Master Graduation Thesis

Revolutionizing pelvic exams: A sustainable, patient-centered redesign of the Vaginal Speculum

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"When we exclude half of humanity from the production of knowledge we lose out on potentially transformative insights."

-Caroline Criado Pérez

Acknowledgements

Dear Reader,

Thank you for reading my project and for your interest in women's healthcare. Although this project has my name on the cover, it would not have been possible without the support of many people. I would like to use this page to express my gratitude.

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I would like to end these acknowledgments with a personal dedication to my family in Barcelona. With your permission, I will write it in Catalan:

Aquest projecte no hauria estat possible sense l'ajuda de la meva família que, tot i estar lluny, m'han donat tot el suport que han pogut. Gràcies, mama i papa, per reconstruir-me cada cop que tornava a casa i per agafar-me totes les trucades de telèfon. Gràcies per entendre'm i saber ajudar-me quan més ho he necessitat. Us estimo molt.

Als meus amics de casa—Marcel, Carla, Andrea, Laia, Curu, Gerard, Anna, i Paula—gràcies per rebre'm a casa com si no hagués marxat.

Having said all that, I can only hope that you, the reader, enjoy and find this report as insightful as I have found it throughout the journey.

Best,
Ariadna Izcara Gual
20.08.2024

Executive Summary

This master's thesis presents a comprehensive redesign of the vaginal speculum, an essential yet historically problematic device used in women's healthcare. The project focuses on addressing three main issues: enhancing patient comfort, fulfilling physician needs, and ensuring environmental sustainability. This work aims to resolve the persistent discomfort and anxiety associated with pelvic exams, which are exacerbated by the current design of the speculum, while also considering the environmental impact of the healthcare sector.

The vaginal speculum has seen little change since its invention in 1845, despite its controversial history and the discomfort it causes to patients. Traditionally, its design prioritized the needs of healthcare providers, often neglecting the experience of the patient. The discomfort caused by the device has been a significant deterrent for women undergoing gynaecological examinations, contributing to delays in diagnosis and treatment of various health conditions. While some modern adjustments have been made—such as the shift from reusable metal speculum to single-use plastic versions in many Dutch hospitals—these changes have increased the environmental burden of healthcare, particularly in the context of global greenhouse gas emissions.

The project followed the Three Diamond design method, encompassing the phases of Discover, Define, Ideate, Conceptualize, Develop, and Deliver, to create a new speculum design. The process began with an in-depth exploration of the needs of three primary stakeholders: patients, healthcare providers, and the environment. This included literature reviews, hands-on explorations, and interviews to understand the diverse perspectives and challenges faced by each group.

The resulting design, named Lilium integrates patient-centred features such as improved ergonomics, reduced invasiveness, and enhanced aesthetics to alleviate patient discomfort. For healthcare providers, the design offers a more efficient and user-friendly tool that facilitates better access and visibility during examinations. In terms of sustainability, the Lilium speculum is designed for re-usability, with a focus on materials that reduce environmental impact while maintaining high standards of hygiene and safety.

Market analysis and SWOT assessments indicate that Lilium has strong potential in the market, positioned as a high-performance, competitively priced product. However, the project also acknowledges certain limitations, such as the regulatory constraints that prevent real-world testing at this stage. Recommendations for future work include further refinement of the design based on clinical feedback and exploration of alternative materials to enhance the device's environmental credentials further.

In conclusion, this thesis presents a viable solution to the long-standing issues associated with the vaginal speculum. By balancing the needs of patients, healthcare providers, and the environment, Lilium speculum represents a significant step forward in women's healthcare, offering a more humane and sustainable approach to pelvic examinations.

Keywords: Women's health, vaginal speculum, patient-centred design, circularity

Reading Guide

This reading guide describes the report layout and guides the reader towards the desired content.

This project is organized into seven chapters grouped into three main sections:

Section 1: Understanding the needs

In this first section, the three main areas will be explored independently. Each chapter includes both a desk research analysis through literature review and a practical analysis through hands-on exploration and interviews.

Section 2: Building the New Speculum

This section covers the design and engineering phase of the project, outlining design methods to develop the new vaginal speculum.

Section 3: Conclusion

This section synthesizes new insights and explores possible limitations and recommendations for future work.

"This is a quote extracted from the interviews"

"This is a quote extracted from the validation interviews"

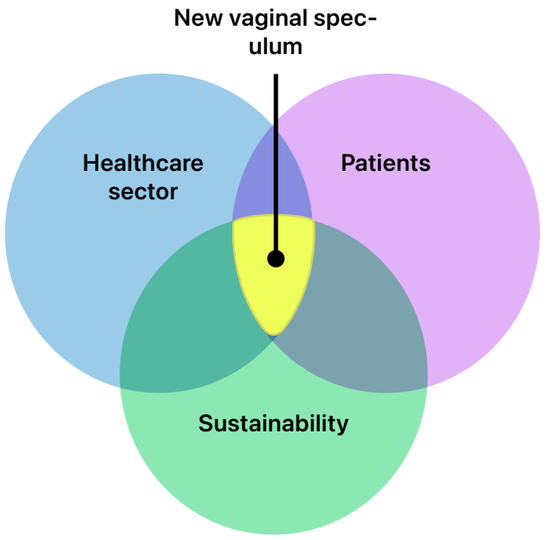

Fig. 1: Framework of the project

At the beginning of each chapter, a short description of the chapter is provided, including the sub-research question the chapter aims to answer and the methods used. At the end of each chapter, a discussion is conducted to answer the questions raised at the beginning of the chapter. Following this, the main takeaways for transforming research insights into design features needed for the redesign are provided. These takeaways are represented in a blue rectangle (Figure 3.

This project follows the Three Diamond method, which divides the work focus into six different stages: Discover, Define, Ideate, Conceptualise, Develop, and Deliver. To indicate the stage in each chapter, the following symbols will be used:

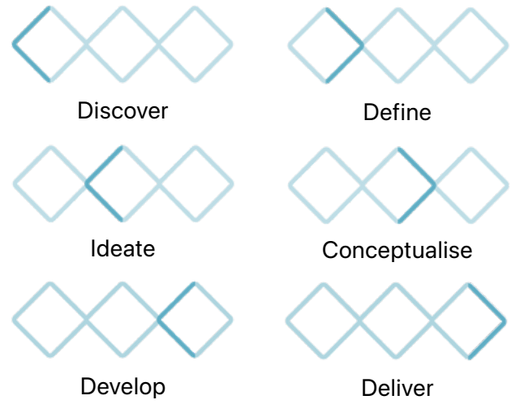

Fig. 2: Icons of the different stages

1. Main affected area

- Takeaway 1
- Takeaway 2
- Takeaway 3

2. Main affected area

- Takeaway 1
- Takeaway 2
- Takeaway 3

Fig. 3: Presentation of chapter takeaways

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General introduction

This chapter provides an overall introduction to the project, defining the problem, scope, and methodology used to achieve the project's goals. Additionally, it includes an introduction to the vaginal speculum and pelvic exams, along with a market research analysis

1.1 Project Introduction

Problem definition

The vaginal speculum, derived from the Latin "specere," meaning "to look," is a widely used device in women's healthcare, aiding practitioners in visualizing or accessing the cervix by retracting the vaginal walls (Rossmann, 2008). The most common use of the device is during generic pelvic exams, primarily for visualizing the cervix and obtaining Pap smears. However, it also serves other purposes, such as IUD insertions, follow-up evaluations of cervical or vaginal lesion treatments, and pre- or post-operative evaluations (CooperSurgical, 2020).

This device was designed by J. Marion Sims in 1845. Its historical usage, particularly involving experimentation on enslaved women without consent or anaesthesia, combined with the historical taboo surrounding women's bodies and sexuality, has led to a challenging legacy for this device, whose design has remained largely unchanged until now (Breternitz, 2018). Furthermore, the original design process focused primarily on meeting the needs of practitioners, with little regard for the comfort and well-being of the patients undergoing the examinations (Arrivillaga et al., 2023).

Discomfort caused by the instrument is one of the reasons why patients may avoid participating in gynaecological examinations, such as pelvic examinations. Despite research efforts by hospitals and institutions to identify factors contributing to these negative experiences, a clear answer remains unclear. Many Dutch hospitals are now addressing this problem by transitioning from reusable (metal) speculum to single-use (plastic) speculum to improve patients' perception of the device. While this transition may alleviate patient discomfort, it exacerbates the climate impact of the healthcare sector, which already contributes significantly to environmental pollution, accounting for approximately 4.4% of global net greenhouse gas emissions (Serres, 2024). The dilemma of choosing the right solution has been accentuated by initiatives such as the Green Deal, which aims to reduce hospital waste. Consequently, hospitals are under pressure to explore alternative solutions.

The main objective of this project is to develop a solution that improves the use of the vaginal speculum by finding the perfect balance between patient comfort, physician needs, and sustainability. This project aims to address the long-standing issues associated with the traditional speculum, such as patient discomfort and fear, as well as the inconveniences faced by healthcare professionals. The design process will incorporate materials and mechanisms to enhance usability, hygiene, and environmental impact. Given that the main product is a medical device, the project will face certain limitations, including the inability to test in real conditions due to strict regulatory requirements.

Project approach

This project is based on the Triple Diamond Design methodology. This approach uses a mix of methods across six phases, framed within three diamonds that represent a process of exploring an issue more widely or deeply (divergent thinking) and then taking focused action (convergent thinking) (Design Council, 2007).

The project aims to answer the following main research question, inside the context of Europe, specifically The Netherlands:

"How we can improve the vaginal speculum considering the physiological and psychological needs of patients, as well as the requirements of practitioners and the healthcare system, and circularity?"

This main question is decomposed into sub-questions that follow the phases proposed by the triple-diamond methodology

- **Discover**: What and why are the specific concerns and needs of the vaginal speculum for the healthcare sector, patients and sustainability?
- **Define**: What are the design requirements to implement a solution in the context? How do the needs and concerns of the three sectors diverge into a design vision?
- **Ideate**: How can the requirements be transformed into a new product?
- **Develop**: How can the concept be feasible and functional in a engineering perspective?
- **Delivery**: Does the proposed design fulfil the established requirements? What are the future opportunities?

To achieve the desired results, the project explores the device from three different perspectives: the healthcare sector, the patient and sustainability. Throughout the project, these areas will diverge and converge, adhering to the triple diamond approach, delving into different aspects of the vaginal speculum. This method ensures a thorough exploration and integration of the viewpoints from each perspective, analysing which design requirements will conflict and which will not.

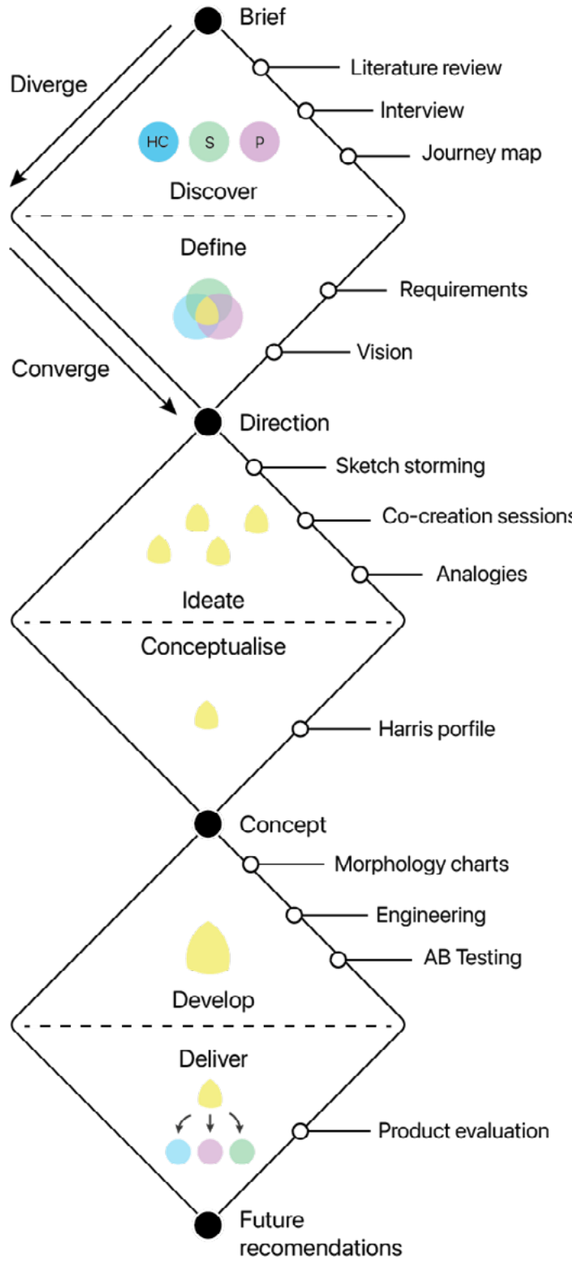


Fig. 4: Triple diamond method.

