REDESIGN OF THE CHLOE GTM

A modular, durable and user-friendly design to improve hands-on training for gynaecological procedures in low-resource settings

ACKNOWLEDGEMENTS

This thesis is the final project of my Master's degree in Integrated Product Design at the Faculty of Industrial Design Engineering at TU Delft. I dedicated my time to researching, designing and writing this thesis from September 2024 to March 2025. This report gives an overview of the work accomplished during these months. During this project, I learned about gynaecology, medical systems, design for emerging markets, the Kenyan culture and had the opportunity to improve my embodiment skills.

I would like to express my gratitude to supervisory team: JC, Sonja and Karl. Thank you for taking the time to meet with me, have inspiring conversations, motivating me but also telling me to slow down when I needed to. It has been a pleasure working with you all. I would also like to thank the rest of the Chloe Innovations team, for the meetings we have had and the amazing work you do. I would like to thank all the people in Kenya who helped me throughout the project with the testing but also for the inspiring conversations we shared.

I would also like to thank everybody else who has been a part of my graduation: the Dutch gynaecologists, experts, PMB staff and my roommate, GJ, for taking amazing pictures of the model. Finally, I would like to thank all my friends and family for their support.

I hope you enjoy reading the report as much as I enjoyed the project.

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Faculty of Industrial Design Engineering
Delft University of Technology

Author
Juliet Samira Schutten
4864018

TU Delft Supervisory Team
Prof. Dr. Ir. Diehl, J.C.
Dr. Ir. Paus-Buzink, S. N.
Ir. Samenjo, K.T.

EXECUTIVE SUMMARY

Expensive and bulky gynaecological training models are often inaccessible in low-resource settings (LRS) in Kenya, leaving medical professionals without adequate hands-on experience. Building upon previous work by Joséphine Kiewiet de Jonge (2024), the Chloe Gynaecological Training Model (GTM) has been further developed from a first prototype to a more effective, user-friendly, and durable training tool for local medical professionals.

The primary focus was to develop a cost-effective and portable design that allows nurses and other healthcare providers to practise essential gynaecological procedures, including paracervical block, manual vacuum aspiration (MVA), loop electrosurgical excision procedure (LEEP), intrauterine device insertions and removals, and cervical cancer screenings. To maximise the training effectiveness in LRS, the redesigned Chloe GTM prioritizes local manufacturing and repair, realistic simulation for accurate procedural practise, consistent stability during use and easy assembly for safe setup.

The process involved several key stages. First, relevant information was gathered through desk research on the design context in LRS, female anatomy, gynaecological procedures, available materials, existing training products and materials. Next, a comprehensive analysis of the existing Chloe GTM was conducted to identify its strengths and weaknesses. User and expert feedback were gathered to determine critical steps of each procedure and the type of feedback needed for effective training. This was used to prioritize features for the redesigned model.

The design was developed through three sprints. Sprint one focused on creating the initial redesign (v.I) by addressing issues such as the fragility of the stand, instability of the body, and difficulty in using the connections. Sprint two involved testing the redesigned model (v.I) in Kenya to gather feedback from medical professionals in a low-resource setting. Twenty local medical professionals were asked to try different procedures on the model and provide feedback on the accuracy and the useful in training. v.II was developed during the time in Kenya. The feedback was used in sprint three to further refine the model in the Netherlands, resulting in design v.III. The model and assembly guide were tested with eight students. Furthermore, the model was tested with a gynaecologist to ensure correct use and effectiveness in training.

The final design, v.IV, is a compact, eight-part model that provides training for various procedures. It incorporates several key improvements, including a more realistic vaginal opening with added external labia and structure, a transparent uterus for visualizing IUD placement, a textured uterus for providing feedback during MVA procedures, the option to place cardboard cervices for cervical cancer screening and sausages for LEEP. The connections of the design have improved to ensure proper alignment, minimizing damage and allowing for correct training. The modular design enhances the model's versatility, enabling users to easily change the silicone components with locally sourced materials like fruit or meat for procedures such as MVA and LEEP.

The redesigned Chloe GTM is a significant improvement to the original model, offering a more stable, user-friendly, and versatile training tool suitable for low-resource settings. The design utilizes only three materials and relies on a single outsourced component, the clasp, with the rest of the model being locally producible, costing €20 per unit. The product remains portable, weighing only 425gr and fitting in a bag of 21x8x14 cm. Future work should focus on testing with students and integrating educational aids to maximize the model's impact. Recommendations include improving the MVA procedure feedback, adding anatomy, exploring sustainable materials, improving the tolerances, and developing demonstration modules. By building on the solid foundation established through analysis and testing, the Chloe GTM has the potential to transform medical training in low-resource settings.

TABLE OF CONTENTS

GLOSSARY

MVA	Manual Vacuum Aspiration
LEEP	Loop Electrosurgical Excision Procedure
IUD	Intrauterine Device
PCB	Paracervical Block
LRS	Low Resource Settings
HRS	High Resource Settings
SED	Syringe Extension Device
GTM	Gynaecological Training Model
OB/GYN	Obstetrician Gynaecologist
TRL	Technology Readiness Level
v.0	Version design - Joséphine Kiewiet de Jonge
v.I	Version design - after sprint one
v.II	Version design - made in Kenya
v.III	Version design - made with improvements in Kenya
v.IV	Version design - final design

INTRODUCTION

This chapter introduces the context, objectives, and approach for the assignment. It begins by outlining the challenges faced in training gynaecological procedures in low-resource settings and the limitations of the current prototype. The design brief and primary goals for the redesign are presented, along with the specific procedures the model must support. Finally, the report structure is explained.

01

1.1 INTRODUCTION

BACKGROUND

In Kenya, medical professionals are not always schooled properly to perform vaginal gynaecological procedures. Existing training models are expensive, limiting their accessibility. They are also extremely bulky, meaning they are not easy to carry to different hospitals, departments or rooms. This results in medical professionals having little or no hands-on training before they need to perform procedures on real patients potentially leading to poor results and unnecessary patient discomfort.

Joséphine Kiewiet de Jonge developed the first version of the Chloe GTM (Gynaecological Training Model); a low-cost, portable training model to specifically practice the placement of a paracervical block (PCB) (See Figure 1 and 2) (Kiewiet De Jonge, 2024). This is a regional nerve block technique used for pain relief during various gynaecological procedures. Currently the PCB procedure relies on the use of long needles to reach the cervix. As these are expensive and cannot be practiced sufficiently, PCB is often neglected, leading to painful gynaecological procedures. Addressing this, Chloe Innovations has developed a syringe extendable device (SED) that can be used as a replacement for the long needles commonly used (Samenjo et al., 2023). The current GTM model has been developed to support the training of PCB procedures with the Chloe SED.

However the model still needs to be optimized. Certain assembly steps are not perceived as logical or user friendly and the design is fragile, held together by a clamp and a ring. Furthermore the current training portfolio needs to be extended. If healthcare facilities are to invest in the product, they want to be able to train different vaginal procedures, such as bimanual examinations, cervical screenings, manual vacuum aspirations (MVA), biopsy collections, the insertion and removal of intrauterine devices (IUDs), thermal ablation and loop electrosurgical excision procedure (LEEP). The design needs to be adapted accordingly.

DESIGN BRIEF

This project aims to design a product to facilitate the training of multiple gynaecological procedures in sub-Saharan Africa (SSA).

The assignment was to:

Improve the design of Chloe GTM to a well-developed TRL level 7-8, making it suitable for training gynaecological procedures in low-resource settings in Kenya.*

* The gynaecological procedures are: bimanual examinations, cervical screenings, injecting into the cervix (PCB) manual vacuum aspirations (MVA), biopsy collections, and the insertion and removal of intrauterine devices (IUDs).

The following question was formulated to guide the project:

How can the Chloe GTM be redesigned to create a better product that allows users to practise multiple procedures and is user-friendly whilst remaining suitable for low-resource settings?

Figure 1: Chloe GTM design v0 by Joséphine de Jonge with the Chloe SED

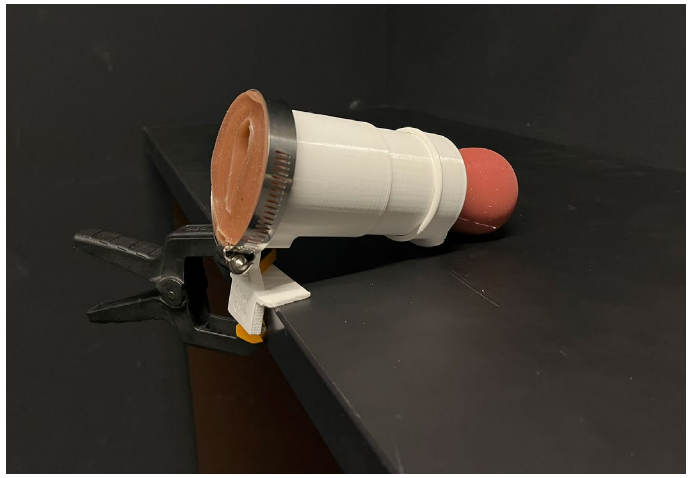


Figure 2: Chloe GTM design v0 including clamps

1.2 STRUCTURE

REPORT SETUP

This report is set up in different chapters, representing the six different parts of the design process (See Figure 3). Each chapter is designated to a specific part in the process (excluding introduction and conclusions).

The design process follows the following structure: First a 'diamond' approach is used, where during the first 'discover' phase relevant information is gathered on the design context, female anatomy, how procedures work, current products, and materials. This will also include a detailed breakdown of the existing design's pros and cons. In the 'define' phase, insights from the analysis are refined, leading to the formation of design requirements and prioritization of features. This phase concludes with the development of a refined design brief.

Next, the design is developed in three sprints. The first sprint uses the new set of requirements to develop the model from v.0 to v.I. The second sprint is based in Kenya. v.I is tested according to the test plan. From the results, new design directions and requirements are set. Sprint three uses those requirements to develop the model further in the Netherlands (v.III). Finally, more validation is done and the final design is presented (v.IV).

READING GUIDE

Figure 3 illustrates the structure of the report. At the start of each chapter, the figure is repeated to indicate your current position within the report.

Different colours are used throughout the report, these colours represent the different reproductive health organs:

Vagina | Cervix | Uterus

REQUIREMENTS

The green blocks represent requirements and key take-aways per chapter. While some requirements identified during the analysis phase remain general, they are re-evaluated and refined during the 'define' phase.

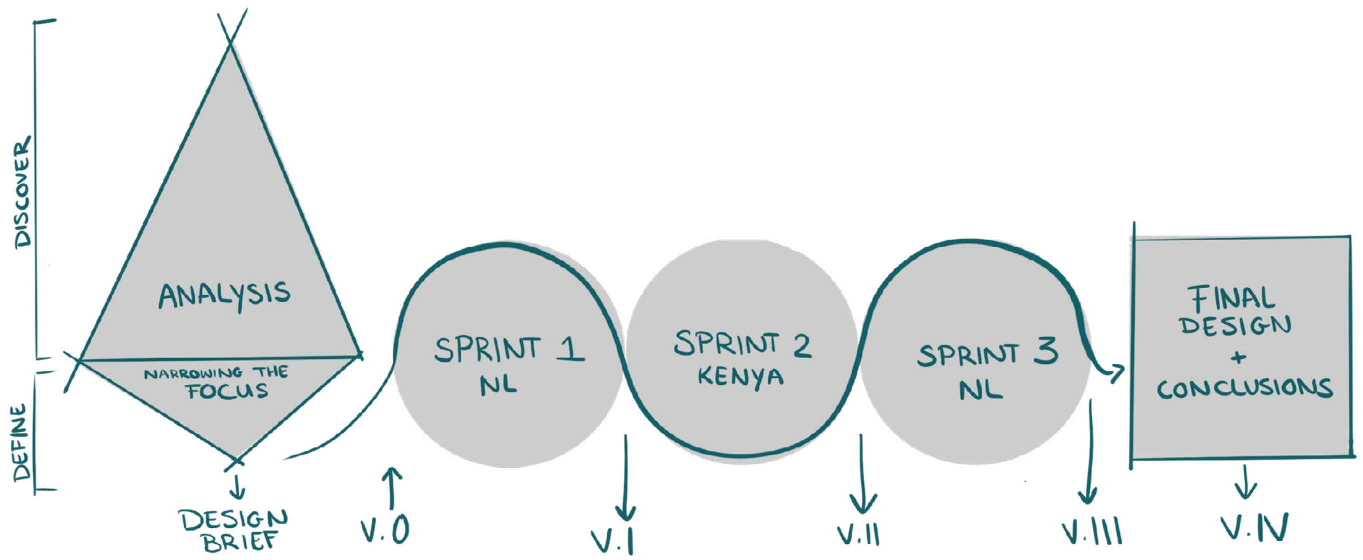


Figure 3: Structure of the report

ANALYSIS

This chapter presents a comprehensive analysis of the key considerations—contextual, anatomical, procedural, material, and user-specific—that are essential for designing an effective gynaecological training model (GTM). It also includes an analysis of the current design. Each section begins by introducing the topic and highlighting a series of questions to clarify why the information is relevant to the GTM. After presenting the core information, each section concludes with a summary of key answers to the guiding questions. This is followed by a list of requirements, which will guide the GTM's design. The information was gathered through literature review (desk research), expert consultations, user feedback, and hands-on testing.

02

2.1 DESIGN CONTEXT

This section will cover the structure and challenges of medical training in low-resource settings in sub-Saharan Africa, with a focus on gynaecological procedures. It will identify key users, and explore the limitations they face in accessing hands-on practice. Finally, the chapter will discuss the need for a training model that addresses these challenges.

QUESTIONS

How does the medical training system work in low-resource settings in sub-Saharan Africa?

To identify the key users of the product and to understand their specific training needs and challenges.

How are different procedures currently trained in low-resource settings in sub-Saharan Africa?

To identify existing gaps in training methods and resources, and to determine how the new training model can address these shortcomings and enhance the effectiveness.

CONTEXT SPECIFIC USE

In low-resource settings in sub-Saharan Africa, gynaecological procedures are performed within various contexts. This analysis focuses specifically on the training system at Lumumba Hospital in Kisumu, Kenya. The primary users of the training model are nurses, who receive instruction from trainers at specialized facilities (See Figure 4 and Appendix 1 for all the users). After completing their training, these nurses return to their respective hospitals to pass on their knowledge through on-the-job training.

A significant challenge to this system is that, without proper training, equipment may not function optimally or may be misused. Many medical professionals believe that training by qualified medical schools or specialized trainers would be more effective. However, this approach presents its own challenges as classes can often contain 15-30 nurses with just one training model limiting individual hands-on practice. Consequently, students rarely have the opportunity to practise the physical steps on a training model, which is often shared among a group (Kiewiet De Jonge, 2024).

Currently, most students acquire their skills during internships or residencies. They typically observe multiple procedures before being asked to perform them on their own. This approach can be overwhelming and intimidating, highlighting the need for more hands-on training to build confidence and competence before working with real patients (Zevin et al., 2012).

In Figure 6, the training hierarchy is portrayed (Kiewiet De Jonge, 2024).

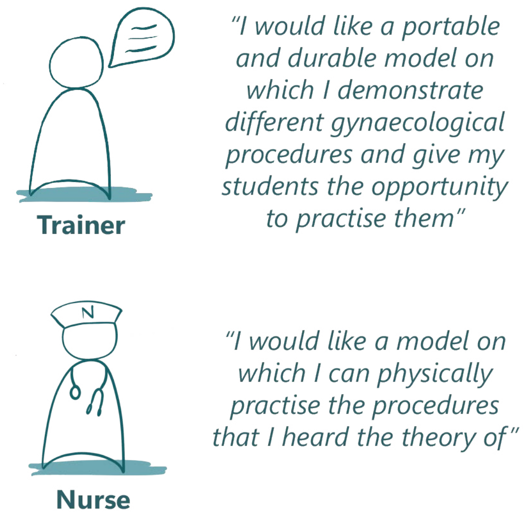


Figure 4: Two of the main users

Figure 5: Current training aids at Jaramogi Oginga Odinga Teaching & Referral Hospital

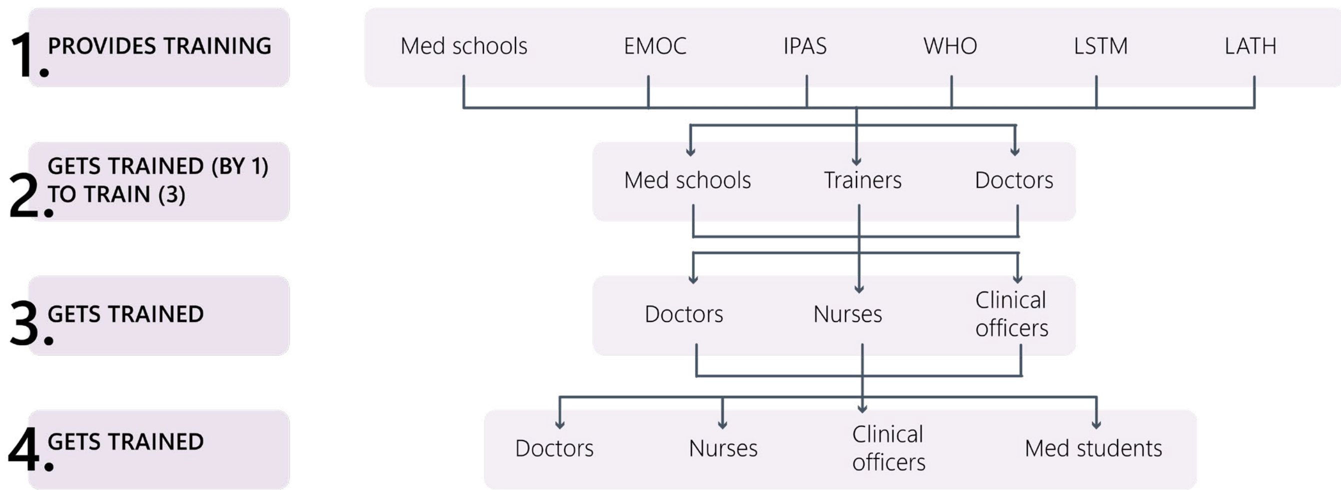


Figure 6: Training hierarchy in Kisumu

ANSWERS

How does the medical training system work in low-resource settings in sub-Saharan Africa?

In Kisumu there are trainers who travel around and teach different classes. The main users are: nurses, residents, medical students, doctors and trainers. Their main interest is to practise their hand on skills on different levels.

How are different procedures currently trained in low-resource settings in sub-Saharan Africa?

Most procedures are taught through lectures, followed by allowing students to observe procedures and, after sufficient exposure, perform them on real patients under supervision. The students lack practical training.

REQUIREMENTS

- The design must be portable, allowing easy transport between training locations
- Components should be durable enough to withstand frequent use and transport without breaking or requiring frequent replacement.
- The model should support group training sessions, allowing multiple users to practice within a limited timeframe.
- It must withstand quick, thorough cleansing in between training sessions
- The model should require minimal maintenance, reducing the need for specialized care
- The model should be able to undergo local repairs
- Clear visual instructions and labels should be incorporated into the model to support self-directed learning and reinforce correct procedure steps.
- The model should be cost-effective

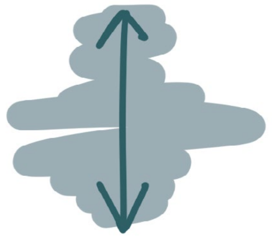
2.2 FEMALE ANATOMY

A study of the female anatomy is crucial for a correct design of the training model. This section explores the different parts of the female reproductive system with a main focus on the shapes and sizes of the different elements.

QUESTIONS

What are the key anatomical features of the female reproductive system?

To ensure accurate representation during medical training.



What is the average range of uterine and cervical dimensions?

To understand the size variations and design the model to suit these anatomies.

What is the average shape of the different reproductive system features?

To understand how the different shapes align with each other.

EXTERNAL ORGANS
The external female genitalia, collectively known as the vulva, play a crucial role in protecting internal organs from infection and supporting sexual function. The vulva includes several key components: the labia majora, two large outer folds that define the boundary of the vulva, and the labia minora, smaller inner folds that extend from the clitoris downward. The clitoris, a highly sensitive organ, is also part of the vulva (See Figure 7). The vaginal opening, or introitus, is located in the rear section of the vulva and appears more open in women who have been sexually active or have given birth. Together, these structures protect the urinary and reproductive systems while contributing to sexual response (Nguyen & Duong, 2023).

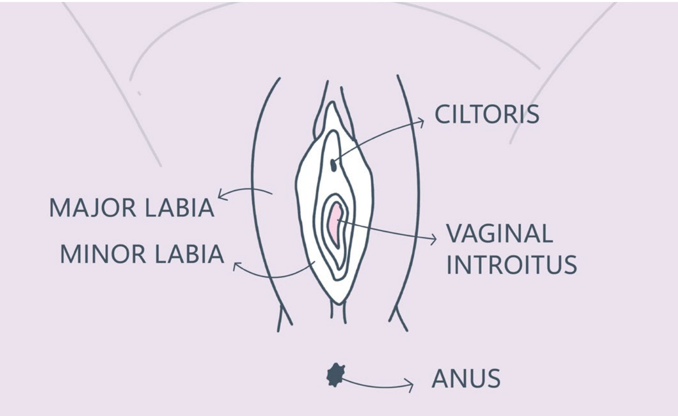


Figure 7: External organs

INTERNAL ORGANS
The internal female reproductive organs begin with the vagina, a fibromuscular canal that connects the external genitalia to the deeper internal organs. The entrance to the vagina, called the vaginal introitus, leads to the canal, which has both an anterior and posterior wall, with the anterior wall being slightly shorter. At the upper end of the vagina is the cervix, the lower part of the uterus. The uterus, located in the pelvis, consists of the cervix and the corpus, or body, of the uterus. Extending from the uterus are the fallopian tubes, which connect the uterus to the ovaries, where eggs are produced. These internal organs work together to support reproductive functions and connect to the external anatomy through the vaginal opening (Barnhartt et al., 2006) (See Figure 8).

THE VAGINA
The vagina is a flexible, muscular tube connecting the vulva to the uterus. Its shape and size are not symmetrical or fixed, variations based on factors like elasticity and surrounding pelvic organs. The vaginal canal runs upward and backward at a 45-degree angle, with the anterior wall measuring 7.5 cm and the posterior wall around 9 cm. The canal is usually collapsed, with the anterior and posterior walls touching (Szmelskyj et al., 2014).

The shape of the vaginal lumen has been described as an "H" or "W" shape near the cervix, while at the introitus, it typically forms an "I" shape (Barnhart et al., 2004). On average, studies have found the vaginal length to be around 62.7 mm, though measurements can range from as short as 40.8 mm to as long as 95 mm. When measured in a more distended state, vaginal lengths have ranged from 68,6mm to 148,1 mm,. The width also varies along its length, being widest at the vaginal fornices (41.87 mm) and narrowing to about 26.15 mm at the introitus (P. B. Pendergrass et al., 1996; Barnhart et al., 2006; Luo et al., 2016; Appelbaum et al., 2018).

Full vaginal casts have revealed several shapes, including parallel-sided, conical, heart, and slug-shaped, though these do not significantly affect function (Belovicz et al., 2003; Pendergrass et al., 1996). Under African woman, the shape 'pumpkin seed' was significantly more found (Belovicz et al., 2003).

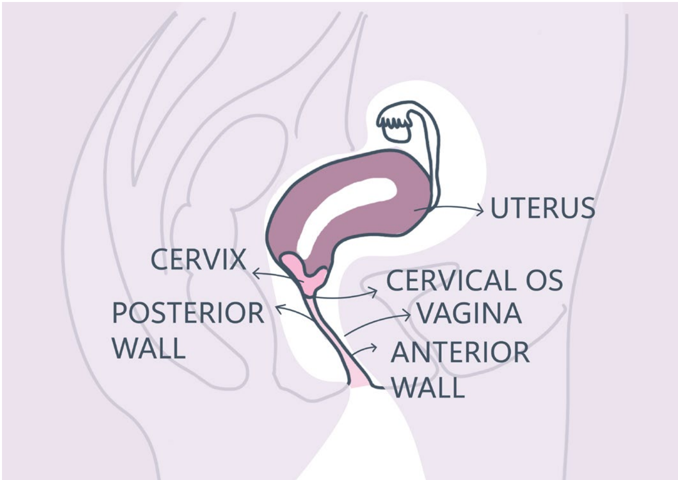


Figure 8: Female pelvic, cross section.

THE CERVIX
To determine the optimal opening size for a device to visualize the cervix effectively, it is crucial to understand the dimensions of the cervix itself. The cervix is the lower, fibromuscular part of the uterus, and its visible portion during a speculum exam, called the ectocervix, is cylindrical or conical in shape. The average diameter of the cervix is 25 mm, though this can range widely from 21.7 mm to 55 mm (Barnhart et al., 2006). Its height typically falls between 20-25 mm (Parra et al., 2019). The cervix is about 3 to 4 cm in length and 2.5 cm in diameter in most cases. Its structure is supported by the cardinal and uterosacral ligaments, which help anchor it to the pelvic walls. The lower half of the cervix, called the portio vaginalis, extends into the vaginal canal, where it can be seen through the external os, an opening that leads into the cervical canal. (Sellors & Sankaranarayanan, 2003) (See Figure 9 and 10).

Cervical size can vary depending on age, hormonal status, and whether a woman has given birth (parity) (Barnhartt, 2006).

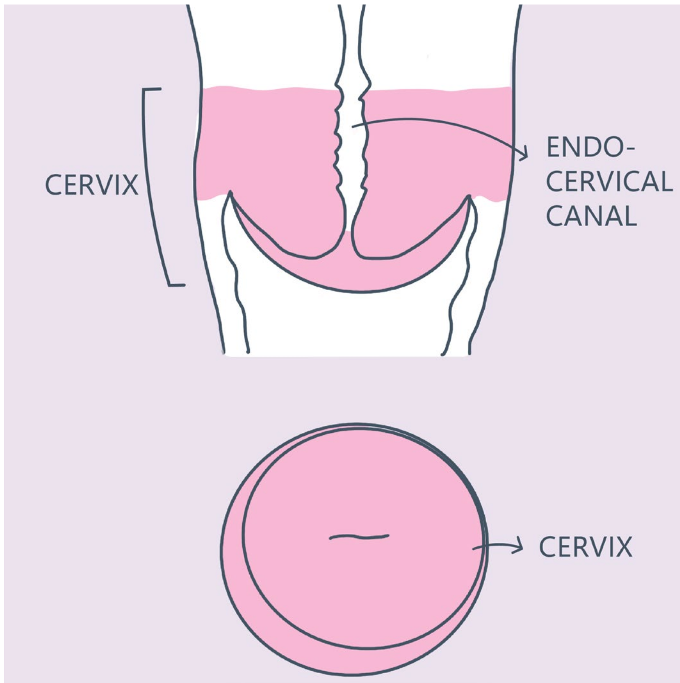


Figure 9: Cervix

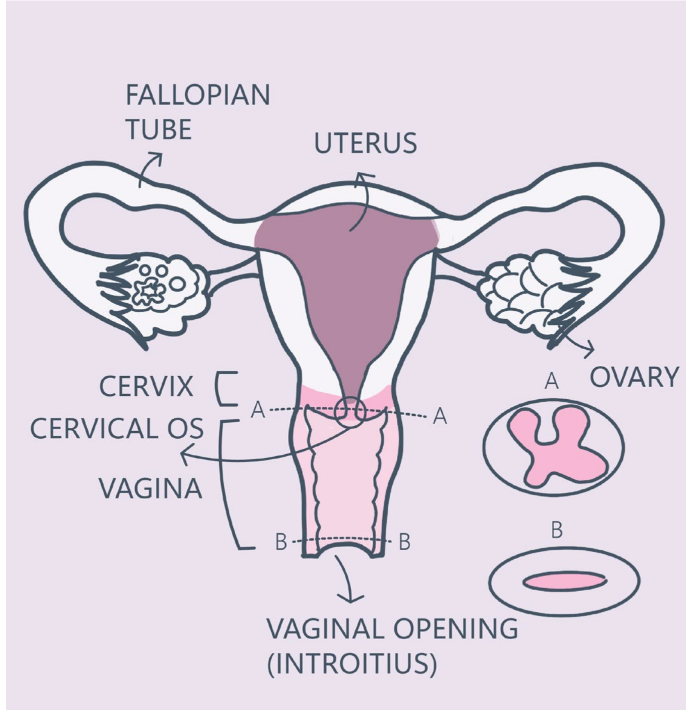


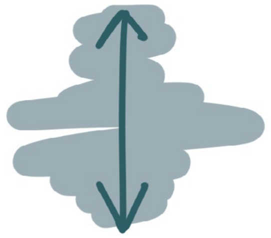
Figure 10: Cervix parts

THE UTERUS
The uterus, positioned between the bladder and rectum, is a hollow, pear-shaped organ. It measures around 7.5–8 cm in length, 5 cm across, and 4 cm thick in adults, with a cavity volume ranging from 80 to 200 mL. Its structure consists of the fundus, body, and cervix, with the uterine tubes entering at the cornua, located near the fundus (Szmelskyj et al., 2014). The uterus can be positioned in the pelvis with two angles: retroverted, where the cervix forms a 90° angle with the vaginal axis, positioning the uterus almost horizontally toward the back and anteverted, the uterus lies towards the front (Ellis, 2011).

ANSWERS

What are the key anatomical features in the female reproductive system?

The key anatomical landmarks are the vagina, cervix, and uterus. Each of these structures must be represented in the model to allow trainees to properly position and handle instruments, as well as to practice specific actions.



What is the average range of uterine and cervical dimensions?

The average dimensions of the uterus are 7.5–8 cm in length, 5 cm across, and 4 cm thick, while the cervical diameter averages 25 mm. The vaginal length ranges from 62.7 mm on average (collapsed) to 148.1 mm (distended), with the width varying between 26.15 mm at the introitus and 41.87 mm at the fornices.

What is the average shape of the different reproductive system parts?

The vagina is an almond shaped opening with a (flat) tube like structure. The cervix should have a cylindrical shape with a central opening. The uterus should be pear-shaped, and these parts should connect at realistic angles and depths to facilitate accurate procedure practice.

- **The vagina**
  Length measured from vulva to cervix:
    Anterior vagina wall: 75mm
    Posterior vagina wall: 95 mm
  Linear length of the vagina canal: 62,7mm (range 40,8mm-95mm)
  Vagina entrance (introitus): 12 mm to 37 mm

- **The cervix**
  Height: 20-25mm
  Diameter: +-32,5 mm

- **The uterus**
  7,5- 8,0 cm in length,
  3–5 cm in width
  4 cm in thickness
  can have a 90° angle with the vaginal os

2.3 PROCEDURES

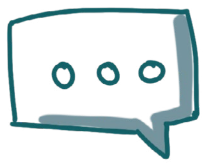
This section outlines all the procedures that could be incorporated into the GTM, drawing from the initial assignment. The primary focus is on transvaginal procedures. For each procedure, an analysis is provided covering how it is performed, its location within the female reproductive system, and the type of feedback that should be expected.

What are the different transvaginal gynaecological procedures that need to be trained?

To understand which procedures could potentially be integrated in the model.

What are the different steps of each procedure and where in the body do they take place?

To understand which parts are most critical to include in the model and what functions it could have.



What type of feedback should the model provide for the training?

To ensure that the training model offers realistic feedback (e.g., tactile sensations, visual cues), improving the students ability to perform procedures correctly and safely.

EQUIPMENT

For the different procedures, different type of equipment is used. Figure 11 shows the equipment in the hospital in Kisumu.

The following section will show all the different procedures. The tables show where in the female body the procedures take place and which equipment is used. The three different colours represent the vagina (v), cervix (c) and uterus (u).

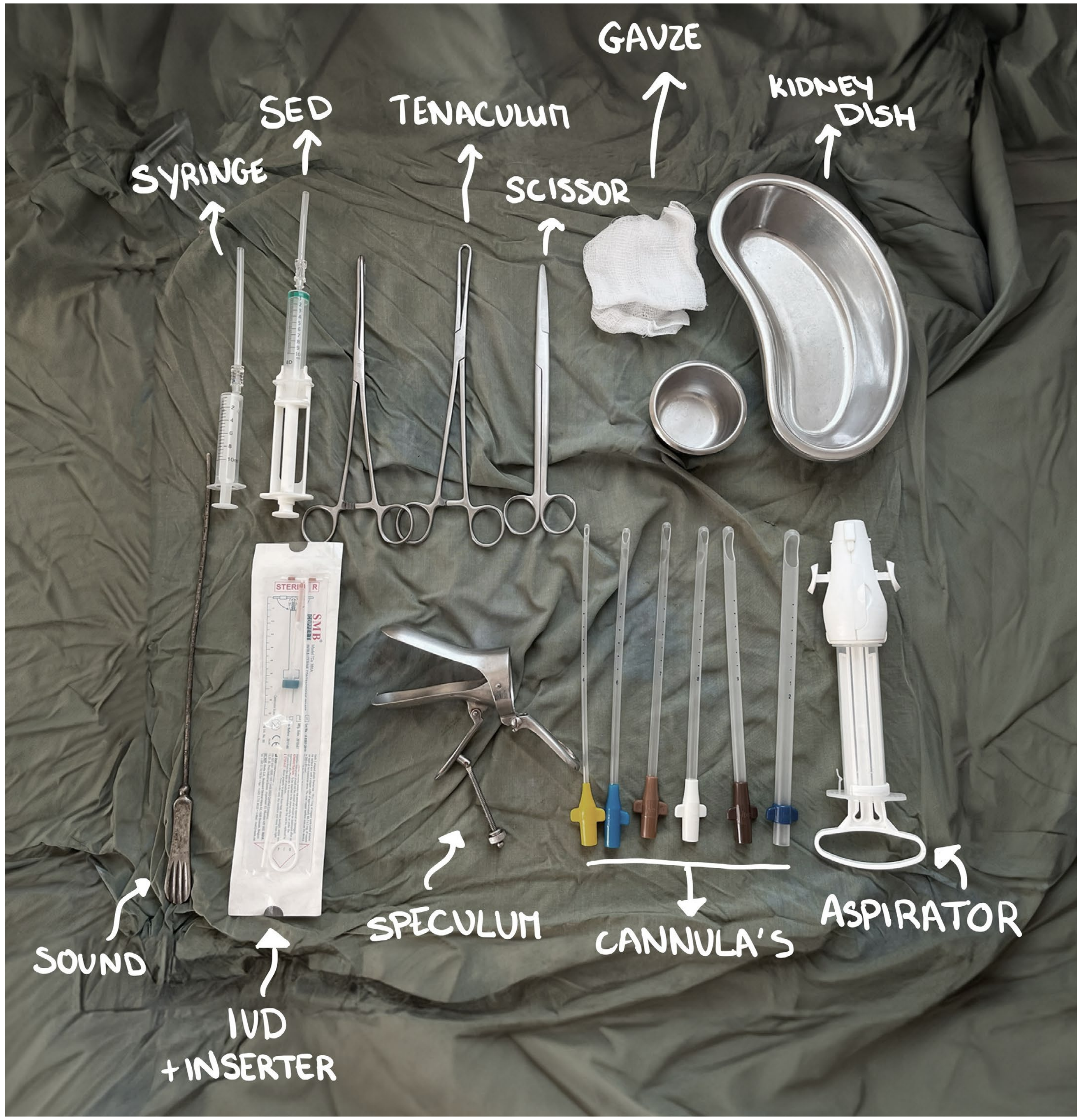


Figure 11: Equipment used at Lumumba Hospital

PARACERVICAL BLOCK

Paracervical block (PCB) is a regional nerve block technique used for pain relief during various gynaecological procedures, including hysteroscopy, cervical biopsies, loop electrosurgical excision procedure (LEEP), intrauterine device (IUD) insertion, dilation and curettage (D&E), ablative therapies, cervical cerclage, the first stage of labor, and manual vacuum aspiration (MVA) (Gómez et al., 2004) (Tangsiriwatthana et al., 2013) (Vidaeff et al., 2023)

The block is performed by injecting an anesthetic solution, lidocaine, around the cervix to numb nearby nerves. The anaestectic is injected into the cervix five times: at 12 o'clock, 10 o'clock, 2 o'clock, 4 o'clock, and 8 o'clock (See Figure 12) (Ipas, 2024).

