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# **Design Project 1 – GI Joe – The Endoscopy Unit**

OstoME

*IBEHS 1P10 – Health Solutions Design Projects*

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Tutorial 04

Team 9

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Submitted: October 30<sup>th</sup>, 2022

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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.

Josiah Kim 400365328



(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.

Marco Tan 400433483



(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.

Aditi Srinivas 400431472



(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.

Aleen Al Barbarwi 400433335



(Student Signature) \*

## **Executive Summary**

An Ostomy bag is a medical device that might be used temporarily or permanently after an ostomy surgery. This device may be necessary to people due to birth defects, cancer, inflammatory bowel disease, diverticulitis, incontinence etc. as well as in cases of severe abdominal or pelvic trauma resulting from accidents [1]. This device allows bodily waste (stool) to pass through a surgically created stoma (opening) on the abdomen into the ostomy bag that is attached to the stoma on the outside of the body, allowing the ostomy bag to be emptied once it is full of stool [2].

While an ostomy bag does improve the quality of life for its users, using this medical device comes with its own set of challenges. Common problems with ostomy bags currently on the market include frequent leakage, lack of adhesion to the body (especially during physical activity due to sweat), high purchase and upkeep costs, and general lack of discreteness. Many ostomates such as Carla Tortelli face these problems, often in conjecture with each other, daily. These problems can be extremely draining both mentally and financially, not allowing ostomates to live life to the fullest.

The solution our team proposed to this problem is called OstoME. This is a take on the common one-piece ostomy bag that has a Velcro emptying mechanism, and attachment to the body via an adhesive patch that can be cut to fit around an ostomate's stoma. However, the OstoME bag has an extra layer of fabric to cover the plastic outside of the bag which helps dampen noise made by the bag moving, making the bag more discrete. Additionally, the size of the adhesive patch has been increased while retaining the size of the bag itself. The adhesive patch uses a high-grade skin friendly adhesive which allows the bag to adhere to the body for as long as necessary allowing the bag to be cost-effective. Finally, a seal has been added around the area where the bag would be cut to fit the stoma, allowing the bag to be more leak resistant.

Overall, the goal of this solution was to retain everything ostomates already liked about the common one-piece ostomy bag while making modifications that allow the bag to perform its functions even better. This would mean our solution is cost-effective and would allow ostomates to live life to the fullest.

## Main Body

### Engineering Design Process

For the design project, it is important that our team utilises the engineering design process as that would help us create a solution that best fit the objectives and constraints of the problem. The engineering design process helps to progressively narrow down the scope of a problem to prevent problems such as developing unnecessary features for a solution or wasting resources when it is determined that a solution does not fit the constraints of the original problem.

The first part of the engineering design process was to identify the problem and to determine the objectives and constraints of the problem. The problem we were handed was to address the leaking ostomy bag of Carla Tortelli. We noted that the following objectives would have to be met to address the problem that we identified:

- The seal of the ostomy bag should be strong/durable.
- It should be comfortable to wear.
- The bag should be long lasting.
- It should be skin friendly.
- It should create less noise.

In addition to these objectives, we recognized the following constraints were necessary to further narrow down the problem definition:

- The bag must be inconspicuous under fitted clothing.
- The bag must support active lifestyle.
- It must fit her physical dimensions (be low profile).
- It must be financially accessible (no more than \$10/per bag).
- All other constraints that are applicable to an ostomy bag are also applicable to this design.

Using these objectives and constraints, the final need statement was generated to be our guiding question during the development of this solution:

*Design improvements upon Carla Tortelli's one-piece ostomy bag to prevent leakage from its seal at the skin and improve overall performance and longevity of the bag. This should improve her quality of life by reducing maintenance costs and stress associated with living with an ileostomy while supporting her lifestyle.*

After we defined our problem, our next step was to brainstorm ideas using preliminary research. To conduct preliminary research as effectively as possible, we opted to break down the research amongst our group and have each person focus on a specific design dimension. We broke down the research into the following design dimensions:

- Materials.
- Form and function.
- User interaction.

Through this research, we were able to start brainstorming about potential ideas that we could use to approach this problem. After collecting our ideas together, we produced three preliminary designs that we wanted to further pursue (see Milestone 2 attached). Our finalized solution (see Milestone 3 attached) ended up being a combination of all three designs as we decided that the combination of all positives for all three designs outweighed the potential deficiencies in each design.

## **Materials Research**

Materials research was conducted from September 22 to September 29, with the goal of compiling a list of materials that would effectively supplement the double-layered pouch design (see Milestone 3 attached). Dividing the inner and outer layers of the pouch and the material composition of the skin barrier, around the stoma, was the first action our team did. Afterwards, research was done for each individual component. The inner layer was expected to be:

- Waterproof, as to mitigate leaking.
- Airtight, as to mitigate odour, although not too airtight as it would encourage bloating.
- Flexible, while resilient to physical and environmental factors.
- Affordable and proven for the above factors.

Given these considerations, our team chose a GoreTex-based inner layer, otherwise known as ePTFE (extended polytetrafluoroethylene), for being waterproof, flexible, and durable in all-weather environments, perfect for our patient's active lifestyle [3]. This was chosen over collagen and cellulose-based organic material, because while they were porous and durable, they were not renewable (being disposed every week) and posed a risk of odour from excrement being absorbed by the layer itself.

For the outer layer, we wanted to both provide a secondary layer of protection and to improve the aesthetic appearance of the ostomy bag, as to reduce stigma and the synthetic look of common ileostomy bag materials. As such, nylon fabric was chosen for the outer layer; nylon is easy to wash, easy to produce, lightweight and doesn't generate as much noise as traditional ostomy bag plastics [4]. Nylon is also colourable,

allowing for a variety of colours and patterns to be applied onto the ostomy bag, making it appear less medicinal and synthetic and more natural as if it was clothing.

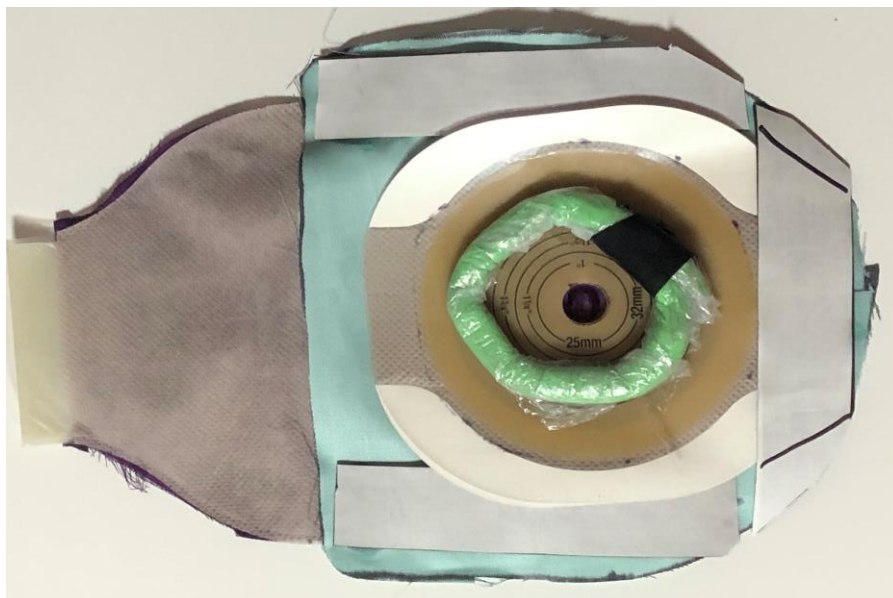
Finally, our team decided to use a hydrogel ostomy adhesive (HOA) to address the skin barrier. HOA is biocompatible with human skin, durable and resilient against external physical forces [5]. It is also soft on skin, reducing potential for irritation. Adding a HOA ring tightly onto the skin barrier would allow comfort and stability around the stoma.

