DESIGNING A SHAPE MORPHING, REUSABLE, BLOOD-COLLECTING HOLLOW TAMPON WITH SHAPE MEMORY WIRE

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Asha International, in particular its brand Beppy

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Executive Summary

This graduation report describes the design of a new suitable menstruation product for Beppy that collects blood, is reusable, has a similar (deployable) size and function as a tampon, and which is perceived as less intimidating to insert and extract than a menstrual cup. The new design, the Beppy Clover, is made from with silicones out of 3D printed moulds to test shapes, and the silicone and has Nitinol, which is a shape memory alloy (SMA), wire embedded. Before insertion, the Clover has a diameter similar to a single use tampon by folding it in three sections. There is no constant external force needed to keep the Clover folded. Once the product is inserted and gets into contact with is created. the body heat and blood in the vagina, the SMA wire (Af = 35° C) reacts and will return to its programmed shape. This results in the three sections with the SMA loops embedded deploying and adapting to the vagina canal. The product will stay in place, collect blood and after 8 hours or less, depending on the flow, can it be retracted by the loop or the attachable silicone extraction cord. The cleaning process works the same as a menstrual cup. rinsing between uses and sterilising at the beginning or end of the period.

evaluation were performed. In the analysis, relevant information and function as a tampon. about the menstrual cycle, the dimensions of the vagina and current insertable (period) products is gathered. Furthermore, interviews with ten people were conducted to get insights into the user experience regarding their period and period products. At last, the materials and production methods of the Beppy cup are inspected, and new possible materials are looked at to integrate into the product, like shape memory alloy. This information is brought together in a list of requirements.

In the development, three main challenges are tackled: how to integrate deployment (1), insertion (2), and extraction (3) in the design, which would satisfy the requirements and, in particular, make it look less intimidating than a cup. Prototypes were made proof of concept of the composite of SMA wire with silicones was tested. A concept is made from the combinations of ideas and evaluated by three people focussing on perception and first impression of the Beppy Clover. With the feedback a final design

The end result of the project is a promising final concept that could be the first step in the right direction regarding development of reusable blood collecting tampons. Utilising emerging materials was interesting to research its possibilities in period products. More tests and research on the combination of silicones and SMA wire reacting to body temperature will be necessary to optimise the force of the deployment of the product. Nevertheless, the Beppy Clover achieved its goal of being a blood collecting, reusable product that is perceived as To come to this final concept, an analysis, development and less intimidating than the cup and has a similar (deployable) size

Acknowledgements

I set up this project because I am interested in femtech. Femtech SMA is technology focused on women's health, or to be more inclusive: IUD the health of people who are assigned female at birth (AFAB). Paritv After reading the book Invisible Women by Caroline Criado-Perez, Gravidity I was sure I wanted to do something that has a positive impact for AFAB people. I was suprised how big the gap was between TSS AMAB and AFAB people on many levels. Definitely a lot can be SaTSS improved with research and designing products taking into POP account the sex and gender of people. My internship focused on AFAB sustainability, one of my main interests, which is why I was also AMAB appealed by reusable menstrual products.

Helping to solve societal issues is something I wanted to explore more. With this project the experience of the user is the main focus. Futhermore, this is a rather sensible/taboo topic which makes it interesting to learn how to address it.

I am very thankful for all the support, tips, patience and feedback I received from my chair Sepideh Ghodrat, mentor Sonia Paus-Buzink, and company mentor Cora Man. I could not have wished for better coaches. Thank you Sepideh for giving me the extra push I needed to start experimenting in the lab and showing that I can do it. Thank you Sonja for the good talks whenever I got stuck and for reminding me to keep my mental health as my first priority. Thank you Cora for giving me the time and freedom to design on my own pace and to show me around at the company.

Other people I would like to thank are my study buddies, colleagues at Beppy, housemates, friends, and family. Thank you for believing in me and helping me out with keeping me motivated, helping me with brainstorming and insights, and with giving me support or distraction in more difficult times. It has been quite the ride but I am grateful for every moment.

Hereby I proudly present my gradution project, enjoy reading!

List of abbreviations

Shape Memory Allov Intra-Uterine Device the number of times a person has given birth the number of times a person has been pregnant (and not necessarily delivered) Toxic Shock Syndrome staphylococcal TSS Pelvic Organ Prolapse Assigned Female At Birth Assigned Male At Birth

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PART I INTRODUCTION

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1.1 Current situation

Currently, there is a limited choice in menstruating products to collect the blood and prevent leakage. The main period products used outside the vagina are sanitary pads, reusable period pads, period underwear, and panty liners (see Figure 1.2 for an overview of existing period products).

Period products that need to be inserted into the vagina mainly consist of tampons, menstrual cups and menstrual discs. Out of these options, the reusable period pads, period underwear and the menstrual cups (and a couple of menstrual discs) are the only reusable products. It is estimated that an individual uses an average of 11.000 tampons in a lifetime (Safe Cosmetics, 2016), which generates a significant source of waste.

Period poverty is also a problem, 9% of women in the Netherlands, between 12 and 25 years old, sometimes do not have enough money to buy necessary period products (Plan Internationaal, 2019). In Flanders this number is even higher: 12% (Caritas Vlaanderen, 2020). Reusability is important because it generates a smaller environmental impact and has a financial advantage (see Figure 1.1). Reusable menstrual products are a one-time investment, resulting in an extended usage period of about five years. This one-time investment weighs in against the repeated purchase of single-use menstrual products over time. At last, some menstrual products can contain harmful chemicals or can have an influence on the vaginal health. These toxins are to be avoided.



Figure 1.1 Infographic about reusable period product alternatives vs disposables (source: Zero Waste Europe)





Figure 1.2 Overview of period products (photos from Pexel) & Beppy products

1.2 Project introduction

1.2.1 STAKEHOLDERS

This project is set up by Asha International, and regards the brand Beppy. They want to expand their portfolio with a reusable, blood-collecting, 'hollow' tampon. No research was done by them before, only a few idea sketches so the assignment could go in any direction I wanted.

Because this is a graduation project for the master Integrated Product Design a the faculty of Industrial Design Engineering of the Delft University of Technology, it has to fulfill certain criteria. One of them it being a technical project. I therefore chose to look into emerging materials and inspect the possibilities of integrating shape memory material into the design.

Besides the company and university as stakeholders, there also other Insertability). people involved who are of interest for this project. These are menstruating people who use menstrual products or want to use them. In particular those who want to use insertable products. Furthermore, their peers also have influence on their judgement.

Less involved, but still relevant are gynaecologists and doctors who would be able to recommend the product to the patient or inform the patient about it.

At last, the European Parliament is of importance regarding regulation of product safety (Directive 2001/95/EC), since it is an insertable product. In the USA the regulations are even stricter because menstrual products are water and toilets, and who are not limited by their culture/ classified as medical products.

1.2.2 PROBLEM DEFINITION

Below the problem definition can be found with the three focus points arranged according to priority for this project.

Menstruating people, with a tampon as preferred use of period product, do not yet have an alternative that is more sustainable, like period pants are for pads (1. Reusability).

The only reusable, insertable alternative that is widely known and available is the menstrual cup. Still, its functions are widely different from a tampon as it sits high into the vagina close to the cervix and has no part sticking out of the vagina for easy access to take it out (2.

Preliminary findings indicated that a significant part of menstruating people, do not feel comfortable inserting a cup and may feel intimidated by its perceived size (3. User experience).

In conclusion, there is a need for a new reusable period product that has a similar size and function as a tampon and which is perceived as less intimidating to insert than a menstrual cup. This concerns menstruating people from 18 to 35 years old, living in Europe with access to clean environment/own body to use insertable period products.

Designing a new suitable menstruation product for Beppy that is **reusable**, has a **similar (deployable)** size and function as a tampon, and which is perceived as **less intimidating** to insert than a menstrual cup. In addition, applying appropriate researched manufacturing techniques during the process.

1.3 Design Approach

To come to the final concept, an analysis, development and evaluation were performed. With every time diverging to collect information and converging to make decisions to come to requirements and a final design.

In the analysis, relevant information about the menstrual cycle, the dimensions of the vagina and current insertable (period) products is gathered. Furthermore, interviews with were conducted to get insights into the user experience regarding their period and period products. At last, the materials and production methods of the Beppy cup are inspected, and new possible materials are looked at to design is created and visualised. At last, recommendations integrate into the product, like shape memory alloy. This information is brought together in a list of requirements.

In the development, three main challenges are tackled: how to integrate deployment (1), insertion (2), and extraction (3) in the design, which would satisfy the requirements and, in particular, make it look less intimidating than a cup. Prototypes were made with silicones out of 3D printed moulds to test shapes, and the proof of concept of the composite of SMA wire with silicones was tested.

A concept is made from the combinations of ideas and evaluated by three people focusing on perception and first impression of the Beppy Clover. With the feedback a final for Beppy are written down for further development of the product.

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2 ASHA INTERNATIONAL

2.1 The company vs the brand Beppy



Asha International is a part of Willems Winkels B.V., which was founded in 1974. Its business transformed from industrial laundry to supplying the sex industry. The switch to the sex industry happened when a gynaecologist from a hospital they got their work from requested to develop a safe sponge-tampon that would allow prostitutes to keep working during their period. The prostitutes commonly used natural sponges, but these can break down inside the vagina causing irritations and infections. The newly developed spongetampon was named the Beppy. Asha International was founded in 1995, and the Beppy was patented a year later.



Currently, Asha International manufactures and sells personal care products, hygienic products, and paramedical products; this includes condoms, tampons, lubricants, massage oils and soa tests. Asha International is also distrubutor for global brands such as Durex (preferred supplier) and Reckitt Benckiser. Asha itself is fragmented into several brands: Euroglider, Beppy, Europharma, Body in Balance, Héros, Soft & Tender, and Beffy. Also, they are expanding their product portfolio with their innovation and product development team.



Body in Balance

Their focus is on business-to-business via their own websites asha.eu, condommessage.com, promocondoom. nl; while a smaller percentage is targeted directly towards consumers on condoomkoerier.nl and beppy.com or on bol. com and amazon.



2.2 Product portfolio

Besides the Beppy tampon (wet and dry), other products are to be found in their portfolio. There are two other menstrual products. First, there is the redesigned menstrual cup named the Beppy Cup, were more will be talked about in later chapters. Second, recently period underwear was developed for Beppy. Besides these products, there are alse products to take care of the cup and yourself in general: a steamer to sterilise the cup, neutral cup soap, comfort gel for easier insertion of the cup, and body foam and condoms.



3 ANATOMY & HEALTH

3.1 The female sexual anatomy

- 3.1.1 The female reproductive system explained
- 3.1.2 Vaginal dimensions of interest
- 3.2 Variables influencing vagina dimensions
- 3.3 The female reproductive cycle

Chapter 3 first examines the anatomy of a human with a female reproductive system. The vulva and reproductive system are visualised and explained. Next, research results about the vagina width and length dimensions are presented. Furthermore, variables are explored that influence the vagina dimensions and health. At last, the workings of a menstrual cycle are explained.



What is the range of the **vaginal length** of menstruating people?

To know the maximal length for the product.



What are the ranges of the **vaginal width** over the length of the vagina?

To know which width would fit the majority of people so that the product would stay in place.



How do **variables influence** the width and length of the vagina?

To know if the product needs to be adaptable in certain ways.



Which **variables** have influence on (menstrual) health?

To know what is healthy for the body and what to avoid.

3.1 The female sexual anatomy

To better understand how insertable menstrual products are designed for the body, this section explores the human female sexual anatomy. Besides the overall naming of the body parts, the ranges of the width and length of the vagina are researched.

3.1.1 THE FEMALE REPRODUCTIVE SYSTEM EXPLAINED

The human female reproductive system consists of internal and external sex organs. The internal sex organs are the vagina, uterus, Fallopian tubes, and ovaries. The external sex organs seen in Figure 3.1, are also known as the genitals. These are the organs of the vulva, including the labia (majora and minora), clitoris, and vaginal opening (introitus). Notice that the 'vagina' is not the outer part as it is still frequently used in daily speech. Therefore, the correct way to refer to that part is the vulva.

THE INTERNAL SEX ORGANS

The vagina is usually collapsed, its anterior (see Figure 3.2 which plane of the body is meant by this) and posterior vagina walls are in contact (Moore et al., 2019), as seen in the cross section in Figure 3.3. The shape of the cross section of the vagina towards the cervix (Figure 3.3 A-A) is described to resemble the letter 'W' in Barnhart et al. 2004, while in earlier studies the letter 'H' was suggested.

The external, or cervical, os is the entrance of the cervix, which transitions into the uterus where sperm will enter to fertilize the egg. Also, IUDs (Intra-Uterine Device) are inserted via the cervical os and then placed in the uterus. Its string will stick out a bit at the cervical os into the vagina canal.

The endometrium (Figure 3.3) is the tissue that grows every menstrual cycle and sheds once the egg is not fertilized. This tissue and blood are what we know as period blood. More about the menstrual cycle in section 3.3.



Figure 3.1 The vulva and its parts named and the anus shown as reference.



Figure 3.2 Anatomical planes of the human body



Figure 3.3 Coronal (frontal) view of the female reproductive system with its parts named. Two transverse cross sections (A-A and B-B) at two different parts of the vagina are shown to display that the posterior and anterior vagina walls are collapsed and touch each other in this plane. Towards the cervix the shape of the cross section differs.

INFLUENCE OF THE BLADDER AND RECTUM

In the sagittal view, it is pictured how the anterior and posterior walls of the vagina are in contact over the whole length (Figure 3.4). Furthermore, the bladder is positioned at the anterior wall and the intestine at the posterior wall. Due to its position, the uterus changes with the degree of fullness of the bladder and the rectum (Moore et al., 2019).

Also, what is inserted into the vagina canal can have an influence on the urethra. For example, bladder support products prevent the urethra from leaking due to coughing or running. More about non-menstrual insertable products in section 4.4.

Sagittal view



3.1.2 VAGINAL DIMENSIONS OF INTEREST

VAGINAL WIDTH

As mentioned before, the anterior and posterior wall of the vagina are in contact over the whole length, which means there is no width to measure in this direction (sagittal view, Figure 3.5 right illustration). This view in the sagittal plane will be used for easier distinction of the points of the cross sections for the width in the coronal (frontal) plane (Figure 3.5 left illustration).

Luo et al. (2016) made magnetic resonance imaging of the The entrance of the vagina (introitus) can go from **12mm to** vagina canal of 80 women with an age range of 28-70 years. In the study of Barnhart et al. (2006) also utilizing MRI, 28 participants with an age range of 18 to 39 years were examined.

By creating an overlay of both MRI's of Luo et al. (2016) and Barnhart et al. (2006) their papers, a conformity can be found in the different locations where the width is measured. This is visualized in Figure 3.6.

The width (in the coronal plane) of the vagina varies, it tends to increase from the introitus to the fornix. Since a tampon sits relatively low, it is most important to look at the widths of the introitus, mid-lower vagina and flexure. In Luo's study these are referenced as the 1st, 2nd, and 3rd point, respectively.

37mm, and the flexure width from 21.7mm to 55mm. This needs to be kept in mind while designing the shape and form of the product. Because of its deployable nature it should be possible to better adapt to more vaginas and therefore include more people.





Figure 3.5 Coronal view of the vagina canal left, and sagittal view of the vagina canal seen right. Five location points to measure the width in coronal view are located along the vagina canal utilizing the sagittal view. Luo et al. used numbers, while Barnhart et al. used location names.

