REDESIGNING THE C SPEC

Enhancing Comfort, Ease of Disassembly, and Healthcare Professional Satisfaction for Cervical Cancer Screening Procedures in Low-Resource Settings

Master Thesis
Mirthe Hofstede

MASTER GRADUATION THESIS

Integrated Product Design

Faculty of Industrial Design Engineering

Delft University of Technology

June 2024

SUPERVISORY TEAM

Prof. Dr. Ir. Jan Carel Diehl

S.M Persaud MSc.

PROJECT CLIENT

GIC Space

K.T. Samenjo MSc.

Dr C. Tankou

ACKNOWLEDGEMENTS

Dear Reader,

I am honoured to present to you my master's graduation thesis. Before starting this journey, I always said I wanted to work on a project that I would love until the very end. I am very pleased that this has indeed been the case. It has been truly humbling to work on a project with the potential to improve gynaecological procedures for women worldwide.

I could not have undertaken this graduation without my fantastic committee. JC, Stefan, and Karl, it was an honour to work with you. Despite being a committee of all men working on a women's health product, I truly value your feedback and your eagerness to the project. I would like to give special thanks to Karl. Travelling to Cameroon with you to observe in hospitals and, of course, eat plantains every day, I am truly thankful for your guidance during this time.

To Dr. Conrad, Blessings, and Carlson at GIC Space, thank you so much for hosting me during my time in Cameroon. I can only imagine the amount of work and energy it took to accommodate me. Your passion and dedication inspired me to work even harder on this project to deliver a product we can all be proud of.

To the nurses who have become my friends, I am humbled that you welcomed me into your workplace with open arms. Learning from you has been an honour, and I hope you are proud of your Naomi.

To the amazing women working on different aspects of this project, I am grateful we could confide in each other through the ups and downs. Femke, Marijke, and Nicole, it was a pleasure to work alongside you.

To my family, I am endlessly grateful. Mum and Dad, thank you for the difficult decision to stay in Malaysia during our childhood. Growing up as a third-culture kid has, I believe, given us the ability to adapt to different contexts, allowing me to feel comfortable wherever I go. Although you are far, I always feel your unconditional love and support. To my siblings Annemijn and Marnix, thank you for being amazing yet annoying. I always value that even though we do not see each other often, when we do, it feels like home.

To Henk Jan, I do not know what I would have done without you. I leaned on you a lot during this project, and words cannot express how grateful I am. We are two weirdos who found each other in the most interesting of ways. I love you and your Abbink matrix, and I cannot wait to see what our future holds together (with me being the boss, of course).

To my sister-in-crime Liza, I seriously would not have stayed sane if we were not graduating at the same time. From daily coffee to massage chairs in the UB, we are Jut en Jul. Laughing and crying together (mostly you) has created an unbreakable bond that I will always treasure. Bouwe and Fiona, thank you for always being there when I needed anything. From good advice to chocolate, I am grateful to have made such friends for life during my master's period.

To the Billenbak, Mirjam, Vicky, Marieke, Benthe, and Sharon, I know my graduation period has not been easy. Your support, or a quick cocktail between UB sessions, has often given me the pick-me-up I needed to keep going.

I am excited to see what my future holds after graduation but for now, enjoy reading my master graduation thesis!

Mirthe Hofstede

ABBREVIATIONS

HPV Human Papillomavirus

WHO World Health Organisation

LRS Low Resource Setting

HRS High Resource Setting

LMIC Low and Middle Income Countries

HIC High Income Countries

SCJ Squamocolumnar Junction

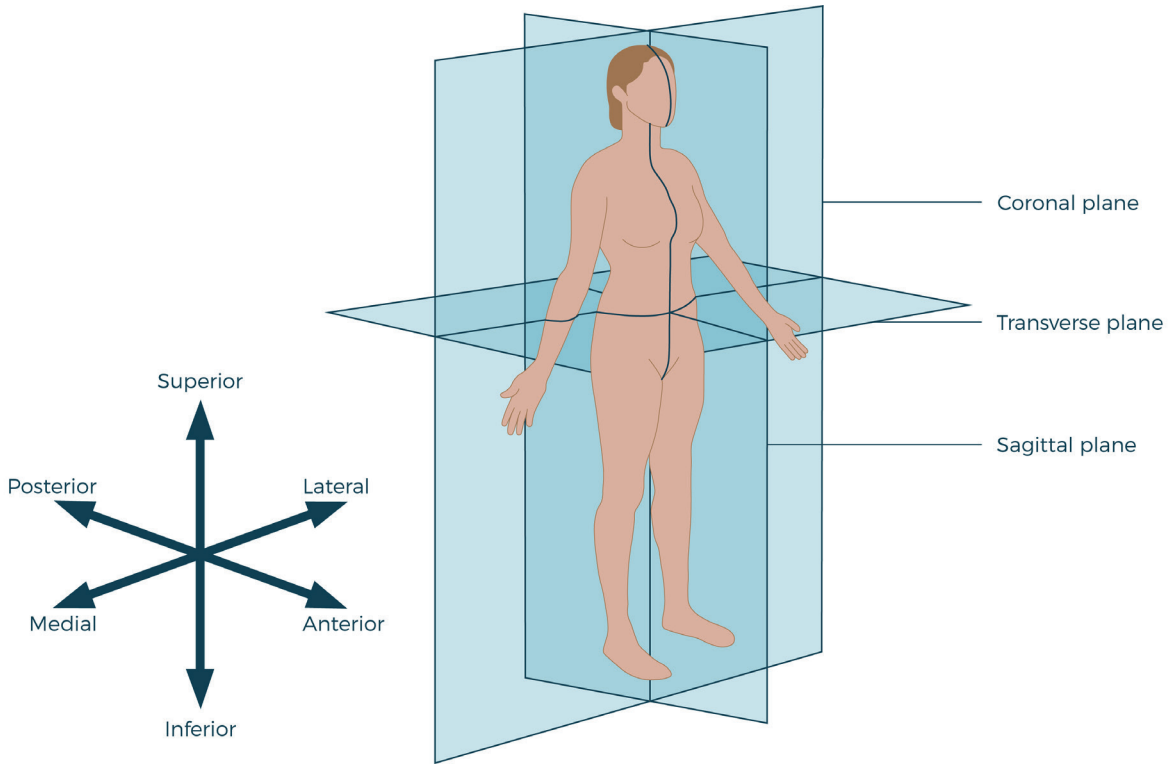
TZ Transformation Zone

VIA Visual Inspection with Acetic Acid

VILI Visual Inspection with Lugol's Iodine

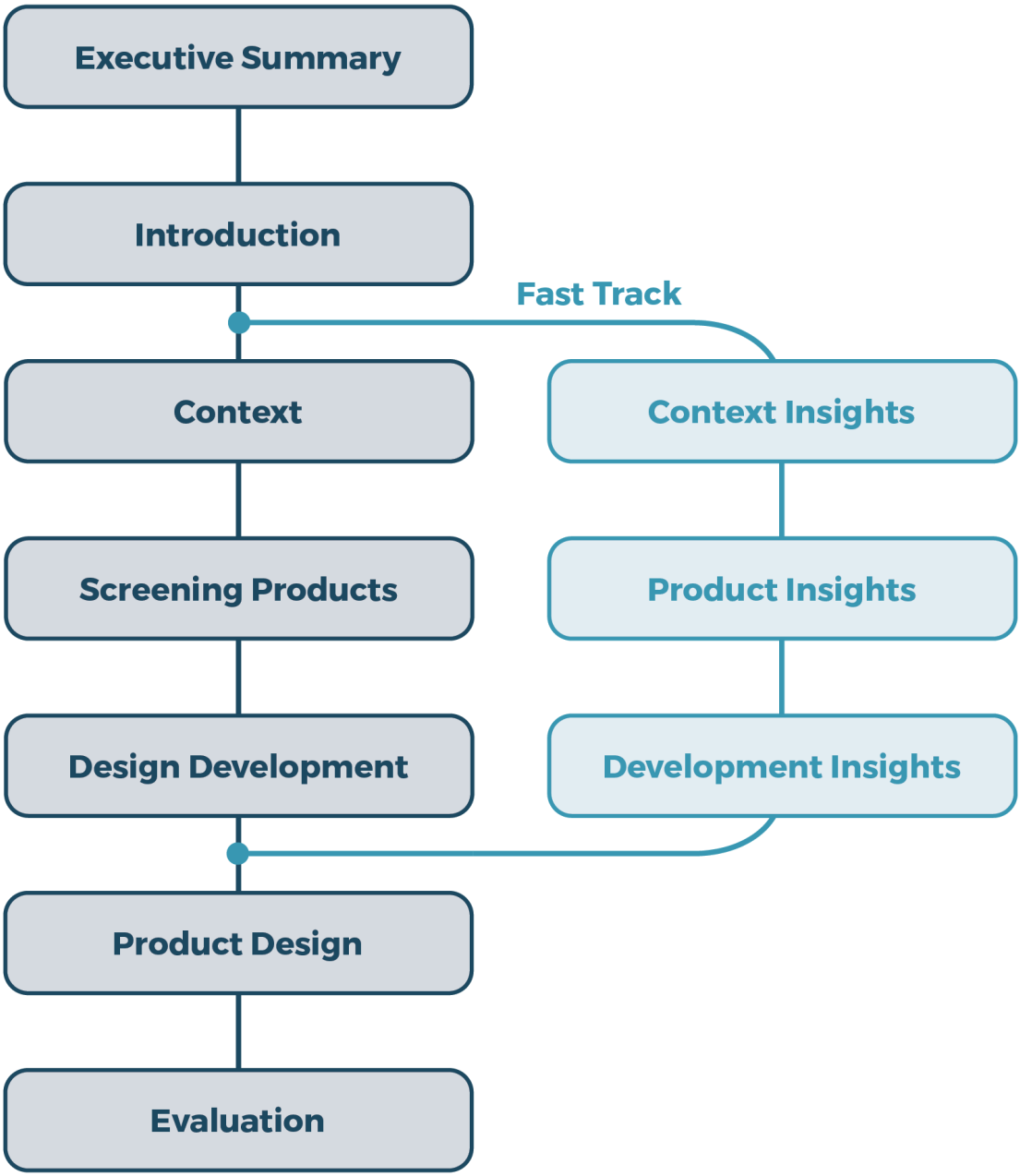
HLD High Level Disinfection

Planes



READING GUIDE

This report can be navigated in two ways. The first is by reading all the information provided, including the sections on the project context, cervical cancer screening products, and design direction. For those who prefer to skim these sections, a key insights page is provided at the end of each section to quickly convey the essential information needed to understand the final product design and product evaluation sections of the report.



EXECUTIVE SUMMARY

SECTION ONE

Cervical cancer is the development of abnormal cell growth in the cervix. In 2020, approximately 342,000 women died of cervical cancer worldwide National Cancer Institute, 2023). What is shocking is that these deaths are unnecessary as cervical cancer is highly preventable and highly curable if detected early (National Cancer Institute, 2023). 22.5% of cervical cancer-related deaths occur in Africa (WHO, 2022). However, even though Africa bears the highest burden of cervical cancer, they have the lowest rate of prevention measures (UICC, 2022).

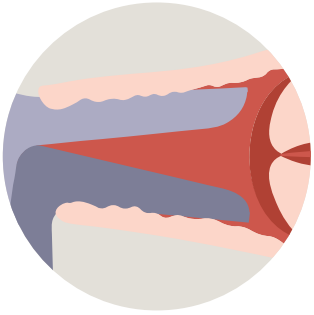
An effective prevention method is through screening women for cervical cancer. There are various screening methods available depending on the country and the degree of cervical cancer (pre)lesions. In low resource settings, visual inspection is the preferred screening procedure due to its affordability and simplicity. During a visual inspection procedure, a healthcare professional will spray solutions on the cervix to highlight possible lesions and then analyse these with the naked eye.

VISUAL INSPECTION SCREENING PROCEDURE USING A SPECULUM

1.

A speculum is a standard apparatus used in gynaecological procedures

2.



A speculum is used to open the vaginal walls to view the cervix by eye

3.

Taking photos before and after applying solutions that aid in highlighting cervical cancer (pre)lesions to determine a diagnosis

SECTION TWO

In Cameroon, where this project is based, a mere 6% of women ages 30-49 have ever undergone a cervical cancer screening (IARC, 2023). A contributing factor to this low screening rate is the fear surrounding the use of a speculum. A speculum is a gynaecological device that dramatically stretches the vaginal canal to allow healthcare professionals to view the cervix during a procedure.

GIC Space, a start-up company based in Cameroon set out with the aim of increasing women's participation in screening procedures by reducing the discomfort barrier associated with the traditional speculum. To tackle this problem, the C Spec was designed.

The C Spec is a cervical cancer screening product that only opens the walls at the back of the vagina, where the cervix is located and where the skin is more flexible. Through using an endoscopic camera to view the cervix on a mobile phone, there is a significant decrease in the diameter the vaginal walls are stretched to, thereby significantly improving patient comfort during the procedure.

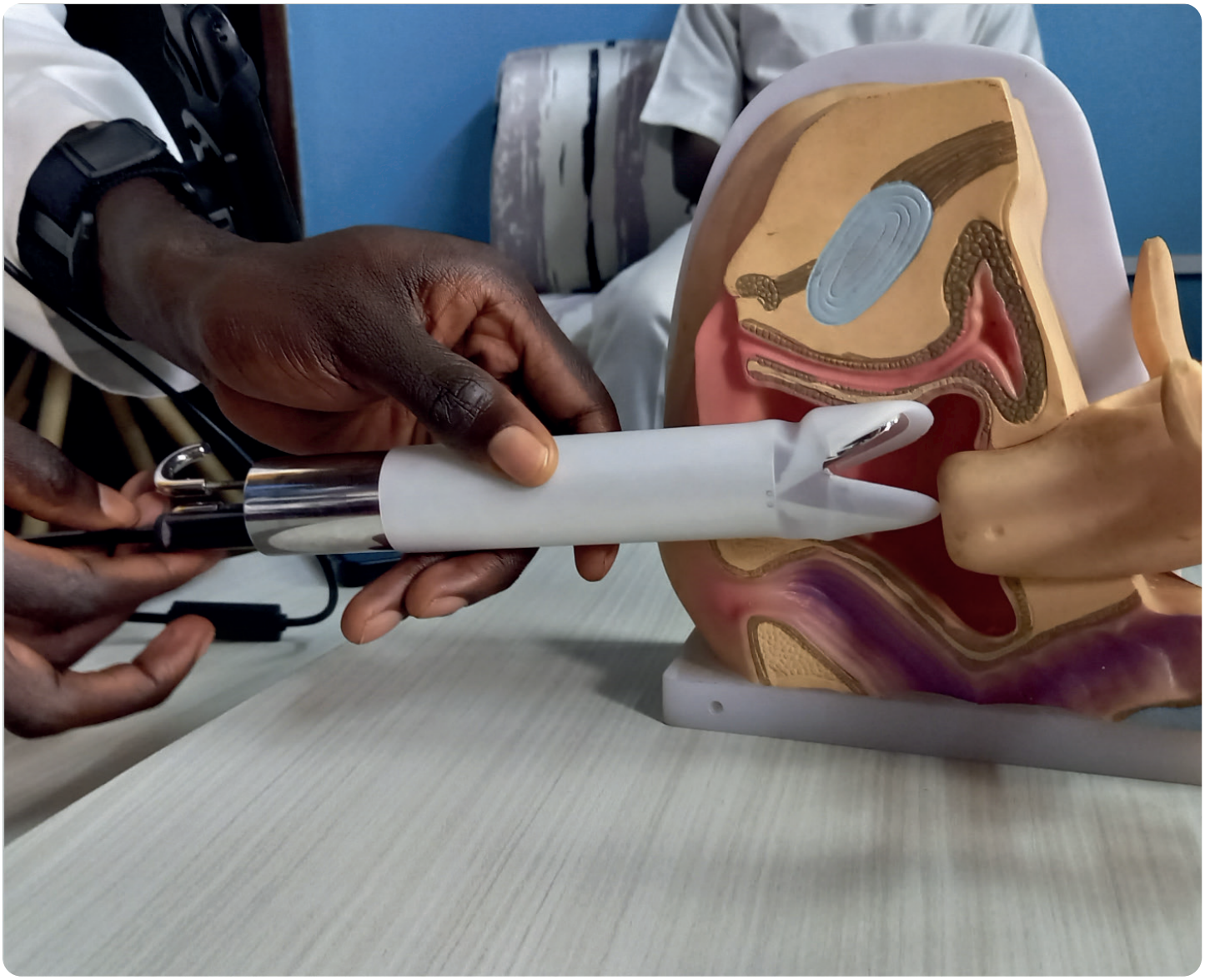


Figure 1 - C Spec use in a vagina model (Bruggen, 2024)

SECTION THREE

Although the C Spec improves a patients screening experience, there are considerable challenges that healthcare professionals face in regards to the functionality of the product. The current C Spec mechanism that opens the flaps to view the cervix for example is significantly difficult to operate. Furthermore, it is not intuitive to healthcare professionals making this product difficult to implement in the future since healthcare professionals can be resistant to changes in apparatus.

With the aim of improving useability and acceptance of the C Spec among healthcare professionals while providing patient screening comfort, the design direction chosen for this project is to design and develop a speculum-style handle that operates the current C Spec main body.

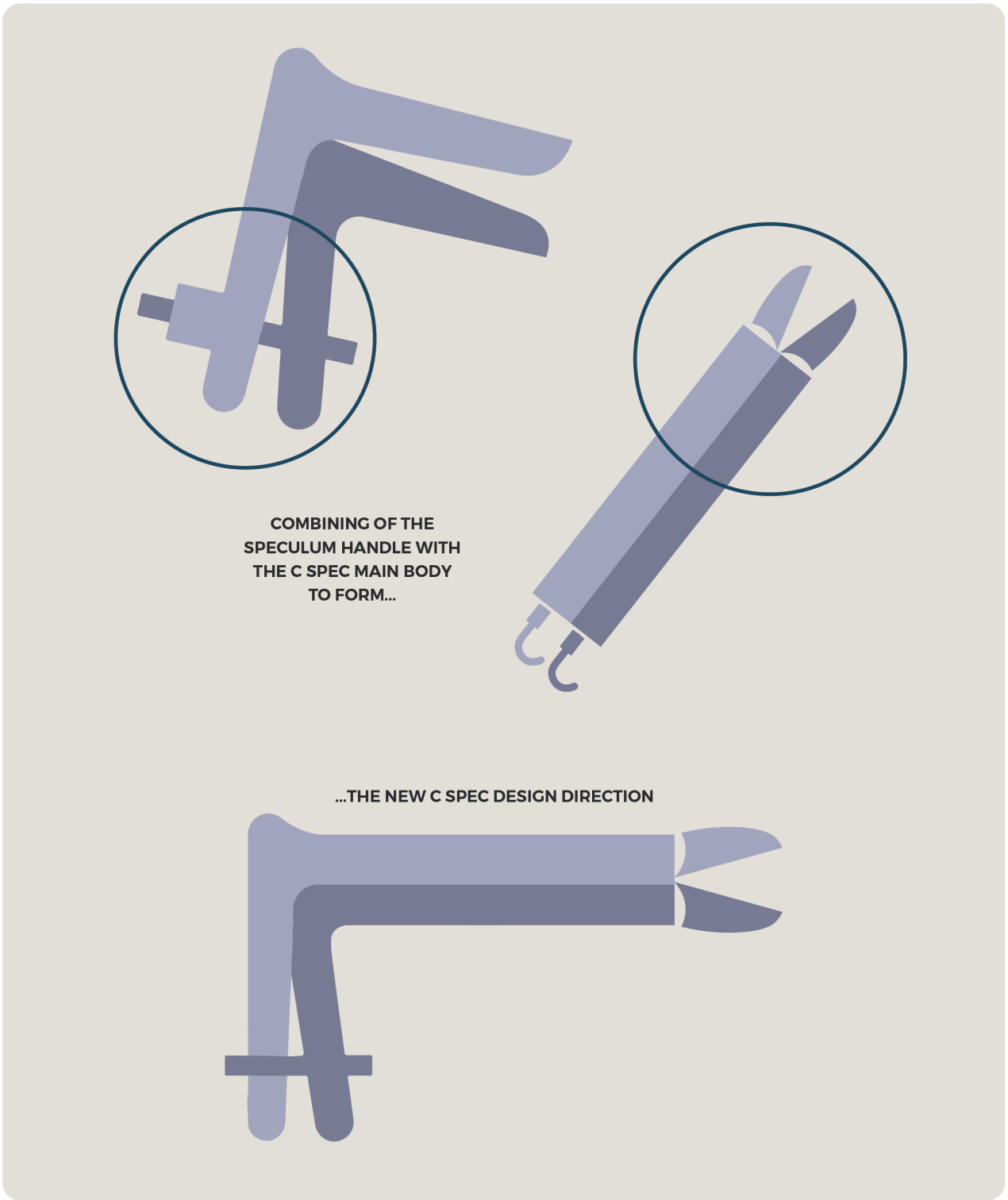


Figure 2 - New C Spec design direction, combination of speculum-style handle with C Spec main body

SECTION FOUR

To fulfil the design requirement of easy disassembly for sterilisation, a linear cam mechanism was chosen to operate the current flap design of the C Spec using the new speculum-style squeeze handle. The linear cam system only requires one axis point per flap, therefore making it easy to disassemble for sterilisation for repeated use.

Through utilising an inner and outer tube, a pin connected to the flaps is pushed along the linear cam path, forcing the flaps of the C Spec open when the speculum-style handle is squeezed. Through implementing a speculum style handle into the C Spec design, healthcare professionals can now confidently and intuitively conduct a visual inspection screening procedure while providing patients with a comfortable screening experience.

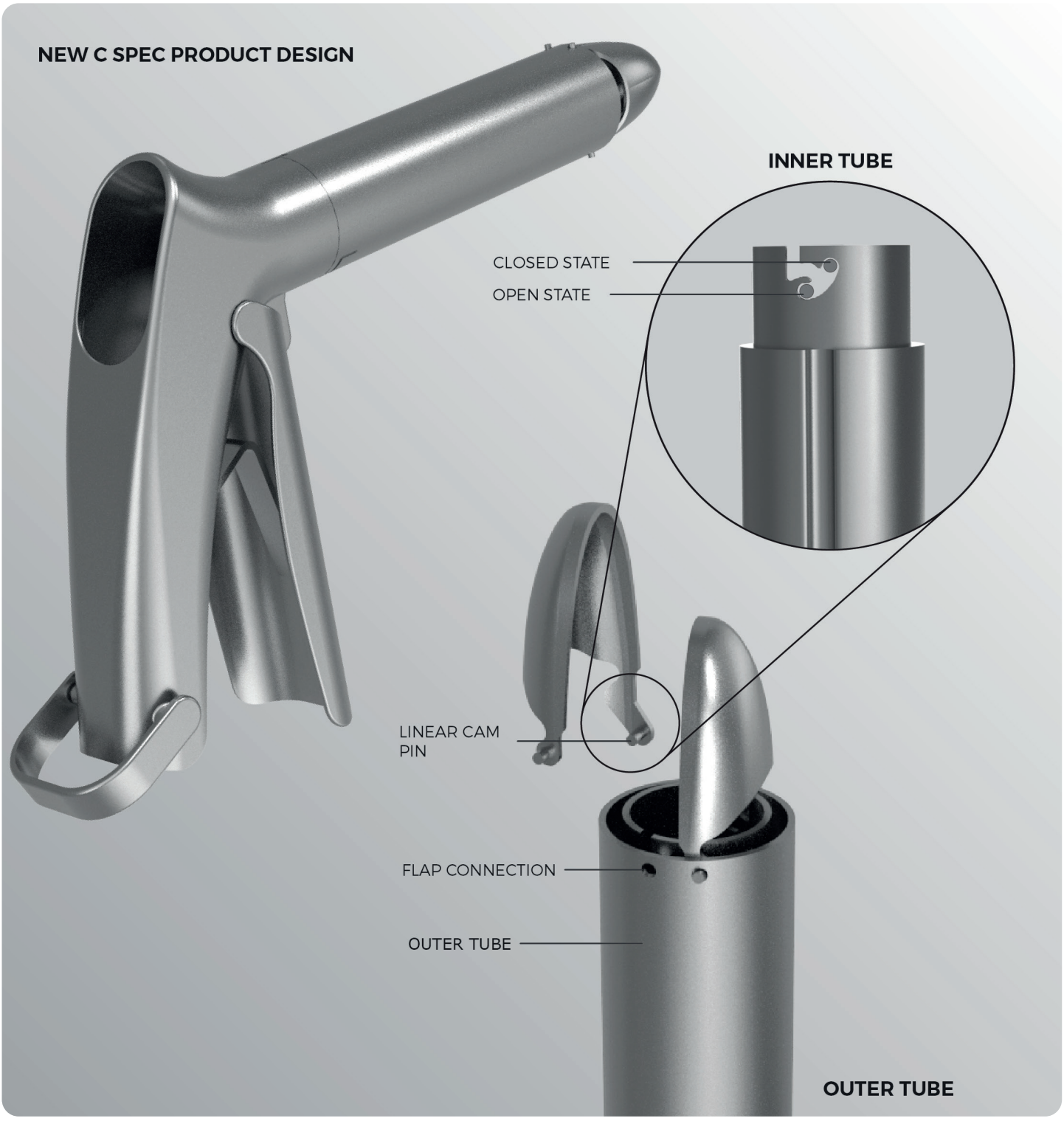


Figure 3 - New C Spec design direction realised through a linear cam path, operated by the pushing of the inner tube

TABLE OF CONTENTS

SECTION 0

PROJECT INTRODUCTION

0.1 | PROBLEM STATEMENT

CERVICAL CANCER

Cervical cancer is the development of abnormal cell growth on a woman's cervix. It is a highly preventable and highly curable disease if detected early (National Cancer Institute, 2023). If these abnormal cells are not removed, they can, over time, progress into cancer cells (National Cancer Institute, 2023).

The leading cause, accounting for 95% of all cervical cancer cases, is persistent infection with the human papillomavirus (HPV)(WHO, 2022). The development of cervical cancer from initial HPV infection to precancerous lesions takes on average 5 years allowing for many opportunities to detect the cancer early through screening (Koot, 2021). The World Health Organization (WHO) has set a target to have 70% of women screened by the age of 35 by 2030 (WHO, 2020).

CERVICAL CANCER IN LOW RESOURCE SETTINGS

Cervical cancer is the fourth most prevalent cancer among women, with approximately 342,000 deaths worldwide in 2020 (National Cancer Institute, 2023). Notably, 22.5% of cervical cancer-related deaths occur in Africa (WHO, 2022). While Africa bears the highest burden of cervical cancer globally, they have the lowest rate of cervical cancer prevention measures (UICC, 2022).

Due to its affordability, simplicity and effectiveness, visual inspection is the recommended cervical cancer screening technique in low resource settings (LRS). To properly visualise the cervix by eye from outside the body, a speculum is used. Many women experience significant discomfort during speculum use (Kent, 2020), creating fear and anxiety which act as barriers to get screened.

THE C SPEC

The C Spec was developed by the startup company GIC Space based in Cameroon, with the goal of improving women's health in LRS through prioritising comfort during cervical cancer screenings using the visual inspection method. The C Spec design utilises a narrow body and an endoscopic camera to visualise the cervix. Through utilising a smartphone, endoscopic images of the cervix can be captured and stored to create a patient database.

PROBLEM STATEMENT

This project focuses on increasing women's participation in cervical cancer screenings through redesigning the C Spec, a product that lowers the discomfort barrier associated with such procedures. Through enhancing product usability for healthcare professionals and ease of disassembly for sufficient sterilisation, the new C Spec design aims to support and facilitate the cervical cancer screening process, to increase the global screening rate of 70% of women screened by the age of 35 (WHO, 2020).

0.2 | STAKEHOLDERS

GIC SPACE

GIC Space, a startup based in Cameroon, has the vision of providing affordable and quality healthcare regardless of location or social status. Their goal is to achieve this through innovative and sustainable MedTech solutions (GICMed, n.d.). Founded by Dr C. Tankou, a medical doctor and entrepreneur from Cameroon, GIC Space designed the C Spec to make cervical cancer screenings more comfortable and accessible for women in low resource settings.

TU Delft

TU DELFT

Through the connection between Dr. C. Tankou and K. Samenjo, multiple faculties at the TU Delft are now collaborating to redesign the C Spec. The interest of providing healthcare access for all through circular design from K. Samenjo aligns with the goals from GIC Space. As a result, Master Graduation projects are being held at the Biomedical Engineering and Industrial Design Engineering faculties.

CBC HOSPITAL

The Cameroon Baptist Convention (CBC) Hospital, is a non-profit organisation that operates 14 hospital locations across Cameroon. Committed to providing care to all, the hospital in Yaounde served as a primary site where multiple observations and interviews were conducted during the field research phase of this project.

0.3 | PROBLEM IDENTIFICATION AND SCOPE

PROBLEM MATRIX

Section 2 of this report outlines the pain and pleasure points of the C Spec and the traditional speculum from both the healthcare professional and patient perspective. Table 0.1 classifies these points into a problem matrix that identifies the product strengths, weaknesses, and identifies what falls in and out the scope of this project.

Green Section: Identifies the strengths of the current C Spec design that must be retained in the new design.

Yellow Section: Identifies weaknesses of the C Spec that will remain after this project, as these fall out of scope.

Red Section: Identifies weaknesses of the C Spec that will be addressed through the new C Spec product design.

PROBLEM IDENTIFICATION

By addressing these identified weaknesses and leveraging the existing strengths, the new C Spec product design aims to enhance usability for healthcare professionals and maintain comfort for patients, ultimately improving the overall cervical cancer screening experience.

	KEEP	IMPROVE
STRENGTHS	• Screening body position of the HCP	
	• Personal space between HCP and patient vulva	
	• Patient comfort during screening procedure	
	• Product material strength	
	• Reducing screening material waste compared to the disposable speculum	
	• HCPs ability to conduct the screening procedure alone	
WEAKNESSES	• Facilitating women with a larger cervix	• Usability of mechanism that operates the flaps
	• Pinching of vaginal walls	• Intuitive feeling of product use for new users
	• Ability to treat (pre)cancerous lesions	• Clear identification of product orientation
	• Visualisation of the vaginal walls	• Ease of inserting apparatus to reach the cervix
	• HCP interaction with a phone to take a photo of the cervix	• Quality of feedback given to the HCP on how open the product is inside the vagina
		• Ease of disassembly for adequate sterilisation

Table 0.1 - Problem Matrix

THE GREEN SECTION

The points mentioned in the green section of table 0.1 are already strengths of the current C Spec design. It is important to keep these strengths in the new C Spec product design. These points are as follows:

Screening body position of the Healthcare Professional	The use of a camera and phone for a live video feed, allows the healthcare professional to stand upright during the procedure. They do not have to bend down to view the cervix.
Personal space between heathcare professional and patient	The C Spec allows the healthcare professional's face to maintain a distance from the patient's vulva, providing a level of personal space.
Patient comfort	The C Spec does not open the vaginal walls as wide as the traditional speculum, creating a more comfortable screening experience for the patient.
Product material strength	The C Spec is made from stainless steel, which withstands the pressures of the vaginal walls and is less susceptible to breakage comapred to the plastic disposable speculum.
Screening material waste	Compared to the disposable speculum, the C Spec is reusable after sterilisation, reducing material waste.
Ability to conduct screening alone	The phone displaying the live feed of the cervix is attached to the healthcare professional's arm, allowing one hand to hold the C Spec while the other inserts the apparatus.

THE YELLOW SECTION (OUT OF SCOPE)

The points mentioned in the yellow section of table 0.1 will not be improved within this project's timeline. This is firstly due to the limited project time, and secondly because context research found that improving the points in the red section are of higher importance to effectively conduct screenings. The following topics fall out of this projects scope:

Flap shape design	Issues regarding pinching of the vagina walls and accommodating larger cervixes will not be addressed since the shape and design of the flaps will remain the same.
Facilitating treatment	Only 0.3% of women screened for cervical cancer in Cameroon receive treatment each year (See Appendix...). Changing the design for this low percentage of cases cannot be justified.
Visualising the vaginal walls	The C Spec does not allow visualisation of the vaginal walls. A following project phase will need to address this since healthcare professionals find this feature important.
Camera specifications and interaction	The project scope will not include selecting a camera, nor will it explore the user interaction with the camera.

THE RED SECTION (PROBLEM IDENTIFICATION)

The points mentioned in the red section of table 0.1 are the problems to be tackled within this project through designing a new C Spec product. Unlike the yellow section, these points have been chosen based on context research, which found them crucial for successful cervical cancer screening.

Usability of flap opening mechanism	Healthcare professionals experience finger pain when operating the hook/nut mechanism to open the C Spec flaps. This is especially difficult when wearing gloves with lubricant.
Feedback on how open the flaps are	Healthcare professionals have no indication of how open the flaps are once the C Spec is inserted, due to the lack of feedback on the opening mechanism. Estimating this is difficult.
Lack of intuitive product use	New users are unsure how to operate the C Spec, particularly the manipulation of the hook and nut mechanism, which requires explanation and practice.
Lack of product orientation	There is no orientation indicator, creating confusion about what is up and what is down. This complicates communication between professionals on the location of cervical lesions.
Difficulty inserting apparatus	The hooks of the current C Spec obstruct the entry of the main body, making inserting apparatus difficult.
Inability to disassemble for sterilisation	The C Spec cannot be disassembled for thorough cleaning. To ensure proper sterilisation, the product must be disassembled to be cleaned on every surface with a brush and soap.

0.4 | DESIGN GOALS

PROBLEM MATRIX

The issues mentioned in the red section in table 0.1 primarily identify challenges regarding the use of the current C Spec design by healthcare professionals. To facilitate the easy implementation of the new C Spec product, it is crucial to address these pain points and ensure healthcare professional satisfaction. It is also essential to retain the strengths noted in the green section of table 0.1 in the new C Spec product design. This leads to the following design goals:

To redesign the C Spec to retain **patient comfort** and healthcare professional **Ways of Working**, while developing a **more intuitive** product design.

To redesign the C Spec to **improve operability** for the healthcare professional **working alone**, while incorporating a feedback system to **increase procedural awareness**.

To redesign the C Spec to ease the process of **disassembly for sterilisation**, **reducing procedural waste**, while **preserving material strength**.

0.5 | DESIGN APPROACH

THE DOUBLE DIAMOND

To structure the design process, this project followed the double diamond model. This model is shown in figure 0.1.

DISCOVER

The first phase is called the discover phase. Here, initial research was conducted through reading literature, and conducting interviews with individuals familiar with topics concerning this project. To understand the context in which the new C Spec product will be used, the author travelled to Cameroon to conduct field research in hospitals. Here, interviews were conducted, and cervical cancer screenings using both the speculum and the C Spec were observed.

DEFINE

After returning from Cameroon, all insights were clustered to identify the project problem. Through the making of a problem matrix the points that fall within this projects scope were identified and design goals were created.

DEVELOP

With the problem now defined, the product development phase could begin. Here ideation and further research was conducted to explore various solutions to the project problem. For this project, multiple prototypes were made using rapid prototyping methods. This is explored further in section 3 of this report.

DELIVER

By selecting the prototypes that work best and continuing to develop these, the solution to the initial problem is produced. In this project's case, this is a high fidelity product prototype as shown in section 4. Section 5 of this report evaluates this prototype and recommends future steps.

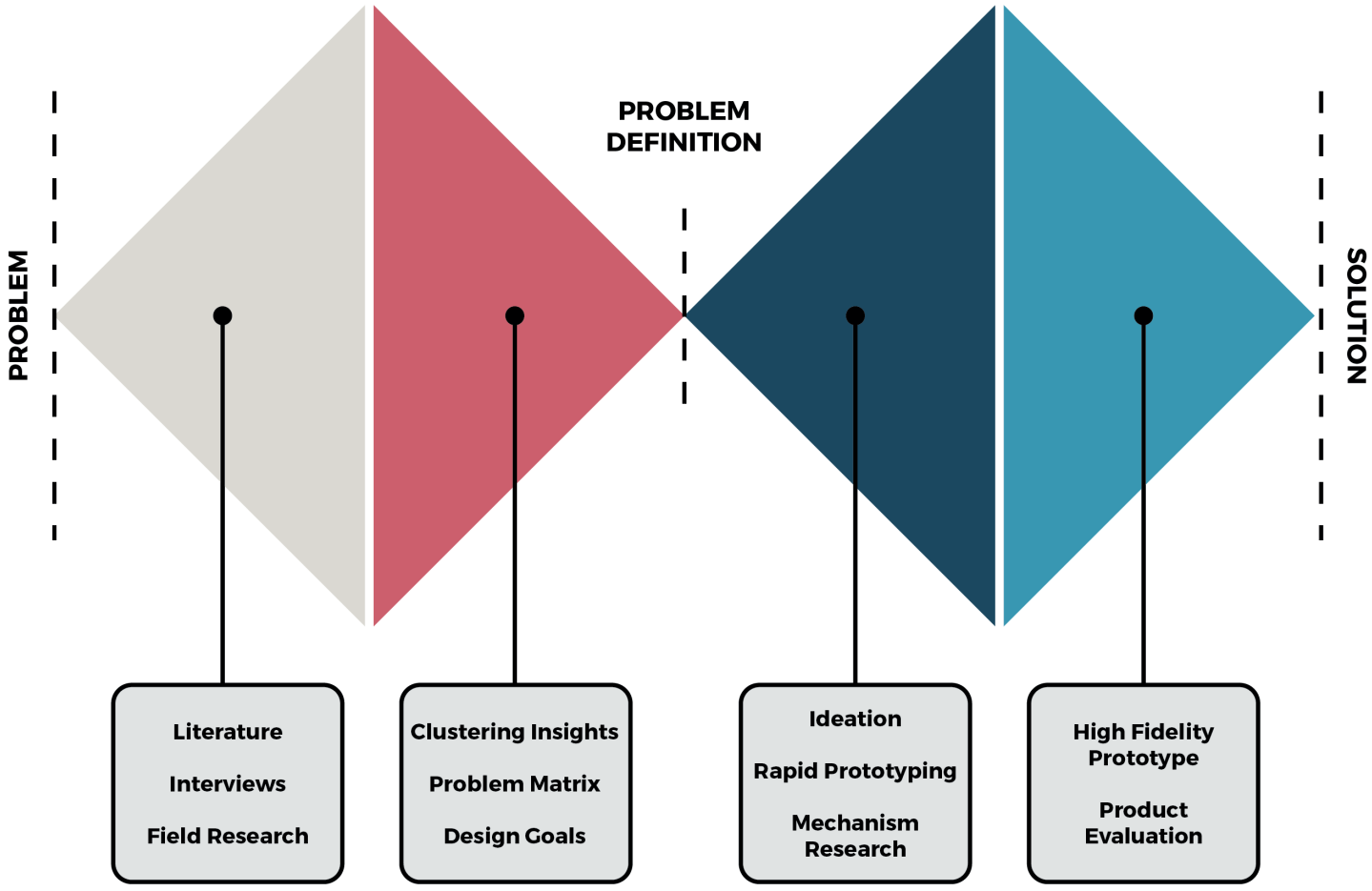


FIgure 0.1 - Double diamond method

Cervical Cancer Explanation with Dr Conrad of GIC Space

SECTION 1

PROJECT CONTEXT

1.1 | THE FEMALE ANATOMY

THE FEMALE GENITALIA

The female genitalia includes several parts that are important to understand since this is the area of the body the C Spec is used. Firstly, there is the exterior structure known as the vulva. Its main purpose is to protect the inner female reproductive organs. Connected to the vulva is the vaginal canal, a tube-like structure acting as a passageway to the uterus. Finally, the cervix sits at the entry to the uterus connecting the vaginal canal to the uterus (Telfer, 2021).

THE VULVA

The term "vulva" defines the external structure of the female genitalia. This structure serves as a protective layer for the woman's internal sexual organs through a pair of inner and outer "lips" known as the labia majora and the labia minora. These "lips" protect the clitoris, the urethral opening, and the vaginal opening called the introitus, leading to the interior vaginal canal (Holland, 2018) (Figure 1.1).

THE VAGINA

Contrary to common belief, "vagina" specifically refers to the interior muscular canal that connects the vulva to the cervix, not the entire female reproductive organ. Located between the bladder and the rectum, the vagina has folds called rugae that let it stretch and expand under pressure (Telfer, 2021) (Figure 1.2). The wider region at the back of the vaginal canal is referred to as the vaginal fornix. This creates an increase in diameter around the cervix, allowing the cervix to slightly protrude into the vaginal canal (National Cancer Institute, 2022).

VAGINAL SIZE

Historically, the anatomy of the vagina has been poorly studied. To complicate matters, determining baseline dimensions is difficult because it varies significantly among women (Barnhart, 2006). To address this challenge, Barnhart (2006) conducted a study that revealed an average vaginal length of 62.7mm, with a range from 40.8mm to 95mm. Interestingly, this measurement varies significantly between sources. For instance, Marieb (2015) describes the length of the vagina as 80mm to 100mm. Although these two ranges overlap, the average length from Barnhart's study does not align with the range specified in Marieb (2015), justifying the uncertainty surrounding vaginal dimensions.

Barnhart, (2006) also identified variations in the width of the vagina throughout its length. The smallest width is observed at the introitus (the entrance of the vagina), averaging 26.1mm. From the introitus to the fornix, the width increases, reaching its highest average transverse diameter of 41.9mm at the vaginal fornices.

VAGINAL SHAPE

The depiction of the vagina as an open tube in many diagrams does not reflect its actual physiological state. Instead, Barnhart (2004) revealed through MRI images that in a relaxed state, the walls of the vagina are flattened under the pressure of surrounding tissues and organs in the pelvis, as shown in figure 1.2

VAGINAL PRESSURE

To properly design the C-Spec, it is important to research the amount of pressure applied to the screening device, since it will be entering the vagina and will be opened after insertion. A study conducted by Egorov (2018), explored vaginal penetration pressure by inserting a probe of diameter 26mm, lined with 96 pressure sensors and asking participants to contract their vaginal wall muscles. Findings revealed the maximum contraction force of 9.52 Newtons, with a mean value of 3.2 Newtons.

Clarke (2018) identifies a interesting factor affecting vaginal penetration. Specifically, using a speculum during cervical cancer screenings is particularly challenging when women have a higher body weight. This is particularly relevant in Africa, including Cameroon, where there is a cultural preference for larger body sizes among females, contributing to an increasing prevalence of obesity (Pradeilles, 2022). Understanding these dynamics is crucial given the context in which the C Spec will be used.