### **Final Product and Post-Design Analysis**

Carla is an active and fashionable woman. She was having leakage problems with her ostomy bag. Additionally, her ostomy bag cost her a lot of money and she was needing to change them quite often. Therefore, we needed a design to prevent leakage from the seal and improve the overall performance and longevity of the bag, while improving her quality of life by reducing costs and stress associated with living with an ileostomy.

Increasing the surface area of the skin barrier and making it more adhesive addresses the problem of high leakage and makes the output much easier. This is done by having a stronger sticky patch that allows more durability while retaining the original size of the bag itself. The highlight of making it more adhesive is that it is easier to maintain an active lifestyle and make the bag more durable during day and night. Additionally, the bag having a double layer in which the outer layer is of fabric helps reduce the noise made by the bag but keeping the inner layer a hydrophobic plastic allows the bag to retain its waterproof qualities.

*Image 1: Low Fidelity Prototype of proposed design solution*



## Reference List

- [1] B. Cancaster, “Choosing an Ostomy Pouch Made Easy,” *Vitality Medical*, Dec. 15, 2015. <https://www.vitalitymedical.com/blog/choosing-an-ostomy-bag.html> (accessed Oct. 18, 2022).
- [2] J. Fletcher and S. M. D. , M. Sethi, “Colostomy bag: Types, uses, and living with one,” *MedicalNewsToday*, Sep. 16, 2019. <https://www.medicalnewstoday.com/articles/326353> (accessed Oct. 15, 2022).
- [3] N. Ph. D. Clough E., “Innovations in ePTFE Fiber Technology : New Capabilities, New Applications, New Opportunities.”
- [4] BCJ Team, “Nylon Plastic Benefits & uses,” BCJ Plastic Products, 02-Aug-2021. [Online]. Available: <https://bcjplastics.com.au/nylon-plastic-benefits-and-uses/>. [Accessed: 30-Oct-2022].
- [5] W. Pan, B. Matsuda, and H. Yuk, “Biocompatible Hydrogel Ostomy adhesive,” *MEDICAL DEVICES AND SENSORS*, vol. 3, no. 6, Oct. 2020.

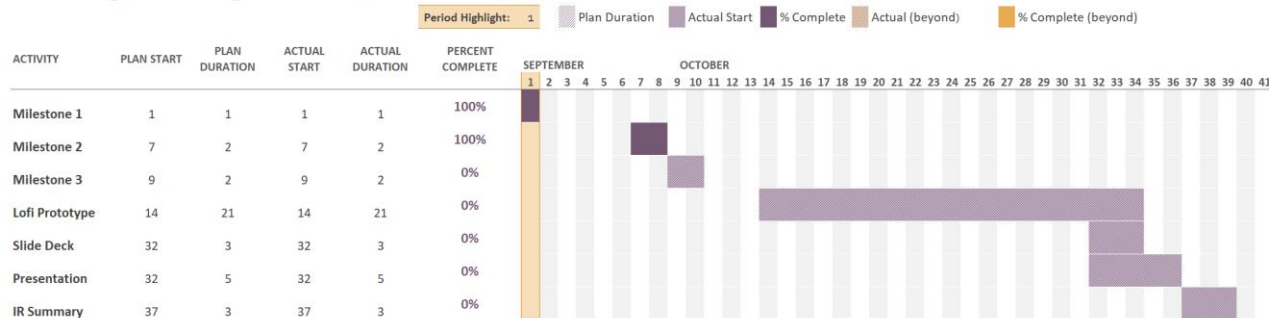


## Appendices

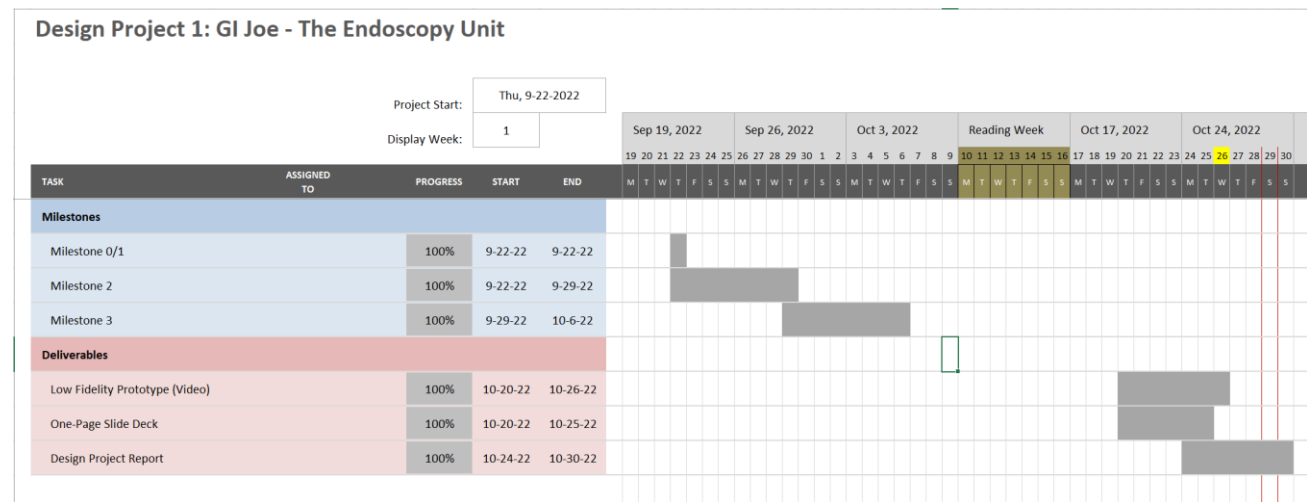
### Appendix A: Project Schedule (Preliminary and Final Gantt Chart)

Preliminary Gantt Chart (Josiah Kim)

#### Design Project 1 [Team 9]



Final Gantt Chart (Aditi Srinivas)



## Appendix B: Scheduled Weekly Meetings

### Design Studio

#### ❖ Had a discussion with the nurse and the patients to get to know how the ostomy bag works and how they live with it

<ul style="list-style-type: none"> <li>• How is an ostomy bag cleaned?</li> </ul>	<ul style="list-style-type: none"> <li>→ depends on the parts involved, e.g.: colon cancer, we take the colon out.</li> <li>→ Easiest way to take faeces out is by the stomach.</li> <li>→ Nutrient absorption// dehydration</li> <li>→ Big, fancy diaper// no conscious way to control</li> <li>→ One piece bag is more flexible</li> <li>→ 2 piece is not flexible, needs coupling</li> </ul>
<ul style="list-style-type: none"> <li>• Does diet need to change/ What do you do to maintain your diet/health?</li> </ul>	<ul style="list-style-type: none"> <li>→ No diet change is need.</li> <li>→ Eating Food that gives u constipation. Eg: salty, vinegar, starch, junk food</li> <li>→ Texture is more important than the actual food</li> </ul>
<ul style="list-style-type: none"> <li>• Night Management</li> </ul>	<ul style="list-style-type: none"> <li>→ Depends. if the leaking is a lot (high output), they must wake up at night or put an alarm.</li> <li>→ Depends on volume, consistency</li> </ul>
<ul style="list-style-type: none"> <li>• The texture of the ostomy bag</li> </ul>	<ul style="list-style-type: none"> <li>→ No irritation or rash</li> <li>→ a lot of technology is put into the product,</li> <li>→ makes the skin friendly.</li> <li>→ Sweaty—absorb sweat from the skin while it still attaches.</li> <li>→ Protects skin by preventing leaking (wax)</li> </ul>
<ul style="list-style-type: none"> <li>• How are materials chosen for an ostomy bag?</li> </ul>	<ul style="list-style-type: none"> <li>→ Skin friendly,</li> <li>→ resistant to breakdown</li> <li>→ flexible</li> <li>→ skin barrier because some patients must catheterize to release</li> </ul>
<ul style="list-style-type: none"> <li>• How do you generalize design to fit the ostomy?</li> </ul>	<ul style="list-style-type: none"> <li>→ Overall shape is very general. Some Pouches are created to be fully closed so they do not have an opening (swap pouches)</li> </ul>