Figure 3.6 Visual representation of ranges of the width of the vagina. Purple represents findings from Luo et al. (2016), and red represents the findings from Barnhart et al. (2006).

PARITY

Several brands do relate parity to the size of the cup, saying that someone to know what can cause them. who has given birth needs a bigger cup than someone who has not or who also has not had sex before. As stated above, pregnancy changes the elasticity of the vaginal canal. The pelvic floor needs time to recover from nine months of strain. The vagina should heal back to its original state over time and for some with the help of exercises for the vaginal muscles and pelvis, those will tighten or loosen the muscles depending on what is necessary for the body.

VAGINAL LENGTH

In the literature, three ways were used to measure the length of the vagina canal because the dimensions of the vaginal canal are variable (Figure 3.7).

- Anterior vagina wall (frontside of the cervix in the anterior fornix to the introitus): **75mm** (D'Herde, 2016); 63mm (± 9mm) (Luo et al., 2016)
- Posterior vagina wall (posterior fornix to the introitus): 105mm (D'Herde, 2016); 98mm (± 18mm) (Luo et al., 2016)
- Linear length of the vagina canal (cervical os to the introitus): 62.7mm (range 40.8mm-95mm) (Barnhart et al., 2006).

In the Syllabus (of Medicine of Ghent University) by D'Herde the measurements were rather general and leave out the width and ranges. Luo's (2016) paper includes those ranges. Furthermore, it was found that the average location of the cervical os was at 83% of the vaginal length.

The range of the linear length of the vagina canal is broad in the sense that the difference between the shortest and largest length is more than 100% (Barnhart et. al., 2006). The vagina canal has not a standard length that will fit everyone, quite a big range needs to be taken into account.



Figure 3.7 Three ways to measure the length of the vagina canal. All starting from the

introitus, going to the anterior fronix (1), the posterior fornix (2), and the cervical os (3)

3.2 Variables influencing the vagina

Certain characteristics about the body could have an influence also on the dimensions of the vagina, the following are discussed next: height, age, and parity. Furthermore, influences on the pH values and relevant vaginal conditions are inspected. Full list of vaginal conditions can be found in Appendix B.

3.1.3 HEIGHT, AGE AND PARITY INFLUENCING VAGINA DIMENSIONS

Taller people tend to have a smaller pelvic flexure width (Barnhart, 2006). Furthermore, older people tend to have a smaller vagina canal length and a wider width than younger people (Luo, 2016). A reason for that is that the vagina like every other part of the body also ages with time and the chances of a prolapse increase.

It was found that parity (the number of times a person has given birth) is associated with significant increase in length of vaginal fornix (see Figure 3.4 for the vaginal fornices, part of the cervix). The increase is especially significant in the upper part of the vagina where an active process takes blood prevents it from touching the vagina walls, could this place, as opposed to the lower vagina where passive stretching occurs during parturition (Barnhart, 2006). Since it is not the goal to cover the cervix (where a cup? the fornix is part of) with the product, I foresee no problems with an increasing length of the vaginal fornix.

To use a menstrual cup after pregnancy, it is important to wait until the postnatal checkup, which is around six weeks postnatal, and doctor approval is also necessary.

3.2.1 INFLUENCES ON THE PH VALUE OF THE VAGINA

The median pH (potential hydrogen) of the vagina is 4.5 (range = 4.0-4.9), which is acidic (Miller, 2016). Lactic acid is produced in the vagina by Lactobacillus, this keeps the pH levels low. These low levels are necessary to **discourage the** growth of yeast and other bacteria that cause infections (Eschenbach et al., 2000).

Vaginal pH values can be influenced by several things like menstrual blood, semen and the menopause (Figure 3.8). These last two are less relevant to this project, However, with menstrual blood in the vagina, the vaginal pH increases (Eschenbach et al., 2000) since the pH value of blood is about 7.4. Which means the chances of getting an infection during menstruation are higher.

The question then arises, with tampons, the blood is still in contact with the vagina walls while a cup collecting the mean that the effect on the change of pH value be less with

It is good to keep in mind that the pH value can be thrown off quite easily. Infections need to be prevented so it is good



Figure 3.8 Several pH values related to the vagina or of influence to the vagina are visualised on the pH scale.

3.2.2 PELVIC ORGAN PROLAPSE (POP)

In Williams Gynecology it is stated that "for pelvic organ prolapse to be considered a disease state, symptoms should be attributable to pelvic organ descent (see Figure 3.9) such that surgical or nonsurgical reduction relieves the symptoms, restores function, and improves quality of life."

In many cases there are no symptoms, so no treatment is required. For mild cases, pelvic floor exercises are recommended to strengthen the muscles. For moderate cases, a vaginal pessary may be inserted to support the vaginal wall. In most severe cases, surgery will be the best option (John Hopkins Medicine, 2021).

A third of women will have a prolapse to a certain degree, often without symptoms. Only a small percentage are in such a state that only surgical or nonsurgical reduction relieves the symptoms, restores function, and improves quality of life. The prevalence of pelvic organ prolapse is 3:500 (0,6%) and especially for 65 years and older it increases to 12:500 (2,4%) (Compendium Geneeskunde, 20xx).

For this project the most interesting **risk factors to keep** in mind are childbirth, pregnancy, post hysterectomy, age and menopause.



Figure 3.9 Overview of possible pelvic organ prolapses.

3.2.3 TOXIC SHOCK SYNDROME

WHAT IS IT?

Toxic shock syndrome is a sudden, potentially fatal condition. It's caused by the release of toxins from an overgrowth of bacteria called Staphylococcus aureus, or staph. The body responds with a sharp drop in blood pressure that deprives organs of oxygen and can lead to death (Figure 3.10 for all symptoms).

Toxic shock syndrome affects menstruating people, especially those who use super-absorbent tampons. But, it can also happen to people who have been exposed to staph bacteria while recovering from surgery, a burn, an open wound, or the use of a prosthetic device.

IN RELATION TO TAMPONS & CUPS

Menstrual staphylococcal TSS (SaTSS) cases peaked in the 1980s before the recognition that super-absorbent tampons introduced oxygen in an otherwise anaerobic vaginal environment which facilitated production of TSST-1 (Burnham, 2015).

In the paper of Nonfoux (2018) is mentioned that due to the introduction of **a higher volume of air** with the cup, a **slight increase of the Staphylococcus aureus growth** and toxin production is observed in comparison with tampons. They suggest to **use a small cup to limit the effect.**

Furthermore, the S. aureus forms a **compact biofilm** in contact with the cup, which is **resistant to simple washes with water** (Nonfoux 2018). Therefore, boiling the cup between uses is recommended and **having a second sterilized cup closeby**. This is the reason why Beppy only sells their cups in pairs. This will also be the case for the new reusable product.



Figure 3.10 Symptoms caused by Toxic Shock Syndrome (Source: Verywellhealth.com)

3.3 The female reproductive cycle

This project is about a new menstrual product, which means taking a look at the menstrual cycle is necessary. How does it happen, what is the time frame. how much blood is lost, ... This is relevant to know for the intensity the product will be used at and its whole life cycle. More details about the cycle can be found in Appendix C.

3.3.1 TWO CYCLES

The female reproductive cycle can be split into two cycles:

- 1. The ovarian cycle where a follicle is developed every cycle
- 2. The uterine or menstrual cycle where the endometrium is prepared to receive an egg every month

The length of the menstrual cycle is the number of days between the first day of menstrual bleeding of one cycle to the beginning of the subsequent bleeding. On average, a menstrual cycle lasts 28 days, with most cycle lengths between **25 to 30 days** (Mihm et al., 2011). Furthermore, the duration of the bleeding itself varies from person to person, ranging from two to eight days with an average duration between four to six days.

The interplay of hormones leads to ovulation and the thickening of the endometrium to about 12-18mm (Tortora & Derrickson, 2017). If fertilization not occur, progesterone, estrogens does levels decline. This withdrawal of progesterone and estrogens causes the functional layer of the endometrium to shed, menstruation begins and a new menstrual cycle starts.

3.3.2 QUANTITY OF BLOOD LOSS

The mean value of the menstrual blood loss was 43.4+ 2.3ml. To get a better grasp of this quantity, one tablespoon is 12ml. There were no great differences in amount of blood lost between different ages except in the 15-year-group which had the smallest and in the 50-year-group which had the highest mean value of menstrual blood loss (Hallberg et al., 1966).

It was concluded that the upper normal limit of the menstrual blood loss is situated between **60-80 ml** and that a blood loss above 80 ml should be regarded as pathological (Hallberg et al., 1966).









Conclusions Anatomy & Health

Which **variables** have influence on (menstrual) health?

- On average, a menstrual cycle lasts 28 days, with most cycle lengths between 25 to 30 days. The duration of the bleeding ranges from **two to eight** days with an average duration between four to six davs.
- The mean value of the menstrual blood loss was **43.4ml.** The **upper normal limit** of the menstrual blood loss is situated between **60-80 ml.** Keep in mind, one tablespoon is 12ml.
- A third of women will have a prolapse to a certain degree, often without symptoms. Risk factors to keep in mind are childbirth, pregnancy, post hysterectomy, age and menopause.
- A higher volume of air with the cup, causes a slight increase of the Staphylococcus aureus growth, which can cause Toxic Shock Syndrome. It is suggested to **use a small cup** to limit the effect.
- The S. aureus forms a **compact biofilm** in contact with the cup, which is **resistant to simple washes** with water. Having a second sterilized product closebv is recommended.
- Blood (pH 7.4) has a higher pH value than the vagina (pH 4.0-4.9) which can disturb the vagina flora and cause infections. Therefore chances of getting an infection during menstruation are higher.



What is the range of the **vaginal length** of menstruating people?

- Anterior vagina wall: **75mm**; **63mm (±** 9mm)
- Posterior vagina wall: **105mm**; **98mm** (± 18mm)
- Linear length of the vagina canal: 62.7mm (range 40.8mm-95mm)

The average location of the **cervical os** was at 83% of the vaginal length.



What are the ranges of the **vaginal** width over the length of the vagina?

The entrance of the vagina (introitus) can go from 12mm to 37mm, and the flexure width from 21.7mm to 55mm.



How do variables influence the width and length of the vagina?

- Taller people tend to have a smaller pelvic flexure width.
- Older people tend to have a smaller vagina canal length and a wider width than younger people.
- · Parity is associated with significant increase in length of vaginal fornix.
- After pregnancy and delivery, the vagina should heal back to its original state over time and for some with the help of exercises for the vaginal muscles and pelvis.

4 CURRENT STATUS OF INSERTABLE (PERIOD) PRODUCTS

4.1 Tampons

4.1.1 What defines a Tampon?

4.1.2 Innovation in Tampon products

4.1.3 Tampon SHAPESshapes

4.1.4 Tampon DIMENSIONSdimensions

4.2 Menstrual cups

4.2.1 What defines a CUP?

4.2.2 Innovation in menstrual cups

4.2.3 Most remarkable shapes

4.2.4 Cup DIMENSIONSdimensions

4.2.5 Capacity

4.2.6 Cup folds to insert

4.3 Tampon vs Cup

4.4 Other insertable products

Chapter 4 is about the current status of insertable period products and products not related to menstruation but which are inserted into the vagina. There is a focus on insertables because this will be an essential characteristic of the new product. Tampons and cups are analysed more in detail to know their dimensions, shapes, capacity, and innovations. Afterwards, a comparison of the cup and tampon is made to select which characteristics are to be kept for the new design and which to discard. At last, insertable products which are not related to menstruation are inspected. Do these products have other characteristics which are interesting but are not yet implemented into menstrual products?





What **shapes** do cups and other **insertable products** have?

To know if there is an overall conformity that can be applied to the new product.

What are the average **dimensions** of **tampons** dry and wet?

To know how much the tampon expands and to have a reference of dimensions.



What **characteristics/features** are **innovative/new** about menstrual products?

To know in which direction the market is going and exploring to see if it is worth building forward on it.



What are the average **dimensions** of menstrual **cups** categorized in different sizes?

To have a reference of dimensions and sizes that are still acceptable for a menstrual product.



What **characteristics/features** from the **tampon & cup** should be kept or excluded?

To create requirements the product should fulfill and how it can be explored how to fulfill them.

4.1 Tampons

This section describes what a tampon is, some innovations, its original shape, and its dimensions while dry and saturated, respectively. The aim is to understand this popular period product's workings better and retrieve a better reference of the dimensions.

4.1.1 WHAT DEFINES A TAMPON?

Tampons have been around for thousands of years (see Appendix D for more about the history) but let us inspect the characteristics of a regular modern single use tampon from brands like Tampax or o.b. (Figure 4.3). They have a lot in common. First off, with inserting (Figure 4.2), it is possible to buy tampons with an applicator (Figure 4.3) which prevents hands getting in contact with the vagina. The tampon has a relatively small diameter and stays in place due to the friction and expands when the cotton absorbs the blood. Because it is inserted into the vagina, there is a risk of Toxic Shock Syndrome. When the tampon is saturated, it is thrown into the trash and cannot be reused. The tampon is retracted by the string, visible from the outside.



Figure 4.2 Visual of how far a tampon should be inserted into the vagina canal.







Figure 4.3 Difference new and saturated tampon; o.b. regular tampons; tampax regular tampons with applicator

4.1.2 INNOVATION IN TAMPON PRODUCTS

TAMPLINER BY CALLALY

The tampliner by Callaly (Figure 4.4) focuses on **user experience** by combining a panty liner and a tampon in one and preventing the finger from touching the vagina by the medical-grade thin film tube that connects the two. Then when taken out, the tampliner wraps itself.

Keeping the fingers clean, is this something the target group would want?

REUSABLE APPLICATOR BY DAME

The DAME applicator (Figure 4.5) is a **reusable** applicator designed to fit "all absorbencies from lite to super plus, and works with any non-applicator tampon". The applicator contains active Sanipolymers, "which kill 99.9% of bacteria and keep it sanitary at all times". On their website they state that there is no need for boiling or soap, only a simply rinse under running water should be enough.

Could a reusable applicator be part/necessary of the new design?

BEPPY TAMPON

The Beppy tampon is developed for sex workers to keep on working during their period. This tampon is not reusable but focuses on the **user experience.** Its shape is not related to the regular tampons but to natural sponges. Since these are not healthy for the body this redesign was made. As seen in the picture (Figure 4.6) it is more recognisable as a sponge than as a single use tampon.

For the new product I will focus on keeping the recognisable cylindrical shape of a tampon **before** insertion.



Figure 4.4 The tampliner by Callaly



Figure 4.5 The reusable tampon applicator by DAME



Figure 4.6 Beppy sponge tampon

4.1.3 TAMPON SHAPES

What is the original shape of a tampon? I inspected tampons saturated with water by taking them apart without damaging the material. As seen in Figure 4.8 the tampon consists of one long cotton strip rolled up around a string. This method is also used for the reusable and washable tampons, as seen in Figure 4.7.

The Playtex tampon (Figure 4.9), which had the same look as every other tampon when dry (Figure 4.10), had a different shape when wet than the five other tampons. The tampon is made by combining two cotton strips positioned perpendicular on top of each other and secured with a string.



perpendicular on top of each other and secured with a Figure 4.7 Imse Vimse reusable washable tampons from organic cotton (3 sizes)





Figure 4.9 Shape of the Playtex tampon: combining two cotton strips positioned perpendicular on top of each other and secured with a string

4.1.4 TAMPON DIMENSIONS

To better grasp what happens with a tampon once it is inside the body and soaking up blood, I measured the dimensions of single use tampons from six different brands (Kotex, Playtex, Natracare, Sanature, Sense, o.b.; Figure 4.10) before and after saturating them in a glass of water. The outcome is visualised in Figure 4.11. The tampon Playtex is excluded from it because its wet shape did not make it possible to give a right diameter (Figure 4.9).