Project scope

To ensure a holistic perspective of the research question, the project will not only focus on the vaginal speculum itself but will also tackle an entire procedure in which the device is used. This approach will allow gathering more information on external factors that influence the experience from the perspectives of the healthcare sector, the patient, and sustainability. Although the vaginal speculum is used in many medical procedures, this project will specifically focus on pelvic examinations, as they are one of the most frequent gynaecological procedures.

Due to time constraints and project limitations, some areas of research and development will be outside the scope, such as business planning and design for mass production, as shown in Figure 5.

Previous projects - TU Delft

Three projects from previous students on women's healthcare and vaginal speculum design are referenced throughout this report.

The first, "Redesigning the C Spec" by Mirthe W. Hofsted, had a similar timeline, allowing for the sharing of expertise among authors and product evaluations.

The second, "A Context-Specific Design of a Training System for Paracervical Block, Using Chloe Syringe Extension Device, for Sub-Saharan Africa within Low-Resource Settings: The First Stage" by Joséphine Kiewiet de Jonge, inspired the design of the training model used to test some prototypes.

Lastly, "Designing a Shape-Morphing, Reusable, Blood-Collecting Hollow Tampon with Shape Memory Wire" by Vinciane Van den Dwey, inspired the development of Concept 1.

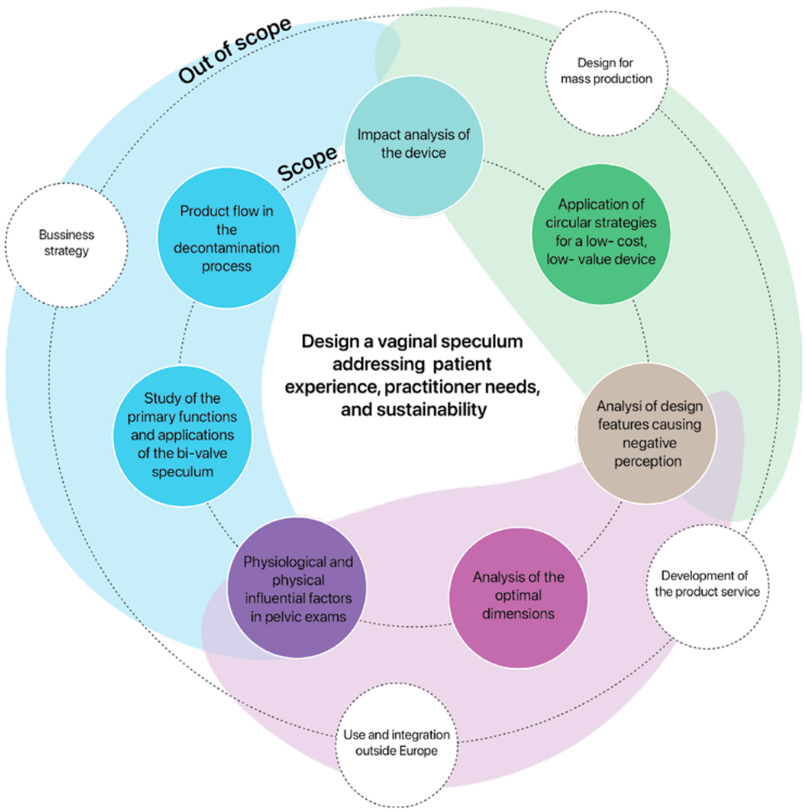


Fig. 5: Scope of the project

1.2 Vaginal speculum and pelvic exams introduction

The vaginal speculum

The main protagonist of this project, the vaginal speculum, is one of the most versatile tools in the medical sector due to the variety of types available on the market. Currently, there are four main categories of vaginal speculum: cylindrical, single-blade (retractors), two blades (bivalve), three blades, and four blades. This project will focus on self-retaining bivalve speculum the most commonly used type today (Loughlin, 2023).

Due to material innovations, bivalve speculums can be either reusable or single-use. Reusable speculums are made of metal alloys such as stainless steel, while single-use speculums are made of high-strength plastics like acrylic. Both types are available in various sizes, typically small, medium, and large, depending on the manufacturer.

As a general rule, small speculum is used for patients with narrow vaginal canals, such as those who are post-menopausal or not sexually active. Large speculum is used for obese patients, patients who have given birth, or those with redundant vaginal tissue (Chai, 2018).

Throughout this project, various parts of the speculum will be mentioned. Below, in the figure 6 is an explanation of the main parts.

In the following chapter how it is used and the different types of bivalve speculum will be explored.

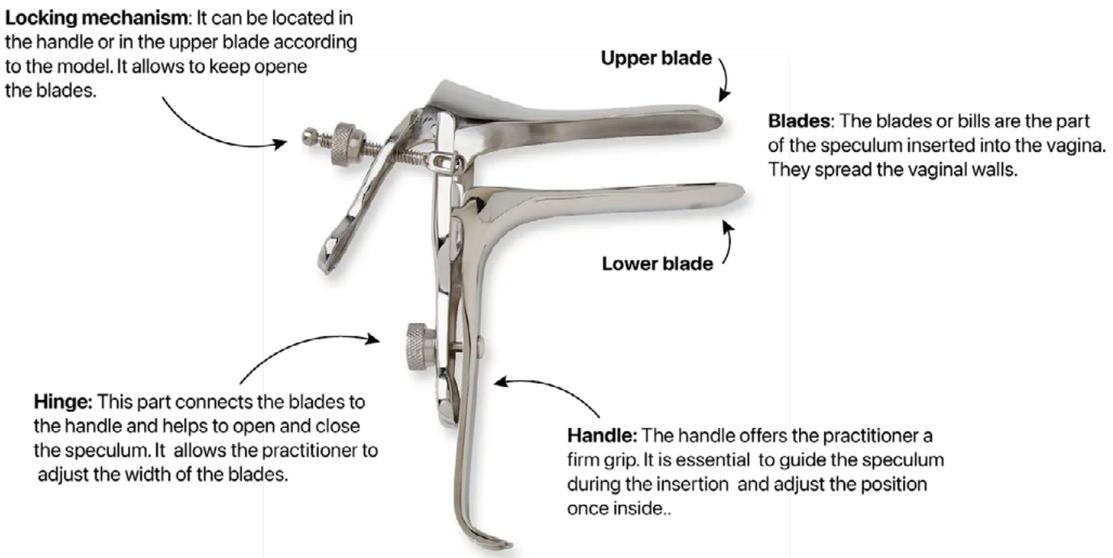


Fig. 6: Parts of the Vaginal Speculum

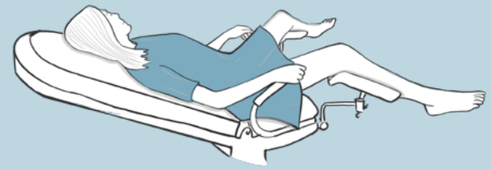
Pelvic exams

The pelvic exam is a regular check-up to check women's sexual and reproductive health. In the Netherlands, this exam is commonly done through the general practitioner, but in some cases like when the patient has insurance it can be done in specialised centres, like hospitals (Piercy & Expatica, 2024).

Rinko et al. (2018) and WNHS Obstetrics and Gynaecology Directorate Staff (n.d), describe the generic pelvic exam in the following steps showed bellow. This information has been checked with professionals and patients through interviews.

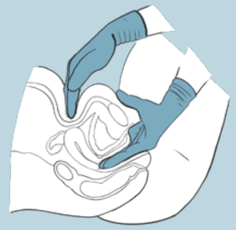
1. Consultation

The doctor or nurse begins by asking the patient about pain, sex life, medical history, and the reason for the appointment



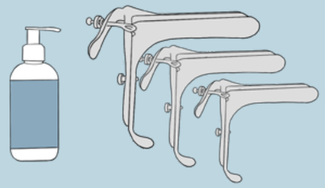
2. Preparation

The patient is positioned in the chair following the instructions of the practitioner.



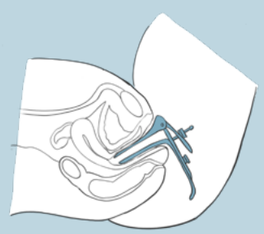
3. Bi-manual exam

The examination typically starts with an abdominal and external genital inspection, followed by a bi-manual examination to assess the size and location of pelvic organs.



4. Preparation of the speculum

The practitioner selects the right-sized speculum, warms a metal one if needed, and applies lubricant to the outer inferior blade.



5. Speculum exam

The practitioner inserts the speculum into the vagina to open the vaginal walls, facilitating the visualization of the cervix and walls, as well as the insertion of other medical devices.

6. Results

The practitioner provides the results to the patient or informs her when she will receive them.

1.3 Market research - New designs

Yona (By Frog) - *Status: Development phase.*

• No visible screws that pinch and no audible clicking, • The speculum has lateral blades to improve visualization • Thumb-press button unlocks/locks the speculum position • Reusable comfort kit that includes socks, a sensory weighted blanket, and a stress ball. • Appearance • Ergonomic handle (105 degrees)	+
• Two materials: Stainless steel covered in autoclave silicone • Difficult to disassembly and clean • Concept	-

(Yonacare, n.d.)

Lotus (By Dayna Mailach)- *Status: Concept student project.*

• Slower pace initial opening fixed • Can be used for self-insertion • Softer shaped bills and form • Unobstructed viewing area	+
• Two materials: Stainless steel covered in autoclave silicone • Small components, difficult assembly and disassembly • No solution for wall prolapse • No locking system • Concept	-

(Mailach, 2019)

Nela (By Ceek)- *Status: In the market*

• Autoclave polymer • 101-degree handle • The speculum has two integrated side-wall retractors additionally • Narrow as a tampon (lateral blades) • Comfort kit that has a single use speculum, socks, stress ball, vaginal wipe to use after the exam, Instruction sheet for your clinician	+
• Expensive. Reusable speculum:$175/unit • Difficult to disassembly and clean • Large number of components	-

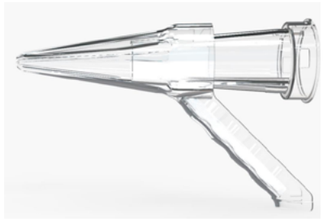
(Ceek Women's Health, n.d.)

Vega (by Induvita)- *Status: Concept. Patented*

• Elastic sideways that provides better visualisation • Friendly design • No noise	+
• No reusable • Use of elastic sideways (more waste) • Different materials in the same device	-

(Induvita, 2023)

Bouquet speculum (by Jean M. Bouquet) - *Status: Firsts clinical trial 2023*



• Opens up opens concentrically and gradually thanks to a dilator • It has a 5-petaled Bouquet Speculum for a better visualization • One hand use (left or right) • Small gaps between the blades to mitigate the pinch risk • Hold lateral walls	+
• No friendly • No ergonomic • Single-use	-

(Maternova Inc., n.d.)

Orchid Spec (By Bridea Medical)- *Status: Market. Used in NL*

• Backward angled front handle allowing for greater access. Large opening (introitus) thus more room for manipulating instruments and retaining a clear overview. • Large rounded edges	+
• No holding lateral walls • Single use option • Too small for obese patients	-

(Bridea Medical, n.d.)

OneSpec (by Feminora)- *Status: Concept. Student project. Cornell University*

• One size fits all women (1) Starts as small as a regular-sized tampon to eliminate pain of insertion 2) Expands to serve patients of any size • Exerts 360-degree pressure to prevent pinching or visual obstruction from tissue. • Maximum opening 5,1 cm	+
• The expansion does not follow the shape of the vagina • Single use • No ergonomic handle • No ergonomic mechanism	-

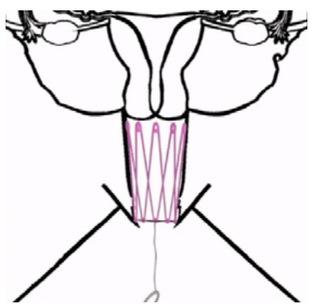
(Feminora, n.d.)

