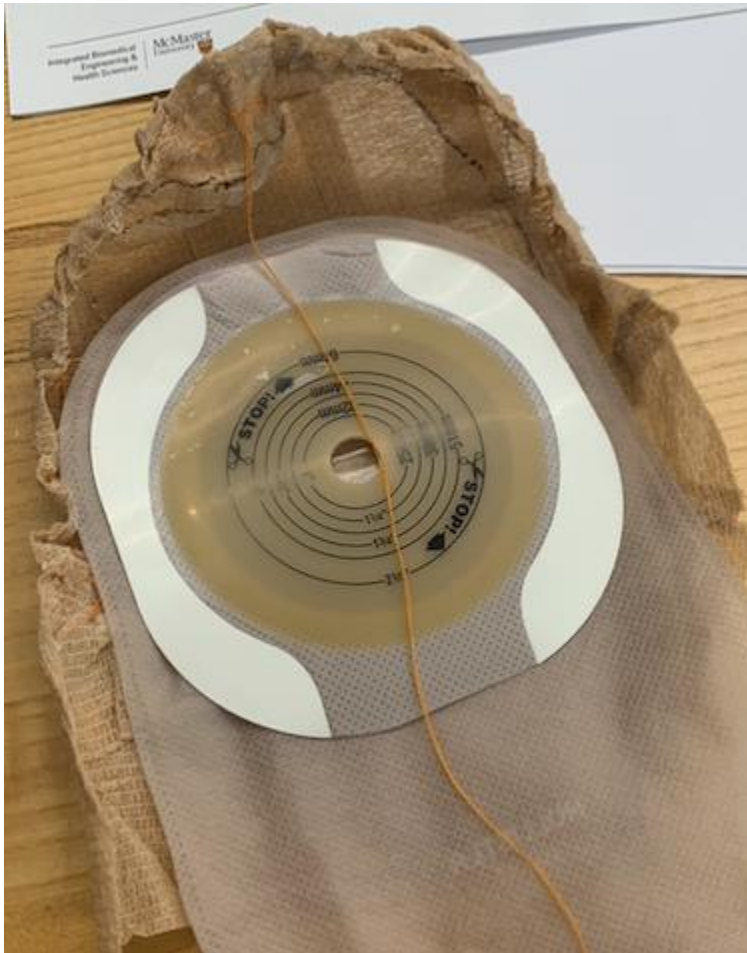
Complete Osto-Sticker Prototype with Securing Patches



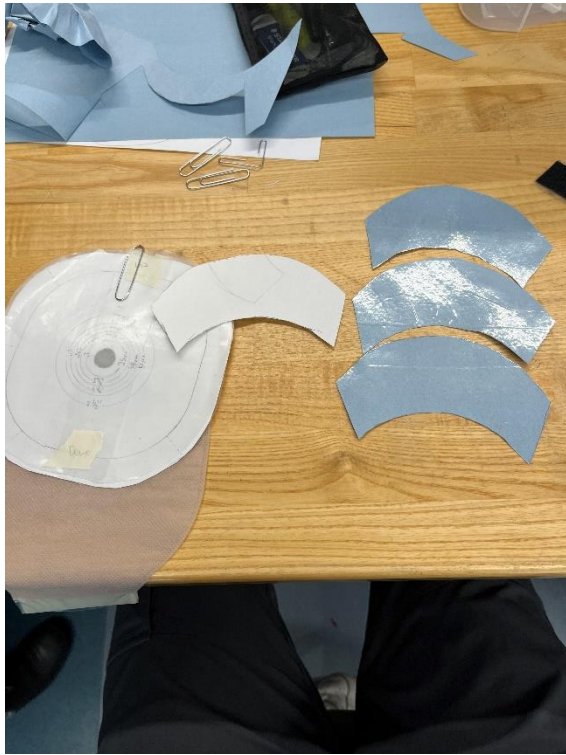
Preliminary Low Fidelity Prototype Outline of Osto-Pouch



Preliminary Low Fidelity Prototype of Osto-Pouch



Low Fidelity Prototype of Osto-Pouch with Sewing



Appendix E: Design Studio Worksheets

All Mini Milestones attached below.

IBEHS 1P10 – Project One: GI Joe – The Endoscopy Unit

Milestone 1 (Team) – Cover Page

Team Number:

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

Full Name:	MacID:
Max Fang	Fangm16
Gloria Cimpu	cimpug
Shelby Tse	tsees8
Yousef Fadhel	fadhely

Any student that is **not** present for Design Studio will not be given credit for completion of the worksheet and may be subject to a 10% deduction to their DP-1 grade.

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How often do you change your ostomy bag?

- Typically 3-7 days
- When bowel is most quiet, takes around 5-15 mins

What type to do you have and why (do you have a preference?)

- Two piece because its more secure, but more expensive

Were there any changes with your ostomy bag from the first time you received it and now?