In the Netherlands, a long needle, such as a V-block, is typically used to reach the cervix. Alternatives like epidural or spinal needles can also be used; however, these are expensive and difficult to obtain, leading to limited use of anaesthesia. The Chloe Syringe Exendable Device (SED) addresses this issue by acting as an extendable attachment for standard syringes, enabling the use of regular-sized needles while still effectively reaching the cervix. In Figure 13, the difference is portrayed.

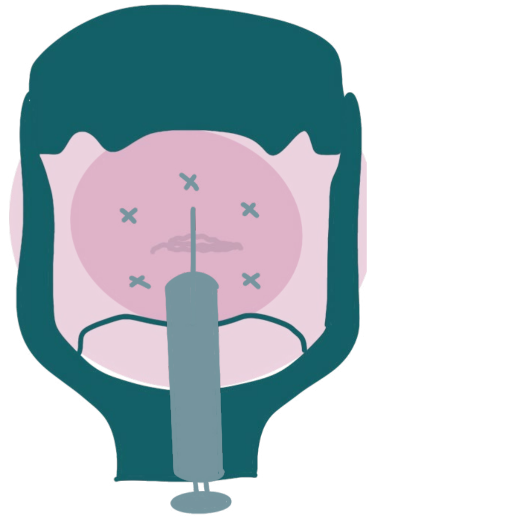


Figure 12: Paracervical block seen from the speculum opening

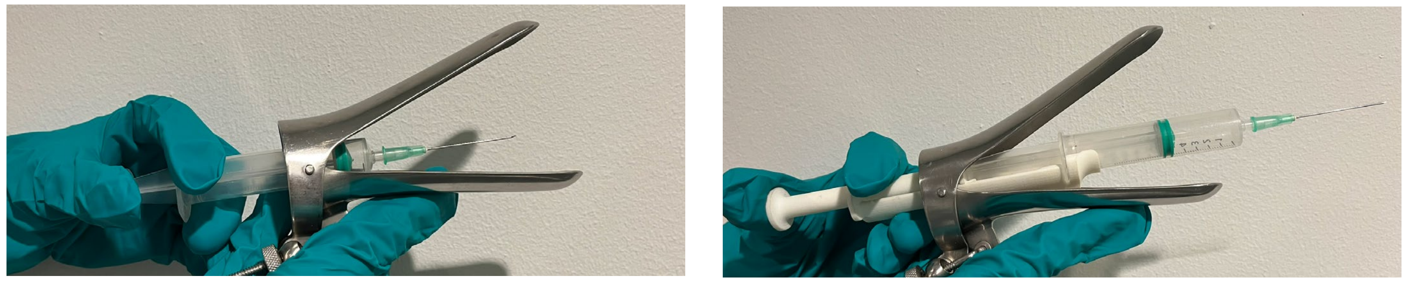


Figure 13: 1. Normal syringe, 2. SED + Normal syringe

Step	Where	Equipment	Requirements/Notes
Insert speculum	v	Speculum	Should fit a regular size speculum Not too much force to open
Clean cervix	c	Forcep, gauze	
Insert needle		Syringe	SED needs to fit through speculum
Place tenaculum	c	Tenaculum	Not always needed
Inject at 2, 4, 8 and 10 o'clock	c	Syringe, tenaculum	Air should be able to be injected in cervix Should have some resistance
Remove needle		Syringe	-
Extract speculum	v	Speculum	Speculum should be easy to retract

Table 1: Paracervical block steps, locations, tools and feedback

MANUAL VACUUM ASPIRATION

Manual Vacuum Aspiration (MVA) is a painful procedure which treats an incomplete abortion. Using a manual aspirator that is inserted into the uterus, pregnancy tissue is gently removed via a vacuum from the womb in a 180 degree rotating scraping motion under a local anaesthetic (PCB) (See Figures 14 and 15) (Manual Vacuum Aspiration (MVA) | NHS Lanarkshire, n.d.)

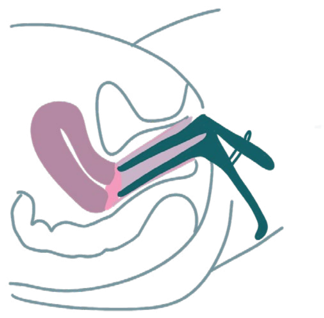


Figure 14: Placing the speculum

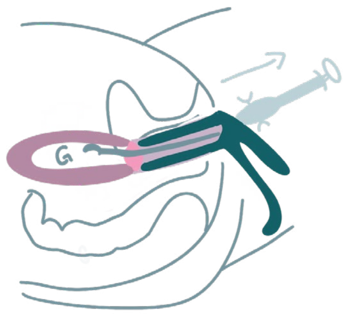


Figure 15: Rotating the MVA syringe and cannula

Step	Where	Equipment	Requirements/Notes
Insert speculum	v	Speculum	Should fit a regular size speculum Not too much force to open
Clean cervix	c	Forcep, gauze	-
Perform PCB	c	Syringe	See PCB
Place tenaculum	c	Tenaculum	Should be able to pull on cervix
Insert cannula	u	MVA syringe, cannulas	Should fit a 6 mm cannula
Extract vacuum	u	MVA syringe, cannulas	-
Rotate cannula	u	MVA syringe, cannulas	Uterus should be large enough to turn around in
Extract cannula	u	MVA syringe, cannulas	-
Extract the tenaculum and speculum	v	Tenaculum and speculum	Speculum should be easy to retract

Table 2: Manual vacuum aspiration steps, locations, tools and feedback

INTRAUTERINE DEVICE INSERTION

The intrauterine device (IUD) is an effective contraceptive. Hormonal IUDs are made of plastic and slowly release a progestogen hormone. A copper IUD is made up of a plastic T wrapped in copper coil. The copper wire produces an inflammatory reaction that is toxic to sperm and eggs. They are placed inside the uterus (See Figure 16) and can sit up to 10 years. (Johnson, 2005) (Healthdirect Australia, n.d.)

Figure 16: Sounding (measuring) of the uterus and IUD placement

Step	Where	Equipment	Requirements/Notes
Insert speculum	v	Speculum	Should fit a regular size speculum Not too much force to open
Clean cervix	c	Forcep, gauze	
Place tenaculum and pull on cervix	c	Tenaculum	Cervix should stay in place
Measure the depth of the uterus	u	Sound	Hollow uterus that shows depth and position
Load IUD inseterter and then into uterus	u	IUD inserter	Uterus should be big enough to fit IUD Uterus should be see through to show IUD
Cut string on IUD	v	Scissors	Scissors should fit through speculum
Extract tenaculum and speculum	v	Tenaculum and speculum	Speculum should be easy to retract

Table 3: IUD insertion steps, locations, tools and feedback

CERVICAL CANCER SCREENING

Cervical cancer screening is a vital preventive health measure designed to detect early signs of cervical cancer or changes in the cervical cells that may lead to cancer. Cervical cancer can be screened in two ways: pap smeer or HPV tests. In both procedures cells are collected using a brush or spatula to gently scrape cells from the cervix (See Figure 17) (Cervical Cancer Screening, 2024).

Figure 17: Swabbing the cervix

Step	Where	Equipment	Requirements/Notes
Insert speculum	v	Speculum	Should fit a regular size speculum Not too much force to open
Insert brush	c	Brush	
Turn brush around	c	Brush	Cervix should stay in place
Retract brush	v	Brush	
Remove speculum	v	Speculum	

Table 4: Cervical cancer screening steps, locations, tools and feedback

LOOP ELECTROSURGICAL EXICISION PROCEDURE

A Loop Electrosurgical Excision Procedure (LEEP) is a treatment used to remove abnormal or precancerous cells from the cervix. The procedure uses a thin, wire loop heated by electrical current to carefully remove abnormal tissue. A PCB is used to numb the cervix and with a circular or linear motion, cells are removed (See Figure 18) (Fatt, 2021).

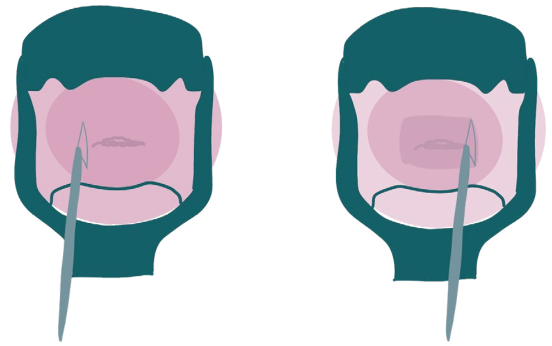


Figure 18: LEEP procedure

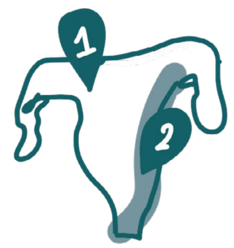
Step	Where	Equipment	Requirements/Notes
Insert speculum	*v*	Speculum	Should fit a regular size speculum Not too much force to open
Clean cervix	*c*	Forcep, gauze	-
Acid solution is sprayed on the cervix	*c*	Acid solution	Change colour transformation zone
Perform PCB	*c*	PCB syringe	See PCB
The loop is pushed into the cervix	*c*	Loop	Should be able to conduct electrical current
The loop is pushed through the trans-formation zone	*c*	Loop	Should be able to cut part of the cervix safely
The loop is removed	*c*	Loop	
The specimen is secured	*c*	Forcep	Should allow a specimen to be removed
Extract the speculum	*v*	Speculum	Speculum should be easy to retract

Table 5: LEEP steps, locations, tools and feedback

ANSWERS

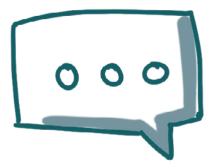
What are the different transvaginal gynaecological procedures that need to be trained?

Paracervical block, manual vacuum aspiration, IUD insertion and removal, LEEP and cervical cancer screening. These are all procedures that are performed through the vagina and take place around the cervix and uterus.



What are the different steps of each procedure and where in the body do they take place?

The visuals highlight each step of the procedures, making it clear which actions are most frequently performed—such as inserting a speculum, placing a PCB, grasping the cervix, and passing instruments through the cervix. This analysis underscores the need for the model to include realistic representations of the vagina, cervix, and uterus.



What type of feedback should the model provide for the training?

Different feedback options have been outlined for each step. The most reoccuring features are having a vagina which fits a speculum and finding the cervix, recognising when a procedure is complete and having the opportunity to perform all the operations within the limited space.

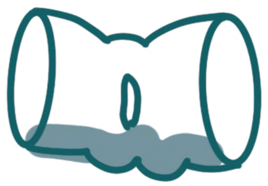
REQUIREMENTS

- The model should have a vagina, cervix and uterus in which medical equipment to be used according to the procedure
- **The vagina**
  needs to be able to be opened with a speculum
  needs to have an anatomically realistic length
- **The cervix**
  needs to be injectable
  needs to be able to be grabbed with an tenaculum
  needs to be cut away with an electrical current using a LEEP procedure
  should be safe to use when using LEEP
  needs to have an open cervix mouth
  should be flexible
- **The uterus**
  needs to be hollow
  needs be big enough to fit an IUD
  should be transparent
  should have a texture that can be felt by the cannula for MVA

2.4 EXISTING PRODUCTS

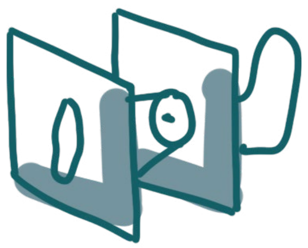
An analysis of existing products was conducted to evaluate their usage, the specific procedures they support, their benefits, and the materials used.

QUESTIONS



What are current training models in high-resource settings?

To explore the advanced models used in well-funded healthcare systems and identify features that could inspire or adapt to the Chloe GTM.



What are current training models in low-resource settings?

To understand the limitations and innovations in existing low-cost models which helps to pinpoint opportunities for improvement in the design of the Chloe GTM.

What are interesting features (shape, material, and functions) that can be used in the Chloe GTM?

To identify design features—such as durability, realistic anatomy, and functionality—that will enhance the effectiveness and practicality of the Chloe GTM.

ANALYSIS OF EXISTING PRODUCTS

Different gynaecological training systems have been found on the internet or were shown during the different hospital and school visits, distinguishing between high- and low resource (HRS and LRS) models. HRS models typically have fewer budget constraints, allowing for advanced features, superior materials and enhanced realism in simulation. These are analysed and the different features can be used as inspiration. In contrast, LRS models often have had budget constraints meaning their solutions needed to be creative. Some models have similar functions as the GTM, so the solutions can also be used as an inspiration. Tables 6 and 7 present the findings.

The different training models have been placed in a C-box determining how expensive they are and how similar the functions are to the GTM (See Figure 19).

Model	Procedures	Materials	Advantages	Disadvantages	Price
 *Mama U*	IUD placement, Uterine balloon tamponade insertions	Neoprene, Polyether, POM, Nylon, Polyseter, PVC, Latex	+ Different uterus positions + Can do a blind as well as visual training + Fabrics makes it soft to use (nothing sticks)	- Uterus is relatively large - Difficult to clean or use with liquids - Not anatomically correct	€75
 *Madam Zoe*	Ultrasounds, Posterior vaginal fornix puncture	High molecular polymer ultrasound	+ Can show ultrasounds + Feedback after a puncture + Simulate blood + Gives feedback when procedure is wrong (different colour fluids)	- Limited procedures - Costly - Large and heavy (11.15kg)	€1500
 *GYN-AID*	Inspection, Inserting speculum, bimanual examination, Utering sounding, IUD insertion and removal	Silicon, Plastics	+ Removable skin + Different uteri and cervices attachments (screw) + Anatomically correct + Airbag can change the position of the uterus	- Very big - Very thorough - Heavy (8 kg)	€600
 *IUD placement*	IUD insertion and removal	Plastics	+ See through to see if IUD is place correctly + Small	- Cannot practise the full procedure	€55

Table 6: Current training models in high-resource settings

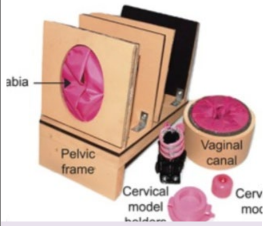
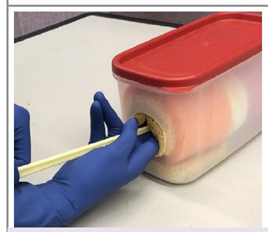
Model	Procedures	Materials	Advantages	Disadvantages	Price
 *VVF repair model*	Transvaginal vesico-vaginal fistula repair	3D-printed PLA, Silicone	+ Silicone used to properly mimic the features + Cheap	- No use of speculum	€21 (material)
 *LUCIA*	Cervical cancer screening, Cervical biopsy, Cryotherapy, LEEP	Wooden frame, PVC pipe, waterproof fabric, Polyactic acid, Ballistic gel	+ Low cost + Easy to set up + Correct measurements	- Different production steps (painting etc)	€47
 *PVC model*	Cervical cancer screening, Endocervical polyp removal, IUD insertion and removal, Endometrial biopsy	PVC, Plywood, Raquetball, Gelatin, Water balloons	+ Simple design	- The glue is difficult to repair - Needs to be held by someone on the table - Long cervix preperation time	*un-known*
 *Pelvic model*	IUD placement, MVA	Silicone	+ Visual uterus (see through) + Anatomically correct + Velcro for MVA	- Not very portable - Suction cups do not always work with dirt and dust	*un-known*
 *Papaya*	Anatomy, Bimanual examination, IUD placement, Uterine aspiration	Papaya (fruit)	+ Easy acces to materials + Cheap + Allow for cutting + Low environmental impact + Grittyness gives feeling of empty uterus	- Single use - No speculum - Anatomically not realistic	€3
 *Exam box*	Cervical dilation, instruction on FSE placement and rupture	Softball, compression stockinette, pool noodle, wood, foam, plastic container, gloves, water balloons	+ Very low cost + Easily accessible materials	- Extensive initial setup steps - Anatomically not realistic	€5

Table 7: Current training models in low-resource settings

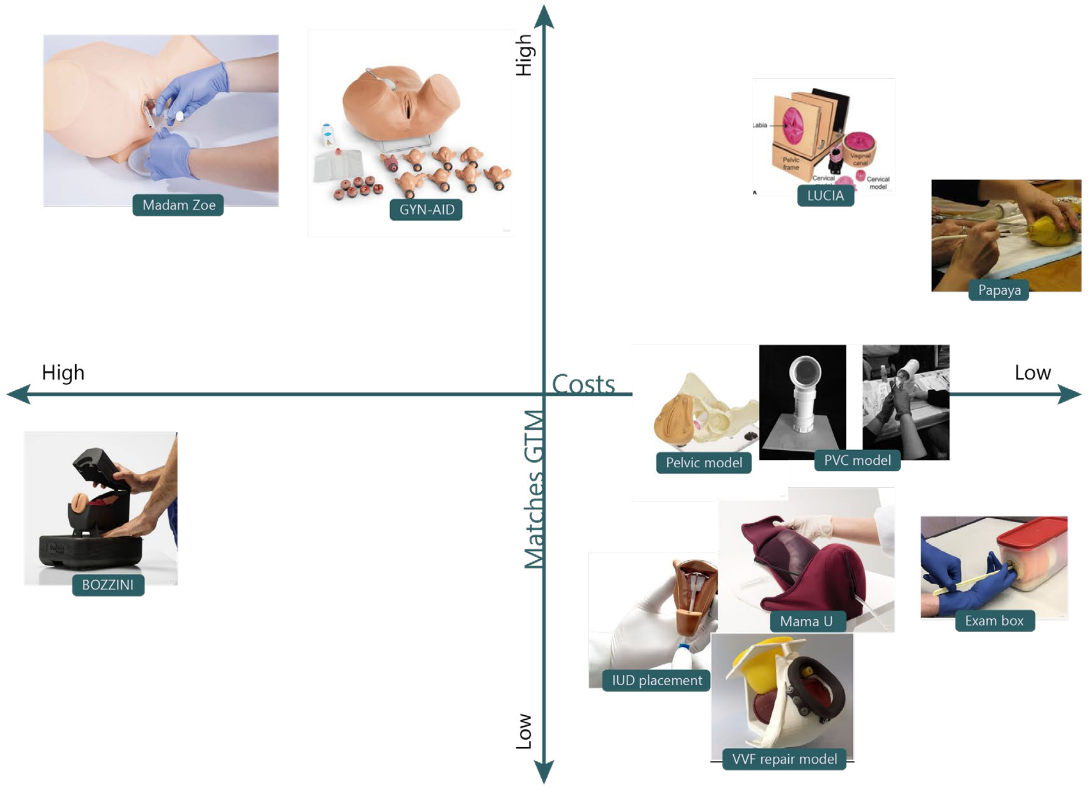
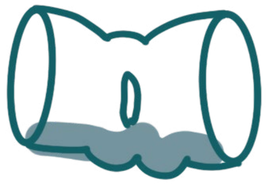


Figure 19: C-box of the models (costs vs GTM match)

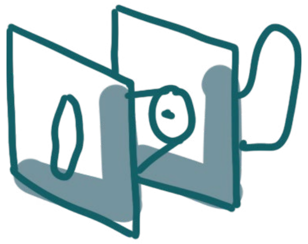
ANSWERS



What are the current training models in high-resource settings?

The most common features in the HRS models are:

- Durable and high quality materials that simulate human tissue accurately
- Detailed anatomical accuracy
- Advanced feedback mechanisms: changing colours, haptic feedback, visual responses
- More procedure specific: less versatile, but better suited per procedure
- Adjustable anatomical configurations: such as moveable uterus positions, interchangeable cervices
- Stability: stable, but heavy models



What are current training models in low-resource settings?

The most common features in the LRS models are:

- Use of simple and easy to replace materials such foam, pvc pipes or natural materials
- Simple anatomy, ensuring that the general shape and orientation of these parts are sufficient
- Simple setup: easy to assemble and lightweight
- Replaceable parts

What are interesting characteristics (shape, material, and functions) that can be used in the Chloe GTM?

Many insights and inspiration can be taken from the different designs. The most relevant are:

- Materials: using affordable, realistic materials which could enable tactile feedback without the high costs (silicone/ballistic gel)
- Modularity and replaceable parts: allowing detachable or replaceable components (e.g., cervices, uteri) would make the model versatile for multiple procedures
- Simple setup: Avoid complex assembly requirements, focusing instead on an intuitive design that is easy to set up, clean, and maintain
- Feedback mechanisms: Simple visual or tactile feedback elements, such as changing colors or textures to signify errors

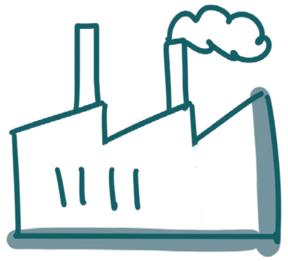
REQUIREMENTS

- Key parts, such as the cervix or uterine sections, should be detachable or replaceable to simulate different conditions or be replaced after one-time-use procedures
- The device should be easy to set up, with no or minimal parts that need to be prepared before the training (DIY)
- The device should have open or transparent walls where feasible to enhance visibility for trainers, providing clear views

2.5 MATERIALS

In this section, different material options that can be used for the reproductive health organs are discussed, as it is important to focus on factors such as durability, realism, and compatibility with low-resource production methods.

QUESTIONS



What materials are often found in training models?

To find which materials reflect human tissue or structure sufficiently.

What materials are suitable to use in the context?

To select materials that can be locally sourced and repaired in low resources settings.

How durable should the materials be to withstand repeated use in training?

To select materials that can endure multiple training sessions without significant wear, ensuring the model's longevity and cost-effectiveness.

SHORE HARDNESS
One of the most effective ways to grade the materials to resemble the reproductive organs is by comparing the shore hardness (See Figure 20).

Shore hardness 00
The Shore 00 scale measures the softness of extremely pliable materials like gels or soft silicone used in products like wound dressings and cushions. These materials have a squishy, gel-like texture, making them suitable for applications that require high levels of cushioning.

Shore hardness A
The Shore A scale is used for materials with medium firmness, such as rubber-like products that are flexible but still offer some resistance. Medical products like catheters, surgical tubing, and face masks for CPAP machines fall within this range. These materials are pliable enough to adapt to body contours but are durable enough to handle stress.

Shore hardness D
The Shore D scale measures much harder materials that are rigid and durable, used for structural components in medical devices. Examples include hard plastics for orthopedic braces or bone simulation models used in surgical training. These materials are essential for situations where stiffness and strength are required. (Smooth-on Inc, n.d.).

MATERIAL OPTIONS IN CURRENT TRAINING MODELS

Silicone
A lot of medical simulators use different types silicone. Silicone is a human-made material. It is a polymer comprised of siloxane that features a rubber-like consistency (Simtec, 2024). Silicone can easily be manipulated by adding additives, which can enhance the shore hardness, increase the durability or change the surface quality. It can be found in products such as needle insertion pads, mannequins and other training simulators.

Thermoplastic elastomer
Medical devices use ultra-soft thermoplastic elastomer (TPE) gel compounds to provide cushioning, padding, or a tight seal. They can be heated, formed, and cooled into a shape, but they retain their rubber-like qualities after they cool (Webtech, 2023). However TPE are less easy to work with on a lower scale as they tend to be injection moulded. Furthermore the shore hardness of TPE is around Shore A 30 to Shore D 50.

Gels
PU gel (polyurethane gel) is a versatile material known for its softness, flexibility, and excellent cushioning properties. It has a shore hardness of A 0-10. It is often used in medical applications such as prosthetics, wound dressings, and cushioning pads. PU gel can mimic the texture of human tissue, making it suitable for simulations in medical training (Geelli, 2016)

Gelatin
Gelatin is a versatile biopolymer derived from collagen, commonly used in food and pharmaceutical industries. It exhibits excellent gelling and thickening properties, making it ideal for applications such as drug delivery systems and wound dressings. The hardness can be classified based on its gel strength, which typically varies depending on its concentration and formulation (Schrieber & Gareis, 2007).

TESTING MATERIALS
To create a durable product, different materials are tested for how they behave after injecting them with a needle 100 times. Different materials where chosen based on their shore hardness:
- Dragon skin 10 (Figure 21)
- Dragon skin 10 + slacker (Figure 22)
- Ecoflex 00-30 (Figure 23)

The tests revealed minimal differences in how the materials reacted to needle injections. Therefore, the main selection criterion was the tactile feel of the materials.

Figure 20: Shore hardness

Figure 21: Dragon skin 10

Figure 22: Dragon skin 10 + Slacker (100:50)

Figure 23: Ecoflex 00-30

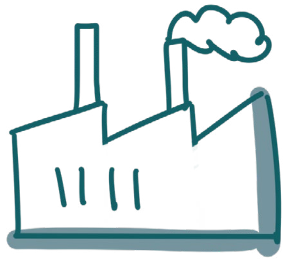
LEEP
For the LEEP (Loop Electrosurgical Excision Procedure), a suitable material is required that can be partially excised while effectively conducting electrical current. During the procedure, part of the cervix is removed using an electrical current that burns away the tissue, so the material must be capable of withstanding this effect whilst remaining safe.

Material options that can be found in existing products are:

Meat
Meat is a common option in LRS models as it is easy to get, renewable and reflects the human body sufficiently. In the current situation, medical professionals often already train on meat, such as cow tongue (Eston et al., 2020). Sausage has been utilized in various training models as a material for practicing LEEP procedures due to its realistic texture and responsiveness. Its proven effectiveness in simulating cervical tissue makes it a suitable choice (Hefler et al., 2012) (Rezniczek et al., 2017).

Fruits and vegetables
Fruit and vegetables are also a renewable source. A good option is a papaya, which is already used in training sessions as it reflects the cervix and structure well (Steinauer et al., 2013).

Gelatine
Gelatin is a versatile material for LEEP training models due to its realistic, soft tissue-like texture and ease of preparation. It can be customized to different firmness levels and shaped to resemble cervical tissue. Adding conductive elements to gelatin, like saline, can simulate the electrical properties needed for excision practice, making it an affordable and renewable option for training in low-resource settings (Schrieber & Gareis, 2007).



ANSWERS

What materials are often found in training models?

The most common materials are defined as silicone, gelatine and plastics because of their ability to mimic human tissue textures and ease of manipulation.

What materials are suitable to use in the context?

Locally sourced options like gelatin, meat (e.g., sausages and cow tongue), and fruits like papaya are cost-effective and accessible in low-resource setting

How durable should the materials be to withstand repeated use in training?

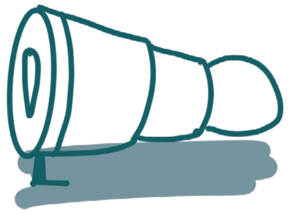
To withstand repeated use in training, materials must be resilient and maintain their functionality over time. Durability ensures the model remains cost-effective and reliable for multiple sessions.

REQUIREMENTS

- The device should be strong enough to withstand the force of a speculum
- The cervix should be durable enough to withstand 200 needle pokes
- The vagina should have a shore hardness of around A-10
- The cervix should have a shore hardness of around 00-10/30
- The uterus should have a shore hardness of around A – 40/50
- The materials should be able to be sourced locally
- All materials used should be safe for medical training purposes and non-toxic
- The materials should be easy to clean
- The materials for LEEP should be easy to find in LRS

2.6 CURRENT PROTOTYPE

In this section, the current prototype will be analysed to see what the weaknesses are, which elements should be taken into the new design, how intuitive the design is to use and what should be adjusted to include more procedures.



QUESTIONS

How does the current prototype look and work during training sessions?

To analyse the positive and negative aspects of the design, see what is already included and what needs to be improved.

Is the current design user-friendly and intuitive in training?

To identify any issues that may hinder effective learning, such as complex assembly or difficulty in handling the model during procedures.

How durable is the current design under repeated use?

To find out if the model can withstand regular training without significant wear or damage, ensuring long-term usability.

The first design (v.0) was created by Joséphine Kiewiet de Jonge (2024) (See Figure 24). The design features eight parts: the stand, clamp, ring, base, back, vagina, cervix and uterus. The different methods were used to discover the largest pain points in the design.

INTERVIEW

Firstly, an interview with Joséphine, who had tested the product in the context, was conducted. The main conclusions from her testing and recommendations were:

- The stand is too fragile, breaks off easily and not designed for the clamp
- The clamp is not easy to use
- The silicone vagina falls off easily without the ring
- The current ring is not user friendly
- The design should be used for multiple procedures

HANDS ON ASSESSMENT

The second method involved a hands-on assessment, where the model was personally disassembled to identify any design flaws or issues impacting user-friendliness. The conclusions were:

- The stand design lacks a logical placement for the clamp
- The collapsible body frequently collapses during setup, causing frustration
- The inconvenience of the collapsible design seems to outweigh its benefit of portability
- The bayonet appears fragile and may break easily with repeated use
- The ring poses a risk of damaging the silicone component.

USER TESTING DfEM

To further investigate these assumptions, the Design for Emerging Markets team did an assembly user test with eight participants (See Appendix 2). They asked their participants to read the instructions and set up the device multiple times to investigate the time it took (See Figure 25) and potential pain points. The following conclusions were made:

- The bayonet lock was unintuitive and hard to use
- People would use the top of the body to connect the bayonet, so the design collapses
- It was unclear how to align the different parts
- It model did not stand stable
- People are afraid to use force which resulted in difficulty attaching the silicone
- The screw on the ring is unhandy to use without tools

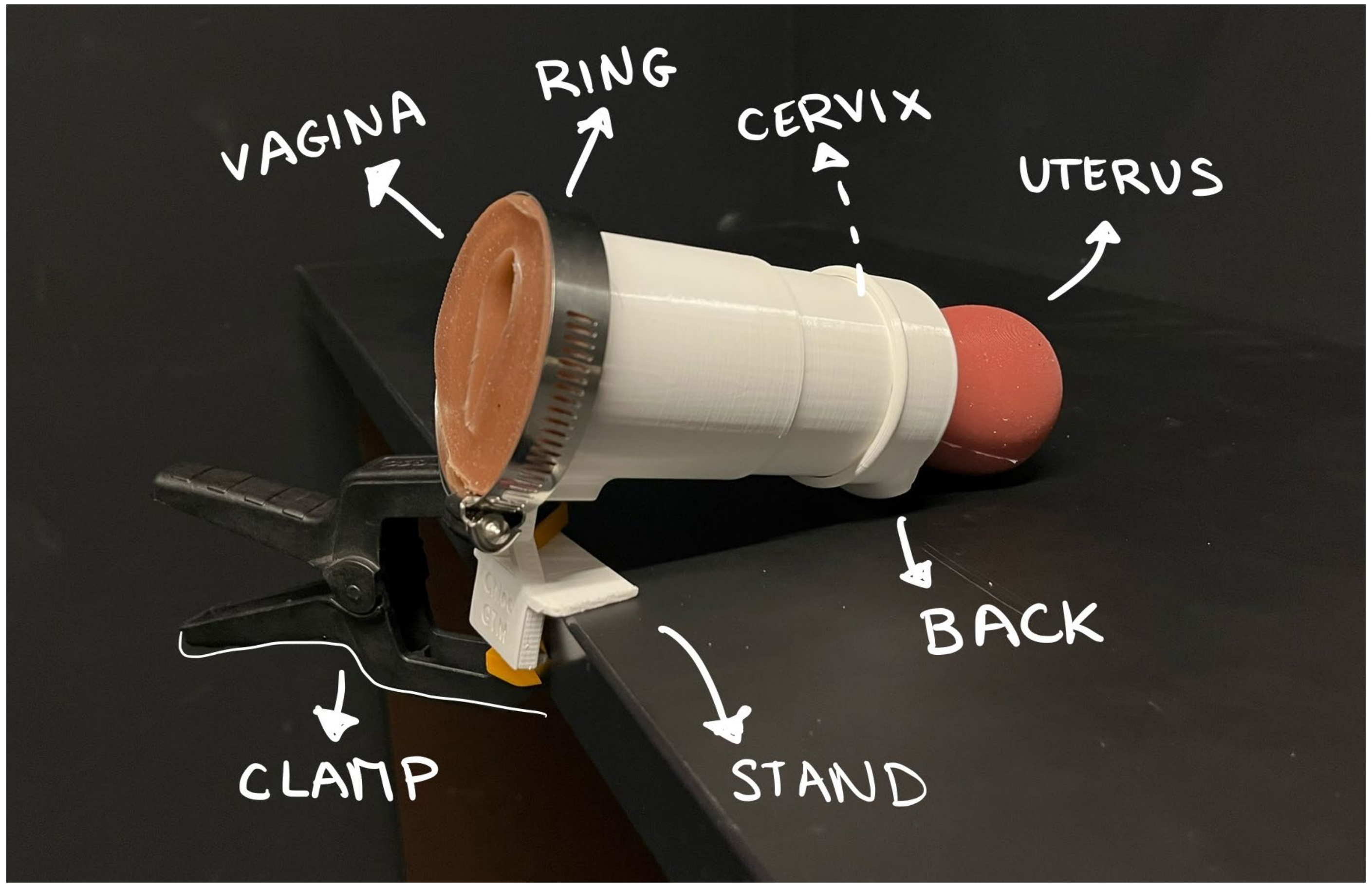


Figure 24: Current prototype

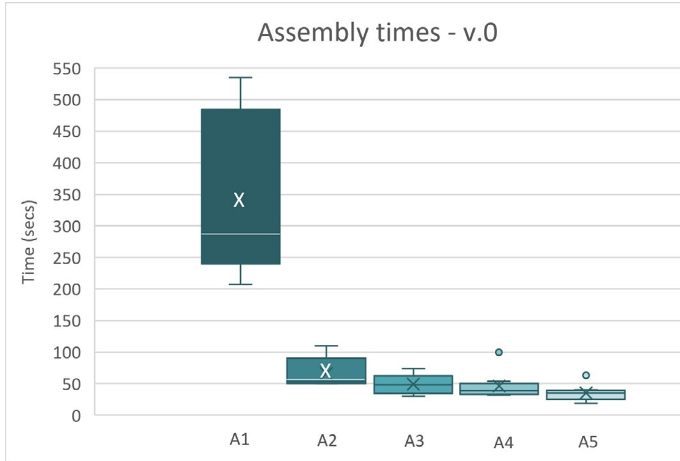


Figure 25: Time it took for seven participants to assemble the GTM v.0 five times

EXPERT REVIEW

Furthermore, an expert review was conducted with two gynaecologists based in the Netherlands. The review followed a semi-structured interview format, allowing the gynaecologists to freely explore the assembled device while being guided through key aspects of the design. They were then asked to perform a PCB procedure on the model (See Figure 26). The following observations were made:

- The device is unstable
- The device feels fragile
- The opening of the vagina is too narrow and the speculum cannot fully open
- If the speculum cannot fully open, the SED does not fit through
- The cervix is too far away
- The structure of the material feels good
- The size of the uterus can be adjusted (smaller)
- You need to inject through the silicone for air to pass

Figure 26: Testing with an expert gynaecologist in the Netherlands

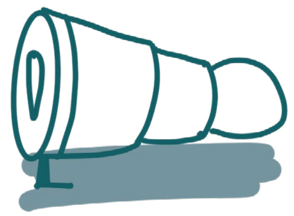
SWOT ANALYSIS

Based on the analysis of the current prototype, key strengths, weaknesses, opportunities, and threats were identified. These insights were synthesised into a SWOT analysis to provide a clear overview of the current design's performance and potential areas for improvement, which can be used to define the design direction. Figure 27 summarises these findings.

S	W
Portability Material feel Shapes Cost efficient Easy repair	Fragile Components Unstable Bayonet lock is unintuitive Clamp and ring not user friendly
O	**T**
Multi procedure design Setup instructions User-friendly setup Robust Durable materials	Improvement costs Complexer assembly process Overcomplication

Figure 27: SWOT analysis current product v.0

ANSWERS



How does the current prototype look and work during training sessions?