With four out of five, the diameter doubled the size. On average, the **diameter** went from **12.8mm to 25.2mm**. For three tampons, the length became shorter when wet. This is probably because the material was pressed together in height to create a smaller diameter. Once wet, the material can move freely and the actual length became visible. On average, the **length** was **47.4mm dry and 45.6mm when saturated**. These tampons where of a regular or super size. Dimensions of super plus and ultra tampons have not been inspected because the sizes of cups will be used as the upper limit of the dimensions.



Figure 4.10 Left to right: Kotex, Playtex, Natracare, Sanature, Sense, Ob



Figure 4.11 Graph showing the length and diameter of five different tampons first when dry and second when saturated with water.

4.2 Menstrual cups

This section describes what a menstrual cup is, some innovations, different shapes of brands, and its dimensions and capacity. The aim is to understand this reusable period product's workings better and retrieve a better reference of the dimensions.

4.2.1 WHAT DEFINES A CUP?

The main characteristic of a cup is that it is made from flexible plastic (silicones or TPE) and is reusable (check Appendix E if interested about the history of the cup). It collects blood like a flexible bucket, is inserted by hand by folding it to make it smaller, stays in place due to a created vacuum, and only leaks when it is placed wrong (Figure 4.12) or if it is not the right size for their vagina. The majority of the cups have a stem to find back the cup and break vauum seal (Figure 4.13). The Beppy Cup (Figure 4.17) has a loop instead of a stem to grab the cup more easily. Just like a tampon, it still has a risk of Toxic Shock Syndrome, but because blood is collected (Figure 4.14), it has a bigger capacity than a tampon making it possible to wear it for a longer time. After use, the cup needs to be sterilised, for example, with boiling water.



Figure 4.12 Wrong and right positions for a menstrual cup



Figure 4.13 Examples of commonly used menstrual cups: Divacup, Mooncup, and AllMatters cup (formerly known as the Organicup)



Figure 4.14 Used Menstrual Cup

4.2.2 INNOVATION IN MENSTRUAL CUPS THE BEPPY CUP

The Beppy Cup (Figure 4.17) focuses on easier retrieval and anti leaking. The shape of the Beppy Cup is a bucket form instead of the more common bell shape. Furthermore, a loop is integrated for easy removal with one finger. The material is skin-friendly, non-toxic, medical-grade silicone, and is thin to shape to the body easily. An anti-leakage rim keeps the risk of leakage low and makes it possible to have penetrative sex without spilling. By selling the cup in pairs, it is possible to always have a sterilised cup on hand, and therefore reduce the risk of TSS.

Characteristics to add to the new product could be the loop, and the selling in pairs. This could even be a pair of the new product together with the Beppy Cup. An anti-leakage rim is not a main consideration.

FLEX CUP

The Flex Cup (Figure 4.15) focuses on the user experience of extracting and in particular the part to break the vacuum seal. The string is attached to the upper rim, breaking the vacuum seal when pulled downwards. Because the string needs to move to pull on the rim, a hole is made in the bottom where the string is threaded through. All while still keeping the product leakproof.

How will the product stay in place, and is this a possible way to extract it?

VALVE MENSTRUAL CUPS

There is a category of cups called valve menstrual cups (Figure 4.16). The otherwise solid stem is made into a hollow tube which works as a valve to empty blood inside. It has advantages in the way that people having problems with insertion or extraction would only need to open the valve. However, this does not mean that people can leave in the cup longer than other brands. The risk of Toxic Shock Syndrome stays the same. It is only an advantage for those who have to empty their cup more often due to higher blood loss. Furthermore, the drain could get clogged by blood clots and other tissue or not close properly over time.

It is an interesting take on the cup but not applicable for this project since this shifts too far away from the tampon, the new product will focus on easier insertion and extraction and the risk of people keeping in the cup too long due to this function is too high.



Figure 4.17 Beppy cup dimensions, anti leak rim and capacity



Figure 4.15 Flex cup having a string connected to the upper rim of the cup to break the vacuum seal once pulled.



Figure 4.16 Collection of valve menstrual cups.



4.2.3 MOST REMARKABLE SHAPES

The range of cups goes from an almost spherelike shape to a bell shape and into a bucket shape (Figure 4.1). The bell shape is the shape produced by the majority of the brands. As seen in the picture, all products do not have a diameter similar to a tampon. Only when they are folded, it may get to that size, but people do not see this folded version when looking for a cup. The size can be intimidating at first glance.



Graph 4.1 Overview of different shapes retrieved from the collage of products seen left.

4.2.4 CUP DIMENSIONS

Browsing the internet, I found an extensive list of cups with brand names and dimensions (the site name is theecofriendlyfamily.com). The complete list can be found in Appendix E. Most brands split up their sizes into the following: small, medium, and large. Furthermore, several brands only have 'one size'. By filtering the sizes, an average of each category could be calculated (see Graph 4.2).

The diameters for small (n=44), medium (n=13), and large (n=54) cups are respectively: 40.7 mm; 41.5 mm; 45.4 mm. Furthermore, the cup ranged from 36 mm to 48 mm.

Next, the lengths are: 47.9mm; 51.3mm; 53.3mm; ranging from 35mm to 62mm. These averages and ranges are new reference points added to the dimensions for the new product.

The most valuable dimension would be the **diameter** range of **36mm to 48mm**, with an average of **42.6mm** (when taking all sizes together).

4.2.5 CAPACITY

Again, the data is from the list of cups found online (see Appendix E). The average capacity measured to the holes (see Graph 4.3) is 19.6ml; 23.4ml; 27.8ml; with a range from 15ml to 38ml. At last, the capacity listed in the specifications is as follows: 22.9ml; 24.7ml; 31.4 ml; ranging from 10ml to 50ml.

One tablespoon is 12ml, so on average, the capacity of the cups is about two tablespoons.

The most valuable capacity would be the capacity range measured to the holes, which is **15ml to 38ml** with an average of **23,6ml** (when taking the average capacities of the different sizes together).





Graph 4.2 Average lengths and diameter of cups labeled with sizes small, medium, large and one size.



Capactiy

Graph 4.3 Average capacity measured to the holes and what was listed by the brand, for the cups labeled with sizes small, medium, large, and one size.

4.2.6 CUP FOLDS TO INSERT

To insert cups, a fold is made to decrease the diameter of the product. In this section, these folds are inspected. The question arises, which fold(s) have the potential to be However, the rest of the cup's body has its original diameter, integrated into the deployment of the product? Do they have which could make it more challenging to insert and extract. an added value, or is a new mechanism necessary? How are How can this be done differently in the new design? A solution cups folded to get the diameter of a tampon to insert?

Figure 4.19 shows the most common folds on how to insert a cup. Some of these still have rather big dimensions at the top to insert into the vagina canal. The punch down fold, the origami, and the triangle fold all look similar in size to the top of a tampon. This is visualised in Figure 4.20.

Creating that similar shape and thus the diameter of a tampon is one of the goals to achieve with the new product. could be looking at the tampon diameter as a starting form instead of an in-between state. Then, there would be no constant external force necessary, like fingers pushing the material together, to keep that diameter similar to a tampon for easier insertion.

C OR U FOLD **PUNCH DOWN** 7 FOLD ORIGAMI S FOLD M, E OR TRIANGLE DIAMOND SQUIGGLE

Figure 4.19 Different folds used for menstrual cups to insert into the vaginal canal.

Figure 4.20 Comparison of tampon size, folded cup size and applicator size. The top of the folded cup is similar in size to the diameter of the tampon and applicator.







REVIVE BLADDER SUPPORT



KEGEL TRAINERS FOR PELVIC FLOOR MUSCLES



PROLAPSE SUPPORT



ELVIE PELVIC FLOOR TRAINER



4.4 Other insertable products

Besides insertable menstrual products, there are other categories where a product is inserted into the vagina or even the uterus. In this section, each category is discussed with one or more examples. These products give inspiration and knowledge about what is possible in the case of insertable products for the vagina. For example, how does its function relate to its shape and size?

BLADDER SUPPORT

First, bladder support products are designed to be inserted into the vagina and can put pressure on the urethra to prevent urine leaks because of their shape. The new menstrual product should not stop people from peeing or pooping.

KEGEL TRAINERS

Next, there are kegel trainers for the pelvic floor muscles. These muscles support the bowel, bladder, vagina and uterus. They can weaken by pregnancy, childbirth, obesity and the straining of chronic constipation. The Elvie pelvic floor trainer is inserted into the vagina, connects with an app, and shows the force exerted when doing Kegels.

PROLAPSE SUPPORT PESSARIES

Prolapse support pessaries come in a lot of diverse shapes. It is interesting to see that all of these different shape can all be inserted into the vagina. What a prolapse is, is discussed in section 3.3.1.

ANTI CONCEPTION & CONCEPTION

Furthermore, there are products to prevent pregnancy like female condoms, IUDs and also pessaries designed for anti conception. On the other hand, some products are designed to help with getting pregnant. The Ferti Lily is a cup that should help direct the sperm into the cervix and uterus. Its most interesting feature is this long extraction part.

SEX TOYS & DILATORS

At last, sex toys and dilators. Sex toys consist of a whole range of shapes, diameters, and lengths, also with several purposes. Vaginal dilators are there to help people restore or expand the tissues and musculature of the vaginal opening. Reasons to do so can be

- conditions that have created anatomical changes within the pelvis
- medical conditions that can cause painful or restricted vaginal penetration or intercourse
- chronic pelvic pain
- vaginismus, they need to learn to control muscle responses, focus on insertion techniques and understand the neuroscience of pain, fear and anxiety

Vaginal dilators start small and go bigger with small steps, these dimensions could be used for minimal and maximal diameter references.

The Milli vaginal trainer has an expanding mechanism. Instead of having up to 8 different insertable sizes, there is only one that can expand from 15mm to 40mm.



SEX TOYS & DILATORS

Conclusions Current status of insertable (period) products



What are the average **dimensions** of **tampons** dry and wet?

The diameter doubles size. on average, the **diameter** went from 12.8mm to 25.2mm

• On average, the **length** was **47.4mm** dry and 45.6mm when saturated. It is getting shorter probably because the material was pressed together in height to create a smaller diameter. Once wet, the material could move freely and the actual length became visible.

What **shapes** do cups and other **insertable products** have?

- Bladder support can influence the bladder and bowel movements by its shape.
- Cups can go from an almost spherelike shape to a bell shape and into a bucket shape.
- Prolapse supporting pessaries have all shapes and sizes, even cube like shapes.
- Sex toys and dilators have different diameters that all should fit the vagina.

What are the average **dimensions** of menstrual **cups** categorized in different sizes?

The most valuable one would be the **diameter** range of 35mm to 62mm with an average of 42.6mm (when taking all sizes together).



What characteristics/features are innovative/new about menstrual products?

- Callaly keeping the finger clean by connecting the tampon to a liner with a thin plastic like tube.
- DAME. using a reusable applicator instead of a single use applicator.
- Beppy Tampon synthetic single use sponge which can be used to not leak during penetrative sex. It does not have a recognisable tampon shape
- Beppy Cup a loop to extract with one finger instead of a stem. Also, an anti leak rim to keep risk of leakage low.
- Flex Cup a string attached to the upper rim threaded through a hole at the bottom of the cup to release the vacuum, all while keeping the product leak proof.
- Valve cups the otherwise solid stem is made into a hollow tube which works as a valve to empty blood inside.





characteristics/features What from the tampon & cup should be kept or excluded?

The pictured characteristics are the ones from both the tampon as the cup that are interesting to keep in the new design. Some may be contradictory like it being visible and invisible from the outside but this means the user will have a choice in what they prefer to do. The four characteristics at the bottom are the more straightforward ones.



5 USER EXPERIENCE

5.1 Menstruation and gender

5.1.1 How does gender relate to menstruation?

5.2 User insights

- 5.2.1 Interviews trans people
- 5.2.2 Influence, perception & trust
- 5.2.3 Pads & menstrual underwear
- 5.2.4 Tampons
- 5.2.6 CuCUps
- 5.2.7 Most important characteristics
- 5.3 Collective period experience

Chapter 5 looks into the relationship between menstruation and gender because periods are not limited to only women. Furthermore, the results of the interviews with menstruators are visualised. These interviews were about how people experience their period and period products, what they search for in a product, and their needs and wants. At last, a compilation is made of certain characteristics of the interviewees which make them more likely to buy the product.





In what way do people who are assigned female at birth (**AFAB**) and who do not (only) identify as woman, **experience their period differently** from cisgender women?

To know how to tailor the product to all menstruators and not only to women.



What are the **most important features** about a menstrual product that should definitely be included?

To know which priorities to set.



What do people **like/dislike**, think are **advantages/disadvantages** about pads, tampons and cups?

To know what to keep and avoid in the new product.



How do people choose what they wear during their period?

To know what influences the decision of using certain products in certain times or environments.

5.1 Menstruation and gender

As a designer, it is my responsibility to look further than the norm. Are there people getting excluded while they are actually part of the target group? Can minor adjustments be made to create a more inclusive target group while staying true to the brand's identity? In this section, it is discussed how gender relates to menstruation.

> gender, gender identity, gender expression, and attraction are explained. All of these terms can act independently of gender at birth (Movisie, 2018). each other. For example, someone is assigned female at birth (AFAB) because they were born with genitals categorised as female, but anatomical sex does not define gender identity or expression. That person can identify as non-binary, dress masculine, use they/he pronouns, but still have their vulva and uterus and thus menstruate. Furthermore, someone born with a penis and testicles will be assigned male at birth (AMAB) but can identify as a woman. Not having the female reproductive system does not make her less of a woman.



How someone identifies (their gender) is more important than their assignment at birth, regardless of sex or surgery later in life. In short, not all women menstruate and not all people who menstruate are women.



5.1.1 HOW DOES GENDER RELATE TO **MENSTRUATION?**

Today, the industry of menstrual products is still primarily focused on women and femininity. In commercials, social media, aesthetics, and even word choices like 'feminine hygienic products'. However, why not open up more and include people who do not (only) identify as women, why not In Appendix F the differences between anatomical sex, design for all menstruators? About 3,9% (1 in 25 people) of the Dutch population does not identify with their assigned

Reasons why this is important:

- it normalises that trans people or those not sure about their identity also menstruate
- it could help transpeople with feeling less dysphoric about their body during their menstruation
- it captures a more significant part of the population
- more products can be sold by including trans people
- more companies could follow by being more inclusive

GENDER DYSPHORIA

Gender dysphoria (GD) is the distress a person feels due to a mismatch between their gender identity and their sex assigned at birth. Not all trans people experience dysphoria, and those who do may experience it at varying intensity levels. For example, someone identifying as a man but who is AFAB could feel gender dysphoria about having breasts. Menstruation can also be a trigger for dysphoria as this is inherently connected to being AFAB and because it is still portrayed in society as something only women experience.

Interviews were held with four people who do not (only) identify as women to learn more about how their period experience. The insights are discussed in the next section, together with the insights from the interviews with people identifying as women.

5.2 Insights Interviews

To get a better grasp of what the target group wants and needs, some in depth interviews (see Appendix G for the questions asked) were executed with 7 participants of different age groups, different nationalities (but have lived or are living in the Netherlands), and have different preference in menstrual product use (see same appendix at the end of it for an overview). From these interviews, requirements could be retracted which will be described in this hap

5.2.1 INTERVIEWS TRANS PEOPLE

By doing interviews with those who do not (only) identify as a woman, I got better insights into what menstruation makes it difficult for them, what can be done differently, and what I can keep in mind while designing the product.