Sophia Götz Speculum- *Status: Concept. Student Graduation Project.*

• Cylindrical, similar opening as the menstrual cup • Silicone material • No handle	+
• No reference if the design can hold the pressure of the walls • No reference single use or reuse device • No reference how it works for the doctor	-

(German Design Graduates, 2024)

Arlette Geller Speculum - *Student project. Duke University. Patent Pending Technology*



• The speculum works as an applicator. • Self-insertion • Ergonomic insertion • Holds lateral walls	+
• Disposable • Removal no explored • Material discomfort	-

(Arlette Geller, 2020)

Wandrille Würz Speculum- *Status: Concept. Student project. University of Limerick*

• Elastic sideways that provides better visualisation • Light included • Reuse • Rounded tip	+
• No designed for assembly and disassembly • No reference of sterilisation with the batteries • Need of elasitic sideway (waste)	-

Würz (n.d.)

C Spec redesign (By Mirthe W. Hofstede)- *Status: Testing. TU Delft*

• Ergonomic • Designed for an easy assembly and disassembly • One hand operation • Reuse • Accessible. Low cost	+
• Metal • No walls visualisation • Limited to certain procedures	-

(Hofstede, 2024)

Chapter 1

The vaginal speculum and the healthcare sector

In this chapter, the primary focus will be on the healthcare sector, which forms the first main pillar of this project. The chapter is divided into two parts: literature review and interview findings. The first part delves into the usability aspects of the device, examining different types of speculum, their usage in hospitals, and decontamination procedures. The second part focuses on the doctor's experience, aiming to identify the advantages and disadvantages of using the current speculum and determining the needs of healthcare professionals.

Questions addressed in this chapter:

1. What are the main functions of the vaginal speculum and how is it used?
2. How is the speculum decontaminated and how can its decontamination be improved through design?
3. Which characteristics of the current speculum should be retained and which ones need to be changed?

Methods used:

- Literature review
- Interviews
- Journey mapping

1.1 Function and use of the vaginal speculum

Function

The vaginal speculum is widely used in gynaecological procedures, including pelvic examinations and Pap smear tests (Bialy et al., 2024). To identify the primary functions of the speculum, a comprehensive study was conducted across various procedures where the device is used (Figure 7).

The research revealed that the most common functions performed by the vaginal speculum are:

- **Retracting the vaginal walls**: The speculum spreads the vaginal walls to allow the practitioner to visually inspect the cervix and vaginal canal.
- **Facilitating the insertion and manipulation of other instruments**: The speculum provides access for other instruments used in procedures like biopsies, intrauterine device (IUD) insertions, and colposcopies.

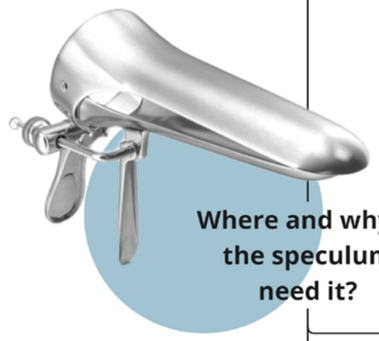


Fig. 7: Function map of the vaginal speculum across different procedures

Use

Although there are different types of procedures, the steps to use the speculum are very similar. The equipment used alongside the device may vary depending on the specific examination being conducted while the specific equipment used with the vaginal speculum includes the following (WNHS Obstetrics and Gynaecology Directorate Staff, n.d.):

- **Speculum**: may be metal or disposable
- **Water-based lubricant**
- **Sterilised examination gloves**
- **Adjustable light source**
- **Condom (if required)**: In some cases, when there are difficulties in visualization, a condom is placed over the device to hold back the vaginal walls (Freeman, 2018)
- **Gyno chair or litter**: A gyno chair helps to position the patient for the examination, some of them have stirrups. Depending on the healthcare centre the room will have a gyno chair if it is a specialised centre like in a hospital or a litter in the case of a general practitioner centre.
- **Self-cleaning tools:** Some centres provide some self-cleaning tools for the patient, like paper or pads after the exam.

How to use the Speculum step by step

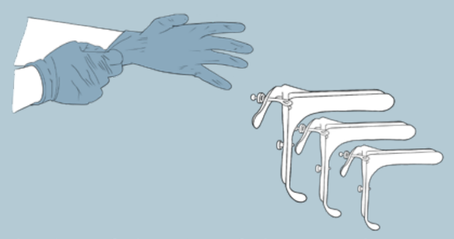
The steps that the practitioner follows to use the vaginal speculum are described below. It was taken as a reference to the Guideline for Cancer Screening of the World Health Organisation and the Obstetrics and Gynaecology Clinical Practice Guideline from the government of Western Australia, with a posterior verification with an expert during an interview.

The steps are generally divided into four phases:

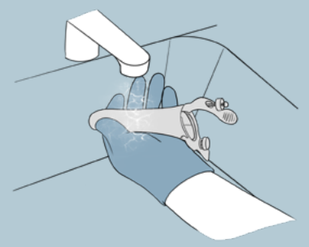
- **Preparation**
- **Insertion**
- **Use** of the speculum for visualisation or examination (this step will vary according to the procedure mentioned in figure 7)
- **Removal** of the device

Later in the project, the cleaning procedure for the device will be described.

1. Preparation

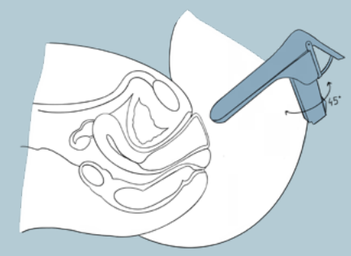


Selection of the size of the speculum, positioning the light, hand hygiene and putting on the gloves.

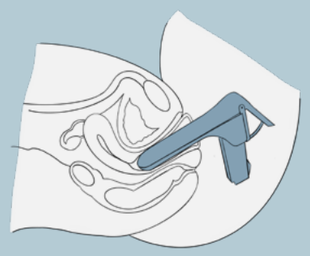


Warming the speculum if it is metal. Application of lubricant on the outer inferior blade of the speculum. Add the condom to the blades is it is needed.

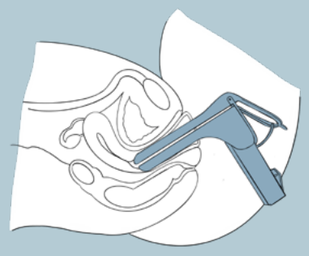
2. Insertion



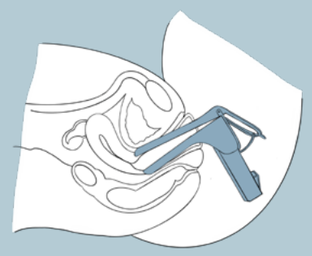
Sliding the closed speculum into the vagina along its axis at a 45° angle to avoid contact with anterior structures like the clitoris and urethra.



Gradual insertion of the speculum.

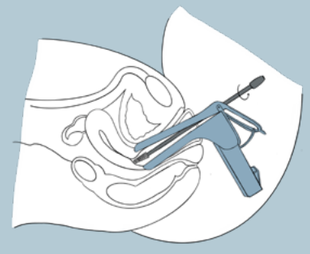


Gently rotating the speculum to the correct angle while exerting steady downward pressure.



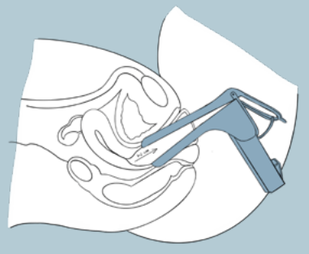
Slowly opening the speculum until the cervix comes into view. Once visible, tighten the screw on the upper blade to secure the speculum in place.

3.Use

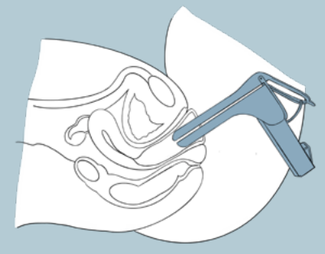


Use of the speculum for visualisation or examination. This step will vary according to the procedure.

4. Removal



Loosening the screw on the blade and withdrawing the speculum approximately 1-2 cm from the posterior vaginal wall to clear the cervix.

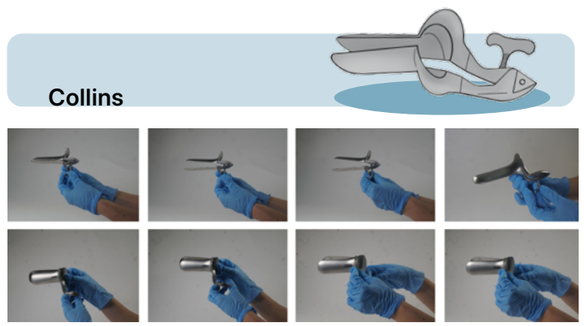
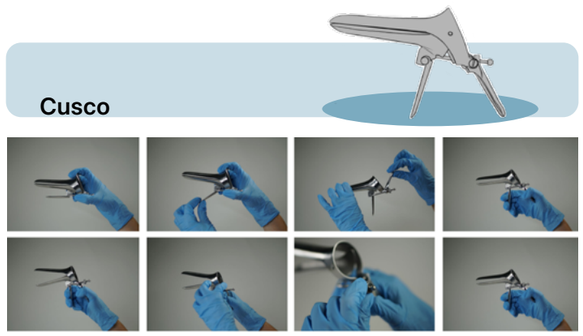
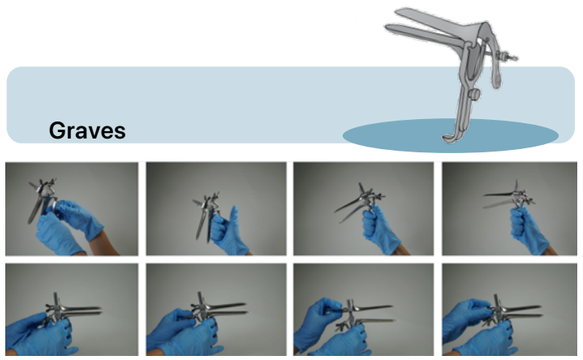
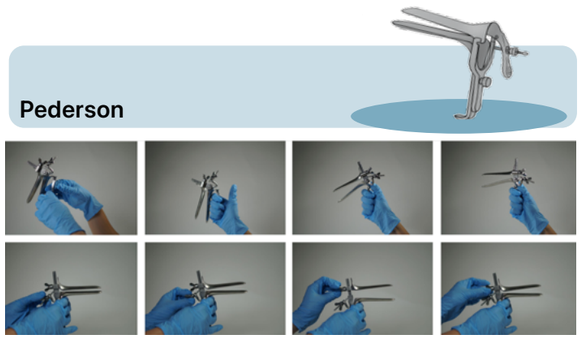


Close the blades and remove the device.

1.2 Exploration of the different types speculum

Nowadays, there are different types of the speculum being the most popular the Graves speculum, Cusco, Collins and Pederson (Rossmann, 2008). All these speculum are self-retaining, designed to stay in position without manual assistance, enabling practitioners to perform other tasks efficiently. The differences among these models and their applications will be explored further in the table below.

*Recommended sizes WHO (2020)

	Collins	Cusco	Graves	Pederson
				
Uses	• Smear sampling • Colposcopy • Minor gynaecological inspection (WHO, 2020)	• Inspection • Smear sampling • colposcopy (WHO, 2020)	• Pelvic and cervix examination (smear sampling) • Gynaecological procedures. • It is used for patients who have an increased elasticity in the vaginal walls or a longer canal structure, for example, a patient case who has given recently or subsequently given birth (Watson, 2018).	• Pelvic and cervix examination (smear sampling) • Gynaecological procedures • It is used for patients who have narrow vaginas like those who have not given birth (WHO, 2020).