The design functions well during PCB training. However the factor remains that the types of procedures in the design should be increased. Furthermore, the clamp and ring do not look in place during use.

Is the current design user-friendly and intuitive in training?

The main pain points of the design are during the set up: how fragile it feels and is and that the connections are not intuitive. People often do not follow the right steps resulting in set up blocks.

How durable is the current design under repeated use?

The silicone holds up well during the tested procedures. However the connections start to fail (foot breaking and bayonette shows friction damage).

REQUIREMENTS

- The stand and components must be made from materials and design features that withstand repeated use without breaking or degrading.
- Fragile parts, such as the bayonet lock, should be redesigned to improve robustness, allowing for repeated assembly and disassembly.
- All parts should have an intuitive design for easy setup, with clear alignment guides to prevent confusion and ensure proper orientation.
- The assembly process should be straightforward, minimizing the number of steps required to set up the model correctly.
- The design should avoid unnecessary complexity, especially in areas where force is needed
- The collapsible body should be re-evaluated to ensure stability during setup and use, preventing unintended collapses.
- The ring and clasp should be re-evaluated to visually integrate into the design, maintaining a secure attachment.
- The model should be adaptable for multiple gynaecological procedures to increase its versatility and value in training sessions.

NARROWING THE FOCUS

This chapter outlines the steps taken to create an updated design brief. Together with the analysis, interviews, and expert feedback done in the previous chapters, the most critical aspects of the design were identified, balancing functionality with cost and time constraints. These insights shaped the updated design brief and established a clear focus on integrating essential features. Additionally, the chapter presents the program of requirements for design v.I.

03

3.1 DEFINING PRIORITY

Before diving into the design, many questions arose from the analysis that needed to be answered. The main question being:

What has priority?

DEFINING PRIORITY

A lot of different options and features can be integrated into the design. However, to create a solution that fits the context, a constant consideration needs to be made regarding functionality and the accuracy of the features in contrast to the costs and the amount of time for the project. If all the considered procedures are integrated with an accurate resemblance, it would become hi-fi and expensive model. Furthermore, there is a time constraint so only the most important procedures and aspects should be tackled.

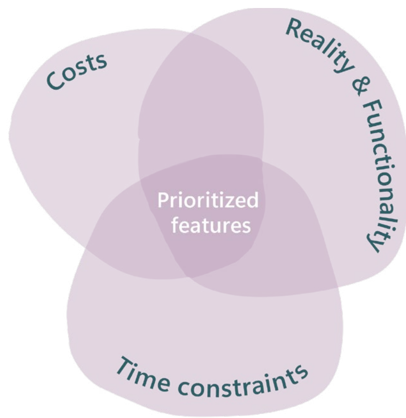


Figure 28: Balance of cost, time and reality + functionality

To help answer the question, a table was created regarding all the relevant steps of the different procedures and the expected feedback the model should give. Three gynaecologists located in different countries (Netherlands, Kenya and United States) were asked to fill this in and provide feedback if the functionality was a **Must have, Should have** or **Nice to have** (See Appendix 3 for the table). From this, the most important focus points became:

- The design should be stronger and more durable
- The most important procedures to practise are the procedures that are directly in line with PCB
- Finding the cervical os with the speculum is one of the most difficult aspects and important to train

INTERVIEWS

To discover which parts of the procedures were most difficult three semi-structured interviews with gynaecologists in the Netherlands were carried out (See Appendix 4). The most important conclusions were:

- The finding of the cervix is most difficult
- Do not always need a tenaculum when performing PCB's if the cervical os is facing forward, meaning the position of the cervix can vary a lot
- MVA feedback is often more on sound than on feeling (scraping on the back on a hand)
- The shape, size, structure and ways the cervix can show cancerous cells vary a lot per person. It is more useful to show pictures than trying to replicate it on silicone
- The most important thing to practise with LEEP is the speed of the loop

3.2 UPDATED DESIGN BRIEF

After all the different analyses and testing, the main design question:

How can the Chloe GTM be redesigned to create a better product that allows users to practise multiple procedures and is user-friendly whilst remaining suitable for low-resource settings?

has been formulated into the following design brief:

*To redesign the Chloe GTM, by enhancing the **stability**, **user-friendliness** and improving the **durability** to create a **low cost, portable** and **validated** design, which allows nurses to practise PCB, MVA, LEEP and IUD insertions/ removals **procedures** to a well-developed **TRL 7-8**.*

3.3 REQUIREMENTS

All the requirements from Chapter 2 have been bundled together and reformulated to create a new program of requirements. The full list of requirements can be found in Appendix 5. The most important requirements are presented in Figure 29 in nine categories:

1. Performance

The model should have a vagina, cervix and uterus
The training model contains an element mimicking the functionalities of the vagina wall:
The training model contains an element mimicking the functionalities of the cervix:
The training model contains an element mimicking the functionalities of the uterus:
The training model should be consistent, so that every medical professional receives the same training, and therefore the same quality of equipment.

2. Physical

The training model must be portable

3. Durability

The stand and components must be made from materials and design features that withstand repeated use without breaking or degrading.

4. Materials

The materials should be easy to clean
The training model uses a material which is impressible to mimic the vagina wall; it should be relatable to the real vagina wall.

5. Installation

The training model set up should not take more than 1 minute.
All parts should have an intuitive design for easy setup, with clear alignment guides to prevent confusion and ensure proper orientation.

6. Use

The training system should be designed to ensure comprehensibility for nurses in Kenya, aiming for widespread accessibility and ease of understanding.
The model should support group training sessions, allowing multiple users to practice within a limited timeframe.

7. Looks

The ring and clasp should be re-evaluated to visually integrate into the design

8. Maintanance

It should be able to be cleaned quickly and easily in between training sessions
The training system's components must be all replacable and easily accessible within the country of the healthcare settings of LRS.
The model should require minimal maintenance

9. Production

The training system should be flexible to produce in terms of required accessories (options to (3D)print at different facilities))

Figure 29: Requirements

SPRINT ONE

The following chapter presents v.I of the GTM. Firstly, the new design is shown. Next, the changes compared to v.0 are highlighted. Each paragraph shows a different part of the design together with a picture. v.0 is shown on the left, v.I is shown on the right.

Design sprint | 4.1

04

4.1 DESIGN SPRINT

All the insights, requirements and feedback, have led to the new design: v.I. In Figure 30 the previous version (v.0) is shown and in Figure 31 the new model (v.I). The model exists of seven parts shown in Figure 32. The process leading to the design (brainstorms, options, prototypes and choices) is presented in Appendix 6.

Figure 30: Assembled v.0

Figure 31: Assembled v.I

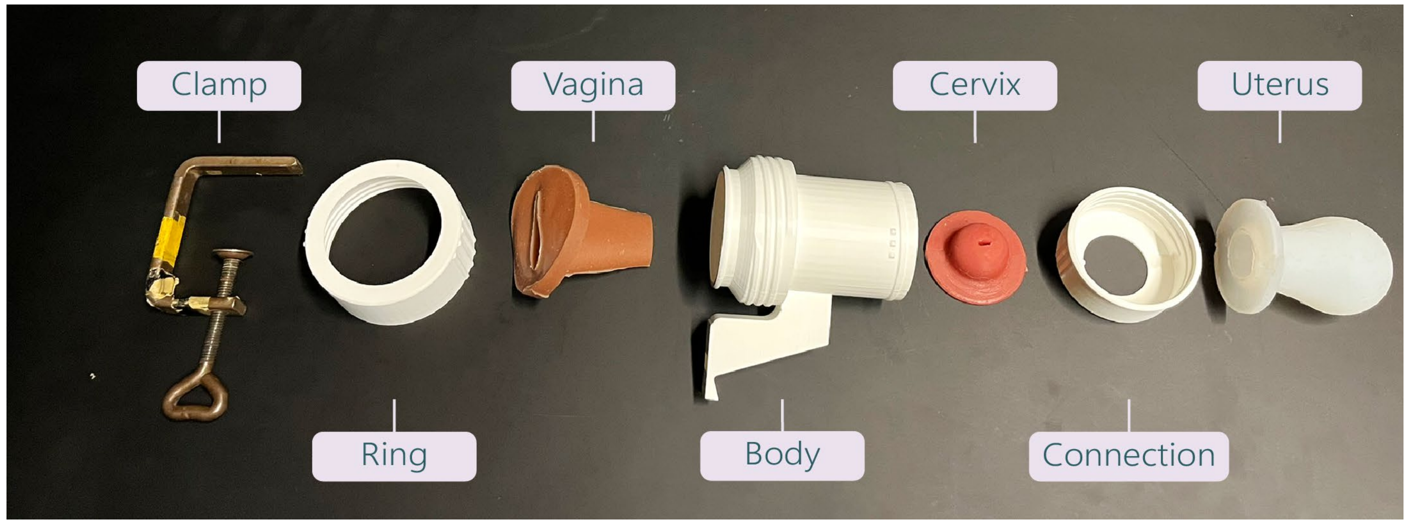


Figure 32: Exploded view of v.I

STAND

The existing stand featured a small foot with a clamp that, while functional, still allowed rotation and interfered with speculum insertion. Additionally, the foot was often the first part to break. In the new design, the clamp has been replaced with a diagonal foot. This adjustment increases stability by spreading forces across a larger area, making the stand stronger overall. The new clamp design no longer obstructs the speculum, as it uses a C-clamp that also fits more tables.

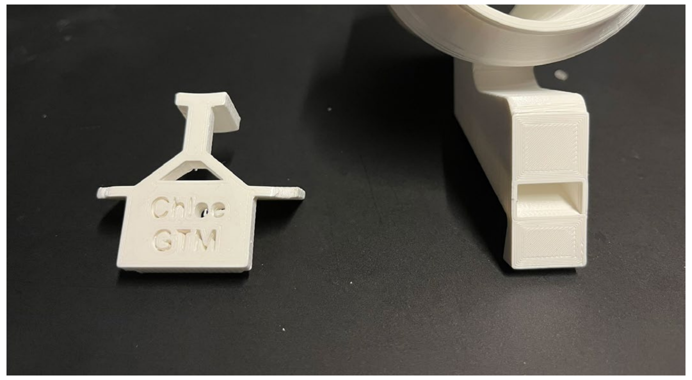


Figure 33: Stand iteration

BODY

The original collapsible body often failed during use, collapsing when users attempted to add the back part or during training. The redesigned body is now a single, solid piece, maintaining the same dimensions for realistic representation but enhancing stability and ease of use.

Figure 34: Body iteration

RING

The metal ring previously used in the model had sharp edges that could damage the silicone and looked intimidating to users. In the updated design, the silicone is held in place by the shape in the silicone and by a new 3D-printed ring. It attaches securely to the body using a thread mechanism, familiar to users from water bottle caps. This front ring helps secure the silicone when the speculum is withdrawn, preventing damage.

Figure 35: Ring iteration

VAGINA

The previous vaginal opening didn't accommodate varying speculum sizes, requiring users to apply excess force to open the speculum fully. To address this, the opening has been widened and the walls shortened. This change allows the speculum to open fully with minimal force, making room for the SED and enhancing user experience.

Figure 36: Vagina iteration

CERVIX

The cervix remained the same, as the material test revealed no significant difference in the wear of the different silicones.

UTERUS

The previous uterus model was slightly undersized and coloured, which made it difficult to place an IUD accurately. Additionally, its construction used excessive material. In the updated design, two different uteri are designed. They are both a bit larger, thinner, and slightly transparent. The version for the MVA has a texture inside to mimic the feedback you receive when a MVA is finished. The version for the IUD is flatter, allowing the IUD to stay in place.

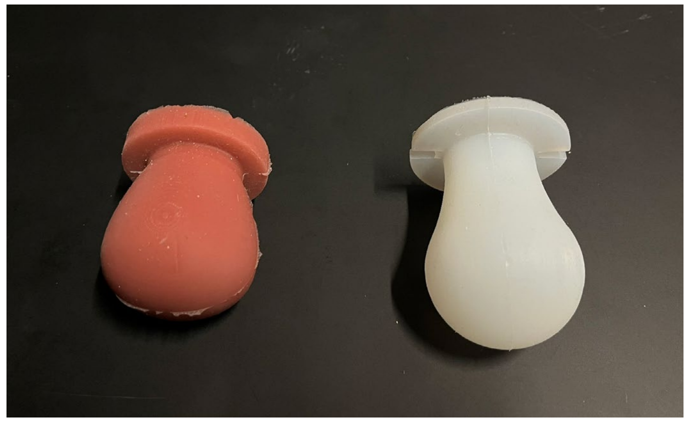


Figure 37: Uterus iteration

CLAMP

The old clamp required significant force to secure, and its positioning (angle) on the foot and table compromised its strength. Additionally, its placement slightly obstructed the speculum and could restrict the user's ability to work efficiently. In contrast, the new clamp, although taking slightly longer to position, offers improved user-friendliness. It is stronger due to its larger surface area, requires less force to use, and does not interfere with the speculum or the user's movements.

Figure 38: Clamp iteration

CONNECTIONS

The back part connection was unintuitive and required significant force to assemble, making setup cumbersome and prone to wear. Additionally, the cervix and uterus setup was complex. To simplify assembly and reduce potential breakage, the back section connections have been redesigned. Now, the back ring, cervix, and uterus remain in one piece when not in use. Following the same thread mechanism used for the front ring, a threaded connection on the back ring holds the uterus and cervix securely in place but allows easy removal to swap out the cervix when needed. This setup also better stabilizes the cervix when using a tenaculum or withdrawing the needle.

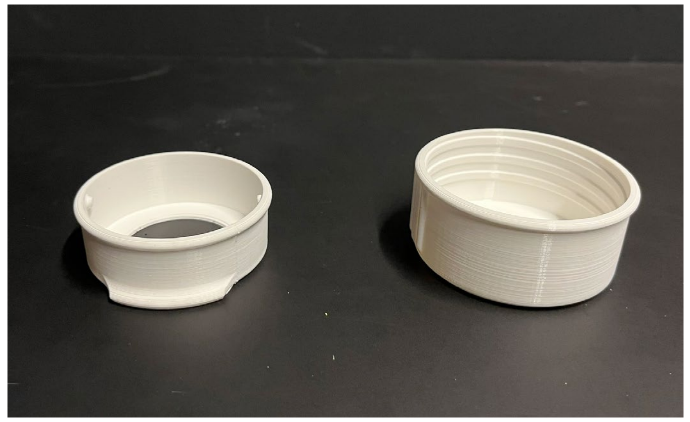


Figure 39: Connections iteration

LEEP

To integrate the LEEP procedure, the existing back design has been updated to include additional holes. These holes enable a sausage to be passed through and securely held in place using skewers.

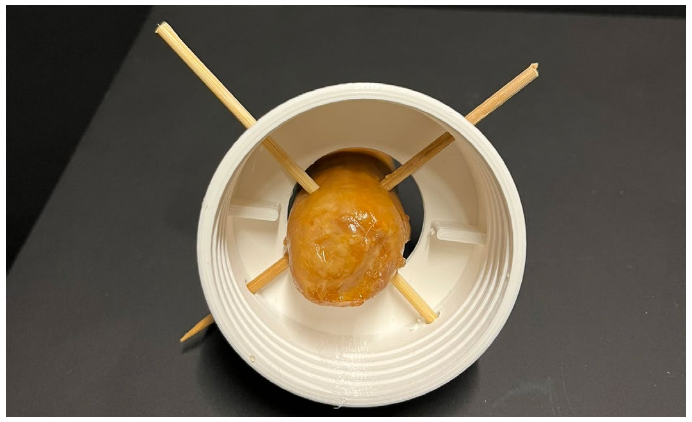


Figure 40: LEEP adjustments

SPRINT TWO

With the new version of the model (v.I), a four week field trip to Kenya was organized. This chapter explains how the testing was done in Kisumu, the main findings and results and the different changes made to the model during the four week period. Finally, all the new insights were used to update the list of requirements and create a new design vision.

05

5.1 TEST PLAN

To validate model v.I, the following research questions was formulated:

Does the device replicate the reality and can it be used to train PCB, MVA and IUD insertion?

To answer this question, a test is set up. The full test plan can be found in the Appendix 7.

The test involved three procedures: PCB, MVA, and IUD insertions. Each procedure was analysed to define the specific steps required. These steps were then reviewed and verified by three expert gynaecologists, who identified the most critical steps to evaluate on the model.

An interview guide was developed to gather feedback, including participant background information and the following questions (see Appendix 8):

- How easy was this step to perform on the model? (1-5 Likert scale)
- How realistic was this step to perform on the model? (1-5 Likert scale)
- How useful do you think this model is for practising the procedure? (1-5 Likert scale)

Finally in a structured interview, more questions were asked regarding which features and procedures could be added. Further remarks could be given (See Figure 41).

Aside from the test with the model, interviews were done with trainers to evaluate their current models and their wishes for a new model (See Appendix 9). The LEEP procedure was also tested with two gynaecologists. They were asked to perform the procedure on different sausages and evaluate if the model could be used for practise.

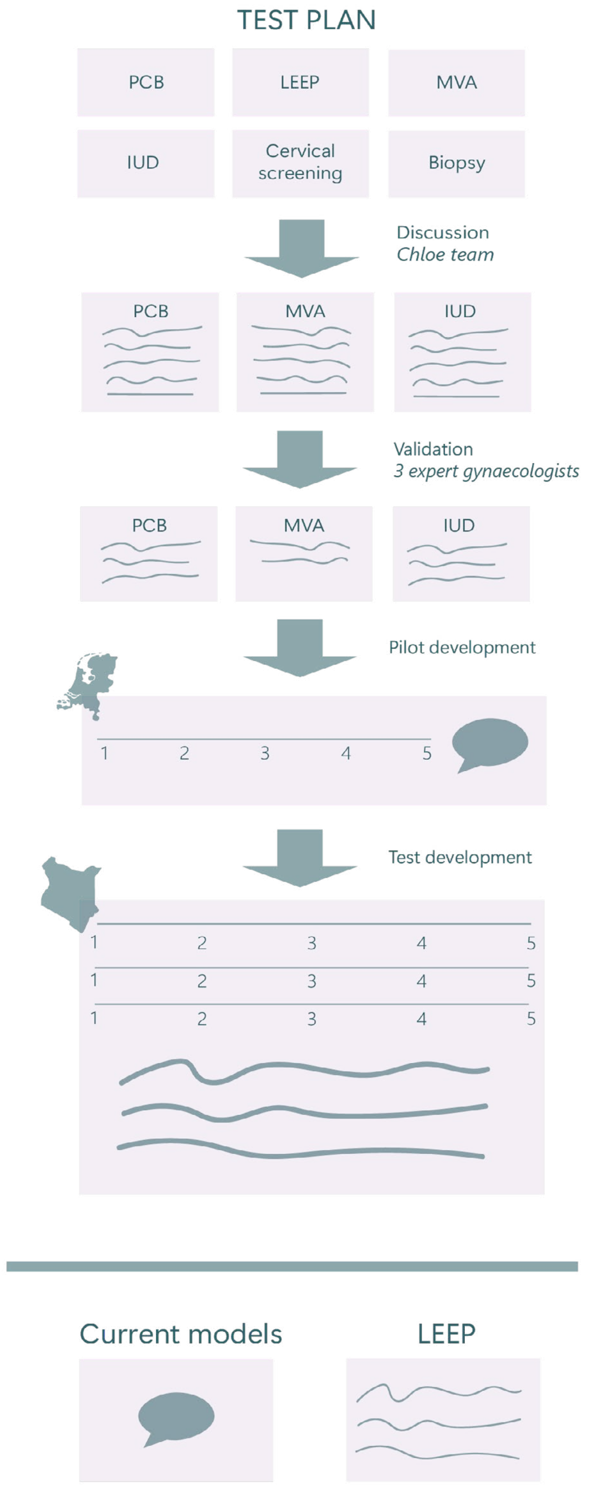


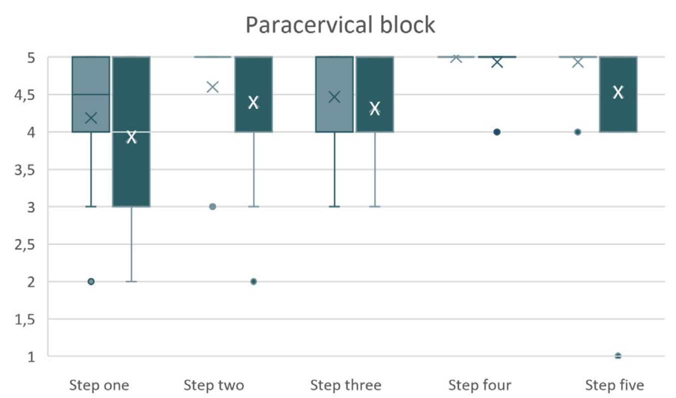
Figure 41: Test plan

Figure 42: Collage of the different tests carried out in Kisumu, Kenya

5.2 RESULTS

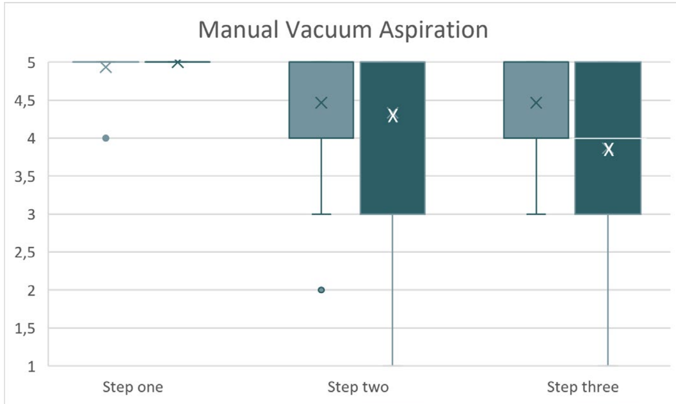
USER TESTING

The results of the testing are analysed and the data is presented in Figures 43, 44, 45 and 46. Left (light green) is the outcome of the question: *How easy was this step to perform on the model?* The right (dark green) is the question: *How realistic was this step to perform on the model?* In Appendix 10, the demographics of the participants can be found.



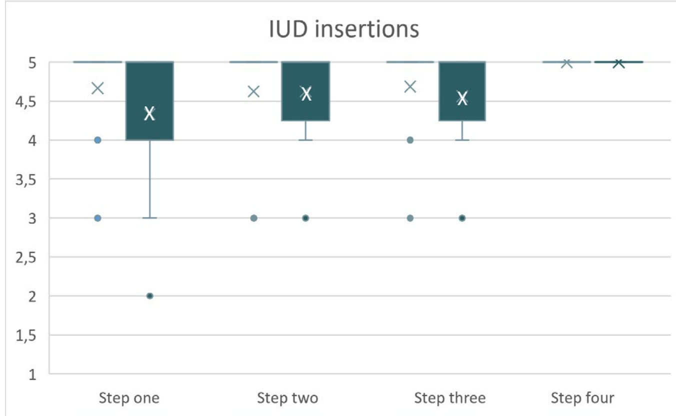
	Step
1	Place the speculum
2	Place the tenaculum
3	Place the injection at 4 o'clock
4	Aspirate the injection
5	Inject 4cc of air

Figure 43: Results Paracervical block test (n=15)



	Step
1	Clean the cervix
2	Insert the cannula
3	Rotate the syringe until complete

Figure 44: Results manual vacuum aspiration test (n=15)



	Step
1	Insert the sound (measure)
2	Pass inserter tube through cervix
3	Release the arms of the IUD
4	Withdraw the tube

Figure 45: Results IUD insertion test (n=15)

OUTCOMES

Twenty experienced medical professional rated the models usefulness and how accurate it represents the reality. Overall, the model's educational utility for teaching PCB, MVA, and IUD insertion was rated as 4.8, 4.9, and 5, respectively. Furthermore, the graphs show that the individual steps are also well perceived. Two steps were rated under a four on average:

- Placing the speculum (reality)
  The feedback given was that it was too easy, as the opening of the vagina is big. The cervix was already visible without the speculum and it looked very simplified.

- Feedback when completing the MVA procedure (reality)
  It was difficult to notice when the procedure was finished as the structure on one of the sides was difficult to feel. Furthermore, the cervix allowed air to pass through which released the vacuum.

The IUD procedure received the highest overall rating due to its straightforward requirements, which the model successfully met. The best-rated steps involved passing instruments through the model, as these were easier to validate during the design phase by ensuring proper fit. These steps were particularly well-rated for difficulty. However, the realism could be enhanced by increasing the grip of the cervix, though this varies significantly among individuals. The lowest-rated steps were those requiring more nuanced feedback, such as determining when the MVA procedure is complete,

accurately visualizing the cervix, or verifying if the injection was performed to the correct depth.
The main improvements that were mentioned are;

- The vagina structure and design can be made more realistic by adding more of the external genitalia and making it more difficult to view the cervix
- Making the uterus more transparent instead of milky, so show how the IUD is placed and if it sits correctly
- Adding more anatomy to the model to give students a more realistic view of the female body
- The distance from the vagina to the cervix is too long
- The uterus measures 9cm, which is the maximum dimensions for a copper IUD insertion and should be between 6-8cm.
- The feedback given when a MVA procedure is completed should be increased to enhance the learning experience.

Vagina more realistic	11
More anatomy	9
Transparent uterus	7
More feedback when MVA is finished	7
Structure/grip of cervix	7
Change the depth from vagina to cervix	6
Different cervices	5
Allow the uterus to be able to change position	3
Clear top	1
Add fluid for MVA	1
More space at vagina	1
Smaller uterus	1

Figure 46: Results extra features

INTERVIEWS

Multiple trainers were consulted to gather their insights on the educational design of the model and their experiences with existing teaching tools. During these visits, trainers were asked about the strengths of their current models, potential areas for improvement, and their vision for an ideal training model. Following this, the GTM design was presented, and trainers were asked to provide feedback from an educational perspective. They were also asked how the model could integrate into their current curriculum and what modifications would enhance its utility. These discussions were conducted through semi-structured interviews (see Appendix 9).
The following models (from Chapter 2.4) were analysed together with the participants.

- Box IUD model (Figure 47)
- Flat IUD model (Figure 48)
- Madam Zoe (Figure 49)
- Pelvic model (Figure 50)
- Mama U (Figure 51)

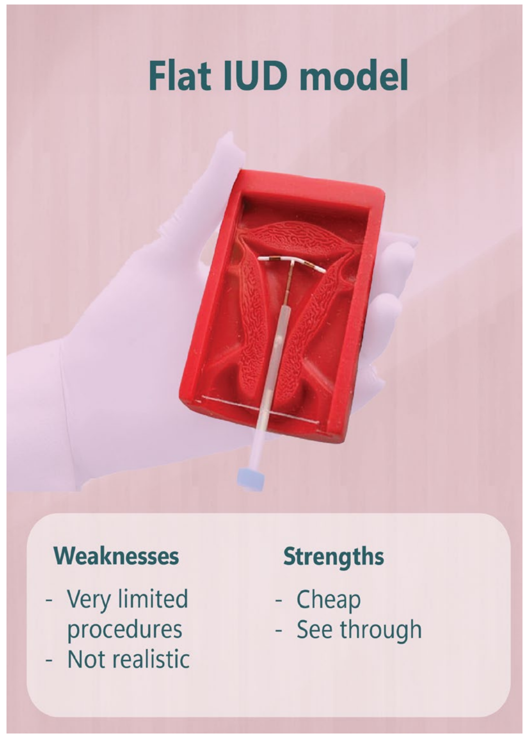


Figure 47: Flat IUD training model with feedback

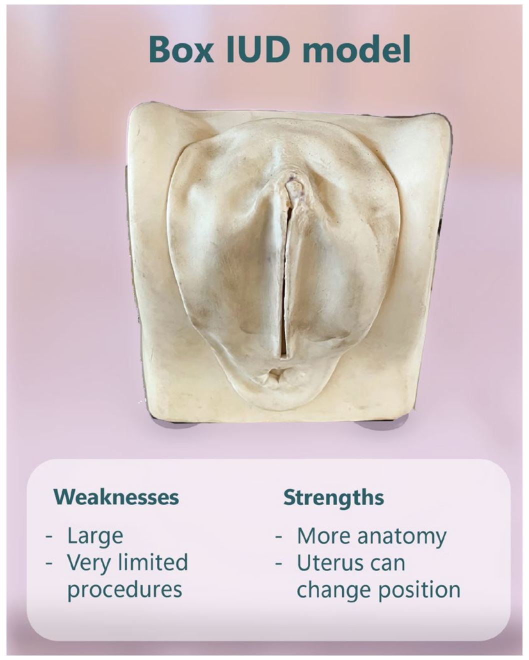


Figure 48: Box IUD training model with feedback

Figure 49: Madam Zoe training model with feedback

Figure 50: Pelvic training model with feedback

Figure 51: Mama U training model with feedback

5.3 DESIGN SPRINT

During the four weeks in Kenya, small design adjustments were made to verify some of the given feedback.

LENGTH
The base of the design was shortened after people mentioned that the cervix was too far away (See Figure 52). When the speculum opens, the cervix aligns properly within its grasp, facilitating ease of use.

Figure 52: Shorted model (above) vs v.I model

OPEN DESIGN
After consulting with one of the trainers, a request was made for an open design. This allows students to clearly observe procedures around the cervix during lessons or demonstrations without needing to look over the instructor's shoulder (See Figure 53).

This was tested and the conclusion was made that it was a good improvement, however when students are practicing it needs to be closed as they tend to look over the top instead of through the speculum.

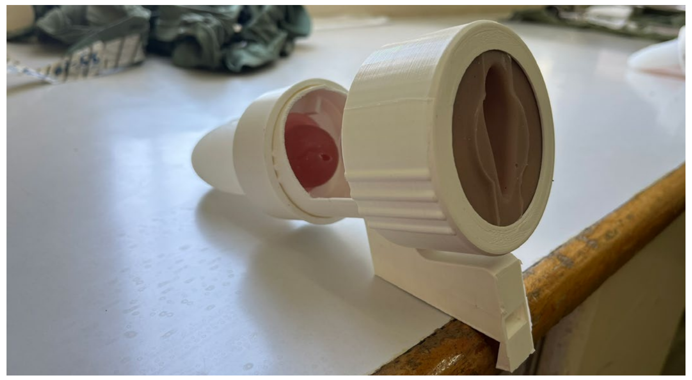


Figure 53: Model with open base showing the cervix

LEEP
To integrate LEEP into the design, it was essential to consider locally available materials in Kenya. After visiting multiple markets and shops, it was found that sausages are widely available and inexpensive. Various types of sausages, both raw and cooked, were tested to determine which would work best (See Figure 54 and 55). It was concluded that only raw sausages with a sturdy texture, which can remain upright, are suitable for the model. Raw sausages also do not require any preparation, making them a convenient choice.

Figure 54: Testing the model for LEEP

Figure 55: Testing different types of sausages

5.4 REQUIREMENTS

REQUIREMENT CHANGES
After the results of the testing were analysed, some requirements needed to be adapted or added based on the new findings. Appendix 5 shows all the requirements including the new changes. The most important adaptations to the list of requirements are highlighted in Figure 56.

Before	After
1. Performance	**1. Performance**
1.4.4 - Should have a structure on the inside to feel the differences during an MVA 1.9 - The device should have open or transparent walls where feasible to enhance visibility for trainers to provide clear views	1.4.4 - The model needs to have significant feedback when an MVA procedure is completed by adding more grittiness in the uterus 1.9 - The device should have open or transparent walls where feasible to enhance visibility for demonstation purposes, that can be closed during practise
2. Physical	**2. Physical**
2.5 The training model adheres to anatomic measurements of the uterus (4 cm in width, 8 cm in length) 2.6 The uterus should be hollow to fit an IUD inside	2.5 The training model adheres to anatomic measurements of the uterus (4 cm in width, 6 cm in length). 2.6 The uterus needs to be hollow enough to fit in IUD inside, but tight enough so that stays in place after placement 2.9 The cervix may not be seen from the front straight away 2.10 There should be more external genetalia that mimics the cleaning process 2.11 The uterus should be transparent to be able to see how the IUD is placed 2.12The model can incorporate part of the pelvic bones
	9. Production
	9.4 The model needs to be able to have accesible replacement parts 9.5 The cervix for LEEP needs to be able to be bought an accesible, local store

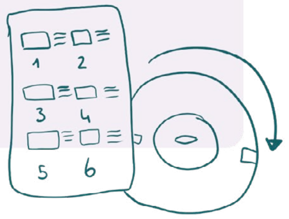
Figure 56: Requirement changes after sprint two

5.5 DESIGN DIRECTIONS

Based on all the findings, new design directions are identified to create a more meaningful product. Figure 57 shows eight of the most important design directions.

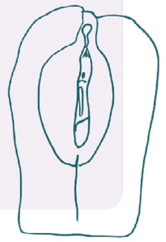
Assembly

- o Instructions
- o Foolproof design (usecues)
- o Design for misuse



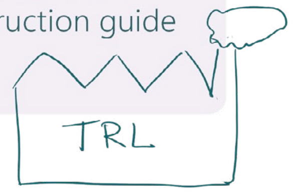
Reality

- o Adjust the sizing of vagina + uterus
- o Add anatomy around pelvis
- o More external genitalia
- o Vagina structure and ease of opening
- o Uterus in an angle
- o Have a gimble system for the back (allow to pull the cervix)



Production

- o Larger scales?
- o TRL 7 but on which scale
- o Create a construction guide

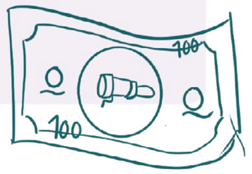


Education

- o Adapt the model for demonstrating
- o Adapt the model for examination
- o Implement in lessons
- o Create job aids with the model
- o Workshops adapted to the model

Business

- o Roadmap
- o Costs
- o Brand

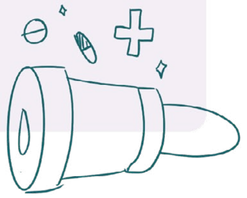


Packaging

- o Create a packaging
- o Easy to transport

Fuction

- o Improve procedures
- o Add procedures
- o Different options



Distribution

- o How to deploy to different places?