THE CERVIX

Shaped like a small cylinder, the cervix sits at the end of the vaginal canal. Its purpose is to connect the vagina to the uterus. The cervix is composed of different sections (Figure 1.3). The first section of the cervix is called the internal ostium (OS), which is the opening that leads to the uterus. Moving downward, we reach the endocervix, the inner part of the cervix that connects the uterus to the vaginal canal. The

THE VULVA

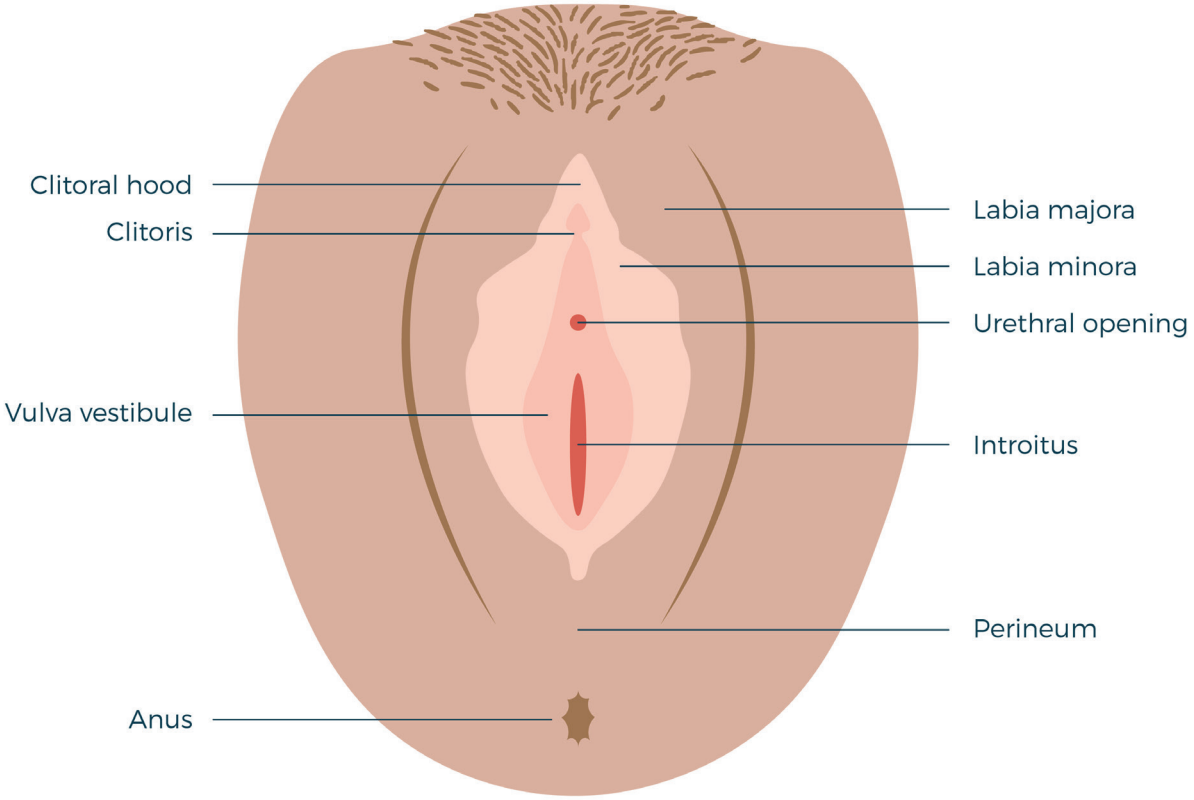


Figure 1.1 - The anatomy of the vulva

FEMALE GENITALIA SAGITTAL PLANE

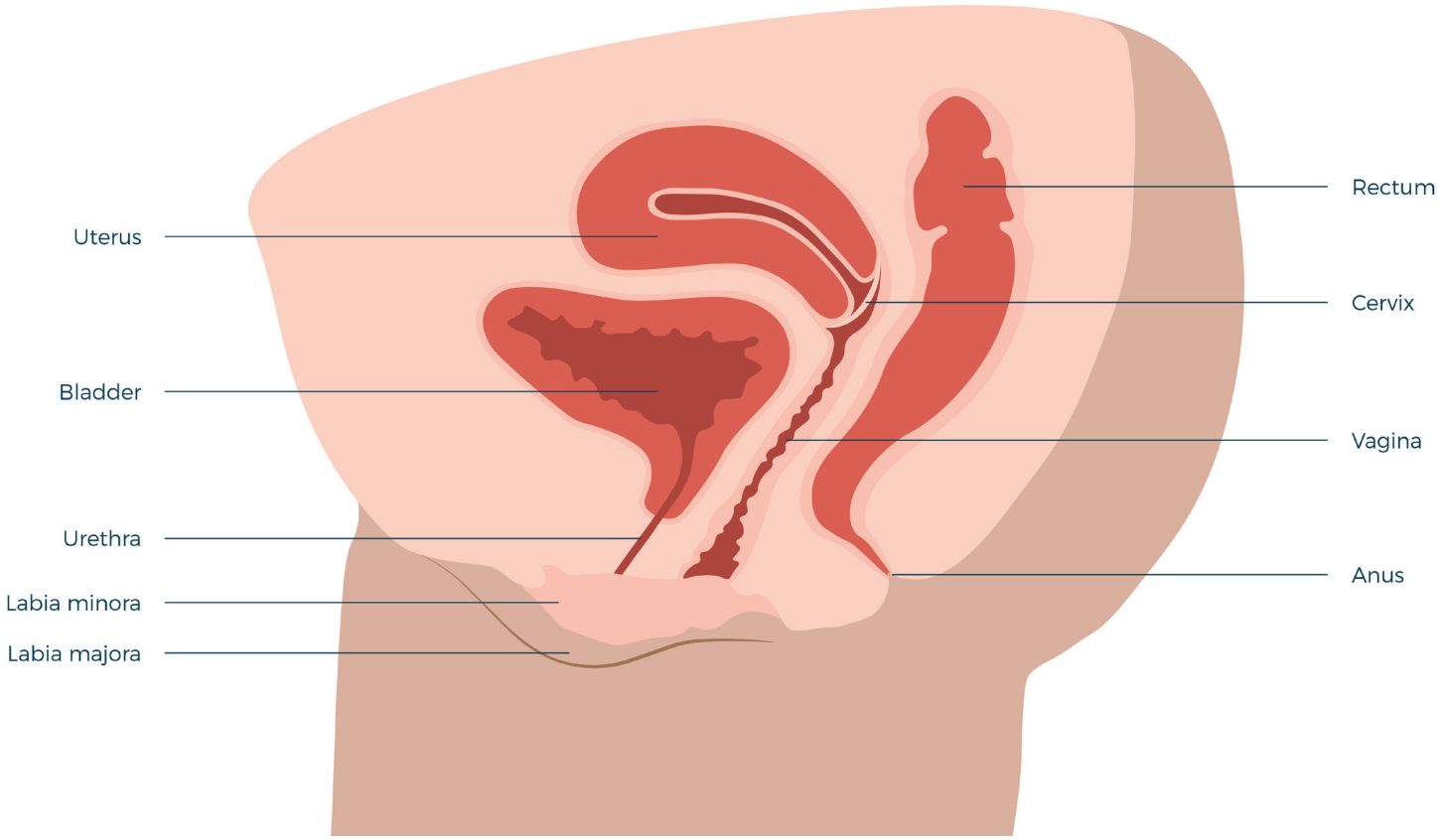


Figure 1.2 - The anatomy of the female genitalia sagittal plane

endocervical canal traverses the endocervix and extends from the internal OS to the ectocervix. The ectocervix is the outer part of the cervix visible during gynaecological exams. Finally, the external OS is the opening of the cervix leading to the vaginal canal (National Cancer Institute, 2023).

CERVIX SKIN TYPES AND TRANSFORMATION ZONE

The cervix is lined by two main types of epithelium: squamous and glandular. The region where these two epithelium meet is defined as the squamocolumnar junction (SCJ), characterised by a distinct boundary due to the difference in epithelium cell height (Figure 1.4) (Prendiville, 2017). This junction is dynamic, migrating from its initial position in the endocervical canal to the ectocervix during early adolescence and first pregnancy. The area between the original SCJ and its new location is known as the transformation zone (TZ). Given that cell changes occur frequently at the TZ, this region consists of vulnerable skin and is therefore of particular interest for cervical cancer screenings (Cleveland Clinic, 2022).

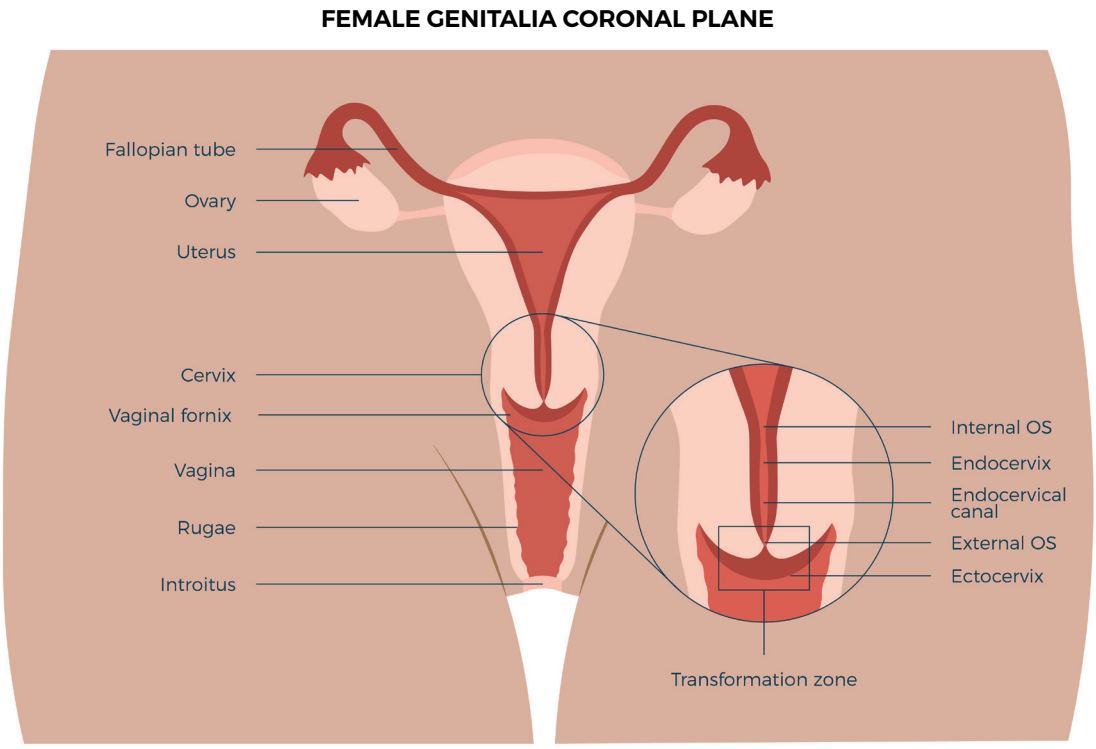


Figure 1.3.- The anatomy of the female genitalia coronal plane

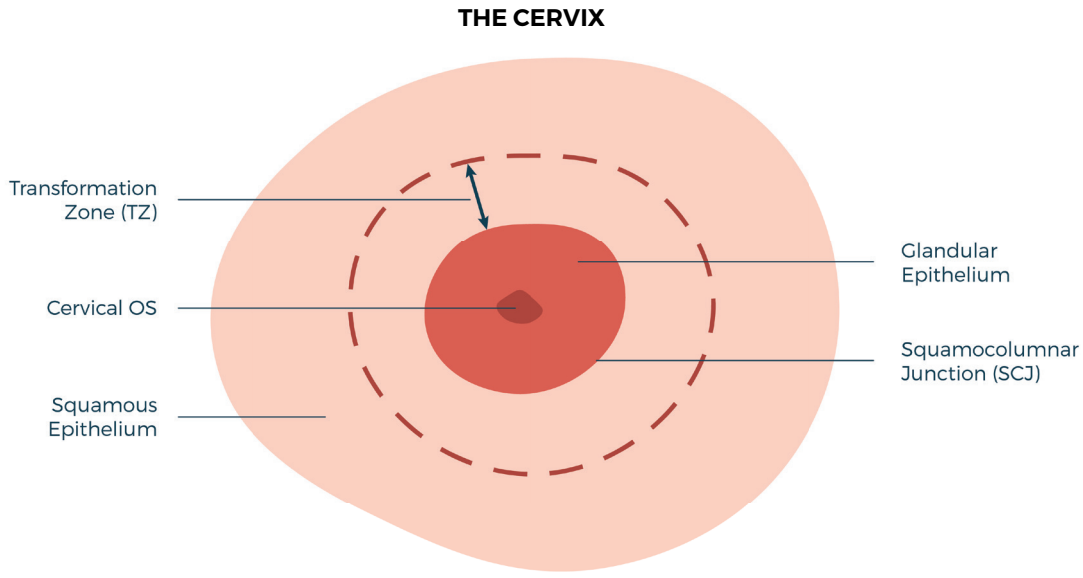


Figure 1.4 - The anatomy of the Cervix in the transverse plane

1.2 | CERVICAL CANCER

HPV AND CERVICAL CANCER

Cervical cancer arises from the abnormal growth of cells in the cervix, which can gradually transform into cancerous cells if they are not destroyed or removed. This cell development process is known as the stages of dysplasia (National Cancer Institute, 2023). Various factors can trigger dysplasia, but the leading cause, accounting for 95% of all cervical cancer cases, is persistent infection with the human papillomavirus (HPV)(WHO, 2022).

HPV is a sexually transmitted disease that most sexually active men and women will be infected with at some point in their lives. There are over 100 strains of HPV, but HPV 16 and HPV 18 are responsible for 70% of cervical cancer cases worldwide (National Cancer Institute, 2023).

When a woman is initially infected with HPV, the body reacts similarly to a skin infection. In over 90% of these cases, the body clears the infection within a year or two without the woman experiencing any issues (WHO, 2022; Koot, 2021). These short-term infections typically do not lead to cancer. In some cases, however, the infection persists, and if left untreated, it can progress to abnormal cell development, resulting in precancerous lesions and ultimately cervical cancer (National Cancer Institute, 2023). In women with weakened immune systems, cervical cancer can develop in 5-10 years, whereas it takes 15-20 years to develop in women with normal immune systems (WHO, 2022).

INCREASED RISK FACTORS OF HPV

Factors that can increase an individual's risk of persistence of HPV are as follows:

- Multiple Sexual Partners
- Weakened Immune System
- Smoking
- Birthing multiple children
- HIV
- Obesity

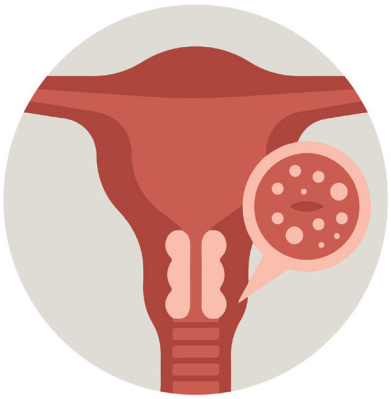
PREVENTION

Cervical cancer is highly preventable and curable if detected early (National Cancer Institute, 2023). Given that the progression from initial HPV infection to precancerous lesions typically takes at least 5 years, there are ample opportunities for early detection. This likelihood is further increased through the implementation of the following three layers of cervical cancer prevention (Koot, 2021):

LAYERS OF PREVENTION

Primary prevention - Vaccination

Recommended that boys and girls are vaccinated between the ages of 9 and 14 before becoming sexually active, as this provides more protection (WHO, 2024).



Secondary prevention - Screening

Cervical cancer screenings for HPV infections and/or cervical lesions. More detail on this prevention method will be provided in subsequent sections of the report.

Tertiary prevention - Treatment

If abnormal cells or lesions are found on the cervix, they should be treated accordingly with appropriate follow-up care. More detail can be found in appendix A.

1.3 | CERVICAL CANCER SCREENING

CERVICAL CANCER SCREENING

Cervical cancer screening is a vital secondary prevention method aimed at detecting precancerous or cancerous lesions present on the cervix (WHO, 2022). Regular screening is crucial as precancerous lesions often present no symptoms, allowing cervical cancer to go undetected (WHO, 2024). Early detection of cervical (pre)cancer lesions enables timely diagnosis and treatment, reducing mortality and morbidity. It also reduces the need for aggressive treatment interventions (WHO, 2022).

The WHO (2024) recommends that women undergo cervical cancer screening every 5-10 years starting from the age of 30. The decision to start cervical cancer screenings at the age of 30 is twofold. Firstly, cervical cancer is most prevalent among women aged 30 to 60 years (American Cancer Society, 2024; RIVM, 2023). Secondly, it is common for individuals under 30 to test positive for HPV however, the infection often clears within one or two years, reducing the need for treatment (Mayo Clinic, 2023).

SCREENING METHODS

Once a woman falls within the age range eligible for screening, various options are available depending on the screening phase, country, and available resources.

HPV DNA:

The HPV DNA screening method involves testing for the presence of HPV using a vaginal mucus swab. Since cervical cancer originates from a persistent HPV infection (WHO, 2022), a negative result on a HPV DNA test effectively rules out the presence of precancerous or cancerous lesions (WHO, 2021). The WHO (2021) recommends it as a preferred screening method due to its effectiveness in detecting and preventing cervical cancer, providing an objective diagnosis free from human error.

Cytology (Pap Smear):

A Cytology test, commonly known as a Pap Smear, involves inserting a speculum into the woman's vagina to open the vaginal canal, and collecting skin cells from the surface of the cervix using a small brush. These cells are examined under a microscope for abnormal changes or signs of cervical cancer (National Cancer Institute, n.d.).

Colposcopy:

A colposcopy involves inserting a speculum into the woman's vagina and using a colposcope to view the cervix and vaginal canal (Mayo Clinic, 2022). The colposcope, a microscope instrument that magnifies the cervix and vaginal wall tissue to be examined by the healthcare professional, stays outside the vagina (Cleveland Clinic, 2022).

Visual Inspection

Visual inspection is a screening method where the cervix is viewed with the naked eye. Two solutions can be used, that when applied to the cervix, highlight abnormal lesions. These solutions are acetic acid (VIA), and lugol's iodine (VILI).

In VIA, a 5% acetic acid solution is sprayed on the cervix, causing it to react with the epithelium tissue layer after about 1 minute. This reaction causes abnormal lesions to turn white while normal epithelium tissue remains pink (Figure 1.5) (Sankaranarayanan, 2003).

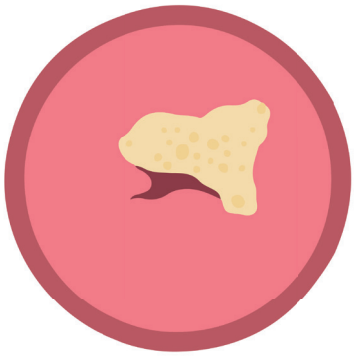


Figure 1.5 - Visual Inspection with Acetic Acid reaction

In VILI, lugol's iodine is utilised to dye the epithelium tissue layer of the cervix. Areas of abnormal cell development, do not take up iodine and therefore appear yellow (Figure 1.6) (Sankaranarayanan, 2003).

Figure 1.6 - Visual Inspection with Lugol's Iodine reaction

The VIA and VILI screening procedures often occur consecutively because the results provide the healthcare professional with different information, both useful for final diagnosis. Through field research in Cameroon, it was found that the VIA procedure is always performed before VILI, because the acetic acid reaction is temporary, while lugol's iodine stains the cervix for a few hours.

FEASIBILITY OF SCREENING METHODS IN LRS

A cervical cancer screening method is chosen based on the phase in the screening, the country in which the screening is taking place, and the available resources. Table 1.1 explores the feasibility of the previously mentioned screening methods within a LRS.

FEASIBILITY OF SCREENING METHODS IN LRS

METHOD	RESULT TIMELINE	POSITIVES	NEGATIVES
HPV DNA *(RIVM, 2014)*	· Wait at least a week · Cannot collect enough samples to run daily	· Objective diagnosis · Free of human error or interpretation	· High cost of buying and running machine · Less affordable unless subsidised
Pap Smear *(Mayo Clinic, 2022) (RIVM, 2014)(IARC, 2022) (Cleveland Clinic, 2022)*	· Three weeks · Backlog of samples and low number of pathologists	· N/A	· Depends on pathologist expertise · Subjective · Very expensive
Colposcope *(Cooper, 2023)*	· Results directly after procedure	· View from outside the vagina reducing sterilisation need	· Depends on pathologist expertise · Highly subjective · Very expensive
VIA/VILI *(Allanson, 2021)*	· Results directly after procedure	· Cost effective · Simple procedure · Effective in LRS	· Depends on pathologist expertise · Highly subjective

Table 1.1 - Showing the feasibility of screening methods in the low resource setting

SCREENING FRAMEWORK

After any cervical cancer screening method, a number of scenarios can follow (Figure 1.7):

The following section is based on consolidated results gathered from several interviews with healthcare professionals along with observations during field research in Cameroon.

Inconclusive: Further investigation is required, possibly involving repeating the screening test, using another screening method, or performing a biopsy.

Negative: No further investigation is necessary. The woman is advised to return for another screening procedure in 5-10 years (3 years for women with HIV).

Positive: If the result is positive, various scenarios can occur. If the positive result is from a HPV DNA test, further investigation is needed using other screening methods. If subsequent tests provide a negative result, then the woman is recommended to return for another screening after 5-10 years. However, if further screening methods return with positive results, treatment will be necessary.

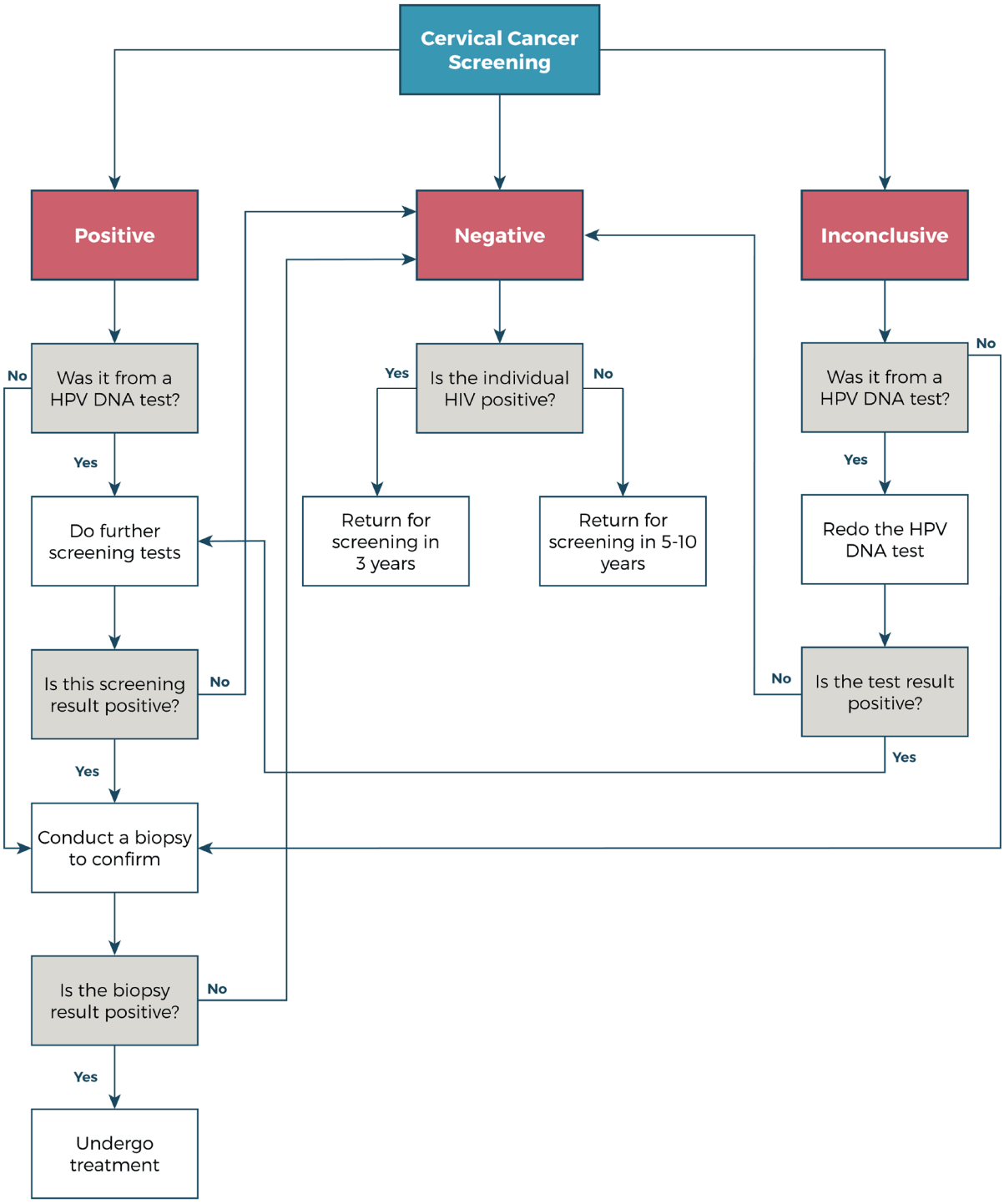


Figure 1.7 - A self designed illustration showing the cervical cancer screening process (derived from interviews and observations during field research in Cameroon)

1.4 | APPARATUS STERILISATION

"Sterilisation is the use of a physical or chemical procedure to destroy all microbial life, including resistant bacterial spores"(Cohen, 2010). Proper sterilisation procedures are crucial to prevent contamination and/or transmission between patients (Sellors, n.d.).

SPAULDING'S CATEGORIZATION

Spauldings categorization classifies medical instruments based on the degree of sterilisation required (Sellors, n.d.). Since a speculum comes into contact with the mucous membrane during a cervical cancer screening, it is considered a critical instrument and must undergo a rigorous sterilisation procedure (Sellors, n.d.). This process, shown in figure 1.8 (Sellors, n.d.).

DECONTAMINATION

After screening, the speculum must first undergo a decontamination process by being placed into a clean plastic bucket with 0.5% chlorine solution for 10 minutes. This step inactivates microorganisms, ensuring safe handling for healthcare professionals during the subsequent cleaning procedure (Sellors, n.d.).

CLEANING

Cleaning involves using a brush, soap and running water to manually remove all biological matter, such as mucus, from the speculum. Special attention must be given to joints or screws, as biological matter can get stuck in these crevasses (Sellors, n.d.).

STERILISATION

This final stage involves removing all microorganisms and bacteria from the speculum. This can be achieved through high temperature/pressure sterilisation using an autoclave, or through chemical methods by placing the speculum into a chemical bath (Cohen, 2010).

HIGH LEVEL DISINFECTION

In situations where sterilisation is not feasible, such as in LMICs, high level disinfection (HLD) serves as a good alternative (Sellors, n.d.). Similar to the decontamination stage, HLD exposes the speculum to a chemical bath; however, the instrument is placed in a higher concentration chemical bath and for a longer period of time (Steris, 2023).

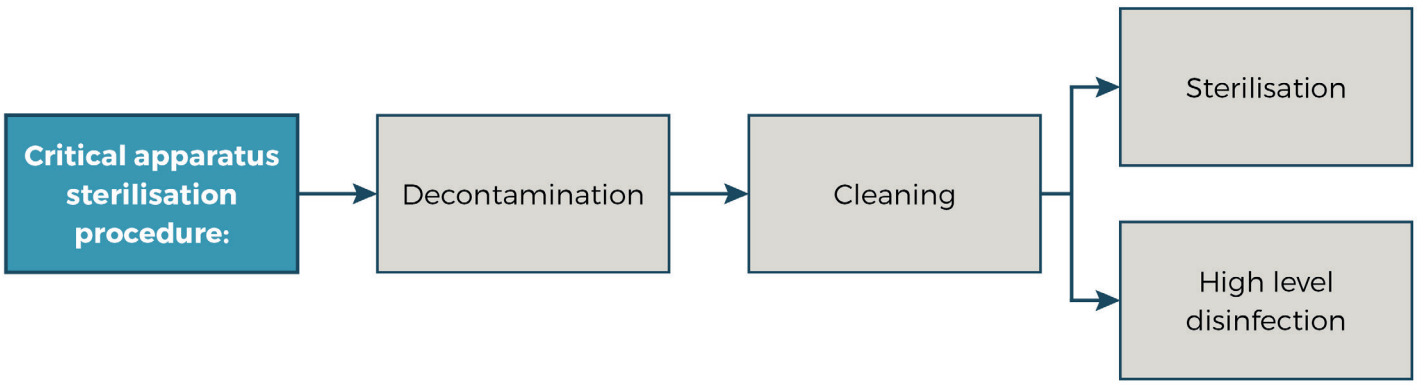


Figure 1.8 - Illustrating the sterilisation procedure for a medical apparatus classified as critical

1.5 | WHO PREVENTION STRATEGY

CERVICAL CANCER EPIDEMIOLOGY

According to the WHO (2022), cervical cancer is the fourth most prevalent cancer among women, with approximately 604,000 diagnoses and 342,000 deaths worldwide in 2020. Notably, 90% of these cervical cancer-related deaths occur in LMICs, with 22.5% originating from Africa. These statistics are alarming for a disease that is both preventable and treatable if diagnosed early (UICC, 2022). Mortality rates for 2022, depicted in figures 1.9 and 1.10, highlight the prevalence of the disease in LMICs.

PREVENTION METHOD INFLUENCE

While Africa bears the highest burden of cervical cancer globally, the region has the lowest rate of cervical cancer prevention measures, such as HPV vaccines and regular screenings, within their healthcare systems (UICC, 2022). Figure 1.10 illustrates the lifetime screening coverage for cervical cancer in women ages 30-49 in 2019 (Bruni, 2022).

High income countries (HIC) have experienced a decline in cervical cancer cases in recent years, thanks to the successful implementation of prevention methods. In contrast, LMICs continue to face challenges in combating cervical cancer (Allanson, 2021).

WHO STRATEGY

To address the pressing issue of cervical cancer in LMICs, the WHO has created a strategy aimed at accelerating the elimination of cervical cancer known as the 90-70-90 targets, to be achieved by 2030 (WHO, 2020):

90% of girls fully vaccinated with the HPV vaccine by the age of 15

70% of women screened using high-performance tests by the age of 35 and again by 45

90% of women diagnosed with cervical cancer receive appropriate treatment

SCREEN AND TREAT STRATEGY

The WHO developed a cervical cancer screen and treat strategy. This involves screening women for cervical cancer and immediately treating those who test positive for (pre) cancerous lesions. This approach addresses the issue of loss to follow up, which often occurs due to barriers such as a lack of funding, fear of treatment, and lack of understanding (UICC, 2022).

The recommended screening technique within this strategy is VIA/VILI. This recommendation is due to its affordability, simplicity, and effectiveness in resource-constrained settings. Equipment required for more advanced screenings, such a colposcopy, are often too expensive for many poorly funded healthcare systems. Additionally, pap smears are also not feasible due to a shortage of pathologists available to analyse the cell samples (Allanson, 2021).

SCREEN, TRIAGE AND TREAT STRATEGY

VIA/VILI exhibits a low specificity and sensitivity. A study conducted by the International Agency for Research on Cancer (IARC) involved the screening of 16,530 women, and showed that the labelling of VIA positive results ranged from 0.7% to 17.6% (UICC, 2022). This variability demonstrates the challenge in providing an accurate diagnosis using VIA/VILI (UICC, 2022).

To tackle this issue, the WHO implemented the screen, triage and treat strategy. This strategy introduces an additional step by first conducting a HPV DNA test. Given that most cervical cancer cases originate from HPV, a negative test result eliminates the need for further screening procedures. This approach offers a more objective test result, reducing the number of misdiagnosed cases (UICC, 2022). If the test is positive, a VIA/VILI procedure is performed as the triage phase to determine if the individual is eligible for treatment (WHO, 2021).

The focus of this project will be to support and facilitate the cervical cancer screening process, aiming to increase the global screening rate to 70% by the age of 35.

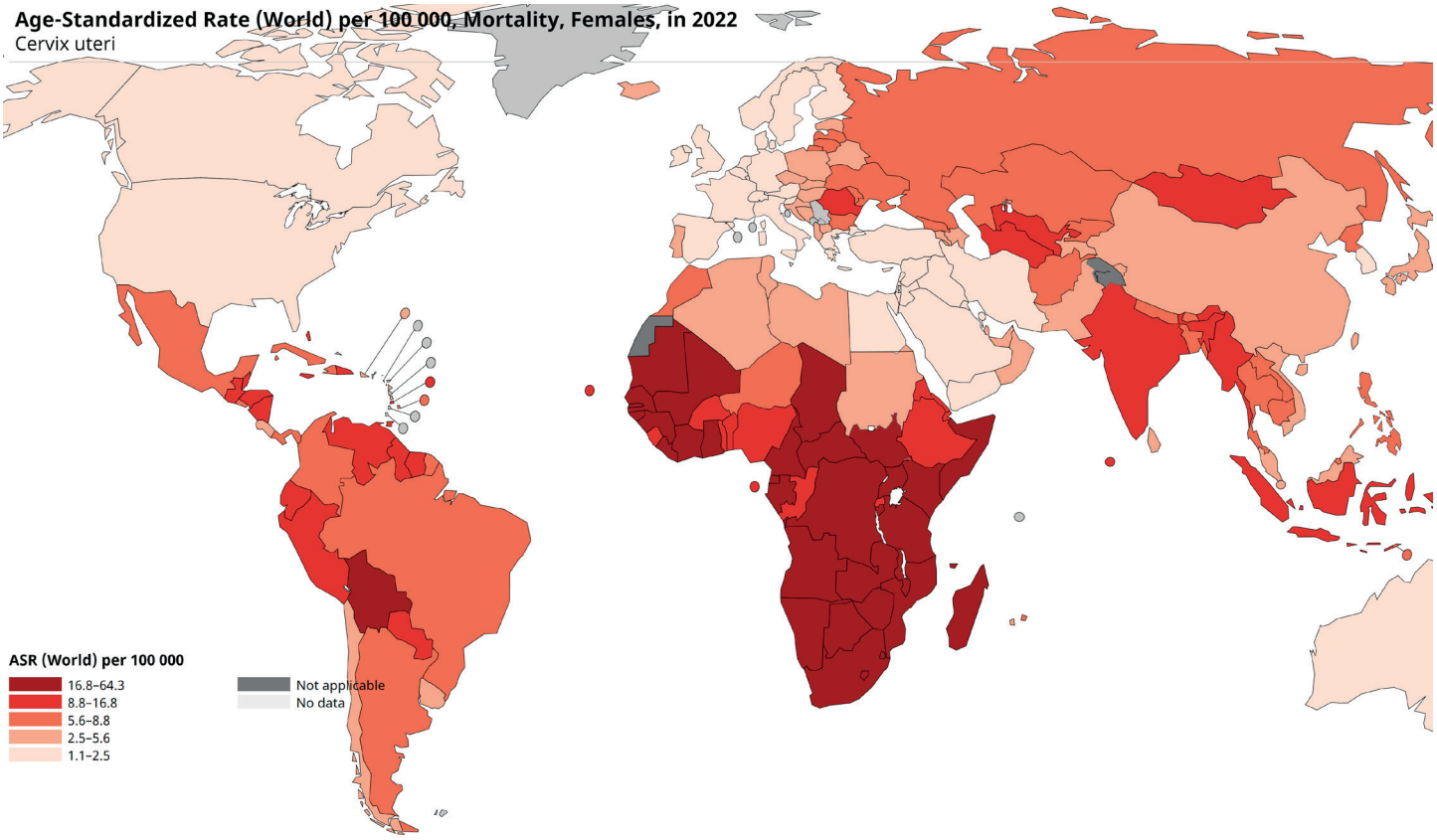


Figure 1.9 - Age standardised rate (world) per 100,000 mortaling, females, in 2022 (IARC, 2022)

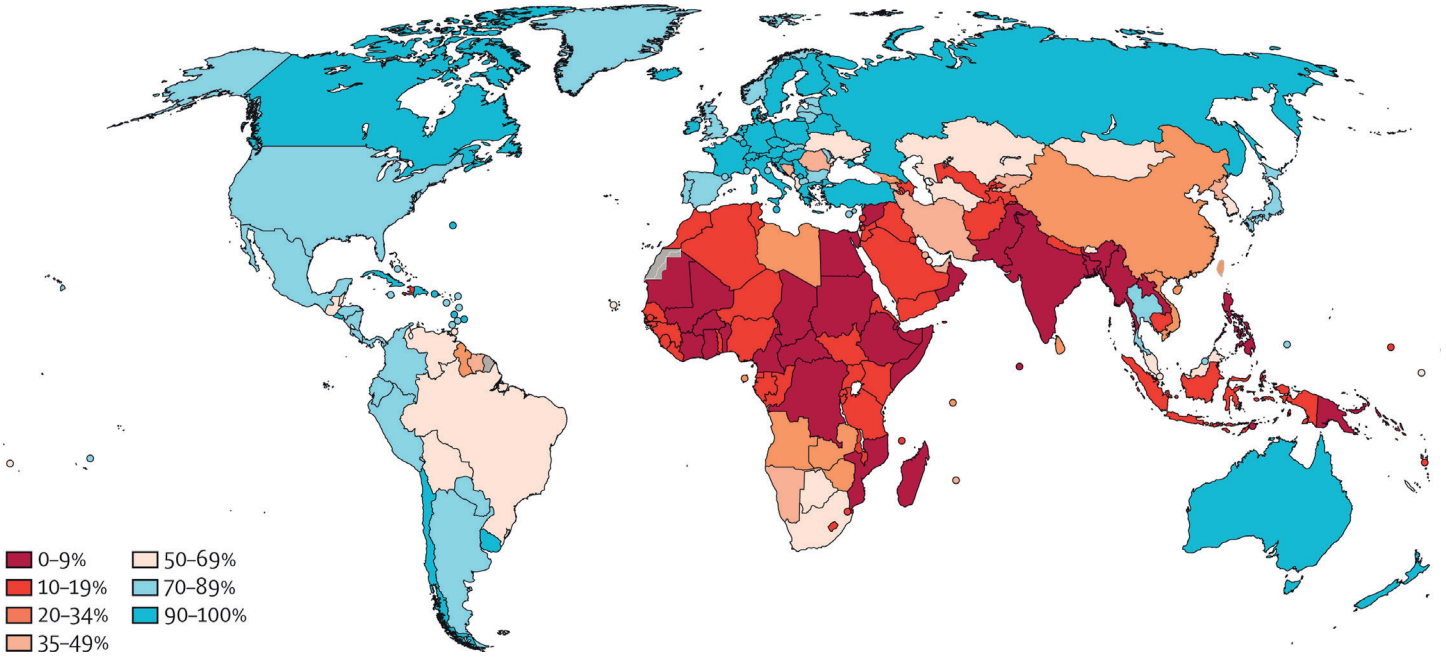


Figure 1.10 - Ever in lifetime cervical cancer screening coverage in women aged 30–49 years in 2019 by country (Bruni, 2022)

1.6 | CERVICAL CANCER IN CAMEROON

PROJECT BACKGROUND

During this project, Cameroon is used as the target research location due to the involvement of stakeholder GIC Space in this region. Field research was conducted in Yaounde, Cameroon and involved interviewing healthcare professionals and observing screening procedures.

CURRENT SCREENING EFFORTS

Cameroon has a population exceeding 29 million people (United Nations, n.d.) where it is estimated that in 2023, a mere 6% of women aged 30-49 had ever undergone a cervical cancer screening (IARC, 2023). This number is extremely low compared to the WHO's target of 70% of women being screened by the age of 35 (WHO, 2020).

In Cameroon, women can get screened for cervical cancer in hospitals, clinics, or during campaigns held in rural areas. Screenings conducted during campaigns are often subsidised by the hosting hospital, making them free of charge, as discovered during field research. However, outside of these campaigns, women are required to cover the costs themselves. This presents women with a significant financial barrier since they perceive the procedure as expensive, particularly considering potential follow up treatments (Biddell, 2021)

VIA/VILI AS A KEY PILLAR

The WHO has transitioned from recommending the "screen and treat" strategy to the "screen, triage, and treat" strategy with the introduction of HPV DNA tests to improve screening accuracy and reduce misdiagnoses (WHO,2021; UICC, 2022). However, field research conducted in Cameroon revealed that there are only two HPV DNA machines available in the country, making access to HPV DNA testing limited. The VIA/VILI screening procedure therefore remains crucial for cervical cancer screenings in LMICs, due to its affordability, simplicity and effectiveness (Allanson, 2021).

Even when HPV DNA testing is available, a VIA/VILI procedure is conducted following a positive or inconclusive HPV DNA result. The VIA/VILI procedure is a fundamental part of screening in LMICs, with or without HPV DNA testing.

CHALLENGES AND NEED FOR IMPROVEMENT

Reliance on VIA/VILI presents challenges due to its limited sensitivity and specificity (UICC, 2022). Improving the VIA/VILI screening method is essential to achieving the WHO 90-70-90 goals by 2030 (WHO, 2020). Enhancements in training, equipment, and procedural accuracy are necessary to ensure more reliable and effective cervical cancer screening in resource-constrained settings like Cameroon.

Figure 1.11 - Treatment oom at Sante Espoir Healthcare Practice in Yaounde, Cameroon

1.7 | KEY INSIGHTS CONTEXT

- The length of the vagina ranges from 40.8mm (Barnhart, 2006) to 100mm (Marieb, 2015).
- The vagina walls are flattened due to pressure from surrounding organs (Barnhart, 2004).
- Vaginal wall pressure is higher in women with a higher body weight making cervical cancer screenings more difficult in Africa since their is a preference towards larger women (Clarke, 2018) (Pradeilles, 2022).
- Cervical cancer is the development of abnormal cell growth in the cervix and is highly preventable and highly curable if detected early (National Cancer Institute, 2023).
- Development of cervical cancer takes on average at least 5 years, providing ample opportunities to detect the pre-cancer early through one of the three layers of prevention in the form of vaccination, screening and treatment (Koot, 2021).
- Africa bears the highest burden of cervical cancer but they have the lowest rate of prevention measures (UICC, 2022).
- The WHO developed the 90-70-90 targets, that aims to increase the global screening rate to 70% by 2030. In many parts of Africa this rate is lower than 10% (WHO, 2020)
- Visual inspection is a screening method where healthcare professionals view the cervix with the naked eye. Acetic acid and Lugol's iodine are solutions that are applied to highlight abnormal areas on the cervix.
- Visual inspection is the preferred screening procedure due to its affordability, simplicity and effectiveness in LRS.
- A speculum is classified as a critical medical instrument and must therefore undergo a process of decontamination, cleaning and finally sterilisation or HLD (Sellors, n.d.).
- During the cleaning phase, all surfaces must be cleaned with a brush and soap and extra attention must be placed on joints to remove biological matter.
- This projects aim will be to support the cervical cancer screening process using visual inspection, aiming to increase the global screening rate to 70%.

Cervical Cancer Explanation with a Consent of GIC Space

SECTION 2

CERVICAL CANCER SCREENING PRODUCTS

2.1 | THE TRADITIONAL SPECULUM

WHAT IS A SPECULUM?

A speculum is a medical instrument, typically made of metal or plastic, used to dilate the vaginal canal for various purposes such as visualising the female genitalia, collecting samples, or conducting cervical cancer screenings (Pardes, 2017). During these procedures, the speculum is inserted, and the handle is squeezed to expand the introitus and the vaginal canal. The flaps are then locked in place by turning the nut until tight.

SPECULUM DISCOMFORT BARRIER

Many patients complain of significant discomfort or pain during gynaecological exams when a speculum is used (Kent, 2020). This discomfort arises as the walls of the vagina are stretched significantly to properly visualise the cervix with the naked eye (Pardes, 2017). For this reason, fear and anxiety surrounding these exams can act as barriers to cervical cancer screenings, especially for women undergoing a gynaecological exam for the first time (Calla Health Foundation, n.d.).

Pre-existing fear and anxiety can exacerbate discomfort during the exam. Nervousness can cause the muscles of the vagina to tense, increasing pain during the procedure. Additionally, having tense vaginal walls can make inserting and opening the speculum more challenging for the healthcare professional, prolonging the screening process (Nella Spec, n.d.). In some cases, excessive pressure from the vaginal walls can cause the disposable speculum to break, posing a risk of injury, as expressed by healthcare professionals during interviews.

APPARATUS USED

The speculum is currently the standard piece of equipment used during VIA/VILI screenings in Cameroon. To properly conduct the screening, additional equipment is needed which is shown in figure 2.1

STERILISATION AFTER PROCEDURE

Through interviews conducted in the field, healthcare professionals expressed that 98% of the time, a disposable speculum is used for cervical cancer screenings. Patients prefer disposable speculums because the plastic material is not as cold as the metal speculum, and they feel more reassured that the disposable speculum is clean. Additionally, cleaning the metal speculum requires following the "critical sterilisation procedure", which is labour intensive for healthcare professionals (Sellors, n.d.).

SCREENING APPARATUS LIST

Speculum — Inserted into the vagina to open the vaginal canal to view the cervix

Forceps — Used to hold the gauze when wiping the cervix for mucus and excess liquid

Gloves — Worn by the healthcare professional to ensure a sanitary procedure

Phone camera — Used to take pictures of the cervix from outside the vagina for diagnosis

Head light — Worn by healthcare professionals to shine light on the cervix

Acetic acid — Sprayed onto the cervix using a syringe to visualise the (pre)cancerous lesions

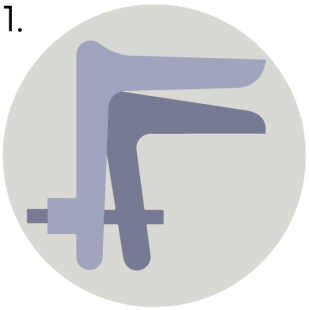
Gauze — Used to wipe away mucus for better visualisation of the cervix

Lugol's iodine — Sprayed onto the cervix using a syringe to visualise the (pre)cancerous lesions

Figure 2.1 - Apparatus list during screening using a Traditional Speculum

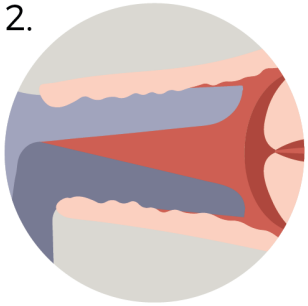
SPECULUM STORYBOARD

1.