Characteristics	• Blade length (+/- 5%) / blade width (+/- 5%)*:
	  • Large : 110mm / 40mm
	  • Medium: 100mm / 35mm
	  • Small: 85mm / 30wmm
	• It retracts the vaginal walls laterally or horizontally.
	• Unlike others, it does not have a proper handle, allowing it to be positioned in different directions (WHO, 2020).
		• Blade length (+/- 5%) / blade width (+/- 5%)*:
		  • Large : 110mm / 40mm
		  • Medium: 100mm / 35mm
		  • Small: 85mm / 30mm
		• It does not have hinged blades
		• More compacted model. The handle can be rotated in a posterior or anterior direction (Obstetrics and Gynaecology Directorate Staff, n.d.)
			• Blade length (+/- 5%) / blade width (+/- 5%)*:
			  • Large : 115mm / 35mm
			  • Medium: 95mm/ 35mm
			  • Small: 75mm/ 20mm
			• It has the widest blades of all the speculums and rounded shapes (WHO, 2020).
			• The wider blades of the speculum provide adequate exposure of the cervix
			• Provides greater aperture at the introitus than Cusco and Collins due to its design (WHO, 2020).
				• Blade length (+/- 5%) / blade width (+/- 5%)*:
				  • Large : 115mm / 25mm
				  • Medium: 95mm / 22mm
				  • Small: 75mm / 13mm
				• Can provide greater aperture than the Cusco and Collins due to its hinged blades that allows to open them in parallel expansion (WHO, 2020).
				• Most narrow blades compared to Cusco, Graves and Collins, facilitating the examination process for healthcare providers (WHO, 2020).
				• There are some models that have apertures in the blades for a better visualization.

Limitations	• No handle: Possibility to touch the body. • Two possible openings. • In the vertical opening, there is no possibility for left-handed users, whereas in the horizontal opening, it is possible. • Two hands are needed. • Among the three, it is the fastest to use	• To unfold the handle for the thumb, it is necessary to touch the blades. • There is no space to manipulate the thumb screw. • Not comfortable for users with big hands • Two hands are needed for operation. • Better visualization between the blades. When the blades are fixed in the open position, there is still a small movement. • The device can be switched for left-handed users, but it needs to be disassembled. The screw is too small to be manipulated with a glove.	• Without thumb pressure on the lower blade, the speculum folds down, which can be a drawback during insertion. • In the lower position, there is no space between the screws. • Two hands are needed for operation • Not suitable for left-handed users. • The thumb screw is not very stable and can become disassembled during use. • Difficult to see between the blades; the mechanism is too big • Wide blades may cause discomfort for women with narrow vaginas, and for adolescents and young women (WHO, 2020). • Wide blades may hide some of the vaginal wall findings (WHO, 2020).	• Narrow blades may cause discomfort for women because the pressure is less distributed (Interviews). • Bivalved specula may hide some of the vaginal wall findings (WHO, 2020)

1.3 Decontamination of the reusable vaginal speculum

Decontamination of medical devices is a complex and highly specialised field. In the UK and Europe, decontamination relates to the entire process, including cleaning (World Health Organization, 2018).

The Spaulding Scale determines the required level of decontamination based on product criticality. “Critical devices” are those that enter tissue or the vascular system, having a high risk of infection and requiring sterilisation. “Semi-critical devices”, are in contact with mucus membranes have a medium risk of infection and require high-level disinfection (HLD). Lastly, “Non-critical devices” which only contact the skin without entering the body, require a medium level (MLD) or low level of disinfection (LLD) (Nanosonics, n.d.).

According to the World Health Organization, (2018), the vaginal speculum is considered a semi-critical instrument. This means it requires either high-level decontamination or sterilisation before use. High-level decontamination involves destroying most of the pathogenic micro-organisms but does not reliably eliminate bacterial endospores, while sterilisation completes the destruction of all micro-organisms

The pathogens are responsible for most infections and are commonly classified as bacteria, fungi, mycrobacteria, prions, protozoa, and viruses, each having different levels of susceptibility to various types of decontamination (Zhou, 2022). Based on this, these groups are ranked in the figure 8 according to their resistance to sterilization and which methods of decontamination are needed to eliminate them (Zhou, 2022, Mohapatra, 2017).

*In the case of the vagina is very rare to find Mycrobacteria which can cause tuberculosis and Prions which cause neurodegenerative diseases.

All of these pathogens mentioned before pose different risks of infection and different consequences to the human body. In the context of pathogen transmission during the use of the vaginal speculum, Pandey et al. (2020) and WHO (2016) identify certain types of infections as high-risk due to their high probability of infection and/or potential causes:

Human Papillomavirus (HPV): It is a Non-Enveloped Viruses. The two most common "high-risk" genotypes (HPV 16 and 18) cause approximately 70% of all cervical cancers. HPV is highly transmissible, with peak incidence soon after the onset of sexual activity, and most persons acquire infection at some time in their lives.

Human immunodeficiency virus (HIV): It is a lipid-enveloped virus. It is one of the most common viral STIs. An estimated 39.0 million people were living with HIV at the end of 2022 (WHO, 2023). HIV-infected patients usually develop symptoms such as fever, myalgias, and swollen lymph nodes. The infection contributes to complications such as liver dysfunction, tuberculosis, and AIDS. It is considered a high-risk infection. It causes patients to be vulnerable to implications, including cervical cancer, vaginal cancer and oropharyngeal cancer (Pandey et al. 2020).

Vulvovaginal Candidiasis (VVC): It is caused by the fungus Candida . Estimated that nearly 75% of women will experience at least one episode of VVC and approximately 10%–20% of women will have complicated VVC (CDC, 2021). Women who are more likely to get vaginal candidiasis include those who are pregnant, have diabetes or use hormonal contraceptives (CDC, 2022).

Trichomoniasis: It is caused by a protozoan parasite, Trichomonas vaginalis. It is a widespread non-viral STI that affected around 5.3% of women worldwide in 2016, with the majority of the cases being asymptomatic (Pandey et al. 2020).

Clostridium: Even though Clostridium infections through the vaginal canal are uncommon, they are among the most frequent nosocomial infections globally, and their spores are only eliminated by sterilization (Rupnik et al., 2009). A study by Chong et al. (2016) found that out of 4,152 participants, between 2010-2012, 3.4% tested positive for Clostridium sordellii, and 10.4% for Clostridium perfringens in the vaginal canal. Despite their rarity, the difficulty of eliminating these spores highlights the necessity of sterilizing the device to completely eliminate infection risks, especially for vulnerable groups (Chong et al., 2016).

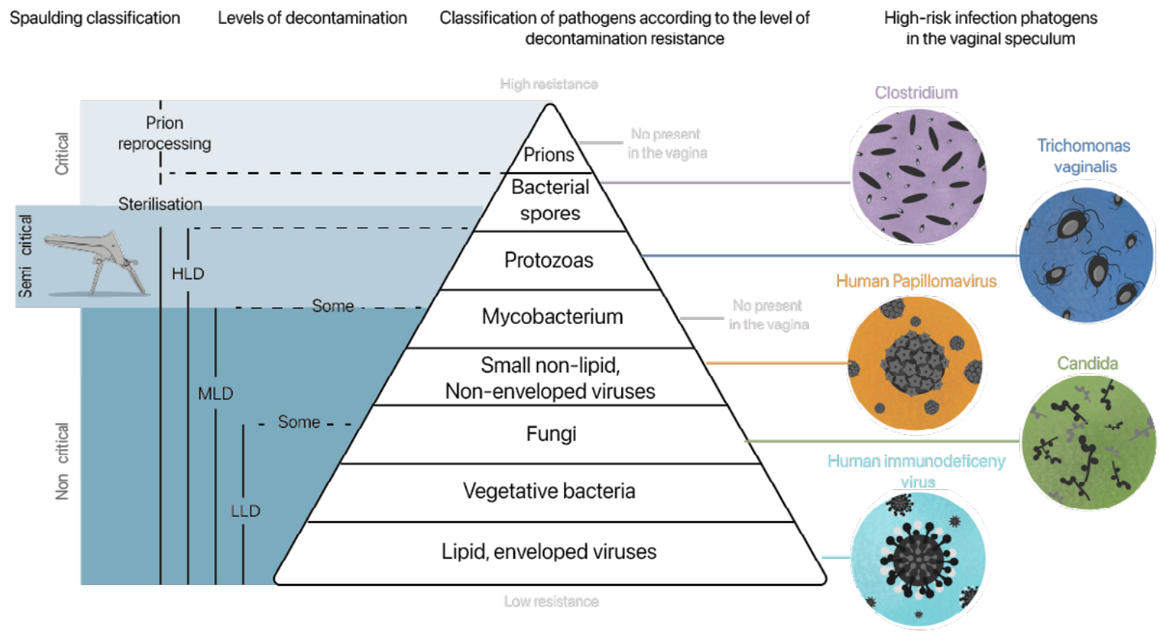


Fig. 8: Classification high risk infections vs level of decontamination needed

According to the classification in figure 8 most of the high-risk infections exhibit low to medium resistance to the decontamination process. Utilizing a HLD process for the speculum would suffice to eliminate all potential high-risk infections, except the Clostridium.

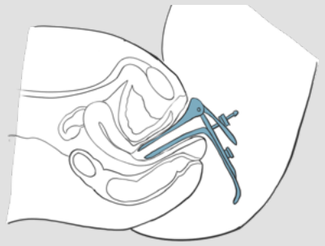
A pertinent case highlighted by Milne et al. (2006) occurred in April 2003 within an English primary care trust (PCT). The PCT discovered that most of the vaginal speculums they had been using for over 12 years had been inadequately decontaminated, undergoing chemical disinfection but not sterilization. Although it was difficult to make an accurate assessment, the Health Protection Agency (HPA) estimated that the risk of infection from this failure was highest for HPV and lowest for HIV. For this reason, despite the risk being low but not negligible, over 400 women were offered screening for chlamydia, hepatitis B, and hepatitis C. The results revealed that the total number of infections the HPA estimated that could have resulted from the failure of decontamination was between zero and two (95% confidence interval) (Milne et al., 2006). This case demonstrates that applying an HLD process to the vaginal speculum would be sufficient to prevent high-risk infections for the patient.

However, more investigation needs to be conducted in this field to address potential concerns regarding which cases is required sterilization, even some hospitals are considering whether sterilization is needed or not for this device (Snijder & Broeren, 2022).

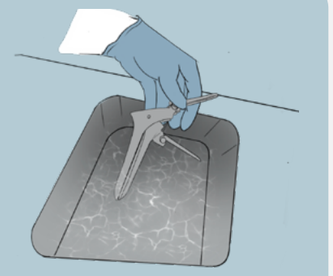
Decontamination process work flow

In order to understand better the full work flow of the decontamination process, an analysis of the current process has been developed. This study is based on the recommendations from the manufacturer Cooper Surgical, the World Health Organization, and further refined through interviews with experts.

Considered critical steps



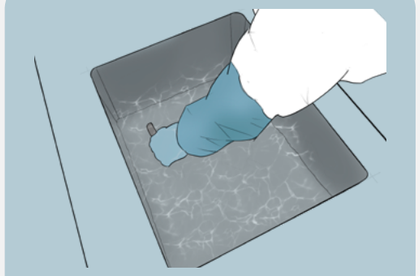
Use



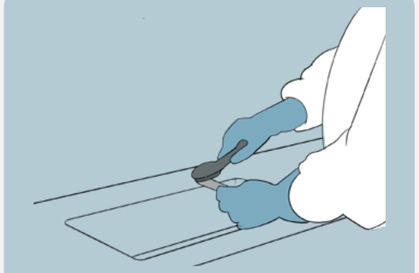
1. Pre-clean the device must take place immediately following the instrument's use for decontamination.