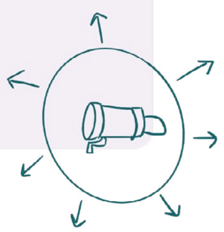


Figure 57: New design directions

5.6 CHOICE

To determine priorities, two discussions were held. The first was with the stakeholders, Chloe Innovations. During this meeting, various design directions were presented, and the question:

"What design elements do you think would be most beneficial for Chloe Innovations' future development?"

was posed. Next a discussion with the graduation team was held about what fitted best into the scope of the project. These insights were used to define the direction of the last phase of the project:

*To create a **durable**, **easy-to-use** product that effectively **supports** gynaecological procedures by replicating reality and providing students with **clear feedback** on their performance. The design should be capable of being used **independently** without supervision, lasting for multiple years, and enabling **local production** and assembly.*

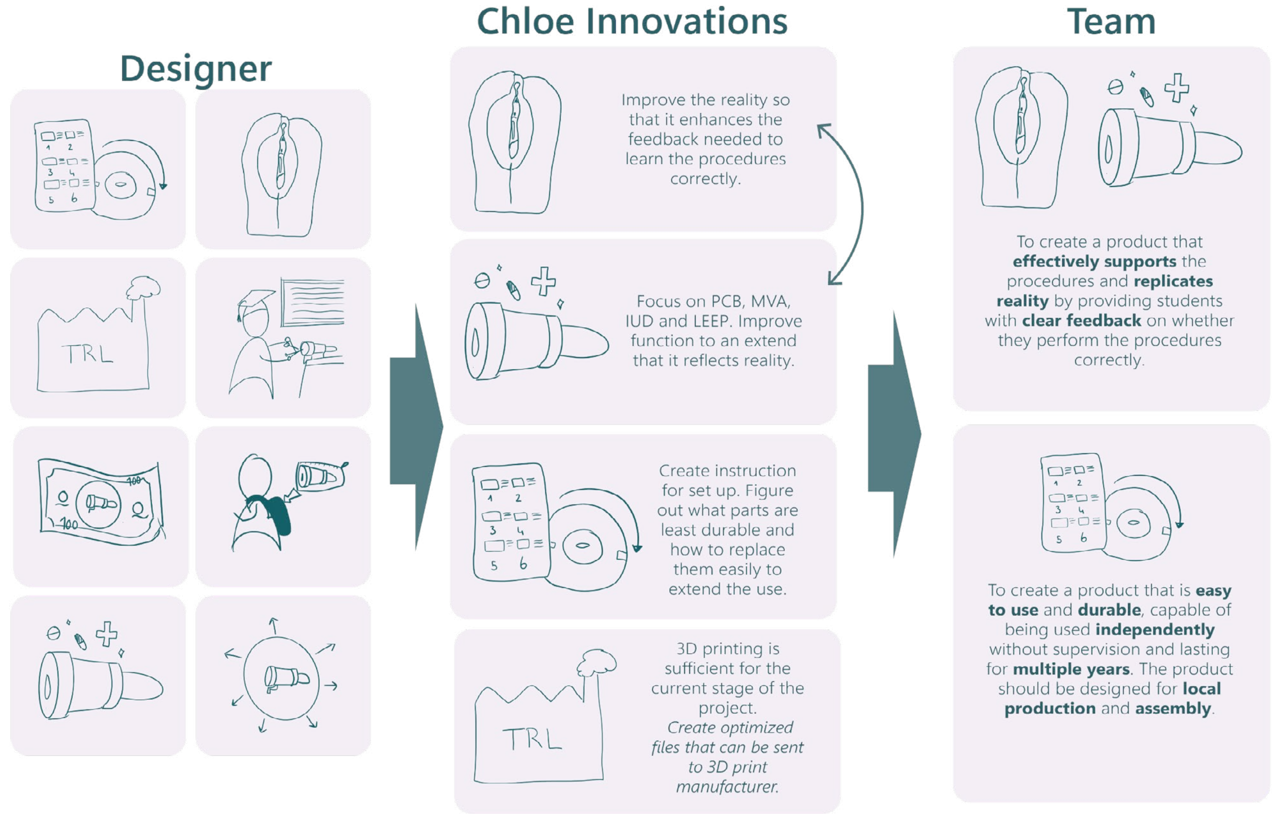


Figure 58: Choice for direction final design

SPRINT THREE

Design v.I will serve as the foundation for incorporating the requirements derived from the testing in Kenya during sprint two, as v.II was only slightly altered in Kenya. This chapter will present a new version of the design v.III, which has been optimized for the various procedures and enhanced for better usability. It will also present a validation plan for design v.III.

06

6.1 DESIGN SPRINT

All the insights, requirements and feedback, have led to the new design: v.III. Figure 59 shows the old model and Figure 60 shows the updated, v.III model. The model exists of seven parts shown in Figure 61. The process leading to the design (brainstorms, options, prototypes and choices) is presented in Appendix 11.

Figure 59: Assembled v.I

Figure 60: Assembled v.III

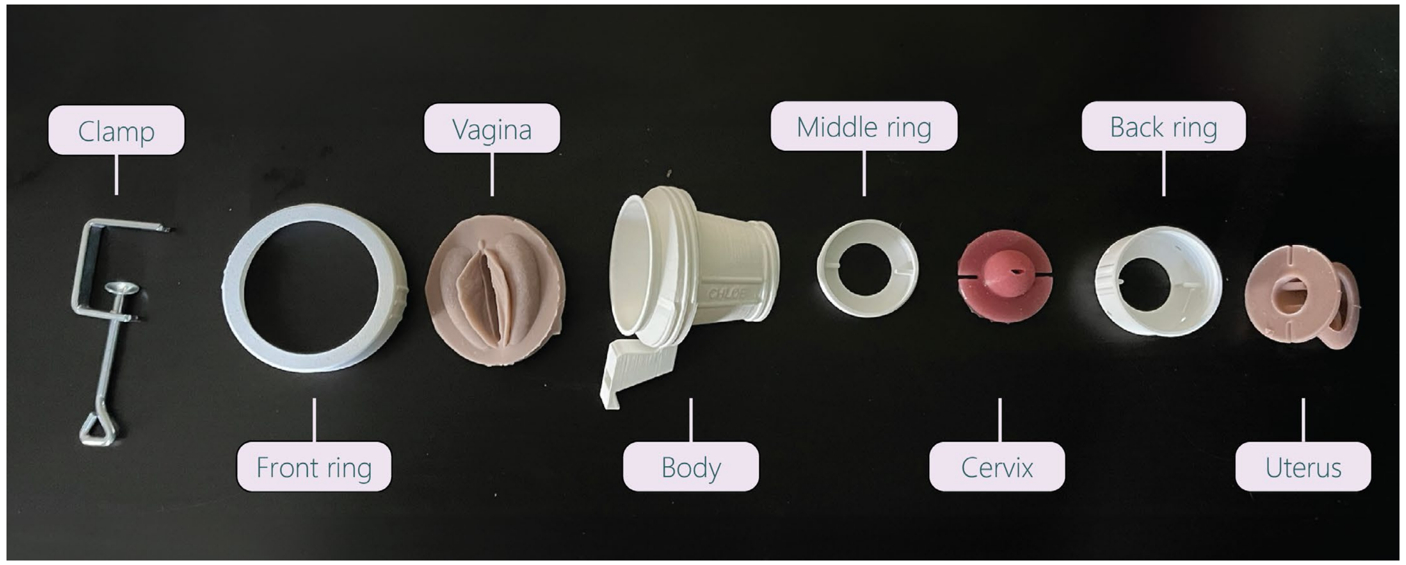


Figure 61: Exploded view of v.III

VAGINA

The user test with Dutch gynaecologists concluded that the vaginal walls should be shortened. However, feedback from the larger group during sprint two indicated that longer walls are beneficial for students to become familiar with the visual aspects. As a result, the original longer walls are retained. Furthermore, one of the main points of feedback was to create a more realistic opening. The external labia and clitoris are added to show students where to clean and what to avoid touching. The gap is made narrower to make it less obvious to see the cervix.

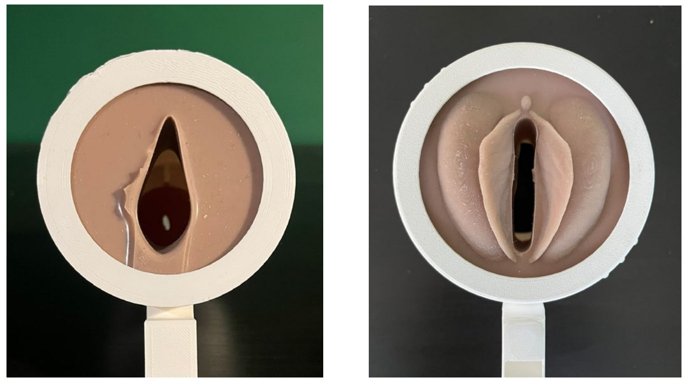


Figure 62: Vagina iteration

UTERUS IUD

After testing, it was concluded that the uterus was too hollow, causing the IUD to shift backward after placement. To address this issue, the shape was adjusted, and a new internal structure was introduced to more accurately mimic the actual anatomy. Tests were also conducted with transparent materials (see Appendix 11); however, to minimise costs and enhance production efficiency, the top of the uterus was removed. This modification allows students to observe their actions while ensuring the IUD remains in place.

Figure 63: Uterus IUD iteration

UTERUS MVA

To enhance feedback during the MVA procedure, various internal structures were developed and tested to determine which provided the most realistic and intuitive tactile experience when using a cannula. Additionally, the size and shape of the uterus were adjusted to better replicate actual anatomy. Even though, structure was added, it remained difficult to feel in the model, an option based on the papaya workshop (Steinauer et al., 2013) was added.

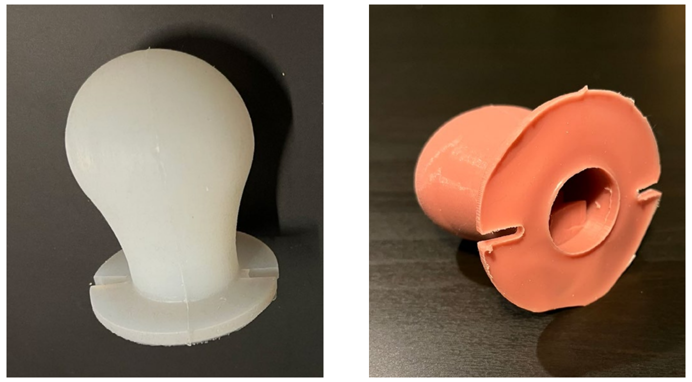


Figure 64: Uterus MVA iteration

BODY

The connections in the design have been refined through numerous prototypes to ensure proper alignment. This enhancement is crucial for users to assemble the model correctly, reducing the risk of damage and ensuring accurate training. Additionally, the ribs have been raised, and end stops have been added to ensure the threads consistently stop at the correct position. Lastly, holes have been added at the back to place skewers to be able to attach a papaya for the MVA procedure.

Figure 65: Body iteration

6.2 VALIDATION

To validate the new design, two specific tests will be conducted on the following design aspects:

1. Assembly: Assessing improvements in the assembly process with students.

2. Procedures: Testing the accuracy of the features and functionality of the design with a gynaecologist

ASSEMBLY TEST

The assembly test is conducted in the same manner as the test by the DfEM group (See Appendix 2). An updated version of the assembly manual is made to explain the different components in the design and how to assemble them. This manual (See Appendix 12) and the setup (See Appendix 13 was piloted with one participant. After this pilot, the first adaptations to the manual were made. The main feedback was:

- Create more space on the page (from one A4 to two A4s)
- Create more alignment guides (pictures)
- Add part names under the parts for clarity
- Improved and larger picture of the final result

With the feedback, the manual was adapted for the final test (See Appendix 13). Eight participants were recruited (See Table 8 for demographics) and asked to assemble and disassemble the model five times (See Figure 66). The test aimed to evaluate how clear the assembly guide is and how user friendly the process is. The time it took for the participants to perform the steps was recorded (see Figure 67 and 68) and observations were noted. The different colours in the graphs stand for the different tries of the participant (A1 is assembly one, A2 try number two, etc)

From the results can be concluded:

- The first assembly (a1) takes an average of 230 seconds (+- 4 minutes), as it takes time for people to read the instructions and understand the form and cues of the product they are assembling.
- The fifth assemble time (a5) takes an average of 60 seconds (1 minute). Assuming a user will have the product for a longer time and assemble multiple times, one minute is a good indication of how long it takes to assemble.
- The assembly time from assembly one (a1) to assembly five (a5) decreases with an average of +-3 minutes. This shows that there is a significant learning curve. Assembling the product for the first time may take a while, which is acceptable as the product will not have to be fully assembled and dissembled after every use.
- People stated that after cycle two and three they did not use the guide anymore.
- The disassembly times remain quite constant. The disassembly process was easy for most participants from the start and only small improvements were made over time (d1 = 33 sec, d5 = 22 sec). This shows that the task is quite straightforward from the beginning.

	Background	Knowledge of project
1	Industrial design engineering	Seen design before
2	Industrial design engineering	Seen design before
3	Industrial design engineering	Has not seen design before
4	Industrial design engineering	Has not seen design before
5	Industrial design engineering	Has not seen design before
6	Industrial design engineering	Has not seen design before
7	Clinical technology	Has not seen design before
8	Clinical technology	Has not seen design before
9	Clinical technology	Has not seen design before

Table 8: Demographics participants

Figure 66: Set up test

When comparing the new data with the data collected by the DfEM group, it is notable that the assembly time increases. The average assembly time of model v.0 was 35 seconds at a5. For model v.III, the average time at a5 was 60 seconds.

This has multiple reasons:

- The middle ring was added. This component ensures the cervix is not pulled out during the different procedures and that the back part can be used separately during demonstration purposes. This step took an average of

10 secs
- There are less alignment specifications for model v.0. As the uterus has changed to a flat model to better suite the procedures, it is important it is placed horizontally.
- Less force is needed in model v.III. Where v.0 was faster, it required more force from the participants (locking the body and placing the clamp). The thread in v.III takes longer, but is more pleasant to do
- The fastening features are more secure. As model v.0 has the tendency to collapse and be unstable during use, extra measures were taken to ensure this does not happen that have a negative impact on the assembly time.

The results from the observations are highlighted on the manual in Figure 69. General notes on the guide are:
- Participants tend to focus on the pictures, only if they do not understand the picture, they read the text
- The alignment cues are very important, but as they look like captions they tend to get skipped
- It is not always clear what the front or back of parts are
- The last three steps are most logical and participants do not tend to look at the guide.
- After two or three turns, participants noted they do not need the guide anymore and the cues are clear enough.

General notes on the design are:
- Finding the start of the thread can be difficult. Participants tend to search in a 2/3 cm range
- The middle ring gives the most problems due to the important alignment. It feels like a lid so people place it the wrong way round. It also blends in the design and gets forgotten during the disassembly
- Both the cervix and vagina tend to twist due to the friction with the rings.

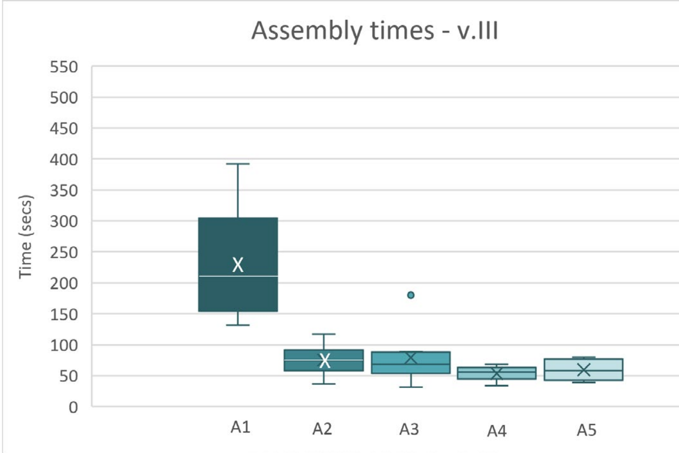


Figure 67: Assembly time in seconds v.III

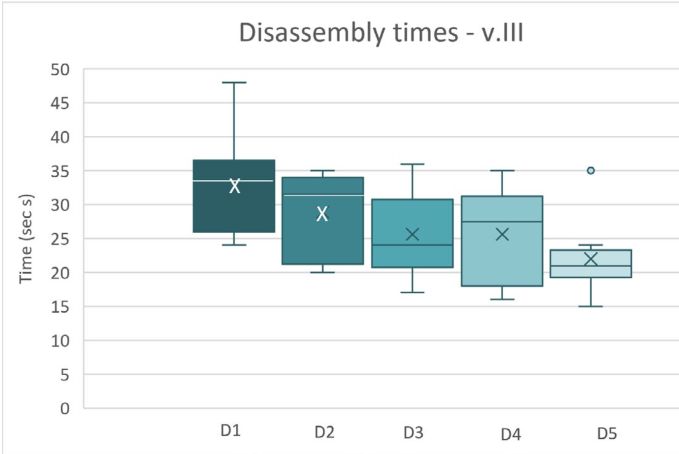


Figure 68: Assembly time in seconds v.III

Figure 69: Assembly guide with comments

PROCEDURE TEST

To validate the final design, an expert in the Netherlands was asked to test the model a final time. Due to time constraints the only procedure tested was IUD placement. The gynaecologist performed the procedure as normal (See Figure 70) and through a semi-structured interview, questions were asked. The test plan can be found in Appendix 14.

The overall outcome was very positive:
- The vagina looked realistic and the added structure provided good dimensionality
- The sizes of the vagina walls and body seemed good for the used speculum
- The size of the uterus was correct
- It was easy to see how the IUD should be placed
- The device felt stable during use

A few noted points of improvement:
- The IUD did not stay in place the first time, as the uterus is still a little rounded. However, she noted that the fact the uterus is open for demonstration purposes would be more valuable for teaching than ensuring the IUD remains at the fundus, as its intended position can still be explained effectively.
- The cervix was easy to view with a speculum as it faces straight forward and seemed like a nulliparous cervix. Creating a cervix that is slightly harder to find would make it more realistic.

Figure 70: Final procedure test

FINAL DESIGN

This chapter present the final design, v.IV. Firstly, it highlights the different features of the design. Next, it describes how different procedures that can be practised on the model, the manufacturing, costs, durability and packaging. Finally, it describes the value of the product and design.

07

Chloe Gynaecological Training Model

The Chloe Gynecological Training Model (GTM) is a low-cost, durable solution for hands-on medical training in low-resource settings.

Its modular design supports five procedures, offering realistic functionality and accurate feedback to enhance learning. Made from three materials and two local manufacturing techniques, the GTM is lightweight, easy to assemble, and simple to maintain, ensuring accessibility across diverse environments.

The GTM supports multiple training purposes. Its detachable back and ring allow close-up views of the cervix, swapping the uterus for MVA, sausage placement, and interchangeable cervixes, enabling various procedures with a single model.

Paracervical block

Manual vacuum aspiration

IUD insertion

LEEP

Cervical cancer screening

7.1 DESIGN FEATURES

DURABILITY

To create a design that fits into the context, durability is an important factor taken into account throughout the whole design.

The first part of the model that will show wear is the cervix, primarily due to the manipulation required during procedures. It is the only part that will be punctured or grabbed with sharp pincers (tenaculum). During the assembly test, it was also noted to wear at the edges. However the design is created in a way it does not need to be assembled every use, reducing wear on the mechanical parts. This means it is assumed it will wear faster from procedural practice rather than frequent reassembly. To solve this, the design can be delivered with extra cervices or sell extra cervices as spare parts.

The second part to be expected to break will be the foot of the model due to the shape. As PETG is less brittle than PLA in which most prototypes were made, the durability increases and the likelihood of breakage is reduced.

Lastly, the thread is expected to wear. The design is designed in a way that it can remain assembled during transport. This will reduce the wear, but will be inevitable in the end. To improve this, different FDM 3D printable filament could be explored such as Nylon or PC or exploring the option to SLS or SLA print.

MODULAR SYSTEM

The connections within the model are all made with thread, as it is very recognizable, easy to use and requires no force. The different parts are easily disassembled allowing for a modular design: silicone parts can be replaced or taken out; fruit, vegetables and meat can be placed; pictures can be fastened and more adaptations can be done in the future.

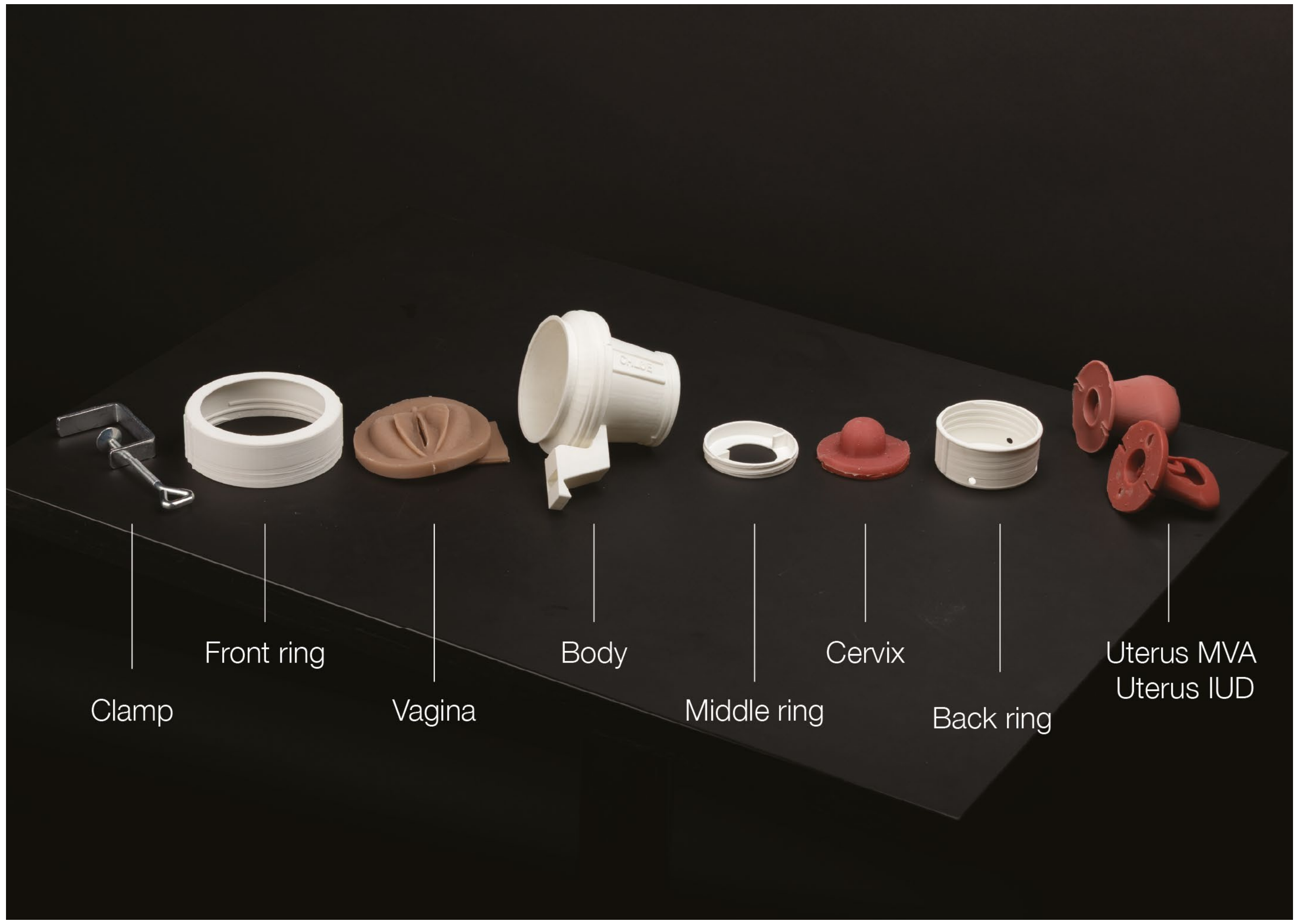


Figure 71: Exploded view of v.IV

PROCEDURES

Paracervical block

To train PCB procedures, the cervix is well-secured in the design. The eco-flex material mimics the cervix and the middle ring ensures the student can pull on the cervix without it becoming undone. For demonstration purposes, the back set can become undone to demonstrate where the injection sites are (See Figure 63).

Figure 72: PCB procedure on the GTM

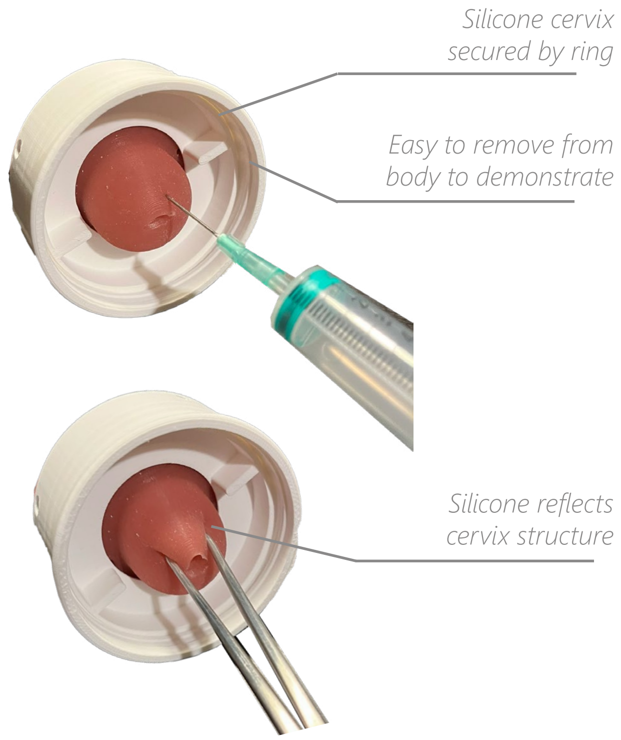


Figure 73: PCB details

IUD insertion

The design comes with two uteri. For IUD insertions a flat uterus is required. Ribs are placed in the uterus to make sure the IUD stays in place. The uterus contains a hole to provide visibility when the IUD is placed, allowing the model to be used for demonstration (See Figure 75). When the IUD needs to be concealed for practising, the uterus can be turned around.

Figure 74: IUD insertion on the GTM

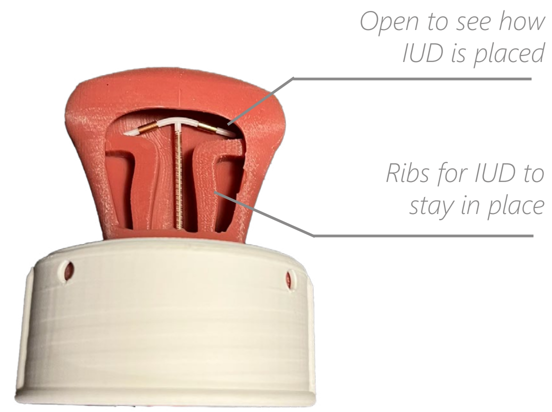


Figure 75: IUD insertion details

Manual vacuum aspiration

The design comes with a uterus specially designed to facilitate MVA's. It is larger than the uterus for IUD insertions as the uterus swells when cells are inside. Additionally, it features two distinct sides: one smooth side to represent the state before cell removal and one textured side to represent the state after the procedure is complete. Furthermore, two holes are added to the body to facilitate a training with a papaya (Steinauer et al., 2013) (See Figure 77).

Figure 76: MVA procedure on the GTM

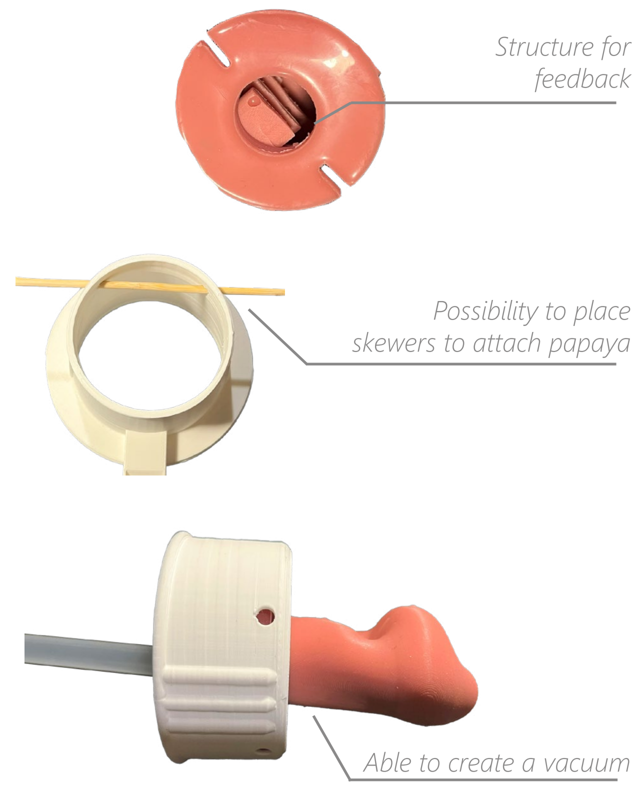


Figure 77: MVA details

LEEP

To facilitate a LEEP procedure, a cervix is needed that can be cut. A sausage can be placed in the back ring and secured using skewers. To make the model look more realistic, the cervix can be placed over the sausage and by placing the middle ring, the setup stays in place (See Figure 79).

Figure 78: LEEP procedure setup

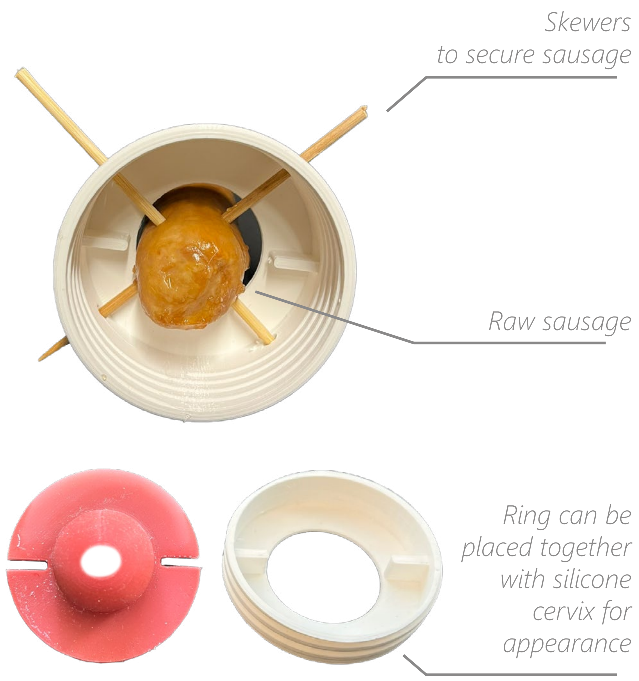


Figure 79: LEEP details

Cervical cancer screening

The easy placement of the middle and back ring allows for different pictures to be inserted and secured in the back ring, enabling students to practice recognizing different conditions. The laminated pictures are durable and can be sprayed with water or acid, as required for certain screening procedures (See Figure 81).

Figure 80: Cervical cancer screening setup

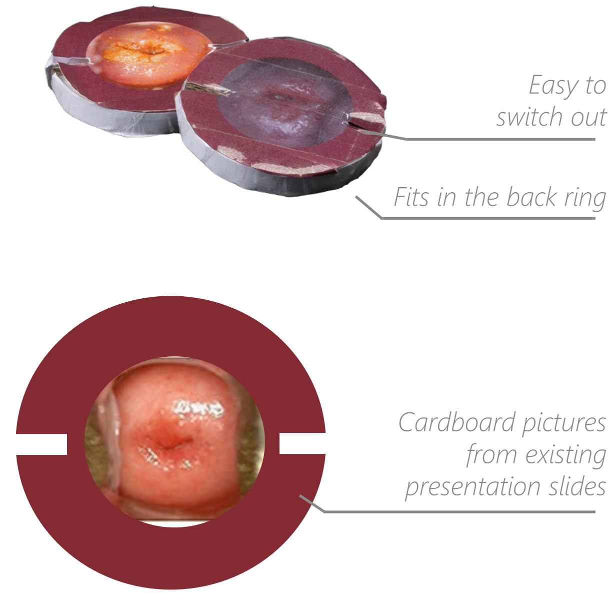


Figure 81: Cervical cancer screening details

PACKAGING

The most important function of the packaging will be to keep the different parts of the model together, clean and prevent damage during transport. The model should be able to be stored without taking it apart, allowing it fit into a 21x14x9 cm bag. Spare parts can be included in the bag. The see through material lets the user view the components inside together with the pictures on the assembly guide (See Figure 82).

Figure 82: Packaging GTM

DESIGN DETAILS

A few details can be highlighted in the design (See Figures 83 and 84):

A. Vagina walls have been made even narrower and structure has been added to mimic the feeling of the canal. This makes the design more realistic and, in the future, could also be used for bimanual examinations.
B. The double threading makes it easier to assemble. There are two entry points for the thread, making it easier to find the beginning.
C. The end stop ensures correct alignment. As the uterus and cervical os should be horizontal, it is important that the thread stops at the same place every time.
D. The Chloe logo has been added on the side for branding purposes.

Figure 83: A) Structure of the vagina walls

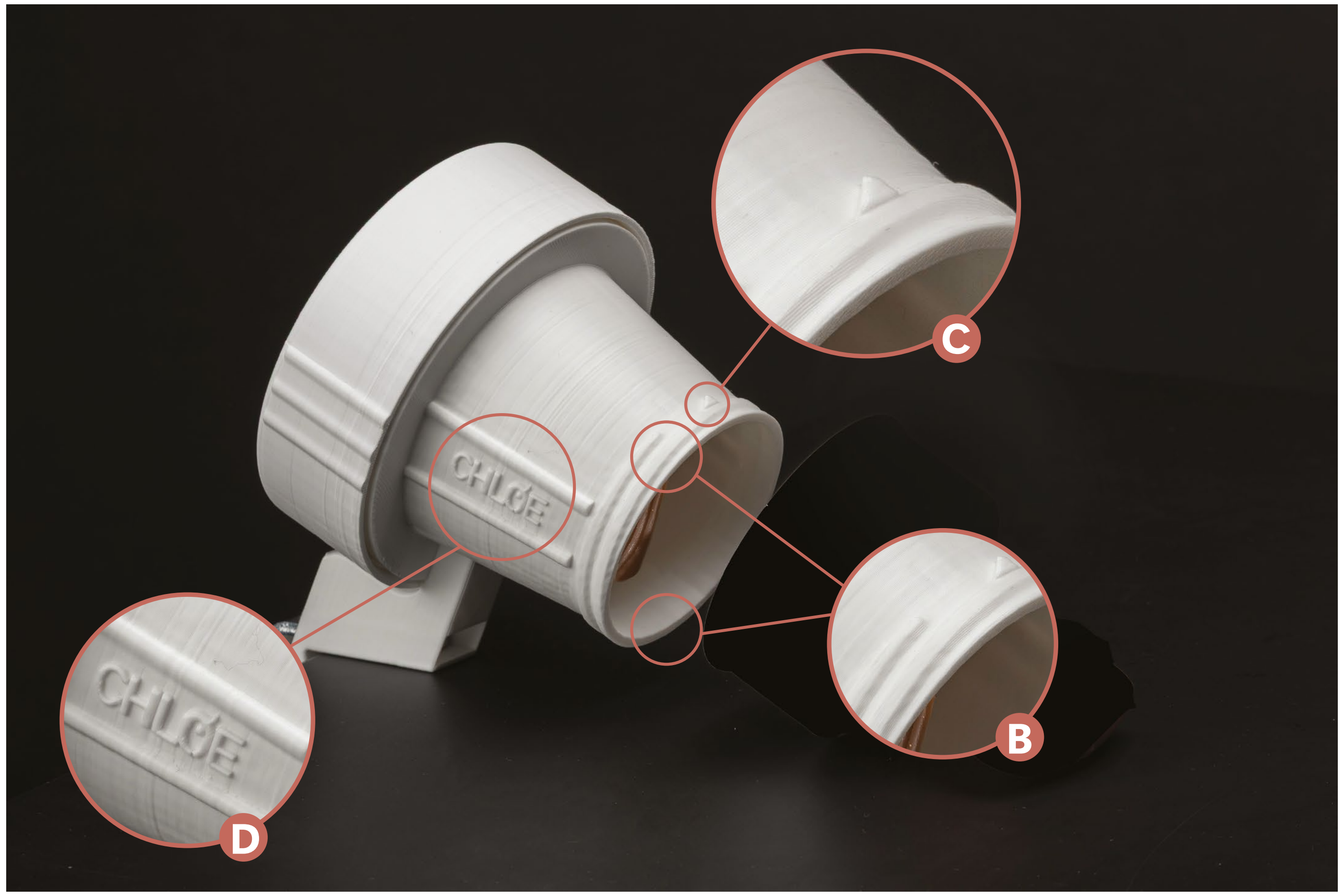


Figure 84: B) Double threading, C) End stop, D) Chloe logo

ASSEMBLY GUIDE

The new assembly guide exists of two pages. The front page shows the assembled product, parts, QR code and can be folded to fit the packaging (See Appendix 15). The back page shows the instructions (See Figure 85).