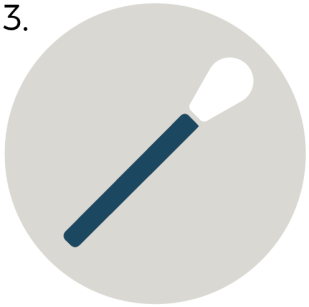
STEPS 1 - 4
Prepare apparatus, including the traditional speculum

2.



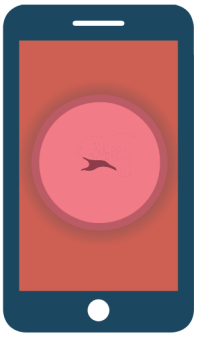
STEPS 5 - 8
Insert the speculum into the vagina, open and lock

3.



STEP 9
Remove mucus from the cervix using a cotton swab

4.

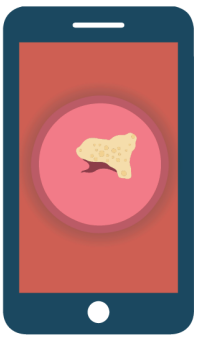


STEPS 10 - 11
Use a mobile phone to take photos of the cervix

5.

STEPS 12 - 14
Spray Acetic Acid solution onto the cervix

6.

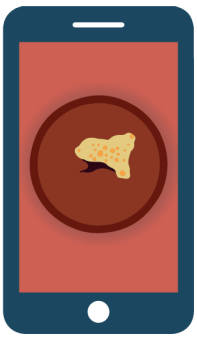


STEPS 15 - 16
After one minute use a mobile phone to take photos of the cervix

7.

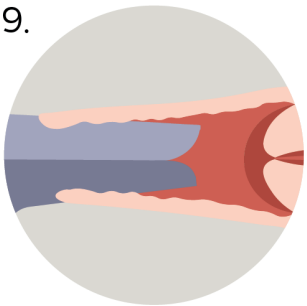
STEPS 17 - 18
Spray Lugol's Iodine solution onto the cervix

8.



STEPS 19 - 20
Use a mobile phone to take photos of the cervix

9.



STEPS 21 - 25
Remove the speculum and conduct sterilisation procedures

SPECULUM SCREENING INSIGHTS

During field research conducted for this project, a number of VIA/VILI screenings were observed and interviews were performed with healthcare professionals. Table 2.1 provides a step by step explanation of how such a screening is performed, including insights where applicable. The visual storyboard references the steps in this table.

	1.	2.	3.	4.	5.
	Preparation of the supplies	Apply gloves to both hands	Pick up speculum with one hand	Insert the speculum into the vagina	Open the speculum by squeezing the handle
DETAILS	Speculum, gauze, forceps, mobile phone, acetic acid, logol's iodine		Use the other hand to open the vulva	Insert sideways as the side profile is thinner, and rotate while inserting	
INSIGHTS	Screening conducted by one HCP unless complications arise		Opening the vulva aids in insertion of the speculum	No lubrication or wetting of the speculum with water was done	Strenuous due to the pressure of vagina. Possible pain for patient

	6.	7.	8.	9.	10.
	Lock the speculum by screwing the nut	Cervix should now be visible	Remove gloves from both hands and throw	Wipe away vaginal mucus using forceps and gauze	Take a photo of the cervix using mobile phone
DETAILS		If cervix not visible, ask patient to cough or use speculum handle to reposition	Gloves are removed to not contaminate the mobile phone	Mucus can obstruct view of the cervix and cause possible misdiagnosis	Use one hand to hold the camera and other hand to zoom, focus and flash
INSIGHTS	If vagina pressure is too high, mechanism on disposable speculum can break	If patient has a retroverted cervix, extra HCP holds speculum in place	Increases waste and HCP not protected if accidentally touch patient		Difficult to stabilise camera, causing blurry photos

	11.	12.	13.	14.	15.
	Take 2-3 photos	Spray Acetic acid solution on the cervix	Wait 1 minute to allow acetic acid to react on skin	Remove excess liquid using forceps and gauze	Take photos of the cervix using mobile phone
DETAILS	This is to ensure at least one good photo is taken that is not blurry	Using a needle to spray from outside the vagina to keep syringe sterile			Use one hand to hold the camera and other hand to zoom, focus and flash
INSIGHTS		Patients get scared as concern HCP will prick them with the needle		Note to remember: This is done without gloves	Patients confronted with camera and question what will be done with photos

	16.	17.	18.	19.	20.
	Take 2-3 photos	Spray Logol's iodine solution on the cervix	Remove excess liquid using forceps and gauze	Take a photo of the cervix using mobile phone	Take 2-3 photos
DETAILS	This is to ensure at least one good photo is taken that is not blurry	Using a needle to spray from outside the vagina to keep sterile		Use one hand to hold the camera and other hand to zoom, focus and flash	This is to ensure at least one good photo is taken that is not blurry
INSIGHTS		Patients get scared as concern HCP will prick them with the needle		Depending on bed height, HCP bends to take photo. Can cause strain	

	21.	22.	23.	24.	25.
	Apply second pair of gloves to both hands	Remove the speculum from the vagina	Throw away the disposable speculum	Place the forceps in the plastic bucket	Remove gloves from both hands and throw
DETAILS		Unscrew the nut of the speculum to release and pull out of vagina		Bucket contains disinfection fluid to be sterilized later	
INSIGHTS	To protect HCP from speculum removal	Unlocking of mechanism and removal can cause pain for patient	Patients and HCPs prefer a disposable speculum		Two pairs of gloves used per screening

Table 2.1 - Traditional Speculum screening insights

2.2 | OTHER EXISTING PRODUCTS

To gain understanding and to identify a potential gap in the market, existing products used in both HRS and LRS settings for cervical cancer screenings were explored. A more detailed explanation of the existing products mentioned in table 2.2 can be found in appendix C.

Existing products high resource settings:

THE PRODUCT	FEATURES	POSITIVES	NEGATIVES
Nella *(Nella Spec, n.d.)* 	· Narrow bill comparable to the size of a tampon · 4-way opening system eliminating bulging of vaginal walls	· Improved comfort during insertion · High density polymer, not cold to touch	· Still expands the introitus and vaginal walls
Yona *(Yona Care, n.d.)* 	· 3-leafed design preventing bulging of vaginal walls · Ergonomic handle for HCPs	· Silicone cover to reduce coldness · Concealing mechanisms to reduce mental stress	· Still expands the introitus and vaginal walls
Fem Spec *(Kent, 2020)* *(Parades, 2017)* 	· Balloon inserted into vagina like a tampon · Inflated similarly to blood pressure cuff	· Conforms to natural contours of the vaginal canal	· Considerable pressure needed to inflate balloon · If balloon bursts, can lead to serious complications

Existing products low resource settings:

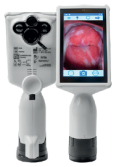
THE PRODUCT	FEATURES	POSITIVES	NEGATIVES
Callascope *(Asiedu, 2020)* 	· 9mm diameter tip to visualise cervix on a screen · Spray system to apply solution to cervix	· More comfortable screening procedure · Low cost due to reduced camera quality	· Inability to insert gauze or cotton swabs to remove mucus · Spray system still in development
Pocket Colposcope *(Duke, 2017)* 	· Camera is brought 3 cm away from the cervix	· Low cost due to reduced camera quality by bringing the camera closer to the cervix	· Requires insertion of a speculum reducing patient comfort
Gynocular *(Gynius, n.d.)* 	· Views the cervix from outside the vagina · Streamlines the training process for HCPs	· Either hand operation or using a tripod · Green filter capabilities	· Requires insertion of a speculum reducing patient comfort
Eva Pro *(Mobile ODT, n.d.)* 	· Portable, digital colposcope · Saves captured images to a cloud server	· Captures high quality images of the cervix · Green filter capabilities	· Requires insertion of a speculum reducing patient comfort

Table 2.2 - Existing cervical cancer screening products in low and high resource settings

2.3 | THE C SPEC

As previously discussed, the traditional speculum is uncomfortable to many women because the introitus and vaginal canal are stretched to view the cervix. To address this issue, GIC Space set out to design the C Spec. Since cervical cancer is highly treatable if detected early (National Cancer Institute, 2023), GIC Space aimed to increase women's participation in screenings by reducing the discomfort barrier associated with the traditional speculum.

DESIGN AND FUNCTIONALITY

The C Spec differs from the traditional speculum by only opening the walls at the back of the vagina, where the skin is more stretchy. This minimises the stretching of the introitus and the initial part of the vaginal canal, making the screening procedure more comfortable.

Instead of visualising the cervix with the naked eye, the C Spec uses an endoscopic camera connected to a mobile phone to visualise the cervix. Since the opening of the C Spec is smaller than that of the traditional speculum, a healthcare professional needs to manipulate the C Spec inside the vaginal canal to find the cervix. This manipulation, however, inflicts little to no discomfort on the patient.

C SPEC PRODUCT PARTS

Main Body:

Functions as a connection from the healthcare professional to the patient's cervix. Comprises two compartments: the camera holder, where the endoscope camera is inserted to view the cervix via a mobile phone, and the apparatus tube, where other necessary tools can be inserted.

Flaps:

The flaps have a smooth rounded shape for comfortable insertion. Once inserted, the flaps are opened to allow the camera to capture an image of the cervix.

Hook and Nut Mechanism:

This is the mechanism used to open the flaps. The nuts are turned to open and lock the flaps in place, facilitated by the metal rod, connecting the hook/nut system to the flap sides. The hooks can be pulled to widen the flaps further, allowing for tighter screwing of the nuts.

C SPEC DESIGN HISTORY

Diameter (29-32mm):

The C Spec's main body currently measures at a diameter of 29mm which is sufficient to hold the necessary apparatus while remaining comfortable for women. The founder of GIC Space expressed that there is some margin of expansion, but the diameter should not exceed 32mm.

Length:

The current length of the C Spec was not tested during the previous development phase. The depth the C Spec reaches depends on the woman. The C Spec length should facilitate the apparatus while providing enough space for the healthcare professional to hold the device.

Flap opening (45mm):

The flaps of the C Spec open to a maximum diameter of 45mm. The founder of GIC Space stated that a cervix can be as large as 70mm in diameter. For women with a larger cervix, an accurate cervical cancer diagnosis cannot be made.

Rounded flap shape:

The flaps are rounded to allow for comfortable insertion of the C Spec.

Half-moon shaped cut-out:

The base of the flaps have a half-moon shaped cut-out. This is to allow the flaps to open wider.

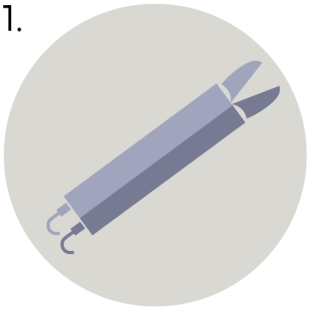
Material:

The C Spec is made from stainless steel. This material can better withstand the pressure of the vaginal walls compared to a disposable speculum and can be sterilised after a screening procedure for reuse. This material does however corrode when exposed to chemicals used during sterilisation (Steris, 2023).

Figure 2.2 - C Spec product explanation

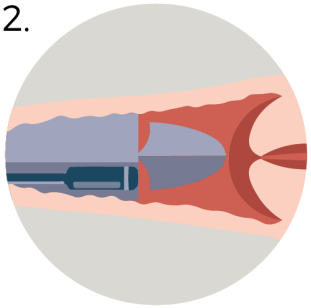
C SPEC STORYBOARD

1.



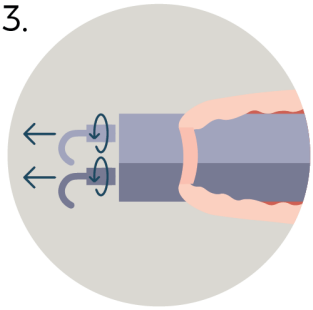
STEPS 1 - 4
Prepare apparatus including the C Spec

2.



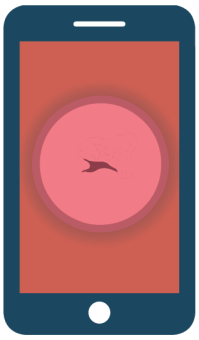
STEPS 5 - 7
Insert the C Spec into the vagina and insert the endoscopic camera

3.



STEPS 8 - 10
Rotate the nuts and pull on the hooks to open the flaps

4.

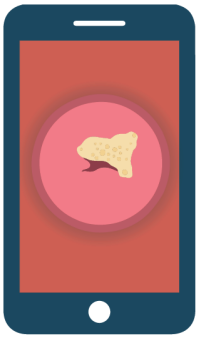


STEPS 11 - 13
Use the mobile phone to take photos of the cervix

5.

STEPS 14 - 15
Spray Acetic Acid solution onto the cervix

6.

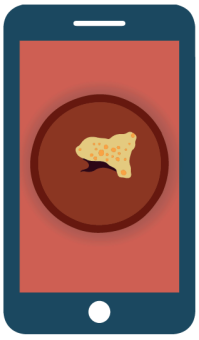


STEPS 16 - 17
After one minute use a mobile phone to take photos of the cervix

7.

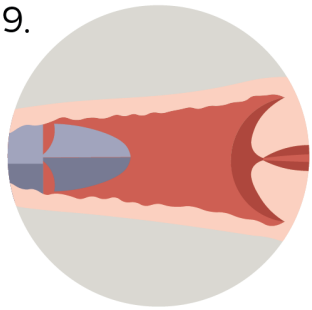
STEP 18
Spray Lugol's Iodine solution onto the cervix

8.



STEPS 19 - 20
Use a mobile phone to take photos of the cervix

9.



STEPS 21 - 25
Remove the C Spec and conduct sterilisation procedures

C SPEC SCREENING INSIGHTS

Conducting interviews and observing VIA/VILI screenings using the C Spec in Cameroon, revealed valuable insights for the future design of the C Spec. These insights can be found in table 2.2 along with a step by step explanation of the screening procedure using the C Spec. The visual storyboard to the left references the steps of the procedure in this table.

	1. Preparation of the supplies	2. Apply gloves to both hands	3. Pull the plastic sleeve over the C Spec	4. Apply lubricant to the C Spec	5. Use one hand to open the vulva
DETAILS	C Spec, sleeve, cotton swab, camera, mobile phone, acetic acid, logol's iodine		Protects patients vagina wall from pinching when flaps are opened	Use only one hand to apply lubricant	Opening the vulva aids in insertion of the C Spec
INSIGHTS	Screening conducted by one or two HCPs depending on availability		Can be difficult to pull the sleeve over the C Spec	If get lubricant on both hands, turning bolts to open flaps becomes difficult	

	6. Insert the C Spec into the vagina	7. Insert camera into camera compartment	8. To open flaps, turn nuts on opening mechanism	9. Pull on hooks to further tighten nuts	10. Rotate C Spec to find cervix
DETAILS	Twist the C Spec while inserting to cover introitus with lubricant		One nut opens one flap. Turn both nuts at the same time to open both flaps	Pulling on hooks allows for extra tightening of the nuts	Find the cervix by looking at camera view on the phone screen
INSIGHTS	Patients express no signs of pain or discomfort	Do not know how far to insert the camera. Can overshoot and touch cervix	Very difficult to turn nuts. HCP has pain in fingers after multiple screenings		Patient experiences no discomfort during manipulation of C Spec

	11. Insert cotton swab to remove mucus from cervix	12. Take photos of cervix by tapping on phone	13. Take 2-3 photos	14. Spray Acetic acid solution on cervix using spray bottle	15. Wait for 1 minute to allow acetic acid to react on skin
DETAILS	Insert the cotton swab through the apparatus cavity	If screening with one HCP, phone is attached to the arm using phone strap	This is to ensure at least one good photo is taken	Insert the spray nozzle through the apparatus cavity	
INSIGHTS	Camera view confuses HCP on orientation of the cervix. Up is not up	Phone is tapped with the gloves on, so phone is no longer sterile	No issue with blurry/shaky photo unlike with speculum	If access spray gets on camera, camera is taken out, wiped and reinserted	

	16. Take photos of cervix by tapping on phone	17. Take 2-3 photos	18. Spray Lugol's iodine on cervix using spray bottle	19. Take photos of cervix by tapping on phone	20. Take 2-3 photos
DETAILS	If screening with two HCPs, one will do screening and other will hold phone	This is to ensure at least one good photo is taken	Insert the spray nozzle through the apparatus cavity		This is to ensure at least one good photo is taken
INSIGHTS	If screening with two HCPs, other HCP will take photo to keep phone sterile	HCP does not need to bend down to take photo, reducing risk of strain		Patient confronted less with camera in C Spec compared to speculum	

	21. Remove camera from C Spec	22. Unscrew the nuts, unlocking flaps	23. Remove the C Spec from the vagina	24. Remove plastic sleeve from C Spec	25. Remove gloves from both hands and throw
DETAILS				Throw away sleeve and place C Spec in sterilization bath	
INSIGHTS	Camera not sterilized. If screening done properly, camera does not touch cervix	Patient experiences no pain or discomfort	Patient experiences no pain or discomfort	Sterilization bath is 1 part bleach to 9 parts water	One pair of gloves used per screening

Table 2.2 - C Spec screening insights

STERILISATION AFTER PROCEDURE

The C Spec is a metal product that is inserted into the vagina. The product therefore must follow the "critical sterilisation procedure" (Sellors, n.d.). Which requires thorough cleaning with a brush and soap to remove any biological matter (Sellors, n.d.).

Unfortunately, due to the difficulty of disassembling the C Spec, healthcare professionals often cannot reach all surfaces for thorough cleaning. As observed during field research in Cameroon, healthcare professionals place the C Spec in a HLD chemical bath of 0.5% chlorine for 20 minutes after the screening procedure (figure 2.4)(Steris, 2023). However, the essential cleaning stage of removing biological matter with a brush and soap is not strictly followed and is sometimes even skipped.

APPARATUS USED

To conduct a successful screening using the C Spec, various pieces of equipment are required shown in figure 2.3.

SCREENING APPARATUS LIST

C Spec	Inserted into the vaginal canal to conduct the screening procedure	**Phone holder**	Used to secure the phone holder to the healthcare professionals arm
Sleeve	Placed around the C Spec to increase comfort for patient	**Cotton swab**	Used to clear mucus from the cervix to better view it
Gloves	Worn by the healthcare professional to ensure a sanitary procedure	**Acetic acid**	Sprayed onto the cervix using a syringe to visualise the (pre)cancerous lesions
Camera	Inserted into C Spec via the camera holder tube to visualise cervix	**Lugol's iodine**	Sprayed onto the cervix using a syringe to visualise the (pre)cancerous lesions
Phone	Used to view camera view of the cervix during the screening		

Figure 2.3 - Apparatus list during screening using the C Spec

Figure 2.4 -Sterilisation of the C Spec using a chemical bath

2.4 | KEY INSIGHTS SCREENING PRODUCTS

SCREENING USING A SPECULUM

Healthcare Professional Pleasure Points

- Low learning curve to operate the speculum sufficiently
- The speculum provides a clear visual of the cervix, aiding informed diagnosis.
- Using a disposable speculum removes the need for sterilisation procedures.

Healthcare Professional Pain points

- When taking photos of the cervix, stabilising the camera is difficult.
- The stance required during the screening can cause back strain.

Patients Pleasure Points

- Patients can see photos of their cervix after the procedure.

Patients Pain Points

- The intense stretching of the vaginal canal and introitus can cause significant discomfort.
- If a woman is nervous and experiences pain, the procedure can take a long time.
- The disposable speculum can break and cause injury.
- Lack of privacy during a screening due to the closeness of the healthcare professional's face.

SCREENING USING THE C SPEC:

Healthcare Professional Pleasure Points

- More comfortable body position during the screening procedure.
- Increased personal space between the healthcare professional's face and patient's vagina.

Healthcare Professional Pain Points

- Can be difficult to find the cervix, increasing the screening procedure time.
- Strenuous to operate the hook nut mechanism resulting in finger pain for healthcare professionals.
- The C Spec is not intuitive for new users
- Lack of feedback on the degree of the flap openness inside the vagina.
- The C Spec has no orientation indication, resulting in confusion on what is up and down.
- The C Spec is difficult to disassemble. The cleaning is therefore often conducted insufficiently.
- Reduced visibility for larger cervixes due to limited flap opening.
- Little to no visual of the vaginal walls which healthcare professionals want to see.

Patient Pleasure Points

- Patient is comfortable during the screening procedure, experiencing pressure but no pain
- Increased personal space between healthcare professional's face and patient's vagina.
- Patient is able to see photos of her cervix after the screening procedure.

Patient Pain Points

- It can be difficult to find the cervix, increasing the screening procedure duration.
- Vaginal walls are pinched when opening the flaps due to their half moon shape.

Interview at Womens Health Centre, Yaounde, Cameroon

SECTION 3

DESIGN DIRECTION AND DEVELOPMENT

3.1 | FULFILLING A GAP IN THE MARKET

FULFILLING A GAP IN THE MARKET

Research into existing cervical cancer screening products in both HRS and LRS revealed a significant gap in the market. Although existing products in HRS provide healthcare professionals with a good visual of the cervix, they still do this by expanding the walls of the vagina significantly, making the procedure uncomfortable for patients.

In contrast, existing products explored in LRS offer a more comfortable method for patients to capture images of the cervix. However, these products are not able to facilitate the necessary apparatus to the cervix to conduct an effective procedure. As a result, a speculum must still be used in conjunction with these products, once again reducing comfort for the patient.

No existing product effectively combines comfortable visualisation of the cervix with the ability to transport necessary medical apparatus during the procedure. The C Spec addresses this market gap by:

Enhancing Comfort:

By only opening the walls at the back of the vagina where the skin is more flexible, the C Spec minimises discomfort compared to a traditional speculum. This design reduces the stretching of the introitus and the initial part of the vaginal canal, making the procedure more comfortable for patients.

Effective Visualisation:

The C Spec uses an endoscopic camera connected to a mobile phone to bring a lower specification endoscope closer to the cervix, providing a clear picture without the need for significant expansion of the vaginal walls.

Facilitating Medical Apparatus:

The C Spec includes a dedicated apparatus area, allowing healthcare professionals to insert necessary tools for standard VIA/VILI screenings without the need for additional speculums. This integrated approach maintains patient comfort while ensuring the procedure is conducted effectively.

THE C SPEC

The C Spec fulfils an unmet need in the market by combining patient comfort, sufficient visualisation of the cervix, and ability to insert apparatus into a single product. This innovation improves a patients' screening experience and therefore has the potential to increase participation in cervical cancer screening, ultimately aiding in the early detection and treatment of cervical cancer.

Although the patient's experience has improved, there are still considerable challenges that healthcare professionals face in regards to the functionality of the C Spec. The following section of this report will outline these problems and will identify design requirements for a new C Spec product design.

3.2 | DESIGN REQUIREMENTS

Based on the context study, the analysis of the product, and its design goals, a set of design requirements for the new C Spec design can be identified. A summary of these design requirements is as follows. The full set of design requirements, along with the insights that led to these requirements, can be found in appendix G.

Requirements Healthcare professional usability

1.1 *Screening Capacity:* Healthcare professional must be able to conduct 10 screenings per day without hand pain.

1.2 *Gripping Force:* A gripping force of maximum 300N is required to open the C Spec flaps (Nilsen, 2011).

1.3 *Feedback System:* Provide feedback on the openness of the C Spec flaps for an informed screening procedure.

1.4 *Handling with Lubricant:* The C Spec must be easy to operate even with lubricant present on both gloves.

1.5 *Single Operator:* The C Spec should only require one healthcare professional to perform the screening.

1.6 *Intuitive Design:* The redesigned C Spec must feel intuitive and familiar for new users.

1.7 *Comfortable Positioning:* The healthcare professional can maintain a comfortable standing position with elbows at 90˚ at a standard bed height of 85cm from the floor.

Requirements patient comfort

2.1 *Comfort During Procedure:* The redesigned C Spec must remain comfortable during the screening procedure.

2.2 *Maximum Diameter:* The C Spec main body must not exceed 32mm in diameter.

2.3 *No Sharp Edges:* There must be no sharp edges on the new design that come into contact with the patient.

2.4 *Personal Space:* A minimum distance of 500mm between a healthcare professional's face and the patient's vulva.

Requirements screening ability

3.1 *Apparatus Insertion:* The new flap operation system must not hinder apparatus insertion into the main body.

3.2 *Apparatus Area:* The area available for apparatus should not decrease below the current value of 555mm^2.

3.3 *Orientation:* The C Spec must have an orientation that is intuitive and easy to identify.

3.4 *Flap Lock System:* Provide a lock system that allows the flaps to remain open during the procedure.

3.5 *Rotation Ability:* The redesigned C Spec must allow for a minimum rotation of 90 degrees after insertion.

3.6 *Length:* The length must allow the healthcare professional to reach the cervix while maintaining space between their hand and the vulva.

Sterilisation

4.1 *Material Suitability:* Must be made from a material suitable for sterilisation.

4.2 *Ease of Disassembly:* Must be easy to disassemble for thorough cleaning with a brush and soap, in accordance with sterilisation procedures (Sellors, n.d.).

3.3 | DESIGN DIRECTION

Through research, it was found that the main selling point of the C Spec is that the main body is comfortable for the patient during the screening procedure. The back end of the C Spec is however very difficult for the healthcare professional to operate as previously discussed in section 2. The traditional speculum on the other hand is very uncomfortable for patients during a screening procedure but very easy for the healthcare professional to operate since the handle is intuitive, and enough strength can be applied to the handle to operate the speculum.

The decision was therefore made to take the positives of both products, and combine them to make a new product that has the main body of a C Spec but the handle operation of a traditional speculum.

RATIONALE FOR DESIGN DIRECTION

A key design goal mentioned in the design requirements that the new C Spec product should be intuitive for healthcare professionals. It is crucial that the healthcare professionals feel comfortable using the device otherwise, they will not use it. Research on existing products indicates that healthcare professionals can be resistant to transitioning to new medical devices. Lowering this barrier by making the new C Spec design feel familiar is therefore of high importance, as this allows for easier implementation and acceptance of the new C Spec design by healthcare professionals into the cervical cancer screening system.

Secondly, since healthcare professionals are less flexible to transfer to new apparatus, patient comfort during a screening procedure is sacrificed. Discomfort for the patient while using the speculum is how it has always been and what the healthcare professionals are used to. By integrating the speculum style handle with the main body of the C Spec, the patient's comfort does not have to come at the cost of the healthcare professionals preference.

BENEFITS OF A SPECULUM-STYLE HANDLE

Integrating a speculum-style handle not only addresses the need for familiarity, but also improves other points mentioned in the design goals. This integration can enhance operability and provide better feedback to the healthcare professional during use.

DESIGN DIRECTION

The design direction chosen for this project is to design and develop a speculum-style handle that maintains the current C Spec main body shape and operates the current C Spec flaps. This approach aims to allow for easy and familiar operation in cervical cancer screenings using the new C Spec, ultimately improving usability and acceptance among healthcare professionals while also providing patients wth a comfortable screening procedure.

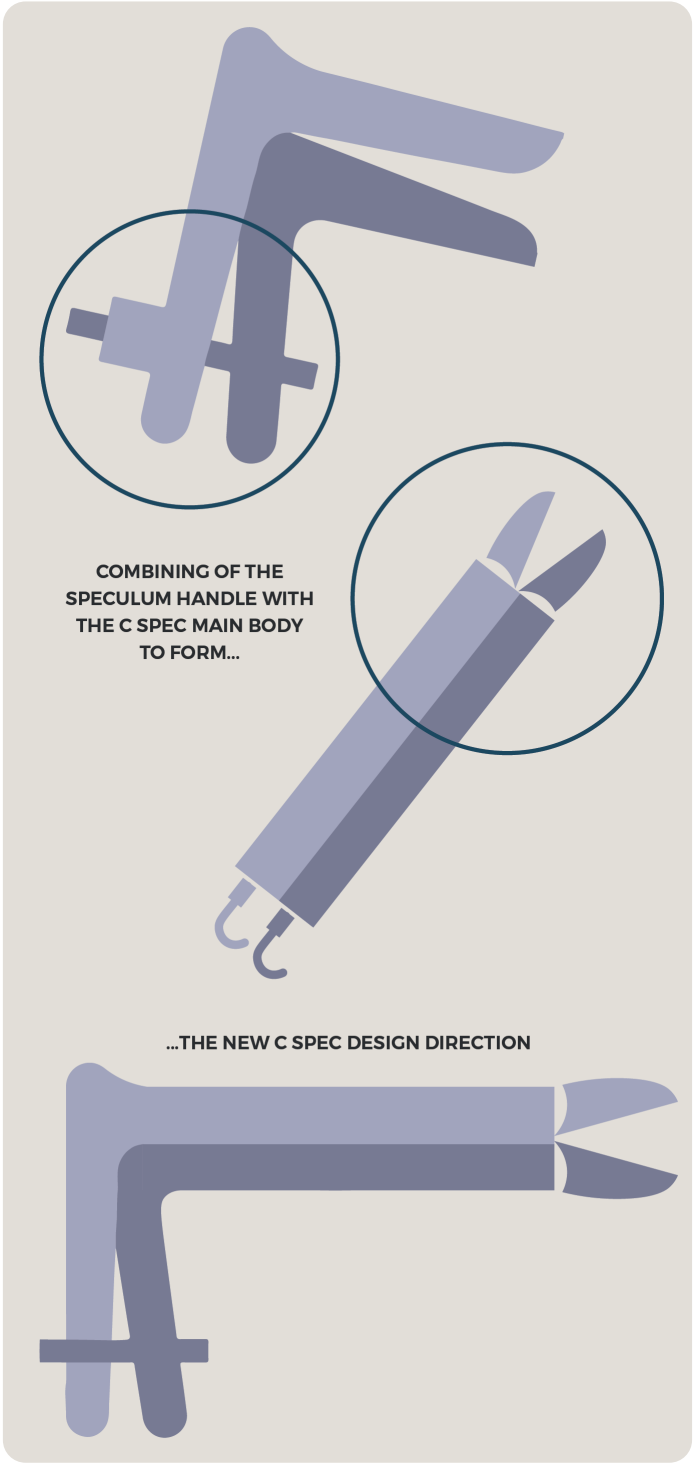


Figure 3.1 -New C Spec design direction

3.4 | MECHANISM SELECTION

To design and develop this speculum-style handle, this project drew inspiration from relatable products on the market that use a squeeze-handle interaction. The mechanisms used within these existing products were explored and implemented into the C Spec product using rapid prototyping methods. The detailed development process of the new design can be found in appendix I.

ANALYSIS OF LAPAROSCOPIC APPARATUS

Mechanism inspiration was drawn from laparoscopic medical apparatus. These medical instruments use a squeeze-style handle to operate flap-style graspers at the end of a long tube. By disassembling existing laparoscopic apparatus, the mechanisms used to operate the flaps were analysed.

KEY DIFFERENCES FOR THE C SPEC

Although the laparoscopic apparatus does mirror some features required in the new C Spec design, there is a limitation that needs to be addressed:

Hollow Design:

The C Spec needs to be hollow to allow for the insertion of additional apparatus, unlike laparoscopic instruments that do not have this requirement.

FLAP OPENING MECHANISM SELECTION

From the analysis of existing laparoscopic devices, two flap opening mechanisms were established and integrated into the C Spec design. This detailed development and testing process can be found in appendix I. A brief explanation of these mechanisms function is as follows:

Rotating Hinge Mechanism:

The rotating hinge mechanism uses four axis points. One axis connects the flaps together, allowing them to rotate open and closed. Two axis points join each individual flap to an individual connecting piece, and the final axis point joins the connecting pieces to a plunger. The plunger pushes to open and pulls to close the flaps. Figures 3.2 visualise the rotating hinge mechanism.

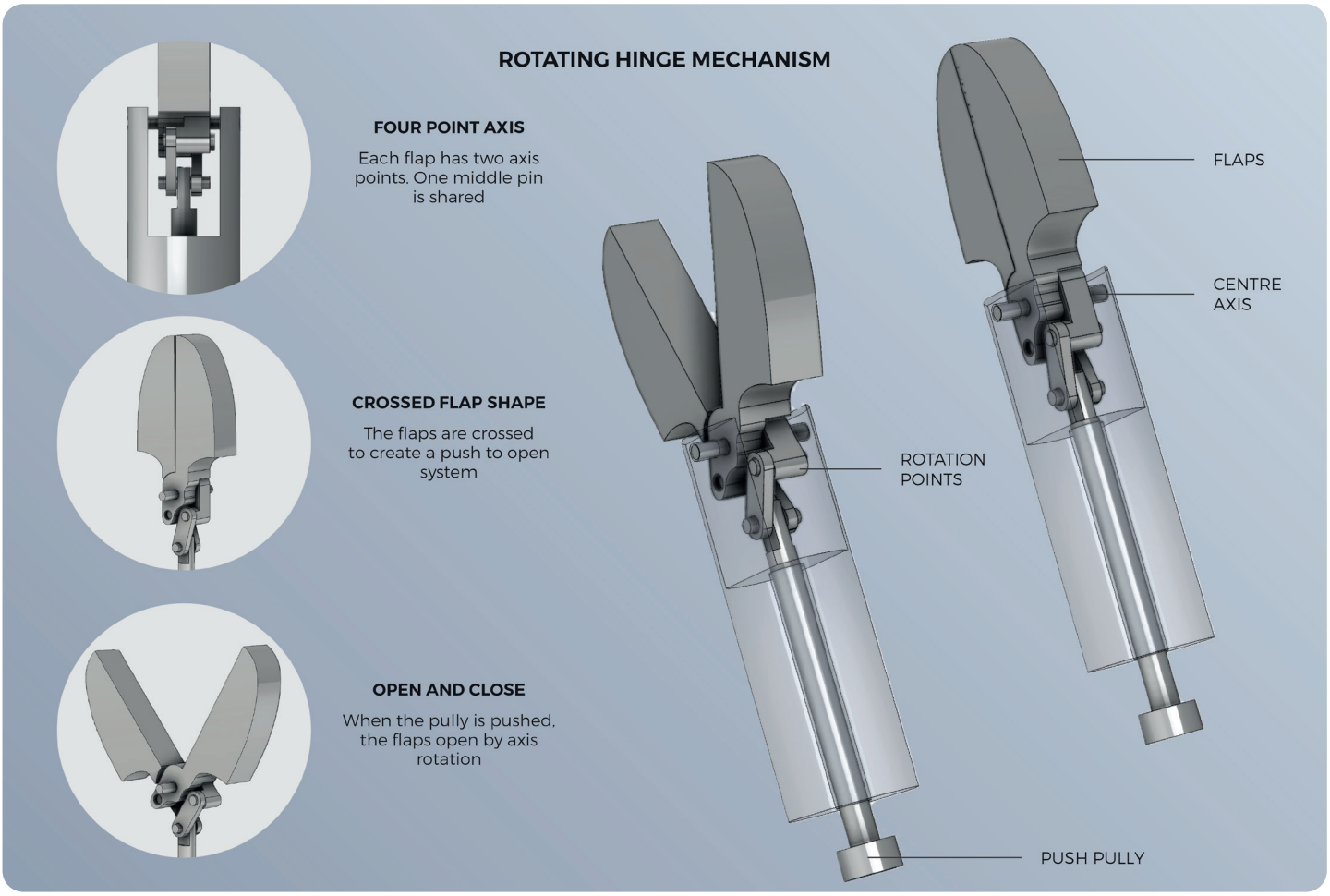


Figure 3.2 - Rotating hinge mechanism

Linear Cam Mechanism:

The linear cam mechanism involves a pin connected to each individual flap, which travels along a dedicated path cut into an additional moving part. Pushing the part forces the pin upward, opening the flap; pulling the part forces the pin downward, closing the flap. This mechanism requires the flaps to be connected to an axis point for rotation, and two faces to keep the pin sliding in the path. Figure 3.3 shows this linear cam mechanism integration into the C Spec.

In both the rotating hinge and linear cam mechanisms, the force exerted to open the flap is opposite to the flap being pushed, addressing the C Spec's inverted motion requirement.

SELECTION OF THE LINEAR CAM MECHANISM

A design requirement is that the new C Spec must be easy to disassemble for sufficient sterilisation. The rotating hinge mechanism, with its four joining points, hinders easy assembly and disassembly. Therefore, the linear cam mechanism was selected for further development due to its facilitation of disassembly.

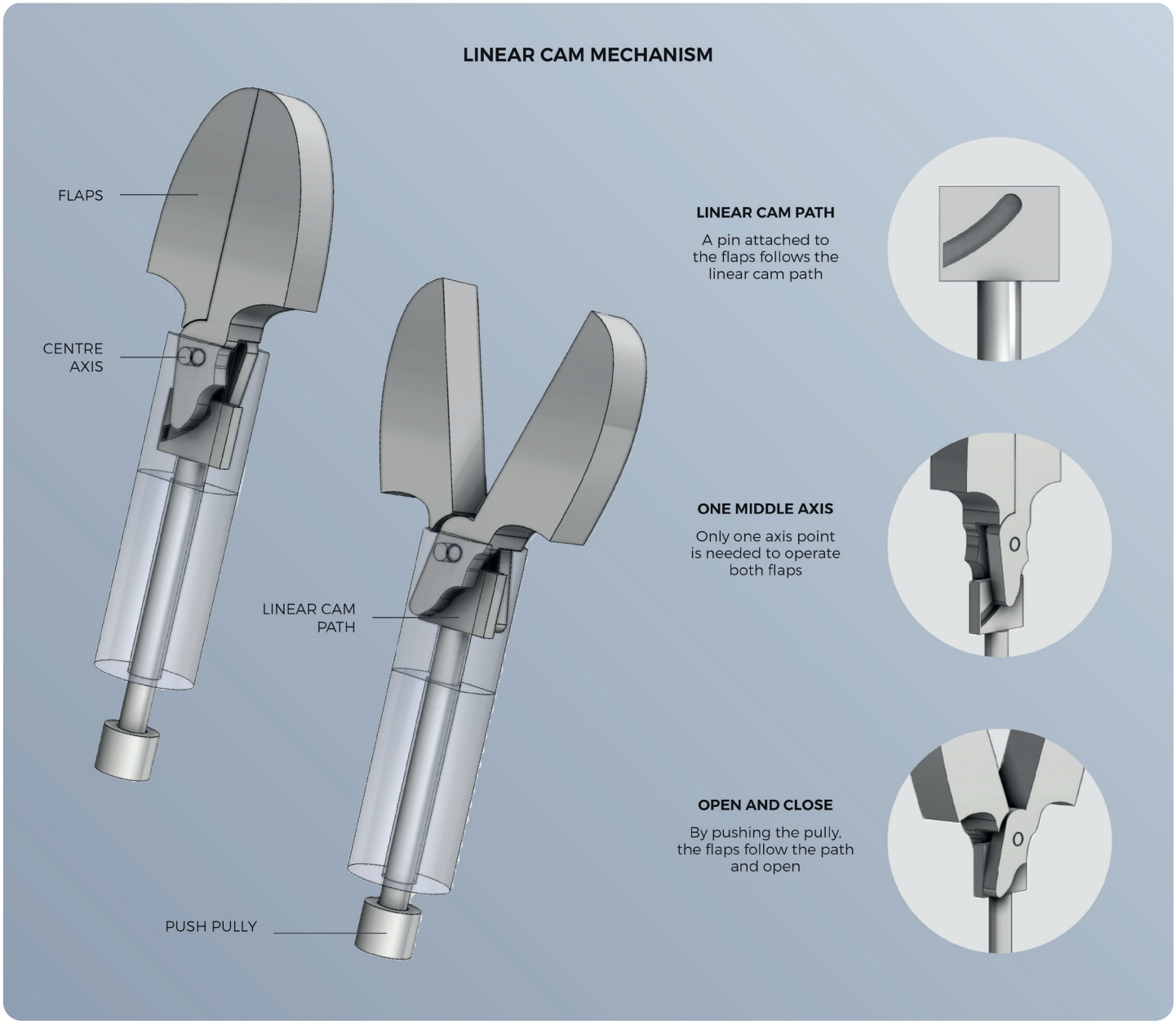


Figure 3.3 - Linear cam mechanism

3.5 | MONO OR BIMANUAL FLAP OPENING

MONOMANUAL VS. BIMANUAL FLAP OPENING

Through research on laparoscopic apparatus, it was found that many use the movement of only one flap (monomanual method) instead of moving both flaps (bimanual method). The monomanual method was therefore prototyped and tested using the linear cam mechanism as previously discussed. The thinking was that by only manipulating one C Spec flap, the linear cam mechanism could be smaller. Therefore increasing the space available for apparatus inside the C Spec main body.

MONOMANUAL METHOD

In the monomanual method, one flap is static while the other is movable. The static flap is angled upon insertion, with the moving flap pressed flush against it. Once inserted, the linear cam mechanism opens one flap, creating a space to view the cervix. The static flap is angled upon insertion to ensure a wide enough diameter to view the cervix.

BIMANUAL METHOD

The bimanual method operates the same as the current C Spec, where both flaps open and close to create the necessary space to view the cervix. The bimanual method was previously explained with the use of the linear cam mechanism. More detailed workings of these prototypes can be found in appendix I.

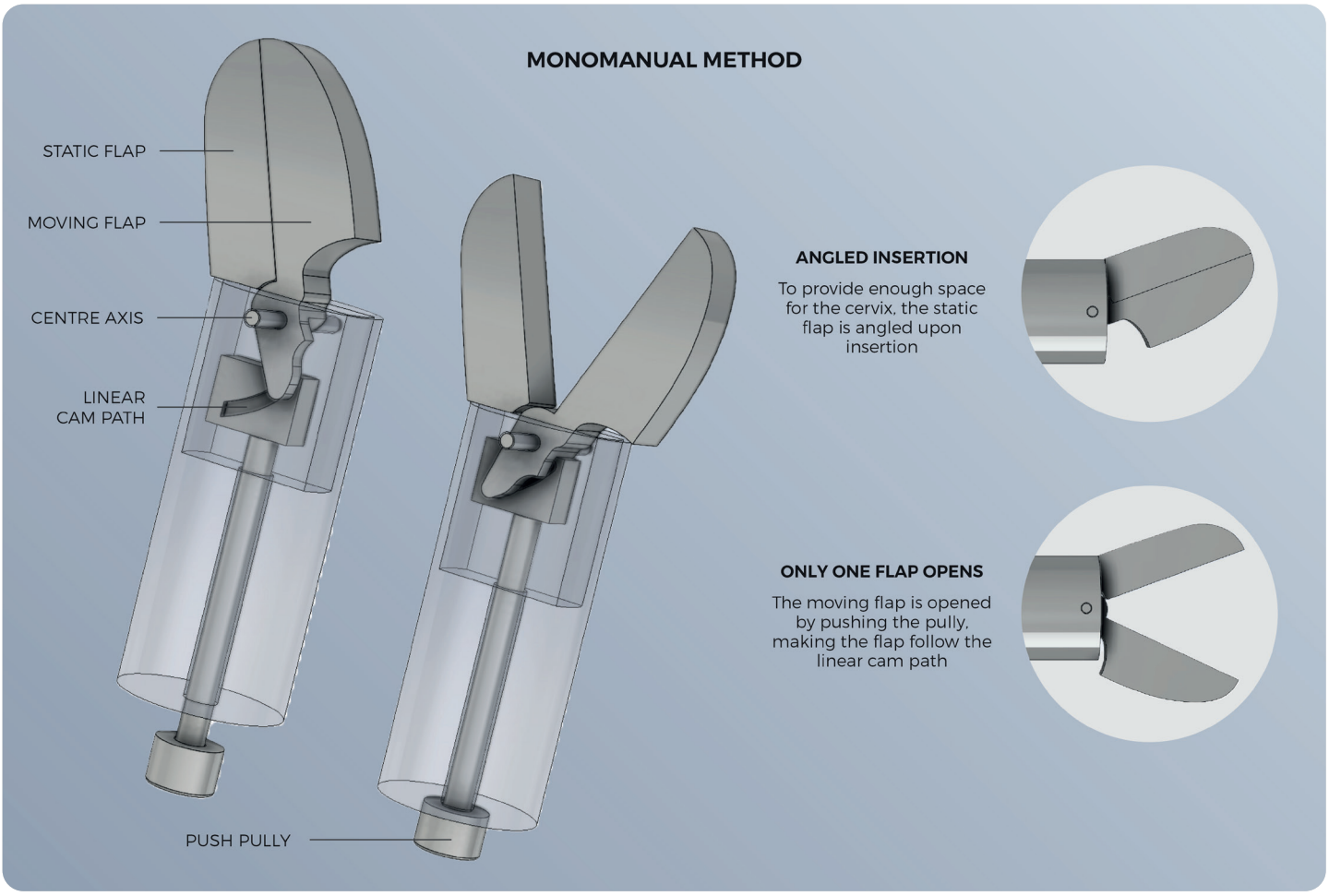


Figure 3.4 - Monomanual flap opening method

HARRIS PROFILE

Using a Harris profile as shown in table 3.1, the two design directions were compared to determine which method best suits the new C Spec design. Design requirements influenced by the decision between the bimanual and monomanual method were selected for the Harris profile.