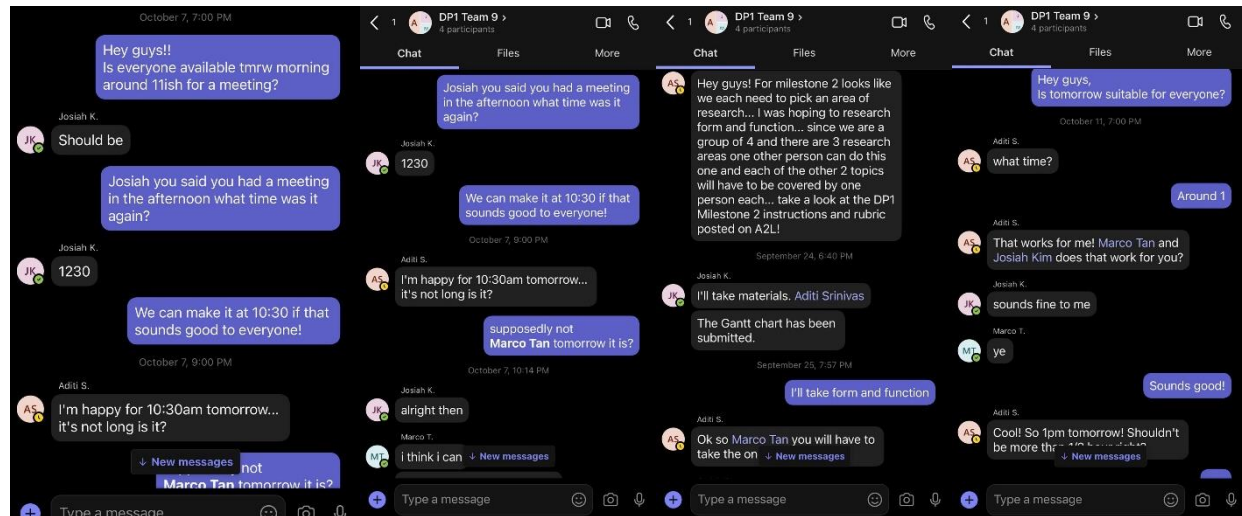
<ul style="list-style-type: none"> <li>• How does it feel like to live with one/ what are the effects on activities?</li> </ul>	<ul style="list-style-type: none"> <li>→ Activities does not affect.</li> <li>→ More sweat leads to changing more often.</li> <li>→ Life does not change.</li> <li>→ Life is better for most people.</li> <li>→ Ostomy is life changing.</li> <li>→ Weight changes, fluctuation, body changes</li> </ul>
<ul style="list-style-type: none"> <li>• Dealing with it psychologically</li> </ul>	<ul style="list-style-type: none"> <li>→ Adjust psychologically (tips and advice),</li> <li>→ talking to someone that has it (understanding)</li> </ul>
<ul style="list-style-type: none"> <li>• Was it a hassle?</li> </ul>	<ul style="list-style-type: none"> <li>→ Marriages were broken up which caused mental issues</li> <li>→ Suicides are life changing</li> <li>→ Creates a barrier especially first year</li> </ul>
<ul style="list-style-type: none"> <li>• Was the Transition hard?</li> </ul>	<ul style="list-style-type: none"> <li>→ It is tougher if they have no idea,</li> <li>→ For kids - they get bullied quickly, yet easier because they are growing up with it</li> <li>→ A Challenge at any age</li> <li>→ Educating/normalizing people is important for them</li> </ul>
<ul style="list-style-type: none"> <li>• Wishlist</li> </ul>	<ul style="list-style-type: none"> <li>→ It happens, more reliable that will not fall apart.</li> <li>→ Soundproof</li> </ul>

❖ **Discussed about assorted designs of the ostomy bag**

- Designing a bag that is reusable, but the seal is replaceable which reduces the cost
- Designing a Double layer bag to reduce noise
- Inner: hydrophobic gortex (used in raincoats) polymer/plastic Outer: fabric
- Seal--> hydrogel ostomy adhesive which keeps the bag in place and removes leakage
- Designing a bag with a larger skin surface area

❖ **Discussed and outlined the properties of each material option and select the best option that fits our needs and can be used in an ostomy bag.**

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

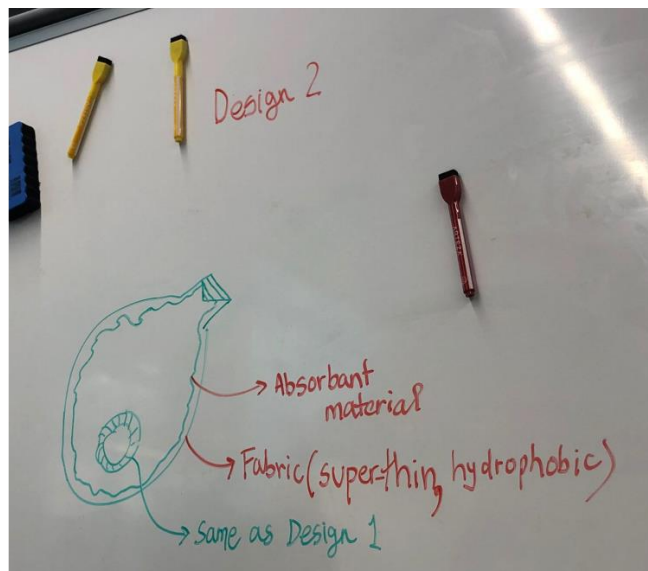
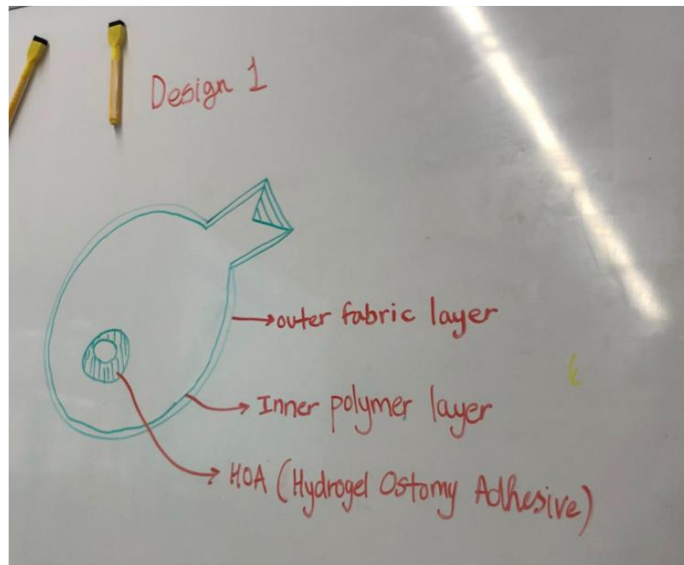