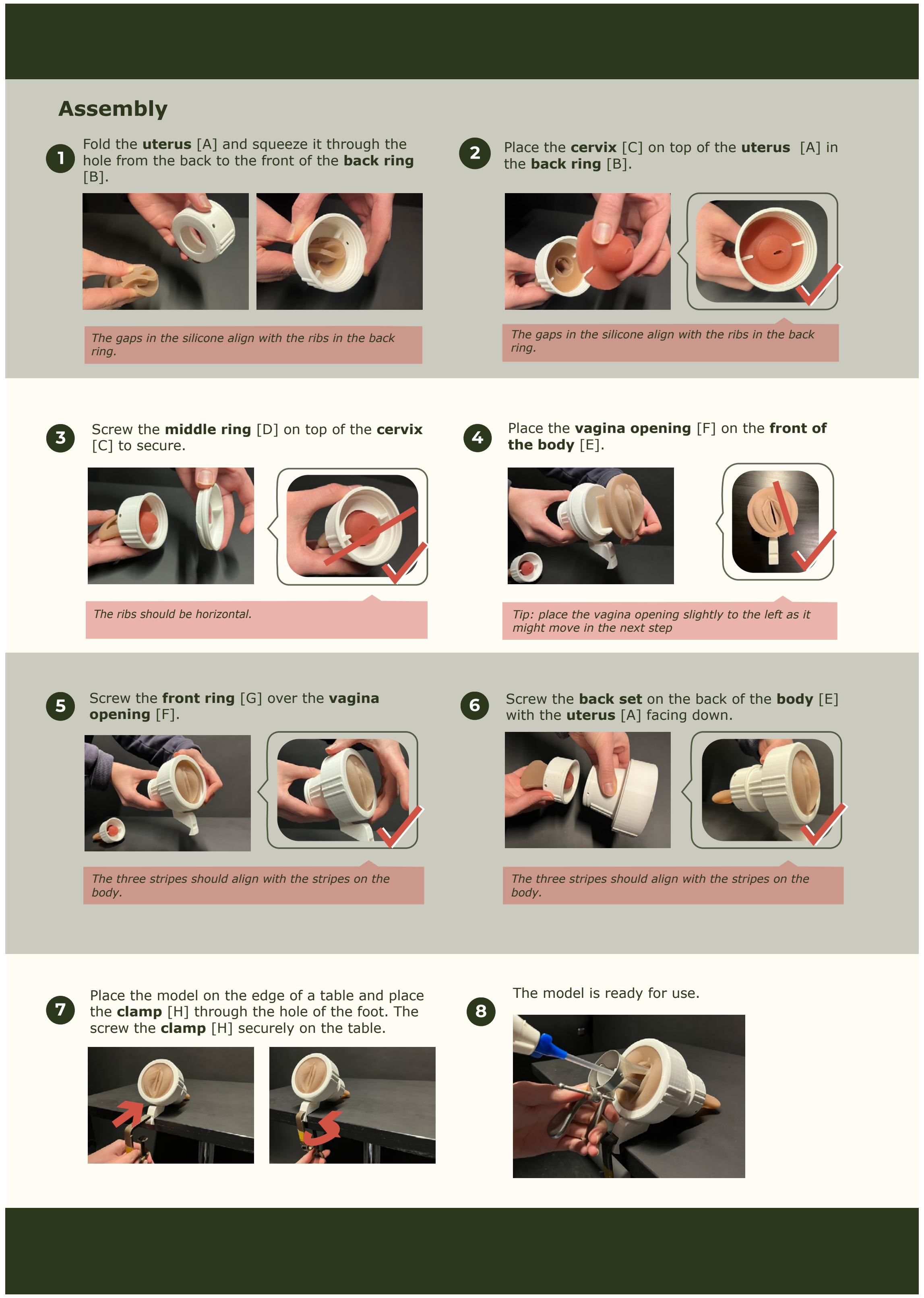


Figure 85: Final assembly guide (back)

MANUFACTURING

The material chosen for the plastic parts is PETG. It is highly resistant to impact and wear, making it suitable for repeated use and ensuring the longevity of the product. PETG is also easy to print with, offering better thermal stability and adhesion compared to PLA (Simplify3D Software, 2022).

The entire model can be locally manufactured without requiring specialized expertise. The body and connections are 3D printed using FDM technology. The design has been optimized to eliminate the need for supports during printing, ensuring a clean finish and no post-processing. Furthermore, extra focus has been given to creating durable threading by using wide, low-profile threads, which help reduce wear and tear from regular use (See Appendix 16).

The reproductive organs are created using silicone moulds that can be 3D printed with the same FDM printer. Silicone is poured and injected into these moulds to form the different parts. The moulds are designed to minimize air bubbles and enhance the final finish by placing the air vents on the back of the parts (see Figure 86). To keep silicone costs as low as possible, the design has been optimized for minimal thickness and the different types of silicone kept to a minimum. A drawback of the silicone is that without a vacuum chamber, the quality of the parts cannot be assured.

The amount of external parts have been brought to a minimum. However, to assure stability, the clamp has to be bought (See Appendix 17).

Furthermore, as the design can be manufactured locally, the production facilities can also create and sell spare parts, ensuring low effort for the users to easily replace components when something breaks.

To make the manufacturing process understandable, a manufacturing guide is created and presented in Appendix 18.

COSTS

The material costs of one model are €18,49. Table 9 shows a cost breakdown (See Appendix 19 for the full table).

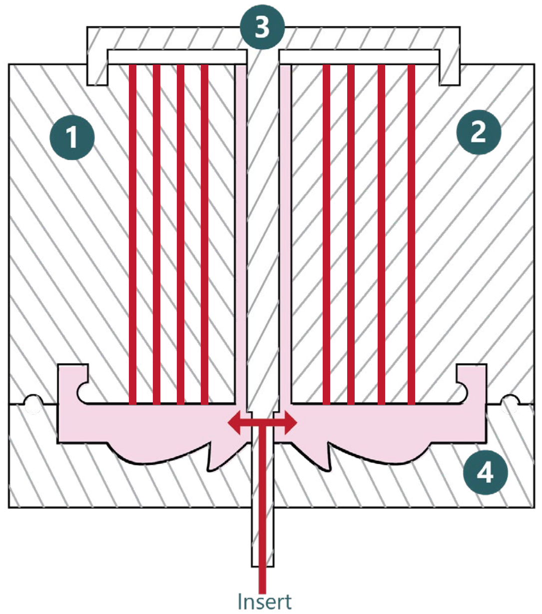


Figure 86: Four part vagina mould to minimize air bubbles

Material costs per GTM			
	Infill/ material	*gr of filament/ silicone*	*Cost per part*
Base	*20%*	*64,86*	*€ 2,80*
Front ring	*20%*	*23,09*	*€ 0,59*
Back ring	*20%*	*18,5*	*€ 0,50*
Small ring	*20%*	*6,55*	*€ 0,14*
Vagina	*Dragonskin*	*60*	*€ 2,88*
Cervix	*Ecoflex*	*21*	*€ 0,63*
Uterus large	*Dragonskin*	*50*	*€ 3,59*
Uterus thin	*Dragonskin*	*35*	*€ 3,24*
Extra silicone	*Ds/Ef*	*75*	*€ 3,26*
Clamp	*-*	*-*	*€ 2,50*
		Total	**€ 18,49**

Table 9: Cost breakdown materials GTM

7.2 PRODUCT VALUE

VIABILITY

Viability refers to the ability of something to work successfully or be feasible in a specific context. The viability of GTM is shown through several key features that ensure its practicality and sustainability in low-resource settings. One of the strengths of the design is its modularity, allowing separate components to be produced and replaced independently. This minimises waste and reduces long-term costs by enabling users to replace only worn or damaged parts rather than the entire model. Additionally, the model is designed with low production costs in mind, using locally available materials and 3D printing techniques to keep it affordable for institutions with limited budgets.

The design has also been tested with existing medical devices, ensuring compatibility with standard gynaecological instruments. This eliminates the need for specialized tools and allows trainees to practice with equipment they are likely to use in real-world scenarios. Moreover, the reliance on external suppliers is kept to a minimum, as most components can be produced locally with accessible materials. This reduces logistical challenges and ensures the model's availability even in areas with limited infrastructure. By focusing on affordability, functionality, and local production, the model enables institutions in low-resource settings regions to provide high-quality education.

DESIRABILITY

The desirability of the GTM lies in its innovative approach to addressing training needs in low-resource settings. Its design balances simplicity, functionality, and realism, making it an appealing tool for a wide range of stakeholders as even Dutch gynaecologists have expressed an interest. Furthermore, the feedback of the local Kenyan medical professionals in sprint two was very positive: 'I think this is a fantastic model' which shows their interest in the project. One of the key factors contributing to the desirability of the GTM is its adaptability. The model integrates multiple procedures, including PCB, MVA, IUD insertions, LEEP, and cervical cancer screenings, into a single compact design. This eliminates the need for multiple training models, saving space and reducing costs while ensuring comprehensive training. The GTM is anatomically improved, with realistic features such as skin-tone and dimensions that replicate human anatomy. This enhances the user experience and makes it more effective for teaching and learning purposes. Its user-friendly connections and minimal material usage make it intuitive to assemble and use. This not only ensures ease of use in training environments but also promotes sustainability by minimizing waste and relying on fewer materials.

The affordability of the GTM is another key factor, as it helps lower barriers to access in low-resource settings. By offering a cost-effective alternative to expensive models, the GTM promotes equality in medical education and healthcare, by ensuring that everyone has the opportunity to develop practical skills.

FEASIBILITY

The feasibility of the GTM is supported by its straightforward production process and minimal reliance on complex techniques. The design is built around simple STL files that can be easily produced in-house, or at a prototyping facility, using a 3D printer and a vacuum chamber. Importantly, no advanced technical skills are required for manufacturing, making the process accessible in low-resource settings.

Another benefit of the design lies in its minimal post-processing requirements, which streamlines production and reduces time and labour costs. The model is also composed of a limited number of components, simplifying both assembly and maintenance. This efficiency ensures that users, without extensive technical backgrounds, can easily understand how to use and interact with the model.

EVALUATION

This chapter summarises the outcomes, limitations, and recommendations of the project. By addressing this, it provides a holistic view of the project's journey. Additionally, it highlights personal insights gained throughout the process.

08

8.1 CONCLUSION

ANSWER TO RESEARCH QUESTION

To conclude, the research question posed at the beginning:

How can the Chloe GTM be redesigned to create a better product that allows users to practise multiple procedures and is user-friendly whilst remaining suitable for low-resource settings?

has been addressed through the development and presentation of the final design, v.IV.

The improved product features a modular system that accommodates procedures beyond PCB, including MVA, IUD insertions, LEEP, and cervical cancer screening. The design enhancements improve realism, thereby enriching the learning experience for students and providing better guidance. Moreover, the assembly process has been simplified and made more intuitive, while the overall structure has been strengthened.

All improvements have been made with low-resource settings in mind. The design utilizes only three materials and relies on a single outsourced component, with the rest of the model being locally producible. The production cost of the model is significantly lower compared to existing models, making it accessible in the context. Finally, the product remains portable with the whole package weighing only 420 grams and fitting in a bag of 21x14x9cm without having to be disassembled and including spare parts.

LIMITATIONS

Different limitations were encountered during the project.

Testing

- Testing the design in the context was an invaluable experience. However, due to the difference in culture, it could be challenging to receive useful feedback. People tend to be very positive and it took multiple sessions to learn how to receive critical answers.
- All the testing was done with experienced people. It was useful to receive their feedback on how realistic the model was, however they thought all the steps were generally easy as they already knew how to do the procedures.
- The person recruiting the participants has a senior position, even though he was not in the same room, it might have affected their answers.
- No students have been asked to review the model and the model has not been tested yet in a learning environment.
- The final design has only been reviewed with one gynaecologist who is not located in the intended context. Also, the gynaecologist worked at a hospital with a large gynaecology department and said a model like the GTM would not be necessary as students there can see so many different procedures on the amount of patients in the hospital. The model would be better to test at an academic medical centres or a general practitioner.

Design

- As the project had to be completed within 100 days, not all the aspects of the design received equal attention. More validations with students would have benefited the quality of the feedback during procedures integrated within the design. Furthermore, a lot of time was spent on the alignment of the parts, which in hind sight might not have been as important as the quality of feedback.
- The quality of the available 3D printers varied a lot. Due to this, a lot of time was lost thinking different parts did not fit whilst the problem lay with the inaccuracy of the printers. It shows that the type of printer influences the quality of the design.
- The current design is optimized for 3D printing, as was defined in the project brief. However, for the future this will have certain limitations:
- If the demand for the product exceeds 50 units, 3D printing will no longer be an efficient production method. The model is not currently designed for injection moulding, as its components require lofted geometries.
- The silicone moulding process remains highly manual, which would need to be optimized for larger production batches.
- The tolerances within the design are quite big, which is good for FDM printing, but will have to be adjusted when a more accurate manufacturing technique is chosen.

8.2 RECOMMENDATIONS

There are still many different improvements that can be made to the design:

FOCUS ON EDUCATIONAL ASPECTS

As mentioned in the limitations, the design has been tested with doctors, but not yet in a real learning environment. Additional validation could be conducted in classroom settings with both trainers and students to assess its effectiveness and usability. Furthermore, exploring the versatility of the design in different scenarios could enhance its impact. This includes developing an open version for demonstration purposes, integrating automatic feedback mechanisms during examinations, or creating detailed instruction guides tailored for self-practice.

IMPROVING THE MVA PROCEDURE

The MVA procedure is difficult to recreate as a simulation, due to the different types of required feedback. An improvement could be to add a sleeve on the cervix (internal os) to ensure the vacuum stays in place during the whole procedure (See Figure 87). This would allow for training with tomatoes (See Appendix 20). Furthermore the papaya fitting can be optimized.

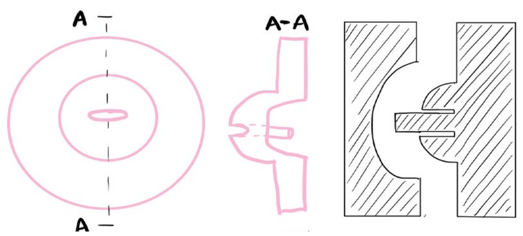


Figure 87: Sleeve design cervix

GIMBLE DESIGN FOR UTERUS

To create a more anatomically correct model, a moving uterus could be made. By using a gimble design, students could pull the cervix which would result in the uterus being straightened (See Figure 88)

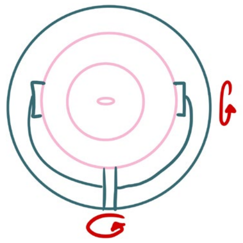


Figure 88: Gimble design cervix + uterus

INTEGRATING ELECTRONICS

Adding a light source + attachment, the cervix can be viewed in different settings (darker rooms, no electricity, etc). Furthermore adding a camera that is linked to a screen could, in slightly higher resource settings, enhance the learning experience as well.

CLICK ON ANATOMY

The model is still a simplified version of the female body, adding more anatomy would create more understanding of the body and enhance the learning experience. This could be done by creating a click-on system so that the model remains portable if needed. Additionally, such a system could open new market opportunities by offering customizable or expanded configurations (See Figure 89).


Figure 89: GTM with anatomy

INCLUSIVENESS

The model is currently based on dimensions derived from literature; however, every body is unique. It would be valuable to explore options for varying the model's size (extremes) to help students understand and practice with the diversity of body types they may encounter.

MORE VALIDATION

The last model is only tested with a single gynaecologist. Doing more tests together with students and using the model during actual training would be valuable.

MATERIALS

The model is made from PET-G and designed for FDM printing, as it is locally available. However, the tolerances used are quite big, sometimes making the design feel a little unstable. Investigating alternative production methods could be beneficial for enhancing efficiency and scalability in the future (See Appendix 16 for further explanation).

PROCEDURES

Other procedures that could be added to the model are:

Hysteroscopy
- By increasing the diameter of the cervix and creating a uterus that is flat on both sides, a hysteroscopy can be placed into the uterus. Using beads or other objects, students can practise their motor skills.

Suturing
- Silicone has proven to be a good material to practise suturing (Gallagher et al., 2020). However the current silicone tears quickly when cut so would only be suitable for +-3 time use. Optimizing the material by adding mesh into the vagina mould when pouring the silicone would give the silicone more strength and allow it to be used multiple times.

8.3 REFLECTIONS

This section provides a reflection on the project from a personal point of view.

First of all, I found this project amazing to work on. The medical field was something that interested me before, but the combination of that and designing for a low-resource setting with all the challenges that come with it, was a process that I truly enjoyed. There are many things I learned and take away from this project:

TRIP TO KENYA

My trip to Kenya was probably the most inspiring journey I have ever taken. Going to a place and immersing myself in daily life there, especially within the hospitals, is an experience I will never forget. It put the life we have in the Netherlands into perspective and taught me to take less for granted.

PEOPLE IN KENYA

I learned a lot from the people in Kenya: how kind and open they are, how excited they are about innovations, how creative they can be, but most of all, how much they look out for each other. I found it extremely inspiring to join a medical camp with two nurses on their day off. The motto 'you can always do good with little' really stuck with me.

THE FEMALE BODY IS AMAZING

During this project, I dove into the world of gynaecology and learned so much about the female body. I also found it interesting to see how little other women knew about their own bodies. Discussing these topics openly helped remove a big part of the stigma surrounding them.

EMBODIMENT DESIGN

I chose this project because I wanted to improve my embodiment skills. I always felt I enjoyed it, but I didn't have a project to show that yet. During this project, I have grown a lot in my prototyping, 3D CAD, and problem-solving skills. I really enjoyed being able to visit the PMB and materials lab multiple times a week and working with my hands.

DESIGN FOR EMERGING MARKET

During the first phase of my project, I worked with the DfEM group. I found it very rewarding to collaborate with a group of students who brought different perspectives to the project. It was my first (small) coaching experience, and I learned a lot about how to collaborate in a way that allowed us to learn from each other.

SETTING PRIORITIES

At the start of my project, I noticed I struggled with figuring out where to begin because everything seemed important. Throughout the process, I learned how to narrow my focus. Even though I got enthusiastic about almost everything, I had to force myself to set priorities and stick with them.


Figure 90: Model v.I in use in Kenya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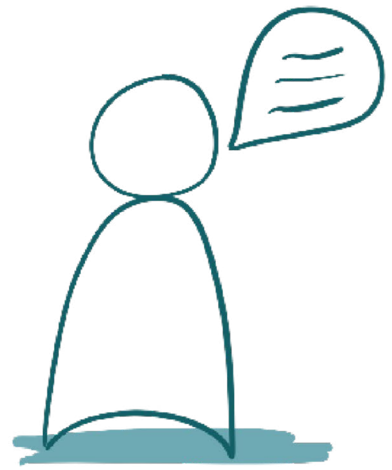
APPENDIX

10

APPENDIX 1: USERS

This appendix shows the different potential users of the Chloe GTM and what their needs are.



Trainer

Profile

Tasks
Moving from facility to facility (hospitals, schools, centres) to teach courses ranging from one year to a day)

Type of training
Lectures, theory, practicals with models, practicals with patients and exams

Wants
A portable and durable model, that allows for demonstration, practise and examination

Resident

Profile

Tasks
Few procedures

Current type of training
4 year residency, learn and observe in hospitals

Training goals
Become full gynaecologist

Workplace
Hospital

"I would like a model on which I can realisticly practise the procedures that I have seen"

Doctor

Profile

Tasks
Performing procedures

Current type of training
Full trained, but can learn specific new skills

Training goals
Teach collegues or new students

Workplace
Hospital

"I would like a realistic model on which I can demonstrate skills I have learned at different hospitals"

Medical student

Profile

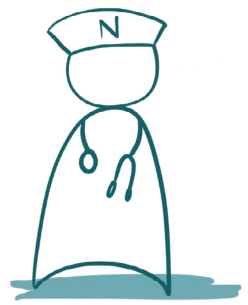
Tasks
Learning

Current type of training
Differs per degree, 3 year study with internships

Training goals
Become general officer

Workplace
School

"I would like a model on which I can physically practise the procedures that I have learned about in class and can demonstrate and examine my skills"



Nurse

Profile

Tasks
Daily care of patients, family planning

Current type of training
One year specilization on the side in reproductive health, 3-5 days training on specific procedures

Training goals
Specializing after a general degree

"I would like a model on which I can physically practise the procedures that I heard the theory of"

Figure A1: Users of GTM

APPENDIX 2: DFEM USER TEST

These are the pages from the report of the Design for Emerging Market group on the user tests they performed. This test was used as a starting point to define requirements for v.I and to use as a reference for the assembly test done in Chapter 6.

2.1 Initial Testing Chloe GTM Use

Goals

Our primary aim is to identify potential issues and gather insights during testing by documenting our initial experiences with the product. There are three specific areas we intend to focus on:

1. **Use** (Bimanual examination) and PCB functionality
2. **Disassembly/Assembly**
3. **Cleaning**

By trying by ourselves, we learn to understand the context of use, discover new issues to discuss and areas to develop.

Methods

All participants test on area a a time then rate the product based on certain criteria from that area. Then think out loud.
For detailed step of test see Appendix C

Step of Test

1. **Bimanual examinations** → Answer the form to note down any initial feelings.
2. **PCB** → Answer the form to note down any initial feelings.
3. **Testing Assembly** → Write reflections
4. **Testing Disassembly** → Write reflections
5. **Test on Cleaning with Water & Soap** → Write reflections

Figure 14: Collage of us exploring the product

Data Collection

Observation & VDO Record

Participant Thinking Out Loud

Participant Fill in Form & Write Reflections

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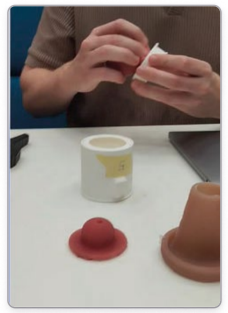
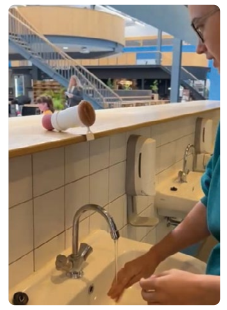
Results

Test

	1 Bimanual Examination	2 PCB Procedure	3 Assembly / Disassembly	4 Cleaning
Test				
Key Insights	• 3/4 participants hold the model with their other hand to make the model more stable. • The vulva came out when removing fingers	• Inserting the speculum to see the cervix is the easy part. • The cervix flipped/ fell off easily. *The test skipped pulling cervix part, which we learn later that would be important for training.*	• Collapsible part creates less stability. • The current lock creates uncertainty during use. We had to redo a few times to get it right. • The guideline for cervix orientation wasn't clear during assembly. • All of us can assemble within 1 min and disassemble in 20 sec.	• Water worked well to remove the dust and debris on the 3D printed parts and the silicon parts.

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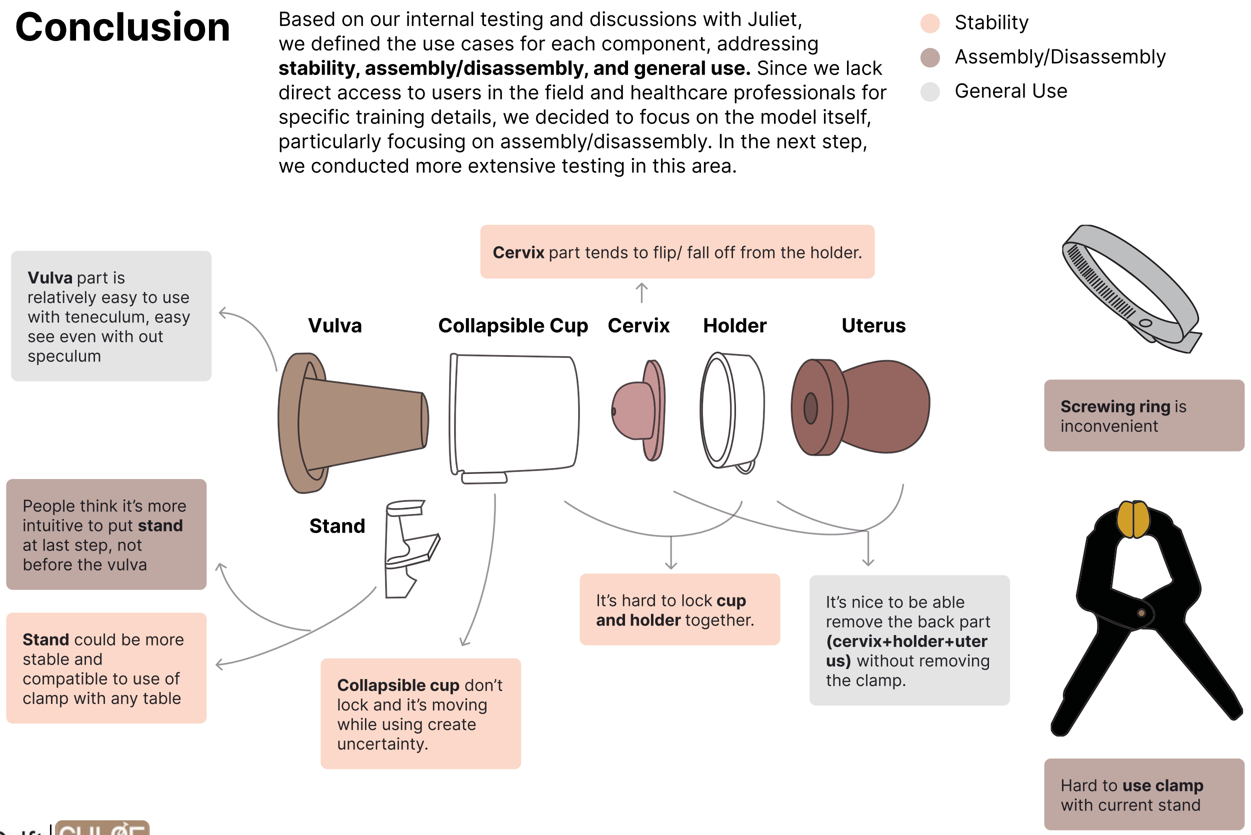
Conclusion

Based on our internal testing and discussions with Juliet, we defined the use cases for each component, addressing **stability, assembly/disassembly, and general use.** Since we lack direct access to users in the field and healthcare professionals for specific training details, we decided to focus on the model itself, particularly focusing on assembly/disassembly. In the next step, we conducted more extensive testing in this area.



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2.2 Testing Assembly & Disassembly

Goals

After our initial testing, we narrowed our focus areas to three key aspects
1) overall form stability,
2) instructions (see chapter 3.2), and
3) DIY cervix.

It's also essential to gather insights from participants with no prior experience or knowledge of Chloe. To improve aspect 1. and 2, we observed how people interacted with the product by assembling and disassembling only the provided instructions, and conducted interviews to understand their thoughts and feelings about each component.

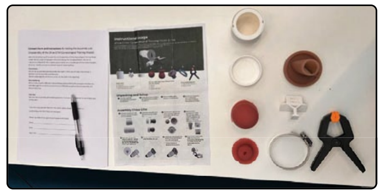
This also gave us an opportunity to validate our assumptions about potential pain points and ask them to compare with the new prototypes we are currently iterating on.

Methods

Participants (n=8) were asked to assemble and disassemble the model five times using only instruction with no guide/help from us, with short breaks between each cycle. Following this, we conducted interviews to identify pain points related to specific steps, parts, and the instructions provided.

Afterward, participants were shown the new prototypes and asked to compare them with the current model, providing feedback on any differences and improvements.

Then we analyze the findings and categorize into parts and suggestions/



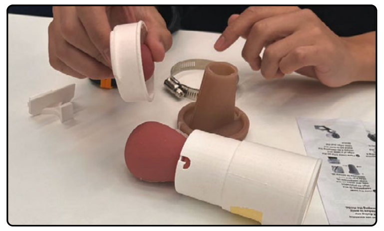


Figure 15: *Images of testing process*

Data Collection

- **Observation & VDO Record**
- **Participant Thinking Out Loud**
- **Interview**
- **Time Recording**

2.3 Qualitative Result

From observing assembly and disassembly for five times with participants (n=8), we identified common pain points by observing users and asking them which steps or parts of the model and instruction they found inconvenient during the first and after fifth attempts.

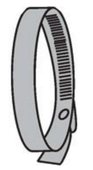
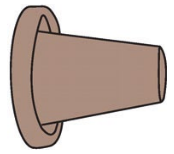
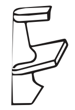
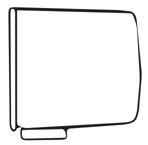
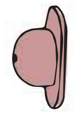
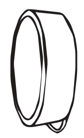
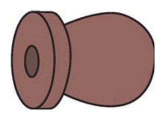
Based on these findings, we suggested potential solutions for each step.

The photos are taken from multiple participants. For more feedback details, see Appendix F.

Pre-Step	Step 1	Step 2	Step 3
			
Arrange part, understand instruction	**Pull until the two parts are lock into position**	**Insert Uterus**	**Put cervix into uterus and align cervical opening with holder.**
Pain Points	**Pain Points**	**Pain Points**	**Pain Points**
• Some people skipped this step and start with trying first and change when faced errors. • Most people looked at visuals then read only when needed.	• Telescope doesn't lock or doesn't feel like it's locked to users. • Many are uncertain if it should kept short or long.	• Unclear orientations and direction. • Mistake the cup and holder as same thing. • Wrong Labels (D/E) • *"Don't use excessive force"* they are afraid to squeeze the uterus in holder.	• Alignment is difficult to understand. • Difficult Wording *(Protrustion)*
Suggestions	**Suggestions**	**Suggestions**	**Suggestions**
• Group Key Component could help them understand the product than seeing it in many separated parts. • Exploding Views could help them understand how all each part related to each other	• After first time, people skipped this step totally, maybe it is not necessary.	• Using isometric view • Explain how the uterus are placed in • In the future, two parts can be connected together so this step is not necessary.	• Using isometric view

Step 4	Step 5	Step 6	Step 7	Step 8
				
Put inner component and outer component to lock in clockwise	**Make sure the stand aligns with the cervical os**	**Put Vagina Opening onto the Outer Part**	**Attach the ring by positioning it over the vulva apply pressure & screw**	**Place Chloe on the edge of the table.**
Pain Points	**Pain Points**	**Pain Points**	**Pain Points**	**Pain Points**
• The lock is difficult and creates uncertainty • Outer & Inner Components has never been mentioned before	• Table and stand doesn't fit. • The stand feels like it's go to break.	• Many times, people attach the stand after the vulva which is a wrong steps. This happens even they have done multiple times.	• Screw is difficult and annoying. • Metal ring feels scary, unfriendly to use.	• People don't know they need to use clamp attaching the model to table. • Clam requires heavy force to operate.
Suggestions	**Suggestions**	**Suggestions**	**Suggestions**	**Suggestions**
• Change the lock to more secured one • Group Key Component could help them understand the product than seeing it in many separated parts.	• Make the stand more strong	• Update the stand to be the last step to be put on for more intuitive assembly.	• Design a new ring that align with the rest of the model.	• Make the stand that fits with the clamp use. • Show the picture of complete Chloe GTM with table in context.

Feedbacks on Parts

Clamp	Metal Ring	Vulva	Stand	Cup	Cervix	Holder	Uterus
							
It needs extra force	Screw metal ring is not nice.	People put the vulva before the stand. They need to re-do.	The stand feels like it's go to break.	The cup sometimes collapses. People don't know if it should be short or long, there for it creates uncertainty.	Some people understand the orientation part of the cervix	It doesn't lock	Don't know it needs to be squeezed in at first time.
	Metal ring feels scary.		At first use, people don't know				To have uterus on the table is not nice.

2.4 Quantitative Results

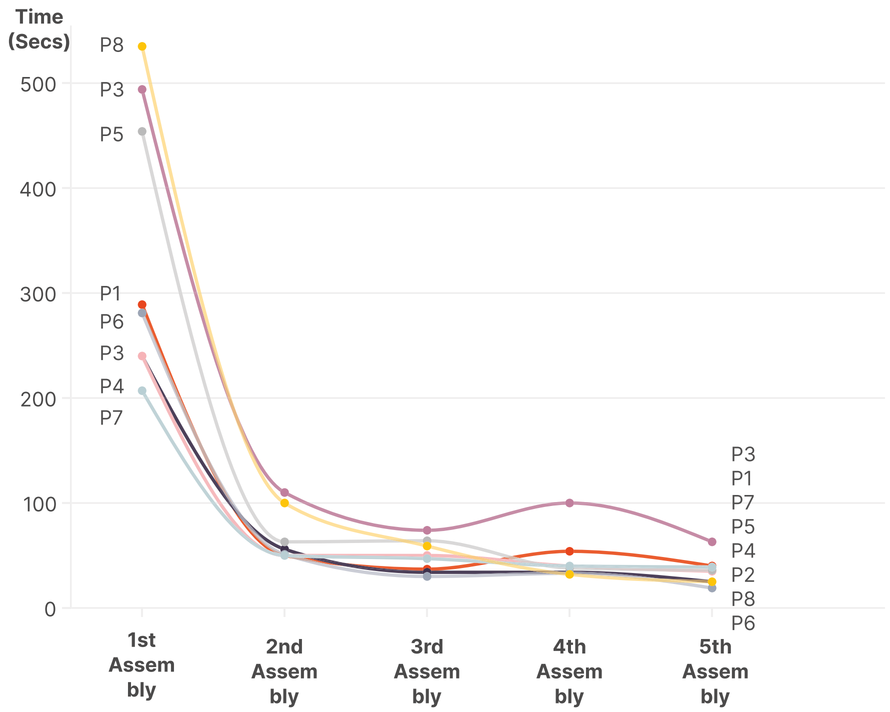
Assembly Time of Five Times

The assembly times show a big improvement after the first time assembly.
Participants took much longer in their 1st assembly varies from *207-535 sec. (avg=350 sec)* but their times dropped significantly by Second time and remained low and steady through Assemblies 3 to 5.

All participants' times became more similar towards the end, showing that they were getting faster to *(avg = 34 seconds)* and more consistent as they practiced.

It could be concluded that the process is learnable to assemble by themselves with help from instruction.

see table for time in appendix G



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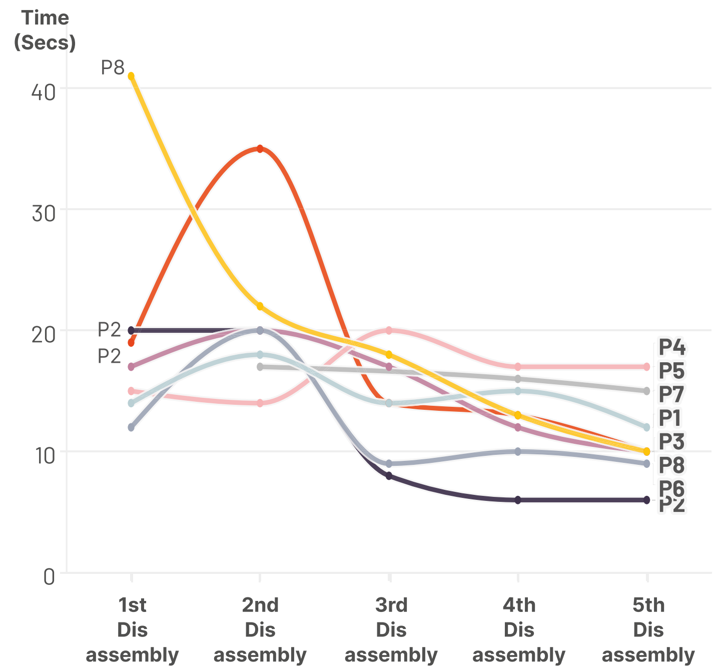
Disassembly Time of Five Times

The disassembly process was easy for most participants from the start, with only small improvements over time.
At most times, it could be done by 30 seconds.

While times fluctuated slightly, most participants quickly got faster, showing that the task was straightforward from the beginning.



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The graphs on the left page do not effectively portray the results. Instead, the data has been transferred into a box plot, allowing for better comparison with the data collected in Chapter 6.