SELECTION OF THE BIMANUAL OPENING METHOD

As shown in table 3.1 the Harris profile clearly identifies a preference towards the bimanual flap opening method. Although the monomanual method saves some space inside the C Spec, the patient comfort is significantly decreased due to its angled flap insertion, exposing the patient to a large sharp edge. The bimanual method, despite taking up more space, ensures better patient comfort and does not compromise significantly in other categories. The decision was therefore made to continue to use a bimanual flap opening method for the new C Spec design.

The following section will conceptualise the new C Spec design featuring a speculum style handle that operates the flaps in a bimanual method using a linear cam mechanism.

HARRIS PROFILE

	DESIGN DIRECTION ONE (MONOMANUAL METHOD)				**DESIGN DIRECTION ONE** (BIMANUAL METHOD)			
	-2	**-1**	**+1**	**+2**	**-2**	**-1**	**+1**	**+2**
Integration into the new handle mechanism								
Easy identification of product orientation								
Ability for HCP to conduct the screening alone								
Ability to maintain a small main body diameter								
Area inside the C Spec lost to the mechanism								
Ease of apparatus insertion								
Ability to maintain patient comfort								
Presence of sharp edges that touch the patient								
TOTAL SCORE:	MONOMANUAL METHOD = **2**				BIMANUAL METHOD = **7**			

Table 3.1 - Harris profile on the selection between the bimanual and monomanual flap method

3.6 | KEY INSIGHTS DESIGN DIRECTION

- No existing product effectively combines comfortable visualisation of the cervix with the ability to transport necessary medical apparatus during the procedure.
- The C Spec addresses this market gap by combining patient comfort, sufficient visualisation of the cervix, and ability to insert apparatus into a single product.
- Although the C Spec improves patient comfort there are still significant difficulties with the operation of the C Spec from a healthcare professional perspective.
- The Speculum handle is comfortable and easy for healthcare professionals to operate but the main body creates significant discomfort in patients.
- The main body of the C Spec provides comfortable insertion for patients but healthcare professionals experience issues with operating the flap opening mechanism.
- The new C Spec design will take the positives of both products, and combine them to make a new product that has the main body of a C Spec but the handle operation of a traditional speculum.
- This new C Spec design will be realised through using a linear cam mechanism that operates the flaps in a bimanual method.

SECTION 4

THE PRODUCT DESIGN

4.1 | PRODUCT PARTS

PRODUCT PARTS

The following section will showcase the new C Spec design, its components and the design decisions made to achieve the final product as shown in figure 4.1. Figure 4.1 shows the terms given to each product part. These terms are important as they will be referenced to explain the design. Furthermore, the terms "main body" and "handle" are used to categorise the two main assemblies of the product. The "main body" refers to the flaps, the inner tube and the outer tube assembly, whereas the handle refers to the static handle and the squeeze handle assembly.

The full design development process including images of rapid prototyping, and reasoning for choosing particular design directions can be found in appendix J.

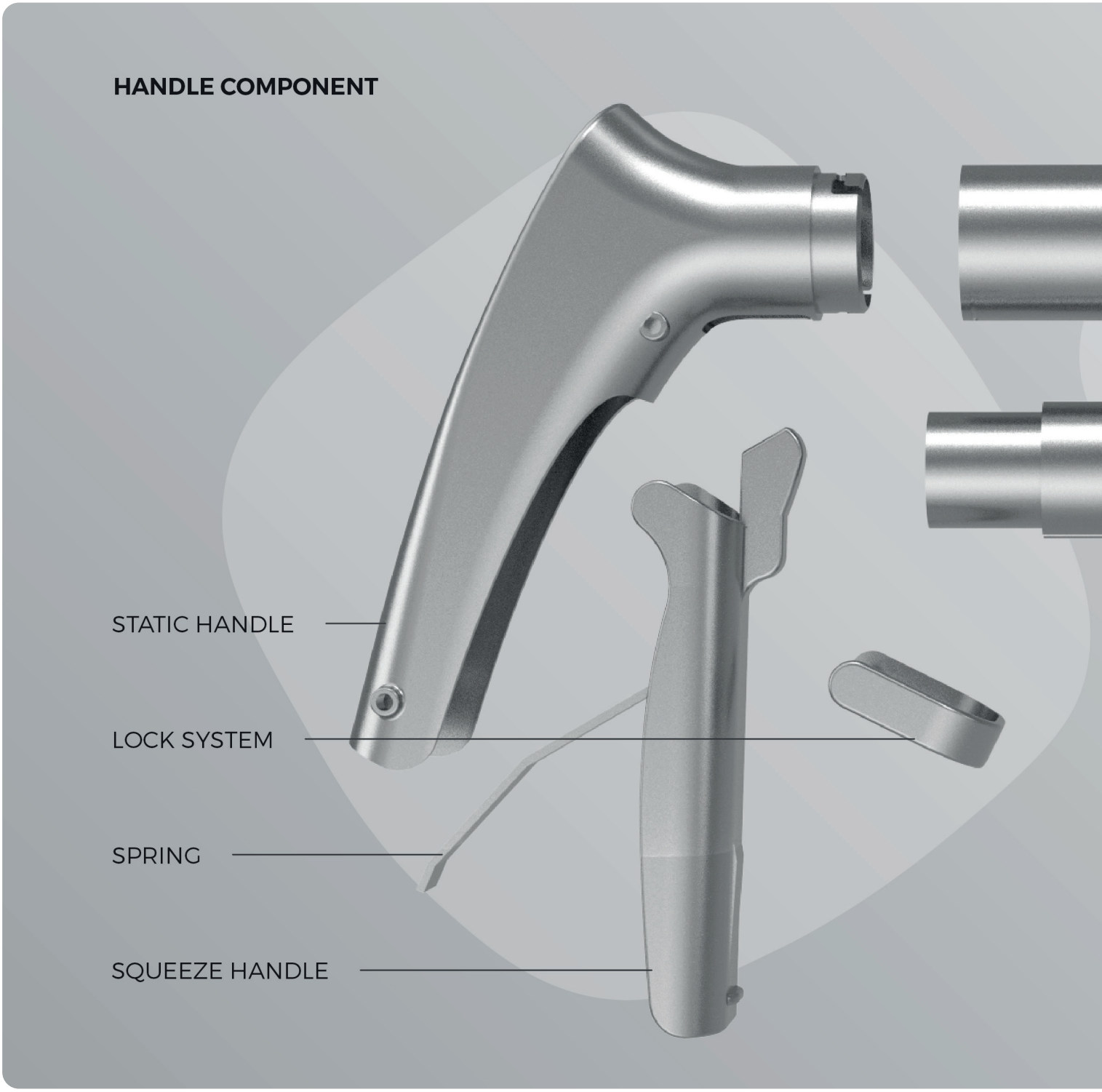
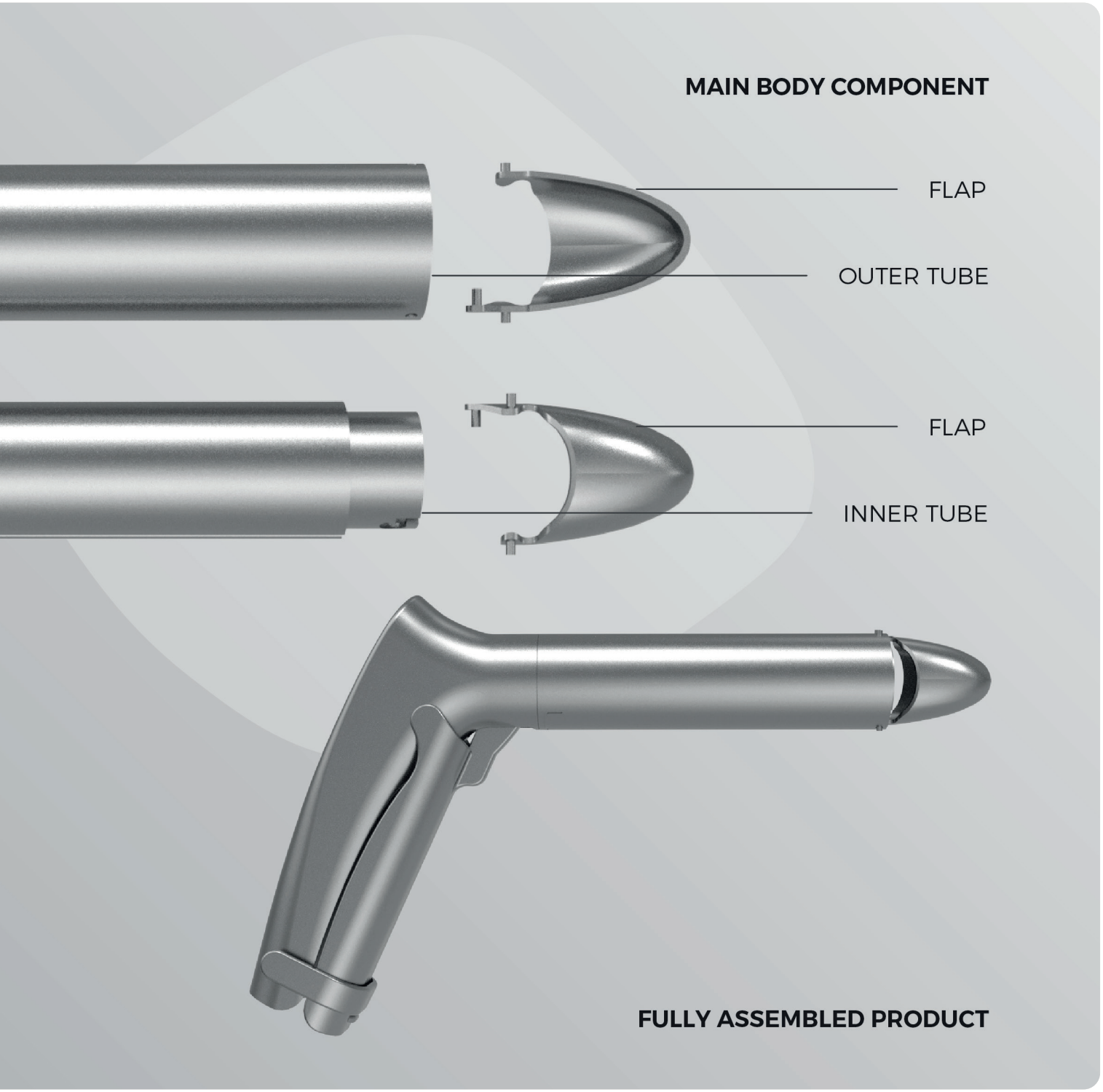


Figure 4.1 - New C Spec design product parts disassembled


MAIN BODY COMPONENT
FLAP
OUTER TUBE
FLAP
INNER TUBE
FULLY ASSEMBLED PRODUCT

4.2 | MAIN BODY DESIGN

CREATING A HOLLOW CENTRE

To continue using the linear flap mechanism with a bimanual flap movement, the next challenge was to create a hollow main body to allow apparatus to be inserted for conducting a cervical cancer screening procedure. To achieve this, an additional main body tube is included that slots into the existing outer main body tube. These tubes are referred to as the inner and outer tubes.

The linear cam mechanism requires two faces that push against each other to function. By moving the linear cam to the sides, a hollow centre is created where the mechanism can utilise the faces of the inner and outer tube to function.

Outer Tube: Comes in contact with the patient's vagina, remains stationary, and secures the flaps.

Inner Tube: Allows the flaps to follow the linear cam path, facilitating their opening and closing movement. Each side of the inner tube has a linear cam path, with each path operating one flap.

Figures 4.2 shows the linear cam paths on either end of the inner tube.

INCREASED INNER TUBE WALL THICKNESS

To create space for the flaps between the tubes, the inner tube diameter is decreased, creating a gap that can cause the tubes to wiggle. To ensure concentric movement for efficient mechanism function, an extra wall thickness is created around the inner tube, but only in the middle. The beginning and end of the tube are kept thinner to accommodate the linear cam and handle lock mechanism (to be explained later).

INCREASED OUTER TUBE DIAMETER

To ensure enough space for inserting both the endoscopic camera and other apparatus during the screening procedure, the outer tube diameter is increased from 29mm to 32mm, which is the maximum diameter the C Spec is allowed to expand to as stated in the design requirements.

FLAP DESIGN

As previously stated, redesigning the flap shape is out of this project's scope. The flaps on the new C Spec will therefore be attached to the outer tube in the same manner as the current C Spec using pins that slot into holes on opposite ends of the outer tube as shown in figure 4.2.

However, to be compatible with the new linear cam mechanism, the flaps are adjusted by extending one of the arms to facilitate a pin that travels in the linear cam path to open and close the flaps. This extension is curved to better follow the tube curvature, optimising space usage.

FLAP ORIENTATION

The flaps are oriented longer from top to bottom direction instead of left to right direction, creating a more comfortable flap insertion for the patient, as the introitus is also longer in length than in width.

LINEAR CAM MECHANISM WITH BAYONET LOCK

To facilitate disassembly for sufficient sterilisation, the pins of the flaps need to be removable from the linear cam path. This is achieved using a bayonet mechanism, which works by creating a path where the pin first has to travel through to get to the linear cam path. This path is complex in nature, and includes a neutral point, to reduce the likelihood of the pin slotting out of the linear cam path during the procedure.

MAIN BODY LENGTH

The length of the new C Spec main body is decreased to 115mm compared to the current C Spec main body length of 150mm, as the new handle removes the need to hold the base of the main tube during the screening procedure.

Insights from healthcare professionals in the field indicate that part of the sheath is always visible during insertion, aiding in determining the optimal length for the main body on the new C Spec. This length allows the C Spec to reach the cervix while maintaining space between the healthcare professional's hand and the patient's vulva.

Figure 4.2 - Main body design explanation

4.3 | HANDLE DESIGN

The new speculum-style handle design as shown in figure 4.3 consists of two parts: the static handle and the squeeze handle. The static handle is attached to the main body, while the squeeze handle is attached via pins to holes in the static handle, creating a rotation axis. During the procedure, the squeeze handle is compressed to open the flaps. The development process of the handle design can be found in appendix J.

CAM HANDLE MECHANISM

When the squeeze handle is compressed, the cam-shaped handle increases the distance from the rotation point, pushing the inner tube of the main body forward. This pushing force is exerted only at the bottom section of the inner tube to facilitate disassembly for sterilisation. When in its compressed state, the cam form does not obstruct the entry to the main body, and instead sits flush with the inner tube.

SQUEEZE HANDLE

The squeeze handle as shown in figure 4.3 is designed to sit flush with the static handle when in its closed position. Its symmetric shape allows comfortable operation for both left and right-handed users. A notch at the top of the squeeze handle acts as a barrier, preventing healthcare professional's fingers from obstructing the cam mechanism. When in its relaxed position, the squeeze handle does not travel past the end of the static handle, ensuring space between the healthcare professional's hand and the patient's vulva during the screening procedure.

STATIC HANDLE

Its curved shape allows the product to comfortably follow the shape of the palm of the hand, providing control to conduct manoeuvres necessary during the procedure. Like the squeeze handle, the static handle shown in figure 4.3 is symmetrically designed for ambidextrous operation. The static handle includes a wider product opening to guide apparatus into the main body and is shelled to reduce product weight and provide space for the spring system. The cam of the squeeze handle slots into a hole cut in the underside of the static handle to push the inner tube forwards.

During the development process this wider opening was made shorter after ergonomics testing was conducted with individuals familiar with this project. This is because apparatus will always be inserted from an upwards position, meaning that a wider opening from the bottom does provide any benefit. Secondly, by making this opening smaller, more space is provided for the palm of the hand. A screening procedure can be conducted with the healthcare professional in a sitting or standing position. By increasing the surface area for the palm it provides more opportunities for the wrist to be comfortable during a screening in either a standing or sitting stance.

HANDLE ERGONOMICS

During the development process DINED was used to research the hand size of west and south-east African males and females to ergonomically design the handle to be comfortable for healthcare professionals.

Hand width (without thumb) determined the length of the front squeeze handle. Healthcare professionals must be able to fit all fingers on the squeeze handle to properly transfer a gripping force to open the C Spec flaps. The figures in DINED show a mean value of 80mm for the hand width of the target group. To allow more individuals to comfortably operate the handle, the figure of 88mm which is the 90th percentile was used to design the handle. Earlier in the product development process, the handle was smaller in size, however due to the figures from DINED, the handle was extended in length and the length of the notch was decreased to accommodate larger hands.

Pointing finger length was used to design the distance between the back of the static handle and the front of the squeeze handle. To apply force to the squeeze handle the healthcare professional must comfortably reach the front of the squeeze handle with at least the tops of their fingers. This distance must accommodate smaller hand sizes, therefore the DINED figure of the 10th percentile was used. This length is 66mm. Unfortunately, due to limited data from DINED, this figure was not available within the west and south-east Africa group. This pointing finger length of 66mm instead represents the hand size of Dutch males and females between the ages 20 and 60.

Figure 4.3 - Handle design explanation

4.4 | SPRING AND LOCK MECHANISM

SPRING SYSTEM

A spring system in the form of an arch is integrated between the two handle components. By staying within the limits of the elastic deformation of the material, the arched spring provides resistance when squeezing the handle, and forces the squeeze handle back into its neutral position once released. Including the spring system provides an increased user experience compared to when it is not included.

The spring is only located at the handle and not at the flaps. If the spring were to influence the closing of the flaps, the cervix could be clamped once the lock is released. Since the walls of the vagina provide enough pressure, the flaps will naturally close once the lock is released.

LOCKING SYSTEM

During the screening procedure, the new C Spec will be locked in place to relieve the gripping force on the healthcare professionals hand from the spring system. This lock is in the form of a band which is attached to the static handle, and wraps around the squeeze handle. A small notch on the squeeze handle and the resistance pressure from the spring hold the band in place during the procedure. Once the healthcare professional has completed the screening, they can further squeeze the handle to release the band from its locking position. For proper sterilisation, the locking band can be fully removed from the static handle.

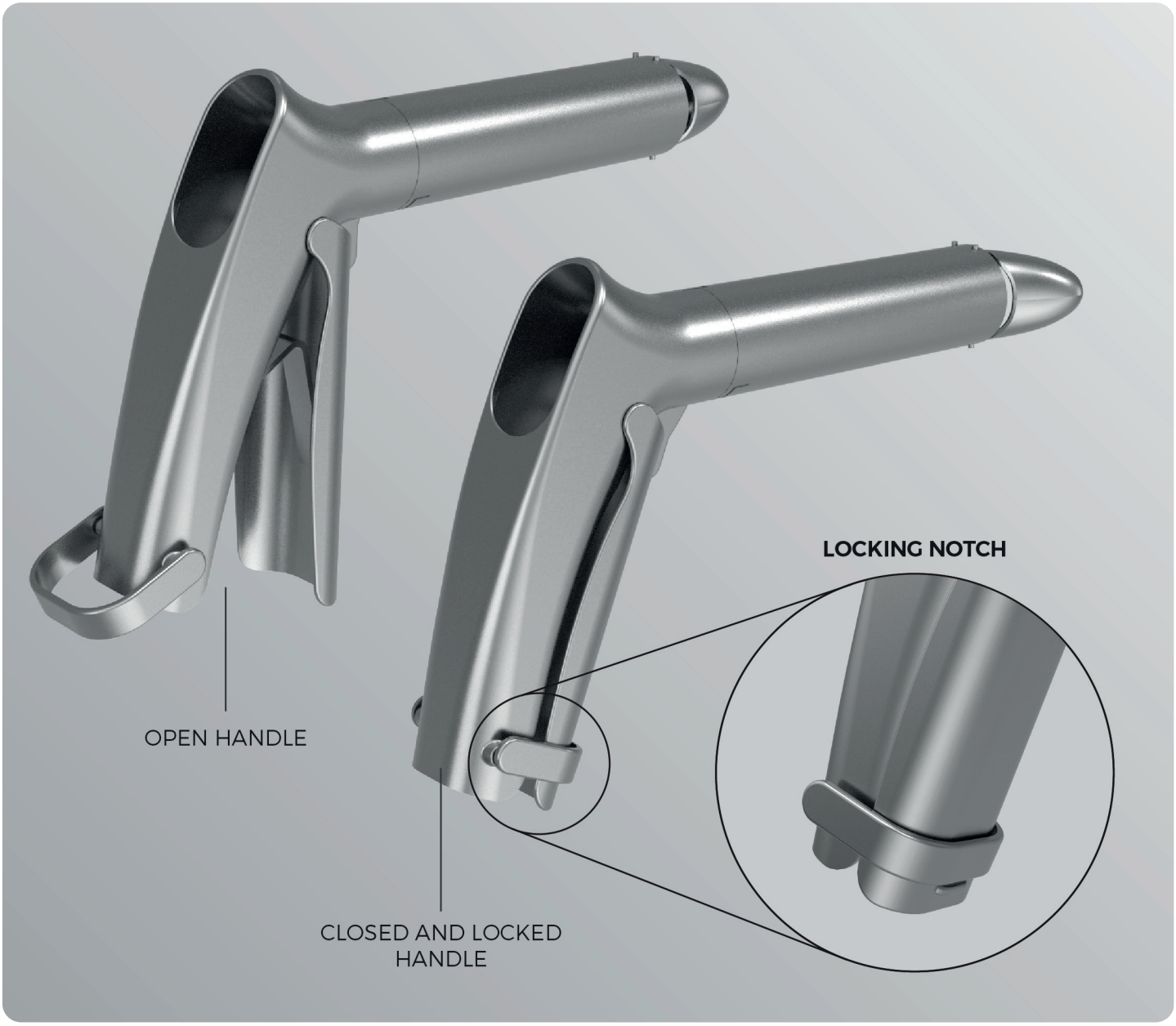


Figure 4.4 - Locking band design explanation

4.5 | HANDLE TO MAIN BODY JOINT

BAYONET MECHANISM

The handle is connected to the main body using a bayonet mechanism. As shown in figure 4.5 two paths are cut out in the static handle, and two pins are located on the inside of the outer tube. The product is assembled by pushing and rotating the outer tube and the static handle together. By concealing the mechanism the product looks less intimidating for patients. The two pins placed inside the outer tube now however block the inner tube from being removed for sterilisation. The inner tube was therefore edited to include two slots to allow the pins to pass through.

FLUSH CONNECTION

To allow for unobstructed insertion of apparatus into the C Spec, the end of the static handle where it meets the inner tube is flush. This is achieved by increasing the wall thickness of the static handle closer to the joint with the main body.

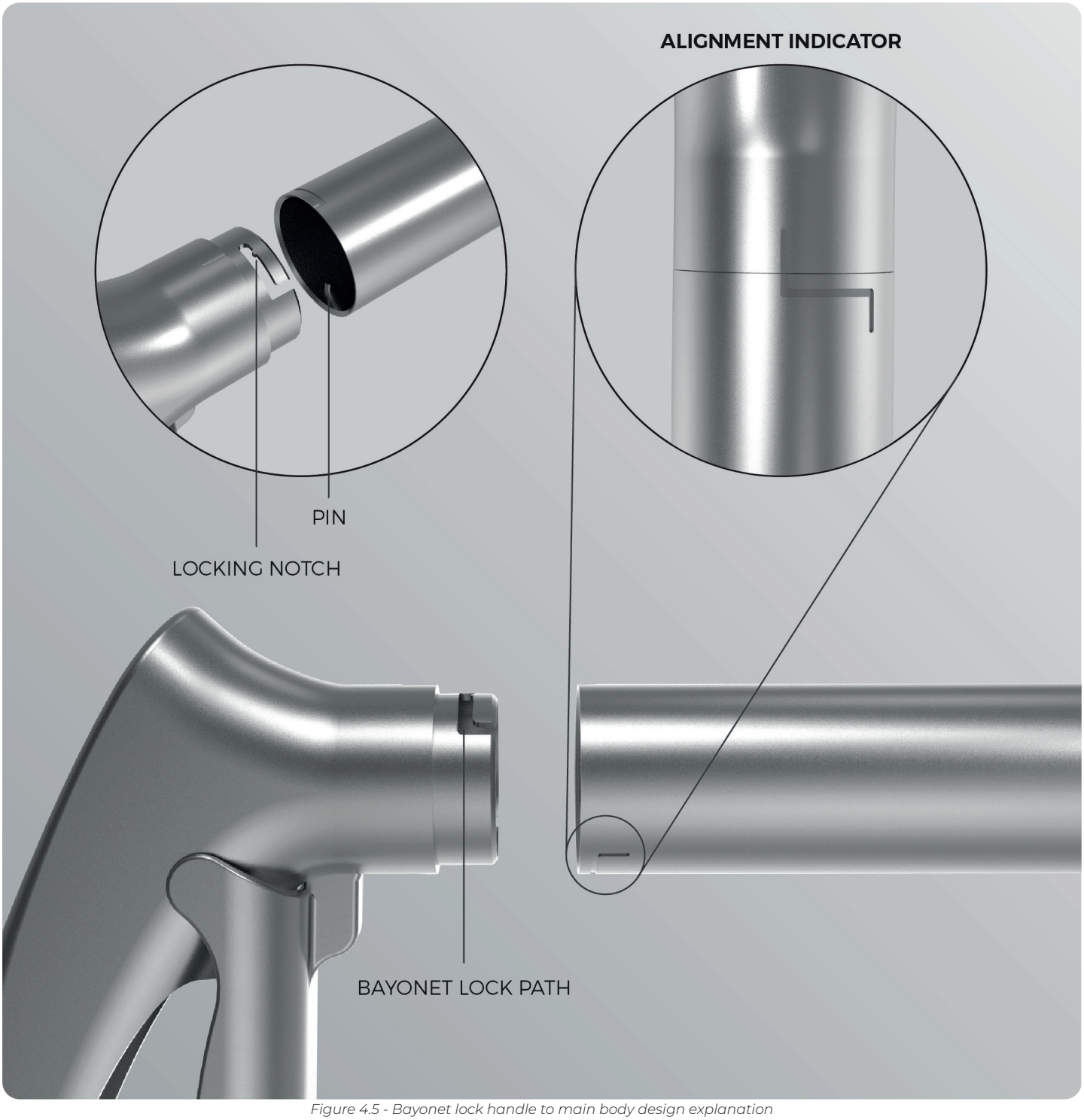


Figure 4.5 - Bayonet lock handle to main body design explanation

4.6 | PRODUCT ASSEMBLY

The new C Spec design can be fully disassembled for ease of sterilisation. The following set of images, visualises how the new C Spec product is again assembled to conduct a cervical cancer screening.

Figure 4.6 - Product assembly storyboard

4.7 | PRODUCT USE

The following set of images with explanations visualises how the new C Spec is used to conduct a cervical cancer screening.

Figure 4.7 - VIA/VILI cervical cancer screening using new C Spec design

4.8 | FINITE ELEMENT ANALYSIS

Finite element analysis (FEA) was conducted using the product model in Solidworks to analyse the stress that different product parts would experience during product use. Using the material database from Solidworks, the yield strength of stainless steel at 1.723e + 08 N/m^2 was identified to analyse if the product part would remain within the elastic deformation region on a stress strain graph as shown in figure 4.8 If the N/m^2 exerted on the product part would exceed the yield strength point, it would come in the plastic deformation region of the stress strain graph, this could have serious consequences to the product's use.

THE FLAPS

The flaps of the new C Spec design are of interest to explore using FEA since this product part must open while under significant pressure of the vaginal walls. As explained in the context section of this report, the maximum recorded contracting force of the vaginal walls is 9.52N (Egorov, 2018). This force along with the maximum gripping force of the 90th percentile at 588N from DINED was used to conduct a simulation on the flap, using the material stainless steel.

As figure 4.9 shows, the stress and strain analysis results of the flaps are good under the forces previously mentioned. The highest point of stress exerted on the flap is 8.431e + 07 N/m^2. This stress does not exceed the yield strength of the stainless steel material, meaning that the flap can resist the forces applied to it during a screening procedure without coming into the plastic deformation region.

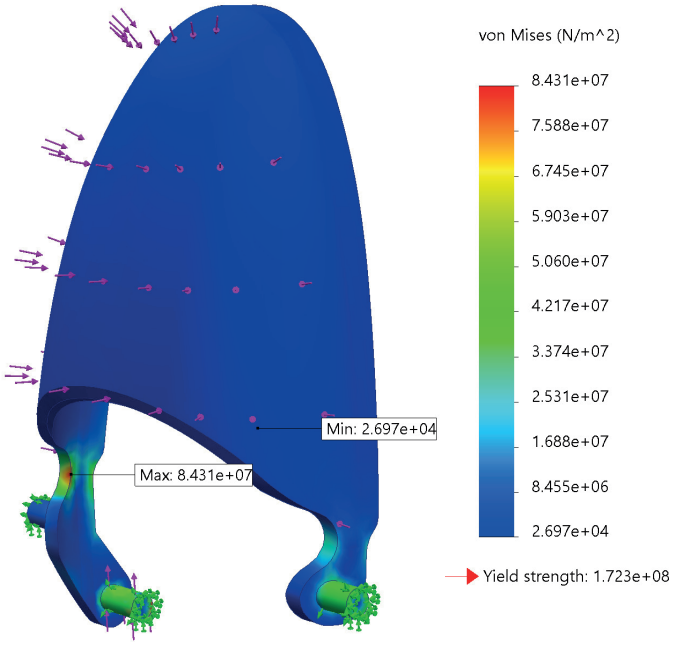


Figure 4.9 - FEA simulation on the flap to withstand vaginal wall pressure

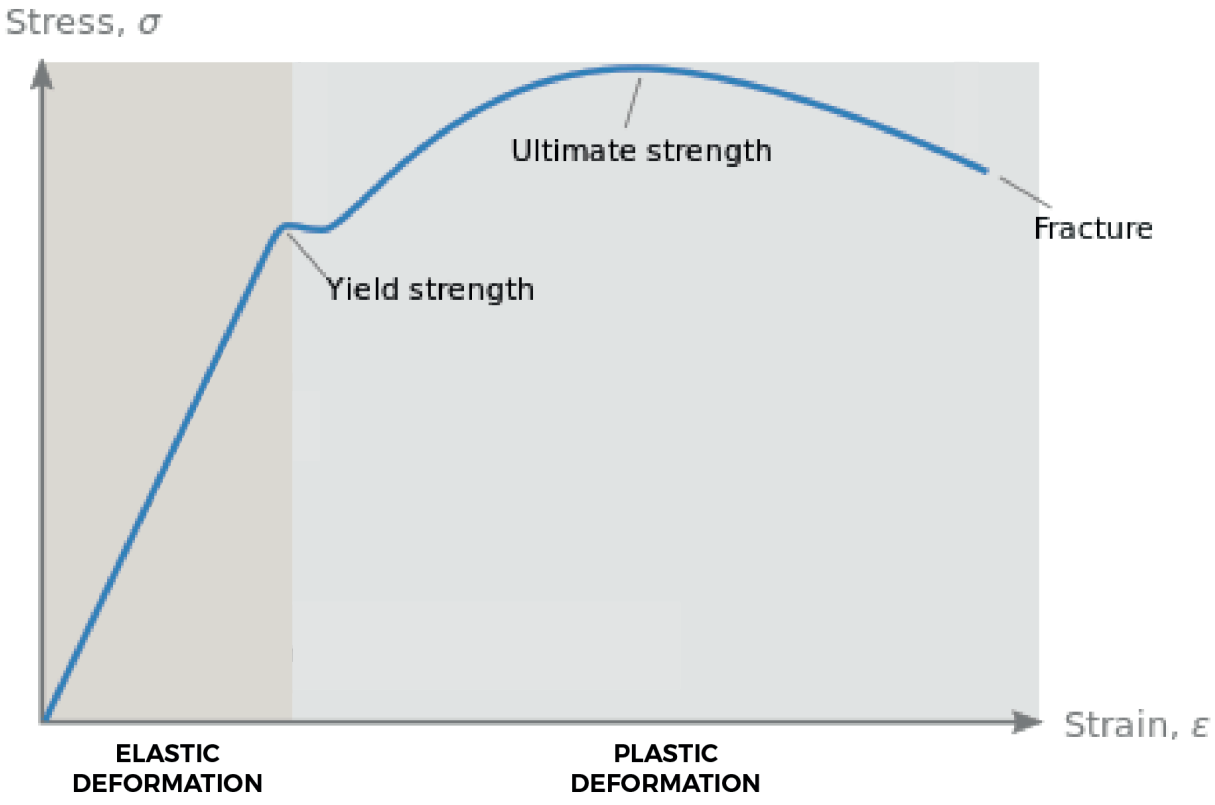


Figure 4.8 - Stress strain graph identifying the yield strength point

FLAP ASSEMBLY DEFORMATION

During the assembly of the product, the sides of the C Spec flaps are squeezed to insert the pins of the flaps into the holes of the outer tube. Some deformation of the part is conducted in the process, however this is no issue as long as this deformation remains within the elastic deformation region on the stress/ strain graph. FEA was conducted to calculate the yield strength reached by the flaps when displaced by 1.2mm (thickness of outer tube) on each side.

Figure 4.10 shows that when a 1.2mm deformation is experienced on both ends of the flap, the stress does not exceed the yield strength point. The flaps therefore remain within the elastic deformation region.

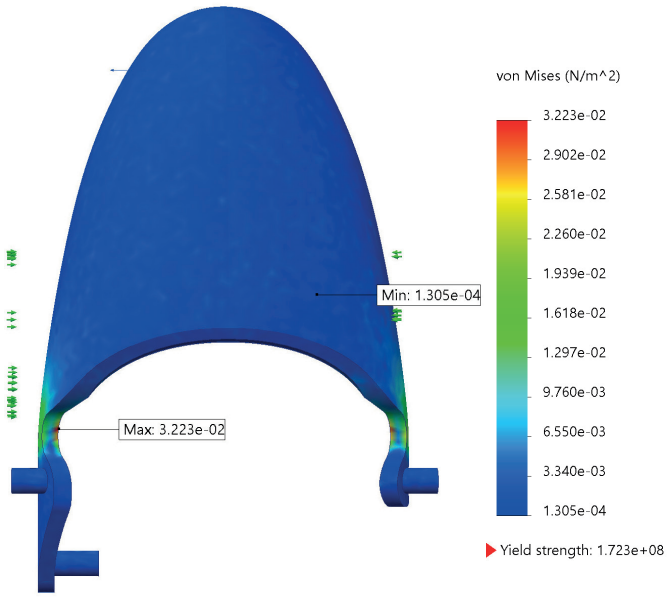


Figure 4.10 - FEA simulation on the flap during assembly

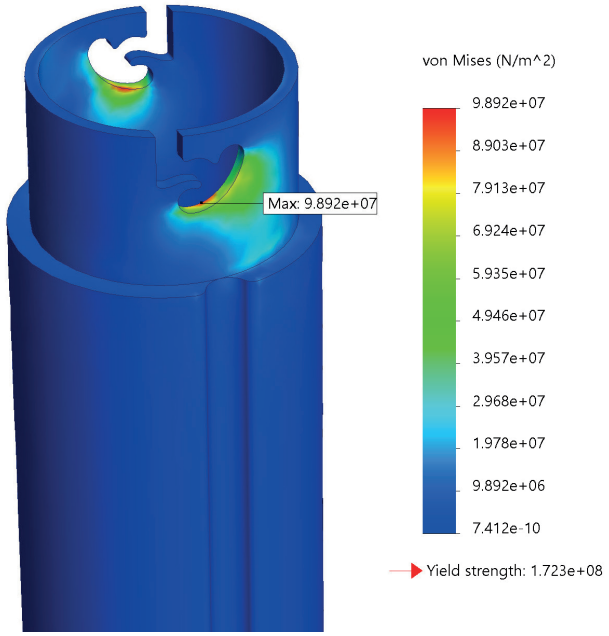


Figure 4.11 - FEA simulation on the inner tube during product use

THE LINEAR CAM PATH

Like with the flap, FEA was conducted on the inner tube, specifically at the linear cam path. The pin previously analysed on the flap sits inside the linear cam path, pushing the flap open during the screening procedure. The stainless steel material at the base of the linear cam path therefore experiences a high force. Figure 4.11 shows that when a force of 588N is exerted to the bottom of the linear cam path, the N/m^2 does not exceed the yield strength of the stainless steel material since the maximum stress experienced by the linear cam path is 9.892e +07.

SQUEEZE HANDLE DEFORMATION

Like the flap assembly, the squeeze handle also needs to be assembled and disassembled from the static handle. To do this, the sides of the squeeze handles are expanded by 2mm on each side to release the pins from the holes in the static handle. As shown in figure 4.12, the part does not experience a stress that exceeds the yield strength of stainless steel. The deformation present within this part is therefore elastic.

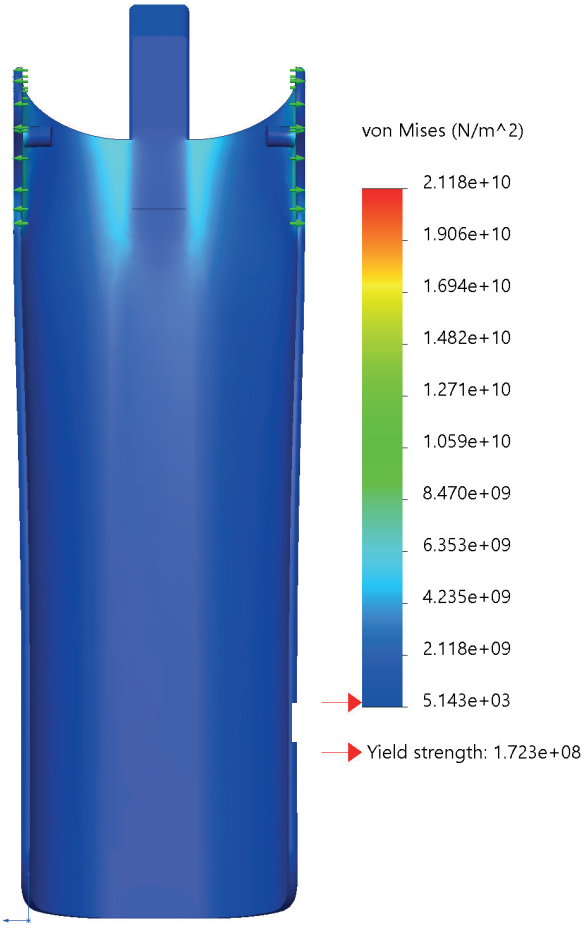


Figure 4.12 - FEA simulation on the squeeze flap during assembly

4.8 | PRODUCT MANUFACTURING

The new C Spec product will be made from stainless steel, which allows it to be sterilised in an autoclave or through HLD in a chemical bath. FEA calculations have demonstrated that stainless steel is strong enough to withstand the pressures exerted by the user's hand and the vaginal walls.

To produce the new C Spec design, multiple manufacturing methods will be required. Components such as the flaps and main body tubes are easier to manufacture due to their consistent material thickness. However, the handle components, which vary in material thickness, are more challenging to produce. The manufacturing methods for each part are as follows:

THE FLAPS

A benefit of the flaps when it comes to manufacturing, is that the left and right flap are identical in shape, thereby reducing the number of different parts required to produce the new C Spec design. Manufacturing the flaps must be done in two steps. The first step is to cut the flap shape out of a 1.2mm thick sheet of stainless steel using a laser cutter. For the second step, this cut steel will then be formed into the curved flap shape by pressing the sheet metal around a premade mould using hydraulic systems. With the base form of the flaps now made, the pins can be cut from a standard thickness rod and attached to the flap shape through welding.

THE INNER AND OUTER TUBES

The inner and outer tubes are relatively simple to produce since the standard industry process of hot rolling seamless pipes can be used. These tubes can then be cut to the intended length required for the new C Spec design.

To produce the linear cam path cut out on the inner tube, the method of tube laser cutting can be used. This allows for a precise cut which is needed for the proper function of the C Spec design. The circular cutouts in the outer tube can be cut in the same manner. The outer tube alo requires two pins to be welded to the inner face allowing the main body to connect via a bayonet system to the handle component.

THE LOCKING BAND

The locking band is made in the same manner as the flaps, only that it requires a different mould to bend the sheet metal around. The process therefore begins with cutting the 2D locking band shape out of a sheet of stainless steel using a laser cutter. This cut part is then bent around a mould using a hydraulic system to form it into the required shape. Finally the two pins that connect the locking band to the handle are welded to the inner face of the part.

THE STATIC AND SQUEEZE HANDLE

The static handle and squeeze handle unlike the other product parts are more organic in shape. Furthermore, the design requires the parts to have varying wall thicknesses. This makes manufacturing these parts more difficult as standard parts cannot be used. The two handle components must therefore be manufactured through stainless steel investment casting. This is where the molten stainless steel is poured into a mould to produce the desired shape. This mould is made by creating a wax pattern using a 3D CAD model. This wax pattern is then used to create a ceramic mould to withstand the high temperatures of the molten stainless steel (Levy, 2021).

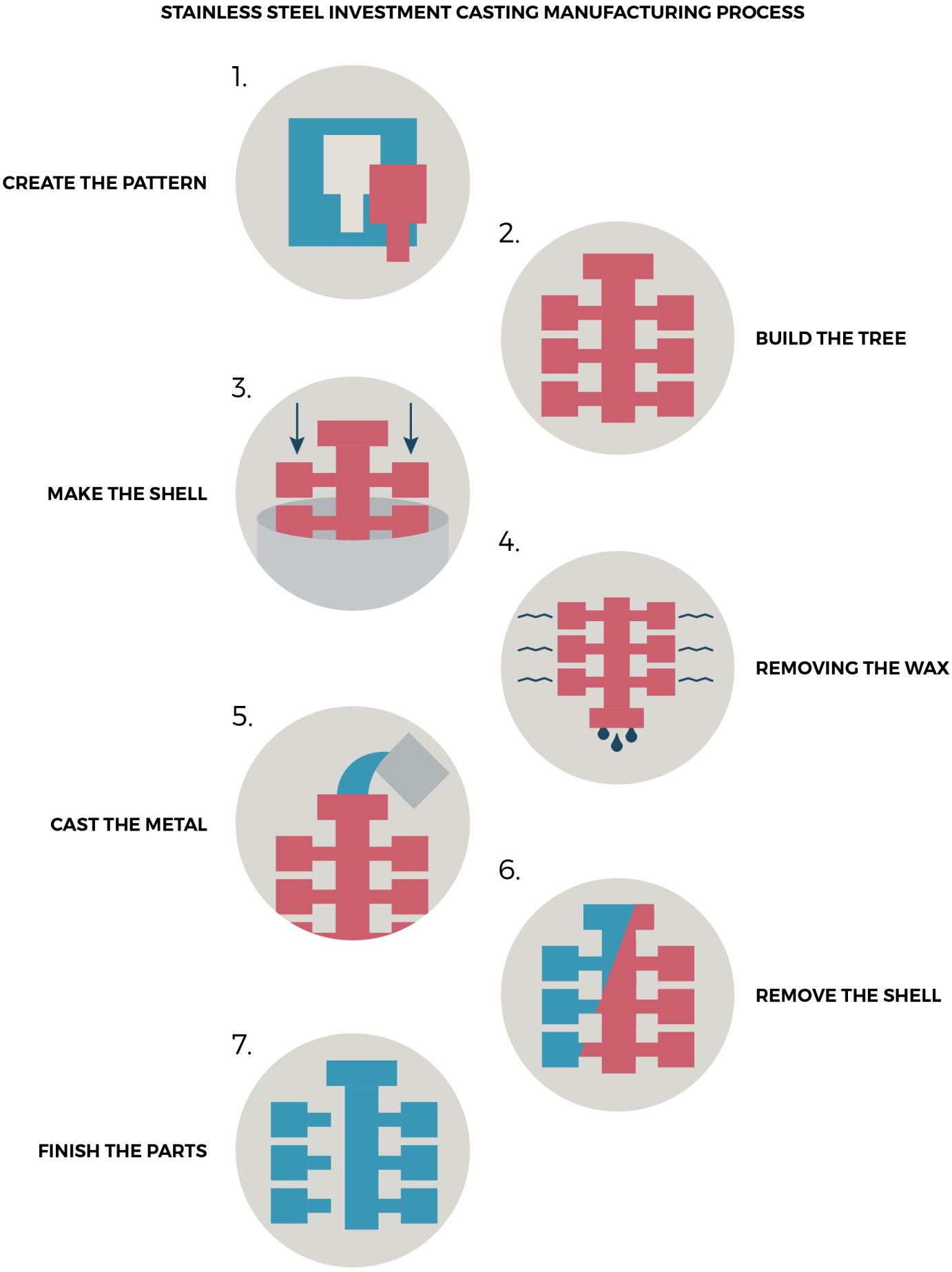


Figure 4.13 - Stainless steel investment casting manufacturing process

SECTION 5

PROJECT EVALUATION

5.1 | PRODUCT VALIDATION

To evaluate the new C Spec design, it was assessed against the previously identified design requirements and project goals. User testing was conducted with individuals familiar with the C Spec, interviews were held with healthcare professionals and FEA simulations were run. Below some key design requirements are highlighted to evaluate the new C Spec design.