## Appendix C: Comprehensive List of Sources (Marco Tan)

- [1] B. Cancaster, “Choosing an Ostomy Pouch Made Easy,” *Vitality Medical*, Dec. 15, 2015. <https://www.vitalitymedical.com/blog/choosing-an-ostomy-bag.html> (accessed Oct. 18, 2022).
- [2] J. Fletcher and S. M. D. , M. Sethi, “Colostomy bag: Types, uses, and living with one,” *MedicalNewsToday*, Sep. 16, 2019. <https://www.medicalnewstoday.com/articles/326353> (accessed Oct. 15, 2022).
- [3] N. Ph. D. Clough E., “Innovations in ePTFE Fiber Technology : New Capabilities, New Applications, New Opportunities.”
- [4] “Nylon Plastic Benefits & Uses,” *BCJ Plastic Products*. <https://www.byramhealthcare.com/ostomy-care/overview> (accessed Oct. 29, 2022).
- [5] “Ostomy Care,” *Byram Healthcare*. <https://www.byramhealthcare.com/ostomy-care/overview> (accessed Oct. 29, 2022).
- [6] Ravikanth, “Advancements in Ostomy Systems,” *Scitech Patent Art*. <https://www.patent-art.com/jp/knowledge-center/advancements-in-ostomy-systems-jp/> (accessed Oct. 29, 2022).
- [7] “Ostomy Nursing: Stoma Care After Surgery,” *Cleveland Clinic*. <https://my.clevelandclinic.org/departments/digestive/depts/woc#woc#overview-tab> (accessed Oct. 29, 2022).
- [8] C. Hirunsupachot, P. Potiyaraj, and A. Kongchan, “Innovation for Biomedical Waste Disposal by Using Inner Ostomy Bag as a Case Study,” 2021.
- [9] W. Pan, B. Matsuda, and H. Yuk, “Biocompatible hydrogel ostomy adhesive,” *Med Devices Sens*, vol. 3, no. 6, Dec. 2020, doi: 10.1002/mds3.10132.
- [10] J. Alexander-williams *et al.*, “Clinical Topics Magnetic continent colostomy device,” 1977.
- [11] F. Alwi, Setiawan, and Asrizal, “Quality of life of persons with permanent colostomy: a phenomenological study,” *Journal of Coloproctology*, vol. 38, no. 4, pp. 295–301, Oct. 2018, doi: 10.1016/j.jcol.2018.06.001.
- [12] K. L. Simmons, J. A. Smith, K. A. Bobb, and L. L. M. Liles, “Adjustment to colostomy: Stoma acceptance, stoma care self-efficacy and interpersonal relationships,” *J Adv Nurs*, vol. 60, no. 6, pp. 627–635, Dec. 2007, doi: 10.1111/j.1365-2648.2007.04446.x.
- [13] J. Alexander-williams *et al.*, “Clinical Topics Magnetic continent colostomy device,” 1977.

## Appendix D: Additional Documentation

Descriptions of prototypes that did not make it past Milestone 2:



## Appendix E: Design Studio Worksheets

### Milestone 0 (Team)

Team Number: 9

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

Full Name:	MacID:
Marco Tan	tanm27
Josiah Kim	Kim190
Aleen Al Barbarawi	albarbaa
Aditi Srinivas	srinia14

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.

Please attach your Team Portrait in the dialog box below.



## Milestone 0 – Team Charter

Team Number:

9

***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

<b>Role:</b>	<b>Team Member Name:</b>	<b>MacID &amp; Signature</b>
Manager	Josiah	kim190
Administrator	Aditi	srinia14
Coordinator	Aleen	albarbaa
Subject Matter Expert	Marco	tanm27



## Milestone 1 (Team)

Team Number: 

9
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Please list full names and MacID's of all *present* Team Members.

Full Name:	MacID:
Marco Tan	tanm27
Josiah Kim	Kim190
Aleen Al Barbarawi	albarbaa
Aditi Srinivas	srinia14

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.

## Milestone 1 (Stage 1) – Gathering Information

Team Number:

9

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

How do you clean an ostomy bag

- depends on the parts involved, e.g.: colon cancer, we take the colon out.
- Easiest way to take faeces out is by the stomach.
- Nutrient absorption// dehydration
- Big, fancy diaper// no conscious way to control
- One piece bag is more flexible
- 2 piece is not flexible, needs coupling

Does diet need to change. / What do you do to maintain your diet/health

- No diet change is need.
- Eating Food that gives u constipation. Eg: salty, vinegar, starch, junk food
- Texture is more important than the actual food

Where is it usually placed?

- lower abdominal area depending on where stoma is

Night Management

- Depends. if the leaking is a lot (high output), they must wake up at night or put an alarm.
- Depends on volume, consistency
- Often depends on how fast you it fills

The texture of the ostomy bag

- No irritation or rash, a lot of technology into the product, makes the skin friendly. Sweaty—absorb sweat from the skin while it still attaches.
- Protect skin by preventing leaking (wax)

Life issues.

- Impacts if there is not confidence
- 1000 dollars by government, financial problems. Impacts so much of their lives.
- If there is a Drug plan that covers that is helpful but if not Some move to different provinces
- Strung down if the if the stoma is behind skin
- You get Hernia if you do not have good muscles
- Alcohol free products are more expensive because it does not work for children/allergies

**How do you make an ostomy bag cost effective to buy?**

- barriers \$100
- pouches \$70
- 100 dollars for 10 bags

**How do you pick materials for ostomy**

- Skin friendly, resistant to breakdown, something flexible, skin barrier because Some Patients must Catheterize to release
- Cons: tear because its plastics, manufacturer problems, tear skin down

**How do you generalize design to fit the ostomy**

Overall shape is very general. Some Pouches are created to be fully closed so they do not have an opening (swap pouches)

-----What  
**does it feel like to live with one/ activities**

- Activities does not affect.
- More sweat leads to changing more often.
- Life does not change.
- Life is better for most people.
- Ostomy is life changing.
- Weight changes, fluctuation, body changes

**How do u manage it**

- Change one day- kills skin
- Changing Average 2-4 days

**Dealing with mental pressure**

- Adjust psychologically (tips and advice),
- talking to someone that has it (understanding)

**From using it, was it a hassle (Life hampering)**

- Marriages broken up (mental issues)
- Suicides --> life changing
- Creates a barrier especially first year

**Was the Transition hard?**

- It is tougher if they have no idea,
- For kids, they get bullied, yet easier because they are growing up with it
- A Challenge at any age
- Educating/normalizing people is important for them

**Wishlist**

1. It happens, more reliable that will not fall apart.
2. Soundproof(sol) (Wishlist)

## Milestone 1 (Stage 2) – Objectives and Constraints

Team Number: 

9
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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

<b>OBJECTIVES</b>	<ul style="list-style-type: none"> <li>• Seal should be strong/durable.</li> <li>• <i>Should be comfortable to wear</i></li> <li>• <i>Bag should be long lasting</i></li> <li>• Should be skin friendly.</li> <li>• <i>Should create less noise</i></li> </ul>
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<b>CONSTRAINTS</b>	<ul style="list-style-type: none"> <li>• Must be inconspicuous under fitted clothing</li> <li>• Must support active lifestyle</li> <li>• It must fit her physical dimensions (be low profile).</li> <li>• It must be financially accessible (<i>no more than \$10/per bag</i>).</li> <li>• <i>All other constraints that are applicable to an ostomy bag</i></li> </ul>
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## Milestone 1 (Stage 3) – Need Statement

Team Number: 

9
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### 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?)

<b>NEED STATEMENT:</b>	Design improvements upon Carla Tortelli’s one-piece ostomy bag to prevent leakage from its seal at the skin and improve overall performance and longevity of the bag. This should improve her quality of life by reducing maintenance costs and stress associated with living with an ileostomy while supporting her lifestyle.
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## Milestone 2 (Individual) – Josiah Kim

Team Number: 9

Please list full name and MacID.

Full Name:	MacID:
Josiah Kim	Kim190

Team Number: 9

Complete this worksheet individually *before* coming to Design Studio 4.