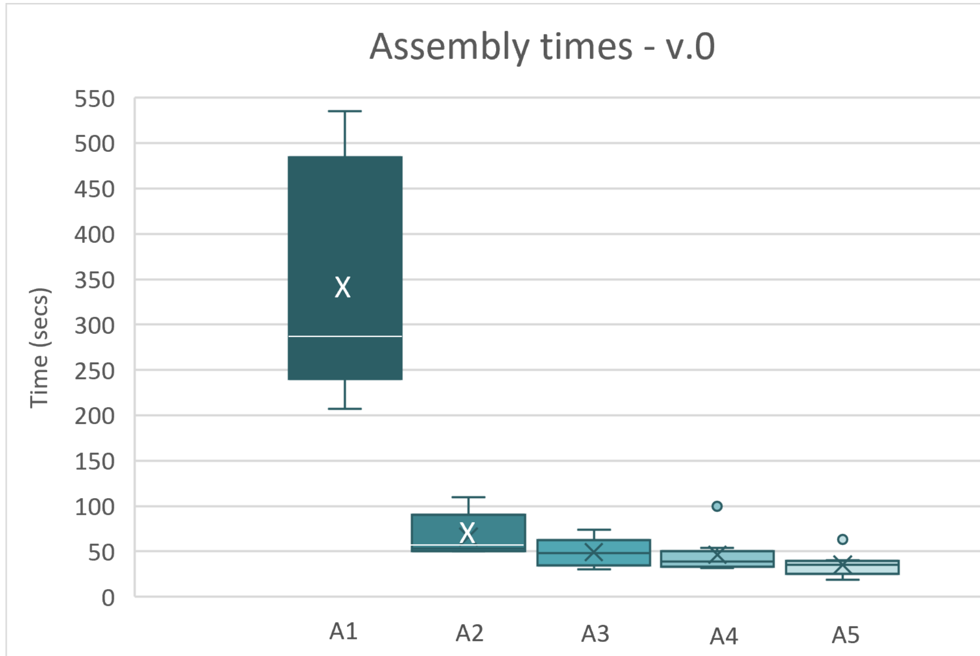


Figure A2: Assembly time in seconds v.0

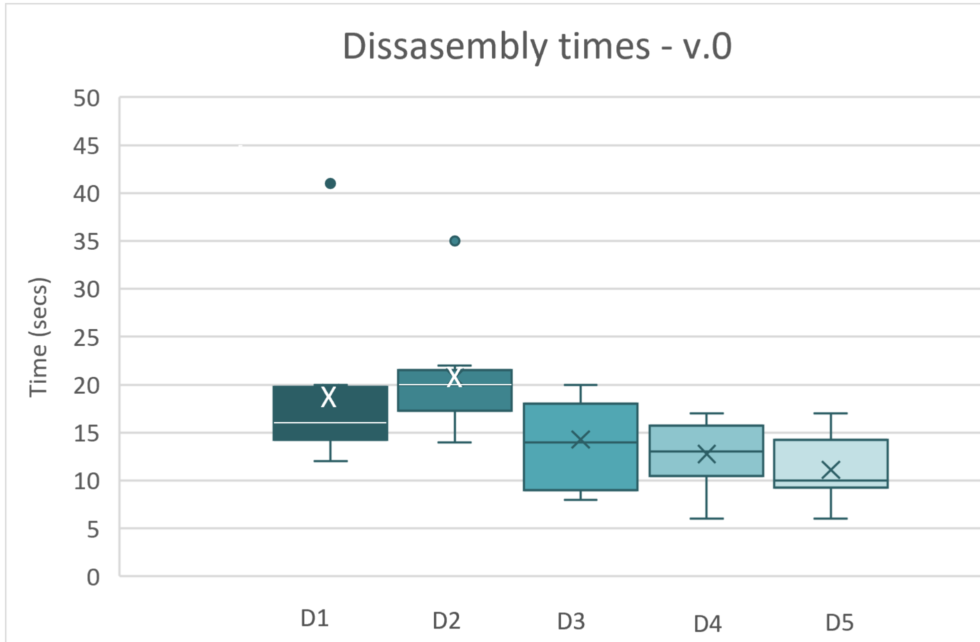


Figure A3: Disassembly time in seconds v.0

APPENDIX 3: PRIORITY CHECKLIST

As the design has a lot of features, but still needs to suite the context, a table (See Table A1) was made to send to multiple experts (n=3) to find out what the most important aspects of the design are. The checklist goes through the different procedures, which feedback the different steps can have, which of these procedures is most important and then what other features could be incorporated. This helped to start the design process.

PARTICIPANT DEMOGRAPHICS

Participant	Years of Experience	Location
Gynaecologist		Netherlands
OB/GYN		Kenya
OB/GYN		America

Table A2: Demographics participants

Hi! To help set priorities and requirements in the project, it would be great if you could fill out the following sheet. The first coloum in pink shows the component of the GTM. The rows in yellow show the procedure. The left coloum is the procedure steps and the right coloumn the feedback/requirements required for this step. There are three boxes for: must have, should have, nice to have [M/S/N]. This way I can set the right priorities for the design. Please select one box for each requirement. If there are any things I have forgotten, please insert this in the box right. Thanks a lot in advance! p.s. I have added a picture underneath the rows.

	PCB		M	S	N
Vagina	Insert speculum	Have the walls closer together jets wijder	☐	☐	☐
Cervix	Clean cervix	Needs to be able to be cleaned with a physical fluid	☐	☐	☐
	Insert needle				
	Place tenaculum	Have the os facing downward	☐	☐	☐
		Current position is good (straight forward and open)	☐	☐	☐
	Inject	Injecting with air	☐	☐	☐
		Injection with fluid	☐	☐	☐
Uterus					

	MVA		M	S	N
Vagina	Insert speculum		☐	☐	☐
Cervix	Find the os with tenaculum	Have the os facing downward	☐	☐	☐
		Current position is good (straight forward and open)	☐	☐	☐
	Pass cannula through cervix (hole with x diameter)	Current hole diameter is okay	☐	☐	☐
Uterus	Rotating cannula	Current size of the uterus is okay	☐	☐	☐
		Uterus should be smaller	☐	☐	☐
		Uterus can be larger	☐	☐	☐
		Tactile feedback (scraping something off)	☐	☐	☐

	Cervical screening		M	S	N
Vagina	Insert speculum				
Cervix	View cervix	Have different cervixes with different conditions	☐	☐	☐
		Apply, for example, flour to brush off (pap smear)	☐	☐	☐

	IUD		M	S	N
Vagina	Insert speculum				
Cervix	Find the os with tenaculum	Have the os facing downward	☐	☐	☐
		Current position is good (straight forward and open)	☐	☐	☐
Uterus	Measuing the depth and position of the uterus	Current size of the uterus is okay	☐	☐	☐
		Uterus should be smaller	☐	☐	☐
	Measuing the depth and position of the uterus	Current size of the uterus is okay	☐	☐	☐
		Uterus should be smaller	☐	☐	☐
		Uterus can be larger	☐	☐	☐
	Load IUD inserter	Clear uterus to view the IUD inside	☐	☐	☐

	Biopsy		M	S	N
Vagina	Insert speculum				
Cervix	Find the os	Have the os facing downward	☐	☐	☐
		Current position is good (straight forward and open)	☐	☐	☐
	Place with tenaculum				
	Swap with iodine?	Needs to be able to be cleaned with a physical fluid	☐	☐	☐
	Biopsy taken (which procedure is most common)	Cervix needs to be scraped	☐	☐	☐
		Cervix needs to be punched	☐	☐	☐
		Other?	*pe*		

	LEEP		M	S	N
Vagina	Insert speculum				
Cervix	Find the os				
	Swap with acid	Needs to be able to be change properties (light up)	☐	☐	☐
	Perform PCB				
	Insert electrosurgical loop	Tactile feedback (for cutting)	☐	☐	☐

General design		M	S	N
The size of the design should be smaller		☐	☐	☐
The product should be easier to set up on the table (no clamps)		☐	☐	☐
The product should be stronger		☐	☐	☐
It should be replacable with 3D prints instead of store bought items		☐	☐	☐
The uterus should be placed in a more realistic angle		☐	☐	☐
Other		Type…		

Most important procedures to train on GTM	Please place the most important on top, least important below
1	PCB
2	PCB
3	PCB
4	PCB
5	PCB
6	PCB

Table A1: Checklist

APPENDIX 4: INTERVIEW GUIDE GYNAECOLOGISTS

This interview guide was used when talked to gynaecologists in the Netherlands during a semi-structured interview:

GENERAL QUESTIONS

1. Which procedures do you perform?
2. Which ones are most common?
3. How often were you allowed to practice?
4. What kind of phantom do you practise on?
5. How does a phantom reflect reality?
6. How much feedback do you expect?
7. Are there any drawbacks to practising on a phantom?
8. What are features per procedure?
9. What things are indispensable?
10. What did you benefit most from during your training?

QUESTIONS ON THE GTM

11. What do you think of the vagina shape and length?
12. What do you think of the texture of the cervix?
13. Would you like to practice a PCB on the model?
14. What do you think of the size of the uterus?
15. What do you think of the position of the uterus?

APPENDIX 5: REQUIREMENTS

From the analysis chapter, different requirements and key take away s for the design were defined. However, not all the requirements were concrete or as important as others. The following tables shows a new LoR which concrete actions for the design. The left side (V1) shows the requirements before sprint one and the right side (V2) shows the new requirements after the validation and tests in sprint two. The colours show is the requirement has been met or not.

List of requirements

Category	V1 - Nr	Requirement	Category	V2 - Nr	Requirement	
01. Performance						
Requirement	1.1	The model should have a vagina, cervix and uterus				y
Requirement	1.2	The training model contains an element mimicking the functionalities of the **vagina wall:**				
Requirement	1.2.1	The vagina needs be able to be opened with a speculum				y
Requirement	1.3	The training model contains an element mimicking the functionalities of the **cervix:**				
Requirement	1.3.1	Needs to be injected at 12, 2, 4, 8 and 10 o'clock				y
Requirement	1.3.2	Needs to be able to be grabbed by a tenaculum				y
Requirement	1.3.3	Needs to be have a correctly oriented SCJ, horizontal				y
Requirement	1.3.4	Needs to be able to be removed from the body for easy demonstration purposes				y
Requirement	1.3.5	Needs to be able to be partly extracted by using a heated current loop				y
Requirement	1.4	The training model contains an element mimicking the functionalities of the **uterus:**				
Requirement	1.4.1	Needs to have the possibility of inserting a cannula to practise removing tissue				y
Nice to have	1.4.2	Should be able to enable nurses to train inserting a needle into the fundus (the back of the uterus)				y
Nice to have	1.4.4	Should have a structure on the inside to feel the differences during an MVA	Requirement	1.4.4	The model needs to have significant feedback when an MVA procedure is completed by adding more grittiness in the uterus	y
Requirement	1.5	The training model must be able to withstand povidone iodine				nt
Requirement	1.6	The training model must be able to withstand acetic acid solution				nt
Requirement	1.7	The training model should be consistent, so that every medical professional receives the same training, and therefore the same quality of equipment.				y
Nice to have	1.8	The training model can be extended with different types of detacheable cervixes to simulate different conditions or be replaced after one-time-use procedures				y
Nice to have	1.9	The device should have open or transparent walls where feasible to enhance visibility for trainers to provide clear views	Nice to have	1.9	The device should have open or transparent walls where feasible to enhance visibility for demonstation purposes, that can be closed during practise	n
02. Physical						
Requirement	2.1	The training model must be portable				y
Requirement	2.2	The training model adheres to anatomic measurements of the vagina wall (average 63 mm)				y
Requirement	2.3	The training model adheres to anatomic measurements of the cervix (3-cm diameter, 2-25 cm length)				y
Requirement	2.4	The training model needs to have open cervical os large enough for a 6 mm cannula				y
Requirement	2.5	The training model adheres to anatomic measurements of the uterus (4 cm in width, 8 cm in length)		2.5	The training model adheres to anatomic measurements of the uterus (4 cm in width, 6 cm in length).	y
Requirement	2.6	The uterus should be hollow to fit an IUD inside		2.6	The uterus needs to be hollow enough to fit in IUD inside, but tight enough so that stays in place after placement	y
Nice to have	2.7	The uterus can have an angle of 90* with the vaginal os				n
Requirement	2.8	The training model should be lightweighted, and not exceed the weight of 0.5 kg				
			Requirement	2.9	The cervix may not be seen from the front straight away	y
			Nice to have	2.10	There should be more external genetalia that mimics the cleaning process	y
			Requirement	2.11	The uterus should be transparent to be able to see how the IUD is placed	y
			Nice to have	2.12	The model can incorporate part of the pelvic bones	n

03. Durability						
Requirement	3.1	The training model incorporates a stabilizing element to withstand 50 newtons and prevent the simulator from slipping during use.	Requirement	3.1	The training model incorporates a stabilizing element to withstand 50 newtons and prevent the simulator from slipping on any tabletop surface during use.	nt
Requirement	3.2	The stand and components must be made from materials and design features that withstand repeated use without breaking or degrading.				y
Requirement	3.3	Fragile parts, such as the bayonet lock, should be redesigned to improve robustness				y
			Requirement	3.4	The design should last 100 procedures	nt
04. Materials						
Requirement	4.1	The vagina should have a shore hardness of around A-10				y
Requirement	4.2	The cervix should have a shore hardness of around 00-10/30				y
Requirement	4.3	The cervix needs to be safe whilst being cut				y
Requirement	4.4	The uterus should have a shore hardness of around A-40/50				y
Nice to have	4.5	The materials should be able to be sourced locally				
Requirement	4.6	The materials should be easy to clean				y
Requirement	4.7	The training system materials needs to endure temperatures up to a maximum of 45 degrees.				y
Requirement	4.8	The training system should be robust and withstand the journey of delivery, as hospitals can be situated in very rural areas that need to reached by difficult roads				y
Requirement	4.9	The training system materials needs to endure humidity level up to a maximum of 100%.				nt
Nice to have	4.10	The training system is made out of recyclable materials				n
Requirement	4.11	The training model uses a material which is impressible to mimic the vagina wall; it should be relatable to the real vagina wall.				y
Requirement	4.12	The training model uses no critical materials				y
			Requirements	4.13	The model does not rust	y
05. Use						
Requirement	5.1	The training system should be designed to ensure comprehensibility for nurses in Kenya, aiming for widespread accessibility and ease of understanding.				y
Requirement	5.2	The training system should be designed to ensure comprehensibility for trainers in Kenya.				y
Requirement	5.3	The model should support group training sessions, allowing multiple users to practice within a limited timeframe.				y
Nice to have	5.4	Clear visual instructions and labels should be incorporated into the model to support self-directed learning and reinforce correct procedure steps.				n
Requirement	5.5	The collapsible body should be re-evaluated to ensure stability during setup and use, preventing unintended collapses.				y
06. Installation						
Requirement	6.1	The training model set up should not take more than 1 minute.				y
Nice to have	6.2	The training model should have no or minimal parts that need to be prepared before the training (no DIY)				y
Requirement	6.3	All parts should have an intuitive design for easy setup, with clear alignment guides to prevent confusion and ensure proper orientation.				y
Nice to have	6.4	The amount of setup steps should be minimized				y
Requirement	6.5	The design should avoid unnecessary complexity, especially in areas where force is needed				y
Requirement	6.6	The clasp should be re-evaluated into a more intuitive and user friendly design				y

07. Maintanance			
Requirement	7.1	It should be able to be cleaned quickly and easily in between training sessions	y
Requirement	7.2	The training system's components must be all replacable and easily accessible within the country of the healthcare settings of LRS.	nt
Nice to have	7.3	The training system should contain a packaging system.	y
Requirement	7.4	The model should require minimal maintenance	y
08. Looks			
Nice to have	8.1	The ring and clasp should be re-evaluated to visually integrate into the design	y
Requirement	8.2	The training model represents a real vagina.	y
Requirement	8.3	The training model represents a dark skin colored vagina to represent the largest part of the population.	y
09. Production			
Requirement	9.1	The training system should be able to be produced locally (Kenia)	y
Requirement	9.2	The training system should be flexible to produce in terms of required accessories (options to (3D)print at different facilities))	y
Requirement	9.3	The training system should not cost more than 50 euros	y
Requirements	9.4	The model needs to be able to have accesible replacement parts	y
Requirements	9.5	The cervix for LEEP needs to be able to be bought an accesible, local store	y

Table A3: Requirements

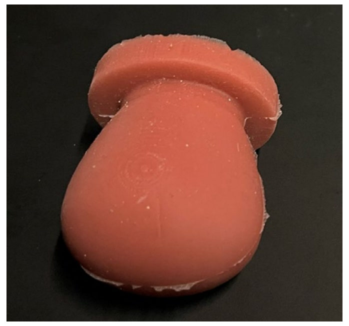
APPENDIX 6: SPRINT ONE

A lot of brainstorming, sketching, prototyping and choices were made to create a design as it is. The following appendix shows these different phases. The goal of the pages is to demonstrate which options were explored and why certain choices were made.

SPRINT 1

UTERUS

CURRENT UTERUS

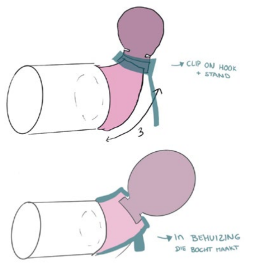


A LOT OF MATERIAL
NO REALISTIC SHAPE
NOT POSSIBLE TO SEE PROCEDURES
NO FEEDBACK PER PROCEDURE

NEW UTERUS

LESS MATERIAL
STRUCTURE ADDED
'TRANSPARENT'

CHALLENGE ONE:
MORE REALISTIC

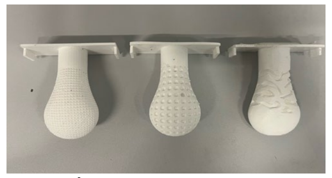


UNDER AN ANGLE
→ DOES NOT MOVE
→ STAYS UPRIGHTS
→ SHOULD BE ANTE/RETROVERTED

WHEN CERVIX IS PULLED IT SHOULD MOVE
↳ RECOMMENDATION

ONLY ADJUST SHAPE AND SIZING

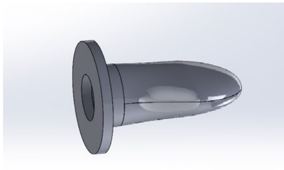
CHALLENGE TWO:
MORE FEEDBACK



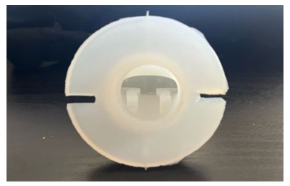
TESTING DIFFERENT STRUCTURES

VERIFY WITH GYN
→ ONLY NOTICE WITH LARGE CANNULA'S

CHALLENGE THREE
COMBINING PROCEDURES



CREATE TWO VERSIONS
↳ BULKY FOR MVA
→ FLATTER FOR IUD
→ IUD STILL MOVES



ADD SIMILAR STRUCTURE + REMOVE COLOUR FOR TRASPARENCY

Figure A3: Process including the challenges of designing the uterus

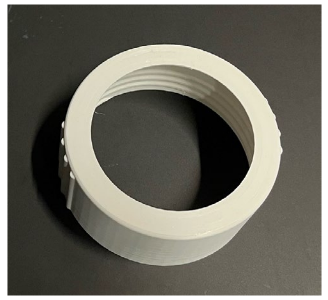
SPRINT 1

RING + CONNECTION

CURRENT RING

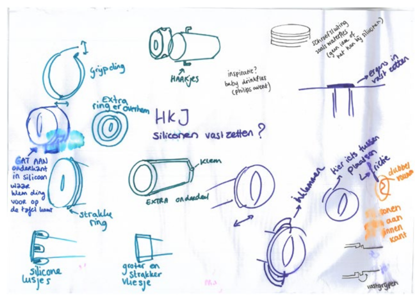
SHARP EDGES
INTIMITATING LOOKS
FALLS OFF
NOT INTUITIVE
NOT EASY TO SECURE

NEW RING



THREAD
TIGHTER
3D PRINTED
RIDGES FOR EASY USE
SAME CONNECTIONS

BRAINSTORMING



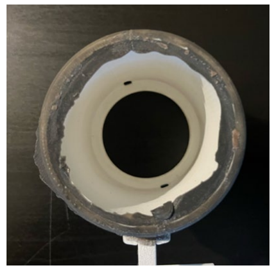
CREATIVE SESSIONS

BOUWMARKT

INTERNET

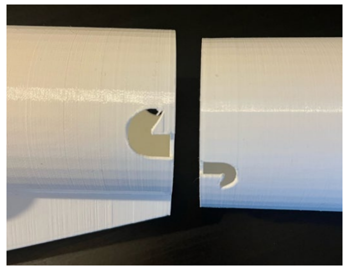
PROTOTYPING + SKETCHING

GLUE



→ NOT SECURE
→ NOT REUSABLE
→ NO EXTRA PART

BAYONETTE BIGGER

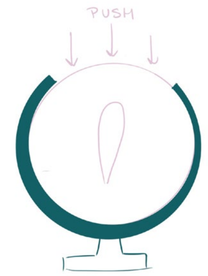


→ EASE OF USE IMPROVES
→ NOT POSSIBLE AT FRONT
→ WEARS WITH USE

TENSION

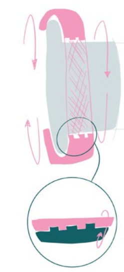
→ MORE MATERIAL
→ NOT 100% SECURE
→ NO EXTRA PART

HOLDER



→ INTEGRATE FOOT AND RING
→ PRONE TO BREAK
→ MIGHT DAMAGE SILICONE

THREAD



→ EASY + RECOGNIZABLE
→ DIFFICULT TO PRINT
→ APPLIED FRONT & BACK

CHOICE

REQUIREMENTS
2.1, 2.8, 3.1, 3.2, 3.3, 4.8
5.1, 5.5, 6.1, 6.3, 6.5, 6.6
7.1, 8.1, 9.2

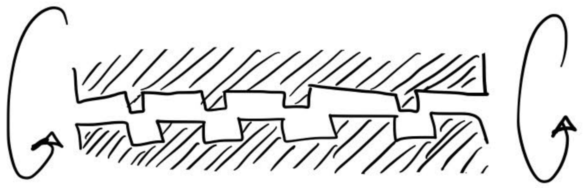
WEIGHTED CRITERIA

		Glue	Larger bayc	Tension	Holder	Thread
Size and weight	1,5	9	8	7	4	7
Stability	3	2	7,5	6	8	8
Durability	2	1	2	6	7	7
Ease of use	1,5	8	6	7	7	7,5
Maintenance	1	2	8	8	7	8
Unity	1	1	1	1	6	9
	10	**36,5**	**56,5**	**60**	**67,5**	**76,75**

Figure A3: Process from brainstorms to prototyping to choosing the new connection method

THREAD AS CONNECTION METHOD

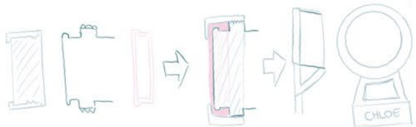
SPRINT 1

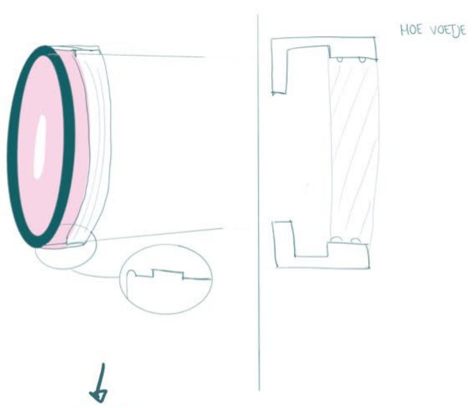


CAN BE USED AT FRONT + BACK

PROBLEM ONE
HOW DOES IT FIT OVER SILICONE?

HAS TO FIT OVER EDGE





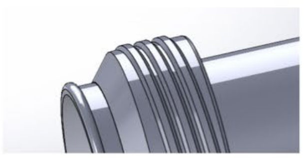
REQUIRES A NEW ATTACHMENT FOR THE FOOT

PROBLEM TWO
COMPLEX TO 3D PRINT

SESSION @ IDE GROUP

PROTOTYPING

MISPRINTING



- CHAMFERS
- FLATTER THREAD
- WIDE THREAD

PROBLEM THREE
CAN GET STUCK

ADD RIDGES
↓
CAN BE USED FOR ALIGNMENT

Figure A5: Process including the problems that arose of using thread as a connection method

ADDING IT TO THE BACK

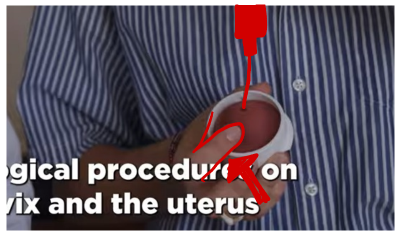
SPRINT 1

WHAT DO YOU REALLY NEED TO TAKE APART?

INPUT
INTERVIEW TRAINER

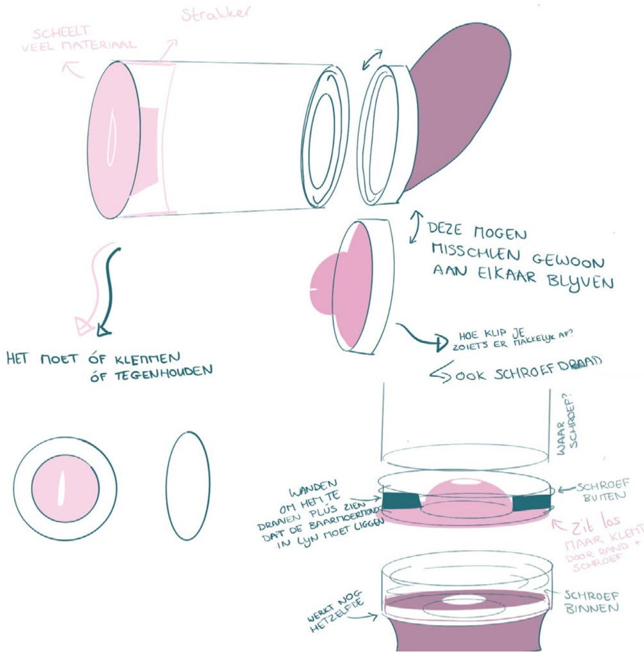
SHOW WHERE TO INJECT

IT IS USEFUL FOR STUDENTS TO SEE WHERE THE INJECTION SITES ARE AT THE CERVIX. REMOVING THE BACK EASILY + SECURING THE CERVIX IS NEEDED.

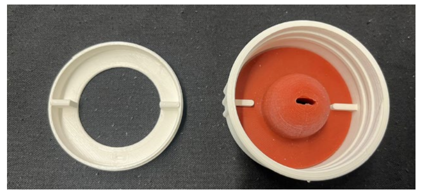


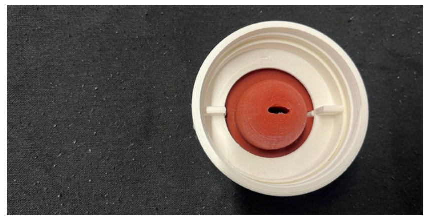
- NEEDS TO BE HELD INTO PLACE WITH FINGER
- BAYONETTE UNFRIENDLY

BRAINSTORM



PROTOTYPING





PROBLEM: HOW TO ENSURE EVERYTHING ALIGNS HORIZONTALLY IF THE SILICONE CHANGES IN THICKNESS?

DUE TO THE MOULD TYPE, THE SILICONE IS NOT ALWAYS AS THICK EVERYWHERE ➜ CANNOT TURN AS THIGHT ➜ NOT HORIZONTAL

Figure A6: Process of figuring out what needed to be connected to each other

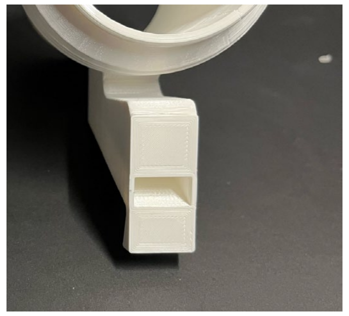
SPRINT 1

FOOT + CLAMP

CURRENT FOOT

FRAGILE
BREAKS FIRST
A LOT OF FORCE
NO LOGICAL ASSEMBLY ORDER
OUT OF PLACE

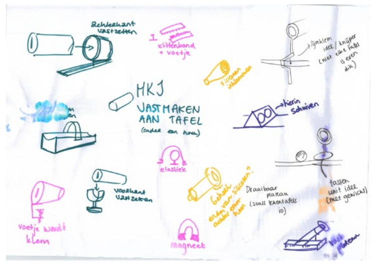
NEW FOOT



INTEGRATED IN BODY
STRONG
FORCE SPREAD

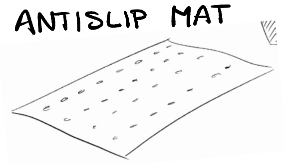
BRAINSTORMING

CREATIVE SESSION



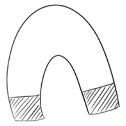
DPEM
- → LARGER STAND
- → SAME CLAMP
- → ATTACHMENT FROM FRONT INSTEAD OF SIDE
- → FITS MORE TABLES
- → FRAGILE

ANTISLIP MAT



- → NO GOOD WITH DUST
- → COULD BE SILICONE
- → NOT STRONG

MAGNET

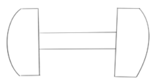


- → EXTRNAL PARTS
- → STILL NEEDS A FOOT SECURED TO TABLE
- → HEAVY

SUCTION CUP

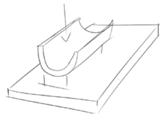
- → NO GOOD WITH DUST
- → ATTACH TO PLATES
- → EXTERNAL PARTS

WEIGHT



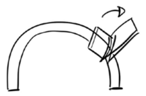
- → HEAVY
- → NO EXTERNAL PIECE
- → NOT 100% SECURE

CONSTRUCTION



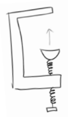
- → LARGE
- → NEEDS TO BE HEAVY

BUCKLE



- → ATTACHEMENT PIECE NEEDED

CLAMP



- → SECURE
- → THREAD
- → EXTERNAL PIECES

PROTOTYPING

CHOICE

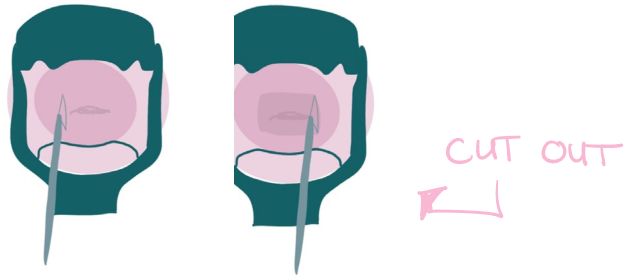
REQUIREMENTS
2.1, 2.8, 3.1, 3.2, 6.1
6.3, 6.4, 6.6, 7.2, 9.1
9.2

		Larger foot	Magnet	Clamp
Size and weight	1,5	6	5	6
Stability	4	6	5	9
Durability	2	3	7	8
Ease of use	1,5	7,5	9	6
Parts	1	5	3	5
	10	55,25	58	75

Figure A7: Process from brainstorms to prototyping to choosing the new foot and clamp

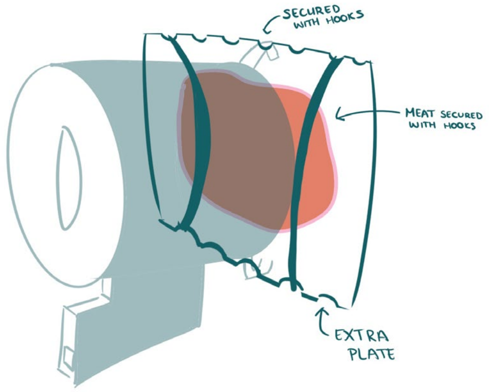
SPRINT 1

LEEP



SILICONE
- NOT REUSABLE
- UNSAFE TO BURN

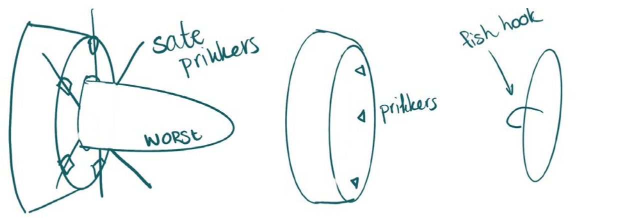
LARGER PIECES OF MEAT (CHICKEN BREAST, COW TONGUE)



USING A PLATE + ELASTICS TO SECURE LARGER PIECES OF MEAT

- EASY TO STICK ELECTRODE BEHIND
- FLEXIBLE IN SIZE
- BULKY
- DIFFICULT TO SECURE

SAUSAGE



- SECURE
- NEEDS EXTERNAL PARTS
- NOT SIZE DEPENDENT

- NOT STRONG
- LIMITED IN SIZE
- INTEGRATED IN DESIGN

- SMALL
- NO ALIGNMENT
- CAN MOVE

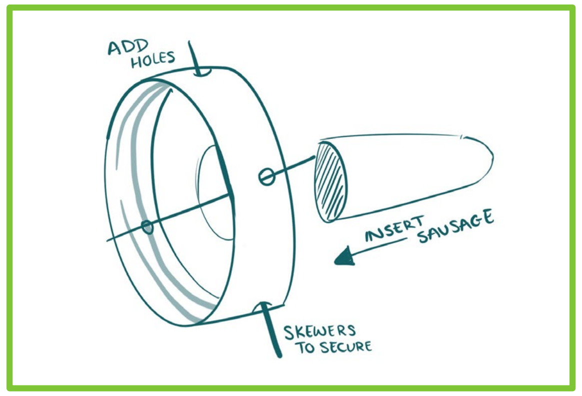


Figure A8: Process from brainstorms a way to integrate LEEP into the model

APPENDIX 7: SPRINT TWO - TEST SETUP

TWO PARTS: EXPERIENCED DOCTORS AND NOVICES

Part one: Experienced doctors

Research question: Can the device effectively be used to train PCB, MVA and an IUD insertion?

Method: Using a verified step by step list, experienced gynaecologists will perform different procedures and rate how easy/difficult the step was and how realistic the model is.

1) Joséphine her research is analysed together with literature and a step by step of the three procedures is created
2) A session with 2 gynaecologists is hosted to check
3) The 5 most important steps per procedure are identified together with a GYN in NL, Kenya and America.

In Kenya
# of participant = 15
The setup will be in the hospital, preferably in theatres or classrooms where the procedures or lessons take place. The GTM will be set up in advance and the step-by-step lists are printed on paper. An informed consent will be signed, asking if the session can be recorded and pictures may be taken.

4) Initial questions are asked
a. What is your professional role? (occupation)
b. How long have you been in the gynaecological field?
c. Which gynaecological training are you giving at the moment? This includes all transvaginal procedures and excludes obstetrics.
d. How long have you been performing the PCB procedure?
e. Please take a look at the step by step lists of PCB, does this differ to how you perform a PCB?
f. Could you tell me which 5 steps you find most important?

The participants are then asked to perform a PCB in the way they are used to. If they do not have their own needle, they may use an SED. This will be noted in the form. It will also be noted how they get their needle (needs to go to surgery/has one ready/other) This is to collect data on how accessible it is (Data for Karl). If they use the SED, they will be briefed that it is to test the GTM, not the SED.

5) The doctors are asked to perform a PCB and rate each of the 5 most important steps (these are identified in NL):
a. How easy/difficult it was per step (point to a likert)
 i.Why?
a. How realistic it was per step (point to a Likert)
 i.Why?

6) A short structured interview is conducted afterwards asking:
a. How useful do you think the device is for teaching PCB (point to a Likert)
 i. Why?
b. Do you have any other remarks on different PCB steps that have not been discussed?

7) Step 4,5 and 6 are repeated but regarding MVA and IUD insertion.

8) A short structured interview is conducted afterwards asking:
a. How useful do you think this device is to train students in general for gynaecological procedures? (point to a likert)
 i.Why?
b. What are your initial thoughts of using this model for training purposes?
c. Which other procedures do you think would be useful to train on the model?
d. What features would you like added or removed?
e. Do you have any other remarks?

Data collection:
The tests will be recorded using my phone or the recorders in Kisumu. During the test, I will interview the participant questions and write down the answers myself, ensuring I can ask 'why' and engage more with the participant. The data will be entered in a Microsoft forms which is stored on the TU Delft One Drive and backed up on my computer and USB daily.

Part two: novices

2a: For in the paper
Research questions: Does using the simulation device improve novice medical professionals' confidence in performing PCB, MVA, and LEEP procedures?
Method: Using a pre and post questionnaire. In between, the students will look at videos and try the procedures on the model.