HEALTHCARE PROFESSIONAL USEABILITY

Req 1.3: *Clear Feedback System*

The current C Spec has issues with providing feedback on the degree of flap openness. The hook/nut mechanism IS difficult to operate, leading healthcare professionals to think that the flaps were fully open when they were not.

This requirement was tested with individuals familiar with the C Spec, asking them to identify the degree of flap openness when squeezing the new C Spec handle with the flaps inside the Mama U model (figure 5.1).

By implementing a speculum-style handle, users can clearly identify the flap openness. It is logical that when they cannot squeeze the handles any closer together, that the flaps are fully open. This intuitive design translates to all stages between minimum and minimum flap openness.

Req 1.5: *Single Operator*

The C Spec is currently operable by one healthcare professional. In LRS, another healthcare professional is not always available to assist. This design requirement must therefore be maintained for the new design.

The new C Spec design allows for operation with one hand. The squeezing movement to open the flaps is conducted with one hand. The ergonomically designed handle allows the healthcare professional to comfortably stabilise the new C Spec, keeping the cervix in view of the camera. This leaves the other hand free for inserting apparatus.

Req 1.6: *Intuitive Design for Healthcare Professional*

Healthcare professionals often resist changing to new medical devices. The traditional speculum, despite being uncomfortable for women, is preferred by healthcare professionals due to its familiarity.

The new C Spec design features a speculum-style handle with the existing C Spec main body. This makes the product feel familiar and healthcare professionals instinctively know how to operate it as it resembles the traditional speculum they are accustomed to.

Req 1.7: *Comfortable Healthcare Professional Positioning*

Healthcare professionals are currently able to sit or stand comfortably during the procedure with their arms at roughly a 90 degree angle.

Testing with individuals familiar with the C Spec revealed that the new design is more dependent on the patient positioning for comfortable use by the healthcare professional. Unlike the parallel flap mechanism of the current C Spec, the new design includes an operation mechanism that is perpendicular, requiring a different hold. Healthcare professionals are therefore more included to sit to avoid wrist strain. If sitting is not an option, the handle includes a curved form that allows for a higher hand placement and therefore reduced wrist strain.

Figure 5.1 - Testing handle ergonomics for the user when the patient bed is lower

PATIENT COMFORT

Req 2.2: *Maximum Main Body Diameter*

The current C Spec design has an external tube diameter of 29mm, which GIC Space tested and found to be comfortable for women. The maximum allowable diameter of the new C Spec is 32mm, as defined by GIC Space.

For the new C Spec design, the external tube diameter was increased from 29mm to 32mm. This change was necessary because the new design features both an inner and outer tube. Without increasing the external tube diameter, the inner tube would be too small to comfortably fit the endoscopic camera and other apparatus.

Req 2.3: *No Sharp Edges*

The current C Spec design is comfortable for patients. Comfort is increased with the use of the sheath that prevents the vagina walls from being pinched by the flaps.

The new C Spec design maintains the same form for the surfaces that contact the patient, since redesigning the flaps was not within this project's scope. Although patient testing was not possible, it is assumed that by maintaining the existing form, the new C Spec design will remain comfortable for patients.

SCREENING ABILITY

Req 3.1: *Easy Apparatus Insertion*

The current C Spec hook and nut flap opening mechanism obstruct the path for apparatus to be inserted into the main body, causing apparatus to get caught.

The new C Spec design incorporates a speculum-style handle, therefore positioning the flap opening mechanism perpendicular to the main body, removing obstructions from the main body tube opening.

To facilitate easier insertion of apparatus, a wider opening was created at the top of the C Spec handle to guide apparatus into the narrow inner tube. The internal path of the apparatus is smooth to prevent apparatus from catching on edges. These design features were validated through mock screenings conducted with individuals familiar with the C Spec using the Mama U model.

Req 3.2: *Area for Apparatus*

The current C Spec provides a cross sectional area of 555mm^2 for the endoscopic camera and apparatus. If unobstructed by the flap opening mechanism, this surface area is sufficient for necessary apparatus to be inserted.

Figure 5.2 - Testing ability to insert apparatus into the narrower inner tube of the C Spec using the Mama U model

Due to the inclusion of an inner and outer tube in the new C Spec design, the inner tube's cross sectional area decreased to 373mm^2. Despite increasing the external tube diameter, the space required for the linear cam mechanism decreases this inner area. This design requirement is therefore not satisfied. Testing however revealed that apparatus could still be inserted due to the previously mentioned unobstructed opening to the main body. This author however still recommends optimising the mechanism in the future to increase the inner tube diameter.

Req 3.4: *Flap Lock System*

The C Spec currently uses small nuts to lock the flaps in place. These nuts are difficult to operate, causing pain and discomfort to healthcare professionals' fingers after repeated screenings.

The new C Spec design implements a band and notch to lock the squeeze handle in place. Although a ratchet system was initially considered, it was deemed unsuitable due to the sterilisation requirements of this project. Additionally, varying flap openness stages are less relevant as the expansion of the introitus remains unchanged. This therefore does not impact patient comfort.

Tests and interviews conducted indicated that the locking band is easy to interpret, aiding in keeping the new C Spec design intuitive for new users.

STERILISATION REQUIREMENTS

Req 4.2: *Ease of Disassembly*

The current C Spec cannot be easily disassembled for thorough sterilisation procedures, which require the product to be cleaned with a brush and soap to remove biological matter before the sterilisation phase.

The new C Spec design allows each component to be disassembled. Using rotation lock and release mechanisms and pin/hole joints, every part can be removed. This allows healthcare professionals to clean product parts more easily and thoroughly. This design requirement is therefore fully satisfied.

Figure 5.3 - Ability to disassemble every product part for sterilisation

5.2 | PROJECT LIMITATIONS

FIELD RESEARCH

Limited Speculum Screenings Observations:

This project took insights from the observations conducted during field research in Cameroon. As noted in section 1, only 7% of women in Cameroon have ever been screened for cervical cancer. During a three week field research period, only four women were observed undergoing a screening using a speculum. This low number means that some issues identified by healthcare professionals during interviews were not observed directly by the author, placing a greater reliance on the accounts of the healthcare professional.

Limited C Spec Screenings Observations:

Similar to screening using a speculum, only four observations were conducted using the C Spec. As a result, some of the issues identified were not directly observed by the author increasing reliance on healthcare professional accounts.

Additionally, these screenings were performed by Dr Conrad, the designer of the C Spec. His knowledge on the means that issues new users might encounter were not seen during observations. Healthcare professionals unfamiliar with the C Spec were asked to perform a screening simulation using the Mama U, but this does not accurately replicate a screening on a real patient.

PRODUCT TESTING

Lack of Healthcare Professional Testing

The final product prototype was tested using the Mama U by TU Delft Industrial Design students who were also working on improving the C Spec. This was done because the healthcare professionals familiar with the C Spec were only available via video call due to their location in Cameroon. Although th students insights were valuable and the healthcare professionals provided feedback to the best of their ability via video call, this feedback does not accurately replicate a screening conducted by a healthcare professional in Cameroon.

Inability to Test on Patients

Since the product is still in its development phase and is not yet part of a clinical trial, it could not be tested on real patients. Instead, FEA simulations and tests using the Mama U were conducted to mimic a real-world screening scenario with the new C Spec design. Informed assumptions can be made based on the previously mentioned data and the fact that the new design incorporates a speculum-style handle with the existing C Spec main body. However, this combination is new for users and, unfortunately, could not be physically tested on users at this time.

Figure 5.4 - User testing with the Mama U, the C Spec and new C Spec users in Cameroon

5.2 | RECOMMENDATIONS

PRODUCT LEVEL

INPUT FROM A MECHANICAL ENGINEER

Due to a limited project time, this project did not have the opportunity to optimise the mechanisms to be, for example, more efficient regarding force distribution and tolerances. As a follow up to this project, someone with a mechanical background should inquire the potential and possibilities to do so.

NEW FLAP DESIGN

The pain point of vaginal walls being pinched when the flaps are opened without the plastic sheath therefore still remains. As a follow up to this project, this pain point should be addressed to remove the need of the silicone sheath. By doing so, product waste of a cervical cancer screening using the C Spec can be lowered or removed altogether.

VISUALISING OF THE VAGINAL WALLS

The C Spec design currently does not incorporate the ability to visualise the vaginal walls, which healthcare professionals expressed is important for an informed diagnosis. Someone with a relevant background should explore the possibilities to use a material and/or mechanism that allows this in the future.

FACILITATING WOMEN WITH LARGER CERVIXES

This design limitation was not addressed in the scope of this project. This is because there is a marginal amount of women experiencing this 'issue', lowering its importance in prioritisation within this project specifically. The possibility to incorporate a system with, for example, bigger flaps should be explored in a future project.

MULTIPLE C SPEC ATTACHMENT OPTIONS

The new C Spec design allows the main body to be removed from the handle using a bayonet mechanism for the purposes of sterilisation. This ability could allow for body attachments used in other gynaecological procedures, such as screening for female genital schistosomiasis (FGS), to be attached as well. By doing this, the C Spec could become a multifunctional gynaecological product, not only limited to cervical cancer screenings.

SYSTEM LEVEL

WORLDWIDE IMPLEMENTATION OF C SPEC

Instead of only being usable in LMICs, this product can be implemented worldwide. The C Specs initial goal was to lower the barriers for cervical cancer screenings for women in LRS. It did this through reducing discomfort experienced by women during such procedures. Discomfort during gynaecological procedures is not only an issue experienced in LMICs, but this is a barrier for women going through gynaecological procedures worldwide. This project should therefore in future explore integrating this product within cervical cancer screenings worldwide.

Furthermore, as previously mentioned, through allowing multiple C Spec bodies to be attached to the same handle, a universal handle could be created. Through universalising this handle, it allows medical professionals to utilise the same range of tools, no matter whether they are operating in a high-or low resource setting. From a business perspective, the ability to potentially be able to universalise a medical equipment handle, allowing for a range of main bodies for gynaecological purposes to be attached, while also preserving comfort for both the healthcare professional and the patient shows lots of potential.

STAINLESS STEEL VS DISPOSABLE DEBATE

The debate between stainless steel and disposable is one where there are many possibilities depending on the use case scenario. In the case of the new C Spec design, both materials are viable options which are extremely beneficial to any stakeholder.

Stainless Steel:

In this project specifically, the new C Spec design is manufactured from stainless steel to minimise waste through the ability to sterilise. This is also why app product parts were made to be easy to disassemble. There are however two other use cases that have been explored throughout this project that can be further explored in the future to suit different use case scenarios.

Disposable:

The new C Spec design can be produced using disposable materials, allowing healthcare professionals to dispose of

the product after a single use. This is currently the norm, and the highly preferred option for healthcare professionals in LRS due to the lack of systems in place to sterilise stainless steel apparatus sufficiently.

Part Disposable, Part Stainless Steel:

This report previously mentioned the possibility to attach multiple C Spec body types for different gynaecological procedures to the same handle assuming both use the bayonet attaching system. If this is indeed the case, this would create the option to produce a handle from stainless steel while producing disposable main body attachments (figure 5.5). Since the stainless steel handle does not come into contact with mucosal tissue, it has a lower set of sterilisation criteria (Sellors, n.d.), making the sufficient cleaning of the handle more achievable for the LRS.

The decision between material choice can be made by each stakeholder individually, and potentials can be further explored in future research projects.

IMPROVEMENT OF SYSTEM FOR STERILISATION

This project aimed to improve the ability to properly sterilise the new C Spec design through ease of disassembly. Even then, sterilisation of the product is an issue among healthcare professionals either due to limited time and/or resources. To enhance the industry's ability to get rid of more and more disposable waste, future research should explore the ability to sterilise medical apparatus at a system level. That, through the implementation of for example a new process, sterilisation can be more achievable for healthcare professionals in a limited setting.

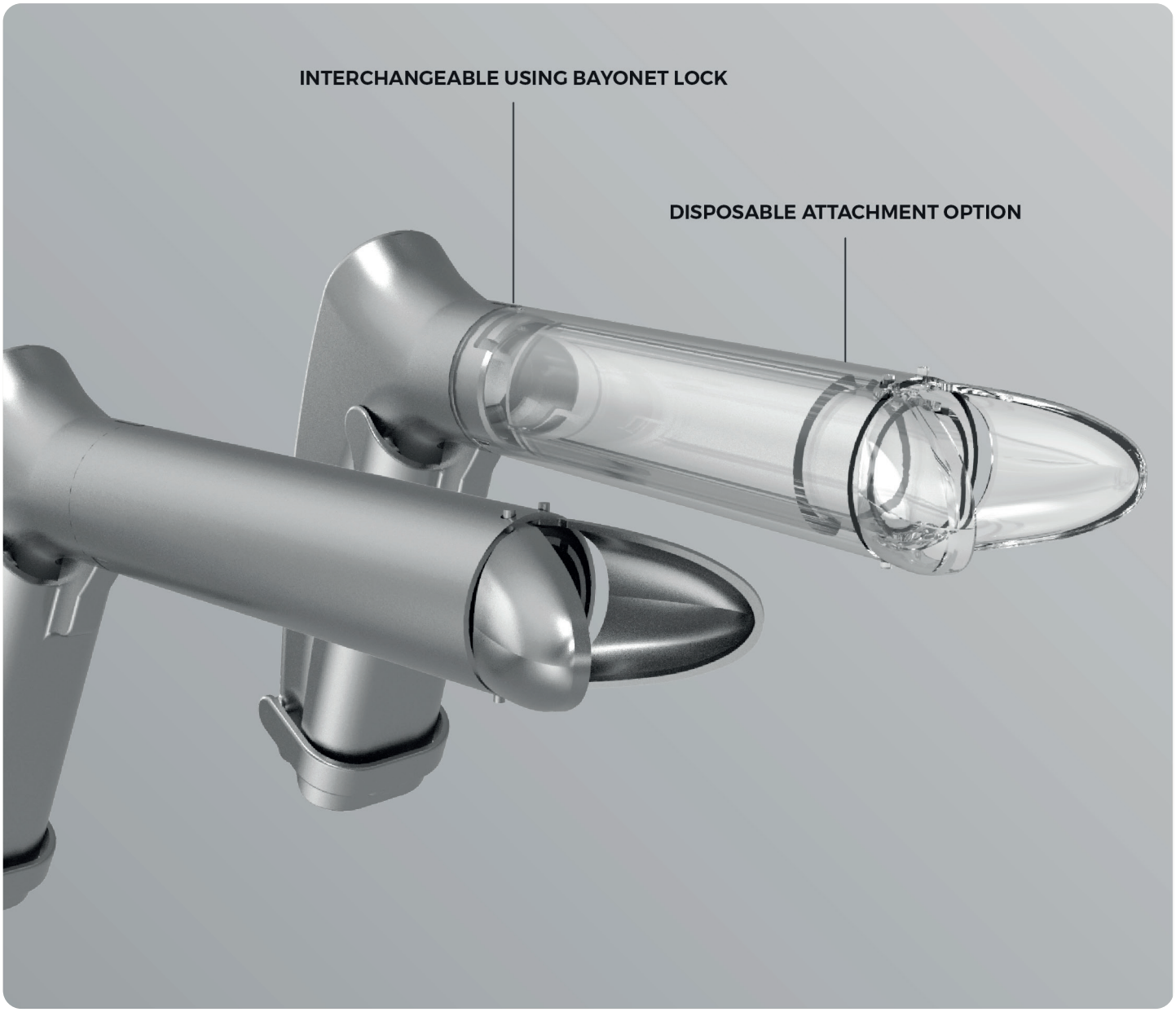


Figure 5.5 - Interchangeable C Spec main body options

5.4 | PERSONAL REFLECTIONS

DRISCOLL'S METHOD

For this personal reflection, Driscoll's what model is used. This model asks this author to reflect by identifying the action, then explain why this action was significant, and to finally explain how this information can inform future practice by asking "what", "so what", "now what".

DESIGN BY DOING

What:

knew I was a designer that learnt by doing and making things. Although this is still the case, I realised that at stages of this project, I was scared to prototype because I wanted to get the design too right. I thought that by doing, I would get sucked into the wrong direction.

So what?

With there being time pressure, and the fact that I needed to show progress at multiple stages during this project, I had to do. The design process is not a clear line that is always logical and right. By doing nothing I do not get further with the project because designing in your head is confusing.

Now what?

I realised that by doing, I could show my ideas to people. As a result, questions were asked that made me question some directions and reconsider others. For me as a designer in the future, I need to have a physical, tactile product to go further in my process as well as that I should not be ashamed to ask for help as this recollects my project ideas.

WORKING ALONE IN A LARGE TEAM

What:

This project had multiple parties working on the C Spec at the same time each tackling a different problem aspect. For this graduation project, I was therefore working alone on my topic, but also working within a large network.

So what?

I saw this ability to work alone within a larger team as a good opportunity to strengthen my own project but to also be valuable in other parties. Working within this larger system allowed me to sharpen my communication skills, and to understand the needs and requirements of other parties for the better of the project end goal.

Now what?

In my future work, these scenarios will arise frequently. Whether it is coordinating with other teams such as engineers within the same company or with external clients, I appreciated being able to practise this scenario.

KNOWING MY AUDIENCE

What?

During the course of this project, I realised that at times I did not properly communicate with my audience as I unconsciously assumed that my audience knew the topic as well as I did.

So what?

By making this realisation halfway through my project period, I was able to adjust and better tell the story of my project depending on who I was talking to. I started this by always at the beginning of a meeting, backtracking and looking at previous steps made to get everyone on the same page.

Now what?

Through learning this and consequently adjusting during my graduation period, I was able to practise this skill. In the future when communicating with my clients at my job I now know to better adjust to my audience.

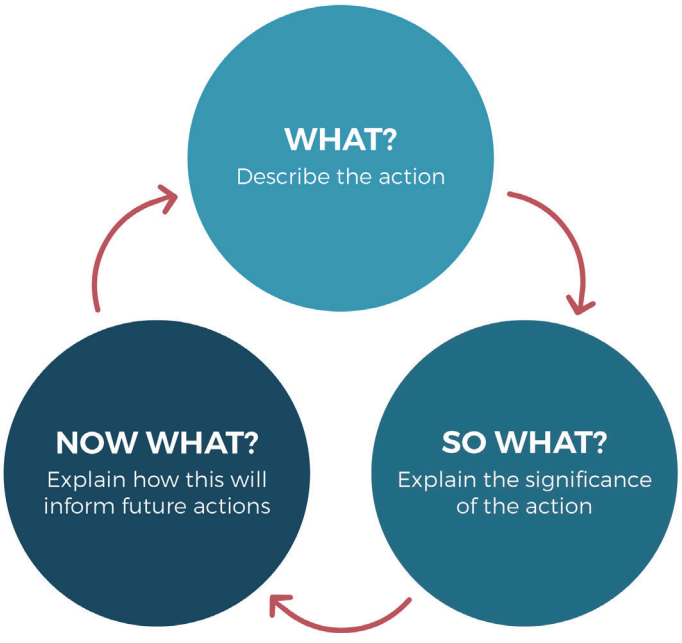


Figure 5.6 - Driscoll's what method of reflection

Raising Awareness for Cervical Cancer Awareness Month during Field Research In Yaounde, Cameroon

REFERENCES

Adedimeji, A., Ajeh, R., Pierz, A., Nkeng, R., Ndenkeh, J., Fuhngwa, N., . . . Castle, P. E. (2021). Challenges and opportunities associated with cervical cancer screening programs in a low income, high HIV prevalence context. BMC Women's Health, 21(1). doi:10.1186/s12905-021-01211-w

Allanson, E., & Schmeler, K. (2021). Cervical cancer prevention in low and middle income countries. Clin Obstet Gynecol.

Alvisi, S., Gava, G., Orsili, I., Giacomelli, G., Baldassarre, M., Seracchioli, R., & Meriggiola, M. C. (2019). Vaginal Health in Menopausal Women. Medicina, 55(10), 615. doi:10.3390/medicina55100615

Asiedu, M. N., Agudogo, J., Krieger, M. S., Miros, R., Proeschold-Bell, R. J., Schmitt, J. W., & Ramanujam, N. (2017). Design and preliminary analysis of a vaginal inserter for speculum-free cervical cancer screening. PLOS ONE, 12(5), e0177782. doi:10.1371/journal.pone.0177782

Asiedu, M. N., Agudogo, J. S., Dotson, M. E., Skerrett, E., Krieger, M. S., Lam, C. T., . . . Ramanujam, N. (2020). A novel speculum-free imaging strategy for visualization of the internal female lower reproductive system. Scientific Reports, 10(1). doi:10.1038/s41598-020-72219-9

Barnhart, K. T., Izquierdo, A., Pretorius, E. S., Shera, D. M., Shabbout, M., & Shaunik, A. (2006). Baseline dimensions of the human vagina. Human Reproduction, 21(6), 1618-1622. doi:10.1093/humrep/del022

Barnhart, K. T., Pretorius, E. S., & Malamud, D. (2004). Lesson learned and dispelled myths: three-dimensional imaging of the human vagina. Fertility and Sterility, 81(5), 1383-1384. doi:10.1016/j.fertnstert.2004.01.016

Biddell, C. B., Spees, L. P., Smith, J. S., Brewer, N. T., Des Marais, A. C., Sanusi, B. O., . . . Wheeler, S. B. (2021). Perceived Financial Barriers to Cervical Cancer Screening and Associated Cost Burden Among Low-Income, Under-Screened Women. Journal of Women's Health, 30(9), 1243-1252. doi:10.1089/jwh.2020.8807

Bruni, L., Serrano, B., Roura, E., Alemany, L., Cowan, M., Herrero, R., . . . De Sanjose, S. (2022). Cervical cancer screening programmes and age-specific coverage estimates for 202 countries and territories worldwide: a review and synthetic analysis. The Lancet Global Health, 10(8), e1115-e1127. doi:10.1016/s2214-109x(22)00241-8

Care, Y. Health for people with Vaginas Retrieved from https://yonacare.com/

Castle, P. E. (2008). How Does Tobacco Smoke Contribute to Cervical Carcinogenesis? Journal of Virology, 82(12), 6084-6086. doi:10.1128/jvi.00103-08

Chen, X., Lu, Y., Chen, T., & Li, R. (2021). The Female Vaginal Microbiome in Health and Bacterial Vaginosis. Frontiers in Cellular and Infection Microbiology, 11. doi:10.3389/fcimb.2021.631972

Clarke, M. A., Fetterman, B., Cheung, L. C., Wentzensen, N., Gage, J. C., Katki, H. A., . . . Schiffman, M. (2018). Epidemiologic Evidence That Excess Body Weight Increases Risk of Cervical Cancer by Decreased

Detection of Precancer. Journal of Clinical Oncology, 36(12), 1184-1191. doi:10.1200/jco.2017.75.3442

Clinic, C. (2021). Cryosurgery of the Cervix. Treatments and Procedures Retrieved from https://my.clevelandclinic.org/health/treatments/9120-cryosurgery-of-the-cervix

Clinic, C. (2022). Cervical Dysplasia. Retrieved from https://my.clevelandclinic.org/health/diseases/15678-cervical-intraepithelial-neoplasia-cin

clinic, C. (2022). Cervix. Retrieved from https://my.clevelandclinic.org/health/body/23279-cervix

Clinic, C. (2022). Colposcopy. Diagnostic and Testing Retrieved from https://my.clevelandclinic.org/health/diagnostics/4044-colposcopy

Clinic, C. (2022). Cone Biopsy. Diagnostics and testing Retrieved from https://my.clevelandclinic.org/health/diagnostics/23381-cone-biopsy

Clinic, C. (2022). Labour and delivery Retrieved from https://my.clevelandclinic.org/health/articles/9676-labor-delivery

Clinic, C. (2022). Loop Electrosurgical Excision Procedure (LEEP). Treatment and Procedures Retrieved from https://my.clevelandclinic.org/health/treatments/4711-loop-electrosurgical-excision-procedure-leep

Clinic, C. (2022). Pap Smear. Diagnosics and testing Retrieved from https://my.clevelandclinic.org/health/diagnostics/4267-pap-smear

Clinic, C. (2022). Uterus. Retrieved from https://my.clevelandclinic.org/health/body/22467-uterus

Clinic, M. (2021). Vaginal atrophy. Diseases and conditions. Retrieved from https://www.mayoclinic.org/diseases-conditions/vaginal-atrophy/symptoms-causes/syc-20352288

Clinic, M. (2022). Colposcopy. Retrieved from https://www.mayoclinic.org/tests-procedures/colposcopy/about/pac-20385036

Clinic, M. (2022). Pap Smear. Tests and Procedures Retrieved from https://www.mayoclinic.org/tests-procedures/pap-smear/about/pac-20394841

Clinic, M. (2023). HPV Test. Tests and Procedures. Retrieved from https://www.mayoclinic.org/tests-procedures/hpv-test/about/pac-20394355#:~:text=Routine%20use%20of%20the%20HPV,within%20a%20year%20or%20two.

Cohen, A. (2010). Dental Sterilization Solutions. Retrieved from https://www.3dmedicalprint.com/userupload/editorupload/files/files/pdf/Dental_Sterilization.pdf

Cooper, D., & Dunton, C. (2023). Colposcopy: StatPearls publishing.

Duke. (2017). Duke Team Reaches Milestone with Portable Cervical Cancer Screening Device. Retrieved from https://globalhealth.duke.edu/news/duke-team-reaches-milestone-portable-cervical-cancer-screening-device

Egorov, V., Murphy, M., Lucente, V., Van Raalte, H., Ephrain, S., Bhatia, N., & Sarvazyan, N. (2018). Quantitative Assessment and Interpretation of Vaginal Conditions. Sexual Medicine, 6(1), 39-48. doi:10.1016/j.esxm.2017.08.002

Europe, W. H. O. R. O. f. (2022). A short guide to cancer screening: increase effectiveness, maximize benefits and minimize harm.

Eveleth, R. (2014). Why No One Can Design a Better Speculum. Retrieved from https://www.theatlantic.com/health/archive/2014/11/why-no-one-can-design-a-better-speculum/382534/

Farage, M., & Maibach, H. (2006). Lifetime changes in the vulva and vagina. Archives of Gynecology and Obstetrics, 273(4), 195-202. doi:10.1007/s00404-005-0079-x

Foundation, C. H. (n.d.). Introducing the Callascope. Retrieved from https://callahealthfoundation.com/callascope/

GICMed. (n.d.). The GICMed vision. Retrieved from http://gictelemed.org/index.html

Gold, J. (2023). Physiology vaginal. Retrieved from https://www.ncbi.nlm.nih.gov/books/NBK545147/

Group, T. a. F. (1952). II The Anatomy of the Uterine Cervix and Isthmus. Acta Radiologica, 38(sup91), 9-12. doi:10.3109/00016925209133068

Gynius. (n.d.). The Gynocular. Retrieved from https://gynius.se/gynocular

Haylen, B. T., Vu, D., Wong, A., & Livingstone, S. (2022). Surgical anatomy of the mid-vagina. Neurourology and Urodynamics, 41(6), 1293-1304. doi:10.1002/nau.24994

Holland, K. (2018). Understanding the vaginal introitus. Retrieved from https://www.healthline.com/health/introitus

IARC. (2022). Cancer Today Dataviz. Retrieved from:https://gco.iarc.fr/today/en/dataviz/maps-heatmap?mode=population&group_crc=0&include_nmsc_other=0&sexes=2&cancers=23&types=1

IARC. (2022). Cervical Cancer Screening (Vol. 18). IARC Publications.

IARC. (2023). Cameroon Human Papillomavirus and related Cancers, Fact sheet 2023. Retrieved from: https://hpvcentre.net/statistics/reports/CMR_FS.pdf

Institute, N. c. Anatomy of the female pelvis. Retrieved from https://training.seer.cancer.gov/cervical-uterine/anatomy/

Institute, N. C. (2022). Cervical Cancer Stages Retrieved from https://www.cancer.gov/types/cervical/stages

Institute, N. c. (2022). Cervical cancer symptoms. Retrieved from https://www.cancer.gov/types/cervical/symptoms

Institute, N. c. (2023). Cervical Cancer Causes, Risk Factors, and Prevention. Retrieved from https://www.cancer.gov/types/cervical/causes-risk-prevention

Institute, N. C. (2023). Cervical Cancer Diagnosis Retrieved from https://www.cancer.gov/types/cervical/diagnosis

Institute, N. c. (2023). Cervical cancer screening Retrieved from https://www.cancer.gov/types/cervical/screening

Institute, N. C. (2023). Cervical Cancer Treatment. Retrieved from https://www.cancer.gov/types/cervical/treatment

Institute, N. c. (2023). HPV and Pap Test Results: Next Steps after an Abnormal Cervical Cancer Screening Test. Retrieved from https://www.cancer.gov/types/cervical/screening/abnormal-hpv-pap-test-results

Institute, N. c. (2023). What is cervical cancer? Retrieved from https://www.cancer.gov/types/cervical#:~:text=The%20ectocervix%20(also%20called%20exocervix,the%20vagina%20to%20the%20uterus

Institute, N. C. (n.d.). Pap Smear. NCI Dictionary of Cancer Terms. Retrieved from https://www.cancer.gov/publications/dictionaries/cancer-terms/def/pap-smear

Kent, C. (2020). Does the vaginal speculum need a redesign? Retrieved from https://www.medicaldevice-network.com/features/does-the-vaginal-speculum-need-a-redesign/

King, H. (2011). The speculum finally gets redesigned – by women. Retrieved from https://research.open.ac.uk/news/speculum-finally-gets-redesigned

Koot, D. J. (2021). Toward elimination of cervical cancer. [Mobile application software]. Retrieved from https://youtu.be/nOygpQfkYU8

Kumar, A., Shankar, Y. U., Prakash, S., Radhika, B., & Fatima, N. (2014). Colposcopy - A Novel Diagnostic Technique for Oral Mucosal Lesions. Retrieved from National library of medicine: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4253295/

Levy, R. (2021). The benefits of stainless steel investment casting Retrieved from https://www.tfgusa.com/benefits-of-stainless-steel-investment-casting/#:~:text=Stainless%20steel%20investment%20casting%20can,Automotive

Lucas, E. (n.d.). Testing and reporting the results of visual inspection with 5% acetic acid (VIA). Retrieved from https://screening.iarc.fr/viavilichap2.php?lang=1

Marieb, E. N., & Hoehn, K. (2015). Human Anatomy & Physiology (Tenth ed.): Pearson

McCarthy, S., & Vaquero, E. (1986). Gynecologic anatomy with magnetic resonance imaging. Am J Obstet Gynecol, 155(2), 255-259. doi:10.1016/0002-9378(86)90801-x

Mello, V., & Sundstrom, R. K. (2023). Cervical Intraepithelial. Retrieved from https://www.ncbi.nlm.nih.gov/books/NBK544371/

Mueller, J., Lam, C., Dahl, D., Asiedu, M., Krieger, M., Bellido-Fuentes, Y., Ramanujam, N. (2018). Portable Pocket colposcopy performs comparably to standard-of-care clinical colposcopy using acetic acid and Lugol's iodine as contrast mediators: an investigational study in Peru. BJOG: An International Journal of Obstetrics & Gynaecology, 125(10), 1321-1329. doi:10.1111/1471-0528.15326

Nations, U. (n.d.). World population prospects. Retrieved from https://population.un.org/wpp/.

Nichols, D., & Randall, C. (1996). Pelvic anatomy of the living. Vaginal surgery. Baltimore, MD: Williams & Wilkins, 1-42.

Nilsen, T., Hermann, M., Eriksen, C., Dagfinrud, H., Mowinckel, P., & Kjeken, I. (2011). Grip force and pinch grip in an adult population: Reference values and factors associated with grip force. doi:http://dx.doi.org/10.3109/11038128.2011.553687

ODT, M. (n.d.). EVA Pro Next Gen Digital Colposcope. Retrieved from https://www.mobileodt.com/products/eva-pro/

Pardes, A. (2017). The Speculum Finally Gets a Modern Redesign. Retrieved from https://www.wired.com/story/the-speculum-finally-gets-a-modern-redesign/

Pendergrass, P. B., Belovicz, M. W., & Reeves, C. A. (2003). Surface area of the human vagina as measured from vinyl polysiloxane casts. Gynecologic and obstetric investigation. doi:10.1159/000070184

Pendergrass, P. B., Reeves, C. A., Belovicz, M. W., Molter, D. J., & White, J. H. (1996). The shape and dimensions of the human vagina as seen in three-dimensional vinyl polysiloxane casts. Gynecol Obstet Invest, 42(3), 178-182. doi:10.1159/000291946

Pendergrass, P. B., Reeves, C. A., Belovicz, M. W., Molter, D. J., & White, J. H. (2000). Comparison of vaginal shapes in Afro-American, caucasian and hispanic women as seen with vinyl polysiloxane casting. Gynecol Obstet Invest, 50(1), 54-59. doi:10.1159/000010281

Pradeilles, R., Holdsworth, M., Olaitan, O., Irache, A., Osei-Kwasi, H. A., Ngandu, C. B., & Cohen, E. (2022). Body size preferences for women and adolescent girls living in Africa: a mixed-methods systematic review. Public Health Nutrition, 25(3), 738-759. doi:10.1017/s1368980021000768

Prendiville, W., & Sankaranarayanan, R. (2017). Colposcopy and treatment of cervical precancer. National library of medicine: IARC technical publications.

Prevention, C. f. D. C. a. (2022). Human papillomavirus (HPV) Division of STD prevention Retrieved from https://www.cdc.gov/std/hpv/stdfact-hpv.htm#:~:text=But%20HPV%20can%20infect%20areas,only%20has%20sex%20with%20you.

Rani, D. S. A., & Rama, D. K. (2016). Comparative Analysis of Visual Inspection with Acetic Acid And Lugol's Iodine And Liquiprep TM in Cervical Cancer Screening with Cervical Biopsy As Gold Standard. IOSR Journal of Dental and Medical Sciences, 15, 54-62.

RIVM. (2014). Cervical Cancer Screening in the Netherlands Retrieved from https://www.rivm.nl/en/news/cervical-cancer-screening-in-netherlands

RIVM. (2023). Information about cervical cancer screening Cervical cancer screening Program Retrieved from https://www.rivm.nl/en/cervical-cancer-screening-programme/information-materials#:~:text=Cervical%20cancer%20is%20most%20common,at%20risk%20of%20cervical%20cancer.

RIVM. (2023). Self-sampling device to be sent automatically, making it easier to take part in cervical cancer screening. Retrieved from https://www.rivm.nl/en/news/self-sampling-device-to-be-sent-automatically-making-it-easier-to-take-part-in-cervical-cancer

Rossmann, J. S. (2008). Built to spec?: The vaginal speculum as a case study of inadequate design. Retrieved from https://ldr.lafayette.edu/concern/publications/nv935328w

Sandoval, M., Slavkovsky, R., Bansil, P., Jeronimo, J., Lim, J., Figueroa, J., & De Sanjose, S. (2019). Acceptability and safety of thermal ablation for the treatment of precancerous cervical lesions in Honduras. Tropical Medicine & International Health, 24(12), 1391-1399. doi:10.1111/tmi.13315

Sankaranarayanan, R., & Ramani, S. (2003). A practical manual on visual screening for cervical neoplasia. Retrieved from World Health Organization: https://screening.iarc.fr/doc/viavilimanual.pdf

Sellors, J. W., & Sankaranarayanan, R. (n.d.). Decontamination, cleaning, high-level disinfection and sterilization of /instruments used during the diagnosis and treatment of cervical neoplasia. Retrieved from https://

screening.iarc.fr/colpochap.php?lang=1&chap=14.php

Society, A. C. (2020). Risk factors for cervical cancer. Cervical cancer. Retrieved from https://www.cancer.org/cancer/types/cervical-cancer/causes-risks-prevention/risk-factors.html

Society, A. C. (2024). Key Statistics for Cervical Cancer. Cervical Cancer. Retrieved from https://www.cancer.org/cancer/types/cervical-cancer/about/key-statistics.html#:~:text=Cervical%20cancer%20is%20most%20frequently,cervical%20cancer%20as%20they%20age.

Spec, N. (n.d.). Nella Spec Retrieved from https://www.nellaspec.com/products/the-nella-comfort-kit

StayWell. (2021). Vaginal Infection: Understanding the Vaginal Environment. Retrieved from https://mountnittany.org/wellness-article/vaginal-infection-understanding-the-vaginal-environment

Steris. (2023). Guide to High-Level Disinfection of Endoscopy Devices. Retrieved from https://www.steris.com/healthcare/knowledge-center/sterile-processing/guide-to-high-level-disinfection

Stoppler, M. C. Definition of Uterine Fornix Retrieved from https://www.rxlist.com/uterine_fornix/definition.htm

Sultanov, M., Zeeuw, J. D., Koot, J., Der Schans, J. V., Beltman, J. J., Fouw, M. D., . . . Stekelenburg, J. (2022). Investigating feasibility of 2021 WHO protocol for cervical cancer screening in underscreened populations: PREvention and SCReening Innovation Project Toward Elimination of Cervical Cancer (PRESCRIP-TEC). BMC Public Health, 22(1). doi:10.1186/s12889-022-13488-z

Tancman, S., Hacohen, N., Lazarus, G., Solt, I., & Sagi-Dain, L. (2022). Silent voices that must be heard – women's perceptions of gynecologic examinations. Journal of Psychosomatic Obstetrics & Gynecology, 43(2), 190-197. doi:10.1080/0167482x.2020.1864727

Telfer, N. (2021). Vaginas 101. Retrieved from https://helloclue.com/articles/cycle-a-z/vaginas-101

Terrell, D. C. (2021, 2023). What Happens at an Ob-Gyn Checkup and Why? One Doctor Explains. Retrieved from https://www.acog.org/womens-health/experts-and-stories/the-latest/what-happens-at-an-ob-gyn-checkup-and-why-one-doctor-explains#:~:text=And%20your%20ob-gyn%20may,feel%20your%20uterus%20and%20ovaries

Thompson, L. (2022). The Vagina. Teach me anatomy. Retrieved from https://teachmeanatomy.info/pelvis/female-reproductive-tract/vagina/

UICC. (2022). Cervical Cancer Elimination in Africa: Where Are We Now and Where Do We Need to Be? : IARC Publications.

UK, C. R. (2023). What is cervical cancer? Retrieved from https://www.cancerresearchuk.org/about-cancer/cervical-cancer/about

Wagner, G., Wabrek, A. J., & Dalgaard, D. (1986). Vaginal penetration pressure: a parameter in impotence diagnosis? World Journal of Urology, 4(4), 250-251. doi:10.1007/bf00326970

WHO. (2016). WHO guidelines for the use of thermal ablation for cervical pre-cancer lesions (WHO Ed.). World Health Organization: World Health Organization.

WHO. (2019). WHO guidelines for the use of thermal ablation for cervical pre-cancer lesions. 108. Retrieved from https://www.who.int/publications/i/item/9789241550598

WHO. (2020). Global strategy to accelerate the elimination of cervical cancer as a public health problem. World Health Organization.

WHO. (2021). WHO guideline for screening and treatment of cervical pre-cancer lesions for cervical cancer prevention, second edition: use of mRNA tests for human papillomavirus (HPV): web annex: evidence-to-decision framework for mRNA testing for HPV. World Health Organization.

WHO. (2021). WHO recommends DNA testing as a first-choice screening method for cervical cancer prevention. Retrieved from https://www.who.int/europe/news/item/11-09-2021-who-recommends-dna-testing-as-a-first-choice-screening-method-for-cervical-cancer-prevention

WHO. (2022). Cervical cancer roadmap - essentials. Retrieved from https://www.who.int/europe/publications/m/item/cervical-cancer-roadmap-essentials

WHO. (2022). A short guide to cancer screening iris WHO Regional Office for Europe

WHO. (2023). New evidence on cervical cancer screening and treatment for women living with HIV. Retrieved from https://www.who.int/news/item/12-12-2023-new-evidence-on-cervical-cancer-screening-and-treatment-for-women-with-hiv

WHO. (2024). Cervical cancer. Retrieved from https://www.who.int/news-room/fact-sheets/detail/cervical-cancer

WHO. (2024). Human papillomavirus and cancer. Retrieved from https://www.who.int/news-room/fact-sheets/detail/human-papilloma-virus-and-cancer

WHO. (n.d.). HPV vaccination: Paving the path toward cervical cancer elimination in Africa. Retrieved from https://www.afro.who.int/sites/default/files/2024-03/HPV%20Vaccination_Paving%20the%20path%20toward%20Cervical%20Cancer%20elimination%20in%20Africa.pdf

APPENDIX

Appendix A

EXTRA CONTEXT INFORMATION

VAGINA BIOLOGY

VAGINAL WALL TISSUE LAYERS

The vaginal walls consist of three distinct layers of tissue, each serving different purposes. The innermost layer is known as the epithelium. Composed of squamous cells similar to the tissue found inside the mouth, this layer can withstand friction and is covered with the previously mentioned rugae. The middle layer of the vaginal wall is the muscularis, composed of smooth muscle tissue. Finally, the outermost layer is made of fibroelastic connective tissue and is referred to as the adventitia (Marieb, 2015).

VAGINA PHYSIOLOGY

The surface of the vaginal canal is covered by the epithelium which releases mucosal fluid, allowing the vagina to remain moist (Marieb, 2015). The squamous cells of the epithelium release large amounts of glycogen, which bacteria in the vagina metabolise anaerobically to produce lactic acid. The pH level of the vagina is, therefore, acidic, with a healthy range between 3.8 and 4.5 (Gold, 2023).

VAGINA DIFFERENCES AND AGE

A woman's vagina undergoes changes due to hormonal fluctuations at different stages of her lifetime. One of the most notable changes occurs during menopause. During this phase, a woman experiences a decrease in her estrogen levels (Farage, 2006) leading to the vaginal walls becoming dryer (Mayo clinic, 2021). Additionally, the walls become thinner, reducing vaginal flexibility which can cause pain or tearing during gynaecological manoeuvres (Alvisi, 2019).

CERVICAL CANCER

INCREASED RISK FACTORS OF HPV

Given that HPV is the leading cause of cervical cancer (WHO, 2022), it is crucial to identify factors that can increase an individual's risk of contracting HPV:

Sexual Activity: Since HPV is a sexually transmitted disease, individuals with multiple sexual partners or those sexually active from a young age (before 18) face a higher risk of infection (National Cancer Institute, 2023).

Weakened Immune System: Women with a weakened immune system are more vulnerable to developing precancerous lesions as their bodies have a reduced ability to fight HPV infections in the early stages (National Cancer Institute, 2023).

Smoking: Women who smoke, including those exposed to secondhand smoke, have a higher risk of developing cervical cancer (National Cancer Institute, 2023). Smokers are roughly twice as likely to develop cervical cancer than non-smokers due to the weakened immune response associated with smoking (American Cancer Society, 2020; Castle, 2008).

Reproduction: Women with a history of giving birth to multiple children have an increased risk of cervical cancer (National Cancer Institute, 2023). This can be due to increased exposure to HPV through sexual activity and/or the reduction in immunity during pregnancy, allowing HPV infections to persist (American Cancer Society, 2020).