High Level Decontamination

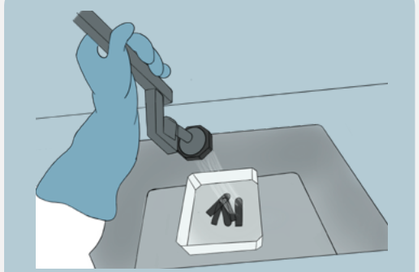
2. Disassembly. Necessary to reach all the spots from the device



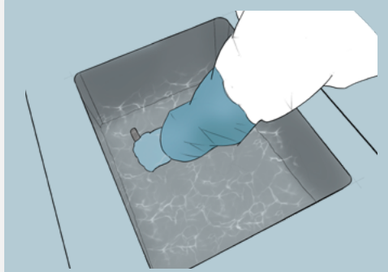
3. Soak of the device in pH enzyme cleaning solution (Enzol) for 1 minute



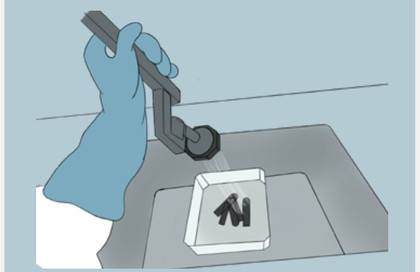
4. Cleaning of the parts of the device by washing with a soft bristle brush with a cleaning solution



5. Rinse of the parts in tap water for half a minute

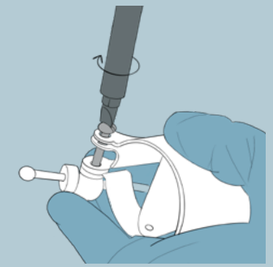


6. Soak again the parts in pH enzyme cleaning solution (Enzol) for 1 minute



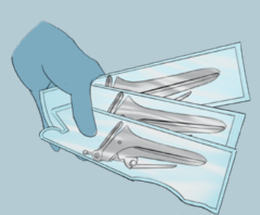
7. Rinse again the parts in tap water for half a minute

8. Visual inspection



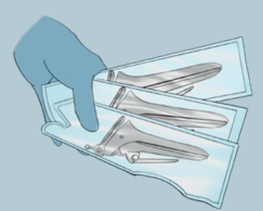
9. Assembly of the device

Sterilisation

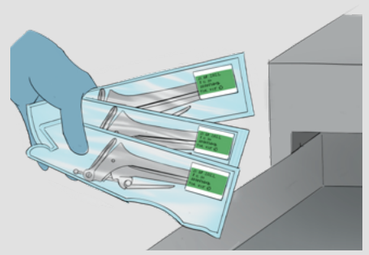


10. Package the devices for posterior autoclave sterilisation

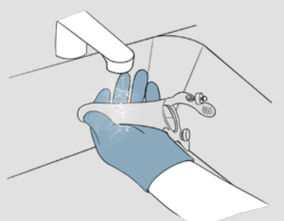
11. Autoclave sterilization. Standard cycle of 132°C for 10 minutes will vary depending on autoclave model, size and load configuration



12. Cool down the device from autoclave to room temperature.



Storage and transport



Use

As a result of the analysis, two critical aspects require attention due to their impact on decontamination, as well as the impact that has this process in healthcare centres.

A. Disassembly and assembly:

Disassembling the devices ensures that the disinfectant thoroughly contacts all surfaces for the full recommended duration (Incision, 2023). An analysis was conducted to determine the time required to disassemble a speculum and to evaluate the benefits and drawbacks of this process:

1. Collins:

- Number of parts: 3
- Time for disassembly: 28 sec.
- Tools needed: 0
- Time for assembly: 36 sec.
- Tools needed: 0

Collins assembly and disassembly were the fastest because the union of the parts is not done through screws but with a small fixation that is easy to disassemble and assemble without tools. Additionally, this model has fewer components and joints. The process is intuitive and does not require an assembly manual.

Fig. 9: Disassembly of the Collins speculum

2. Graves

- Number of parts: 7
- Time for disassembly: 48 sec.
- Tools needed: 2
- Time for assembly: 1 minute 33 sec.
- Tools needed: 2

Graves assembly and disassembly are not very intuitive the first time. Two different tools are needed to complete the process. Furthermore, the device requires a lot of manual manipulation. The most time-consuming part of the assembly is the hinge.

Fig. 10: Disassembly of the Graves speculum

3. Cusco

- Number of parts: 9
- Time for disassembly: 1 minute 45 sec.
- Tools needed: 2 or 1
- Time for assembly: 1 minute 5 sec.
- Tools needed: 2 or 1

The Cusco design is the most difficult to assemble and disassemble of all three models. This is due to the number of components and the small parts. The most challenging part is disassembling the handle and the thumb hinge. The blades of this model stay intact. The device requires a lot of manual manipulation and one or two tools.

Fig. 11: Disassembly of the Cusco speculum

In conclusion, each type of speculum shows specific disassembly requirements. Models with multiple types of screws, like Graves, and hinges, like Graves and Cusco, take longer to disassemble. Furthermore, those designs include very small parts that are easy to lose, increasing the risk of the device becoming unusable or requiring spare parts to be available in hospitals

B. Trapped microorganisms:

In the cleaning phase with the brush during the HLD, it is necessary to have particular care for the curved inner edges, joints, and screws of self-retaining specula, where organic material and microorganisms may remain trapped (Mittal & Basu, 2020). Based on this information, an analysis of the vaginal speculum was conducted to identify which design features are the most critical for cleaning (figure 12).

As shown in the image, the handle contains most of the critical parts for cleaning. The handle is a component of the device that does not come into direct contact with the vaginal canal and rarely interacts with the patient's body. In addition, these parts are handled by professionals wearing sterile gloves. Therefore, the risk of transmission of infections through these components is relatively low. However, pathogens or high-risk organic material may be retained in the inner curves of the blades.

Fig. 12: Critical parts for possible trapped micro-organisms

C. Cost and time:

Reprocessing the device has a better climate impact than using single-use (Snijder & Broeren, 2022) but for some healthcare centres, it is more cost-effective to purchase single-use vaginal speculums rather than reusable versions. This is due to some GPs preferring to accept the costs of purchasing single-use speculum, rather than invest in training, testing, equipment and maintenance for the reprocessing practises.

Despite the externalisation of the decontamination process can be a good option for some practices, for many GPs, this is too expensive and the turnaround of instruments can be too slow (Tattersall, 2006). On the other hand, in the case of local sterilisation, the loading of the machines can have different impacts. For example, sterilising items in packs rather than individually can have carbon and financial savings (Drayton et al., 2023).

According to the analysis conducted by the Nord -American manufacturer Welch Allyn in 2018, the estimated total annual cost of a metal speculum is around $17.411 whereas for disposable speculums is approximately $9.126. The main cost associated with the metal speculum is concentrated on reprocessing and purchasing the equipment for the reprocessing, in particular the autoclave (estimated price $4500, capitalised over five years).

The same company conducted a time-savings analysis indicating that the use of disposable speculum can save approximately 455 hours per year. This is because the time spent on reprocessing the metal speculum can be around 2 hours per day, while the time spent on disposal during use is almost irrelevant.

1.4 Study of the Doctor's experience

Practitioners are the primary users of the vaginal speculum. In the Netherlands, this exam is typically performed by general practitioners, but in some cases, such as when the patient has insurance coverage, it can be conducted in specialized centres like hospitals (Piercy & Expatica, 2024).

During a pelvic exam, in addition to the steps explained on page 19, doctors must perform additional actions such as disposing of packaging and the device in the correct bin and calming the patient.

An analysis of the entire pelvic exam process has been conducted to identify factors that may affect the doctor's experience while using the speculum.

To conduct this analysis, a journey map was developed (Figure 13) through three interviews with two nurses and one gynaecologist specialist. This method is used to understand the experience and gain insights across different phases of a process (Van Boeijen et al., 2020).

Detailed information about the method and interviews can be found in Appendix A.

1.4.1 Analysis of the journey map

The development of the journey map has provided the following key factors critical to the practitioner's experience during pelvic exams, along with identification of pain points in activities.

A. Key factors

1. Relationship between doctor and patient

For doctors creating a good relationship from the beginning is very necessary, especially with those patients who are doing the test for the first time. They need the patient to trust them and answer honestly the questions to make good decisions, like choosing the size of the speculum or the way they have to treat the patient. Also, if the patient does not trust them, the exam can be difficult to conduct.

"I really have to make them comfortable and I have to gain some trust of them, it is the most crucial moment for me"

Creating a good relationship is also very important when the patient has suffered sexual abuse as the procedure is slightly different.

"I think it's especially important or hard if you have a woman that was assaulted, that's very difficult. For example, I'm not going to sit between their legs at first. I'm going to sit next to them so that they get comfortable"

2. Vaginal speculum

For practitioners and healthcare centres, the choice of speculum can significantly impact their ability to perform exams, even though it is a crucial tool. Participants noted that while there are many different models available on the market, they tend to avoid those that require the use of both hands. Furthermore, tiny blades and designs with numerous rounded features are often less preferred.

The tiny blades are not suitable for manipulating the lateral walls in cases of multiparous patients, for example. In addition, one physician commented that the tiny blades, once the speculum is inserted, may cause more discomfort because the pressure is not as widely distributed. Rounded features can make it difficult to fix the device in the canal, as they can cause the speculum to rotate, thus impeding proper visualisation.

"If you have blades that are wide enough, it also makes it easier, because then you don't have the bulging vagina walls, but the downside to that is how the bigger speculum is the less comfortable for women"

Additionally, all the doctors in the interview mentioned that hospitals are starting to switch from metal speculums to fossil plastic to address concerns regarding patient comfort and stress. However, some doctors, still prefer metal speculums because the material can act as a mirror improving the visualisation.

"I prefer the plastic ones that are also sterile or the non-metal ones because are more friendly"

Another aspect that is crucial for the doctors is to have always different sizes available and easy to recognize them, by colours or levels.

"In my opinion, It's very important to have different options in different sizes"

3. Insertion of the speculum

For doctors, it is described as well as the most critical step, especially finding the cervix, especially when they do not have a lot of experience. Not finding the cervix implies having to remove the vaginal speculum and insert it again, causing discomfort for the patient. For practitioners, the lower blade must be a bit longer than the upper blade. The reason behind this will be studied further in the chapter 2.

4. Fixing the vaginal speculum

Facilitating the work flow of doctors is very important for them. Therefore, speculum models that require the use of both hands are not preferred by practitioners. Additionally, devices with many rounded features can pose challenges for fixation, as they may easily turn or move during examinations.

B. Pain point activities

Finding pain point activities using the journey map method helps to identify specific activities where the doctor's experience is negative. Throughout the analysis of the interviews, the following activities are considered pain points:

1. Questions

The initial contact with the doctor and patient is crucial, as it sets the relationship for the entire experience. During this phase, doctors need to create a good atmosphere and sometimes calm the patient.

2. Show the device to the patient

In some cases, the aesthetics of the device can be intimidating for the patient. Some doctors may not show the device to the patient increasing the lack of information and resulting in fear. In other cases when the speculum is shown, it can increase the patient's stress.