1. Select **ONE design dimension** from the Milestone Two instructions
2. Document your preliminary search
  - Bullet-point format is acceptable
3. Indicate the sources of your research
  - At this stage, it is ***not required*** that you properly cite your work using IEEE (however, this will be required as part of your final submission)

Selected Design Dimension	Materials
---------------------------	-----------

<b>Preliminary Research</b>	<p><i>Document your preliminary research in the space below</i></p> <ul style="list-style-type: none"> <li>• Collagen and cellulose provide a relatively durable and porous material for ostomy bags that are quiet; although they are not renewable and must be disposed thoroughly.</li> <li>• Leakage is a health problem as bacteria from human excrement inside the ostomy bag can cause infection and irritation. The main source of leakage is at the skin barrier.</li> <li>• Adhesives used to connect the skin barrier with the bag are often prone to tearing and require additional support through other pastes, attachments and supplements.</li> <li>• Modern adhesive layers are a blend of polyisobutylene, pectin, gelatine and sodium carboxymethylcellulose. This mixture requires supplements to provide comfort and additional durability such as pastes, powders or additional layers of adhesive.</li> <li>• HOA (hydrogel ostomy adhesive) has potential to be a viable alternative to current adhesives: it is biocompatible with human skin, robust and durable to external forces which would otherwise peel it off and has mechanical softness to mitigate irritation.</li> <li>• One method of skin care and adhesive that should be considered is double layering; with one layer providing comfort and softness while the other provides practical durability and adhesiveness to keep the bag together. An example of this is SenSura.</li> </ul>
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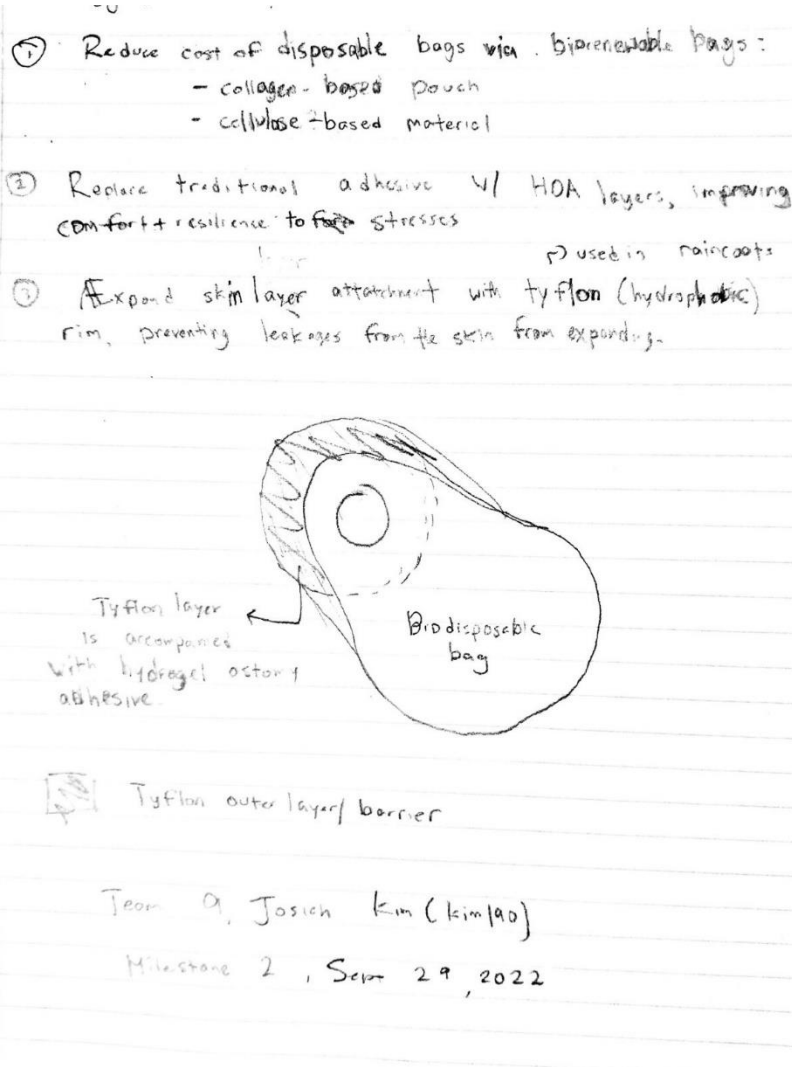
<b>Sources</b>	<p><i>List all your sources (e.g., journal articles, book chapters, websites, etc.)</i></p> <ul style="list-style-type: none"><li>• <a href="https://onlinelibrary.wiley.com/doi/full/10.1002/mds3.10132">https://onlinelibrary.wiley.com/doi/full/10.1002/mds3.10132</a></li><li>• <a href="http://buscompress.com/uploads/3/4/9/8/34980536/riber_10-s1_26_u20-026_294-321.pdf">http://buscompress.com/uploads/3/4/9/8/34980536/riber_10-s1_26_u20-026_294-321.pdf</a></li><li>• <a href="https://products.coloplast.ca/coloplast/ostomy-care/sensura-hospital-assortment/sensura-post-op-pouch/">https://products.coloplast.ca/coloplast/ostomy-care/sensura-hospital-assortment/sensura-post-op-pouch/</a></li></ul>
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Team Number:

9

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2. Take a photo of your work
3. Insert your photo as a Picture (Insert > Picture > This Device)



Milestone 2 (Individual) - Aditi Srinivas

Team Number:

9

Please list full name and MacID.

Full Name:	MacID:
Aditi Srinivas	srinia14

Team Number: 9

Complete this worksheet individually *before* coming to Design Studio 4.

1. Select **ONE design dimension** from the Milestone Two instructions
2. Document your preliminary search
  - Bullet-point format is acceptable
3. Indicate the sources of your research
  - At this stage, it is ***not required*** that you properly cite your work using IEEE (however, this will be required as part of your final submission)

Selected Design Dimension	<i>Form and Function</i>
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<b>Preliminary Research</b>	<ul style="list-style-type: none"> <li>• Bag that collects fecal matter from the digestive tract through an opening in the abdominal wall called a stoma.</li> <li>• A pouching system consists of:                             <ul style="list-style-type: none"> <li>○ A flange, wafer, or skin barrier that attaches to the skin around the stoma.</li> <li>○ A pouch that attaches to the flange and collects the stool as it passes through the stoma.</li> </ul> </li> <li>• Pouching systems come in two basic types:                             <ul style="list-style-type: none"> <li>○ A one-piece system where the bag attaches directly to the skin around the stoma.</li> <li>○ A two-piece system where the flange attaches to the skin around the stoma and the bag attaches to the flange.</li> </ul> </li> <li>• Qualities looked for by ostomy bag users                             <ul style="list-style-type: none"> <li>○ Odour proof</li> <li>○ Comfortable</li> <li>○ Skin Friendly</li> <li>○ Easy to use</li> <li>○ Leak proof</li> <li>○ Discreet/Low Profile</li> </ul> </li> </ul> <p>More detail when actually building the prototype</p> <ul style="list-style-type: none"> <li>• Design features/decisions will vary based on need of the user/features required in bag</li> <li>• No bag can do everything...necessary to prioritize the functions that are the most important</li> </ul>
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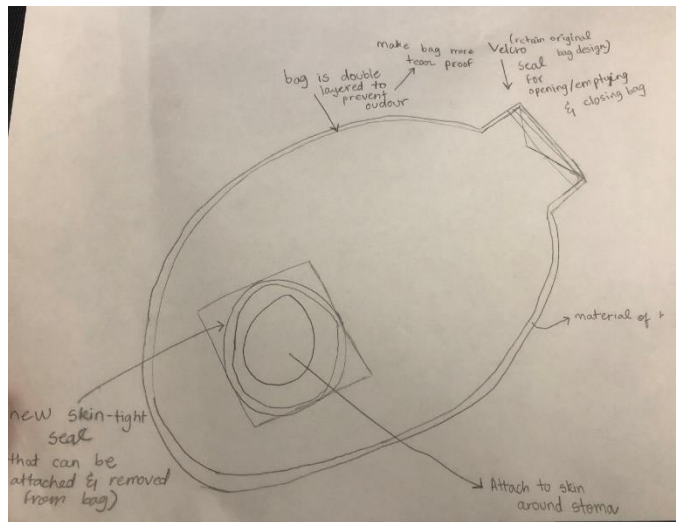
	<ul style="list-style-type: none"> <li>Type of bag required by a patient will also depend on the kind of ostomy they have had as the needs of each ostomy situation are different à Refer to case study when talking about solution for our specific patient.</li> </ul>
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<b>Sources</b>	<ol style="list-style-type: none"> <li><a href="https://www.medicalnewstoday.com/articles/326353">https://www.medicalnewstoday.com/articles/326353</a></li> <li><a href="https://www.vitalitymedical.com/blog/choosing-an-ostomy-bag.html">https://www.vitalitymedical.com/blog/choosing-an-ostomy-bag.html</a></li> </ol>
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Team Number: 9