The main take-aways were making the appearance more neutral, not the colours and figures related to (only) femininity. Alternatively, giving more options and adding more masculine looking appearances and figures.

There was much overlap with the interviews of those who trust. identify as women, but the reasons behind certain parts would be different. For example, using a pad makes it more apparent that someone has their period, which was also an issue some of the other group of interviewees had. For genderqueer people, gender dysphoria is added on top of the discomfort of using pads.

Menstruating can already be tough to go through, but genderqueer people could experience even more gender dysphoria during that time. This is why it should be a priority to make it more bearable and to include them in the target group as it is a small effort. They are part of the target group, they menstruate. So they should feel like they are actually part of the target group and not as an outsider.

5.2.2 INFLUENCE, PERCEPTION & TRUST

INFLUENCE OF PEERS

R: It should be a product that users want to recommend to their peers or would want to use when recommended to them.

> "My older sister recommended to switch to tampons quite early. She said that it would make my life a lot easier. The people in my immediate environment have a bigger influence on me than what I see on social media."

At a younger age, one of the parents (mostly the mother) buys the menstrual products, so they tend to go with what is given. Also, they tend to utilise what their mother has lying around until they are old enough to look for alternatives themselves by researching on the internet and talking with friends about what they know and their opinions.

PERCEPTION & TRUST

R: The product should be perceived in the right context to give a positive association between user and product and create

> "I do not like the period blood when changing a tampon, especially in a public restroom when you need to put on your pants with a dirty finger, open the door and wash your hands with other people present. With an applicator, this is better because I can avoid touching the blood."

> "I feel comfortable with inserting my fingers during sex with my partner also when I'm on my period because sex is already 'dirty', a lot of liquids are involved, so it does not matter if I am touching slime or blood."

Surprisingly these quotes are from the same person. The context has a significant influence on how things are perceived. A different association can give other experiences.

5.2.3 PADS & MENSTRUAL UNDERWEAR

To the right the comments are presented the interviewees gave about wearing pads/liners during their period. Also their opinion about reusable pads and menstrual underwear is included.

It is seen that the majority of the comments are negatively towards pads. Though for some only that one advantage weighs in more than all the negative like using pads to prevent getting vaginal infections or toxic shock syndrome instead of using insertable products. Due to it easy straight forward way of using, it is a good product to start with.

> "You can hear it when you put it on. When it is a big pad it gets very bulky and I would be thinking that someone would notice it. It feels like wearing a diaper. The blood smells and it makes you sweat."

> "I do not feel sexy with pads, also you can see the wings of the pads. My kids see and ask about it when I walk around in it in underwear."

REQUIREMENTS AND WISHES

R. It should be of an easy size to take it with them to the bathroom, not bigger than the size of a pad.

R. It should not make them feel like they smell or can be smelled by others.

R. It should not make the period something on the foreground.

R. It should not make the user feel dirty while or after using it.

W. It should preferably make the user still feel sexy.

|--|--|--|

PRACTICALITIES

- Can sit between the butt cheeks depending on the underwear
- Produces much trash
- Placement needs to be careful to prevent leaking at night
- Not subtle to take to the restroom
- Can make a sound while walking
- Gives off a **smell** ("It makes me paranoid that others can smell that I am on my period")
- Not possible to **swim** with
- Separated from the body, not inserted, no fear or risk of TSS
- Possible to **see** the **flow** (informative for some, dirty feeling for others)
- Will not leak if put in the right way

RELATED TO FEELINGS

-	Wings on the pad ("It keeps it in place, but it is visible, this makes me feel unsexy")
-	Outspoken feeling of blood leaking/ flowing out
-	Irritating of the skin due to friction of wearing it several days in a row
-	Is sweaty
-	Bulky and diaper feeling
-	Dirty feeling
	BLE PADS AND MENSTRUAL WEAR
-	Having to wash it
+	Reusable so less waste
+	Fabric instead of plastic makes it less irritating
+	No/less of dirty feeling

5.2.4 TAMPONS

Tampons are received more positively, but there are more health concerns and a higher skill level is needed the properly insert a tampon. Once mastered, it is quick and easy to use but because it is made from cotton, the fabric can get over saturated and leak.

> "I sometimes have a painful feeling while inserting due to a wrong angle or I was having a lighter flow so less lubricant to slide it in."

> "I do have a fear that it will leak, I have had a couple of times that it came through my pants."

> "I have a light flow which makes it difficult to insert a tampon. I did not put it well and hurt myself while taking it out. There are so many ways to put it in wrong, while with the Beppy tampon there is not really a wrong way to put it."

REQUIREMENTS AND WISHES

R. It should not leave material of the product behind in the vagina canal.

R. It should give a safe feeling of it being retractable at any given moment.

R. It should be prevented that the product is pushed out while peeing/pooping.

W. It should preferably be not visible while swimming or going to the sauna.

W. Preferably, it can be prevented to pee on it without taking it out.

R. It should not look too mechanical, not like a tool.

R. It should not feel like giving themselves an injection.



PRACTICALITIES

- Residue of fluff can be left behind
- Getting pushed out due to force of muscles while peeing and pooping
- String can be felt

String being visible not preferred when going to the sauna or being intimate

+ String is a visible cue not to forget having a tampon inside

String gives confidence and trust to extract tampon at any point

Less visible than a pad (good for swimming)

- --- Small package to take with
- --- Gives off less of a smell

RELATED TO FEELINGS

- Difficulties and painful feeling to insert
- Unpleasant feeling to take out
- Afraid it gets stuck
- Fear of infections and TSS
- Is not felt when wearing
- Does not feel like a diaper
- Takes up less head space
- Does not feel like blood is leaking out

REUSABLE TAMPON FROM COTTON



What to do once it's saturated and taken out?

+

Would not trust it to collect all the blood

5.2.6 CUPS

Creating a better first experience by making it more user friendly to use. This done by focusing on deployment, insertion and extraction. Creating an easier learning curve

> "I did a lot of research and talked to friends about the cup. When I finally bought one from Saalt, it took me half an hour to get it back out. I never looked forward to extracting the cup, it took me 3 fingers to take it out which was hurtful. I stopped using the cup after having an internal infection twice. I switched back to using pads which are way more comfortable."

> "I do not like the cups with stem because you can feel the stem while inside and it is very difficult to remove it with."

> "Because you do not see the cup and do not feel it I am afraid that I would keep it in too long and forget about it. I would not mind having a reminder on the outside."

Finding a balance between a visible cue on the outside but still possible to go to the sauna without others noticing. Should make it worth it on lighter days too

R. It should be able to be inserted and taking out with one finger or max two fingers.

R. It should not take more than 1 minute to insert or take it out.

R. Information about the product should be accessible in ways like the package, the website, social media and contact with the company.

R. The process of sterilising should not take more time/steps than with the cup.

R. It should prevent as much contact of the fingers with the vagina as possible.

W. Preferably, it should prevent opening before it is in the right place



PRACTICALITIES

- Stem not meant to be used to pull out only to break the seal
- Difficult first experience, big learning curve
- Extracting takes practice
- Is reusable and can be used for +vears
- No visible cue on the outside, makes it perfect for swimming and sauna
- No visible cue on the outside makes it easier to forget having cup inside
- Can be left inside for longer period of time. Only emptying in the morning and evening.
- Takes time to take care of the product with cleaning and sterilising.

One time big financial investment

Less waste

RELATED TO FEELINGS

- Perceived as big
- Painful to insert when it is too big.
- Difficult to know which size to use
- Once known how to insert. then easier to repeat
- Can feel unpleasant to extract
- Can be difficult to get enough grip without being painful
- Not looking forward to _ inserting and extracting with lower flow

5.2.7 MOST IMPORTANT CHARACTERISTICS

Every interviewee was asked what they thought to be the three most important characteristics of a menstrual product. Furthermore, they had to describe their worst menstrual product, which gave a better understanding where and what frustrations exist. These characteristics are close to the opposites of their most valued characteristics.

R: It should not leak when wearing it in the correct manner and during the right time frame.

"I would rather use a bigger tampon to make sure I would not leak and therefore accept having the unpleasant feeling while taking it out, than having a smaller tampon that is easier to extract but has a bigger chance of leaking through."

R: While wearing it should not be felt or be actively conscious about.

"It should feel like a shirt, you know you are wearing one but you are not actively conscious about it."

Other important characteristics that were quoted are it should be easy to insert and take out, it should not smell, it has little environmental impact. it should not be expensive because it is not something they choose, and it should have a background story in a way that you feel apart of something.

The worst product for the majority would be one where they are aware of it the whole time while it is inside <-> not wanting to feel it. Furthermore, that it does not help and that it leaks <-> should not leak. Also, it being like a diaper or a very big pad which not only feels unpleasant but could also form a bulge that can be seen while wearing pants.

R. It should not make a sound while wearing it. R. It should not be bulgy like a diaper. R. It should not be recognised when wearing every day clothes.

Other worse characteristics would include it being painful while inserting and taking out. Some that were mentioned once: having to insert fingers, not being able to pee or poop with it, that it does not fit, and that it does not feel feminine.





SHOULD NOT MAKE A SOUND WHILE WEARING





SHOULD NOT BE VISIBLE WHILE WEARING CLOTHING

5.3 Collective period experiences

After doing the interviewees, I retrieved a lot of new perspectives and experiences on how people go through their periods. A lot of opposites with experiences. The goal will be to find a balance between all of these, selecting which problems are most important to solve and integrate.

There is a distinction of people wanting to be more **sustainable** and therefore are looking for a reusable alternative, and other people who prioritize their comfort and sustainability is only a nice extra, not a main focus.

People can be **forgetful** about having insertable products in, while others never have that problem because they get constantly reminded by heavy cramps. A solution can be having a visible cue on the outside, like in the case of a tampon where a string sticks out. However, this does not prevent people from never forgetting it or leaking through.

Being afraid to catch infections withholds people to use cups or tampons with applicator because of their **fingers getting in contact with the vagina** and blood. It is also possible that they find the blood just dirty and do not want to touch it, others do not bother and have no problems inserting their fingers.

Those who only use pads will never go **swimming** or go to the **sauna** while on their period. They are limited by there product use. While tampons can be used for swimming and the sauna, not everyone feels comfortable with them, for example the fear of the string showing.

As for every product **money** is a motivator to buy or not buy a product. Most would be willing to make an investment and try out something new. However, if it is not yet common enough, and intimidating at first look, the threshold may be higher, like with the cup.

Someones motivator to use a new product can differ significantly. For some, they try out new things all the time, while others would rather stay in their comfort zone or do a lot of research on there own before trying it out. However, their **peers** have a great influence regarding menstrual products. Because menstruating is still taboo and something more intimate and private, people will **trust** their friends judgment and experience more easily than for example an advertisement.

There is a **learning curve** with a lot of steps of the cup like cleaning and sterilising, inserting, and extracting. If not done properly, this can keep a user from utilising the product again, while this could have been a good product for them if there was better guidance and more knowledge available.

Conclusions User Experience



What are the **most important features** about a menstrual product that should definitely be included?



The product should not leak when worn in the right way.



R.S.

The product should not be painful when extracting.

The product should not give of a smell after wearing it 8 hours.



The product should not make a sound while wearing it



The product should not be recognisable while wearing clothing, or be visible through clothing.



What do people **like/dislike**, think are **advantages/disadvantages** about pads, tampons and cups?

- Most negative towards pads, it is bulky, it can smell, it not possible to swim, is sweaty, ... but prevents vaginal infections or TSS. It is easy and straight forward to use, good product to start with.
- Tampons are received more positively, but there are chances to get infections or TSS. Sometimes difficult to find the right position or to insert with low flow. It produces a lot of trash. Advantages is, it is small, quick to use, able to swim with.
- Cups are advantageous regarding sustainability, lower investment over time, and not being visible from the outside. However, the last one can also be negative. Other problems are the size and inserting with low flow.

^r ^r ^r

In what way do people who are assigned female at birth (**AFAB**) and who do not (only) identify as woman, **experience their period differently** from cisgender women?

The main take-aways were making the appearance more neutral, not the colours and figures related to (only) femininity. Alternatively, giving more options and adding more masculine looking appearances and figures.

There was much overlap with the interviews of those who identify as women, but the reasons behind certain parts would be different. For example, using a pad makes it more apparent that someone has their period, which was also an issue some of the other group of interviewees had. For genderqueer people, gender dysphoria is added on top of the discomfort of using pads.

The product should be addressed to all menstruators, so also intersex people, trans men, non binary people, and others who do not identify as women. Not all women menstruate and not all menstruators are women.

How do people choose what they wear during their period?

- They look at what their environment use like mother, sister, and friends
- Some do their own research others trust on recommendations from their peers
- It depends on what flow they have or what day of their period it is

6 MATERIALS & MANUFACTURING

6.1 Materials & manufacturing of current insertable products

6.1.1 Materials of cups

6.1.2 Production process of the Beppy cup

6.2 Important properties & characteristics for menstrual products

6.1.3 Bio-compatible materials

6.1.4 Shore hardness

6.3 Shape Memory Material

6.3.1 The working of the shape memory effect

6.3.2 Nitinol as Shape memory alloy

6.3.3 Applications in the medical field of Nitinol & other shape memory material

Chapter 6 explores the current materials used for menstrual cups. Furthermore, looking into which characteristics are essential to keep in mind for the product. At last, we dive into shape memory alloy, how the effect works, which material can be used in the body and what applications are interesting regarding menstrual products. Which materials are already used and would be appropriate to use for an insertable menstrual product?

To know what materials there are and how to select them.

What material properties & physical characteristics are most important to research and test for?

To know which material to select or not to select.

What manufacturing techniques are utilized for cups and especially the Beppy cup?

To know if this manufacturing technique is applicable for the new product.

How can a shape memory alloy be applied to a menstrual product?

To know its constraints and what it can do, to keep in mind for ideation

6.1 Materials & manufacturing of current insertable products

Menstrual cups are not only made from silicones, some consist of thermoplastic elastomer. In this section a comparison is performed between medical grade silicone and TPE. Furthermore, the production process of the Beppy Cup is visualised together with the mold.

6.1.1 MATERIALS OF CUPS

MEDICAL GRADE SILICONES VS MEDICAL GRADE THERMOPLASTIC ELASTOMER (TPE)

Medical grade silicones are primarily used for cups and also sex toys. The Beppy Cup is currently made from medical grade silicone (Figure 6.1). TPE is also used in some menstrual products like the Hello Cup (Figure 6.2). Advantages are that it is able to conform to the shape of the vagina under the influence of body heat, otherwise the cup is more firm than a silicone one. TPE cups are manufactured using pure medical-grade TPE granules. TPE is recyclable by remelting them at the end of the life cycle and can be re-purposed after use.

While a silicone cup still makes a seal against the vaginal wall, it does so more by creating even pressure all along the rim of the cup. TPE, however, still has a firmness to create pressure, will warm up inside the body and conform to the user's shape. Additionally, TPE has less reported incidences of causing an allergic reaction as compared to silicone.