Doctor's journey map

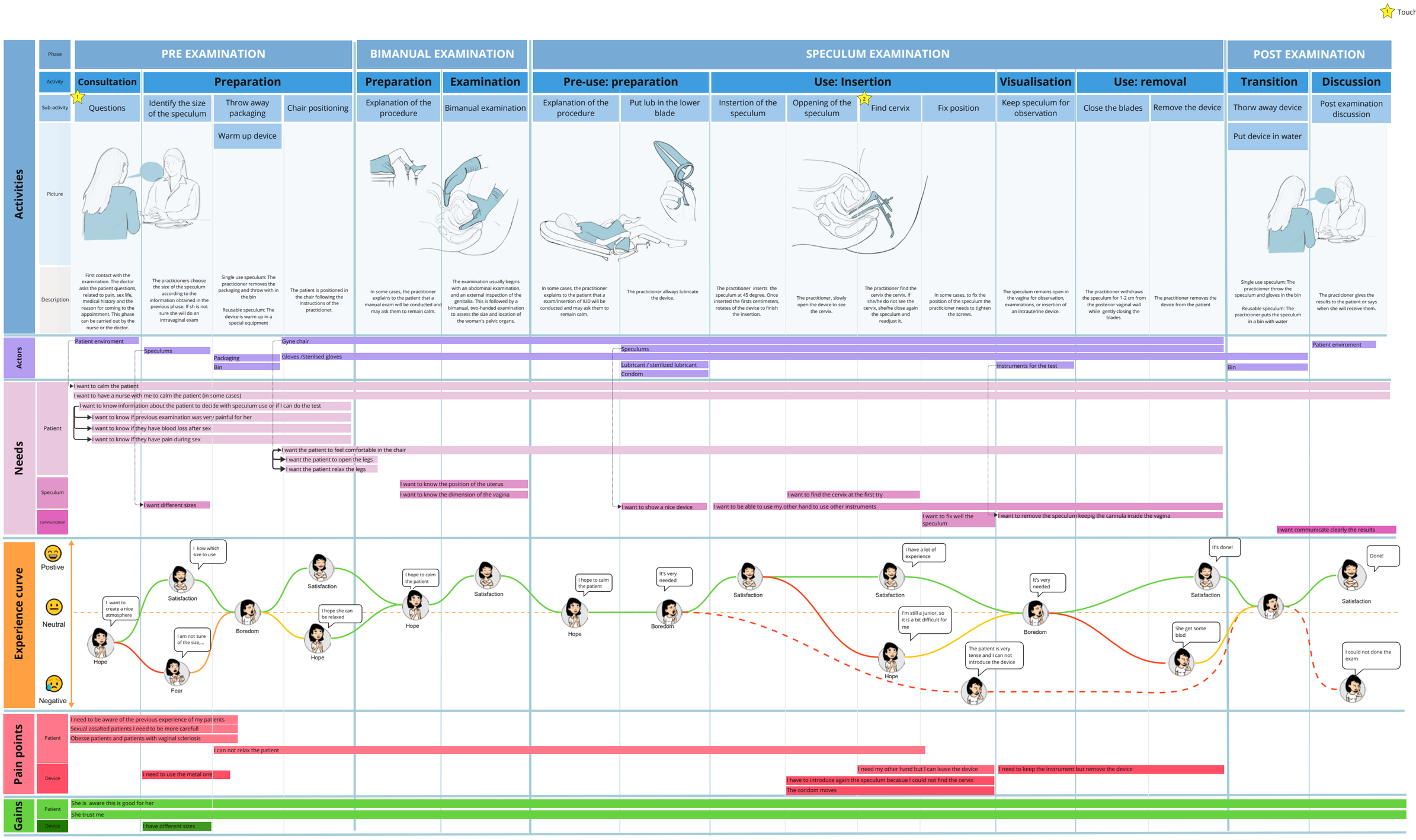


Fig. 13: Doctor journey map conducted during the interviews with doctors and nurses

1.5 How do doctors envision the device?

Doctors typically envision the vaginal speculum as a practical tool that prioritizes functionality, ease of use, sustainability and patient comfort. During the interviews, physicians were asked to provide their insights and wishes on the future redesign of the speculum. How do physicians envision the speculum of the future?

More sustainable:

With the implementation of the Green Deal initiative, there is a need for healthcare centres to consider also environmentally friendly options. Consequently, there is growing interest among doctors in envisioning a non-metal speculum that is also environmentally sustainable.

Better usability:

Doctors emphasized the importance of certain features in future speculum designs, such as the ability to be operated with one hand and minimized rounded features to make more easy the stabilisation of the device once is inserted.

Furthermore, they suggested that it would be interesting to design a speculum that when it is needed to keep the cannula inside the uterus, is easy to remove.

Better visualization:

Visualisation of the cervix is crucial for the exam and it is one of the main functions of the device. However, the lateral walls can make the visualization difficult. In this cases, they have to use a condom but this is not fixed in the device and it can difficult the exam. For this reason, some doctors envision the device with a better visualisation. One doctor proposed the inclusion of lateral blades to support better the vaginal canal.

More sizes available:

As mentioned before, doctors envision a device that has different sizes available and easy to recognize, to make the exam more comfortable for the patient. When the doctor chooses the wrong size it can be painful for the patient.

Bellow, some of the quotes and suggested changes resulting from the interviews are illustrated (Figure 14.

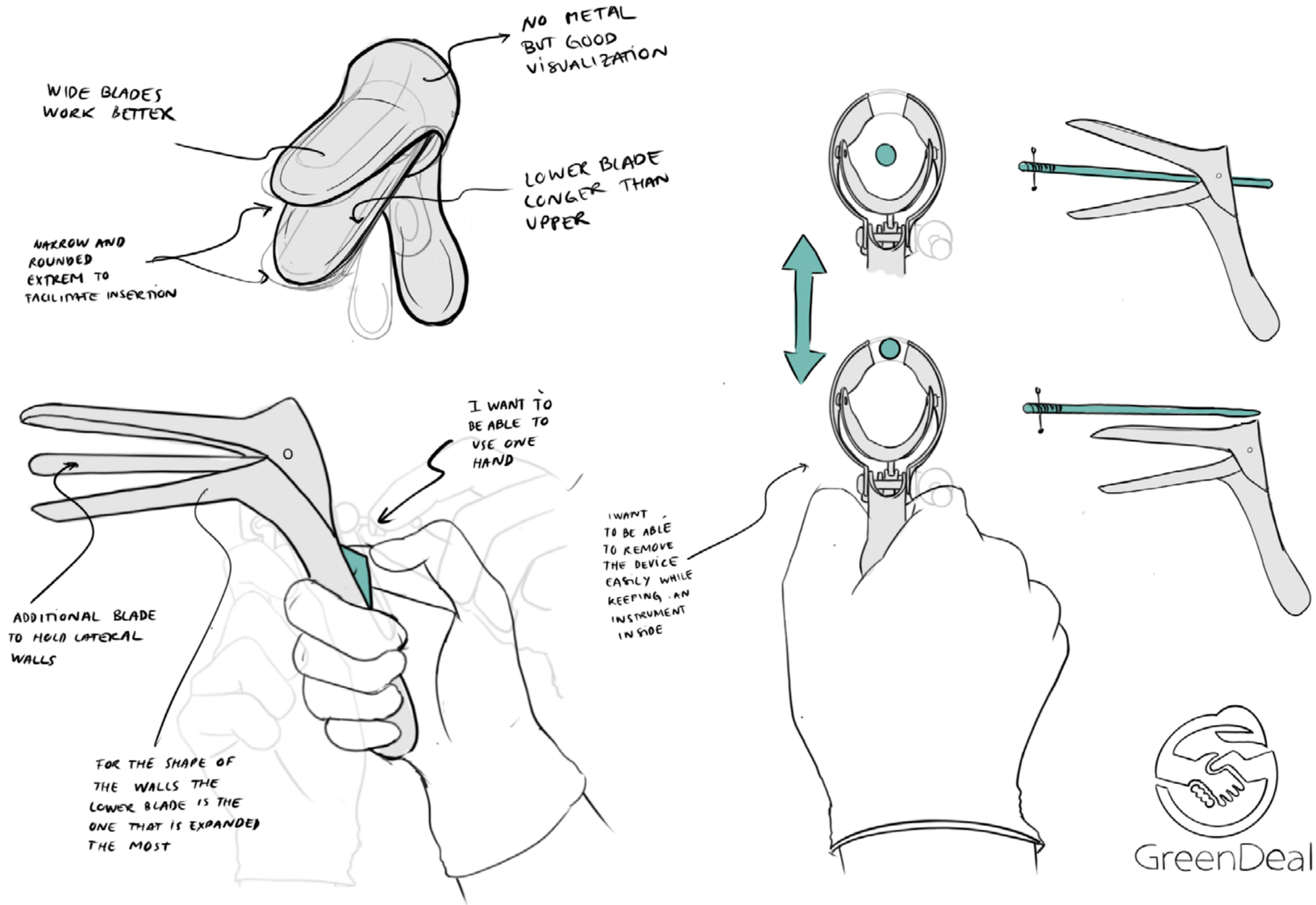


Fig. 14: Vision of practitioners of the future device

1.6 Discussion and takeaways chapter 1

In this chapter it was compiled many relevant facts about the vaginal speculum from the perspective of the healthcare sector. As a medical device, functionality and hygiene are crucial for this sector, along with cost-effectiveness of examinations. Through desk research and interviews, the questions raised at the beginning of the chapter have been addressed.

1. **What are the main functions of the vaginal speculum and how is it used?**

The vaginal speculum is widely used in the gynaecological field, serving two crucial functions in most procedures. First, it spreads the vaginal walls, allowing the practitioner to visualize the cervix and vaginal walls. Second, it facilitates the insertion and manipulation of other instruments, maintaining an inner diameter of at least 29mm. These two primary functions must be preserved as much as possible in the redesign.

2. **How is the speculum decontaminated and how can its decontamination be improved through design?**

To meet the strict hygiene standards in the healthcare sector, the vaginal speculum must undergo decontamination before reuse. Classified as a semi-critical instrument according to the Spaulding scale, it requires high-level decontamination or sterilization. A study was conducted to determine the necessity of sterilization, focusing on the relationship between high-risk infections potentially transmitted via the speculum and the level of decontamination required to eliminate these pathogens. The findings suggest that most high-risk infections can be eradicated through high-level decontamination, making full sterilization unnecessary and thus saving hospitals time and costs. Additionally, critical design features like screws or small holes are primarily located in the handle, a part that does not enter the body, further indicating that full sterilization may not be required.However, there is a small possibility of infection from Clostridium, a common hospital-acquired infection that can be deadly in specific cases. This pathogen requires sterilization to be completely eradicated. Given the lack of research and expertise in this area, this project assumes that sterilization is necessary for the vaginal speculum.

Several design changes were identified to improve the sterilization process, making it more cost-efficient. These include reducing the number of screws, minimizing inner curves, and designing the device to be easily disassembled.

3. **Which features of the current speculum should be retained and which ones need to be changed?**

Most practitioners agree that the metal material of the speculum should be changed, but not at the expense of visual clarity. Additionally, practitioners are seeking strategies to encourage more women to undergo the test, indicating that the new device must enhance patient comfort while maintaining its functionality and efficiency.

Chapter 1 takeaways and its relevance for the design are summarised in the following figures:

1. **Versatility**

- The new redesign should maintain versatility to fit the largest number of patients by having different sizes or one-size fits all approach..
- The device should communicate the size being chosen to the practitioner through colours or indicators in order to facilitate the work flow of practitioner

2. **Use**

- The device shape and/or functionality should be changed to reduce the need to use disposable condoms for patients with vaginal wall prolapse.
- To facilitate cervix visualization, the lower blade must be longer than the upper blade.
- To optimize device fixation, rounded features should be minimized.
- Ideally, the speculum could be designed to allow extraction while a cannula remains inside the uterus, held by a practitioner (Out of the scope for this project)

3. **Ergonomics**

- Ensure all movements of the speculum can be performed with one hand to free up the other hand during procedures.
- Design the speculum to be usable by both left-handed and right-handed doctors.
- Address ergonomic issues in the handles to reduce thumb strain and joint pain observed with current models (Graves and Collin).
- Incorporate rounded features or soft materials into the handles for improved comfort during use.

4. **Decontamination**

- Consider a hybrid decontamination device with two detachable modules: blades and handle. Blades can be sterilized, while the handle undergoes high-level decontamination, reducing time and cost.
- Enable the speculum to be purchased in two parts, akin to syringes, for ease of maintenance and decontamination.
- Minimize the number of joints and tools required for disassembly to simplify the decontamination process. Aim for one tool or none.
- Use standard components where possible to streamline maintenance and reduce complexity.
- Design with few inner curves and screws to facilitate cleaning and minimize contamination risks.
- Ensure the device has flat surfaces for stable placement during disassembly and assembly to reduce the need for additional supports.
- Create an intuitive design to prevent human errors, such as incorrect placement of components like hinges.

5. **Aesthetics**

- Transition from metal to plastic speculums due to patient preference and perception, already noticed for hospitals being one of their main request. However, the alternative needs to maintain hygiene, durability, and visibility standards.

6. **Sustainability**

- Healthcare centres prioritize speculums with minimal environmental impact, aligning with EU regulations.
- Evaluate materials, manufacturing processes, and end-of-life disposal options for sustainability.
- Ensure compliance with EU environmental regulations and standards for medical devices.

7. **External to the physical design**

- Improvement between doctor-patient relationship it is necessary
- Design features that promote patient comfort and relaxation during examinations.
- Incorporate ergonomic and user-friendly design elements to minimize discomfort.

Chapter 2

The vaginal speculum and the patient

This chapter explores the second main area of this project: patients. Like the previous chapter, this one is also divided into two blocks: literature review and interview findings. The first block examines the reproductive system and analyses whether the dimensions of the current speculum fit anatomical dimensions. Additionally, it investigates different methods of visualizing the cervix. The second block focuses on the patient's experience with the device to understand why so many women are scared of the vaginal speculum and what changes are needed to address this.