HIV: Women living with HIV are six times more likely to develop cervical cancer than those without the infection, accounting for 5% of all cervical cancer cases (WHO, 2022). HIV weakens the body's immune system, making these individuals more vulnerable to HPV (WHO, 2023).

Obesity: A higher body weight in women increases pressure on the vaginal walls, making it challenging to open a speculum (Fouw, 2023). This creates difficulty in visualising the cervix properly, increasing the risk of precancerous lesions going undetected (National Cancer Institute, 2023).

SYMPTOMS

As discussed earlier, a woman can clear a HPV infection within a year or two without even knowing or experiencing any issues (WHO, 2022; Koot, 2021). This makes early-stage cervical cancer challenging to detect, as symptoms typically only appear once the cancer has progressed (National Cancer Institute, 2022). When symptoms do arise, they include:

Early-stage cervical cancer symptoms (National Cancer Institute, 2022):
- (Pelvic) pain during sex - Bleeding after sex - Bleeding after menopause - Bleeding between periods - Period bleeding heavier and longer than normal - Changes in discharge

Advanced-stage cervical cancer symptoms (National Cancer Institute, 2022):
- Difficulty or pain with urination - Blood in urine - Difficulty or pain with bowel movements - Bleeding from the rectum - Back or abdominal pain - Fatigue

Table A.1 - Early stage and advanced stage Cervical Cancer symptoms

PROGRESSION

Dysplasia, also referred to as cervical intraepithelial neoplasia (CIN), describes abnormal cells found on the surface of the cervix that develop due to the persistence of HPV over a long period of time. There are different grades of CIN, ranging from one to three. The longer the duration of HPV persistence, the higher the risk of having a higher grade of CIN, as the abnormal cells have had more time to progress. The grade of CIN is determined by the proportion of cervical epithelium that displays abnormal cells (Mello, 2023)(figure A.2).

CIN 1: This term refers to cases where up to one-third of the thickness of the epithelium is occupied by abnormal cells. CIN 1 is classified as a low-grade squamous intraepithelial lesion (LSIL)(Cleveland Clinic, 2022). Lesions in the CIN 1 phase do not always progress to cancer; approximately 60% of the CIN1 lesions will regress on their own making treatment unnecessary in many cases (Mello, 2023).

CIN 2: CIN 2 is characterised by the presence of abnormal cells in one to two-thirds of the thickness of the epithelium. This grade of CIN is classified as a high-grade squamous intraepithelial lesion (HSIL) and requires treatment, as CIN 2 lesions do not regress spontaneously (Cleveland Clinic, 2022).

CIN 3: When more than two-thirds of the epithelium's thickness is occupied by abnormal cells, the condition is classified as CIN 3. CIN 3 is also classified as a HSIL and requires treatment (Cleveland Clinic, 2022). Lesions within the HSIL category are considered precancerous.

ICC: In cases where abnormal cells invade the basal membrane layer of the cervix, the condition is diagnosed as invasive cervical cancer (ICC)(Mello, 2023).

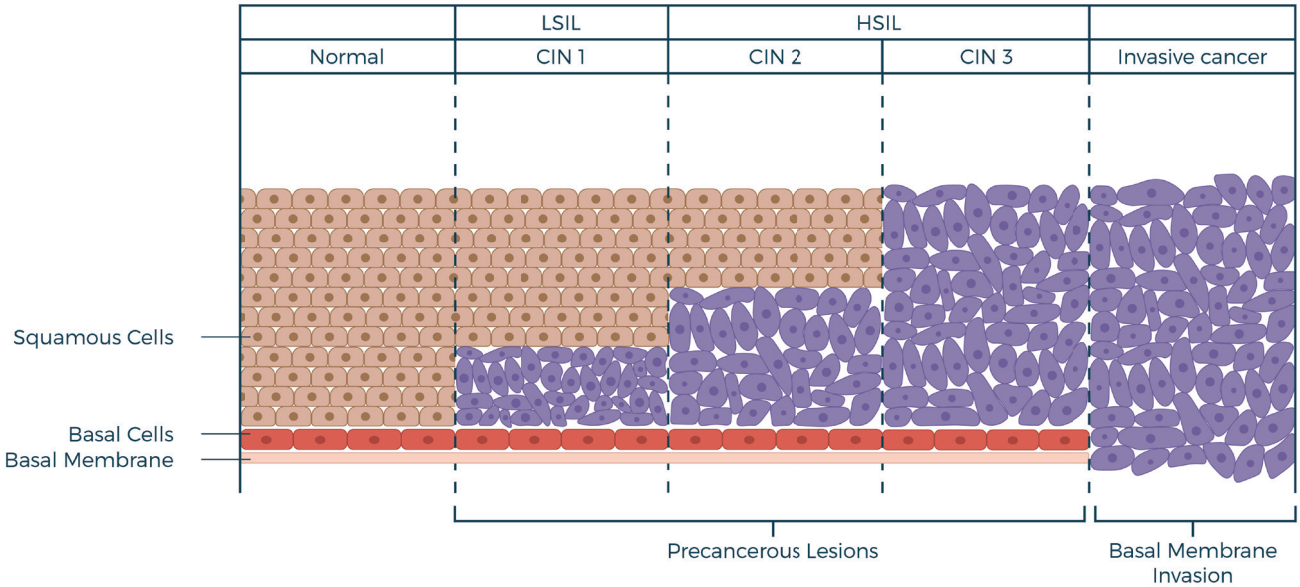


Figure A.2 - Stages of Cervical Intrasepithelial Neoplasia

CERVICAL CANCER TREATMENT

If a woman has been diagnosed with precancerous or cancerous lesions on her cervix, treatment is necessary to remove the abnormal cells. Several methods can be used, depending on the severity of CIN and the extent to which the lesion covers the cervix.

ABLATIVE TREATMENT

Ablative treatment is commonly used for lesions in the precancerous phase, particularly when there is no suspicion of invasive or glandular disease (World Health Organization, 2016). This ablative category includes thermal ablation and cryotherapy treatment. A woman is eligible for ablative treatment when the entire lesion is visible and does not extend into the endocervix. She is also eligible if she has a type 1 or 2 TZ (World Health Organization, 2016).

Thermal ablation involves pressing a hot probe (typically at 100 degree Celsius) against the cervix for 20-30 seconds, effectively eliminating abnormal cells from the epithelial tissue layer (World Health Organization, 2016). Cryotherapy, on the other hand, eliminates abnormal cells by freezing the cervical tissue (typically at about -20 degrees Celsius) for a few minutes (Cleveland Clinic, 2021).

Ablative treatments are usually performed without local anaesthesia, as there are relatively few nerve endings in the ectocervix. These procedures are therefore generally well tolerated by most women only causing mild discomfort (Prendiville, 2017).

LOOP ELECTROSURGICAL EXICISION PROCEDURE

If a woman is not eligible for an ablative treatment, it may be because she has a type 3 TZ or the lesion extends to the endocervix (World Health Organization, 2016). In such cases, a loop electrosurgical excision procedure (LEEP) is recommended. This procedure involves cutting (pre) cancerous lesions from the surface of the cervical tissue using an electrically heated insulated wire loop. LEEP is performed under local anaesthetic and takes between 10 and 20 minutes (Cleveland Clinic, 2022).

COLD KNIFE CONIZATION

Cold knife conization (CKC) works similarly to LEEP, involving the removal of abnormal cells from the cervical tissue through cutting. However, CKC is used when a larger area of tissue needs to be removed, using a surgical knife. Due to its complexity, CKC is performed under general anaesthesia. The recovery period for CKC is longer compared to LEEP, which is why LEEP is often preferred unless deemed necessary. The cut away tissue is sent to the pathologist for biopsy to determine the level of CIN (Cleveland Clinic, 2022).

SURGERY

If cervical lesions develop from precancerous to cancerous lesions, and spread further, surgery may be required, either in the form of a trachelectomy or hysterectomy. A trachelectomy involves removing the womens cervix when the cervical cancer tumour measures 2cm or less. On the other hand, a hysterectomy involves removing the uterus. This procedure is necessary when the cancer has spread beyond the point where a trachelectomy is sufficient.

TREATMENT IN LOW RESOURCE CONTEXT

Cervical (pre)cancerous lesions can be treated through ablative treatments such as thermal ablation and cryotherapy (World Health Organization, 2016). The difference between these two ablative treatment types is that thermal ablation burns the abnormal cells (World Health Organization, 2016) whereas cryotherapy freezes them (Cleveland Clinic, 2021). In LMICs, there is a preference towards thermal ablation over cryotherapy since the thermal ablation equipment is simple, lightweight and portable whereas the gas used for cryotherapy is heavy and not always readily available. If the precancerous lesions detected are inaccessible with the thermal ablation probe or if the lesions have progressed to cancer, alternative treatments through methods of cutting must be explored.

Appendix B

TESTING WITH THE MAMA U

THE MAMA U

A Mama-U is a postpartum uterus trainer. For the purpose of testing the C spec from the perspective of a healthcare professional, the Mama-U model was transformed to mimic a vaginal canal and cervix.

REPLICATING A CERVIX

On the inside of the Mama-U model there is a flap that can be turned around. This flap was tied together with an elastic band to create a scrunched up shape. This scrunched up shape mimics the cervix and can be seen in figure B.1 both when pushed out of the model and when inside the model using a speculum.

Figure B.1 - Replicating a cervix inside the Mama U Model

VAGINAL WALL PRESSURE

The Mama-U does not simulate the pressure of the vaginal walls properly. Because it is a uterus training model, the focus of the model is more on the uterus element instead of the vaginal canal. The vaginal canal is therefore simulated in the original Mama-U model as a thin mesh. To create more pressure to be able to better experience the use of the C-Spec from a healthcare professionals perspective, a thick foam strip was wrapped around the vaginal canal mesh of the original Mama-U model. This foam creates pressure but also moves out of the way when the speculum of C spec is inserted. The foam wall is shown in figure B.2

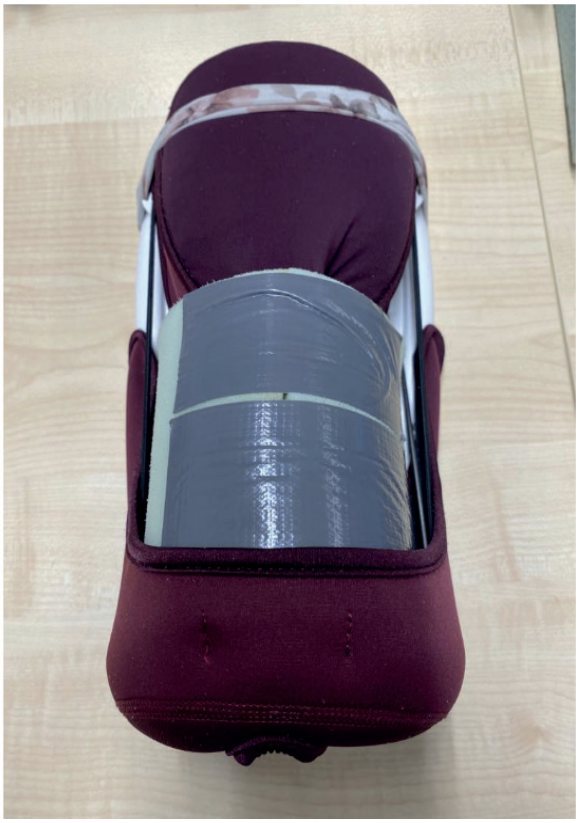
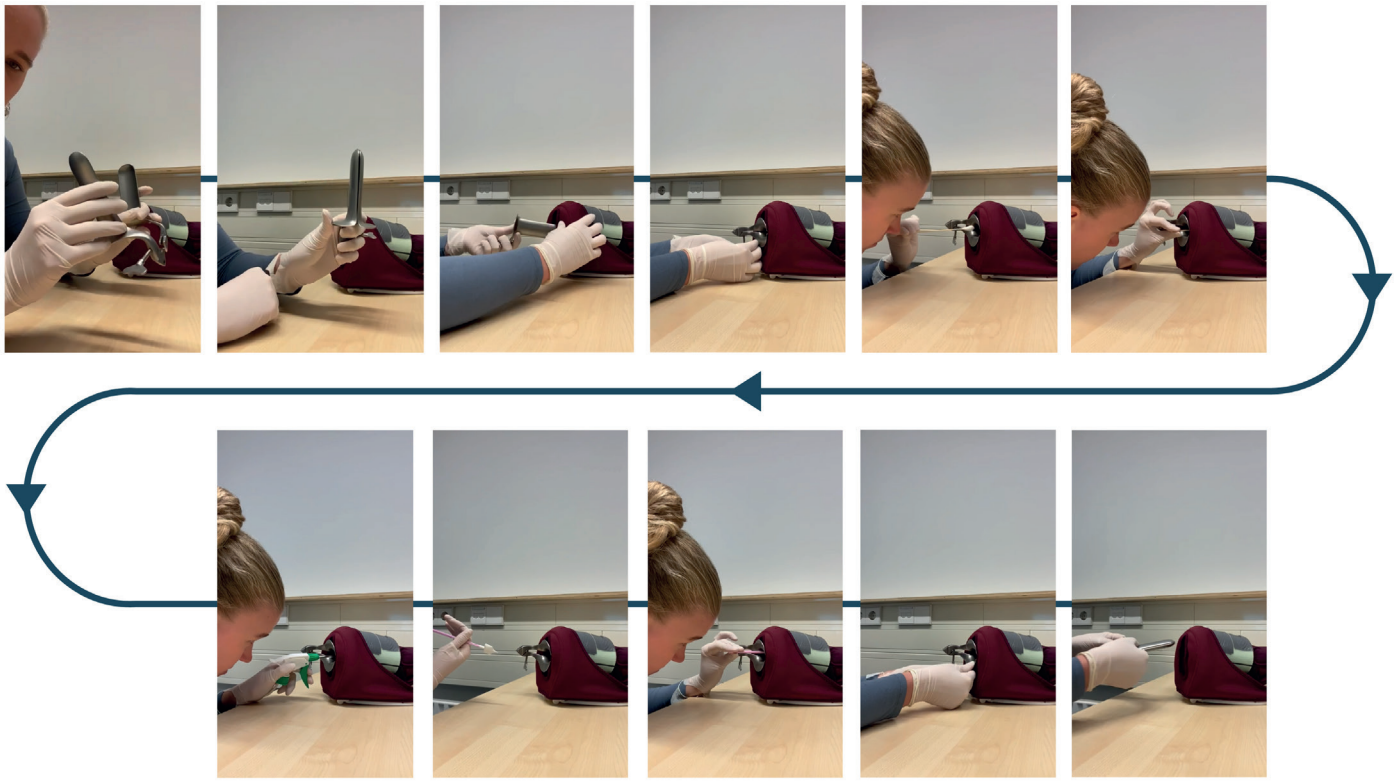


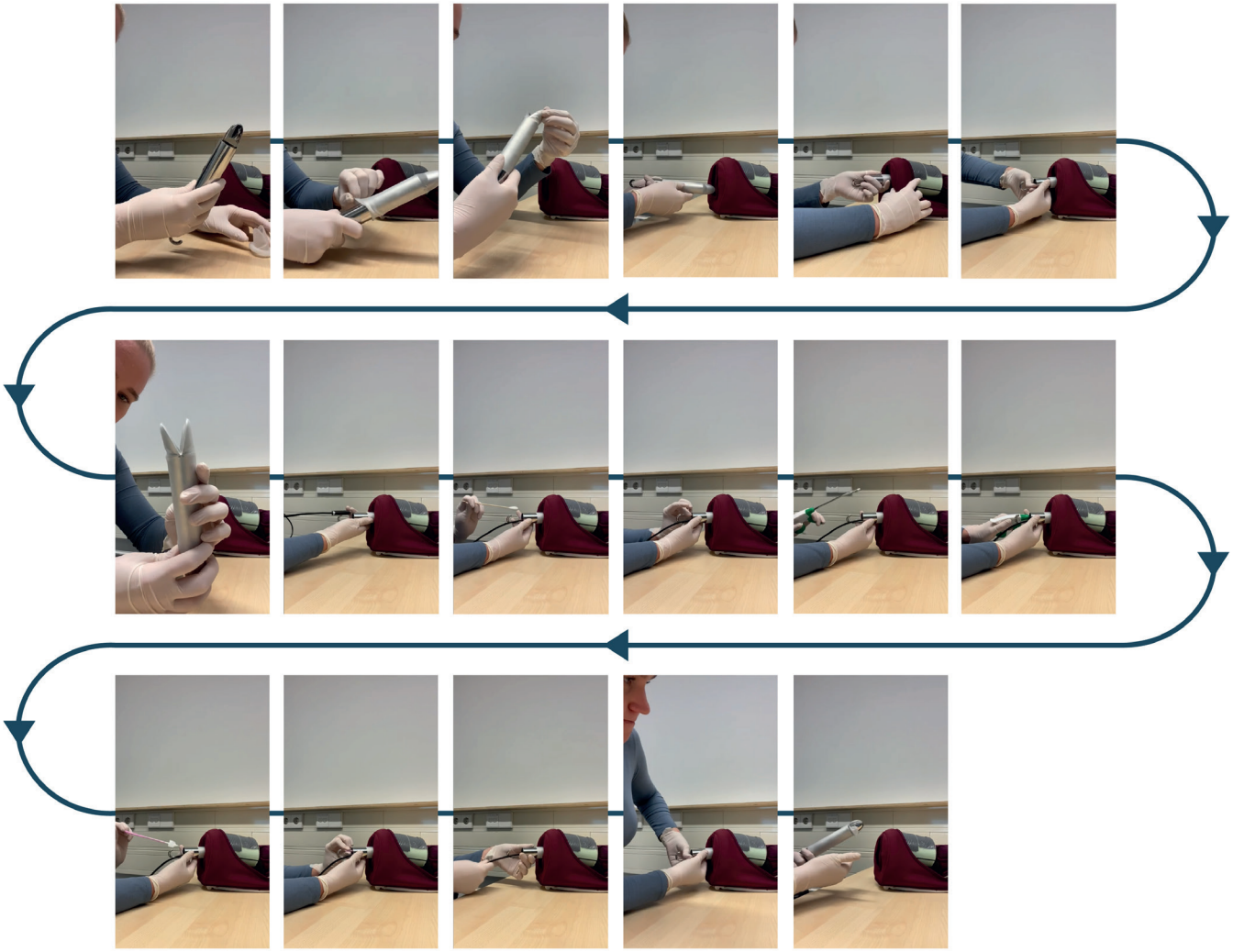
Figure B.2 - Replicating vaginal wall pressure using the Mama U

SCREENING STORYLINE VIA TESTING WITH A SPECULUM



1. With this speculum it comes in two parts. Step one is therefore to assemble the two pieces of the speculum together
2. The speculum is assembled
3. The speculum is inserted into the vaginal canal
4. Once inserted, the screw is turned to gradually open the speculum
5. Once opened, a cotton ball on a stick is used to clean the cervix and
6. ThIs is to rid the cervix of any mucus that might obstruct the view of determining pre-cancerous lesions etc.
7. Next the spray bottle with Acetic acid is inserted into the speculum and this is sprayed onto the cervix. From this, the abnormal cells can be visualised through looking through the speculum using the colposcope (not shown in the video)
8. If a sample needs to be taken of the cervix, then the brush tool is inserted
9. The brush tool is brushed over the cervix and through the shape of the bristles, a sample is taken. This can be used to test for HPV
10. One the tests are completed, the screw of the speculum is released
11. Finally, the speculum is removed from the vagina

SCREENING STORYLINE VIA TESTING WITH THE C SPEC



1. The C spec is used in this scenario for the VIA test
2. The silicone sleeve is pulled over the C-Spec. The intention to use the silicone sleeve was to keep the C spec sterile so that it does not need to be sterilised after every use and can instead just be disinfected. This is not correct. But the silicone sleeve also provides a form of comfort.
3. The two flaps of the silicone sleeve need to be pulled over the flaps of the C spec
4. The C spec is inserted into the vagina
5. The C spec is pushed in until it touches the cervix and can therefore not go any further. It is not clear what the orientation of the C spec is
6. The bolts of the C spec are turned to open the flaps inside the vagina to be able to properly visualise the cervix. They are turned as far as possible with the strength available
7. As shown in the image, when taken out of the vagina, the flaps of the C spec are actually not open very far. This is because the pressure of the vagina is quite high so can give a lot of push force back
8. Once the flaps are open, the camera is inserted into the camera holder of the C spec. This is moved forwards and backwards until and the C spec itself is also moved until a clear picture of the cervix is found
9. Then the cotton ball at the end of the stick is inserted into the apparatus compartment of the C spec
10. The cotton ball at the end of the stick is used to clean the cervix and remove any mucus that could be obstructing the visual
11. Then the sprayer of the bottle of Acetic acid is inserted into the apparatus compartment of the C Spec
12. This Acetic acid allows abnormal cells to be seen more clearly since they turn white
13. If a HPV test is done, the brush apparatus is inserted into the C spec
14. This is turned to collect cells from the cervix which can later be used to test in the lab
15. Once done, the camera is removed from the camera holder in the C spec
16. The bolts of the C spec are loosened
17. Finally, the C spec is removed from the vagina where it could be seen in this test that the silicone sleeve partly came off.

OBSERVATIONS WHILE TESTING WITH MAMA U

The Bolts/Hooks:

- The bolts to open the C spec are hard to turn. Especially with gloves and lubrication. It creates friction on the fingers which can hurt, especially after doing it multiple times a day. Also creates strain on the wrist
- When pulling on the hooks of the C spec, the doctor does not actually know if they are fully open
- When are the flaps fully open? Due to the pressure, it is hard to feel when they are turned to the max
- The flaps of the C spec do they close when loosened due to the vaginal wall? From the model they do slightly but not fully. But this is fine since it is still easy to pull out
- Hooks get in the way of the apparatus e.g. the spray gun
- When pulling on the hooks to open the C spec wider, the one hand needs to be on the C spec body and the other hand is used to pull the hook. There needs to be a third hand to then screw the bolt tighter. If this is not done, then the flaps collapse again due to the pressure of the vaginal walls

The Speculum:

- With the speculum, the sides of the vagina close in. This decreases visibility of the cervix
- A faster procedure compared to using the C spec

The C Spec Size and Shape:

- C-spec – The ridge after the flaps is hard. This creates a hard stop ridge that can cause friction and discomfort
- What is the orientation of the C spec? Do the flaps go outwards or do they go up and down? How does that correlate with the hook position?
- The C spec is quite long. Apparatus such as the brush does not fit into the length of the cervix
- A lot of the C-spec is outside the vagina
- Is it needed to hold the C spec in place?
- Does the fact that it sticks out quite a bit from the vagina make it easy to move inside the vagina due to the weight?
- Due to the long length of the C spec, the space left to hold the brush is small
- The edges of the biopsy cell brush get stuck on the edges of the C spec flaps

Insertion and extraction from the vagina:

- With the C-spec, you do not know how far to push it in – how far is too far?
- How far is too far to push the camera in? No lip etc. so once I pushed it too far that the camera came out the other end and I could not get it back into the camera hold
- The condom-like silicone sheath comes off when pulling the C-spec out of the vagina.
- The flaps of the C spec do they close when loosened due to the vaginal wall? From the model they do slightly but not fully. But this is fine since it is still easy to pull out

Locating The Cervix:

- Do not know if this is dependent on the model, but there is up and down movement of the C-spec which might therefore be difficult to find the cervix
- Relatively easy to move the C-spec, loose location of the cervix
- Always need to keep one hand on the C-Spec to keep it in place to visualise the cervix

The Camera:

- There is no stopper on the camera. How far do you push the camera in?
- But you also need to move the camera forward and backward to view the cervix.
- What if the camera had a few set positions? Then it would also not move and slide
- Would this allow for hands free use?
- If you included a stopper lip, would this then obstruct the camera view if it was moved backwards?

Taking a sample:

- There is not much wiggle room for the brush. Unsure if a good enough sample is taken
- I broke the brush trying to pull the brush out
- Using the C spec takes longer than using the other speculums

Noise:

- A lot of annoying noise is experienced due to the brushing of metal against each other

Privacy:

- When using the C spec, the doctors face is further away from the C-spec compared to with a speculum because the camera is used and with the speculum you need to physically look

Appendix C

CERVICAL CANCER SCREENING EXISTING PRODUCTS

EXISTING PRODUCTS HRS

THE NELLA

The Nella speculum was designed with the aim of enhancing both patient and healthcare professional comfort. Its narrow bill is comparable to the size of a tampon, allowing for a more comfortable insertion. The Nella features a 4-way opening system, eliminating the issue of the vaginal walls bulging in on the sides, thereby improving the view of the cervix. The Nella is also designed to enhance healthcare professional comfort. Its design incorporates a mechanism that allows for single-handed operation, along with an ergonomically angled handle. Made of a high-density autoclavable medical polymer, the Nella is both durable and comfortable, as it does not feel cold to the touch (Nella Spec, n.d.).

THE YONA

The Yona is a speculum designed to enhance comfort for both patients and healthcare professionals while improving cervix visualisation. The speculum uses a 3-leafed flap design, the speculum prevents the vaginal walls from bulging into view. Additionally, the ergonomically angled handle improves comfort for healthcare professionals and enables one-handed operation of the speculum. The mechanisms used are concealed within autoclavable silicone, and are designed to operate silently to prevent any patient discomfort from scary noises (Yona Care, n.d.).

THE FEM SPEC

The Fem Spec, developed by FemSuite, features a balloon style design that is inserted into the vagina like a tampon. Once inserted, the balloon is inflated similarly to a blood pressure cuff to open the vaginal walls (Pardes, 2017). The design aims to improve patient comfort by allowing the balloon to conform more closely to the natural contours of the woman's vaginal canal. A drawback of this design is the considerable pressure required to inflate the balloon. If the Fem Spec were to burst, it could lead to a lot of discomfort for the woman and potentially complications, such as an air embolism (Kent, 2020).

EXISTING PRODUCTS LRS

THE CALLASCOPE

The Callascope is a device with a 9mm diameter and a tip shaped like a calla lily. Once inserted into the woman, it utilises a camera to visualise the cervix on a screen (Asiedu, 2020). Priced between 200 and 800 dollars, this product is designed for low-income countries since other apparatus such as the colposcope are significantly more expensive, costing between 2,000 and 8,000 dollars (Kent, 2020). The callascope is currently in development to include a spray mechanism, enabling solutions such as acetic acid and lugol's iodine to be applied to the cervix (Asiedu, 2020). This addition would significantly enhance the device's utility since purely visualising the cervix is insufficient for a cervical cancer screening. A remaining challenge however is the inability to insert gauze or cotton swabs into the callascope to remove vaginal mucus, which can obstruct the camera view.

THE POCKEY COLPOSCOPE

The traditional colposcope views the cervix from outside the body at a distance of about 30 cm, necessitating a high-resolution camera. The pocket colposcope revolutionises this approach by bringing the camera closer to the cervix, reducing the required camera specification and thereby lowering the product cost. With the camera being positioned 3 cm away from the cervix, the pocket colposcope makes the device more affordable and suitable for low-resource settings. Images captured of the cervix are transmitted to a screen for viewing during the procedure (Duke, 2017). Interestingly, the pocket colposcope can be used either with or without a speculum. When used without a speculum, solutions applied during VIA/VILI screenings cannot be applied. On the other hand, including a speculum reintroduced the discomfort associated with traditional screening procedures.

THE GYNOCULAR

The Gynocular is a portable colposcope capable of capturing images of the cervix either through hand held operation or by being mounted on a tripod addition. When used with the tripod, the Gynocular can be operated hands-free during surgery. The device does however require the insertion of a speculum to provide a clear view of the cervix. On the positive side, the Gynocular is designed to streamline the training process of healthcare professionals, and includes a green filter that allows for more detailed tissue analysis during a VILI procedure (Gynius, n.d.).

THE EVA PRO

The Eva pro designed by Mobile ODT, is a portable digital colposcope similar to the Gynocular, that captures high-quality images of the cervix. With excellent camera magnifying properties, the Eva Pro captures images that are saved on its own cloud server. Additionally, this handheld device includes a green filter allowing blood vessels to be analysed during the VILI procedure (Mobile ODT, n.d.). Unfortunately, the Eva Pro requires the use of a speculum to capture a clear image of the cervix. Therefore, although the product is beneficial in that it is designed to be suitable for low resource settings, it may still cause discomfort for women during the screening procedure.

Appendix D

SPECULUM FIELD RESEARCH INSIGHTS

HEALTHCARE PROFESSIONAL MANOEUVRES

One screening, one nurse: A single nurse can typically operate the speculum themselves, since the speculum remains in place after insertion, freeing up both hands for the procedure. In cases where the woman has a retroverted cervix, additional assistance may be needed to angle the speculum for clearer visualisation.

Time to master the Speculum: Healthcare professionals expressed initially facing challenges with speculum operation since it requires some practice to properly insert. They have since mastered it but still experience issues if a woman is too tense during the procedure.

Two pairs of gloves per screening: Two pairs of gloves are worn during a single screening procedure. One pair is worn during the speculum insertion phase and the second pair when removing the speculum at the end of the procedure. No gloves are worn during the solution application and camera operation phase to ensure sterilisation of the mobile phone.

PATIENT COMFORT

Speculum discomfort: Most women expressed discomfort from the speculum particularly during insertion, opening, and closing. In no scenario did the healthcare professional apply lubricant to allow for a more comfortable insertion. Smaller speculums can be used but this obstructs proper visualisation.

Spraying with a needle: A syringe with a needle was used to apply solution onto the cervix. This is done to spray the solution from outside the vagina, keeping the syringe sterile, reducing the apparatus needed to be cleaned. Many women raised concerns about being pricked which raised feelings of discomfort during the screening.

HEALTHCARE PROFESSIONAL COMFORT

Uncomfortable body position: Depending on the height of the observation bed, the healthcare professional is required to bend down to view the cervix. This may cause physical strain particularly in rural scenarios where numerous screenings are conducted per day.

Visualisation:

The cervix is visible: When using a regular-sized speculum for screening, the cervix is usually easy to visualise due to the significant opening of the vaginal walls. If a smaller speculum is used however, due to patient discomfort, the quality of visualisation decreases.

PATIENT PRIVACY

No personal space: The healthcare professionals' close proximity to the vulva required for proper visualisation of the cervix may invade the privacy of the patient and cause discomfort especially since the patient is in a compromising position.

Patient confidentiality: Photos are captured with a mobile phone camera during the procedure. Patients expressed concern with how these images will be used and stored.

CAMERA HEALTHCARE PROFESSIONALS

Blurry photos taken: Healthcare professionals encounter difficulties in handling the camera, especially in the beginning phase of their training resulting in shaky photos that cannot be analysed. Photos are taken at each phase, but the inability to retake photos after solution is applied poses challenges for diagnosis.

Sterile camera consequences: To maintain a sterile mobile phone, gloves are removed to take photos. This could potentially lead to unintentional contact between a health professionals hands and a patients vulva especially since photos need to be captured from close up.

SPECULUM MATERIAL

Preference for disposable speculums: 98% of the time, disposable plastic speculums are used during a screening due to their cost-effectiveness, ease of disposal and therefore reduced sterilisation burden. The remaining 2% occurs when a speculum breaks due to an increased vaginal wall pressure of a woman. Patients also perceive the disposable speculum as cleaner and less painful.

Appendix E

C SPEC FIELD RESEARCH INSIGHTS

HEALTHCARE PROFESSIONAL MANOEUVRES

Lubricant gel makes turning the nuts difficult: Healthcare professionals need to be careful not to get lubricant on both gloves since this makes opening the C Spec very difficult. They have to be very aware of which task they conduct with which hand.

Lack of orientation creates confusion for HCPs: There is no orientation with the C Spec. The product itself has no correct way to be inserted and the camera inserted also has no orientation of insertion. This is an issue since healthcare professionals get lost identifying what is up and what is down when viewing the images on the mobile phone. This also poses an issue when communicating with other healthcare professionals on where the lesion is located.

The C Spec is not intuitive for new users: When healthcare professionals are given the C Spec for the first time, they are unsure how to operate it. They understand that the flaps are supposed to open but manipulation of the hook and nut opening mechanism requires explanation.

No feedback on degree of flap openness: Once the C Spec is inserted, the healthcare professional has no indication of how open the flaps are on the inside. The struggle to open the flaps in the first place makes estimating this more difficult.

Tangling and obstruction of apparatus: The camera wire connected to the phone can get caught in the hook mechanism. The hooks of the C Spec obstruct the entry to the main body, sometimes making it difficult to insert apparatus.

HEALTHCARE PROFESSIONAL COMFORT

Pain when operating the opening mechanism: Healthcare professionals' fingers hurt after only a few screenings due to how hard they have to twist the nuts to open the C Spec flaps. This would cause issues if multiple screenings are conducted per day.

Comfortable screening body position: The body position of the healthcare professionals is comfortable during a screening procedure. They can stand up straight and hold their elbows at a 90 degree angle to operate the C Spec. This is because they view the cervix on the mobile phone and not through a direct line of sight.

PATIENT PRIVACY

Improvement in personal space with C Spec: Due to the cervix being seen on the mobile phone, the healthcare professional can stand up straight. They can therefore keep a greater distance between their face and the patient's vulva, maintaining some form of personal space.

Less confrontation with camera capturing cervix photos: It is less obvious to the patient that a camera is used to capture their cervix compared to a traditional speculum procedure. This provides the patient with some comfort since it is less confronting.

HEALTHCARE PROFESSIONAL PRIVACY

Improvement in personal space with C Spec: The healthcare professional can keep more distance between themselves and the patient due to their face not needing to be close to the vulva to view the cervix. This provides some comfort for the healthcare professional since both them and the patient maintain some level of personal space.

Appendix F

WOMEN RECEIVING TREATMENT CALCULATION

Population of women in Cameroon aged 30-49 = 5,462,240
7% of women aged 30-49 are screened per year in Cameroon
7% of 5,462,240 = 382,356 women screened per year ages 30-49 in Cameroon

Women diagnosed with cervical cancer in Cameroon per year aged 30-49 = 4,203
4,203 / 382,356 x100 = 1.099% of women screened are diagnosed with cervical cancer per year aged 30-49 in Cameroon

1/3 of women show up for treatment of cervical cancer

Therefore only 0.3% of women screened for cervical cancer per year will be treated

Appendix G

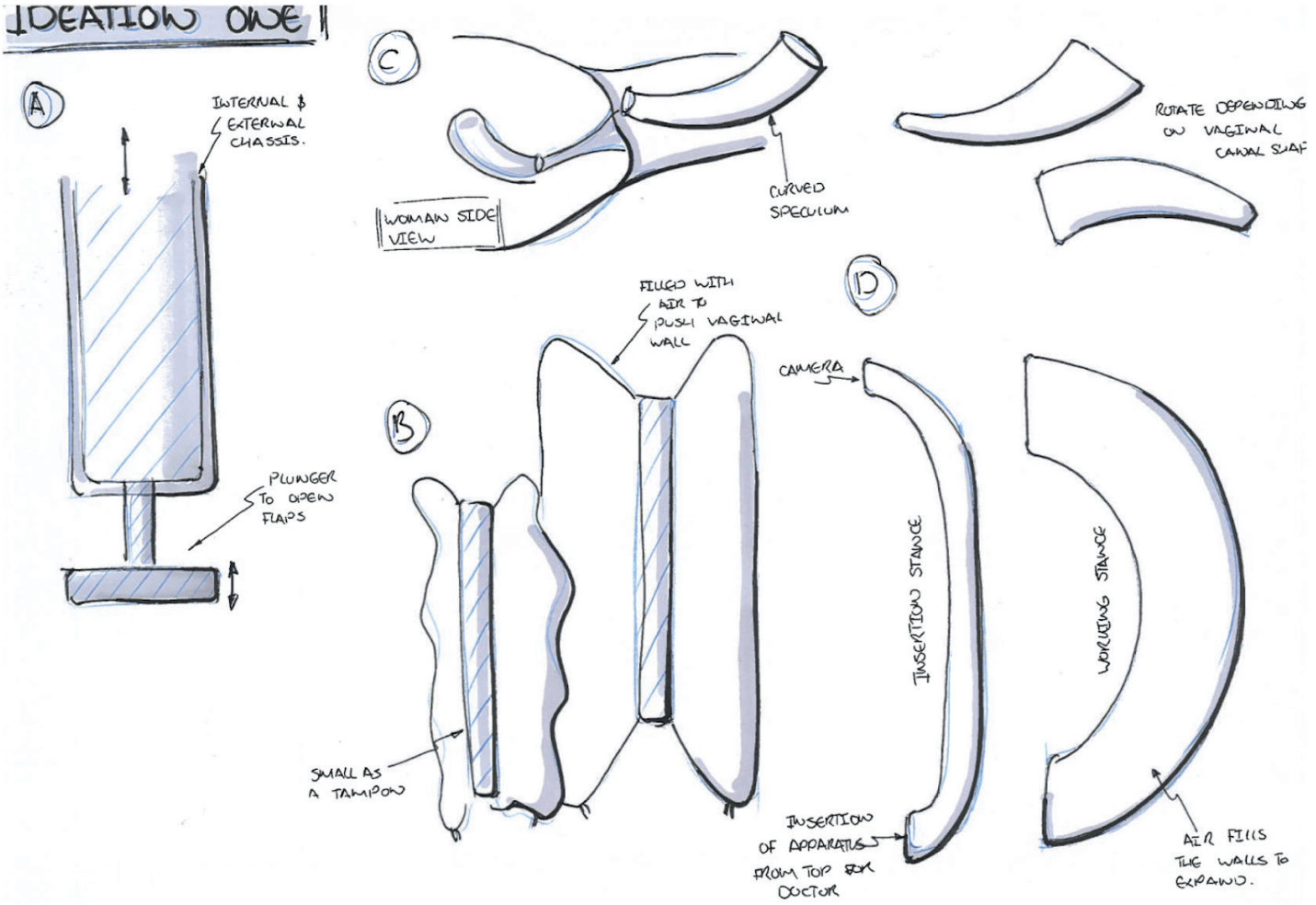
LIST OF DESIGN REQUIREMENTS

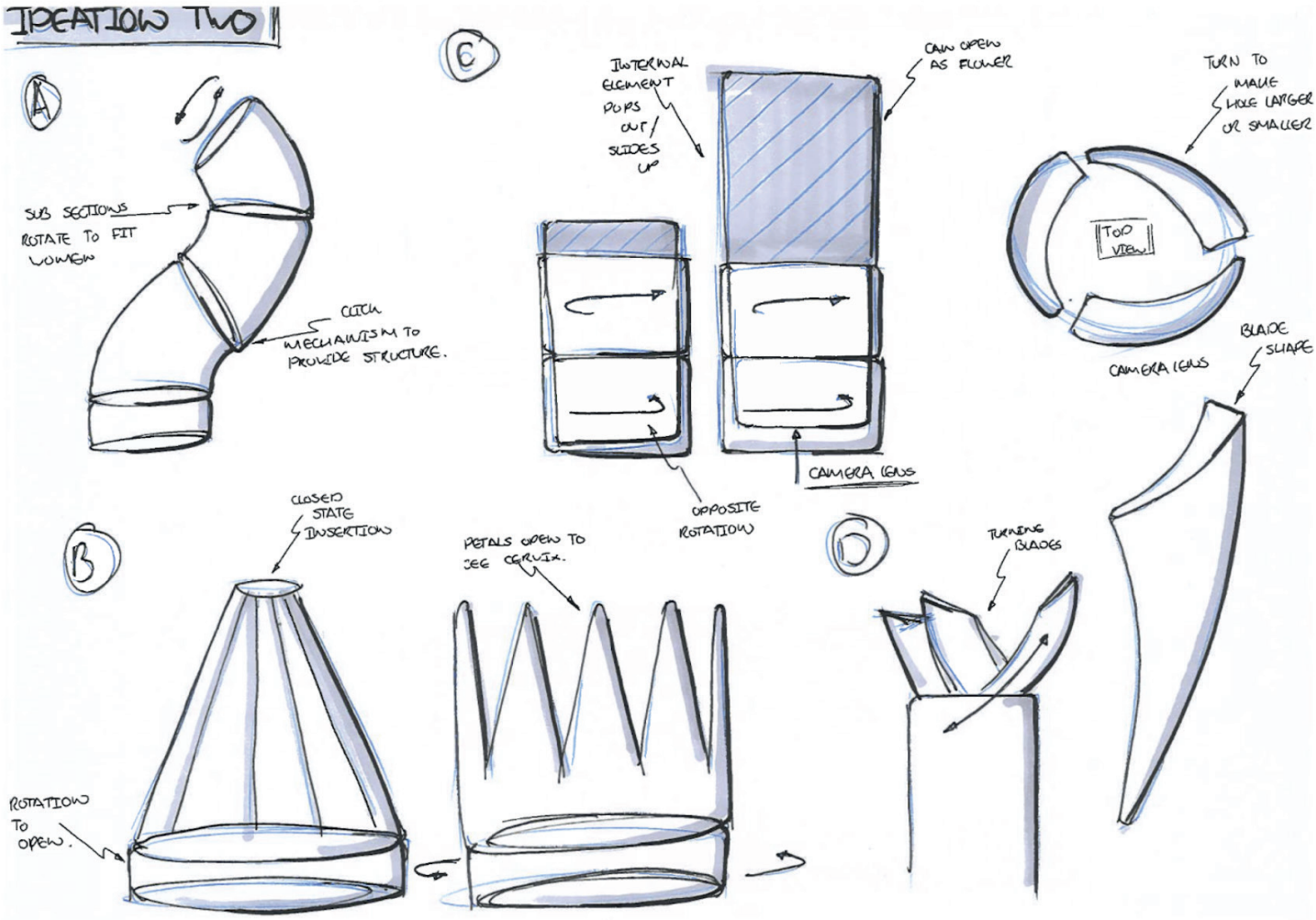
List of Design Requirements

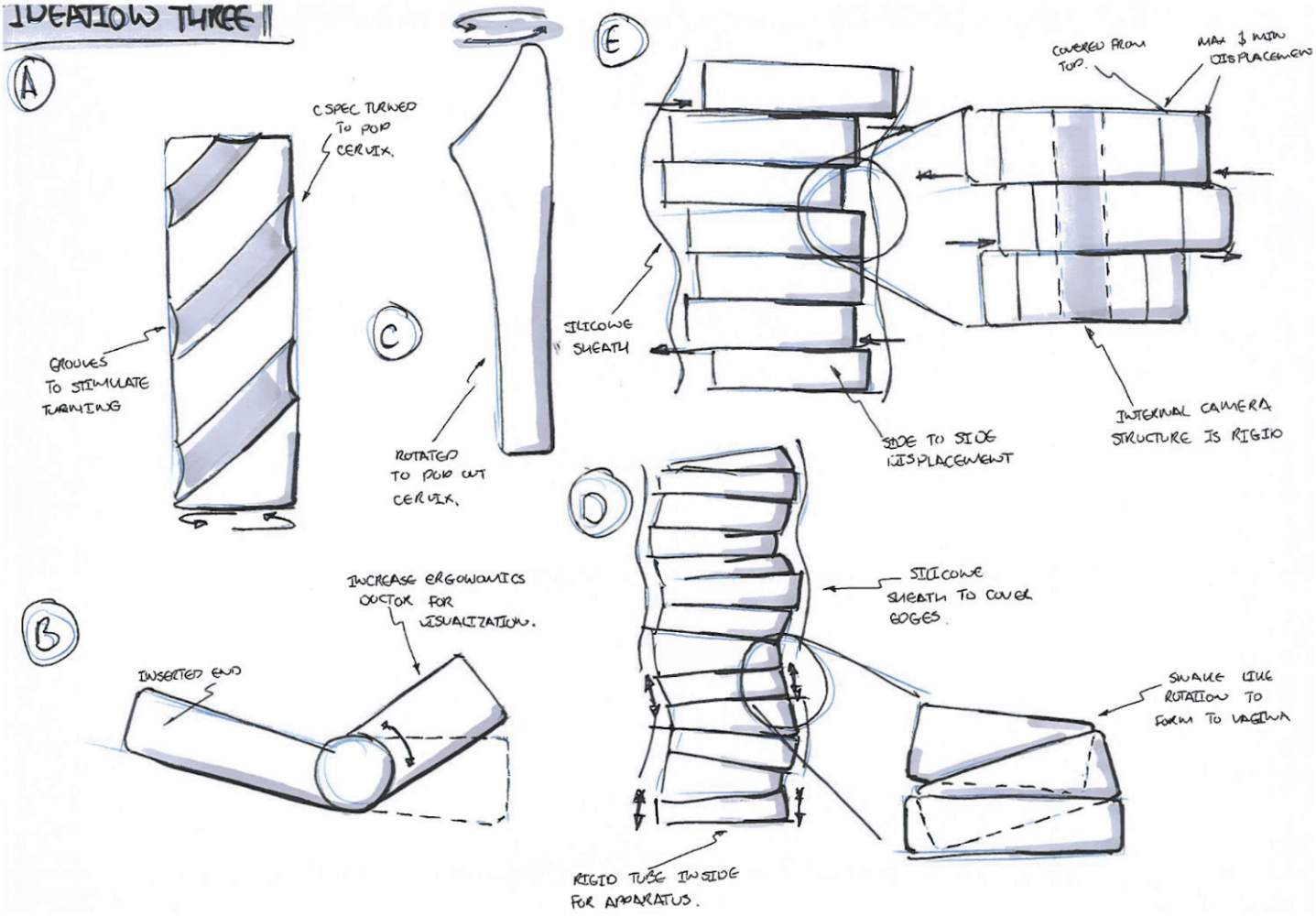
Category	ID.	Type	Insight	Requirement
1. Healthcare provider usability				
	1.1	Performance	The flaps are difficult to open, creating friction and therefore pain on the fingers of the healthcare professional, especially after repeat screenings	The healthcare professional must be able to conduct 10 screenings using the C Spec per day without pain to their hands
	1.2	Performance	Significant strength is needed to open the flaps of the C Spec, even then, the flaps do not open to the maximum diameter	A gripping force of maximum 300N is required to open the C Spec flaps to their maximum diameter, to be tested using the Mama U model (Nilsen, 2011)
	1.3	Performance	Due to a lack of feedback healthcare professionals think that the flaps are fully opened when they are only openened a small amount	Provide healthcare professionals with feedback on how open the C Spec flaps are to better inform during the screening procedure
	1.4	Performance	Lubricant, used to aid in the insertion of the C Spec can get on the healthcare professionals gloves, making the C Spec flaps more difficult to open	The C Spec must be easy to operate with lubricant present on both gloves of the healthcare professional
	1.5	Performance	Depending on the scenario, the C Spec can be operated by either one or two healthcare professionals	Screening with the C Spec will only require one healthcare professional to perform the screening
	1.6	Performance	Operating the C Spec does not require healthcare professionals to bend their upper body forwards to conduct the screening, which is very comfortable	The healthcare professional can maintain a comfortable standing position with elbows at 90 degrees at a standard bed height of 85cm from the floor
	1.7	Aesthetics	New users are currently left confused by the hook and bolt mechanism of the C Spec and do not know how to operate it	The redesigned C Spec must feel intuitive and familiar for new users
2. Patient Comfort				
	2.1	Performance	The C Spec is currently comfortable for patients during the insertion, manipulation and removal phases of the screening procedure	The redesigned C Spec must remain comfortable during the insertion, manipulation and removal phases of the screening procedure
	2.2	Size and weight	The main body of the C Spec currently has a diameter of 29mm. This has shown to be comfortable for patients	The C Spec main body must not exceed 32mm in diameter. (This is the maximum diameter to maintain comfort as tested by GIC Space)
	2.3	Performance	There are currently no sharp edges on the C Spec design that can harm the patient	There must be no sharp edges on the new C Spec design that come into contact with the vagina walls and/or vulva
	2.4	Performance	When using a traditional speculum, healthcare professionals enter a womans personal space as they view the cervix with their face close to the womans vulva	The redesign must allow for a minimum distance of 500mm between the healthcare professionals face and the patients vulva during screening
3. Screening ability				
	3.1	Performance	Apparatus can get caught on the hook and bolt opening mechanism of the C Spec	The redesign must have a flap operation system that does not hinder apparatus insertion into the main body of the C Spec
	3.2	Performance	There is limited space for apparatus inside the C Spec since the camera is also inserted and the overall diameter must be smaller than 32mm for patient comfort	The area available for apparatus inside the C Spec should not decrease below the current area value of 660mm^2
	3.3	Aesthetics	The current C Spec design has no specified orientation, creating issues when determining the location of a (pre)cancerous lesion in correlation with the body axis	Provide the C Spec with an orientation that is intuitive and easy to identify
	3.4	Performance	The size of a womans cervix can vary. If the C Spec flaps are opened too wide, for a small cervix, excess vaginal mucus can enter the field of view of the camera	Provide multiple stages of openness of the C Spec flaps to accommodate different cervix sizes of women
	3.5	Performance	Once inserted, the C Spec is rotated to give the cervix an opportunity to bulge into place between the flaps, and into view of the camera	The redesigned C Spec has the ability to have a minimum rotation of 90 degrees after insertion (45 degrees left and right of the vertical axis)
	3.6	Performance	There is no reasoning behind the current length of the C Spec	The length of the C Spec must allow for the healthcare professional to reach the cervix while maintaining some space between their hand and the vulva
4. Sterilization				
	4.1	Materials	The C Spec is currently made from stainless steel which can be placed in the autoclave for sterilization or a chemical bath for HLD after a screening procedure	The new C Spec must be made from a material suitable for sterilisation in the autoclave machine and the chemical bath
	4.2	Maintanance	The C Spec is difficult to disassemble. Without disassembly, the C Spec cannot be cleaned properly according to the sterilization procedure (Sellors, n.d.)	The new C Spec must be easy to disassemble to clean sufficiently using a brush and soap as to follow the sterilization procedure (Sellors, n.d.)