TPE's used on the market: thermoplastic vulcanizate (TPV) or polyurethane thermoplastic elastomer (TPU). Typically, conventional rubbers will be deformed and unusable after melting. However, using TPE can avoid this limitation since they are easily melted down, reprocessed and/or remoulded





Figure 6.2 TPE Hello Cup

GRANTA EDUPACK COMPARISON

Utilising Granta Edupack I could find the following plastics (see Appendix H for data):

- Silicone (VMQ, heat cured, 10-30% fumed silica)
- Silicone (VMQ, thermally conductive 40-70% mineral)
- TPU (Ester, aromatic Shore A70)
- TPV (PP+EP(D)M. Shore A55
- TPV (PP+EP(D)M. Shore A55

The first Silicone has a shore around A50 and the second a shore around A75. Keeping in mind that the Beppy Cup has a shore of A55, I narrowed the selection criteria of Granta Edupack down to Silicones and thermoplastic elastomers close to that shore hardness. The five above are the result of that. TPU and TPV are both thermoplastic elastomers.

Looking at the durability. TPU has limited use with weak acids. From chapter 3, it became clear that the vagina has an average pH value of 4,5 which is slightly acidic. Furthermore, TPU is the highest in price per kg. On the other hand TPU scores the highest in Yield strength, tensile strength, elongation, and tear strength.

Both silicones have lower energy, CO2 and water user for processing energy. For primary production it is only the second silicone which has the lowest energy, CO2 and water.

Silicones are not recyclable while thermoplastic elastomers are recyclable. It is possible to remelt them. Silicones are incinerated at the end of life.

At the moment they are experimenting at Beppy to produce the Beppy Cup from a TPE. This takes some trial and error. For this project I will be focusing on using silicones because it is already in use for the Beppy Cup and it is easy to prototype with. However, TPE has some very interesting advantages, especially the recyclable part and the adjusting to the body due to its warmth. There should be looked further into this in the future of this project.

6.1.2 PRODUCTION PROCESS OF THE **BEPPY CUP**

Below the production process of the Beppy Cup is visualised (Figure 6.3). The production process is quite straight forward, mix the silicone and pigment, inject the silicone in the mold, demould by blowing air in the mould, and cleaning

There can be 30 cups produced with one injection by one person (Figure 6.4). In a factory of about four people handling these machines, about 1000 cups can be made per hour.

It is manufactured in a factory experienced with silicones and then passed on to a quality control company named KM Global Novelties Co. Limited. Both are situated in China so shipping to the Netherlands can take up to a month. up the edges after. The production of the cup costs 80 cents. From there it gets distributed over Europe. One exception is Colombia. There the products are shipped to in one go, this is also the only country in the American continent where Beppy sells at the moment.



Figure 6.3 Production process of the Beppy Cup



Figure 6.4 Worker handling the injection moulding machine.

THE MOULD OF THE BEPPY CUP

The mould of the Beppy cup is more complex because of the anti leakage rim. With other cups there would only be one core part necessary which can be lifted straight out of it. Figure 6.5 shows a prototype of the mould for the Beppy cup, it consists out of four parts. The two outer parts are held together by the press, also, in one of the parts the Beppy logo is embossed to transfer it to the silicone (Figure 6.6).

The core consists of another two parts. One part is on the inside of the anti leakage rim and has the form of a bucket. This part gets screwed into the top part, the second part of the core, which forms the outside of the rim (Figure 6.7). It is necessary to be able to screw them apart to get the rim loose from the mould (Figure 6.8).

The cost of the actually molds used to produce the cups is around 16.000 to 24.000 euro. It can stay in production to around 300.000 units. Now they are at 100.000 since 2 years ago when they began.



Figure 6.8 Showing how the different parts of the mould are placed to create the Beppy cup.



Figure 6.5 Prototype of the 4 part mould of the Beppy Cup. The core parts Figure 6.6 Close up of outer parts of Figure 6.7 Other view of the core of the are on the right



the mould.



mold

6.1.3 BIO-COMPATIBLE MATERIALS

clean.

6.2 Important properties & characteristics for menstrual products During the analysis of the insertable (menstrual) products, there was also

looked into which materials are used. In this section, these materials will be discussed.

The term 'biocompatibility' may be simply defined as the ability of a material to be accepted by the body. Since all materials generate a 'foreign body reaction' when implanted in the body, the degree of biocompatibility is related to the extent of this reaction. Therefore, biocompatibility is directly related to the corrosion behavior of the material in a specified solution and the tendency for an alloy to release potential toxic ions (Duerig et al., 1999).

Silicones get the term medical grade allocated when the following three requirements are fulfilled (Braley, 1970):

- 1. A long history of successful implantation in animals and humans.
- 2. Manufactured under pharmaceutically clean conditions.
- 3. Quality controlled for medical applications.

Planned Parenthood (2021) says If you're putting a sex toy inside your body (mouth, vagina, or anus), it's best to use one made of a body-safe, non-porous material — like 100% silicone (not silicone blends), hard plastic, stainless steel. aluminum, and break-resistant glass. Toys made from nonporous materials don't absorb germs and are easier to keep

Sex toys made from materials that may be porous — like silicone blends, jelly rubber, PVC, vinyl, TPR, TPE, elastomer, or other rubbery plastics — can absorb germs that can lead to infections, even if the toys are washed.

6.1.4 SHORE HARDNESS

One of the more relevant properties for this product is the shore hardness. There are three different Shore Hardness scales ranging from 0 to 100 for measuring the hardness of different materials: Shore 00. Shore A. and Shore D.

The first one Shore 00, is used for rubbers and gels that are very soft. Shore A goes from very soft and flexible to hard with almost no flexibility at all. At last, there is Shore D which is for hard rubbers and plastics, and semi-rigid plastics. Between the shores there is overlap.

Existing menstrual cups have a shore hardness ranging from 30A to 60A, the Beppy Cup has a shore hardness of 55. The Shore Hardness scale of Shore A is used for menstrual cups so this is also the scale that will be used throughout this report and testing.



Figure 6.9 Shore hardness scale with examples used in real life. Menstrual cups have a shore hardness between shore 30A and 60A

6.3 Shape Memory Material

6.3.1 THE WORKING OF THE SHAPE MEMORY EFFECT

At temperatures above 500 degrees Celsius, nitinol can be shaped into whatever form. On atomic level, the structure consists out of cubic crystals. This phase is called the **austenitic phase**, the SMA sample is at a temperature above $A_{\rm F}$ (austenite finish temperature)

When the temperature of the sample decreases and crosses the line related to M_s (martensite start temperature), the phase transformation begins to take place and the twinned structure forms (**twinned martensite**), the cubic crystal structure has turned into a rhombustic structure. This change in atoms does not visually affect the overall shape. This martensite twinned structure replaces the austenite. The transformation is complete when the sample temperature is below M_F (martensite finish temperature).

Under a constant temperature a mechanical load (σ) is applied, deforming the wire. The atoms in the crystallites shift in the grains to some unequal mixture of left and right rhombuses, which is known as the **detwinned martensite**. When this load vanishes the sample presents a residual strain.

The former programmed shape of the sample can be recovered through a heating process by reaching $A_{\rm F}$, causing the reverse martensitic transformation (detwinned martensite \rightarrow austenite). When the shape cools down again, the atoms go back to their twinned structure, everything can be repeated from here.

This process is the shape memory effect, also known as one way shape memory effect. Shape memory material has a broad application in many fields covering aerospace engineering, biomedical devices, flexible electronics, soft robotics, shape memory arrays, and 4D printing (Xia et al., 2020).









Figure 6.10 SMA wires fastened between the plate and the screw.



Figure 6.11 Outside and inside of the ceramic oven.

Figure 6.12 Process of taking out the metal plate with safety gear.

SMA PROCESS IN PRACTICE

In order to create the shape memory effect, the wire needs to be programmed. Below is explained how I have done this with the help of the tools available in the TU Delft Materials Lab at the Industrial Design Engineering faculty. For production size this of course will be done on a bigger scale and more automated but the essentials are the same: fastening in the desired shape, program it in an oven around 550°C, cool it down.

The SMA wires can be fastened on the metal plate by placing it between the plate and the screws. It needs to be tightened quite well to ensure it will be programmed in the chosen shape.

To program the shape, the wire needs to reach high temperatures. For this, the ceramic oven was utilised. The oven was preheated to 550°C, which took about one hour. With protecting heat gear, I could safely place the metal plate with the wires in the oven. The wires are kept in the oven for about one hour, taken out with safety gear, and cooled down in a bucket of water. Afterwards, the screws can be loosened, and the programmed SMA shape is finished.

6.3.2 NITINOL AS SHAPE MEMORY ALLOY

Although a relatively wide variety of alloys present the shape memory effect, only those that can recover from a large amount of strain or generate an expressive restitution force are of commercial interest (Tarnita et al., 2009). Essentially Nitinol is an alloy containing approximately 50 % Nickel and 50% Titanium.

BIO-COMPATIBILITY

Titanium is not toxic when used in the human body;however, nickel is extremely toxic. Nitinol forms a passive titanium oxide layer (TiO 2) that acts as both a physical barrier to nickel oxidation and protects the material from corrosion. This layer is responsible for the high resistance to corrosion of titanium alloys, and the fact that they are harmless to the human body (Machado, 2002).

Its corrosion resistance is greater than that of stainless steel. It has been shown that the cytotoxicity of nitinol is comparable with other implantable alloys. (Tarnita et al., 2009)

NiTi is a suitable material for biomedical applications due to its excellent biocompatibility (Parvizi et al., 2012; (Bansiddhi et al., 2008) high corrosion resistance (Barbarino et al., 2014), low stiffness (Pfeifer et al., 2013) (around 1/4 of other material stiffness), and good compatibility with magnetic resonance imaging and computer tomography scanning (Duerig et al., 1999).

STRESS AND STRAIN

Three parameters control the behavior of the material: the stress, s (where F is the force); the strain, e (or the length L); and the temperature, T. Mantovani (2000). In the figure below it can be seen that high elasticity, low deformation forces and constant force over wide ranges of strain are characteristic of bone as well as Nitinol. On the other hand stainless steel is not at all elastic and will break at half of the strain Nitinol can handle.



JOINING

In the graduation report of Liselotte Stolk the following was found about joining Nitinol:

"Nitinol is not suitable for soldering, since it has a tough oxide outer layer. However, an aggressive flux could be used to remove the oxide, after which soldering is possible. A more effective method is welding. Laser, TIG and resistance welding are all methods that are effective. Nitinol welded to dissimilar metals, such as stainless steel, does not give acceptable results since the outcome is a brittle inter metallic interface which cannot be stress relieved.

Nitinol can be bonded to other materials using medicalgrade epoxies and adhesives. Mechanical techniques such as crimping and swaging are possible. Another mechanical technique is to use Nitinol's shape memory or superelastic properties to join materials. A Nitinol tube connector can be expanded either mechanically or by cooling it to martensite and deforming it. The Nitinol connector is then applied over another element and allowed to return to austenite, causing it to clamp down on the element."

FATIGUE BEHAVIOUR

Biomedical devices manufactured from Nitinol (e.g. peripheral vascular stents) can experience up to 40 million loading cycles each year. Therefore, these implants need to be designed to survive some 108–109 fatigue cycles without failure over the lifetime of the patient (Robertson, 2012).

Van Humbeeck identified three different types of fatigue that are important for SMAs. The first is the usual failure due to fracture caused by cycling under stresses or strains at a constant temperature. The second is changes in material properties, such as the transformation temperatures and transformation hysteresis because of thermal cycling through the transformation. The third is the degradation of the SME because of mechanical or thermal cycling (Wilkes, 2000).

Shape memory material seems to have superior fatigue resistance compared to superelastic material. The surface finish as wall as the A_f temperature of Nitinol has an effect on the fatigue resistance: increased fatigue life was observed for electropolished wire and for higher A_f Nitinol wire (Wick, 2006).

Since the ${\rm A}_{\rm f}$ will be on body temperature the fatigue resistance will be lower.

6.3.3 APPLICATIONS IN THE MEDICAL FIELD OF NITINOL & OTHER SHAPE MEMORY MATERIAL

In this section five applications of Nitinol or other shape memory material are discussed. These applications are all utilized in the medical field and therefore are a could inspiration for what is possible in this field.



Figure 6.13 Simon vena cave filter, top and front view (left), deployment process (right)

SIMON VENA CAVE FILTER

The Simon vena cave filter (Figure 6.2) is a stent to prevent clots from reaching the heart and lungs by filtering them. The clots are trapped by the legs and the filter's 'flower', then dissolve over time (Duerig et al., 1999). The device is preloaded into a continuous cooled catheter to keep the filter in its martensitic state while positioned at the deployment site. When released, the **device is warmed by the surrounding blood and recovers** its 'pre-programmed' shape (Duerig et al., 1999).



20°C



41°C

SUTURE FOR WOUND CLOSURE

A shape memory polymer application is this biodegradable suture for wound closure. The wound is loosely sutured with a standard surgical needle, and when the temperature is increased to 41°C, the shape memory effect gets actuated (Lendlein et al., 2002). This actuation ensures the defined stress is applied to the wound lips. This can be seen in figure at the left. Removel of the implant in follow-up surgery is not necessary, as the implant degrades within a predefined time interval.

ORTHODONTIC NITI ARCHWIRES

Stainless steel and other conventional appliances require adjustment by the orthodontist, which can cause pain and discomfort to the patient. Nitinol wire is able to move with the teeth, applying a constant force over a broad treatment time and position, resulting in fewer archwire changes and thus visits to the orthodontist. The lighter forces give less patient discomfort. In addition, **different grades of wire stiffness allow for different stresses** in the treatment (Duerig et al., 1999).







EVOLUT PRO TRANSCATHETER AORTIC VALVE REPLACEMENT (TAVR)

The Evolut PRO is a self-expanding transcatheter aortic valve with advanced sealing capability. The system features a design with **an external porcine pericardial tissue wrap fastened around the outer sealing zone of the frame** (Medtronic, 2020). This addition adds surface area contact between the valve and the native aortic annulus to further increase valve sealing performance.

The self-expandable Nitinol frame of the stent shows a diamond-like cell design with struts at different lengths and thicknesses to optimise the expansion to a nonregular shape (Petrini, 2011). The insertion procedure consists of positioning the device with a specifically designed catheter without the need for removal of the native valve.



SHAPE MEMORY STAPLE

The shape memory staple, in its opened shape, is placed at the site where to rebuild the fractured bone. **Through heating by an external device, not the body temperature, this staple tends to close**, compressing the separated part of bones (Machado, 2003). The force generated by this process accelerates healing, reducing the time of recovery. Figure to the left shows an application of these staples during the healing process of a patient's foot fracture.

Conclusions Materials & Manufacturing

Which materials are already used and would be appropriate to use for an insertable menstrual product?

Chosen to go for medical grade silicone because it is already in use for the Beppy Cup and it is easy to prototype with. But since they are experimenting at Beppy with TPE, it takes trial and error to do it right, so better to wait for these results first. What material properties & physical characteristics are most important to research and test for?

JOINING

- Nitinol not suitable for soldering because of tough oxide outer layer
- A more effective method is welding. Laser, TIG and resistance welding
- A Nitinol tube connector can be expanded either mechanically or by cooling it to martensite and deforming it. The Nitinol connector is then applied over another element and allowed to return to austenite, causing it to clamp down on the element.

FATIGUE

- Shape memory material seems to have superior fatigue resistance compared to superelastic material.
- Increased fatigue life was observed for electropolished wire and for higher A_f Nitinol wire (Wick, 2006).
- Since the A_f will be on body temperature the fatigue resistance will be lower.

What manufacturing techniques are utilized for cups and especially the Beppy cup?

- Silicones get mixed in the right color, then injection moulded, demoulded with air blown in the mould, finished up by cleaning the edges
- The mould for the Beppy Cup consists of four parts
- It is produced in a silicone factory in China, checked for quality at other company in China, transported via train or ship to NL and Colombia. Distributed from NL to other countries.