Questions addressed in this chapter:

1. What are the optimal device dimensions and structure to improve patient comfort?
2. Why are most patients scared of the vaginal speculum but not of menstrual cups or tampons?
3. Are there factors other than physical ones that cause patients to perceive pelvic exams negatively?

Methods used:

- Literature review
- Interviews
- Journey mapping

2.1 Female reproductive system

The study of the female anatomy is crucial for the design of the vaginal speculum. For this reason, a deep study of parts and dimensions has been conducted throughout this section.

The female reproductive system consists of the internal and external organs.

External organs

The external organs is the collective known as the vulva, and have the function of protecting the internal organs from infections. The vulva consists of several parts, including the labia majora which are two large folds forming the boundary of the vulva and the labia minora two smaller folds that begin at the clitoris and extend downward. There is also the clitoris a sensory organ, the vestibule that surrounds the opening of the vagina and the urethra, and the perineum is a roughly triangular area extending from the base of the labia minora to the anal canal (Nguyen & Duong, 2023, Seladi-Schulman, 2020).

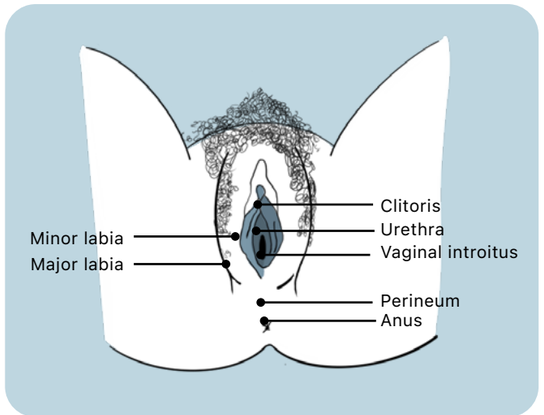


Fig. 15: External genitalia. Adapted from World Health Organization (2020)

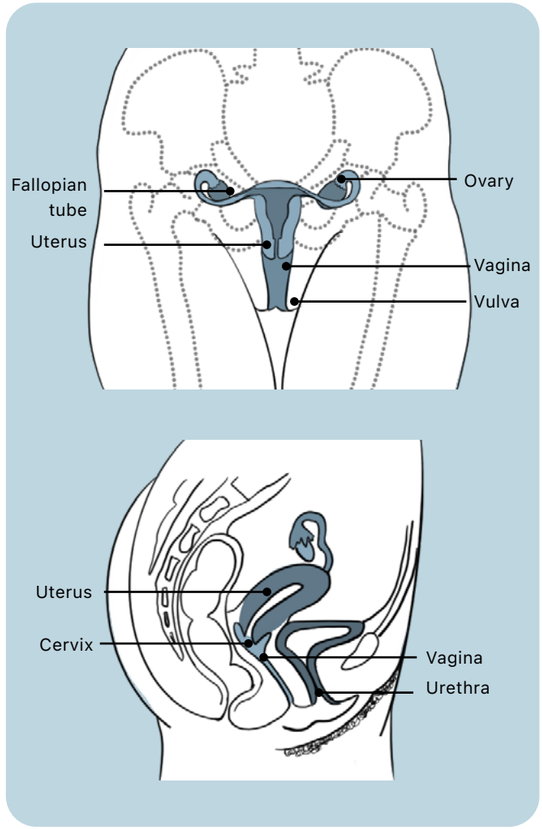


Fig. 16: Internal genitalia. Adapted from World Health Organization (2020)

Internal organs

The internal organs include the uterus, which is situated in the pelvis and connected to the ovaries via the fallopian tubes. The uterus consists of the cervix, located in its lower portion, and the corpus, which is the body of the uterus. The cervix connects to the external organs through a fibromuscular canal called the vagina. The vagina has both a posterior and anterior wall, with the anterior wall being slightly shorter. The entrance to the vagina, known as the vaginal introitus, includes the anterior and posterior vestibules and the perineum (Hoare & Khan, 2023; Barnhart et al., 2006).

2.2 The vagina

The study of vaginal dimensions is important for the design of the vaginal speculum. Understanding the anatomical variations in vaginal length, width, and shape helps ensure that the speculum is appropriately sized.

Shape:

The shape and stretching of the vaginal canal depends on the elasticity of the walls and its relationship with other pelvic organs. The canal is oriented upward and backwards at a 45-degree angle with the uterus and about a 60-degree angle to the horizontal (Loukopoulou, 2023, Szmelskyj, 2015). The vagina is usually collapsed, which means that the posterior and anterior walls are in contact. According to Barnhart et al. (2004), the shape of the vaginal cross-section towards the cervix is described as "W" or "H" and the cross section of the introitus is described as a "I" (Figure 17).

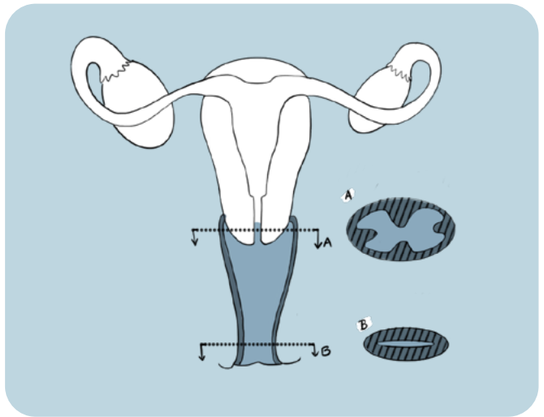


Fig. 17: Shape cross-section of the vagina walls

Pressure:

Asiedu et al. (2017) described the range of pressures the walls withstand between 0.1 and 12 cm H2O. To convert these measurements to international units, 0.1 cm H2O refers to the pressure exerted by a column of water 1 centimetre high, which applies this force over an area of 1 square centimetre. Therefore, the pressures can vary from 9.81 Pa to 1185.20 Pa.

Length and width:

The length of the vagina can vary from 68,6 to 148,1 mm (Pendergrass et al., 1996) while the width tends to increase from the introitus to the fornix. According to Barnhart et al. (2006), the width at the introitus ranges from 18.7 mm to 37 mm, with an average of 26.1 mm, and the fornix varies from 26 mm to 82.8 mm, with an average of 41.9 mm.

Luo et al. 2016 also studied the dimensions of the vagina finding lengths for the anterior and posterior vagina walls of 63± 9 and 98 ± 18 mm, respectively. They found the mean widths in five different points (figure 18), being at the introitus 17± 5mm and in the cervix 41± 9. In the figure 19, it can be seen the results and the percentiles of their study.

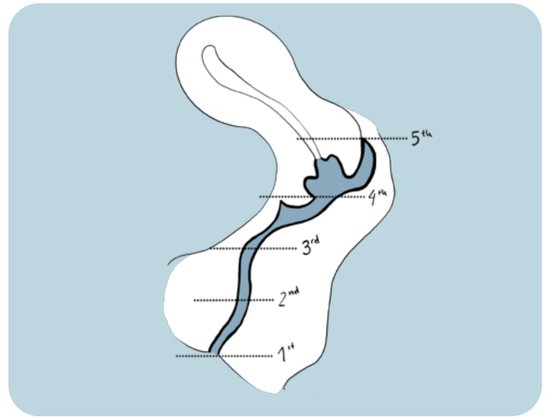


Fig. 18: Five location points to measure the width in vagina. Adaptation from Luo et al. (2016)

Parameters	Mean	SD	Minimum	Percentiles					Maximum
				5th	25th	50th	75th	95th	
AVW length	63	9	44	48	56	63	69	77	84
PVW length	98	18	51	71	86	97	109	131	144
Anterior fornix length	18	7	8	9	13	17	22	31	35
Posterior fornix length	21	5	11	13	17	21	25	31	34
Cervix curved length	40	10	21	25	32	40	45	58	60
Cervix transverse width	25	5	18	19	22	24	27	35	43
V 1st diameter	17	5	9	11	13	16	19	27	31
V 2nd diameter	24	4	16	18	21	23	26	31	33
V 3rd diameter	30	7	15	21	26	29	34	43	56
V 4th diameter	41	9	17	28	35	40	47	58	69
V 5th diameter	45	12	24	29	35	43	52	64	81
V 1st perimeter	38	12	18	23	28	36	46	57	94
V 2nd perimeter	64	11	42	49	56	62	70	80	118
V 3rd perimeter	71	15	45	51	63	68	78	98	124
V 4th perimeter	93	25	55	59	75	88	109	137	209
V 5th perimeter	101	28	51	63	76	95	121	162	187
V lower axis (°)	90	11	60	73	82	89	99	107	121
V middle axis (°)	72	21	40	45	55	67	86	114	126
V upper axis (°)	41	22	−26	10	28	41	56	76	88
AVW surface area (cm^2)	35	10	17	20	30	35	40	48	82
PVW surface area (cm^2)	37	11	17	22	30	35	42	57	88
V surface area (cm^2)	72	21	34	43	60	70	81	106	164

Unless otherwise specified, all dimensions are in millimeters
V vagina, *AVW* anterior vaginal wall, *PVW* posterior vaginal wall

Fig. 19: Luo et al. (2016) results

2.2.1 Analysis of the recommended speculum sizes *vs* the real dimensions of the vagina

Currently, there are no standardized sizes, except the recommended ones by the WHO (2020) or specific target groups for vaginal speculum across manufacturers, leading to variations in device dimensions depending on the model purchased by healthcare centres. Doctors typically determine the appropriate speculum size during the initial consultation by asking patients about pain during intercourse and childbirth history, which provides an estimate of the most suitable size. However, this approach is not always accurate and can sometimes cause patient discomfort.

While there are no specific guidelines to assist in selecting the correct speculum size, the general principle is that a wider speculum offers better visualization by more effectively holding the vaginal walls and preventing prolapse between the blades. However, this advantage often comes at the cost of increased discomfort during insertion and use (Bates et al., 2011).

Based on the information gathered, a critical analysis (Figure 20) is conducted to compare the WHO's size and patient recommendations for different speculum models with the actual anatomical dimensions of women as documented in the study by Luo et al. (2016). This analysis aims to assess whether the WHO's recommended sizes are appropriate for future design considerations or if alternative sizes are required to ensure both patient comfort and optimal visualization. Additionally, the analysis seeks to create a more accurate guideline for identifying the target group.

Small

	Width												Length		
Percentile	**1st diameter (mm)**	**Pederson (13 mm) (+-5)**	**Graves (20mm)**	**Cusco and Collins (30mm)**	**3rd diameter (mm)**	**Pederson (13 mm)**	**Graves (20mm)**	**Cusco and Collins (30mm)**	**5th diameter (mm)**	**Pederson (13 mm)**	**Graves (20mm)**	**Cusco and Collins (30mm)**	**PVW lenght**	**Pederson Graves (75mm)**	**Cusco / Collins (85mm)**
5th	11	Too big	Too big	Too big	21	Adequate	Adequate	Adequate	29	Adequate	Adequate	Too big	71	Too big	Too big
25th	13	Adequate	Too big	Too big	26	Adequate	Adequate	Adequate	35	Adequate	Adequate	Adequate	86	Adequate	Adequate
50th	16	Adequate	Adequate	Too big	29	Adequate	Adequate	Adequate	40	Adequate	Adequate	Adequate	97	Adequate	Adequate
75th	19	Adequate	Adequate	Too big	34	Adequate	Adequate	Adequate	47	Adequate	Adequate	Adequate	109	Too small	Too small
95th	27	Adequate	Adequate	Too big	43	Adequate	Adequate	Adequate	58	Adequate	Adequate	Adequate	131	Too small	Too small

Medium

	Width												Length		
Percentile	**1st diameter (mm)**	**Pederson (22 mm)**	**Graves (35mm)**	**Cusco and Collins (35mm)**	**3rd diameter (mm)**	**Pederson (22 mm)**	**Graves (35mm)**	**Cusco and Collins (35mm)**	**5th diameter (mm)**	**Pederson (22 mm)**	**Graves (35mm)**	**Cusco and Collins (35mm)**	**PVW lenght**	**Pederson Graves (95mm)**	**Cusco / Collins (100mm)**
5th	11	Too big	Too big	Too big	21	Too big	Too big	Too big	29	Adequate	Too big	Too big	71	Too big	Too big
25th	13	Too big	Too big	Too big	26	Adequate	Too big	Too big	35	Adequate	Adequate	Adequate	86	Adequate	Too big
50th	16	Too big	Too big	Too big	29	Adequate	Too big	Too big	40	Adequate	Adequate	Adequate	97	Adequate	Adequate
75th	19	Too big	Too big	Too big	34	Adequate	Adequate	Adequate	47	Adequate	Adequate	Adequate	109	Too small	Adequate
95th	27	Adequate	Too big	Too big	43	Adequate	Adequate	Adequate	58	Adequate	Adequate	Adequate	131	Too small	Too small