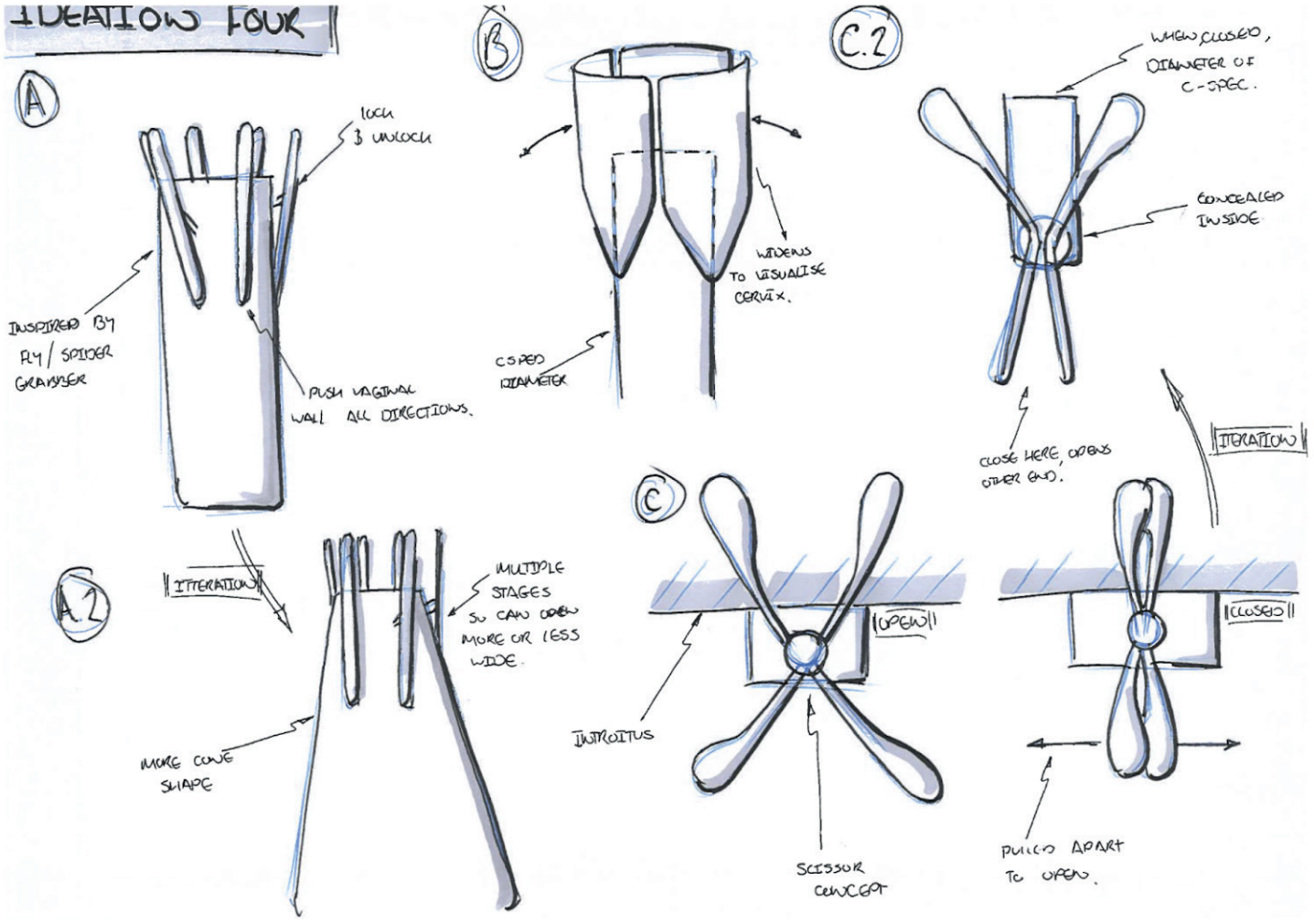
Appendix H

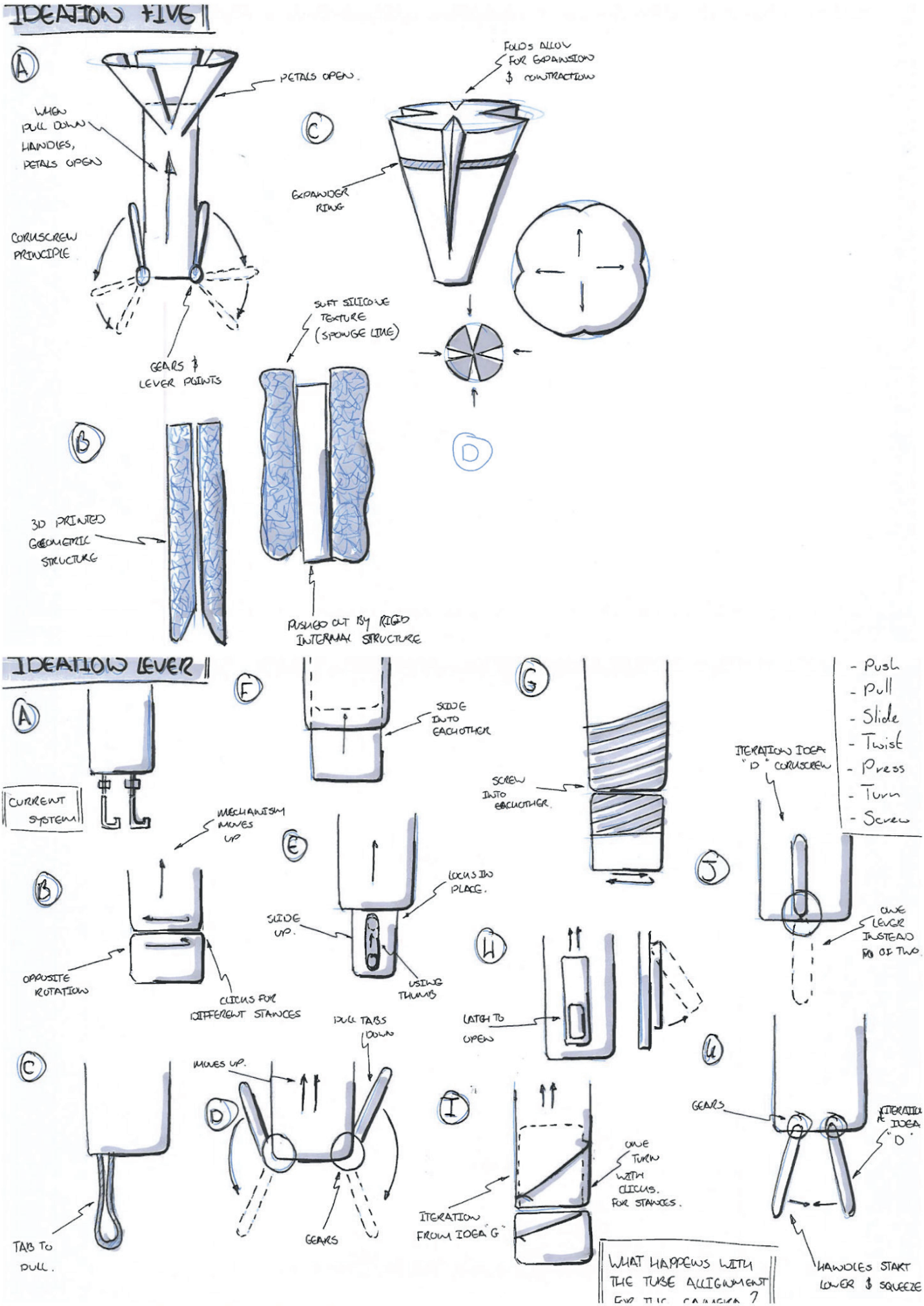
DESIGN IN A WEEK IDEATION

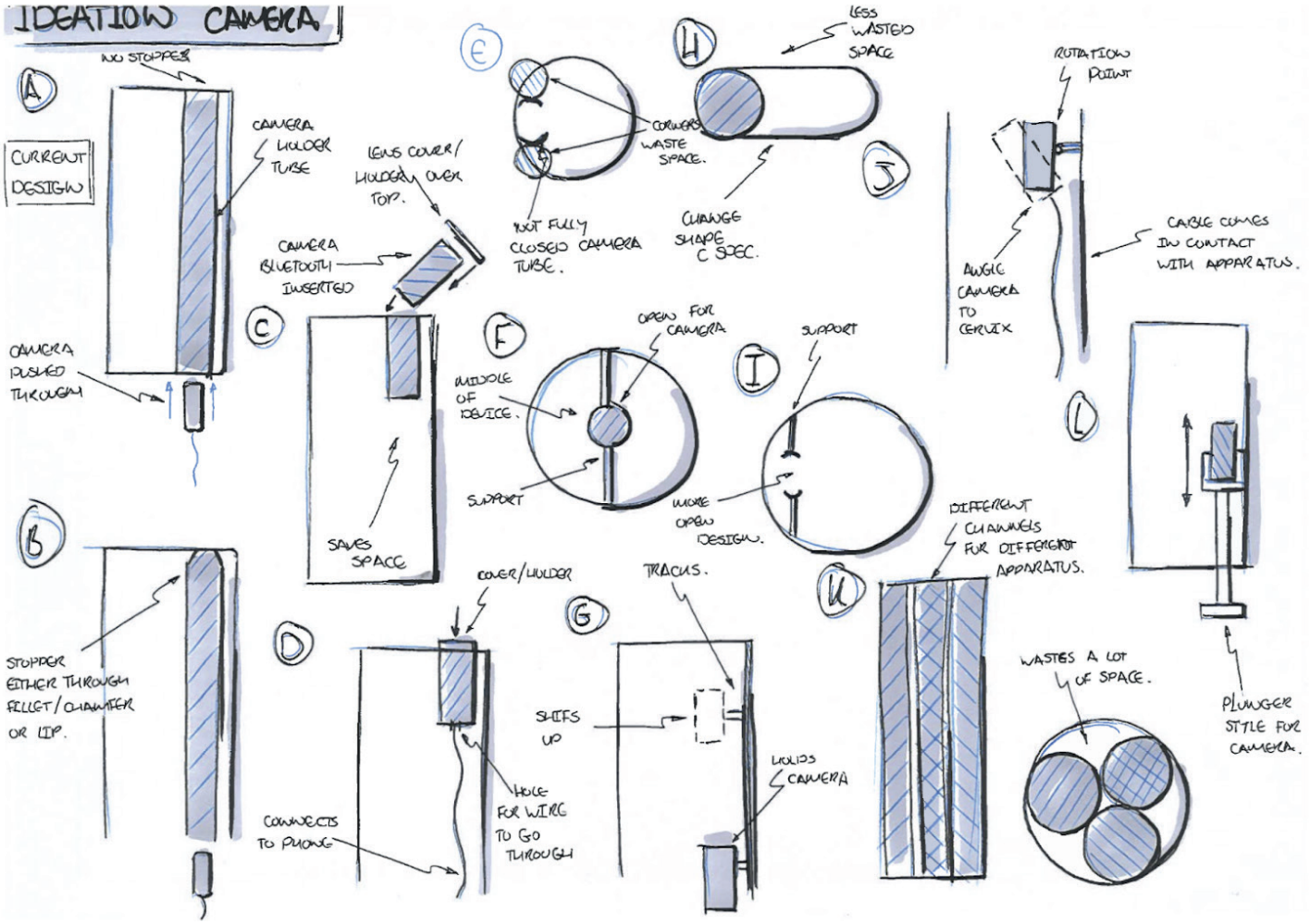

IDEATION ONE
A
INTERNAL & EXTERNAL CHASSIS.
PLUNGER TO OPEN FLAPS
C
WOMAN SIDE VIEW
CURVED SPECULUM
ROTATE DEPENDING ON VAGINAL CANAL SHAP
B
FILLED WITH AIR TO PUSH VAGINAL WALL
SMALL AS A TAMPON
D
CAMERA
INSERTION STANCE
WORKING STANCE
INSERTION OF APPARATUS FROM TOP BY DOCTOR
AIR FILLS THE WALLS TO EXPAND.

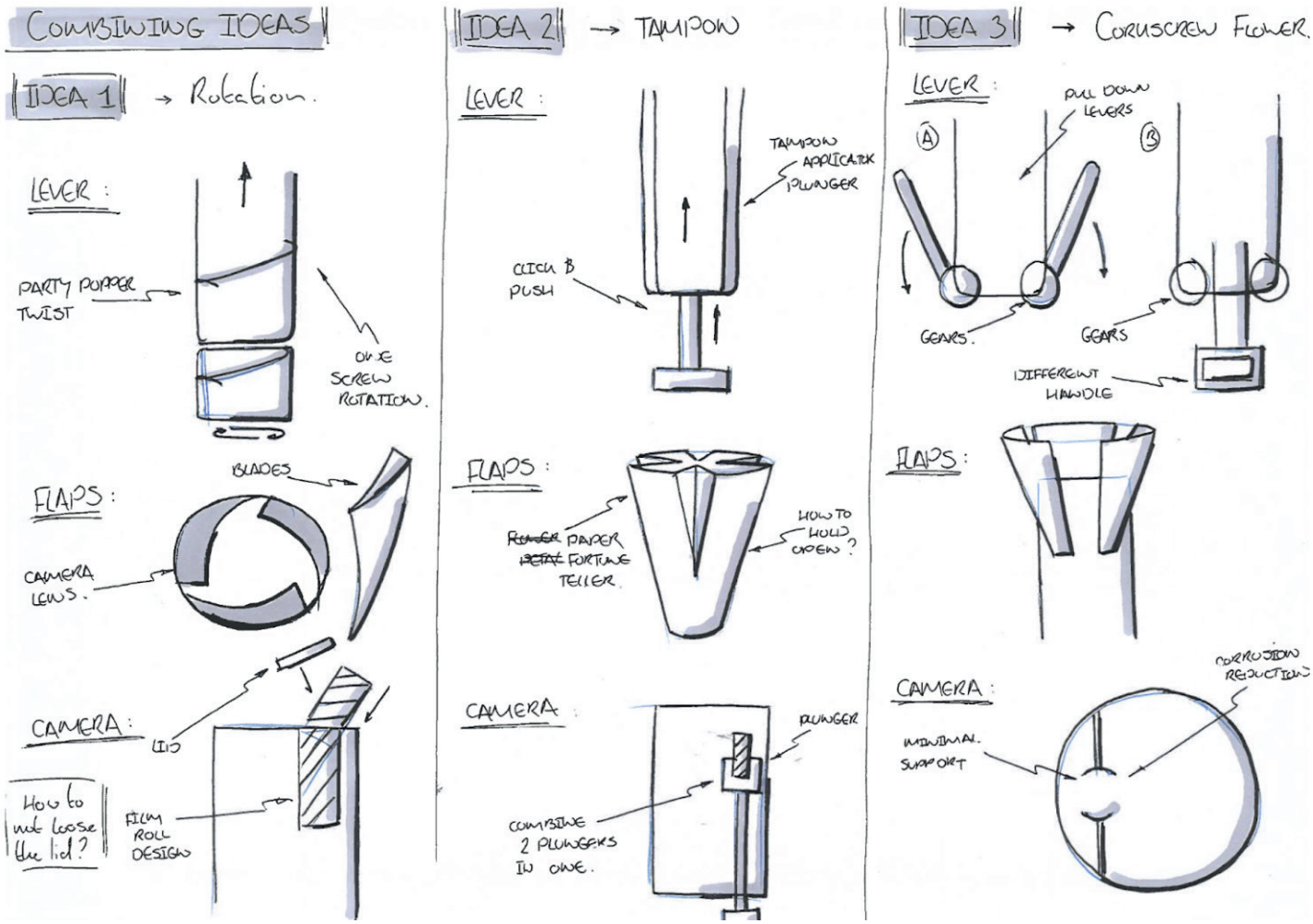

IDEATION TWO
A
SUB SECTIONS ROTATE TO FIT WOMEN
CLICK MECHANISM TO PROVIDE STRUCTURE.
C
INTERNAL ELEMENT PUPS OUT / SLIDES UP
CAN OPEN AS FLOWER
TURN TO MAKE HOLE LARGER OR SMALLER
TOP VIEW
CAMERA LENS
BLADE SHAPE
CAMERA LENS
OPPOSITE ROTATION
B
CLOSED STATE INSERTION
PETALS OPEN TO SEE CERVIX.
ROTATION TO OPEN.
D
TURNING BLADES


IDEATION THREE
A
C SPEC TURNED TO POP CERVIX.
GROOVES TO STIMULATE TURNING
C
ROTATED TO POP OUT CERVIX.
E
COVERED FROM TOP.
MAX & MIN DISPLACEMENT
SILICONE SHEATH
SIDE TO SIDE DISPLACEMENT
INTERNAL CAMERA STRUCTURE IS RIGID
D
SILICONE SHEATH TO COVER EDGES.
SNAKE LIKE ROTATION TO FORM TO VAGINA
RIGID TUBE INSIDE FOR APPARATUS.
B
INCREASE ERGONOMICS OUCTOR FOR VISUALIZATION.
INSERTED END


IDEATION FOUR
A
LOCK & UNLOCK
INSPIRED BY FLY / SPIDER GRABBER
PUSH VAGINAL WALL ALL DIRECTIONS.
B
WIDENS TO VISUALISE CERVIX.
C SPEC DIAMETER
C.2
WHEN CLOSED, DIAMETER OF C-SPEC.
CONCEALED INSIDE
CLOSE HERE, OPENS OTHER END.
ITERATION
A.2
ITERATION
MULTIPLE STAGES SO CAN OPEN MORE OR LESS WIDE.
MORE CONE SHAPE
C
OPEN
INTROITUS
SCISSOR CONCEPT
CLOSED
PULLED APART TO OPEN.


IDEATION FIVE
A
PETALS OPEN.
WHEN PULL DOWN HANDLES, PETALS OPEN
CORKSCREW PRINCIPLE
GEARS & LEVER POINTS
C
FOLDS ALLOW FOR EXPANSION & CONTRACTION
EXPANDER RING
B
3D PRINTED GEOMETRIC STRUCTURE
SOFT SILICONE TEXTURE (SPONGE LIKE)
PUSHED OUT BY RIGID INTERNAL STRUCTURE
D
IDEATION LEVER
A
CURRENT SYSTEM
F
SLIDE INTO EACHOTHER
G
SCREW INTO EACHOTHER
- Push
- Pull
- Slide
- Twist
- Press
- Turn
- Screw
ITERATION IDEA "D" CORKSCREW
B
MECHANISM MOVES UP
OPPOSITE ROTATION
CLICKS FOR DIFFERENT STANCES
E
LOCKS IN PLACE.
SLIDE UP.
USING THUMB
J
ONE LEVER INSTEAD OF TWO.
H
LATCH TO OPEN
C
TAB TO PULL.
PULL TABS DOWN
MOVES UP.
D
GEARS
I
ITERATION FROM IDEA G
ONE TURN WITH CLICKS. FOR STANCES.
WHAT HAPPENS WITH THE TUBE ALLIGNMENT
4
GEARS
ITERATION IDEA "D"
HANDLES START LOWER & SQUEEZE


IDEATION CAMERA
A
CURRENT DESIGN
NO STOPPER
CAMERA HOLDER TUBE
CAMERA PUSHED THROUGH
B
STOPPER EITHER THROUGH FILLET/CHAMFER OR LIP.
C
LENS COVER/ HOLDER OVER TOP.
CAMERA BLUETOOTH INSERTED
SAVES SPACE
D
COVER/HOLDER
CONNECTS TO PHONE
HOLE FOR WIRE TO GO THROUGH
E
NOT FULLY CLOSED CAMERA TUBE.
F
OPEN FOR CAMERA
MIDDLE OF DEVICE.
SUPPORT
G
TRACKS.
SHIFTS UP
HOLDS CAMERA
H
LESS WASTED SPACE
CORNERS WASTE SPACE.
CHANGE SHAPE C SPEC.
I
SUPPORT
MORE OPEN DESIGN.
J
ROTATION POINT
ANGLE CAMERA TO CERVIX
CABLE COMES IN CONTACT WITH APPARATUS.
K
DIFFERENT CHANNELS FOR DIFFERENT APPARATUS.
WASTES A LOT OF SPACE.
L
PLUNGER STYLE FOR CAMERA.

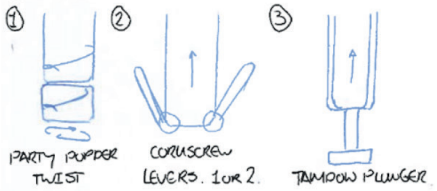

COMBINING IDEAS
IDEA 1 → Rotation.
LEVER :
PARTY POPPER TWIST
ONE SCREW ROTATION.
FLAPS :
BLADES
CAMERA LENS.
CAMERA :
LID
How to not loose the lid?
FILM ROLL DESIGN
IDEA 2 → TAMPON
LEVER :
TAMPON APPLICATOR PLUNGER
CLICK & PUSH
FLAPS :
PAPER FORTUNE TELLER.
HOW TO HOLD OPEN?
CAMERA :
PLUNGER
COMBINE 2 PLUNGERS IN ONE.
IDEA 3 → CORKSCREW FLOWER.
LEVER :
PULL DOWN LEVERS
A
B
GEARS.
GEARS
DIFFERENT HANDLE
FLAPS :
CAMERA :
MINIMAL SUPPORT
CORROSION REDUCTION

DESIGN DECISIONS

LEVER

- Max 2 parts
- Few grooves
- Steps possible.
- Low applied force.

TOP OPTIONS

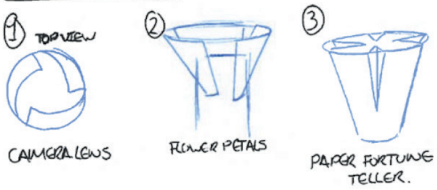


- TEST ALL 3 OPTIONS & PROTOTYPE.
  - ↳ TOILET ROLL
  - ↳ TAMPON
  - ↳ CORKSCREW.

FLAPS

- Enough strength to push away the vaginal wall
- Good visualization Cervix
- Does not pinch.
- All sizes cervix & positions
- Steps possible.
- Few grooves.

TOP OPTIONS

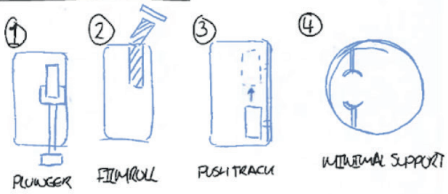


- ↳ RESEARCH MECHANISMS FOR ALL 3.
- ↳ & SEE HOW TO PROTOTYPE.
- ↳ COMBINE THEM WITH THE LEVER SYSTEM OPTIONS.

CAMERA

- Able to move up & down or/& rotate during examination
- With cable ... bluetooth difficult?
- Less wasted space.
- Do not have to hold during examination / screening
- Steps possible.
- Sealed (sterilization wise)

TOP OPTIONS



- ↳ RESEARCH MECHANISMS.
- ↳ PROTOTYPE
- ↳ TEST WITH ORDERED CAMERAS.
- ↳ COMBINE WITH THE LEVER & SYSTEM OPTIONS.

Appendix I

PRODUCT DEVELOPMENT

INITIAL PRODUCT FORM

PROTOTYPE ONE

A first prototype was made to understand the rough form of the new C Spec design. This form included a speculum style handle attached to the C Spec main body.

DESIGN FEATURES AND DECISIONS

Wider opening: A wide opening was included at the entrance of the design to allow for the easier insertion of the apparatus into the C Spec. This is to promote standing for the HCP during the procedure. Also the diameter of the C Spec is narrow so this wider opening acts as a guide for apparatus.

Squeeze handle mechanism: The squeeze handle was designed to look more like a normal speculum. This gives a sense of familiarity for new users of the C Spec.

Lock mechanism: A lock mechanism was designed externally to the handle. The decision was made to not integrate any system inside the handle of the new C Spec since this will create complications with sterilisation.

PROTOTYPE INSIGHTS

Wider apparatus opening: The implementation of a wider opening allows for easier insertion of apparatus into the C Spec and promotes a standing position for the HCP.

Squeeze handle mechanism: The first prototype made has a handle that is quite large. The front of the handle was rounded but the back was not, making it sharp in the hand.

More use ques need to be included into the handle design to allow for easy holding and directed hand placement.

Lock mechanism: The lock mechanism in prototype 1 would work to provide different stages on the C Spec flap opening. The problem however is that this sticks out and could poke the patient. The system should be simple. By not building it into the C Spec handle, the handle does not need to be taken apart for sterilisation.

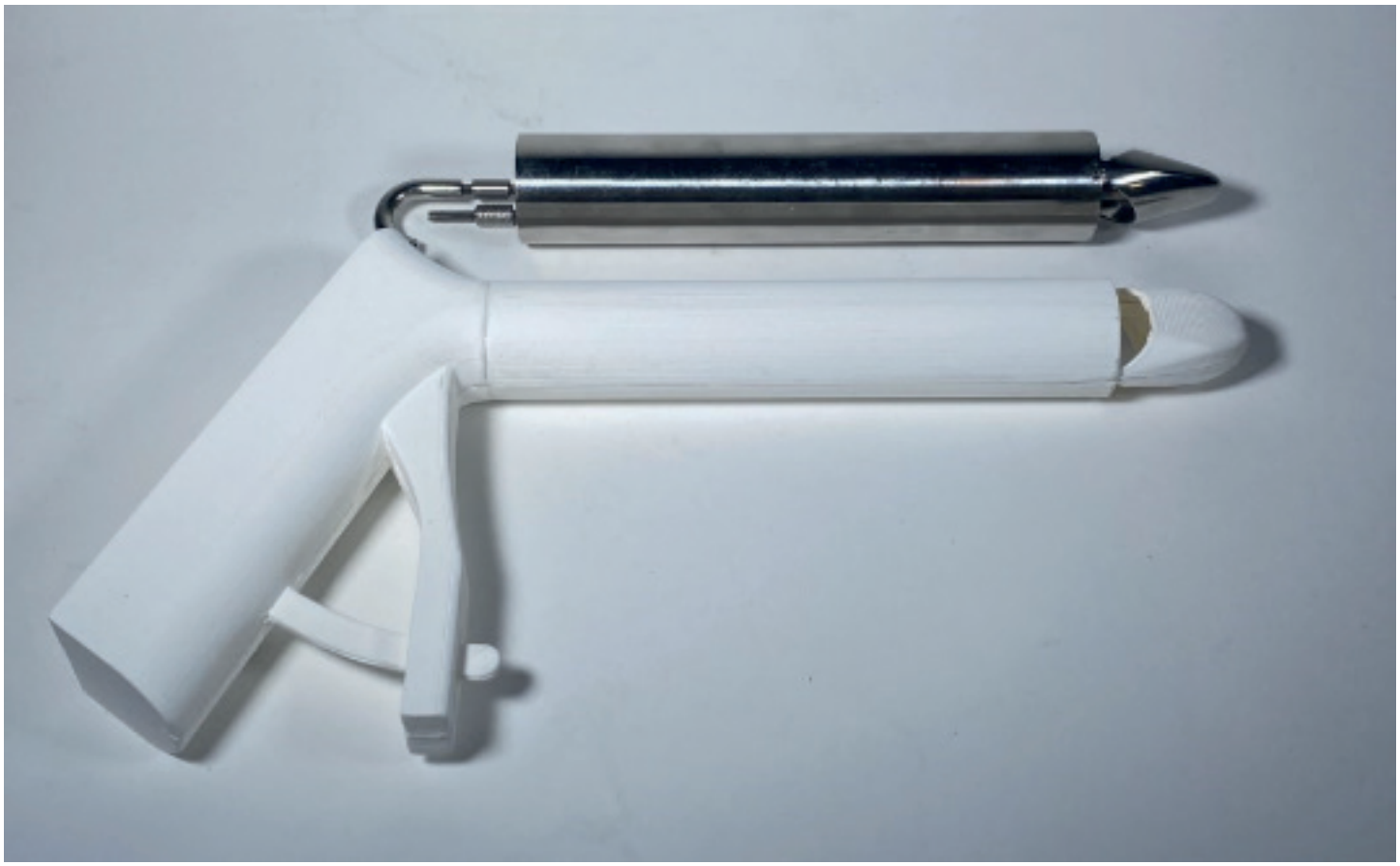


Figure I.1 - Prototype 1, Initial Product Form

Length of the main body: The length of the main C Spec body is too long. The length given to this first prototype was the same length as the C Spec which is not needed since a handle is now added, removing the need to hold the bottom of the C Spec.

The length of the C Spec main body which is inserted should be long enough to reach the cervix while maintaining some space between the vulva and the HCP's hand. We do not want the hand of the HCP to touch the vulva the whole time during the screening.

Flap orientation: The orientation of the flaps compared to the angle of the handle was chosen to be top to bottom instead of left to right. This is because the introitus is longer in length than in width, increasing patient comfort. This does not affect the ability to find the cervix.

ACTION POINTS

Bimanual opening: Why do both flaps open? Do both flaps need to open or is it also okay if only one flap is opened?

Handle ergonomics: Once the C Spec flap mechanism is chosen, look at the ergonomics of the handle to be held by the HCP.

Main body length: Experiment with different lengths of the C Spec to determine what is optimal

Ratchet system: Once the C Spec flap mechanism is chosen, look at the function and ergonomics of the ratchet system.

Figure I.2 - Prototype 1, Wider Opening

Figure I.3 - Prototype 1, Lock Mechanism

PROTOTYPE TWO

EDITS MADE

- Decrease in C Spec body length by 50mm
- Rounded the handle
- Removed external ratchet system

Rounded handle:

A rounding was applied to the back of the handle where the palm of the hand sits. This made the C Spec more comfortable to hold.

Removed lock system

The lock was removed since this should not stick out in the direction of the patient as this might poke them. This will be explored later in the process in an isolated manner as to design an adjustable system suitable for the rest of the C Spec.

INSIGHTS

Ability to stand: The second prototype is able to stand up on its handle without tipping over or falling. With prototype one, this is not possible. The ability to stand the C Spec up on the handle is interesting. Is this necessary?

Length: The length of the C Spec is now a lot less intimidating however the C Spec might now be too short, resulting in constant touching of the HCP's hand on the patient's vulva. A length between the two prototypes must be explored using the Mama U.

Figure I.4 - Prototype 1 with Prototype 2

Figure I.5 - Prototype 1, with Prototype 2

DISASSEMBLY OF A LAPARASCOPIC GRASPER

Before progressing further with prototyping, to better understand the mechanisms used in laparoscopic apparatus (where inspiration for the C Spec is drawn from), a bimanual laparoscopic grasper was disassembled.

The flaps of the grasper are connected by a rivet. The rivet also goes through the external casing around the flaps. This rivet acts as the rotation point of the flaps.

DISASSEMBLED PRODUCT

The flaps: The flaps sit on top of each other. Between the flaps is a piece of metal with two slot paths. Pins on both flaps slot into this path and when pushed upwards by the handle mechanism, these pins glide along the slot, opening the flaps. This system is the same as the linear cam mechanisms tested previously only, they are integrated into one push rod instead of two.

The handle mechanism: The ratchet is built into the injection moulded handle of laparoscopic apparatus. The handle uses a spring to create resistance and a smaller trigger to lock the flaps in place. The front handle piece is static, and the back handle piece moves to open the flaps. When the handles are pressed together, the flaps are open, and when the handles are pulled apart, the flaps are closed.

INSIGHTS FROM DISASSEMBLY

- A linear cam mechanism is used same as the previously prototypes only, one push rod is used instead of two
- The flaps sit on top of each other and have thinner sections of material where they cross
- The handle has a built in ratchet system
- The back handle piece moves, but with the C Spec we want front handle piece to move

ACTION POINTS

Two flaps with one push rod: Inspiration can be taken from the disassembled laparoscopic bimanual grasper on how to integrate the two moving flaps into one push rod for the next prototype.

Figure I.6 - Laparoscopic bimanual grasper before disassembly

Figure I.7 - Linear Cam Path

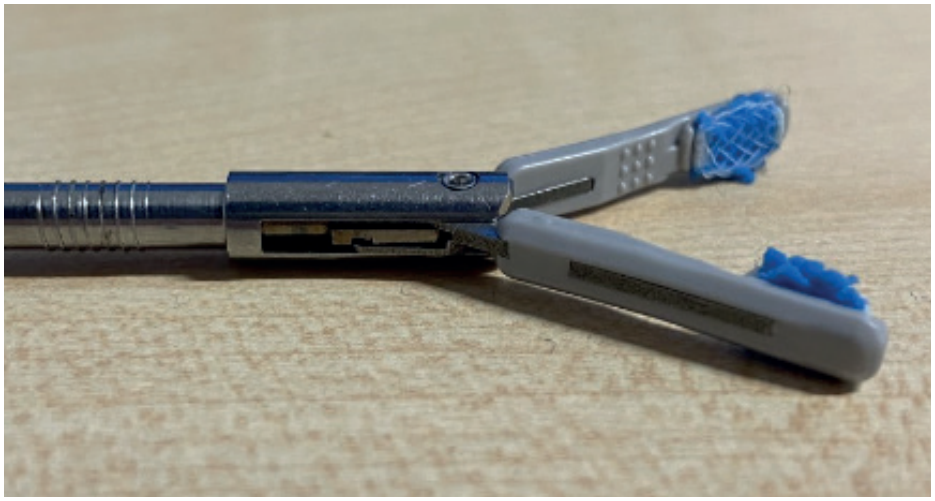


Figure I.8 - Laparoscopic flaps before disassembly

SPRINT ONE - BIMANUAL FLAP MECHANISM

METHOD

Two sprints were done within the design of the C Spec flap mechanism, each sprint lasting one week. Sprint 1 looked at a bimanual flap mechanism (both flaps move symmetrical to each other). Sprint 2 explored a single flap opening mechanism, where one static flap is already angled upon insertion and the other flap opens to visualise the C Spec.

PROTOTYPE ONE - DUAL ACTING LINEAR CAM

INSIGHTS

- Through pushing the base of the prototype the flaps open using a linear cam system. They rotate around the middle pinpoint
- Increased distance between the push hinge point and the rotating hinge point, making the mechanism more efficient
- The flaps need to be connected to the same push point so they move in sync. Currently, if the pushing is not equal, the flaps open at different speeds and angles from each other.

ACTION POINTS

Curved linear cam path: In the aim to create a more gradual flap opening instead of an instant shift compared to a straight cam path.

Flap shape: Where do the flaps currently come into contact and obstruct the further opening of the flaps?

One push rod: Have both flaps connected to one push rod instead of the current two to allow for symmetrical opening of the flaps.

Figure I.9 - Dual acting linear cam closed stance

Figure I.10 - Dual acting linear cam open stance

PROTOTYPE TWO - DUAL ACTING LINEAR CAM WITH ONE PUSH ROD

INSIGHTS

- A linear cam mechanism was used
- The strength of the mechanism is good. The flaps can be squeezed hard without the mechanism breaking or the flaps closing again
- The flaps open smoothly
- The flaps do not open to a wide enough angle. This can be fixed by making the linear cam path longer, allowing for a wider flap angle

ACTION POINTS

Handle integration: Implement this linear cam flap mechanism into the C Spec handle. Include a spring to allow the flaps to close when the handle is released. How will the handle be designed to push the mechanism forward to open the flaps?

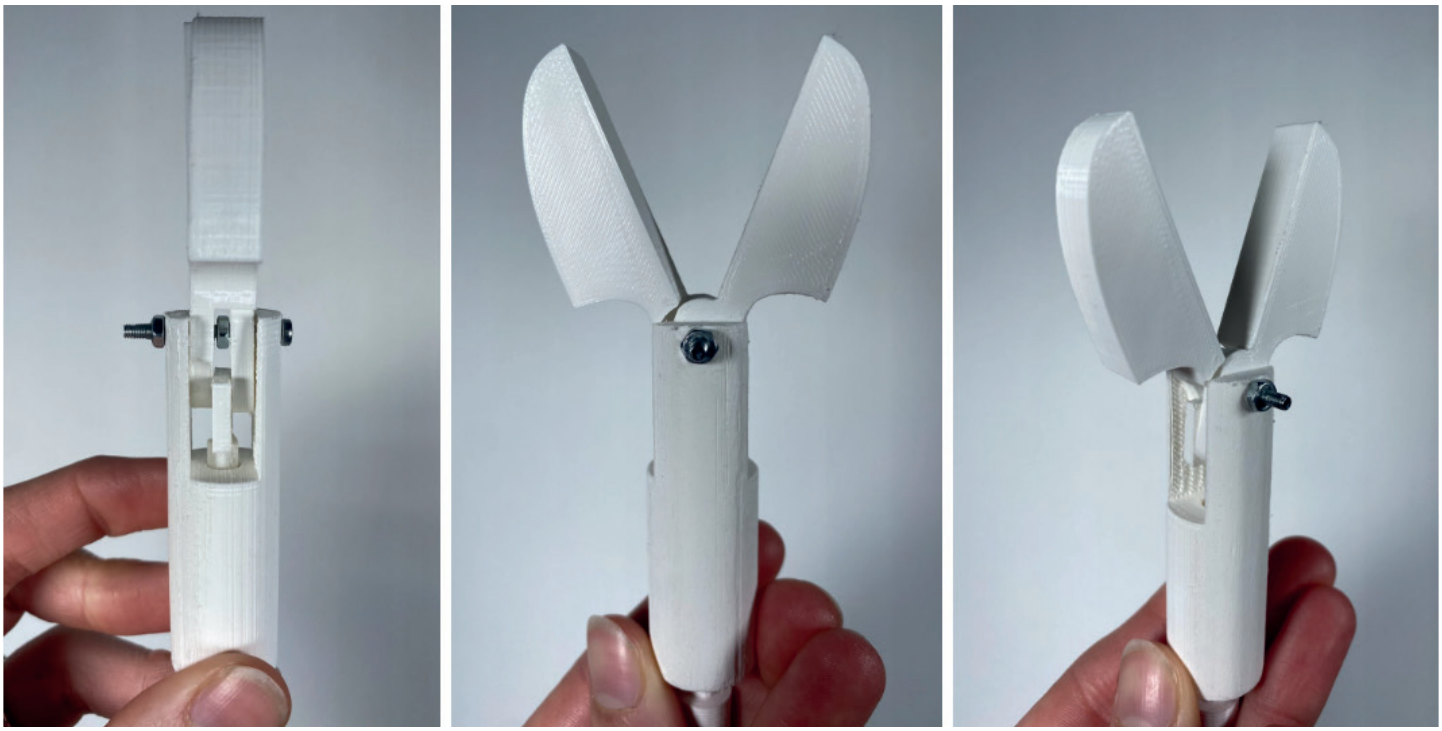


Figure I.11 - Images of the linear cam mechanism with one push rod

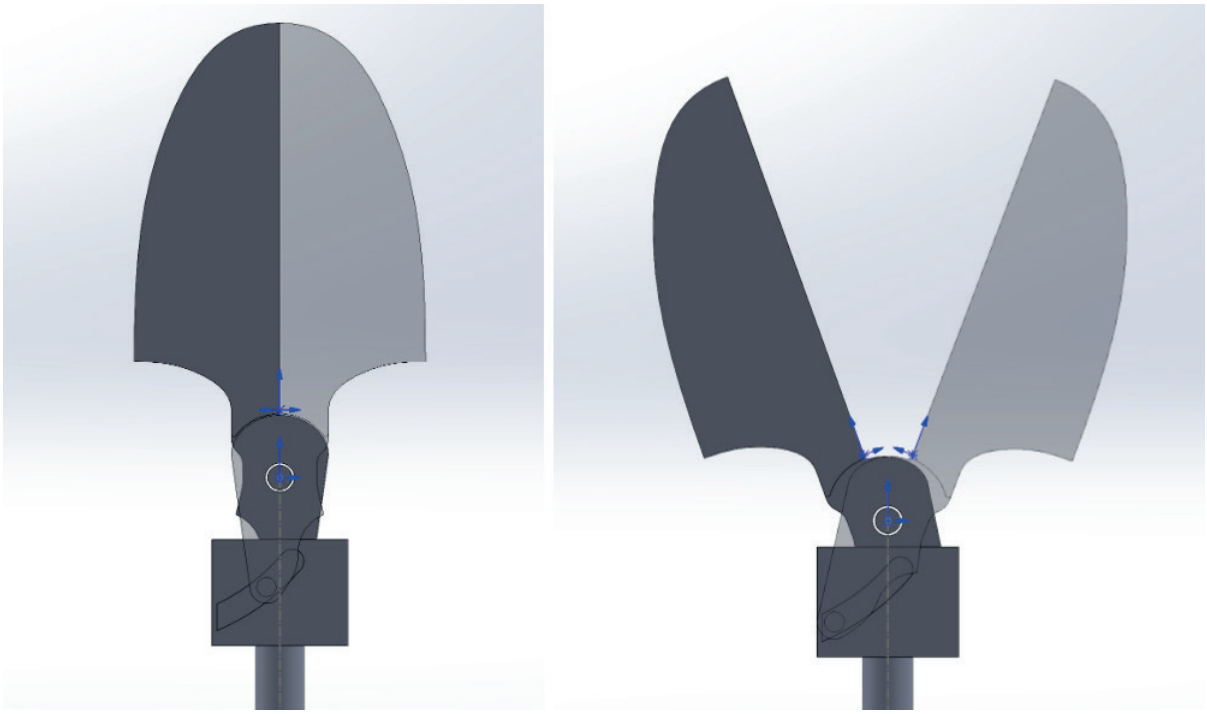


Figure I.12 - Solidworks images showing the linear cam mechanism in the closed and open state

PROTOTYPE THREE - DUAL ACTING LINEAR CAM WITH ONE PUSH ROD, INTEGRATED INTO HANDLE

THE MECHANISM

A handle was now attached to the linear cam flap mechanism, allowing the flaps to be opened by squeezing the front handle towards the back handle. The following images show the stages of opening.