Pros/Cons for 1 and 2-piece (guest's experience specifically)

- Peristomal hernia are common ~30%, companies will make hernia belts w an opening for the stoma
- Belt for first few hours to stick to skin (12-24hr)
- Sitting/driving brushes against flange, start leaks
- Nurse advice – rinse what you can w water, some people use alcohol wipes to remove adhesive (may be contaminated w stool)
 - o If it's still stuck after 7 days, next appliance will still stick
 - o "Less is more" when it comes to additional appliances
- Adhesive can last through a hot tub (around 5 degrees above body temperature)
- Pain when stool leaks onto damaged skin around stoma

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MILESTONE 1 (STAGE 1) – GATHERING INFORMATION

Team Number:

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.

- Complete details in this space
- Carla Tortelli
 - Age 27
 - Has an active lifestyle
 - Financial constraints
 - Prefers fitted style of clothing (1-piece > 2-piece)

Questions:

Ask about ileostomy – loosen/liquid stool consistency, would contaminate charcoal filter rendering it ineffective – instead, slightly open called "burping" to press gas out (usually go to bathroom and drain)

- plastic structure helps to convex it and prevent belt from rubbing on stoma, also bc stoma doesn't protrude enough so the structure pushes the stoma out for easier seal around it and prevent stool from going underneath
- Barrier rings (against flat part of flange) also create convexing
- Unable to eat high fibre foods
 - o Should mainly be liquid, high fibre food will solidify the stool, could cause problem with the skin opening
- Stool is very acidic especially with ileostomy
 - o If stomach acid comes in contact with skin, it burns
 - o With a poor seal, chance of skin burn from stomach acid

Have you experienced leaks with the ostomy bag, if so, approximately after how many days?

- Usually leaks at the flange

How is the pricing of healthcare surrounding this ostomy?

- Two pieces
 - o 10 bags is 300 dollars for 2 piece
 - o 10 flange are 220

How did you first adjust when starting with an ostomy bag?

Are there any constraints with the ostomy bag with an active lifestyle?

- Often use

Were there any appliances that you used to increase wear time, and how did it change your experience?

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MILESTONE 1 (STAGE 2) – OBJECTIVES AND CONSTRAINTS

Team Number:

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: attributes and/or behaviours that a design solution should have or exhibit

• e.g. should be easy to use

→ Constraints: limits or restrictions to be adhered to

• e.g. must be sterile

OBJECTIVES	<ul style="list-style-type: none"> • Reduce the occurrence of leaks • Easy to use • Improve longevity of the appliance
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CONSTRAINTS	<ul style="list-style-type: none"> • List each constraint as a separate bullet, add more if needed • Cost efficient • Lower profile for fitted clothing (preferably one piece) • Long lasting • Comfortable/flexible/good for exercise
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MILESTONE 1 (STAGE 3) – NEED STATEMENT

Team Number: **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: Design a device for Celia that reduces the frequency of leaks while maximizing wear time, in order to support an active lifestyle. This device should be able to maintain adhesion to the body through exercise, and have a lower profile.

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MILESTONE 2 (STAGE 3) – CONCEPT GENERATION

Team Number:

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 pages

IBEHS 1P10 – Project One: *Design Solutions for Improving Quality of Life*

Milestone 2 (Team) – Cover Page

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

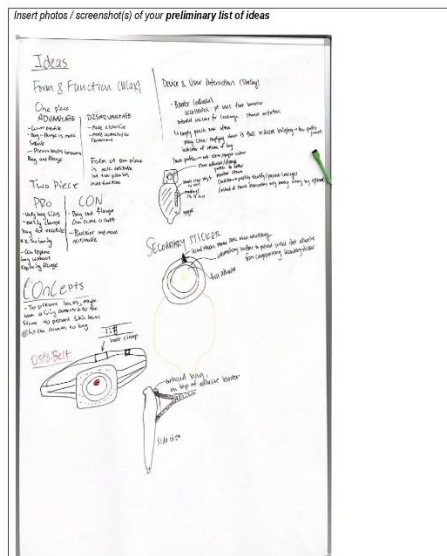
Full Name:	MacID:
Max Fang	Fangm16
Yousif Fadhel	FadhelY
Gloria Cimpu	cimpug
Shelby Tso	tsos8

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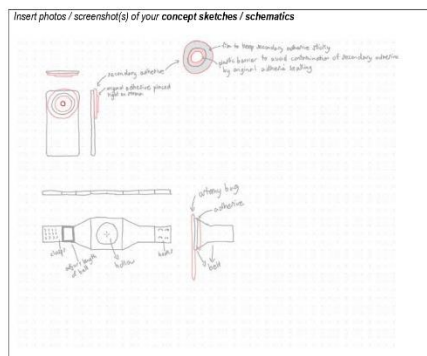
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Team Number: 

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Team Number: 

*For multiple photos / screenshots, please copy and paste the above on a new page

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MILESTONE 2 (STAGE 4) – GROUP DISCUSSION

Team Number:

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**?