How can a shape memory alloy be applied to a menstrual product?

- Nitinol works in the body and in an environment surrounded by blood. Body temp = temp when expands
- Different grades of stiffness give different stresses
- The actuation of the shape memory results in the defines stress (programmed shape) being applied
- There are biodegradable shape memory polymers, these are to be avoided This all proves in theory that a menstrual product
- Centration goits with encothern state in a mensural product
 Centration goits with encothern state in a product is possible.
- It is possible to make the material in a shape that closes and compresses parts of the body when activated, the other way around, opening up with a delivered stress could be possible

PARTI DESIGN DIRECTION

The next two pages give an overview of the retrieved requirements from the analysis. These give a reference for the product.

One of the requirements is to design the product in a way that the initial With the information of the analysis kept in mind, the problem definition is diameter of the product used to insert should be similar to the diameter of a inspected again and some additions will be made: tampon, without having to use a constant external force, like fingers pushing • it collects blood --> because people when they hear 'tampon' directly think the material together.

To still collect a similar amount of blood as the cup and to make sure the product stays in place, it should be made deployable. Deployment of the • less intimidating to insert **and extract** --> some interviewees indicated that inserting was not a problem but taking out a cup was painful and took product is a challenge more related to the functionality of the product. a lot of time

The updated problem definition is found below.

(Unforseen) circumstances or environment depending circumstances that will not be inspected further are as follows:

7.1 Updating the problem definition 7.2 Design challenges

of the cotton cylindrical shape

UNFORSEEN CIRCUMSTANCES

- Forgetting to take the product with them when they know they are menstruating
- Bleeding out of nowhere without having anything with them
- Not having enough or the right products with them
- No toilet closeby to change within the time frame of 8 hours
- Not having the tools to sterilize the product

These circumstances are more related to the actions of the person than the functions of the product. Though, there will be some comprimising, looking at point 3, the product should still be able to collect an average amount of blood.

7.1.1 HOW TO DEPLOY?

7.1.2 HOW TO INSERT?

Insertion and the deployment go hand in hand. To insert, the diameter of the product should be small, and once inside the vagina canal it will deploy and adapt to the vagina walls.

Since people can get intimidated by the size of a menstrual cup, it is an important characteristic of the new design to have the initial diameter similar to a regular tampon. With the goal giving users a more trustworthy feeling and less intimidating feeling than the menstrual cup. Insertion of the product is a challenge more related to the user experience of the user.

7.1.3 HOW TO EXTRACT?

Extracting an insertable products can be with a string like the tampon, or with a stem or loop with a cup. Some people like a visible cue on the outside others do not, and this also depends on the environment. So preferably the design gives the user a choice on how to extract the products.

Designing a new suitable menstruation product for Beppy that is reusable, collects blood, has a similar (deployable) size and function as a tampon, and which is perceived as **less intimidating** to insert and extract than a menstrual cup. In addition, applying appropriate researched **manufacturing techniques** during the process.


The width of the product can range from **12mm to 37mm**, at the entracne of the vagina, and **21.7mm to 55mm** at the flexure width from



The product should be smaller than or around the length of the lower side of the ranges of the vagina lengths, namely anterior wall: **63mm (± 9mm)**; posterior wall: **98mm (± 18mm)**; linear length **62.7mm (range 40.8mm-95mm).**



The product should be able to collect 43.4 ± 2.3 ml over the duration of the period which can be two to eight days. The upper limit is **60-80ml**.

The product should be able to minimise the volume of air trapped when inserted. To prevent an increase in Staphylococcus aureus growth.

The material of the product should be resistant to the acidic level of the vagina, pH value 4.5.



The size of the product should be measured by comparing with sizes of products the user already uses and not with if they have been pregnant, since the vagina walls heal back after delivery. Maybe extra help is needed with pelvic floor exercises.

Anatomy & Health



The product should be able to double its diameter size like regular tampons do: going from **12.8mm to 25.2mm**

The length of the product before insertion should be similar to the length of a dry tampon which is **47.4mm**



The product should as a maximum limit have the deployed diameter similar to menstrual cups: range of **35mm to 62mm** with an average of **42.6mm**



The product should not have a shape similar to a bladder support, because this can put pressure on the bladder and prevent from peeing.



The product should preferably work without an applicator, but if an applicator is necessary it should also work with existing reusable applicators.



It should have the recognisable cylindrical shape of a tampon as begin state.

The product should be able to be removed with one finger



The product should give the user the choice of showing something on the outside or not either to not forget having something inside or the retract the product.



The product should collect blood like a menstrual cup and not absorb blood like a tampon. It should also be able to collect blood clots.



There should be no constant external force necessary, like fingers pushing the material together, to keep that diameter similar to a tampon for easier insertion.

Current status of (period) products



The product should not leak when worn in the right way.

R.S.

The product should not be felt while wearing it the whole time. It should feel like a shirt, knowing you are wearing one but not being actively conscious about it.

The product should not be painful when extracting. The product should not give of a smell after wearing it 8 hours.



The product should not make a sound while wearing it

The product should not be recognisable while wearing clothing, or be visible through clothing.

The product should be addressed to all menstruators, so also trans men, non binary people, and others who do not identify as women. Not all women menstruate and not all menstruators are women.

The product should be used by people looking for a sustainable alternative who tried a cup once before but painfully struggled with inserting and extracting

The product should be used by people who do not yet feel comfortable with menstrual cups (how they look, their size), but who also does not use tampons to much because of fear of infections. This product is a good comprimise.

User Experience

The product should be made with medical grade silicone if the company keeps using the same factory. Alternatively, if more research is done by Beppy the product could be made with a TPE, this way it can be recycled.

The mould should at maximum cost 24.000 euro for the production of 300.000 products

The mould should preferable have a maximum of 4 parts.

The production of the production should cost around 80 cents

The product should have a shore hardness between A30 and A60 $\,$

The product should be able to exist out of a composite of shape memory wire and silicone.

Materials & Manufacturing

PARTIV FINAL CONCEPT **FROM IDEATION** TOFINALISATION

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The Beppy Clover

The name is chosen because of its physical appearance, having three sections. Therefore, similar to a clover having three petals. Furthermore it is a link to nature which can show its reusability. Clover is easy to say and has a positive association to it which will help to find the product less intimidating.

shape are similar to a single use tampon.

Opening in the top parts to open up together with the rest. Otherwise it will be restricted and hang over.

Ribs added for

more grip.

Thickness of the silicone parts with SMA is 2mm.

Length and

Loop added to the bottom, to

extract with one finger. The

indents are made to attach

the extraction cord.

Only three petal parts to keep it easy to fold the parts back in.

> Thickness of the silicone parts without SMA, that are folded, is 1mm.

The 1mm parts also help to give room to fold back in a bit when extracting. This makes extracting easier.

 SMA wire is loop shaped and programmed to bend, this way the three petals will deploy.

Capacity is one tablespoon (12mm).

Difference in diameter going from 16mm to 30 mm.



On the left, the final concept is presented: the Beppy Clover! Below some parts are covered in short. The more in depth explanation regarding the deployment. extraction and insertion can be found in the following chapters.

MECHANISM

Before insertion the product has the shape and form similar to a single use tampon. This shape is obtained by folding the thinner section of the product inside. Furthermore, Shape Memory Alloy wire is embedded in the three thicker sections of the product. These are shaped in vertical loops and are programmed to bend and therefore open the product. The wire has an activation temperature of body temperature. This means once the product is inserted into the vagina canal the product will deploy due to the warmth of the vagina and the blood. The deployed form will then collect blood.

INSERTION

The top is similar to the top of a tampon or an applicator. The material is hard enough to be able to push it but soft enough to deploy. For comfort it is possible to combine it with water based lubrication.

EXTRACTION

The users has the choice how to extract the product. One option is by the loop attached to the body of the product, the other option is threading the silicone cord through the loop before inserting and taking it out by pulling the string. Different sizes will be 'meegeleverd' to give user the choice to use different lengths for different situations. For example, a shorter one for intimacy or going to the sauna, but a longer one clearly sticking out the labia, for a day at home when quick changes are necessary.



DIMENSIONS

Dimensions are carefully thought out by researching the dimensions of current products like tampons and cups, but also other insertable products like dilators. The goal was to have dimensions similar enough to a tampon but great enough to have capacity similar to a menstrual cup.

CLEANING

Just as a menstrual cup, this product is reusable and needs to be cleaned between emptyings and sterilised at the end or beginning of a cycle. This can be done in a pan of boiling water, which does not affect the mechanism of the SMA. The SMA can only change its programmed shape if the temperature is 550 degrees Celsius and baked for over an hour.

8.4.1 DIMENSIONS

16MM

30MM



	47MM

The most important dimensions are explained below. A more detailed version can be found in Appendix I.

INITIAL DIAMETER

- Should be similar to the average regular single use tampon dry: 12.8mm
- Should be similar to the lower bound of the range of the introitus: 12.0mm - 37mm
- Should be similar to or greater than the smallest dilator size: 12.7mm

The chosen **diameter** of the **undeployed** Beppy Clover is **16mm.**

DEPLOYED DIAMETER

- Should be similar to or greater than the average regular single use tampon - wet: 25.2mm
- Should be similar or smaller than the diameter range of cups: 36mm - 48mm
- Should be similar to double the size of the diameter of the initial diameter (the diameter of a wet tampon also doubles): ~32mm
- Should be similar or smaller than the largest dilator size: 41.3mm

The chosen **diameter** of the **deployed** Beppy Clover is **30mm.**

LENGTH (WITHOUT EXTRACTION LOOP)

- Should be similar to the average regular single use tampon length dry: 47.4mm
- Should be similar or smaller than the lower bound of the range of the vaginal linear length: 40.8mm - 95mm

The chosen length without the extraction loop of the undeployed Beppy Clover is **47mm**

THICKNESS

• Should be similar to the thickness of the Beppy Cup: 1mm-2mm

The chosen **thickness** for the Beppy Clover for the section that are not folded is **2mm**. The folded sections are **1mm**. The **extraction cord** has a diameter of 2.5mm







Depending if it is the beginning of the period or already the during the use of the product, it should be sterilised. Afterwards, the user can choose a cord length or no cord at all. The cord is attached and the three sections of the Clover need to be manually pushed inside. The product will keep its shape due to the shape memory alloy wire inside.

Cup.

again!

8.4.2 USER CYCLE

Now the Clover can be inserted. Wait about 10-20 seconds and check if the product stays in place by giving it a gentle pull. The SMA wire should be activated in that time and deploy the Clover.

Do not keep it in longer than 8hours to reduce the risk of TSS. It is possible that changing is necessary even before the 8hours are over. This is because the capacity of the Beppy Clover is less than the Beppy

Extract by pulling on the cord or to grab the loop with one finger. Due to the thinner walls of the folding sections, these will automatically fold in a little while extracting. This should make it a more pleasant experience. Now the Clover can be emptied and rinsed, ready to insert



DEPLOYMENT 9

9.1 Ways to deploy?

STUDIO DRIFT

By making a collage (see Appendix J) inspecting what ways something can expand/deploy, a selection of three manners was done. Origami, biomimicry, and utilizing shape memory material. In this section, these are discussed and a decision is made for the final design.

9.1.1 BIOMIMICRY

Inspecting the sepals (the green leaves) of both the open and closed state of flowers it is clear that they stand up at first and then make an angle of more than 90 degrees (Figure 8.10). This way the petals have room to open and flourish.

A change, whether it be an increase or decrease, in temperature and light intensity is a trigger for most flower species to open or close. A small temperature rise in the morning was adequate for full opening of ficaria (Figure 8.4) and other down. flowers (van Doorn & van Meeteren, 2003).

Combining this mechanism with shape memory alloy wire is a plausible way to deploy the top of the product once it is inserted inside. Just like the flower it would react due to a temperature change and open up due to it.





Figure 8.1 Cherry blossom Figure 8.2 Ficaria; number (white): number of sepals is five.



of sepals is three



Figure 8.3 Sepal opening



Figure 8.4 Kinetic installation (Shylight & Semblance) by Studio Drift

Studio Drift has a kinetic installation (Shylight & Semblance, Figure 8.4) that replicates the movement of flowers. The installation mirrors the natural mechanism called 'nyctinasty', in the case of flowers the closing of the petals at dusk.

Reflecting this to a menstrual product, it is desired to have that smaller diameter initially (closed flower), which transforms and deploys into a bigger diameter due to a trigger. In the case of the installation the flower is dropped

9.1.2 ORIGAMI BY KURIBAYASHI

A known way to deploy something is by using origami. There are origami figures like a bird or a plane but origami techniques can also be used in the medical field. Kuribayashi developed a stent from shape memory alloy material to deploy and therefore adapt to the artery by combining it with an origami shape (Figure 9.1).

More about the details of Kuribayashi's folding pattern can be found in Appendix K. Ni-rich TiNi foils were used because martensitic transformation temperature is adjustable to the temperature near human body by appropriate aging (Kuribayashi, 2006).

Unfortunately this origami pattern would not be feasible to use in a menstrual product. It is a complicated fold to recreate and it seems to have sharp edges (see Appendix K to see a replication of part of the fold).



Figure 9.1 Series of frames from video recording showing self-deployment of the stent after inserted into an acrylic tube of 25mm radius. The stent graft was self-expanding at above $A_{\pm}(319 \text{ K})$.

9.1.3 SHAPE MEMORY ALLOYS - NITINOL

In the analysis several applications of Nitinol have been discussed, in this section I will further look into one of them, namely the Simon vena cave filter (Figure 9.2).

Inspecting how this product is constructed, some things from both the origami and biomimicry seem to be present. The shape is symmetrical in a way that it repeats itself. This is also the case for flowers.

Due to it shape it is possible to pass through a tube with a very small diameter. This kind of deployment is what I am looking for. Thinking of the tube being the size of the introitus and the artery the vagina canal.



Figure 9.2 Simon vena cave filter, top and front view (left), deployment process (right)

9.2 Proof of concept

This section research the feasibility of the idea of using shape memory alloy as a composite in silicones. Does the shape memory effect still work when the wire is encapsulated in silicones? What shapes are possible? And how much difference does it make in time to go back to the programmed shape?

The figure below (Figure 9.3) shows which variables related to the SMA wire or silicones influences the time and force of deployment. For each variable, a range or if possible one unit was chosen. Ideally, the **temperature of** the surroundings in which the SMA will react will be body temperature - the vagina canal. Furthermore, the wire's activation temperature should also be body temperature.

Looking at the **composition of the SMA**, this will be Nitinol or NiTiCu. Nitinol is already used for medical devices, but NiTiCu has some other properties, like the fatigue behaviour will be different. Unfortunately, due to time constricts, this project does not have enough research to determine which SMA material is the best.

The diameter of the SMA wire depends on the thickness of the silicone shape. After the tests, a good balance became clear to be 0.5mm wire thickness encapsulated in 2mm silicone. However, the tests were limited by manually produced prototypes. It is possible that with more professional machinery, the thicknesses can be optimised.

The shore hardness of the silicones will depend on the silicone thickness and the SMA wire's diameter. A good balance must be found, where the product is stiff enough to keep its shape but not too stiff that it cannot deploy anymore.



the time and force it would need to deploy the product.

Graph 9.1 Comparison of test with NiTiCu wire (A. = 65°C: 0.5mm thickness) programmed in a 90° angle versus the same NiTiCu wire encapsulated in 2mm thick silicone. Starting position is a 180° angle. The shapes reacts with hot water. Figure 9.6 SMA wire reacting with hot water going from straight back to the programmed 90° angle

angle.