In Kenya
# of participant = aim is 10 per procedure
The setup will be in the classroom of the KMTC. First, a discussion with James will take place to discuss if all the students learn these three procedures. If needed, a selection will be made which procedures will be tested. Depending on the amount of students and their available time, a selection can be made on the amount of students per procedure. The video's and step-by-step will be checked with the teacher to ensure that the way of teaching is similar.

1) Asking the students to fill in a pre-questionnaire with the following questions:
a. How long have you been studying GYN?
b. Have you ever seen a PCB, MVA or IUD insertion in person?
c. Have you ever performed a PCB, MVA or IUD insertion yourself?
d. How confident are you now to perform a PCB, MVA or IUD on a patient? (Likert)

2) Show the students a video on how to perform a PCB, MVA or IUD

3) Ask the students to fill in a questionnaire:
a. How confident are you now to perform a PCB, MVA or IUD on a patient? (Likert)

4) Ask the student to perform the procedures on the GTM

5) Ask the students to fill in a questionnaire:
a. How confident are you now to perform a PCB, MVA or IUD on a patient? (Likert)
b. This device increased my skills (Likert)
c. Open questions:
 i. Which specific skills do you feel you improved by using the device?
 ii. Would you recommend this device for other students learning this procedure?

2b: For my design
Research questions: What aspects of the device's design require improvement based on novice user feedback and observed interactions?
Methods: Using the same post questionnaire as before and observing the students

1) Perform tests as described above

2) Observe how students use the device
 - What breaks the easiest?
 - What is unclear/do they fumble more doing specific steps?
 - What is touched the most?
 - When do you use the most force?

3) Add open questions to the previous questionnaire
Open questions:
a. How does this simulator compare with other methods of training you might have had?
b. What are the main advantages this simulator would provide to you?
c. What do you think was most difficult to practise? Showing the step by step list from part 1
d. What was the easiest to practise? Showing the step by step list from part 1
e. Do you think the device could be improved to enhance learning? If so, how?

4) Potentially come back at the end of my time in Kenya with a new iteration of the design and ask the same questions

Data collection:
The tests will be recorded using my phone or the recorders in Kisumu. During the test, I will interview the participant questions and write down the answers myself, ensuring I can ask 'why' and engage more with the participant. The data will be entered in a Microsoft forms which is stored on the TU Delft One Drive and backed up on my computer and USB daily.

STEP BY STEP LISTS

Paracervical block

By Kiewiet De Jonge (2024):

1. Place and adjust the speculum to ensure the entire cervix is in view
2. Place the injection at 12 o'clock, ensure a depth of 0,5cm
3. Aspirate the injection
4. Inject air 2 cc
5. Place the tenaculum
6. Place the injection at 4 o'clock, ensure a depth of 0,5cm
7. Aspirate the injection
8. Inject air 4 cc
9. Place the injection at 2 o'clock, ensure a depth of 0,5cm
10. Aspirate the injection
11. Inject air 4 cc
12. Place the injection at 8 o'clock, ensure a depth of 0,5cm
13. Aspirate the injection
14. Inject air 4 cc
15. Place the injection at 10 o'clock, ensure a depth of 0,5cm
16. Aspirate the injection
17. Inject air (check max 20 cc)
18. Remove the speculum

Manual vacuum aspiration

By Sliwowska and Amico (2019):

1. Place and adjust the speculum to ensure the entire cervix is in view
2. Clean the cervix with an antiseptic in a spiral movement
3. Place a PCB
 - Place the injection at 12 o'clock, ensure a depth of 0,5cm
 - Aspirate and inject
 - Place a tenaculum at 12 o'clock (for an anteverted uterus)
 - Place the injection at 2, 4, 8 and 10 o'clock
4. Dilate the cervix using a no touch technique
5. Insert the cannula into the cervix, past the cervical os and into the uterine cavity
6. Attach a MVA syringe and release the valve buttons
7. Gently and slowly rotate the syringe 180 degree, using an in-and-out motion at the same time.
8. Disconnect the cannula
9. Remove the aspirator and empty
10. Repeat the steps until signs of complete emptying are achieved (including a gritty sensation)

11. Remove the cannula and aspirator
12. Remove the tenaculum
13. Clean any remaining blood
14. Remove the speculum

IUD insertion for a copper T

Based on the Maseno Universtiry IUCD insertion protocols:

1. Place and adjust the speculum to ensure the entire cervix is in view
2. Clean the cervix with an antiseptic in a spiral movement
3. Grasp the cervix with a tenaculum at 12 o'clock
4. While gently pulling on the tenaculum, passes the sound through the cervix to the top of the uterus to measure the depth
5. Removes the sound
6. Prepare the IUD inserter
7. While gently pulling on the tenaculum, passes the loaded inserter tube through the cervix (without touching the vagina and blades of the speculum) until the flange touches the fundus or slight resistance is felt
8. Releases the arms of the IUD using withdrawal technique: pulling the inserter tube toward herself/himself while holding the white rod stable
9. Remove the white rod
10. Moves the inserter tube upward toward the top of the uterus until slight resistance is felt.
11. Removes the inserter tube from the cervical canal
12. Cut the strings
13. Remove the speculum

APPENDIX 8: INTERVIEW GUIDE EXPERTS

INITIAL QUESTIONS

1. What is your professional role? (Occupation)
2. How long have you been in the gynaecological field?
3. Which gynaecological training are you giving at the moment? This includes all transvaginal procedures and excludes obstetrics.

PARACERVICAL BLOCK

1. How long have you been performing the PCB procedure?
2. Please take a look at the step by step lists of PCB, does this differ to how you perform a PCB?
3. Could you tell me which 5 steps you find most important?
4. Step 1: Place and adjust the speculum to ensure the entire cervix is in view
   Performing this step on the model was: 1-5, why?
   How realistic was it to perform on the model: 1-5, why?
5. Step 5: Place the tenaculum
   Performing this step on the model was: 1-5, why?
   How realistic was it to perform on the model: 1-5, why?
6. Step 6: Place the injection at 4 o'clock, ensure a depth of 0,5cm
   Performing this step on the model was: 1-5, why?
   How realistic was it to perform on the model: 1-5, why?
7. Step 7: Aspirate the injection
   Performing this step on the model was: 1-5, why?
   How realistic was it to perform on the model: 1-5, why?
8. Step 8: Inject air (4 cc)
   Performing this step on the model was: 1-5, why?
   How realistic was it to perform on the model: 1-5, why?
9. Do you have any other remarks on different PCB steps that have not been discussed?
10. How useful do you think the device is when learning PCB?

MANUAL VACUUM ASPIRATION

1. How long have you been performing the MVA procedure?
2. Please take a look at the step by step lists of MVA, does this differ to how you perform a MVA?
3. Could you tell me which 5 steps you find most important?
4. Step 2: Clean the cervix with an antiseptic in a spiral movement
   Performing this step on the model was: 1-5, why?
   How realistic was it to perform on the model: 1-5, why?
5. Step 4: Dilate the cervix using a no touch technique
   Performing this step on the model was: 1-5, why?
   How realistic was it to perform on the model: 1-5, why?
6. Step 5: Insert the cannula into the cervix, past the cervical os and into the uterine cavity
   Performing this step on the model was: 1-5, why?
   How realistic was it to perform on the model: 1-5, why?
7. Step 6: Gently and slowly rotate the syringe 180 degree, using an in-and-out motion at the same time.
   Performing this step on the model was: 1-5, why?
   How realistic was it to perform on the model: 1-5, why?
8. Do you have any other remarks on different MVA steps that have not been discussed?
9. How useful do you think the device is when learning MVA?
10. Which uterus structure do you prefer?

IUD INSERTIONS

1. How long have you been performing the PCB procedure?
2. Please take a look at the step by step lists of PCB, does this differ to how you perform a PCB?
3. Could you tell me which 5 steps you find most important?
4. Step 4: While gently pulling on the tenaculum, passes the sound through the cervix to the top of the uterus to measure the depth
   Performing this step on the model was: 1-5, why?
   How realistic was it to perform on the model: 1-5, why?
5. Step 7: While gently pulling on the tenaculum, passes the loaded inserter tube through the cervix (without touching the vagina and blades of the speculum) until the flange touches the fundus or slight resistance is felt
   Performing this step on the model was: 1-5, why?
   How realistic was it to perform on the model: 1-5, why?
6. Step 8: Releases the arms of the IUD using withdrawal technique: pulling the inserter tube toward herself/himself while holding the white rod stable
   Performing this step on the model was: 1-5, why?
   How realistic was it to perform on the model: 1-5, why?
7. Step 9: Remove the white rod
   Performing this step on the model was: 1-5, why?
   How realistic was it to perform on the model: 1-5, why?
8. Do you have any other remarks on different IUD steps that have not been discussed?
9. How useful do you think the device is when learning IUD?

FURTHER QUESTIONS

1. How useful do you think this device is to train students in general for gynaecological procedures?
2. What are your initial thoughts of using this model for training purposes?
3. What other procedures do you think would be useful to train on the model?
4. What features would you like added or removed?
5. Do you have any other remarks?
6. How did you get trained?

APPENDIX 9: INTERVIEW GUIDE USERS

- What types of training models or equipment do you currently use for teaching gynaecological procedures such as PCB, MVA, IUD insertion, and cervical cancer screening?
- How often are these models used in your training sessions?
- What specific features of these models do you find most useful for training healthcare professionals?
- What are the limitations or challenges you face with the current training models?
- Do the models provide realistic feedback during procedures like MVA or IUD insertion? If not, what improvements would you suggest to make the training more realistic?
- Are the models suitable for use by non-experts (nurses or medical trainees with little experience)?
- Is portability a key concern for you when using training models? How do you typically transport the equipment?
- Do you feel that more interactive elements, such as visual aids or feedback mechanisms (e.g., resistance feedback during procedures), would improve the training experience?
- If there was one thing you could change about the current training models to improve their effectiveness, what would it be?
- If you would describe your perfect model, what kind of features would it have?
- If you were to buy 50 new models, which features would you be looking for?

APPENDIX 10: DEMOGRAPHICS SPRINT TWO

The following table shows the demographics of the recruited participants during sprint two. These participants did different procedures on the models, depending on their knowledge and skills.

Profession	**Amount**	**Average (years)**	**Min (years)**	**Max (years)**
OBGYN (specialist)	4	17,75	12	24
Nurse	7	9	1	17
OBGYN Resident	9	4,5	1	13

Table A4: Demographics participants user testing

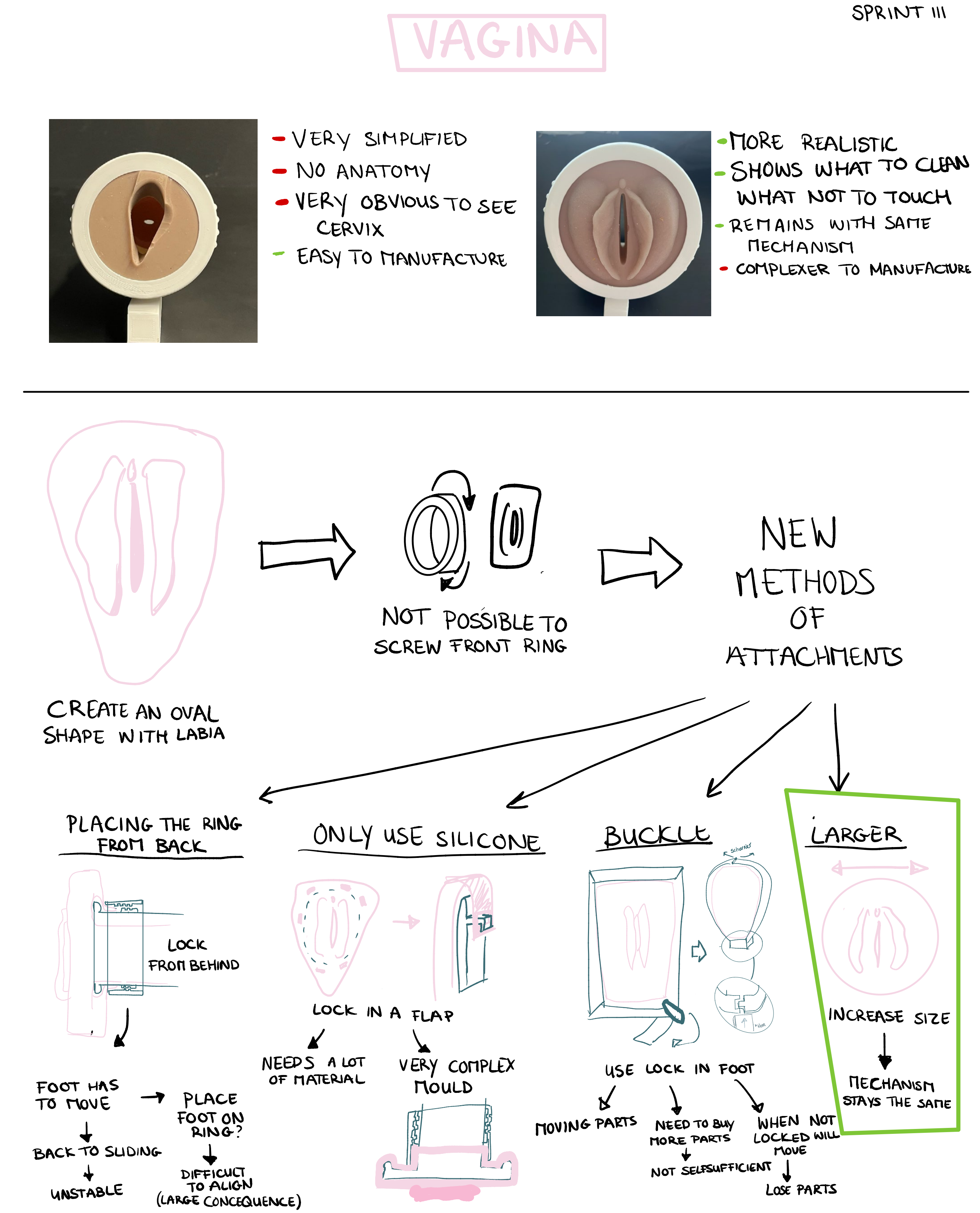


Figure A9: Process of deciding how to make an oval vagina opening turning into a larger round one

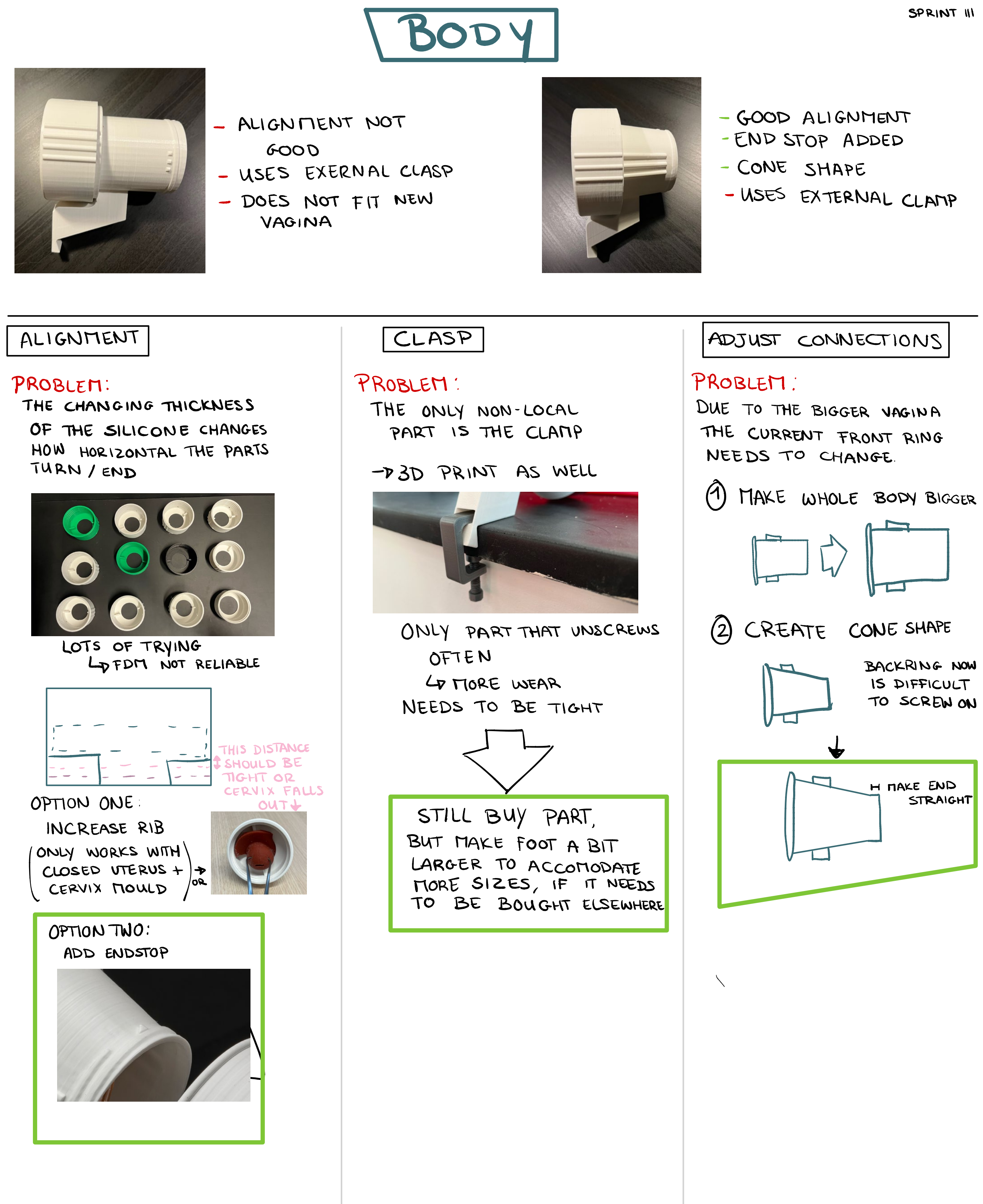
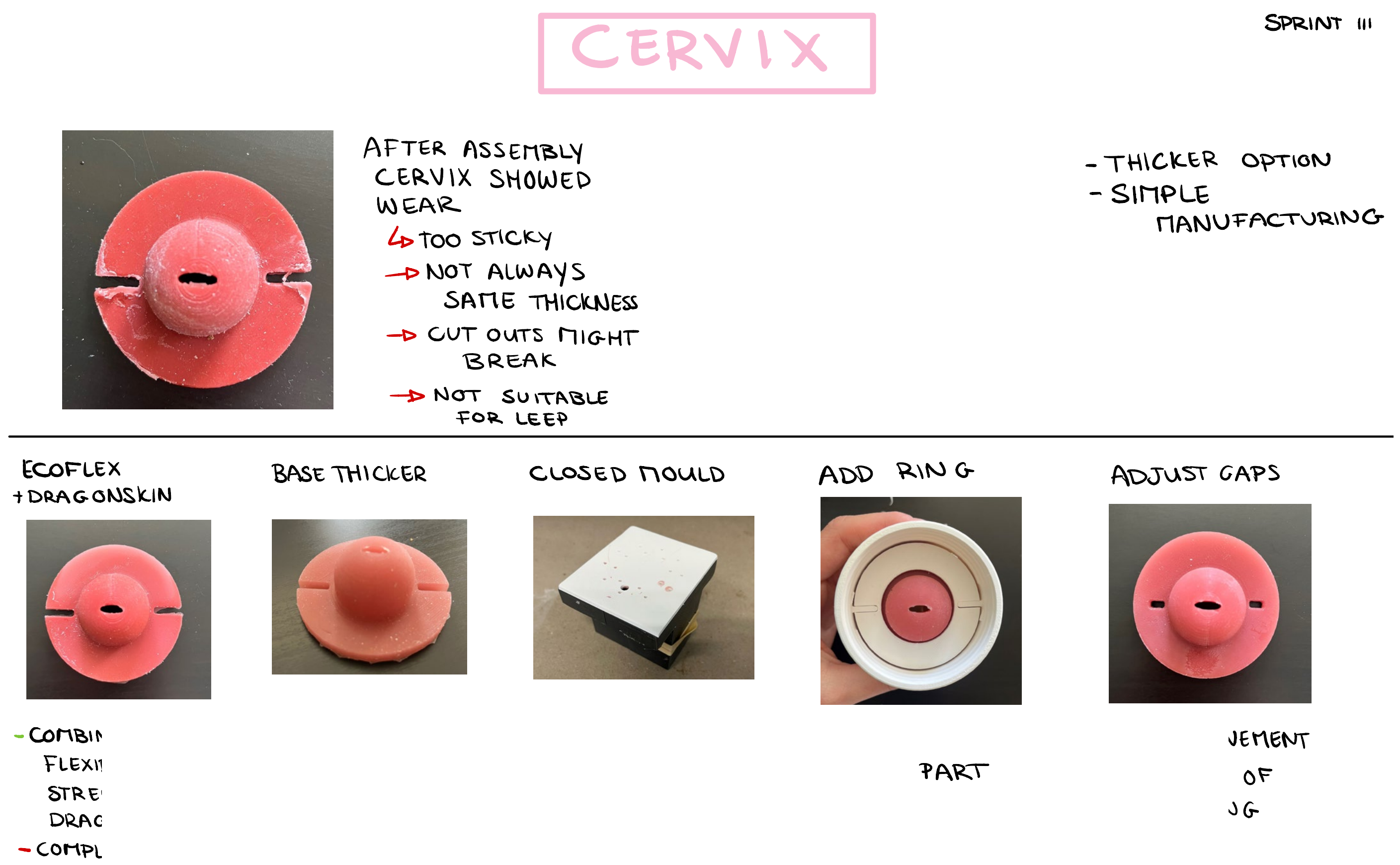


Figure A10: Process of fine-tuning the body and connections with the problems that arose



Choice matrix - cervix

1. Prone to break
2. Thickness differs
3. Material sticky

Idea	Costs part €	Materials	Manufacturing complexity	Pro's	Con's	Other factors
- Normal	€1,01	- Ecoflex	– –	- Easy to manufacture - No new materials	- Prone to break - Thickness differs - Material sticky (turns with middle ring)	
- Double material 1 - 3	↑ €1,07	- Dragon skin - Ecoflex	+ +	- Combines benefits of ecoflex and dragonskin	- Complexer manufacturing (time restrictions) - More material	
- Thicker base	↓ €1,15	- Ecoflex	– –	- Simple solution	- More material - Still sticky	
- Closed mould 2	- €1,01	- Ecoflex	+	- No further design changes needed	- Air bubbles - Slightly more complex manufacturing	
- Extra part 1 - 3	↑ €1,01+ 0,06	- Dragon skin - Ecoflex - PLA	–	- No friction	- More parts	

Figure A11: Designing and choosing an improved cervix

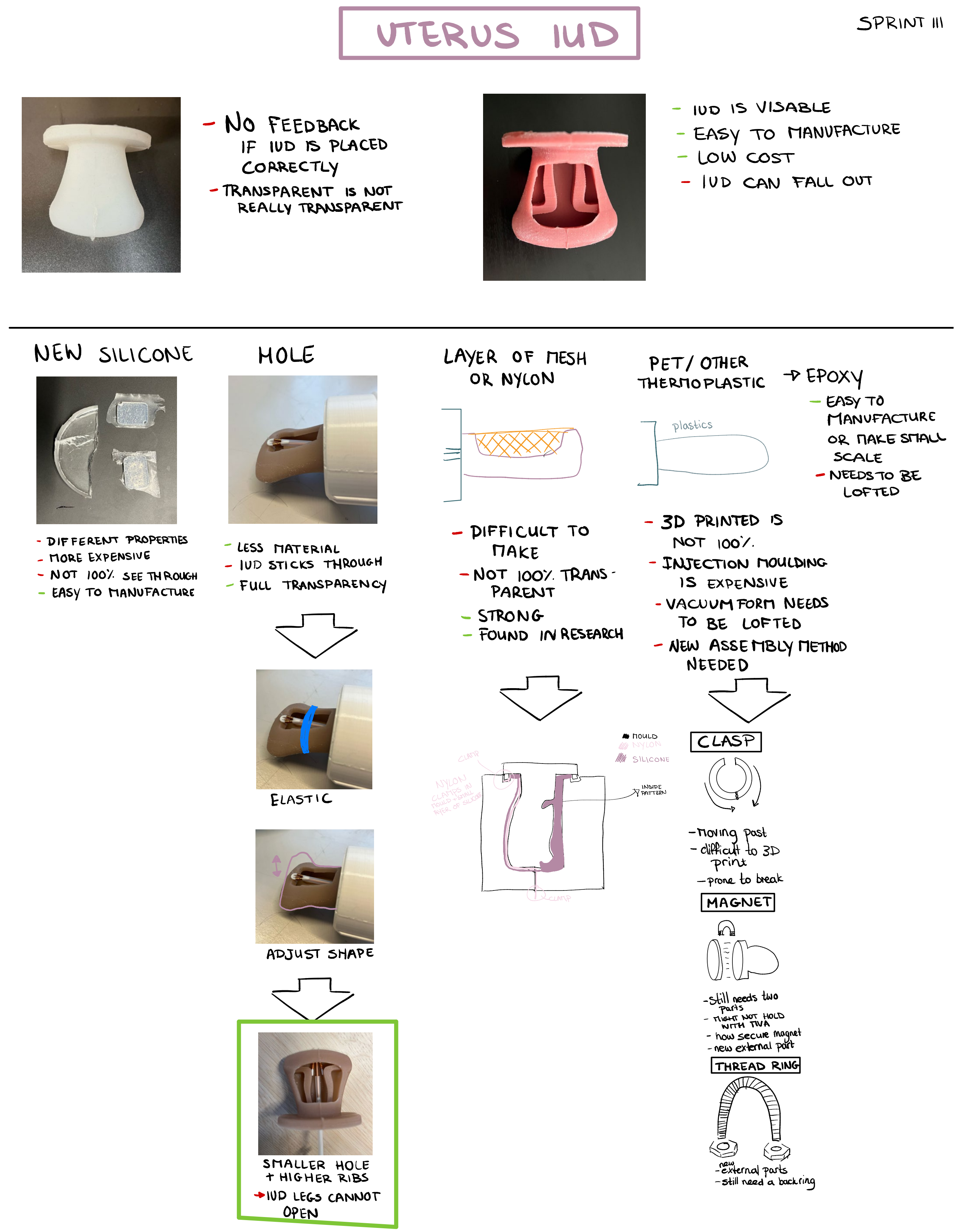


Figure A12: Design options for an uterus which shows the IUD placement

Choice matrix IUD - uterus

Idea	Costs part €	Materials	Manufac-turing complexity	Pro's	Con's	Other factors
- Normal	€2,16	- Dragon skin - Ecoflex	− −	- Easy to manufacture - No new materials	- No visibilty	
- Other materials	↑ €2,02 €2,29 €2,78 €2,83 €5,73	- Dragon skin - Ecoflex - Near clear?	−	- More transparent - Depending on material, easy to manufacture	- Three different materials in product - Not similar properties as Dragon Skin - Not 100% clear	- Possibly cervix back to dragon skin
- Open top	↓ €1,79	- Dragon skin - Ecoflex	− −	- Easy to manufacture - Shows what top/bottom is on model - Less material	- IUD can stick out	
→ Rounder	↓ €1,90	- Dragon skin - Ecoflex	− −	- Easy solution	- Not as realistic - Might still be possible to stick IUD through	
→ Elastic	↓ €1,79+0,05	- Dragon skin - Ecoflex - Elastic	− −	- Easy solution	- Looks very lo-fi	
→ Mesh	− €1,79+0,20	- Dragon skin - Ecoflex - Mesh	+ +	- Relatively strong	- Not 100% transparent - Not easy to clean	
- Epoxy (thermoset)	↓ €0,64	- Dragon skin - Ecoflex - Epoxy	−	- Fully transparent - Strong and durable	- Design needs to be drafted	- New assembly method needed > more moving parts
- PC (thermoplastic)	↓	- Dragon skin - Ecoflex - PC	+	- Fully transparent - Strong and durable	- Design needs to be drafted - Only suitable for larger volumes	- New assembly method needed > more moving parts

Figure A13: Choosing the uterus

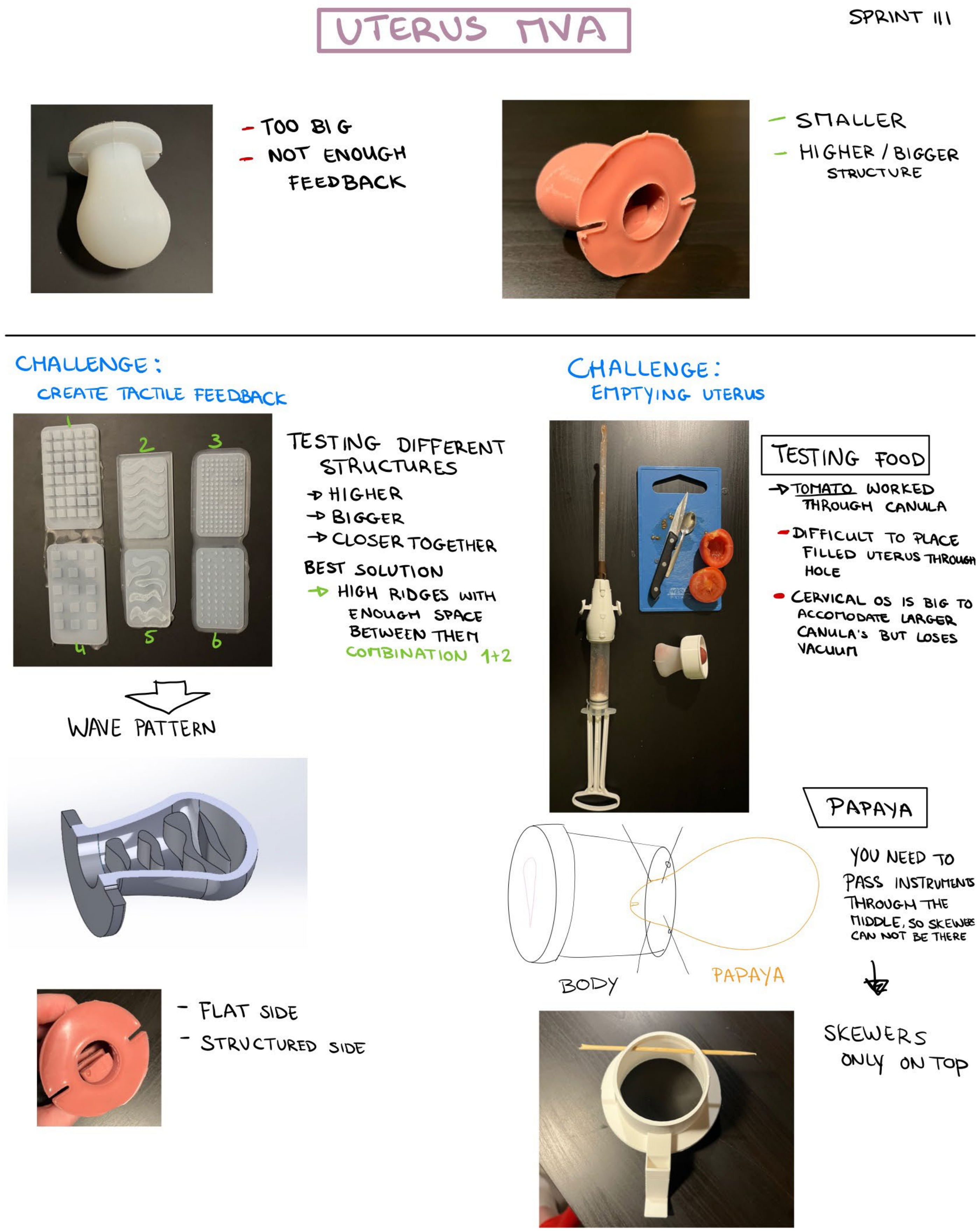


Figure A14: Challenges of improving the MVA feedback in the design

APPENDIX 12: PILOT ASSEMBLY GUIDE

Instructional usage
of the Chloe Gynaecological Training Model (GTM)

The gynaecological training model offers a realistic, portable, and comprehensive tool for practicing gynaecological procedures skills. The assembly manual covers a part list and a instruction guide for optimal training.

Back set

A B C D E F G H

Silicone parts
A. Uterus
C. Cervix
F. Vagina opening

Plastic parts
B. Back ring
D. Middle ring
E. Body
G. Front ring

Extra positioning gear
H. Clamp

Unpacking

1. Carefully open the packaging and remove all the components
2. Verify that all the parts listed in the Part List are present.
3. Ensure a stable, clean surface in a well-lit area.

Assembly

1. Fold the **uterus** and squeeze it through the hole from the back to the front of the **back ring**.
2. Place the **cervix** on top of the **uterus** in the **back ring.**
3. Screw the **middle ring** on top of the **cervix** to secure.
4. The **back set** can be screwed on the back of the **body.**

The gaps in the silicone align with the .. in the back ring.

The .. should be horizontal

The three stripes should align with the stripes on the body

5. Place the vagina opening on the front of the body.
6. Screw the front ring over the vagina opening
7. Place the model on the edge of a table, place the clamp through the hole of the foot
8. Screw tight and the model is ready for use

The groove fits over the top of the body

The three stripes should align with the stripes on the body

Figure A15: Assembly guide used in during the pilot

APPENDIX 13: ASSEMBLY TEST PLAN

TEST SETUP

Goal: To test the assembly guide and user friendliness of the design

Output: See if the design has improved vs v.0, gather pain points of v.III, recommendations on how to improve.

Amount: 8 participants, recruitment via Whatsapp and friends

Setup: Using an empty table, the participants will receive a bag which includes the different GTM parts. The GTM will not be assembled and the assembly guide will lie on the table.

Method: Using the same setup as the DfEM team.

1. Ask participant to sign consent form (including filming of their actions)
2. Give bag with lose GTM components
3. Ask participant to read the instructions and assemble the GTM
    a. Time the assembly from start to finish
    b. Ask participants to think out loud
4. Ask the participant to disassemble the GTM
    a. Time the assembly from start to finish
    b. Ask participants to think out loud
5. Repeat the process 4 more times

Guiding questions:

1. How easy or difficult was it to assemble the device? (Likert 1 easy – 5 difficult)
2. Did you encounter any steps that were confusing or unclear?
3. Do you feel the assembly time was reasonable or did it take longer than expected?
4. Were there any specific parts of the assembly that took more time than others?
5. Did all the components fit together securely during assembly or did you feel parts were loose?
6. Did the model feel stable and secure once assembled?
7. Were there any components that seemed misaligned or difficult to fit properly?
8. Were there any parts of the model that you feel could be simplified or made easier to assemble?
9. Did you make any mistakes during the assembly process and if so, were they easy to correct?
10. Did any part of the model require excessive force to disassemble?
11. Do you believe the model can withstand multiple cycles of assembly and disassembly without breaking?
12. Are there any parts of the model that you would redesign to make both assembly and disassembly more user-friendly?

Data: The data gathered will be twofold:

- The assembly/disassembly time

Entered into an excel to create a graph. This shows the average assembly time and the difference between the first assembly and the rest (how difficult is it to understand the instructions vs how long does it take to assemble once you know how it works)

- Input on the user friendliness of the design

Clustered into different pain points (visual cues/movements/understanding of assembly guide/etc) This can be user to improve the design and write recommendations.