<p>Clear adhesive barrier, opaque ostomy bag, clear strip to see volume of bag</p> <ul style="list-style-type: none"> - Ostomy bag remains low profile, works with constraint - Ostomy cover in skin tone with small strip to see stool bag - Strip has measured intervals/increments <p>Advantages:</p> <ul style="list-style-type: none"> - More discrete, increases the confidence and comfortability of the user - Allows the user more accuracy when seeing when they will need to drain their bag – more frequent emptying (recommended when bag is 1/3 full) can reduce bulging and increase low profile of ostomy bag <p>Disadvantages:</p> <ul style="list-style-type: none"> - Could slightly hinder visibility <p>Secondary Sticker</p> <ul style="list-style-type: none"> - Second sticker, remove seal when necessary → when first adhesive is soiled, to prevent leakage - Intermediary surface between the two adhesives to prevent the soiled first adhesive from compromising secondary sticker - Advantage: Improves lifespan of bag, since Carla cannot replace the ostomy bags as regularly due to her financial situation. Also solves the frequent 2-3 day leakages while still using the same device for the next few days - Possible Disadvantage: Feasibility – from user end point, is it easy for Carla to attach the second sticker on top of the original flange <p>Osto-Belt</p> <ul style="list-style-type: none"> - A nylon belt that will go around the waist and connects to the ostomy bag. - It will connect behind the bag itself, but on top of the adhesives, to prevent affecting the functionality of the bag while increasing the skin adhesiveness. - The belt will be attached to the waist with hooks and eyes and a strap adjuster <p>Advantages</p>	
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- Reduces skin leaks by keeping the bag stuck to the skin
- Low profile and due to the nature of an ileostomy, the belt will be worn around the waist
- Secure yet easy to use hook and eyes

*If you prefer, you may document your discussion in a separate document / file / format, take a photo/screenshot and insert it above.

- For multiple photos / screenshots, please copy and paste the above on a new page

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Milestone 3 (Team) – Cover Page

Team Number:

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

Full Name:	MacID:
Max Fang	fangm16
Yousif Fadhol	fadholy
Shelby Tse	tset8
Gloria Cimpu	cimpug

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MILESTONE 3 (STAGE 1) – DESIGN CONFIGURATION

Team Number:

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.

Form and Function

- **Ostobelt:**
 - *Form:* The ostobelt will come in the form of a narrow, slightly elastic, and comfortable belt that will hang around the waist. The belt will be made of different fabrics of different elasticity. There will be a stiffer fabric to secure the ostomy belt, and a softer fabric around the waist for comfort.
 - *Function:* The belt will be attached to the upper and lower ends of the ostomy bag and will not impact ostomy bag function. The belt will be help together with a secure hook and eyes mechanism and will secure the ostomy bag through a g hook and fabric loop.
- **Cover:**
 - *Form:* Close to the shape of the ostomy bag to fit snugly over it without losing shape, skin-coloured, small transparent slit with volume markings.
 - *Function:* Skin-coloured cover is low profile, which is one of Carla's desired traits. Provides an easy and accessible way to monitor how full the bag is so Carla can empty it more often to prevent leakages. Since the material will not stretch out to lose shape, the volume markings will remain consistent and the cover can be reused multiple times (making it more cost efficient).
- **Secondary Sticker:**
 - *Form:* The secondary sticker will be another adhesive layer that goes on top of the original sticker and wraps around the entire original sticker, sticking on to the material on the back of the flange. The secondary sticker will serve the same purpose of the original sticker and will create a tight adhesion to the skin.
 - *Function:* The goal of the secondary sticker is to maximize the lifespan of one ostomy bag. The secondary sticker allows the ostomy bag to still be usable even after a skin leak. In the case of a leak, the user will be able to take the exterior, non-usable sticker off and use the brand-new sticker underneath.

Fabrication and Assembly

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MILESTONE 3 (STAGE 2) – PRELIMINARY PROTOTYPING

Team Number:

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	<i>Document your work in the space below</i> <ul style="list-style-type: none">• Ostomy belt that hangs around the waist and is connected by a hook and eyes clamp and secures the ostomy bag through a g hook with a fabric loop.• A secondary sticker that attaches on to the original sticker that creates another adhesive layer.• An ostomy bag cover that goes over the original bag and is secured behind to the original bag through an elastic ring.
Modifications to existing medical device (if applicable)	<i>Document your work in the space below</i> <p>We will not be modifying our original bag. Our components are more of an addition to the ostomy bag, instead of a modification.</p>
Materials to be used	<i>Document your work in the space below</i> <ul style="list-style-type: none">• For our ostomy belt prototype, we would use nylon fabric for the belt, and a rubber band to mimic the clasp. We would also need to cut a hole in the nylon fabric for where the use would insert the flange.• For the secondary sticker's low fidelity prototype we would use a paper to represent the sticker, and how it would attach on to the original flange.• Ostomy bag cover: For our ostomy bag cover we will use thin fabric to represent the spandex material. A loose elastic band or string will be used to create the elastic lining and threaded through the fabric

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Tools and processes required to fabricate your prototype	Document your work in the space below
	<ul style="list-style-type: none">• Scissors• Measuring devices (Measuring tape, rulers)• Sewing materials (thread, needle)

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Team Number:

If applicable, insert photos / screenshot(s) documenting any early builds of your prototype
**Important: this is NOT required, but should be done for documentation purposes (if your team has progressed to this point)*

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