9.2.1 COMPARISON PERFORMANCE OF SMA WIRE & COMPOSITE, 90° ANGLE

Two tests were executed with SMA wire only and with the composite of a NiTiCu SMA wire with silicone A50 shore. The SMA wire was programmed into a 90° angle. With applied stress, the shape was deformed into a 180° angle (1) (Graph 9.1; Figure 9.6; Figure 9.4) and a folded wire (2) (Graph 9.2; Figure 9.7; Figure 9.5). The SMA wire was then activated by putting the shape in a container filled with almost boiling water.

The goal was to see if the SMA effect would still work once it is encapsulated in silicones and to what extent it differs from SMA wire only timewise.

> $(A_{r} = 65^{\circ}C; 0.5mm)$ (A50 shore, 2mm) (1) NITICU WIRE VS NITICU WIRE IN SILICONE **REACTING AT 90° C WATER**

As expected, the SMA wire with a 0.5mm thickness guickly, within two seconds, goes back to its programmed shape. This is probably related to how hot the water was. Because by repeating the test when the water cooled off a bit, the wire did not fully return to a 90° angle. The mechanism could be applied to deploy the menstrual product. The straight shape to an angle can be seen as the product opening up.

The shape of the composite can still return to the 90° angle of the SMA wire, although it takes a longer time: nine seconds. There was no significant difference between the two starting positions, and no significant difference between the different silicone thicknesses.

Knowing that the composite of silicones and SMA wire works is benefitial for further ideation of a deployable menstrual product.

(A50 shore: 2mm)



(A_r=65°C;0.5mm)

Graph 9.2 Comparison of test with NiTiCu wire $(A_{c} =$ 65°C: 0.5mm thickness) programmed in a 90° angle versus the same NiTiCu wire encapsulated in 2mm thick silicone. Starting position is folded in the way that the two legs of the angle are parallel. The shapes react with hot water.

Figure 9.7 SMA wire reacting with hot water going from the two sides being parallel back to the programmed 90° angle

Figure 9.5 Composite of SMA 0.5mm wire and A50 shore silicone reacting with hot water going from parallel legs to angle.

Figure 9.4 Composite of SMA 0.5mm wire and A50 shore silicone reacting with hot water going from straight to



Three 3D-printed molds were made with three different thicknesses: 1mm, 1.5mm, and 2mm (Figure 9.8). There was chosen to use the programmed shape of the SMA wire (Figure 9.10) as the shape for the mold. This way, the material is encouraged more to go back to this angle.

Doing the tests in hot water with all thicknesses there was not a significant difference timewise. However, the 2mm thickness gave the best protection of the wire, to fully encapsulate it with less chances of the wire getting exposed.

A challenge was positioning the SMA wire at the same height for all three models since the mould was not designed to do that. Instead, the mould was filled with silicones, and the wire was freehandedly pushed to about half the height. However, this came out differently for all three thicknesses, as shown in Figure 9.9. Further research is necessary to inspect if it is more valuable to encapsulate the ceramic oven wire, not in the middle but more to one of the sides.



Figure 9.10 SMA wire restrained to be programmed in the



Figure 9.8 The 3D-printed molds filled with A50 silicones and SMA wire of 0.5mm. Thickness of the mold from left to right: 1mm, 1.5mm, and 2mm.



Figure 9.9 Different position of wire in 1mm, 1.5mm, and 2mm thickness cast.

9.2.2 COMPARISON PERFORMANCE OF SMA WIRE & COMPOSITE, HEXAGON SHAPE

The 3D-printed mold (Figure 9.11) had the same problem as the However, the composite in the hexagon shape did work. As 90-degree angle molds, correctly positioning the SMA wire at about half of the height. The thickness of the mold was 1.5mm. Furthermore, NiTiCu SMA wire with a thickness of 0.5 mm was used because it uniformly returned to its hexagon shape in about nine became clear that the body temperature Nitinol wire of 0.25 mm would be too thin to exert a big enough force when encapsulated in composite of the 90° angle. the silicones. The thinner SMA wire was also twice as fast to go back to its shape than the 0.50mm wire from the 90° angle tests.

 $(A_{E}=35^{\circ}C; 0.25mm)$ $(A_{E}=65^{\circ}C; 0.5mm)$ (A50 shore, 2mm) **REACTING AT 90° C WATER**

Graph 9.3 Comparison of test with NiTi wire (A, = 35°C; 0.25mm thickness) programmed in a hexagon shape versus a thicker NiTiCu wire $(A_{c} = 65^{\circ}C; 0.5mm)$ encapsulated in 2mm thick silicone. Starting position is a folded inwards into having a smaller diameter. The shapes reacts with hot water.



water and returning to its original hexagon shape.



Figure 9.14 Composite of SMA 0.5mm wire and A50 shore silicone reacting with hot water returning to its original hexagon shape

seen in Figure 9.14 the hexagon was first deformed into a smaller diameter and, once in contact with hot water. seconds, which is the same amount of time it took for the

The hexagon shape was chosen because the SMA wire was limited by the raster of holes which could not make a whole circle (Figure 9.15). Looking back, this was an advantage because it was easier to fold the shape into a smaller diameter.

The closed loop hexagon composite works, which means this principle could be implemented in the design of the new menstrual product as this is also based on a closed loop.

The disadvantage of SMA wires is that they cannot be soldered without changing the finish, so the end of the wires could not be fastened together at these points (Figure 9.12).





Figure 9.15 Shape to program Figure 9.11 The 3D-printed Figure 9.12Theendsofthewires SMA wire, difficult to create molds filled with A50 silicones not attached to each other and circle, so it became a hexagon. and SMA wire of 0.5mm. were not able to be aligned. Thickness of the mold is 1.5mm





9.3 First sketches on how to deploy

With the information of the analysis kept in mind, brainstorming and sketching was done. Three brainstorm sessions were organised to go into specific questions or problems.

9.3.1 DRAWINGS

I started sketching to tackle the following challenge:

Have a product with an initial diameter and shape similar to a tampon where no constant external force, like fingers pushing the material, is necessary to keep that diameter, which then deploys into a bigger diameter once inserted into the vagina canal.

Eventually, with the help of the brainstorming sessions, three ideas were interesting to explore further. Two with shape memory wire integrated and one without-more about that in the following sections.

The second session was with a fellow student colleague from my master's study (Figure 9.19). With her, we went into the more technical side: how to deploy with and without shape memory alloy and how the extract aid could be designed (Figure 9.17). See Appendix L for more information.

At last, together with Sarah (Figure 9.20), the product designer from Beppy, we reflected on the earlier brainstorms and explored shapes by drawing random lines and shapes on paper. Using these lines to find possible product shapes, as can be seen in Figure 9.16.

9.3.2 BRAINSTORMING SESSIONS

The first brainstorming session was with two women in their 20's (Figure 9.18). Due to restrictions, this was held online using the online whiteboard Miro, makingit possible to use post-its together. In Appendix L these boards can be found. Three questions were explored:

- How can you make something adaptable to a form?
- How can you not forget something?
- How can you keep something in its place?



Figure 9.16 Exploring shapes by first drawing random lines and shapes and afterwards making 3D products out of them.



Figure 9.17 Brainstrom with post-its on how to deploy with SMA (left), how to deploy without SMA (right).



Figure 9.18 Setup of first brainstorm session.

Figure 9.19 Setup of second brainstorm session.

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9.4 Prototyping the ideas with silicones and SMA wire

After sketching and brainstorming, three ideas were chosen to explore more to see what is possible in practice. Do these ideas on paper also work in real life? For this, 3D printed PLA moulds are made to create silicone shapes. Besides, SMA wire was programmed and added.

9.4.1 SILICONE POURING & CURING PROCESS

In section 6.1.2, the production process of the silicone Beppy Cup was described. A part of this process was used by me but then in a lower quality way and with the material accessible in the TU Delft lab. However, overall it still works the same: create a mould (Figure 9.22), choose the proper shore hardness of the silicone, mix the silicones in the correct ratio and make them air bubble-free (Figure 9.21), inject them into the mould and let it cure for 3 hours (Figure 9.23), at last, demould the product/ prototype (Figure 9.24).

I decided to order silicone with hardness 50A and 5A at siliconesandmore.com, which was described to be safe to use for the erotic industry. By mixing both of them and depending on the ratio, it is possible to create the shore hardnesses between 5A and 50A. Keep in mind that a menstrual cup can have a shore hardness between 30A and 60A.



Figure 9.21 Vacuum chamber (left) and silicone cup before with all the air bubbles inside (top right), and after being in vacuum (bottom right)



Figure 9.22 Part of mould 3D printed Figure 9.23 Mould after silicone Figure 9.24 Mould after opening,
by an Ultimaker 2+ with PLA poured into and secured with screws prototype with SMA wire inside.

9.4.2 FLOWER DESIGN WITH ROUND SMA WIRE

IDEA : Line up a SMA wire in the rim at the top, with a circle as the programmed shape. It is pressed together when inserted and deploys by the SMA wire going back to its round shape.

GOAL : Testing with this prototype if it works in practice to insert the SMA wire in the rim to deploy the top and therefore the whole product.

- The mold was not designed to fit the wire, the wire was forced to fit, which is why it sticks out
- It
- It did not go back to its programmed circle shape at A_r



- Depending on only one SMA wire to work, is a high load
- The wire is superelastic which makes it difficult to bend into angles
- Weak point where the ends meet

With a better shape it could be possible that this mechanism would work. A special rim should be made to fit the wire. But the rim would become closer to the thickness of a regular rim of a cup which is something to prevent.

Difficult to fold due to the SMA wire going all around



Can easily adapt to different shapes



Diameter after deployment is doubled



Simple loop shape of the SMA wire is programmed in an angle, which works well

9.4.3 FLOWER DESIGN WITH VERTICAL LOOP SMA WIRE

IDEA : Using folds with thinner thickness to create the smaller diameter when pressed together, furthermore adding SMA loops in the four sections to make it open up once activated.

GOAL : Checking how the silicone prototype folds and testing if the position of the SMA wire works and how much the it opens up

Using difference in silicone thickness for folds

—

Deployment does not depend on the performance of only one SMA wire

One wire needed for each section, can increase the costs

The four sections can be difficult to fold, lowering to three could be better

The difference in diameter in the out of mould position and the activated one is rather small. This is probably because it is limited by the shape to deploy even more. 4

-

The combination of two sides having a thickness of 1mm and two sides 2mm works well together. It still has some great strength and does not look fragile.

 The idea worked of pushing two side together to colapse it worked in 2D but not in 3D or at least not with this shape and not without extra help

9.4.4 DESIGN WITHOUT SMA WIRE

IDEA : Pushing together two sides would make the two thinner sides collapse and form a diameter similar to a regular tampon

GOAL: Test if the idea works in practice and if something can be combined with the other ideas. Also, this prototype tested one of the extraction aids, see Chapter 10 about Extraction.

> Does not have the look of a tampon, looks like a redesign of a menstrual cup

It is possible to fold the top into a smaller diameter only it is not yet possible to keep it in this fold without holding it at the top



Trying out some folds by pinching the thinner side inwards also lowers the diameter at the top

But the design should have a beginning shape with the diameter of a regular tamon without external force needed

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9.5 Design decisions regarding deployment

In this section there is reflected on the results from the prototype testing and the final deploying mechanism is explained.



9.5.1 CONCLUSIONS FROM PROTOTYPES

- Keep multiple SMA wires. Not a good idea to only have one wire doing all the work, also it does not fit to be put in the top rim.
- Keep the SMA wires divided vertically over the section.
- Keep the SMA vertical loop shape
- Use three sections instead of four
- Keep the difference in silicone thickness of 1mm for the folds and 2mm for the sections where the SMA wire is encapsulated
- Remember that the design of the mould and the design shape also has a great effect on how good the SMA wire works
- Without SMA wire it is not possible to design something that stays in a tampon like beginning shape, with the designs tried

9.5.2 CHARACTERISTICS OF THE DEPLOYMENT DESIGN AND MECHANISM

The SMA wire utilised should be one of 5mm thickness and has an activation temperature of body temperature. The exact material will need to be researched further depending on, amongst other things, fatigue behaviour. The two potential materials are Nitinol and NiTiCu. Nitinol is known to be used in the medical field and inside the body.

The loop is programmed so that it makes an angle when activated. The programmed angle can be greater than the angle the product will make with deploying. This way, more force is exerted on the sections, making deploying faster.

The Beppy Clover can be sterilised in boiling water just as a cup. That will not influence the wire since the temperature to program the metal has to be 550°C. The only thing that will happen is it deploys into its open state. After sterilising, the Clover can be closed by manually pushing the sections together. It is then ready to insert.

10 INSERTION

Part of the user cycle is, of course, inserting the product. It already helps that with the deployment design, the diameter is more similar to a single use tampon, but now the top needs to be designed.

With the prototypes from deployment, the top was not taken into account. While the diameter of the body is important to insert, the top can also make a difference in how comfortable something is.

Looking at single use tampons and tampon applicators (Figure 10.3), they all have a rounded top. This is the goal to replicate. Furthermore, the DAME. The reusable applicator was an excellent inspiration since it has a top consisting of three sections.

Ideally, the Beppy Clover also fits into the DAME. applicator for people who would like to use an applicator. the top of the Beppy Clover, since it opens up. However, some lubricant will probably be necessary because both are plastics, making it more difficult to slide out, depending on the texture.

The final design has three top sections closed off enough to comfortably slide in and not block the blood from entering the cup once deployed. In addition, each section has a central cut in it to make it more flexible to deploy.



Figure 10.4 Perspective view of the Undeployed Beppy Clover and top view.



Figure 10.1 Part of the DAME. applicator as inspiration for Figure 10.3 A regular single use

applicator where the top is divided into sections.



Figure 10.2 Besides as inspiration, the applicator can also actually be used to insert the Beppy Clover

11 EXTRACTION

11.5.1 STATE OF THE ART

Beppy sets itself apart from most other brands by using a loop which can be easily grabbed by the finger (Figure 11.3). Other brands use a stem and add ribbing for more grip (Figure 11.4). There are different sizes and shapes. However, it is said that the stem acts as a guide to locate the cup and should not be used to pull out the cup. Which is opposite to what a string is used for in a single use tampon.

In Figure 11.1 the three kegel trainers of Intimate Health are displayed. These are made from 100% silicone, which reflects in the products' extraction chord being visibly flexible. What is not known is the shore hardness of the silicone. The vibrating exercise egg (Figure 11.2) has a touch button and a magnetic recharging point at the end of the retrieval cord which makes it more stiff in comparison to the kegel trainers.

These products show that it is possible to have a chord or extensions specifically made to retrieve the product. The only difference is that these products are primarily used for a shorter time. This can be about 5 minutes to half an hour per day. So the question arises if this retrieval cord is comfortable, meaning not being felt when worn the whole day and a couple of days in a row, the length of a period.



Figure 11.3 Extraction loop of the Beppy Сир



Figure 11.4 The DivaCup with stem and ribbing



Figure 11.1 Pelvic floor trainers by Intimate Health made from silicone with flexible silicone extraction cord



Figure 11.2 Vibrating exercise egg by Intimate Health made from silicone with a flexible silicone extraction cord.



Figure 11.5 Take out aid idea string and loop in Figure 11.6 Removable string method 1 one by turning inside out



securing it by replicating principle of a press stud



loop from the product

Figure 11.7 Spiral string manner



USER INSIGHTS 11.5.2

By interviewing people and talking about this subject in general with other people, it became clear that there needs to be found a balance. Namely, the balance between the product not being visible when swimming/going to the sauna/ being intimate with someone, and the product not being forgotten to take out in time. For some, the string of a tampon is a visual reminder that they have something inside. However, not having that visual cue is a reason people can be hesitant about using a cup.