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Milestone 2 (Individual) – Marco Tan

Team Number: 

9
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Please list full name and MacID.

Full Name:	MacID:
Marco Tan	tanm27

Team Number: 9

Complete this worksheet individually *before* coming to Design Studio 4.

1. Select **ONE design dimension** from the Milestone Two instructions
2. Document your preliminary search
  - Bullet-point format is acceptable
3. Indicate the sources of your research
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<b>Selected Design Dimension</b>	<i>Device and User Interaction</i>
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<b>Preliminary Research</b>	<p><i>Document your preliminary research in the space below</i></p> <ul style="list-style-type: none"> <li>• Patients have low competence in maintenance of their colostomies with current colostomy technologies. [4]</li> <li>• The difficulty of maintaining a stoma (financially, management, social stigma) means people are less likely to accept their colostomies, causing a feedback loop. [4]</li> <li>• Leakage is one of the main problems with maintaining a stoma (leakage at the stoma site). [4], [5]</li> <li>• Continence is also an issue. [6]</li> </ul>
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<b>Sources</b>	<p><i>List all your sources (e.g., journal articles, book chapters, websites, etc.)</i></p> <p>[1] B. Cancaster, “Choosing an Ostomy Pouch Made Easy,” <i>Vitality Medical</i>, Dec. 15, 2015. <a href="https://www.vitalitymedical.com/blog/choosing-an-ostomy-bag.html">https://www.vitalitymedical.com/blog/choosing-an-ostomy-bag.html</a> (accessed Oct. 18, 2022).</p> <p>[2] J. Fletcher and S. M. D. , M. Sethi, “Colostomy bag: Types, uses, and living with one,” <i>MedicalNewsToday</i>, Sep. 16, 2019. <a href="https://www.medicalnewstoday.com/articles/326353">https://www.medicalnewstoday.com/articles/326353</a> (accessed Oct. 15, 2022).</p> <p>[3] N. Ph. D. Clough E., “Innovations in ePTFE Fiber Technology : New Capabilities, New Applications, New Opportunities.”</p>
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	<p>[4] F. Alwi, Setiawan, and Asrizal, “Quality of life of persons with permanent colostomy: a phenomenological study,” <i>Journal of Coloproctology</i>, vol. 38, no. 4, pp. 295–301, Oct. 2018, doi: 10.1016/j.jcol.2018.06.001.</p> <p>[5] K. L. Simmons, J. A. Smith, K. A. Bobb, and L. L. M. Liles, “Adjustment to colostomy: Stoma acceptance, stoma care self-efficacy and interpersonal relationships,” <i>J Adv Nurs</i>, vol. 60, no. 6, pp. 627–635, Dec. 2007, doi: 10.1111/j.1365-2648.2007.04446.x.</p> <p>[6] J. Alexander-williams <i>et al.</i>, “Clinical Topics Magnetic continent colostomy device,” 1977.</p>
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*Insert photos / screenshot(s) of your preliminary brainstorming below*



Team 9  
Marco Tan  
tam27

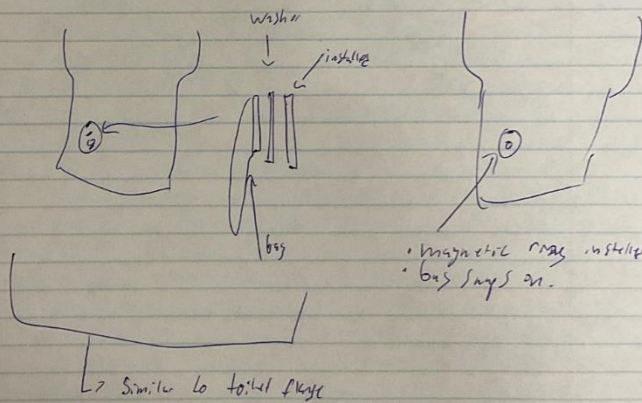
## DP-1 Brainstorming

Dimension: Device & User Interaction.  
↳ function, not form.

- Leakage results from improper use  
↳ improper use comes from lack of ease of use.
- easier system than adhesive.

• Click lock system

• magnet



Milestone 2 (Individual) – Aleen Al Barbarawi

Team Number:

9

Please list full name and MacID.

Full Name:	MacID:
Aleen Al Barbarawi	albarbaa

Team Number:

9

Complete this worksheet individually *before* coming to Design Studio 4.

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3. Indicate the sources of your research
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<b>Selected Design Dimension</b>	<i>Form and Function</i>
----------------------------------	--------------------------

<b>Preliminary Research</b>	<p><i>Document your preliminary research in the space below</i></p> <ul style="list-style-type: none"> <li>• Ileostomy bags collect poop discharged through the stoma. It is a small pouch that lies flat on the abdomen. They are attached to the stoma, which is the small opening in the abdomen that routes poop from the small intestine</li> <li>• The barrier and pouch are connected with a coupling ring, and during a replacement, the existing bag is removed and a new one is fixed while the flange/barrier remains in place. The flange may be flat or convex.</li> <li>• Stomas vary in size and can be round, oval, or irregular in shape.</li> <li>• A bag where its size free and u can adjust it within the bag, if the stoma increases or decreases in size</li> <li>• <b><i>Material would be fabric for shape to be more fit</i></b></li> </ul>
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<b>Sources</b>	<p><i>List all your sources (e.g., journal articles, book chapters, websites, etc.)</i></p> <ul style="list-style-type: none"><li>• <b><i>Cleveland clinic (website)</i></b></li><li>• <b><i>Patent art (Journal)</i></b></li><li>• <b><i>Byram Health care (website)</i></b></li></ul>
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Team Number:

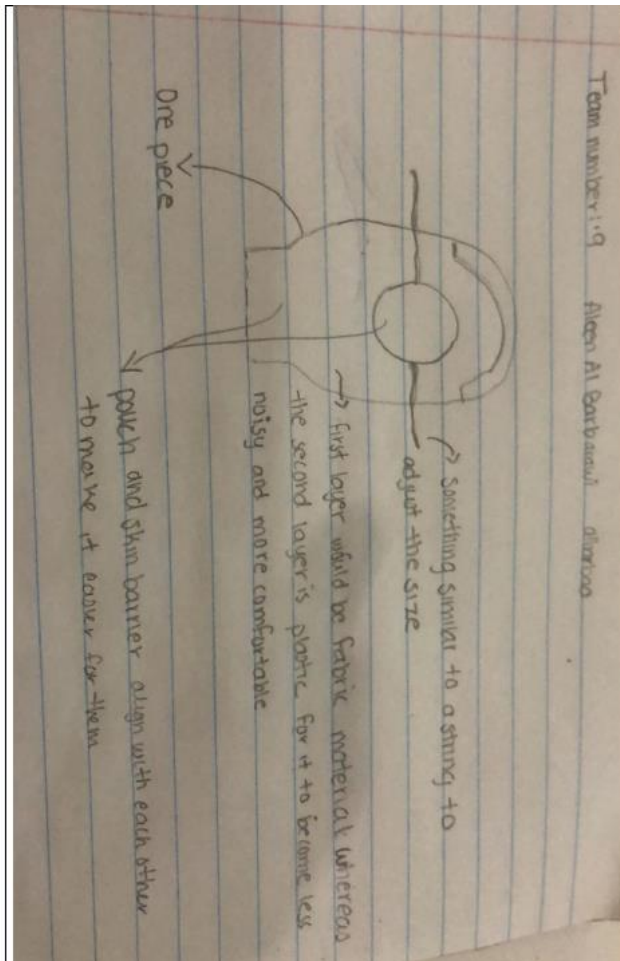
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3. Insert your photo as a Picture (Insert > Picture > This Device)



## Milestone 2 (Team)

Team Number:

9

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

Full Name:	MacID:
Marco Tan	tanm27
Aditi Srinivas	srinia14
Aleen Al Barbarawi	albarbaa
Josiah Kim	Kim190

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.

## Milestone 2 (Stage 3) – Concept Generation

Team Number:

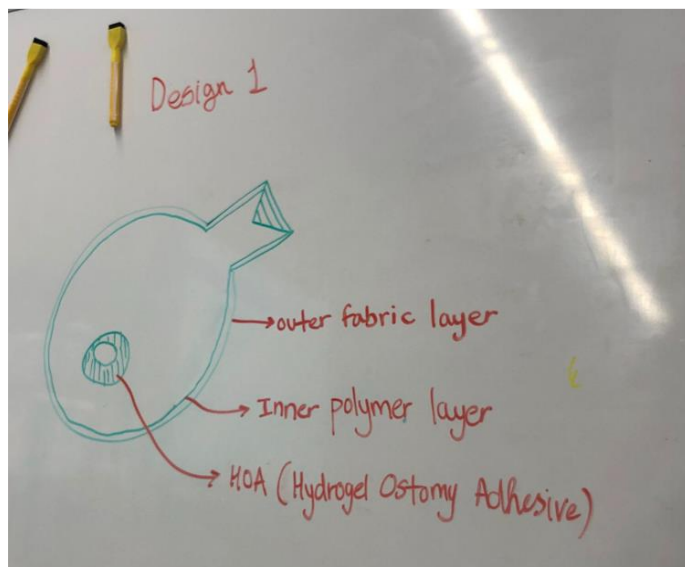
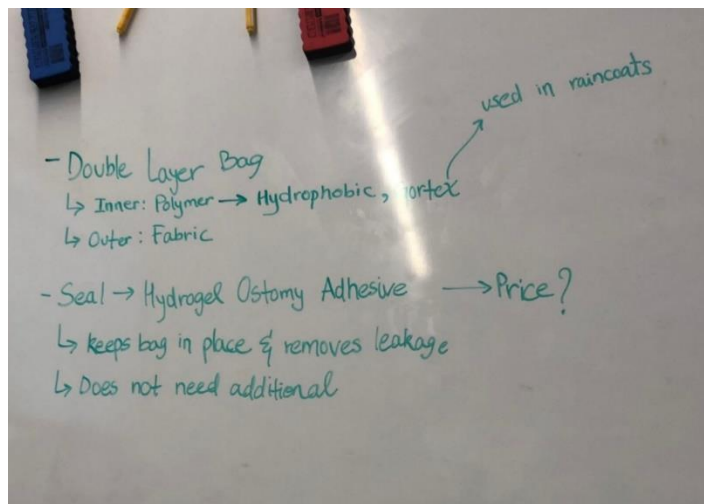
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As a team, generate several different means for solving your assigned design challenge.

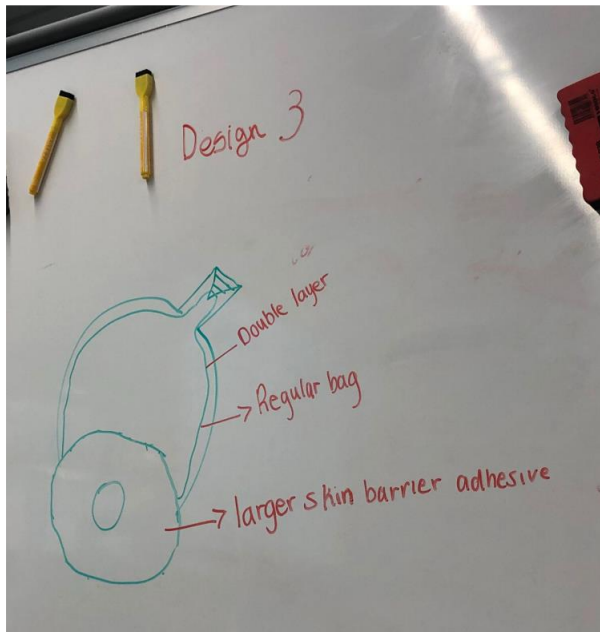
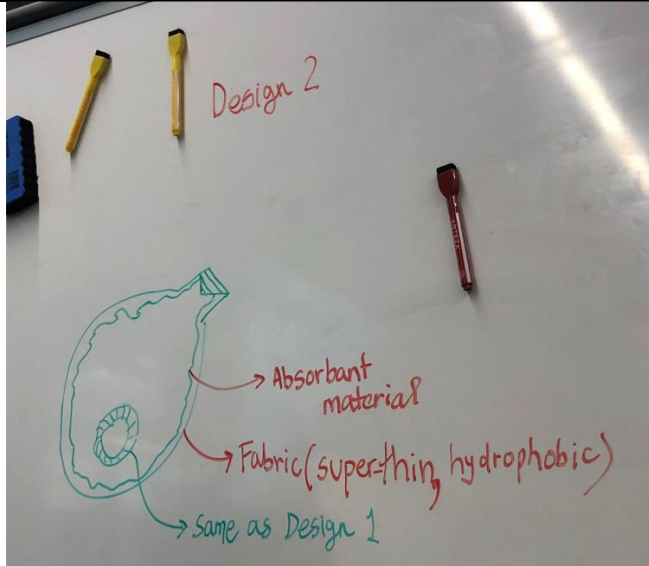
1. Generate ideas that either includes or builds on each team members preliminary list of ideas (i.e., Stage 2)
  - You can complete this activity by any means you wish
    - e.g., sheet of paper, notepads and sticky notes, whiteboard, etc.
  - Document this process on the following pages
2. Generate 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

Team Number:

9







## Milestone 2 (Stage 4) – Group Discussion

Team Number: 

9
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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?

### *Advantages and Disadvantages*

- Design 1:  
Advantages:
  - Simple revisions allow for improved storage of fluids in the bag through the polymer.
  - Outer fabric layer provides basic sound proofing for a traditionally noisy bag.
  - HOA (Hydrogel Ostomy Adhesive) provides much in durability, mechanical softness, and leak prevention in the skin barrier.Disadvantages:
  - HOA may be too expensive to produce for a disposable design.
  - May potentially be too big and inflexible due to the stacked bag layers, reducing performance in an active lifestyle.
  - Production cost due to more complex ostomy bag materials may outweigh longevity and durability in terms of positives in solving patient's needs.
- Design 2:  
Advantages:
  - Addresses the problem of high output failing the seal.
  - Would make output much more manageable, especially very watery outputs.
  - No significant cosmetic changes.Disadvantages:
  - The absorbent material might make the bag heavy which will be disturbing for the patient.
  - Depending on absorbent polymer used, may increase the price but not drastically.
  - The design has problems with releasing the absorbed water.
- Design 3:  
Advantages:
  - It is the simplest solution to create.