INSIGHTS FLAP MECHANISM

- Force could be applied to the flaps without the mechanism breaking or the flaps moving from their position
- Iterations must be made to make the C Spec hollow creating space for apparatus to go through.

INSIGHTS HANDLE

- Includes a spring mechanism to allow the flaps to close once the handle is released. This spring might need to be removed for the final C Spec prototype since the spring mechanism could clamp the cervix after the handle is released. The vagina by itself produces a lot of pressure and will make the flaps close anyway.
- A cam shaped handle was created allowing the handle to push the flap mechanism forward and open when squeezed.
- The handle at this point is not optimal for ergonomics. The moving handle that is squeezed, is in its relaxed state too far away from the static handle.

ACTION POINTS

A hollow C Spec: The prototype is currently not hollow. It must now be designed to have a hollow centre to allow apparatus to be inserted

Other mechanism types: Look at other laparoscopic apparatus for more mechanisms styles used.

Figure I.13 - Images of the stages of opening of the linear cam mechanism attached to a working handle

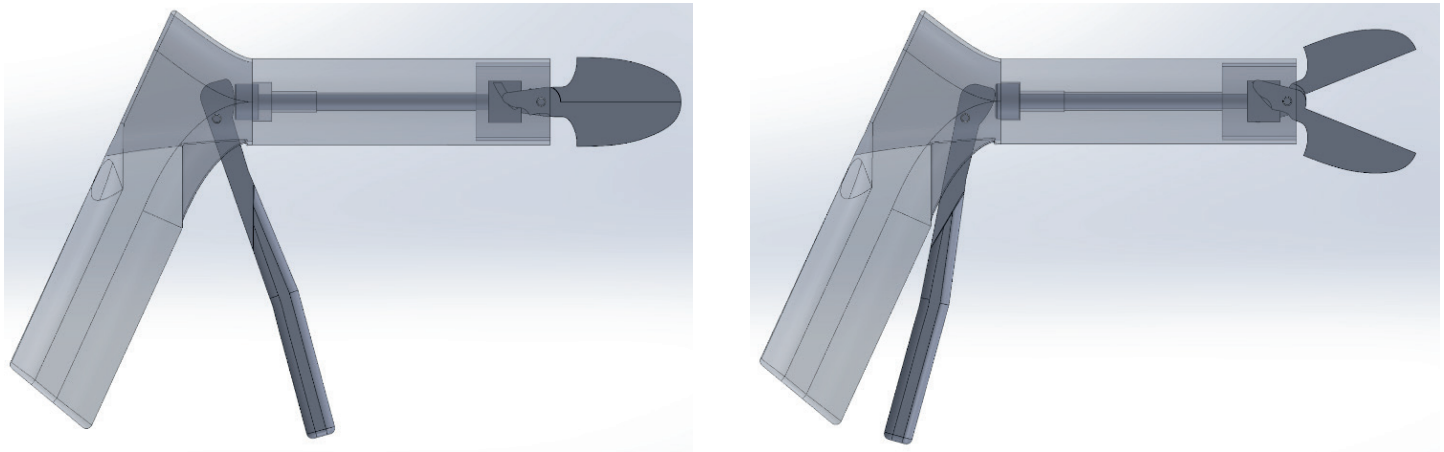


Figure I.14 - Solidworks image of the handle and flaps in an closed and open state

PROTOTYPE FOUR - ROTATING HINGE MECHANISM

Further research on laparoscopic apparatus was conducted to find other mechanisms used. As a result, the following rotating hinge mechanism was prototyped. This was later compared with the previous linear cam mechanism.

THE MECHANISM

This prototype uses a series of pins with two hinges to open the flaps. Each flap is connected to one end of their own hinge, and the two hinges are then connected to the central axis point to allow both flaps to operate with one plunge. Crossing the flaps allows for a pushing motion to open the flaps and a pulling/release motion to close.

INSIGHTS

- Like the previous linear cam mechanism, this rotating hinge system works very smoothly
- More pins used to create the same movement so regarding ease of assembly, this system scores lower

ACTION POINTS

Handle integration: he next step is to integrate this mechanism into a handle with a spring

Hollow centre: This can be done by making the system smaller, moving it to the side and making the turning point on one side of the flaps.

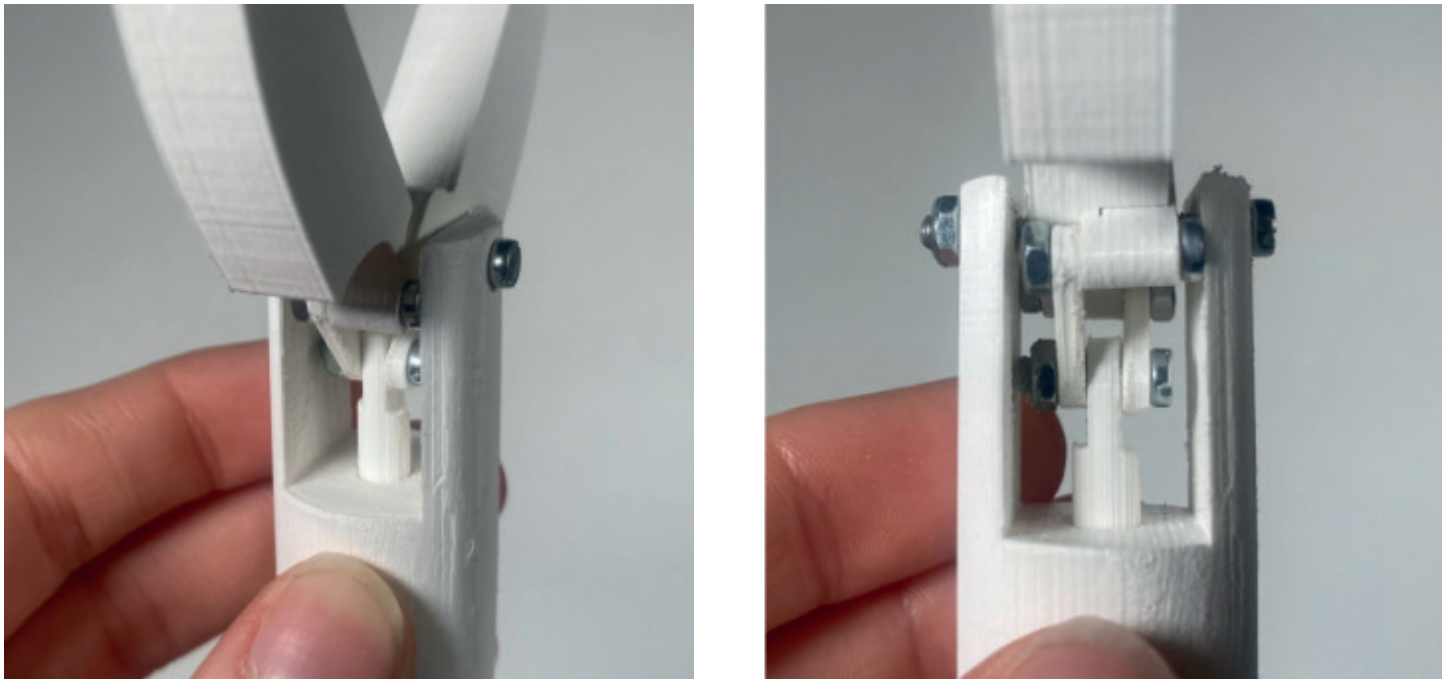


Figure I.15 - Image of the rotating hinge mechanism

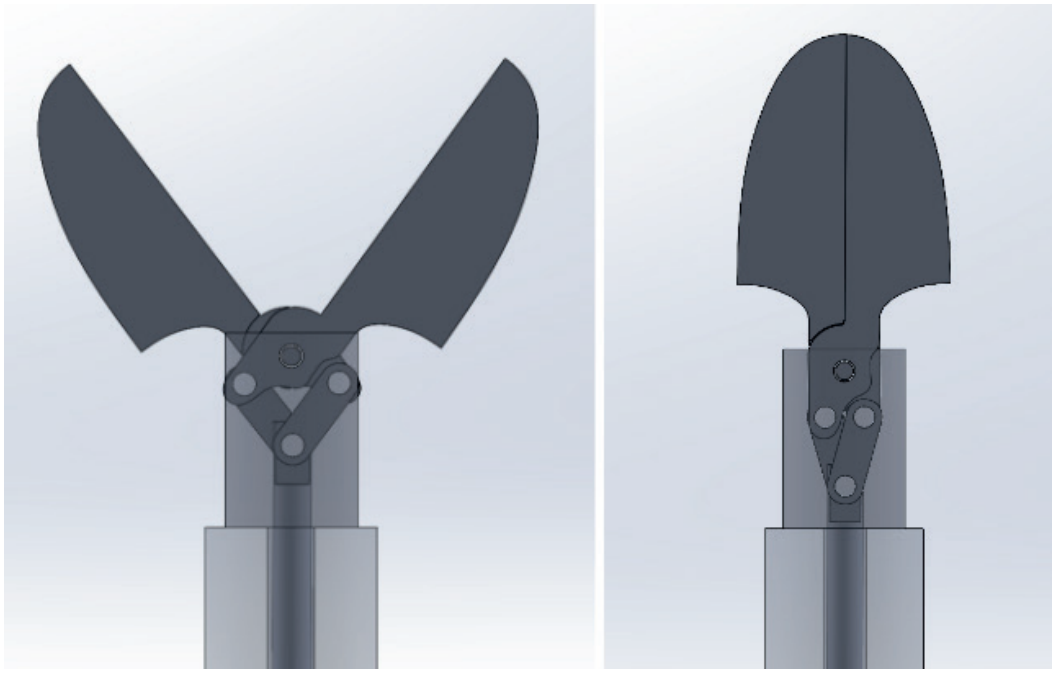


Figure I.16 - S olidworks images of the rotating hinge mechanism in the open and closed state

PROTOTYPE SIX - ROTATING HINGE MECHANISM INTEGRATED INTO THE HANDLE

THE MECHANISM

The new handle was attached to the new flap mechanism. Using a spring, ensured that when the handle was released, the flaps went back to their original state.

REFLECTION OF BIMANUAL OPNING MECHANISM

Assembly and disassembly: The linear cam mechanism is easier compared to the rotating hinge system. This is because the rotating hinge requires 3 joining points whereas the linear cam only requires one.

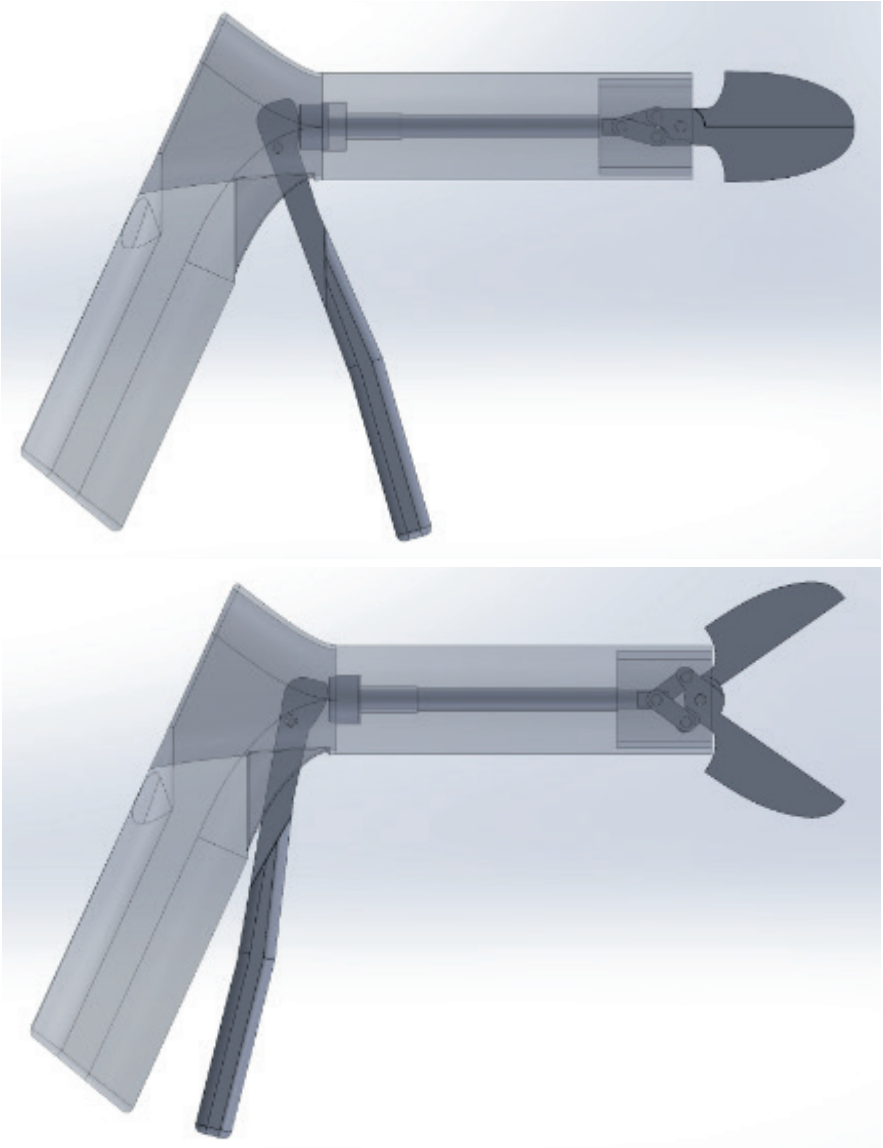


Figure I.17 - Solidworks images of the rotating hinge mechanism integrated into the handle in an open and closed stage

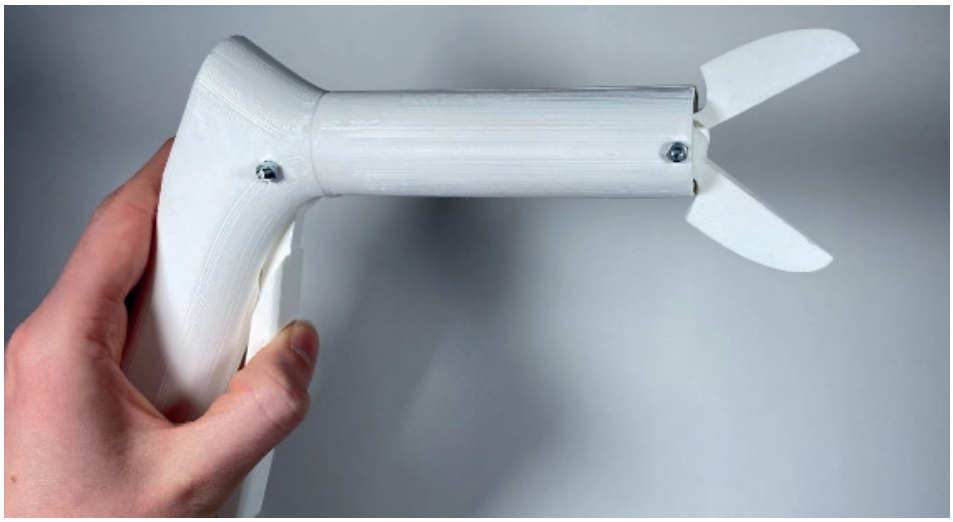


Figure I.18 - Images of the rotating hinge mechanism close up integrated into the handle in an open state

SPRINT TWO - MONOMANUAL FLAP MECHANISM

METHOD

In the second sprint, the product was designed where only one flap of the C Spec would open. The thinking behind that was that through only moving one flap, the mechanism could be made smaller. To allow for a large enough opening angle, the static flap would be positioned at an angle.

PROTOTYPE ONE - SINGLE FLAP LINEAR CAM

MECHANISM

The first mechanism to be tested uses the same linear cam principle as in sprint 1. The difference this time is that instead of needing to place two linear cam slots, only one linear cam slot needs to be included as only one flap needs to move.

Since a larger angle needs to be achieved by the moving flap, it was unsure if this mechanism would be applicable for a one flap system. An initial prototype was therefore created not including the handle system, and also not including a hollow tube. If this system works, these further iterations can be made.

INSIGHTS

- The single flap using a linear cam mechanism works well
- The angle of the static flap was now set at 20 degrees from the vertical line. This is quite an angle but it does not look as if it would be an issue regarding comfort. If the single flap mechanism is chosen, different flap angles must be tested to decide what would be the most ideal regarding comfort and visualisation
- The moving flap must be designed in a way that there is a smooth enough path between the end of the flap and the beginning of the C Spec main body edge. We do not want this edge to be sharp
- An idea is that the edge of the C Spec main body could include a chamfer to make the edge less sharp and to improve the flow of insertion. The issue with this however is that this will block the view of the camera.

ACTION POINTS

Hollow: Next steps will be to first make the product hollow. How will the mechanism operate when the mechanism is moved to the side of the C Spec?

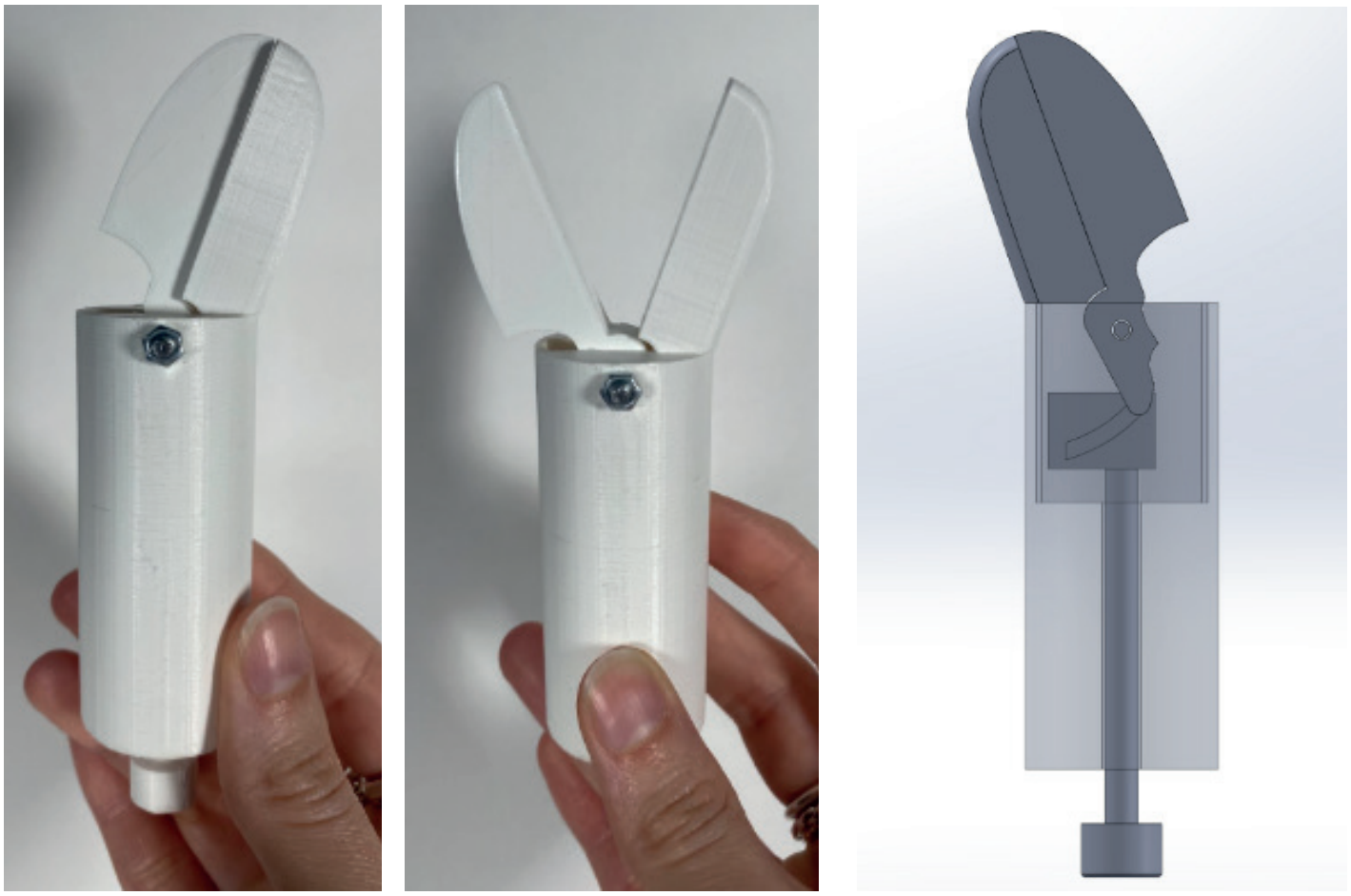


Figure I.19 - Images of the single flap moving mechanism using a linear cam in an open and closed state

PROTOTYPE TWO - SINGLE FLAP LINEAR CAM WITH HOLLOW CENTRE

MECHANISM

A hollow single flap mechanism using a linear cam was made. This was done by moving the mechanism to the side. The mechanism was blocked off to create a separate section to stop apparatus used during a screening from entering this mechanism section. This closed off section also provides support for the push pulley to push the flap open in a straight line.

INSIGHTS

- Moving the mechanism to the side of the product works well. The mechanism still moves as intended. Since the system is made smaller, it is a bit tedious since a 3D printer struggles to make these small items.
- Implementing the separate mechanism section works well but is not ideal for sterilisation because dirt could get into it easily.
- The jump from the end of the moving flap to the edge of the C Spec main body is quite large. This would be an issue regarding comfort when inserting. A solution must be thought of if the direction of the single moving flap is chosen.

ACTION POINTS

Design direction: Both sprint periods are now completed. Based on the prototypes made, a decision must now be made as to which direction to take the C Spec design. This decision can be found in the report in section 4.

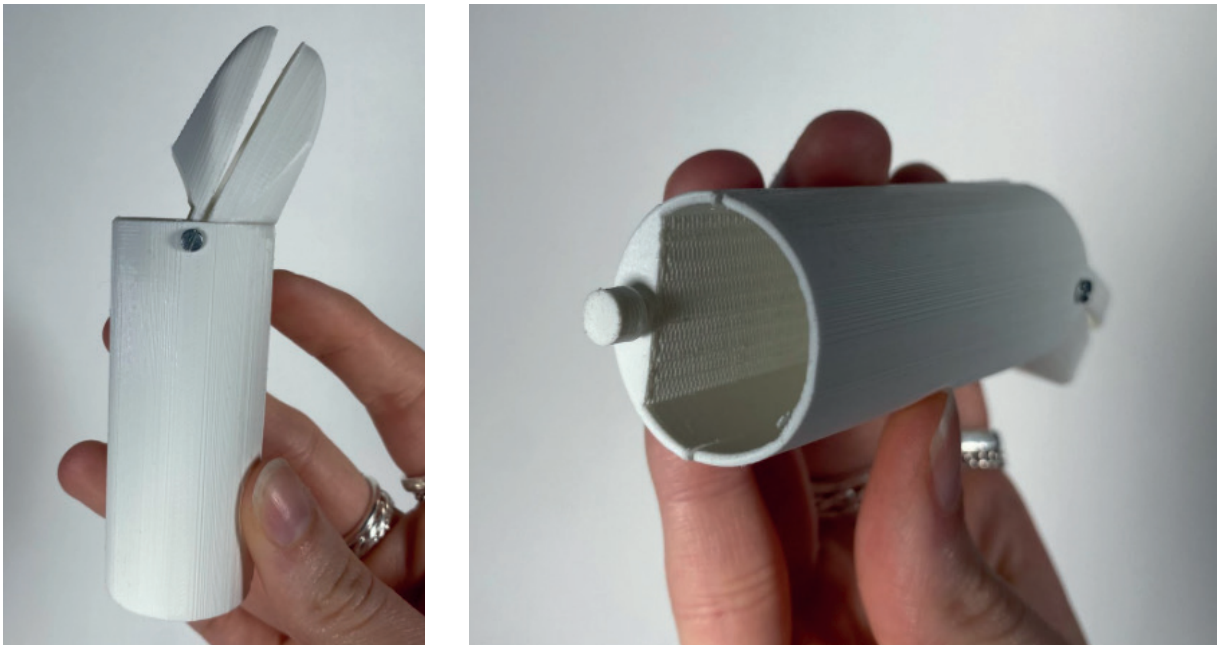


Figure I.20 - Images of the single flap moving mechanism using a linear cam showing the hollow feature

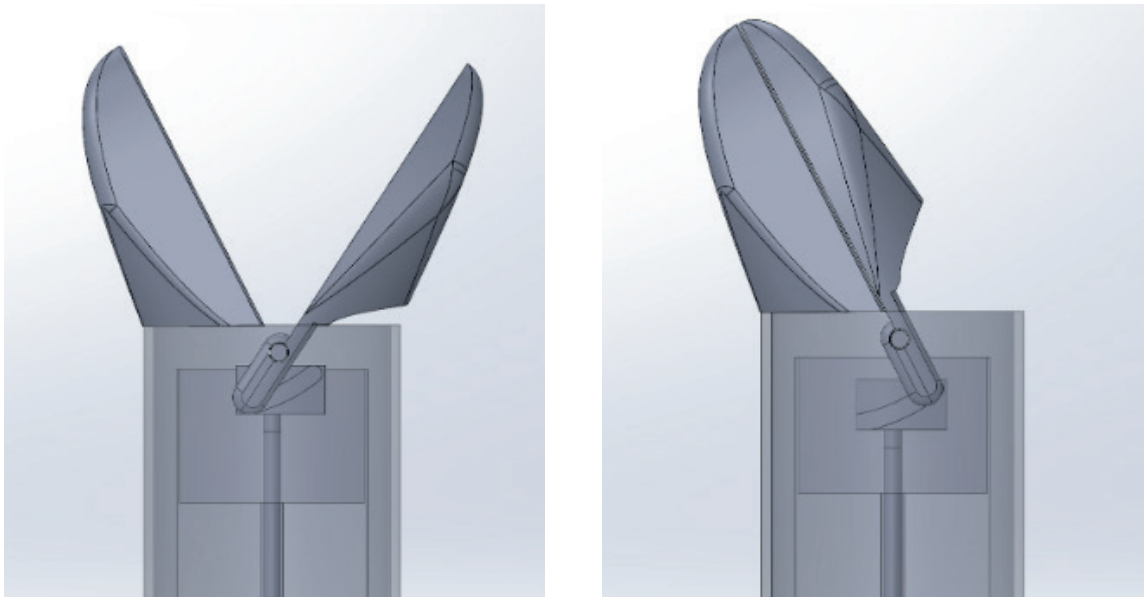


Figure I.21 - Solidworks images of the single flap moving mechanism using a linear cam with the hollow feature in an open and closed state

Appendix J

PRODUCT CONCEPTUALISATION

FLAP DESIGN UPDATE

The flap design had to change to include an extra inner pin. The arm of the one flap had to be increased in length to facilitate this pin.

When creating this prototype, it was found that the length of the straight arm still took up a lot of space between the two tubes. Another iteration was therefore made where the arms of the flaps are slightly curved to follow the form of the inner and outer tubes better.

Figure J.22 - Flap iteration using rapid prototyping

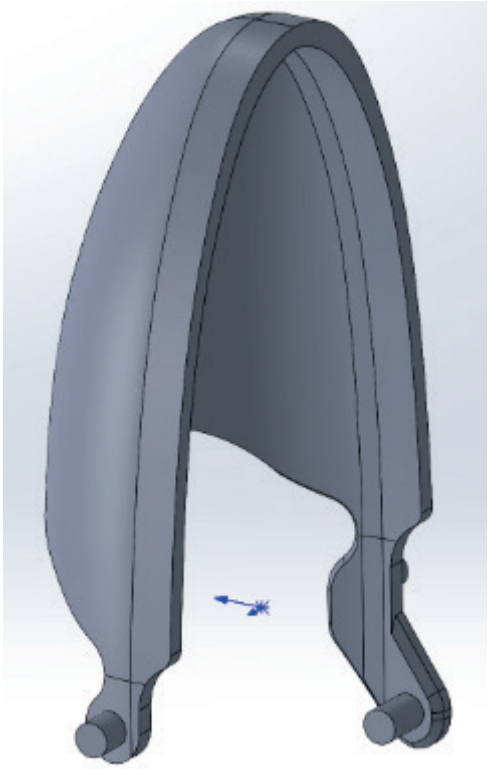


Figure J.23 - Flap design of new C Spec

CREATING SPACE FOR THE MECHANISM

To fit the new flap design, the diameter of the inner tube had to decrease to give the mechanism enough space. The inner tube decreased from a diameter of 29.6mm to 24.2mm.

The inner and outer tube need to move concentric to each other, with the inner tube now being made smaller, there is a gap between the two tubes which causes the inner tube to wiggle. An extra diameter was therefore included at the sides of the outer tube. This thickness was on the sides perpendicular to the mechanism.

Even with this extra thickness, the inner tube still wiggled. The decision was therefore made to place the extra thickness along the whole tube. Also, this extra thickness was moved from being on the outer tube, to being on the inner tube. The top of the inner tube was kept open to provide the space for the mechanism. Figure I.24 shows the extra space created for the mechanism with the extra diameter thickness around the inner tube. Figure I.25 shows the inner and outer tubes before and after the extra inner tube thickness.

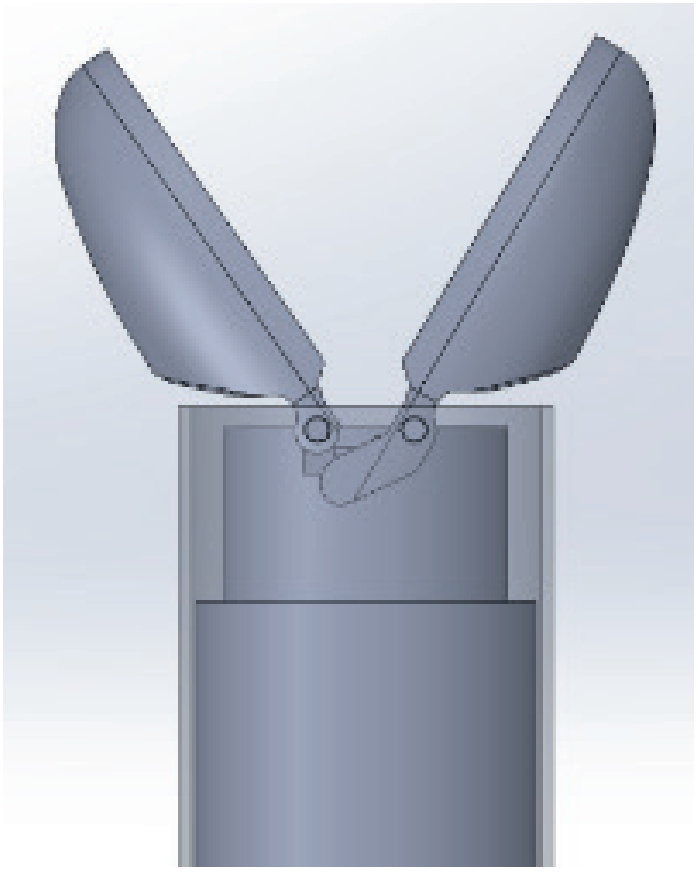


Figure J.24 - Flap mechanism with extra thickness inner tube in an open state

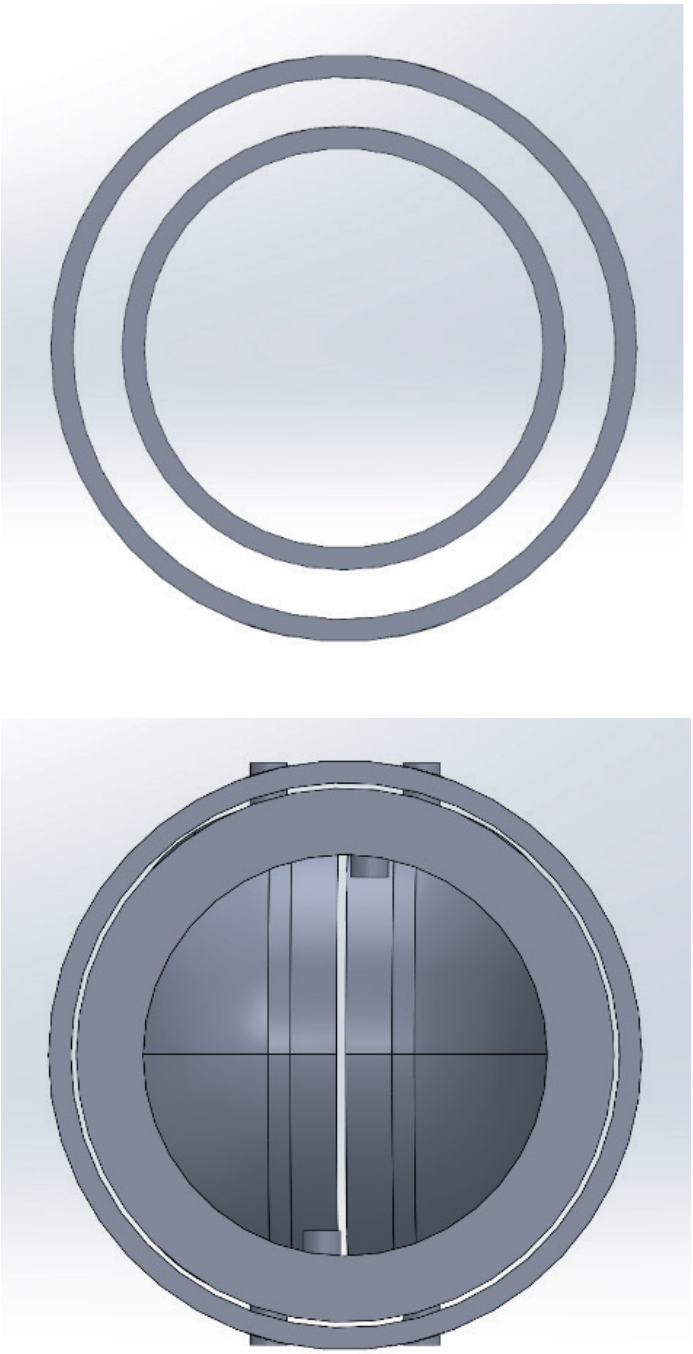


Figure J.25 - Before and after adding inner tube thickness

HANDLE DEVELOPMENT

CAM Style Handle

In previous designs the hinge point of the cam style handle was in the middle of the entry to the C Spec because in previous designs the linear cam was pushed from the middle. When making the C Spec hollow, the design of the cam mechanism had to change.

It was decided that the cam style handle would push the inner tube from only the base. If the hinge point of the cam style handle were to be kept in the middle, then the cam would not work since the hinge point is higher than the cam itself. A location lower than the cam was therefore selected for the hinge point as shown in figure I.26. The method of connecting the handles is through clicking pins into holes on the static handle as shown in figure I.27 and I.28 . These figures also shows the hole cut into the static handle to facilitate the cam shape to push the base of the inner tube.

Figure J.26 - The new hinge point location for the cam squeeze handle

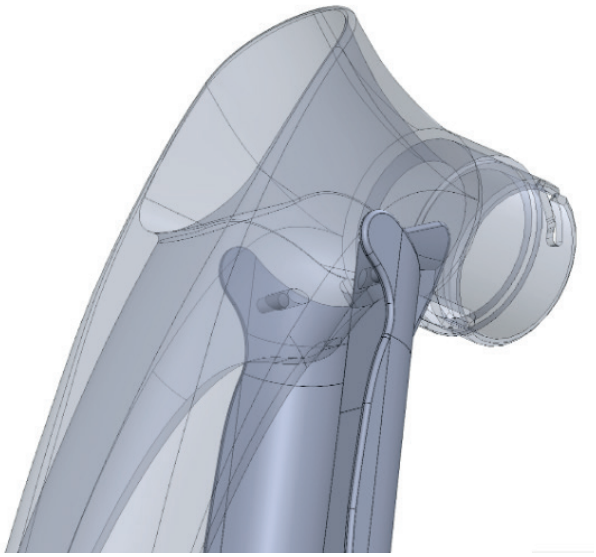


Figure J.27 - The joining method between the handles

Figure J.28 - The joining method between the handles

FLUSH CAM WHEN CONDUCTING PROCEDURE

As shown in figure I.29. The cam obstructs the entrance to the main body when the squeeze handle is not compressed. This is fine for when the flaps are closed and a procedure is not conducted but when wanting to insert apparatus, the cam should not obstruct. The cam shape was therefore designed to be flat on its back face. So that when the handle is squeezed, the cam is flush and does not block the entry. This is shown in figure I.30.

Figure I.31 shows that the thickness of the static handle was increased. Previously, the handle had the same thickness of 1.2mm everywhere. This however meant that when looking into the C Spec, the bottom edge of the inner tube could be seen. The extra handle thickness near to the connection of the main body provides a flush entry for the apparatus.

Figure J.29 - Cam obstructs entry to main body when squeeze handle not compressed

Figure J.30 - Cam sits flush to entry to main body when squeeze handle is compressed

ACTION POINT

Since the top is flat, when the squeeze handle is compressed, the cam handle sometimes overshoots and the inner tube releases again. This is an issue but it can be fixed either by implementing a notch where the inner tube cannot travel over or by redesigning the squeeze handle so that it cannot be compressed past a particular point.

HANDLE TO MAIN BODY CONNECTION

Two methods were explored to attach the handle to the main body. The first is the bayonet mechanism and the second is through a screw thread.

The decision was made to use the bayonet system as the walls on the main body are so thin that implementing a screw thread would be difficult, and a screw thread increases issues with thorough cleaning when sterilising the product due to all the spaces bacteria could get in.

The bayonet system could be executed in two ways:

1 - Path cut out of the outer tube with two lock pins placed on the static handle

2 - Path cut into the static handle, with two lock pins placed inside the outer tube

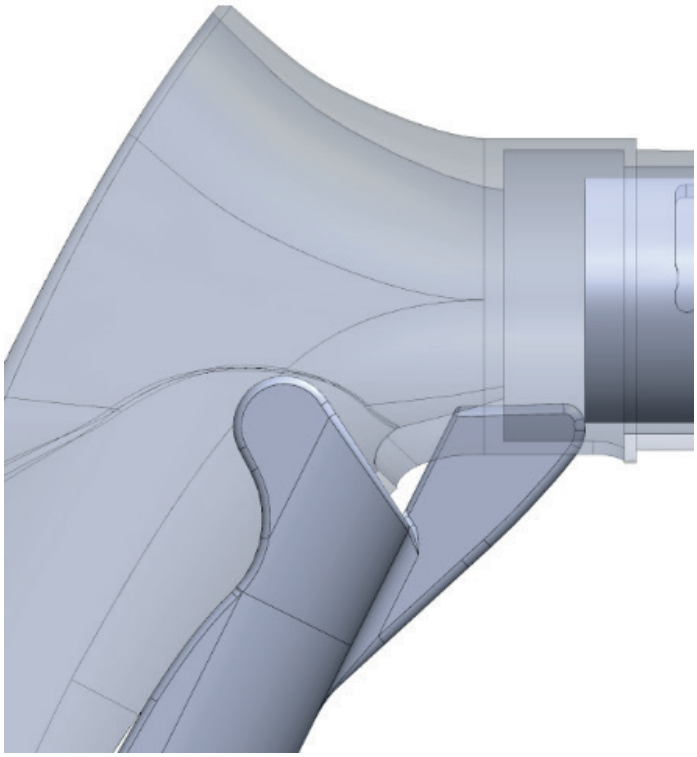


Figure J.31 - Cam sits flush to entry to main body when squeeze handle is compressed

Option 1 Insights:

- Mechanism works very well
- The mechanism can however be seen which could intimidate patients
- Want to keep a smooth exterior to not expose the patient to sharp edges

Option 2 Insights:

- Works well as well as option 1 but now the mechanism is hidden which looks a lot less intimidating for patient comfort
- The exterior of the mechanism is kept smooth which is also beneficial for patient comfort

CONCLUSION

The bayonet mechanism in the form of option 2 is chosen since both options work just as well on a mechanism function level, but option 2 provides more comfort for the patient both mentally and physically.

ACTION POINTS

- During the procedure, the C Spec is rotated. The bayonet lock could release during this rotation. A click/neutral point is included to block the bayonet from releasing during product use.
- For user interaction, the main body and the static handle will include an indicator to visualise to users where to join the two mechanisms together and when the two components cannot be turned any further.
- Because the pins stick out inside the outer tube, the inner tube can no longer be inserted. Slots were therefore made in the extra thickness of the inner tube to allow it to be inserted into the outer tube.

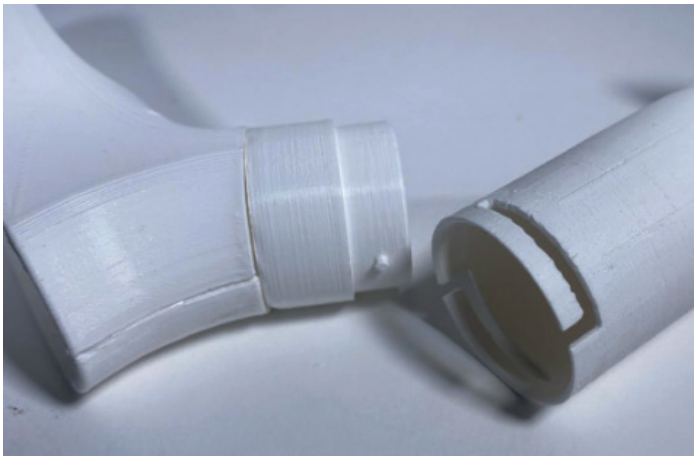


Figure I.33 - Bayonet lock option 1 disassembled

Figure J.34 - Bayonet lock option 2 disassembled outer tube

Figure J.35 - Bayonet lock option 2 disassembled static handle

Figure J.32 - Bayonet lock option 1 connected

Figure J.36 - Bayonet lock option 2 assembled