Assembly guide
of the Chloe Gynaecological Training Model (GTM)

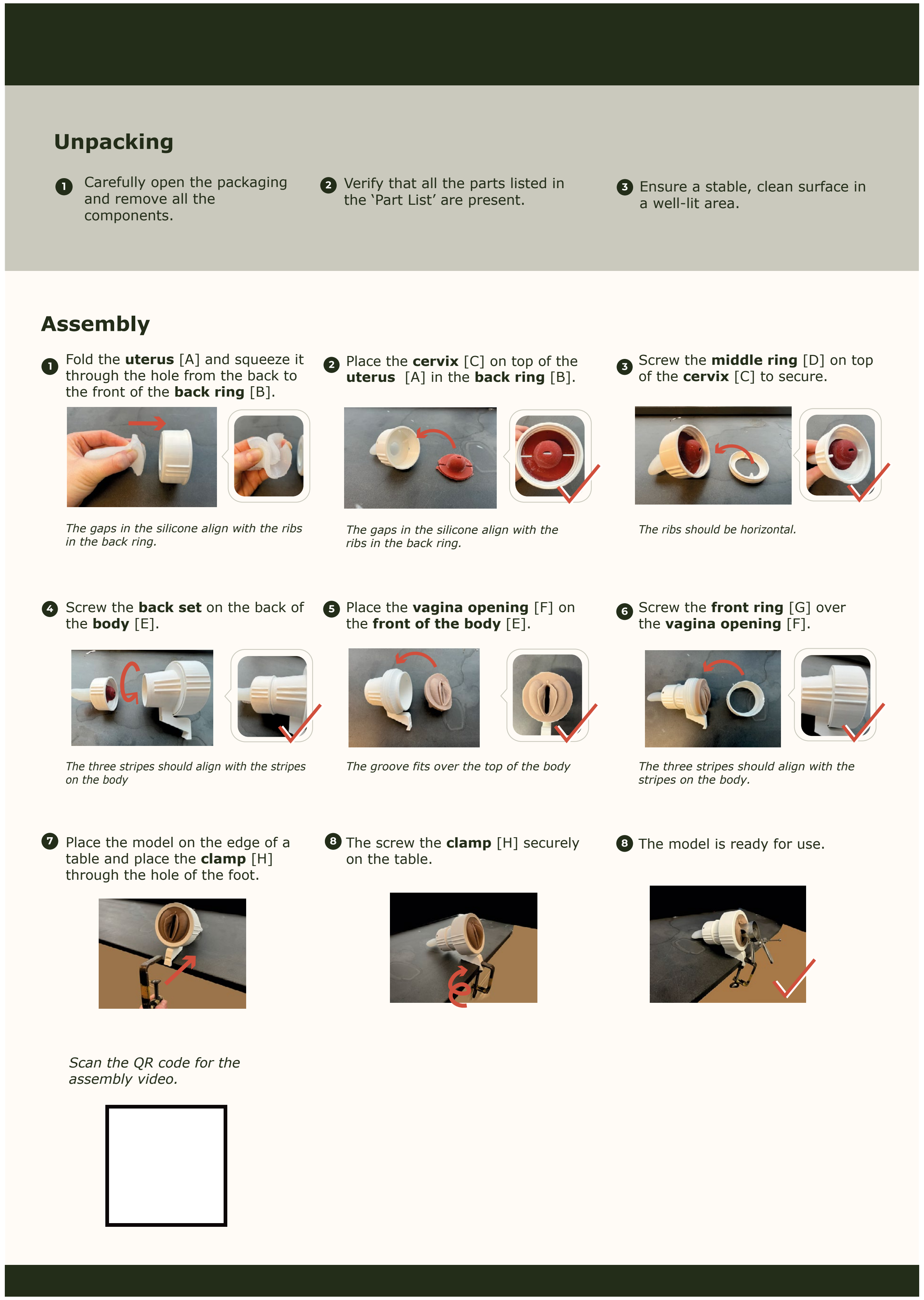
CHLOE Innovations

The gynaecological training model offers a realistic, portable, and versetile tool for practicing gynaecological procedure skills. This assembly manual covers a part list and a stap-by-step instruction for assembling the GTM.

Back set

- A Uterus
- B Back ring
- C Cervix
- D Middle ring
- E Body
- F Vagina opening
- G Front ring
- H Clamp

Figure A16: Assembly manual during test - front page



Unpacking

1. Carefully open the packaging and remove all the components.
2. Verify that all the parts listed in the 'Part List' are present.
3. Ensure a stable, clean surface in a well-lit area.

Assembly

1. Fold the **uterus** [A] and squeeze it through the hole from the back to the front of the **back ring** [B].
   The gaps in the silicone align with the ribs in the back ring.
2. Place the **cervix** [C] on top of the **uterus** [A] in the **back ring** [B].
   The gaps in the silicone align with the ribs in the back ring.
3. Screw the **middle ring** [D] on top of the **cervix** [C] to secure.
   The ribs should be horizontal.
4. Screw the **back set** on the back of the **body** [E].
   The three stripes should align with the stripes on the body
5. Place the **vagina opening** [F] on the **front of the body** [E].
   The groove fits over the top of the body
6. Screw the **front ring** [G] over the **vagina opening** [F].
   The three stripes should align with the stripes on the body.
7. Place the model on the edge of a table and place the **clamp** [H] through the hole of the foot.
8. The screw the **clamp** [H] securely on the table.
8. The model is ready for use.

Scan the QR code for the assembly video.

Figure A17: Assembly manual during test - back page

APPENDIX 14: SPRINT THREE - USER TEST PLAN

Goal: To test the assembly guide and user friendliness of the design

Output: See if the design has improved vs v.I, if the feedback is correctly implemented and gathering any final input.
Amount: One participant, expert gynaecologist (ie 10 years of experience) recruited via email

Setup: The GTM will be setup on the table. The necessary equipment will be taken to the hospital. The gynaecologist will be asked to perform the different procedures. As they do not always perform MVA's in the same way, she will be asked if she is comfortable and has the skills. Otherwise this will be skipped.

- Chloe SED + needle
- Speculum
- Copper IUD
- MVA kit
- Sausage
- Skewers
- Papaya?

Method: The gynaecologist will be asked to perform the four procedures. As she has already validated the step-by-steps, this will be skipped. She will then be asked to rate how easy/ difficult and how realistic (all on Likert scale) the different steps are to perform on the model. Finally the following questions will be asked:

- How useful is the model to practise gynaecological in general procedures? (Likert)
- Which aspects of the design do you think could still be improved (ie. Texture, sizes)?
- Which other procedures do you think could be incorporated into the model?
- How do you think the GTM could be incorporated into Dutch medical schools?
- If you could design a perfect model, what features would it include?
- How much would you pay for the GTM?

APPENDIX 15: FINAL ASSEMBLY GUIDE FRONT

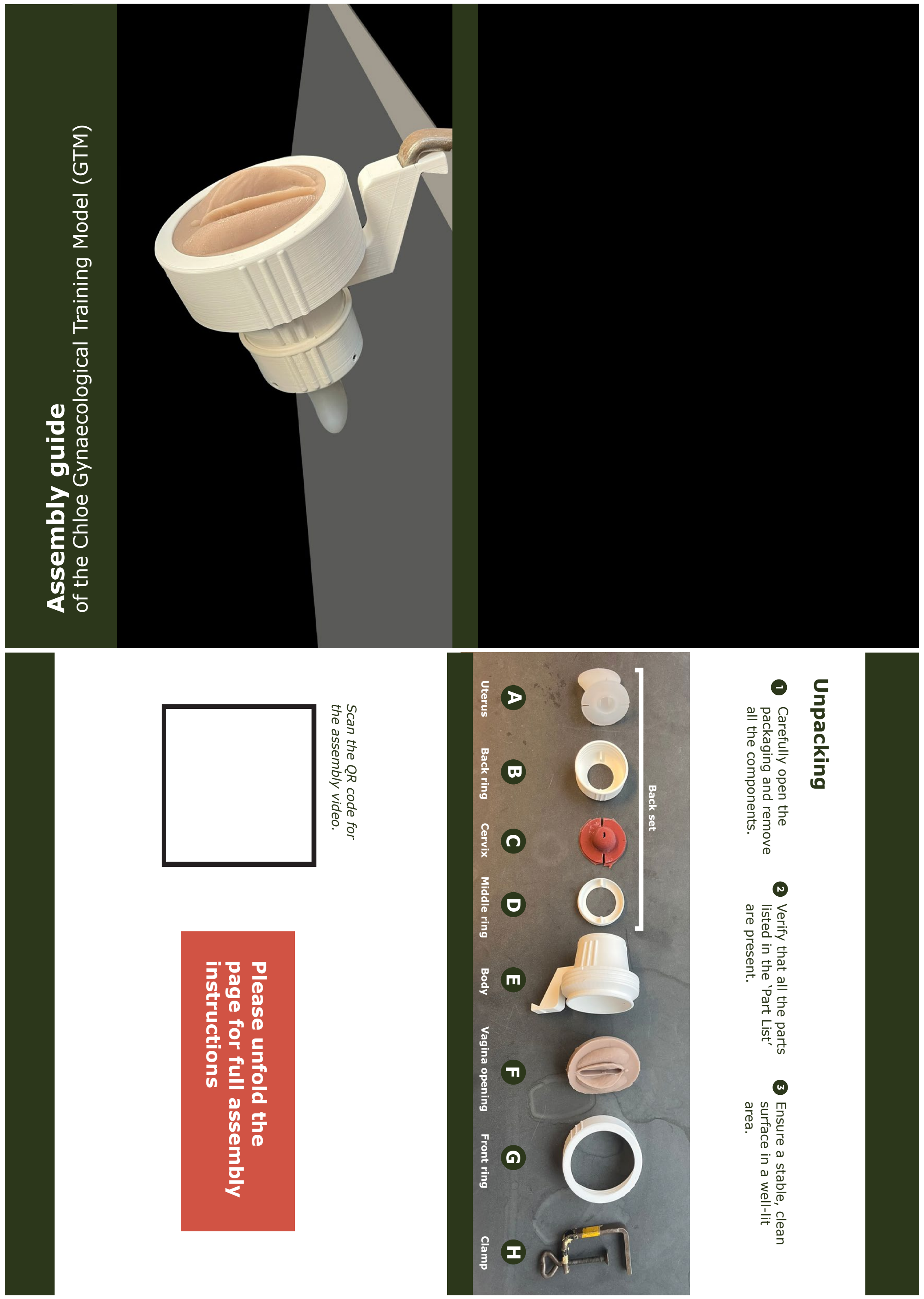


Figure A18: Front of the final assembly guide,

APPENDIX 16: MATERIAL

MATERIAL CHOICE

For the body, the most important parts that needs special considering regarding the material properties are:

Thread:

- Precision and Dimensional Stability: To ensure the threads fit properly without deforming or wearing out.
- Durability for Repeated Use: Threads will experience stress during assembly and disassembly.
- Surface Smoothness: Smooth threads reduce friction and wear over time.

Foot:

- Shape: The foot sticks out, so might break after impact

As FDM printing is the chosen manufacturing technique due to the local availability, three different filament options are explored. The properties discussed above are compared as well as the costs (due to the design context) and ease of printing (to be easy to manufacture locally).

Property	PLA	PETG	ABS
Not too brittle if it falls	Fair: Brittle, prone to cracking or shattering. May break if dropped.	Good: More impact-resistant than PLA, less likely to break.	Good: High impact resistance, suitable for drops.
Strength for tight threading	Fair: Can work for threading but risks cracking under high stress.	Good: Stronger and flexible enough to handle tight threads.	Good: Durable and able to handle tight threads well.
Thread wear resistance	Poor: Threads may wear quickly over time due to its brittleness.	Good: Better wear resistance than PLA; threads last longer with frequent use.	Best: High wear resistance, excellent for repeated threading.
Ease of Printing	Excellent: Very easy to print, no special requirements.	Good: Slightly harder to print than PLA, may need controlled cooling.	Fair: Requires a heated bed, enclosure, and precise control of temperature.
Cost	Low: Cheapest filament option.	Moderate: Slightly more expensive than PLA.	Moderate: Similar cost to PETG but may require higher energy for printing.

Table A5: Material properties

When looking at the criteria for materials, PETG seems the best option. Due to its balance of strength, wear resistance, and ease of printing. Slightly more expensive than PLA but worth the durability for threads, as the costs per GTM only increase with +- 60 cents.

TOLERANCE

The tolerance required for FDM printing is ±0.5% (±0.5 mm for a 100 mm dimension) (Tolerances & Accuracy in 3D Printing Technologies | Xometry Pro, 2024). To ensure smooth movement and minimize wear, the thread connection has been designed with a specific clearance (See Figures A19 and A20). While the tolerance is relatively large, this approach accommodates variations in printer quality, ensuring consistent functionality across different printers. It also means that a spare part can be printed on a different printer or batch without having the risk it will not fit. It is still recommended to print the parts on the same printer to ensure a better quality.

However, this design choice has a drawback: when using highly accurate printers, the increased tolerance can lead to excessive play between parts, potentially impacting the overall feel of the connection. If the production will be scaled up and a more precise manufacturing technique is chosen, the tolerances should be revised.

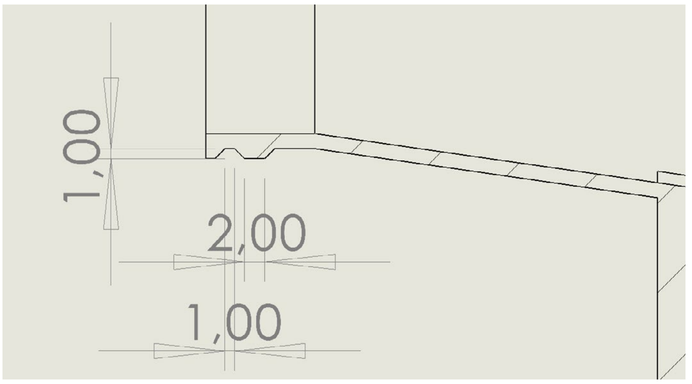


Figure A19: Thread measurements body (back)

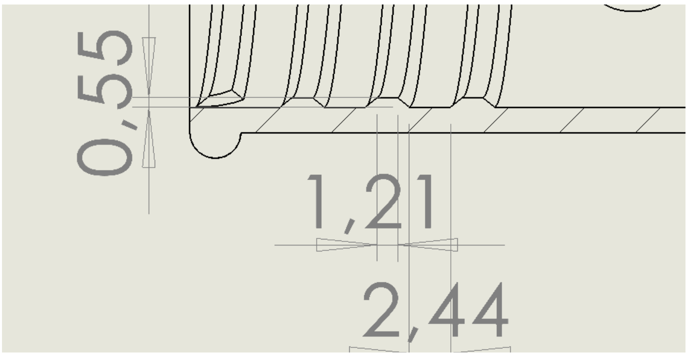


Figure A20: Thread measurements back ring

APPENDIX 17: TESTING 3D CLAMP

TESTING

The only outsourced component in the product is the clamp. To make the design fully locally manufacturable, the clamp could be 3D printed. This would eliminate the need for external suppliers and enhance self-sufficiency for the manufacturer.

A prototype clamp was designed and 3D printed using PLA on an FDM printer (See Figure A23). The design was slightly smaller than the outsourced version, as increasing the size of the clamp's rod heightened the risk of misprints.

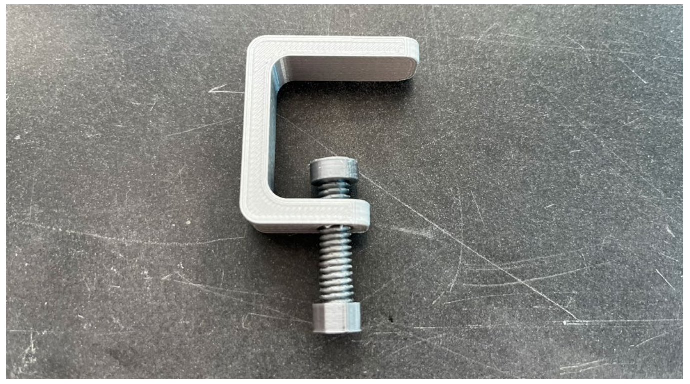


Figure A21: 3D printed clamp

The clamp was also printed in PETG, a material less brittle than PLA. However, after consultation with the PMB staff, it was concluded that the steel clamps should remain in use. The strength and stiffness of the clamp are critical during operation, and FDM-printed versions posed challenges. The required larger tolerances made it difficult to achieve precise prints for small clamps, while the printed material lacked sufficient stiffness and could snap under pressure.

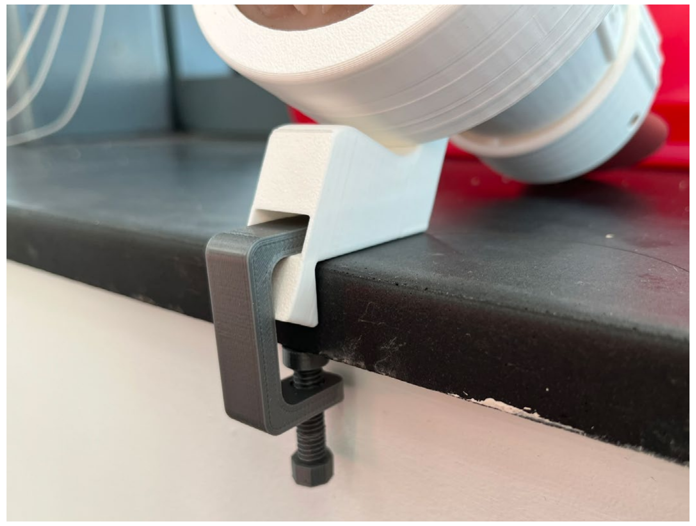


Figure A22: GTM with clamp

APPENDIX 18: MANUFACTURING GUIDE

Manufacturing guide

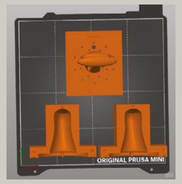
3D prints

1. Open .stl files
2. Load the .stl files into the slicer program (Ultimaker Cura, Prusa Slicer, etc)
   A. All the prints fit onto a bed of Prusa MINI (18x18x18 cm)
3. Use the following settings to print the parts
   A. Infill = 20%
   B. Brim = Off
   C. Support = Off
4. Export the G-CODE
5. Print the .gcode file on the printer
6. Check regularly to see if the print is okay

Manufacturing video

Body

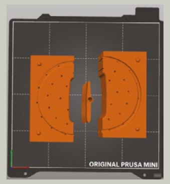
Uterus IUD



Uterus MVA

Cervix

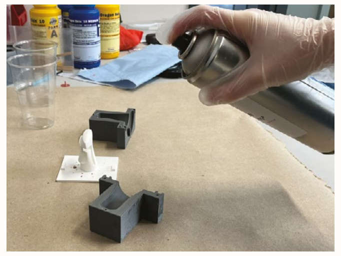
Vagina pt 1



Print with brim

Vagina pt 2

Silicone



1. Spray the mould with mold release agent

2. Mix part A and part B thoroughly

3. Measure the exact amount of part A and part B on a scale

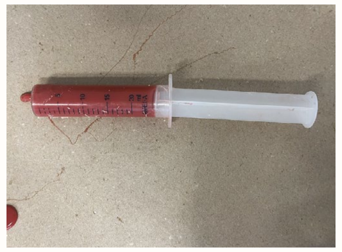
4. Add pigment drops

5. Mix part A, part B and the pigment together for 3 minutes

6. Place the cups in the vacuum chamber. The silicone will 'rise' due to the bubbles

Figure A23: Manufacturing guide front

7. Wait until the silicone has 'collapsed' and all the bubbles are removed from the mixture



8. Put the silicone in the syringe

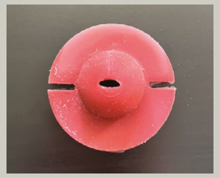
9. Place syringe in hole and empty slowly into mould

10. When the silicone comes through the air vents, the mould is filled

11. Wait 5 hours and cut off any excess parts

12. The part is ready for use

Silicone material



Cervix
Material: Ecoflex 30
Amount: 15gr A + 15gr B
Pigment: 4 drops red

Uterus IUD
Material: Dragon Skin 10
Amount: 22gr A + 22gr B
Pigment: 1 drop white, 5 drops red

Vagina
Material: Dragon skin 10
Amount: 45gr A + 45gr B
Pigment: 1 drop white, 5 drops brown

Uterus MVA
Material: Dragon Skin 10
Amount: 35gr A + 35gr B
Pigment: 1 drop white, 5 drops red

Figure A24: Manufacturing guide back

APPENDIX 19: MATERIAL COSTS

COST OVERVIEW

Table A6 shows the material cost breakdown of the GTM. The total material costs of the GTM are €18,49. These costs exclude the cardboard cervices and the packaging. This is because the packaging is now bought at HEMA, but when it will be manufactured locally, a new packaging should be found.

Furthermore, the silicone parts are weighed after the silicone is cured. At this stage, the silicone is mixed in cups and it is not possible to remove everything from the cup. Additionally, the parts must be slightly overfilled to avoid any air bubbles. As a result, an extra cost item, "extra silicone," is added to ensure sufficient silicone per model. When the process becomes more automated, it is expected to become cheaper (€15,23).

Aside from the materials costs, an initial cost setup is made, if a local manufacturer would like to setup a production centre. These costs are €606,19.

In the future, other costs that should be taken into account are:

- Overhead
- Labour
- Shipping
- Packaging
- Branding
- Profits

Cost overview					
Material costs					
	Amount (gr)	Price	Price per gr	Extra silicone marge	
Dragon skin	900	39,14	0,043	0,652333333	
Ecoflex 00-30	910	34,41	0,038	0,567197802	
PLA	1000	22,5	0,023	https://www.123-3d.nl/123-3D-Filament-PL	
PETG	1000	27,5	0,028	https://www.123-3d.nl/123-3D-Filament-Wi	
	Per roll of filament				
	8,849557522	GTMs			
	Infill/material	Grams of filament/silicone	Cost per part (PLA	Cost per part (PETG)	
Base	20%	64,86	€ 1,46	€ 1,78	
Front ring	20%	23,09	€ 0,52	€ 0,63	
Back ring	20%	18,5	€ 0,42	€ 0,51	
Middle ring	20%	6,55	€ 0,15	€ 0,18	
Vagina	Dragonskin	60	€ 3,26	€ 3,26	
Cervix	Ecoflex	21	€ 1,36	€ 1,36	
Uterus large	Dragonskin	50	€ 2,83	€ 2,83	
Uterus thin	Dragonskin	35	€ 2,17	€ 2,17	
Extra silicone	Dragonskin/ecoflex	75	€ 3,26	€ 3,26	
Clamp	-	-	€ 2,50	€ 2,50	https://www.amazon.nl/I
		Price per GTM	€ 17,93	€ 18,49	€ 0,57 Difference
Initial costs					
Mould vagina	15%	184,04	€ 4,14		
Mould uterus large	15%	132,05	€ 2,97		
Mould uterus thin	15%	89,25	€ 2,01		
Mould cervix	15%	47,64	€ 1,07	€ 10,19	
3D printer	-	-	€ 459,00		https://www.prusa3d.cor
Vacuum chamber	-	-	€ 137,00		https://www.vevor.nl/vac
		Initial costs	€ 606,19		

Table A6: Costs GTM

APPENDIX 20: MVA TOMATO

Another option for feedback during the MVA procedure, was to actually extract material from the uterus. Tomato was chosen as it had been tested before in a previous study (Owens et al., 2024). The tomato was cut in half, emptied into the uterus and then using two different sized cannula's (6 and 9 mm), the procedure was tried (See Figure A25)

The following observations could be made:

- It was difficult to place a full silicone uterus trough the middle ring as you need to squeeze it, causing some of the tomato contents to spill.
- Continuous suction was required for the aspirator to function effectively. The cervical os was too flexible to maintain a tight seal around the cannula, resulting in suction loss when air entered.
- The tomato contents were easily aspirated into the cannula
- It was easy to clean the cervix without structure on the inside.

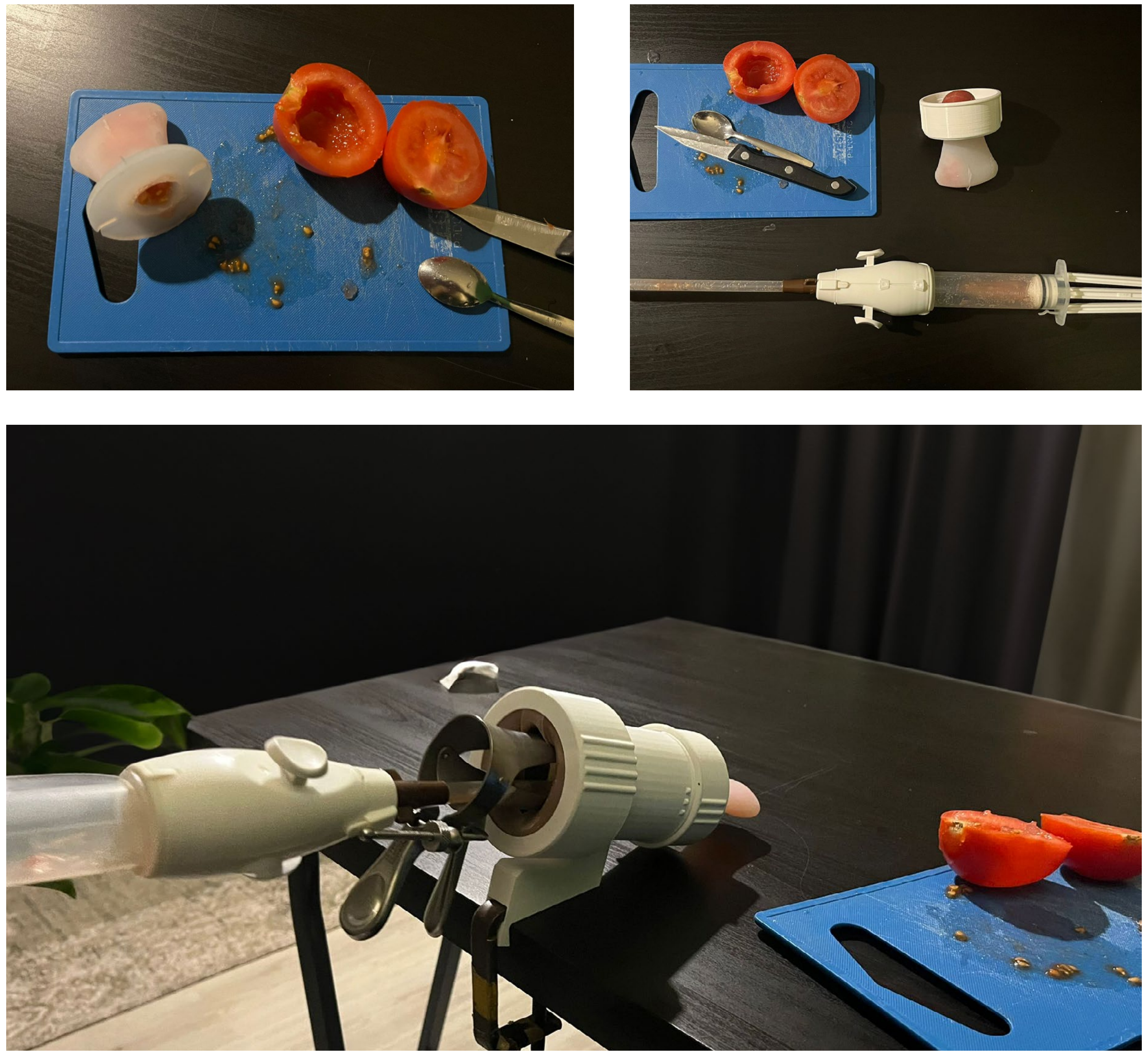


Figure A25: Testing the tomato as MVA aspirator

Personal Project Brief – IDE Master Graduation Project

Name student | **Student number**

PROJECT TITLE, INTRODUCTION, PROBLEM DEFINITION and ASSIGNMENT
Complete all fields, keep information clear, specific and concise

Project title Improving the design of the Chloe Gynaecological Training Model (GTM)

Please state the title of your graduation project (above). Keep the title compact and simple. Do not use abbreviations. The remainder of this document allows you to define and clarify your graduation project.

Introduction

Describe the context of your project here; What is the domain in which your project takes place? Who are the main stakeholders and what interests are at stake? Describe the opportunities (and limitations) in this domain to better serve the stakeholder interests. (max 250 words)

In Kenya, medical professionals are not always schooled properly to perform vaginal genealogical procedures. Often they only learn the theory and are expected to perform the procedure on a client without any hands-on training. Genealogical procedures are therefore often uncomfortable and need to be performed as accurately as possible to calm the patient and reduce pain.

The Chloe GTM was developed firstly to allow gynaecologists, nurses, clinicians and medical students to practice with the Chloe SED, a device that provides additional length for administering anaesthetic, but also to enable these medical professionals, especially in remote and distant communities in Africa, to gain hand-on practise for other vaginal genealogical procedures on a low cost physical model (Figure 1). This model is created using the insights from Kenyan hospitals and tested with its user.

There are several stakeholders involved in the project, such as the users: nurses, gynaecologists, clinicians, medical students and health trainers. The client: Chloe Innovations, who own the product and the hospital in Kisumu, to gain information about the context.

Opportunities: Hands on practise on gynaecological procedures and there by improve the patient experience and quality, designing a product that can be locally produced increasing accessibility and repairability, testing the product in operational environments.

Limitations: designing the product in the Netherlands could allow for different insights and outcomes then suitable in the context

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introduction (continued): space for images

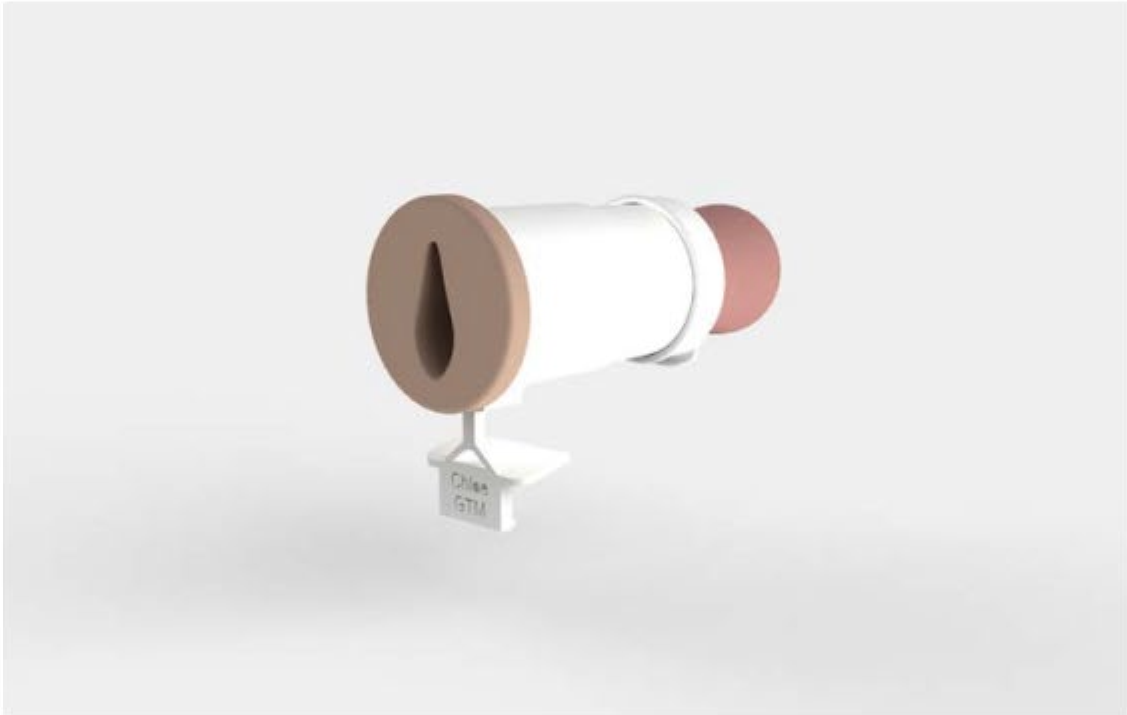

image / figure 1 Current Chloe GTM

image / figure 2 Current Chloe GTM in use

DESIGN FOR our future

TU Delft

Personal Project Brief – IDE Master Graduation Project

Problem Definition

What problem do you want to solve in the context described in the introduction, and within the available time frame of 100 working days? (= Master Graduation Project of 30 EC). What opportunities do you see to create added value for the described stakeholders? Substantiate your choice.
(max 200 words)

Currently, there is a functional prototype. However, the current design has limitations that reduce its effectiveness. Key issues include insufficient stability, user-friendliness, and durability. The stand and holder do not provide adequate support, causing the model to shift during use, which disrupts training. Feedback indicates that the model's assembly and operational steps are not intuitive, creating barriers for users with limited experience. Additionally, the durability of the model has not been tested. Given that frequent use of the tools results in wear and tear, the prototype should be strong enough to be used for the given amount of time.

To address these challenges, the Chloe GTM must be redesigned to enhance stability, ease of use, and robustness, ensuring that it can withstand repeated use while maintaining its functionality. This redesign will improve the training experience, empowering healthcare professionals with practical skills to provide better care. With these problems the context needs to be kept in mind and the product should remain simple and low-cost.

Assignment

This is the most important part of the project brief because it will give a clear direction of what you are heading for. Formulate an assignment to yourself regarding what you expect to deliver as result at the end of your project. (1 sentence) As you graduate as an industrial design engineer, your assignment will start with a verb (Design/Investigate/Validate/Create), and you may use the green text format:

To redesign the Chloe GTM, by enhancing the stability, user-friendliness and improving the durability to create a low cost, portable design, to a well-developed TRL level 7-8.

Then explain your project approach to carrying out your graduation project and what research and design methods you plan to use to generate your design solution (max 150 words)

Throughout my project I will use the double diamond approach. The project begins with the discovery phase, where research is gathered through reviewing literature, conducting interviews and taking apart and testing the current prototype. The second phase focuses on defining the product challenge, during which design requirements are established and ideation using sketches and lo-fi prototyping takes place. In the development phase, the design direction is refined, and high-fidelity prototypes are created for testing. These prototypes will then be taken to Kenia for field research. Finally, the delivery phase will produce the final product design, incorporating insights gained from the field research.

The final deliverable will be a hi-fi prototype of a redesign of the Chloe GTM in a TRL level 7-8, that is durable, takes the local context into consideration and enhances the training of the local nurses.

Out of scope: Business model, clinical safety, high volume production

Project planning and key moments

*To make visible how you plan to spend your time, you must make a planning for the full project. You are advised to use a Gantt chart format to show the different phases of your project, deliverables you have in mind, meetings and in-between deadlines. Keep in mind that all activities should fit within the given run time of 100 working days. Your planning should include a **kick-off meeting**, **mid-term evaluation meeting**, **green light meeting** and **graduation ceremony**. Please indicate periods of part-time activities and/or periods of not spending time on your graduation project, if any (for instance because of holidays or parallel course activities).*

Make sure to attach the full plan to this project brief.
The four key moment dates must be filled in below

Kick off meeting	2 sept 2024
Mid-term evaluation	23 okt 2024
Green light meeting	6 feb 2025
Graduation ceremony	13 mrt 2025

In exceptional cases (part of) the Graduation Project may need to be scheduled part-time. Indicate here if such applies to your project

Part of project scheduled part-time	✔
For how many project weeks	20
Number of project days per week	4,0

Comments:
Due to one day of working exierence at IDE Group

Motivation and personal ambitions

Explain why you wish to start this project, what competencies you want to prove or develop (e.g. competencies acquired in your MSc programme, electives, extra-curricular activities or other).

Optionally, describe whether you have some personal learning ambitions which you explicitly want to address in this project, on top of the learning objectives of the Graduation Project itself. You might think of e.g. acquiring in depth knowledge on a specific subject, broadening your competencies or experimenting with a specific tool or methodology. Personal learning ambitions are limited to a maximum number of five.
(200 words max)

I would like to use my design skills for useful products, not for products that are focussed on fast paced consumers and unnecessary material. During my AED project I have found a passion for global development and medical designs. The goal of these projects is often so clear, which motivates me a lot. I can instantly feel why I am using my skills on this and understand the effects I hope to have.

This project will also help me to improve my embodiment design skills. I enjoy fitting different puzzle pieces together and designing a complete product from many different parts. In my previous projects I have always shared the responsibility so I would like to improve my hard skills (CAD, rendering, sketching) as well as thinking about out of the box solutions for a concept that already exists. Furthermore, I have always found materials very interesting but have never had the opportunity to research and implement them in depth.