- No novel materials are required.
- Costs will not significantly rise.

Disadvantages:

- Does not address the root problem of high output ruining the seal, it only makes it potentially last longer because more adhesive.
- A larger skin barrier patch may affect cosmetic appearance.

*Concept Alignment with Milestone One Objective and Constraints*

- Design 1: While more performant (noise-reduction, leakage mitigation), its design contradicts the “expensive” constraint due to the new materials introduced to manufacture these short-use bags (HOA + doubled ostomy bag layers).
- Design 2: the bag addresses the problem of high leakage and makes the output much easier however its design cost may increase due to the absorbent polymer used and may not be financially accessible
- Design 3: as its more affordable and durable, the design itself does not solve the high frequency of leaks

*Concept addressing need statement*

- Design 1: The bag addresses some elements of the need statement while worsening the problem in other needs for the patient, as outlined in objectives and constraints.
- Design 2: This design meets the need statement. However, it risks being heavy (as it absorbs water) and expensive due to the use of HOA
- Design 3: This design addresses the need statement the as it best accounts for the patient’s financial situation as well as retain the structure of pouching system that she is already comfortable with.

Team Number:

9

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

Full Name:	MacID:
Aleen Al Barbarawi	Albaraa
Aditi Srinivas	srinia14
Josiah Kim	Kim190
Marco Tan	tanm27

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## Milestone 3 (Stage 1) – Design Configuration

Team Number:

9

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:*

- *Enlarging the sticky patch*
- *Increase in surface area/size of the skin barrier.*
- *More adhesive on all sides.*

*Fabrication and Assembly:*

- *Double layer:*
  - *Plastic on the inside and fabric on the outside.*
- *Larger skin barrier:*
  - *Expand skin barrier with [FILL OUT]*

*Device/User Interaction:*

- *Usage is the same as the original ostomy bag.*
- *Outside Design to be more fashionable with patterned fabric:*  
*Graphic design ostomy bag for kids*

Team Number: 9

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.

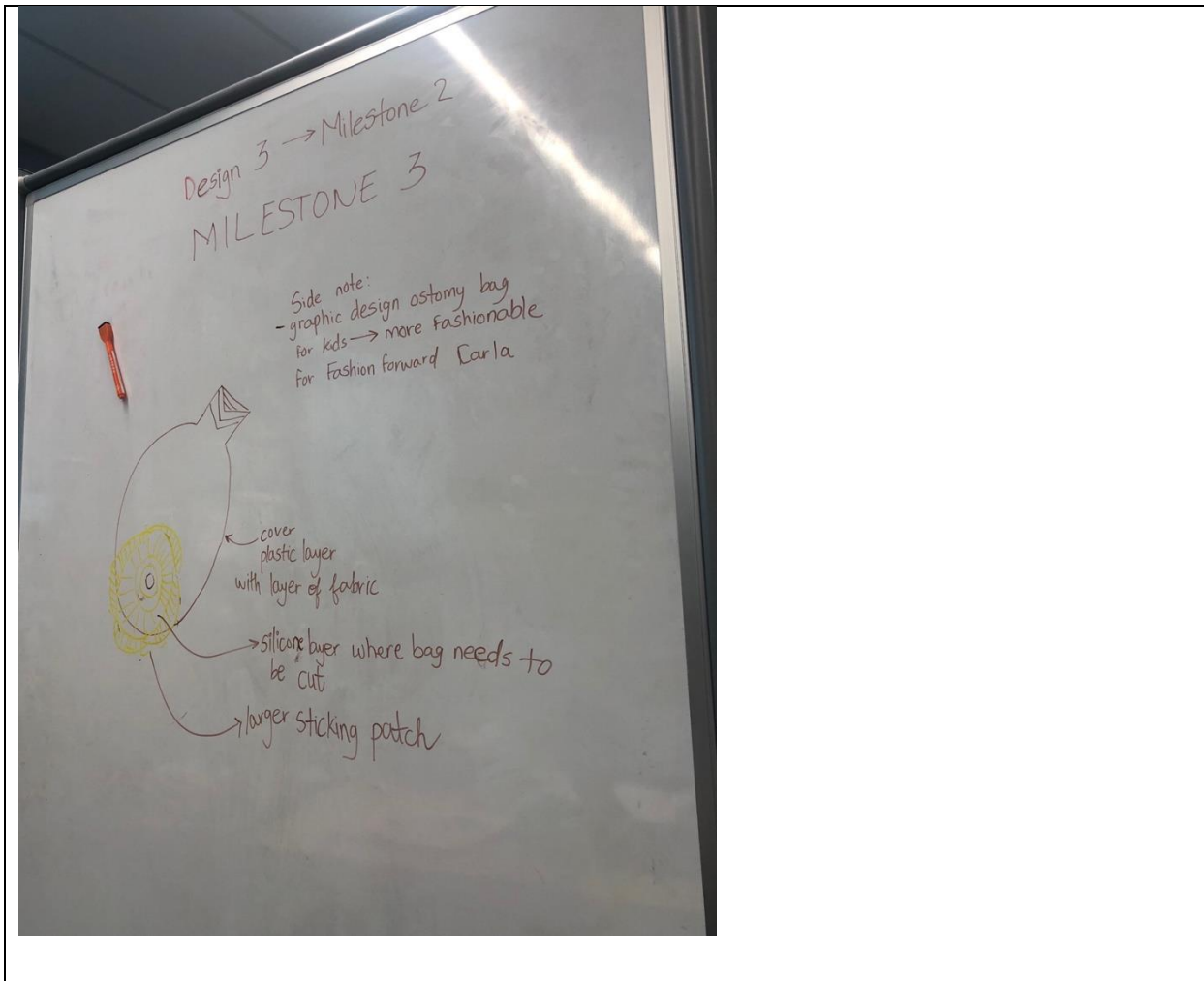
There is no explicitly required format for submission

<b>Components to be fabricated</b>	<p><i>Document your work in the space below</i></p> <ul style="list-style-type: none"> <li>• Layer of fabric to cover the plastic layer of the ostomy bag</li> <li>• Fabric to cover plastic.</li> </ul>
<b>Modifications to existing medical device (if applicable)</b>	<p><i>Document your work in the space below</i></p> <ul style="list-style-type: none"> <li>• Larger skin barrier. <ul style="list-style-type: none"> <li>○ Expanded ring of fabric.</li> <li>○ More adhesive.</li> <li>○ Replacement of current fitting ring with silicone.</li> </ul> </li> </ul>
<b>Materials to be used</b>	<p><i>Document your work in the space below</i></p> <ul style="list-style-type: none"> <li>• Fabric (tablecloth)</li> <li>• Hydrocolloid wafer (play-doh wrapped in plastic) <ul style="list-style-type: none"> <li>○ Making the hydrocolloid wafer more compliant (currently a little rigid).</li> <li>○ Rubber/silicone ring (this is a substitute for Hydrogel ostomy adhesive)</li> <li>○ Hydrocolloid is made of pectins, gelatines, and cellulose, absorbs water and swells into a gel.</li> </ul> </li> <li>• A Hydrogel adhesive material around the hydrocolloid layer (double sided tape)</li> </ul>

<b>Tools and processes required to fabricate your prototype</b>	<i>Document your work in the space below</i> <ul style="list-style-type: none"><li>• Cut fabric to fit the size and shape of the colostomy bag, and glue onto the fabric (a light adhesive so we do not permanently modify the colostomy bag).</li><li>• Play-doh stand-in for the hydrocolloid wafer.</li></ul>
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Team Number:

9



**\*Important:** this is NOT required, but should be done for documentation purposes (if your team has progressed to this point)