Furthermore, there can be the (irrational) fear of not being able to retrieve the product at all or not retrieving it in time. For example, three people using a menstrual cup (a bell shaped one with a stem) struggled for more than half an hour to take it out. This can be due to not being experienced with the product, but they were uncomfortable and in pain which should be avoided. An assumption of mine is that these three would need a smaller cup size for easier retrieval.

11.5.3 SILICONE EXTRACTION IDEAS

Four main ideas were retrieved after brainstorming and were then prototyped (more details see Appendix M). They are discussed below.

The inside out string and loop (Figure 11.5) can only be used when the walls of the product are straight. Otherwise, the product deforms when turned inside out. The removable string method with the press stud (Figure 11.6) was a good competitor, but since preventing leaks is one of the top priorities, people are less likely to trust something with a hole in the bottom even though it is blocked. The spiral string (Figure 11.7) was designed to sit close to the vulva to prevent the string from showing, for example, while swimming. Unfortunately, this is not similar to the single use tampon, which makes people hesitant about it. The other removable string method (Figure 11.8) was the most familiar, a simple string that sticks out. An added feature was it being removable.

After speaking with some people and evaluating the silicone prototypes, the preferred design was the second method of the removable string (Figure 11.8). It looks the most familiar, and people like the idea of having the choice of whether they want the string or the loop.

11.5.4 THE PROTOTYPE

The mechanism of the extraction works as follows: thread the cord through the loop of the product and then through its own loop and pull (Figure 11.9 & Figure 11.10). The strings will be of different lengths to give people the choice for different occasions. It could also be a possibility to customise the cords, for example like the hearts of the pelvic floor trainer (Figure 11.1).

Some problems with the current prototype were that the string did not stay in place, the loop of the string itself was not tight enough. Furthermore, the diameter of the string can be reduced. At last, it should be made less bulky where it is attached to the product loop.

- Figure 11.9 Removable string method 2 securing it by threading it through its own loop
- The user can choose the length they want or only the original loop of the product
- Easy to put on by threading through the hole
- Could be difficult to remove when pulled to hard
- Could tear more easily due to several friction points
- The different size strings could become lost



Figure 11.10 Removable string method 2 - instructions on how to thread the string through its loop

11.5.5 ITERATION

An iteration was made to solve some of the problems. Two ribs are added to where the cord needs to be secured. This way, when pulling, the stress is divided more, and the connection point will be less loaded and, therefore, less likely to tear. Also, now when releasing the cord, it will still be secure. Furthermore, the shape of the loop of the product is made slimmer, and the string is connected on top and not at the side. This will help with keeping the string in place. The size of the string diameter is made smaller and three ribs are added at the end to have some grip to pull out. The hole of the loop is the same diameter as the string, 2.5mm. Since it is made from silicone, the material has more room to be flexible, so it is still possible to thread the string through it. The strings will be delivered in three different sizes: 80mm, 55mm, and 30mm.







12 PRODUCTION

The production process will be similar to the Beppy Cup, The question is in which position of deployment it is most discussed in section 6.1.2, only the step of encapsulating desirable to mould the product. When it is fully closed, the the SMA material is added. There are companies that mould will be very difficult to be made, but when it is fully manufacture SMA and can also create the shape requested.

Since the silicone factory is situated in China, it would be best to stay close to that environment for the SMA wire. This way the transport between the two places is minimised.

Next to the body of the Clover, there are also the extraction cord with three different lengths. These will have their own mould.

The customer demand fluctuates through the year. There is not yet a clear pattern to find in it. So sometimes products will be out of stock.

The Beppy Cup costs 80 cents to produce and a minimum of 2500 cups get produced in one batch of one colour.

The costs of the Beppy Clover will be higher due to

- Extra moulds for the three extraction cords
- SMA material and production of the SMA wire loops
- More precision and testing necessary

opened, the will be more difficult to keep the shape closed. On the other hand, it is preferred that the silicones also help with deploying and not everything is left to the strength of the SMA wire.

However, it should be kept in mind that the temperature has influence on the SMA wire, so an in-between state would also mean an in-between state of the SMA wire. This is difficult to regulate since a change in temperature can cause the SMA wire not fit the silicone mould anymore.

It is therefore recommended to mould the Beppy Clover in its open deployed state. This means the SMA wire should be activated to a certain point. After the injection moulding and the finishing, the product should be fitted into its undeployed state.



Clover

13 BRANDING

Beppy is focused on giving the customer a surprise element. For example, the packaging of the Beppy Cup (Figure 13.1). When opening the pastel-coloured box, the illustrations inside give an explosion of colours, which is not something For example, they talk about pubic hairstyles, what happens to be expected. Besides the packaging, the surprise factor of the Beppy Clover would be its changing deploying shape. This will spark interest in people.

The Beppy Clover would be similarly packaged because, just like the cup, it will be sold in pairs or in a pair of the Clover and the Cup. The reason for that is always to have a sterilised product at hand.

Looking at colour, the current palette (Figure 13.2) can be applied to the Beppy Clover, since the same silicones will be used.

- Wonder: Purple/Turquoise
- Ocean: Transparent/Turquoise
- Sunrise: Red/Orange
- Midnight: Black/Purple
- Cotten Candy: Purple/Pink
- Cherry: Red/Black

Figure 13.2 Combinations of colors for the Beppy Cup that can also be utilised for the Beppy

Beppy is known to be active on social media such as Instagram and TikTok. There are made multiple posts per week, which are not only promotional but also educational. to the vagina after birth, and how to clean the cup.

These canals are perfect for explaining step-by-step how to use the Clover because it is a product never seen before. and people will want and need that extra knowledge.



Figure 13.1 Packaging of the Beppy Cup

PART V EVALUATION

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14.1 Evaluation with three interviewees

To evaluate the concept I especially search for people who never used a cup before and are hesitant to actually buy one, or who have used one but switched back to other menstrual products, or who are looking for a more sustainable alternative.

Variables that were not taken into account were age, parity, and nationality. As was seen in the analysis these may have an influence on the usability but because this evaluation was focused on the perception of the product, I chose to go with people who fit the restrictions listed above.

In the figure to the right the set up of the interview can be seen, in the Appendix N the full interview can be found. Besides questions, they also got the assignment to arrange five menstrual products according to least intimidating to most intimidating to insert. The five products in question are:

- A single use tampon by o.b.
- A tampon with applicator
- The Organi Cup (bell shape)
- The Beppy Cup
- The reusable tampon (a PLA 3D print of it)



The reason to go with both the bell shaped standard cup and the Beppy Cup is because their shape is vastly different, also the way of extraction and its diameter. This redesign is not yet popular or known so this is interesting to see if these features also affect their perception.



14.1.1 NEW INSIGHTS

The heaviness of the flow is a variable that has a significant impact on the decision which product to use.

"I use tampons when I do not have my cup with me or when my flow is light, like on the first or last day, because it is more dry. This makes it more difficult to properly insert the cup." -P2

"I always use tampons when I menstruate, on the first days bigger ones, and at the end the mini tampons are good enough." -P3

It was mentioned that they would see the Beppy Clover as an addition to the cup and not a replacement or not only as an in between phase of going from tampon to a cup. P3 said they would want to use the Clover on lighter days when inserting a cup is difficult because there is not enough lubricant due to the blood yet. Also, there is just not that much blood to be collected, so inserting a menstrual cup would be unnecessary. This is definitely something to keep in mind on how to present the product to the user. First impressions of the new concept. They all said it resembles a tampon when it was closed. Also, very interestingly, all three mentioned it could depend on how it is depicted on the packaging.

> "Looking at its form and size it looks like a tampon but because you can see it is made from silicones I would suspect it to be a cup. Also, if the deployed shape is portrayed on the packaging and if you read how it works I would get the idea that it is a cup." -P1

> "It has the same shape as a tampon, definitely when it is not yet deployed. But it depends on what is shown on the **packaging**. Closed I would say it leans towards a tampon, open it is more like a cup." -P2

> "I instantly associate it with a tampon, because it has the shape of a tampon. If the **packaging** says it is reusable then I would be influenced to think it is more towards a cup." -P3

14.2 Evaluating the problem definition

Designing a new suitable menstruation product for Beppy that is reusable, collects blood, has a similar (deployable) size and function as a tampon, and which is perceived as less intimidating to insert and extract than a menstrual cup. In addition, applying appropriate researched manufacturing techniques during the process.

IT SHOULD HAVE A SIMILAR (DEPLOYABLE) SIZE AND FUNCTION AS A TAMPON

First impressions about inserting.

"Depends on where you are in your cycle, the last days can feel quite dry and it can rub when inserting a tampon and feel it inside. So I suppose this will also be for the cup. But on for example the second day I can imagine it easily gliding inside." -P1

"I have never seen the Beppy Cup before. I am used to the bell shaped cup, which seems less intimidating. The Beppy Cup also looks more difficult to fold which makes it more intimidating." -P2

"Quite a big thing, due to the size I can almost imagine it pushing on my vagina walls."-P3 Interestingly, the person who uses the cup regularly for the past 6 years (P2) also says to find the tampon less intimidating to insert than the cup.

I would have imagined the applicator being less intimidating because it still has a tampon shape but learning from the interviewees the length also plays a role. They never used one and it looks long and big. P1 said It is so big for no good reason and it has a lot of plastic for only one use. Furthermore P 2 mentioned that they knew it was easy to use but it looks quite big due to the stick added to it. At last P3 likes to have control, the same as why she would not use gloves while doing the dishes, then you cannot feel if you are cleaning the dirt. With an applicator she would not know if it sits the right way.



IT SHOULD BE PERCEIVED AS LESS INTIMIDATING TO INSERT AND EXTRACT THAN A MENSTRUAL CUP

The most important requirement regarding the impression would be that it looks less intimidating to insert and extract than a cup. As seen in the figure below, they all positioned the Beppy Cup as most intimidating, and the new design on the second place. Reasons mentioned were the cup being the largest which probably means it is most difficult to insert (P1), P3 said it looks like a cow bell, but that it seems nice to have a loop to extract.

Positioning the concept on two because it resembles a tampon, the only intimidating part could be that it deploys and how it would be to make it smaller again. The material was one of the reasons for P3 to position it behind the single use tampon. The silicone would made it a bit more intimidating in the beginning.

14.3 Evaluating the requirements and wishes

In general

- The Clover has a smaller volume as the cup. This is good in terms of decreasing the risk of TSS. Because inserting a higher volume of air results in a slight increase of the bacteria that causes TSS.
- The size is similar to a tampon or cup, which makes it easy to take to the bathroom.
- The product collects blood like a menstrual cup and does not absorb blood like a tampon. It is also able to collect blood clots.
- Requirements related to the dimensions are discussed in the dimensions section before. These requirements are fulfilled. However, it is necessary to test with a working prototype if the product actually fits the majority of vaginas.

Related to branding

- Information about the product should be accessible in ways like the package, the website, social media and contact with the company. This is already done with the Beppy Cup and other products, so I forsee no problems with this.
- The Clover will be sold in pairs to have a second sterilised one available. I would recoomend that this can be in pairs of two Clovers but also as a combi of the Clover and the cup
- The name Beppy Clover is a neutral name and not specifically related or associated with something feminine. This way the product can be branded in a more inclusive way for all menstruators.
- It is recommended that the Clover should be branded as an addition to everyones collection of menstrual products and not as a replacement of the cup.

| | | | | | | |

Related to insertion

- It has the recognisable cylinderical shape of a tampon as a begin state.
- There is no constant external force necessary to keep the diameter similar to a tampon for easier insertion. Pressure needs to be put on the three sections to deform the product back into the undeployed state, but once the hands are released. The product stays that way.
- The product works without an applicator but there could be checked if it works with a reusable applicator like DAME. for user who feel more comfortable with that.
- The product is insertable which does not make it bulgy like a diaper.
- Since the product is inserted and probably only part of the extraction cord sticks out, it will not be recognised when wearing every day clothes.

Related to retraction

- The product gives the user the choice of showing something on the outside or not. Either to not forget having something inside or the retract the product.
- Due to the given choice on how to retract the Clover it fulfills the requirements of giving a safe feeling of the product being retractable at any given moment.
- The retraction cord is removable so it is possible to wear it while not being visible while swimming or going to the sauna. There are also three sizes of the cord which can make it less visible.
- In theory it seems to be possible to insert and take out the product with one or maximum two fingers. This should be checked with testing a working prototype.

Related to cleaning

• The same cleaning routine as the cup can be kept

Physical things to check when testing with a working prototype is possible.

- It should not leak when wearing it in the correct manner and during the right time frame.
- While wearing it should not be felt. It should feel like a shirt, knowing you are wearing one but not being actively conscious about it.
- It should not make a sound while wearing it.
- It should not stop people from peeing or pooping.
- It should not make them feel like they smell or can be smelled by others.
- It should not make the user feel dirty while or after using it.
- It should preferably make the user still feel sexy
- It should not take more than 1 minute to insert or take out
- The product should not give of a smell after wearing it 8 hours.
- The product should not be painful when extracting. This is probably going to be okay since the product can fold a bit when extracting.

Recommendations on further research related to deployment

- Further research to where the SMA wire should bend
- Further research to measure the force the wires can give and therefore how the deploying will work
- How long the life of the mechanism is if there is fatigue of the metal, and which SMA to choose, Nitinol or NiTiCu?
- How much does it costs to join the ends of the SMA loops, because it cannot be soldered. Is it worth the price?
- Research to whether it is easy to bring back the shape to its original form after deployment
- Further research would be necessary to inspect how to fold the Clover to its closed state. Is it influenced by the temperature of the hands? And what about environments where the temperature is above 35 degrees Celsius?
- How sustainable is the product when there is SMA wire embedded?
- How does the product function with the SMA wire embedded? Does it still collect blood? This would be interesting to research if the option with SMA is too expensive

In conclusion the end result of the project is a promising final concept that could be the first step in the right direction regarding development of reusable blood collecting tampons.

Utilising emerging materials was interesting to research its possibilities in period products. More tests and research on the combination of silicones and SMA wire reacting to body temperature will be necessary to optimise the force of the deployment of the product. Nevertheless, the Beppy Clover achieved its goal of being a blood collecting, reusable product that is perceived as less intimidating than the cup and has a similar (deployable) size and function as a tampon.



14.4 Reflection on personal ambitions

In my design brief I formulated the following personal ambitions:

- Finding a working style that fits me and has a better balance between work and mental health, minimizing stress and setting clear boundaries that I will not cross.
- Using at least two new design methods/tools/way of prototyping
- Learning how to talk about and address a taboo subject
- Being more proactive about reaching out to and using more resources.
- Improving my skills with Illustrator by making my own illustrations for the report

WORKING STYLE - I put myself on the first place even if I did not always wanted to do this. I learned more about my needs and rhythm of studying. I really listened to my body.

NEW DESIGN TOOL/METHODS/PROTOTYPING -

Learned how to use silicones and program shape memory wire.

TABOO - I am so used to talking about vagina's now and this project was a good conversation starter.

REACHING OUT - I reached out to a lot of people, mostly students. This could improve some more but it was already more challenging with the corona restrictions.

ILLUSTRATOR SKILL - Towards my green light I explored some more with illustrator and actually made quite some illustrations that I am proud of.

Overall I can happily say that I achieved my personal ambitions.

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