Large

	Width												Length		
Percentile	**1st diameter (mm)**	**Pederson (25 mm)**	**Graves (35mm)**	**Cusco and Collins (40mm)**	**3rd diameter (mm)**	**Pederson (25 mm)**	**Graves (35mm)**	**Cusco and Collins (40mm)**	**5th diameter (mm)**	**Pederson (25 mm)**	**Graves (35mm)**	**Cusco and Collins (40mm)**	**PVW lenght**	**Pederson Graves (115mm)**	**Cusco / Collins (110mm)**
5th	11	Too big	Too big	Too big	21	Too big	Too big	Too big	29	Adequate	Too big	Too big	71	Too big	Too big
25th	13	Too big	Too big	Too big	26	Adequate	Too big	Too big	35	Adequate	Adequate	Too big	86	Adequate	Too big
50th	16	Too big	Too big	Too big	29	Adequate	Too big	Too big	40	Adequate	Adequate	Adequate	97	Adequate	Adequate
75th	19	Too big	Too big	Too big	34	Adequate	Adequate	Too big	47	Adequate	Adequate	Adequate	109	Adequate	Adequate
95th	27	Adequate	Too big	Too big	43	Adequate	Adequate	Adequate	58	Adequate	Adequate	Adequate	131	Too small	Too small

Fig. 20: Comparative analysis Luo et al (2016) *vs* Recommended sizes WHO (2020)

Discussion analysis and results

Bellow it can be find a discussion about the analysis in the figure 20.. An analysis of the small,medium and large option for the four different models and a proposal of the considered optimal dimensions.

Small dimensions

1. Pederson:

As can be seen in the comparative table (figure 20), the small recommended dimensions of the small Pederson speculum are the most suitable for a wide range of patients. However, it is important to consider that while the Pederson speculum offers better comfort due to its small width, there can be vaginal wall prolapse , particularly in obese and multiparous patients, which can impede proper visualization.

Therefore, using a small Pederson speculum for the patients with narrow vaginas can be appropriate, but some adjustments to the dimensions could broaden its suitability while maintaining the same level of comfort.

Optimal sizes

Extra small Pederson:
Width: 11mm / Length <75 mm
Small Pederson:
Width 13-15mm / length 80-100mm
(possibility of add a later blades)

Optimal target group

Extra small Pederson:
Young women <12 years
Small Pederson:
Young women
Stressed patients,
Patients with pain during sexual intercourse

While the width of the speculum suits most patients, the length can be too short for some, so increasing it to 80-100mm is recommended. For the 5% of patients with a narrower introitus, an extra small speculum with a width of 11mm or less and a length under 75mm is needed. By keeping the Pederson blade width at 13-15mm and adding lateral blades, the speculum can also better serve obese and multiparous patients who had pain during intercourse. These lateral blades would hold the vaginal walls in place, prevent prolapse, and improve cervix visualization, thereby increasing comfort.

2. Graves:

The dimensions of the small Graves speculum are generally suitable for a broader range of the population. Especially for patients who do not have narrow vaginas, like those who have not given birth but have had intercourse. It may create some difficulties in the case of obese and multiparous patients due to the prolongation of the walls.

While the width of the speculum can be suitable for most patients, the length can be too short for some.

Optimal sizes

Small Graves:
Gradual width 20 mm / length 80-100mm
(possibility of add a later blades)

Optimal target group

Small Graves:

Patients those who have not given birth but have had sexual intercourse

For this reason, a possible adjustment will be the length to 80-100mm, having extra small Graves for these patients with a shorter vagina canal.

3. Cusco and Collins:

When using the small Cusco or Collins model, 95% of patients may experience some discomfort during insertion because the width is greater than the diameter of the introitus. This discomfort will be higher for patients with narrow vaginas, such as those with postmenopausal atrophy, prior surgery or radiation, no prior vaginal intercourse, or those who simply experience discomfort during digital bimanual examination.

The recommended 30mm width for a small size

Optimal sizes

Small Cusco and Collins:
Width 20 mm / length 80-100mm
(possibility of add a later blades)

Optimal target group

Small Cusco and Collins:

Patients who are sexually active or given birth but do not have wall prolongation

may be too large. A possible adjustment for these models would be a width of 25mm, which is the size most manufacturers use (see page 30). Alternatively, it could be appropriate to keep the recommendation at 30mm if there is a design requirement for a gradual increase in width, starting from a very small width like 20mm and increasing to 30mm.

Conclusion:

Small dimensions are preferred for women with a narrow introitus due to postmenopausal atrophy, prior surgery or radiation, absent prior penile or sex toy vaginal insertion, or who simply experience discomfort during digital bimanual examination (Bates et al., 2011). According to this definition and the dimensions recommended by the WHO, is correct to use the small Pederson in these cases.

To optimise the use of the small speculums some possible adjustments on the width and length will allow more patients to feel more comfortable using a small speculum than medium or large. Furthermore, lateral blades can be added to the Pederson and Graves models to achieve the smallest speculum that permits optimal visualisation and ensures patient comfort. This modification would enhance comfort and improve visualization for obese and multiparous patients.

2. Medium dimensions:

1. Pederson:

Medium size for Pederson will be appropriate for patients who need a slightly wider speculum than the standard small size.

2. Graves:

The medium-sized Graves speculum may be too large for the majority of the population at the entrance of the introitus and in the third diameter. An adjustment to 25mm-30mm is suggested for the medium Graves speculum to align with the dimensions of Cusco and Collins medium sizes.

3. Cusco/Collins:

Optimal sizes

Medium Graves:
Width 30 mm / length 80-100mm
(possibility of add a later blades)

Optimal target group

Medium Graves:

Multiparous patients or those who have increased elasticity in the vaginal walls

Similar to the medium Graves speculum, the medium Cusco and Collins speculums may also be too large for most patients at the entrance of the introitus and the third diameter. However, the medium width can enhance visualization of the cervix by better holding the vaginal walls, making medium Cusco and Collins speculums suitable for patients who have given birth.

Conclusions:

Optimal sizes

Medium Cusco / Collins:
Gradual width 35 mm / length 80-100mm
Medium with lateral blades:
Gradual width 30 mm / length 80-100mm

Optimal target group

Medium Cusco / Collins:

Multiparous patients or those who have increased elasticity in the vaginal walls or obese patients

In general medium recommendations are suitable for most of patients

3. Large dimensions:

The large dimensions are predominantly suitable for patients in the upper percentiles with wider vaginal diameters. These sizes provide excellent cervical visualization and are beneficial for patients with more elastic vaginal walls. However, they are likely to cause significant discomfort for patients with narrower or less elastic vaginal walls. According to the literature speculums up to 40 mm wide and 120–160 mm long are appropriate when redundant vaginal walls prolapse between the bills and obscure the view of the cervix (Bates et al., 2011), making the Cusco and Collins speculum recommendations suitable for such cases.

2.3 The cervix

In addition to considering vaginal dimensions, determining the optimal opening size for the device to achieve effective visualization of the cervix requires studying the dimensions of the cervix itself.

The cervix, the lower fibromuscular portion of the uterus, has an exterior part called the ectocervix, see figure 21. This part is easily visible with the speculum examination. The shape of cervix is cylindrical or conical in shape and has a diameter of 25 mm (Sellors & Sankaranarayanan, 2003), with a range of 21,7 - 55 mm (Barnhart et al., 2006). The size and shape of the cervix can vary depending on factors such as a woman's age, parity, and hormonal status (Sellors & Sankaranarayanan, 2003).

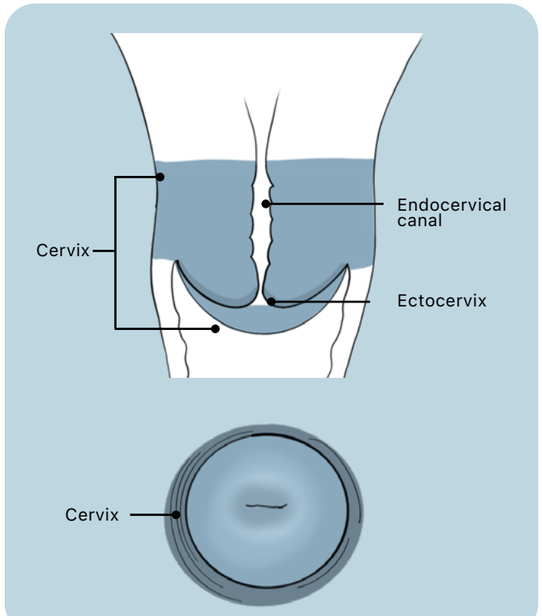


Fig. 21: Cervix parts. Adapted from Sellors & Sankaranarayanan (2003)

2.3.1 Analysis of the shape and number of blades for optimal cervix visualisation

During interviews with practitioners, it was remarked that a speculum with a longer lower blade improves both ease of localisation and visualisation of the cervix compared to models where both blades are the same length. In addition, practitioners mentioned that when patients have lost flexibility of the vaginal wall, it is sometimes necessary to use a condom to prevent wall prolapse. This section will address these issues by reviewing the literature on speculum design for optimal cervical visualisation and exploring alternatives to using a condom to treat wall prolapse.

1. Shape and cervix visualisation

Asiedu et al. (2017) conducted a study to analyse which speculum shape is better for visualising the cervix. They explored four shapes (figure 22):

- Standard speculum (1)
- Billed expander (2)
- Silicone expander with the same material and geometry as menstrual cups (3)
- Flat tip inserted based on the vaginal suppository design (4)

All of these designs were intended to have included a camera.

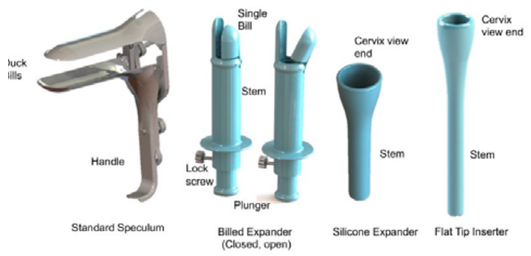


Fig. 22: Design iterations made by Asiedu et al. (2017)

To test the devices they created a custom-made vaginal phantom using a synthetic female reproductive organ obtained from Syndaver labs. The results showed that the flat tip inserter had the most favourable visualization due to it can envelope better the cervix and hold better the wall prolapse under maximum pressure (figure 23).

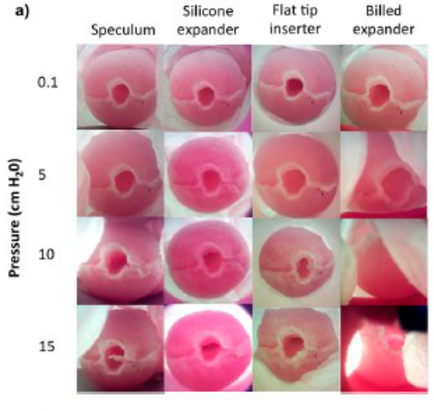


Fig. 23: Results of the test pressure-visualisation by Asiedu et al. (2017)

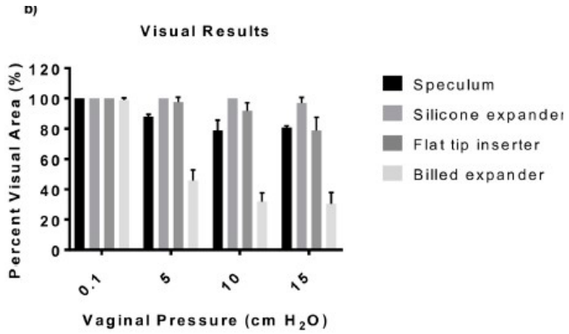


Fig. 24: Results of the test pressure- % visualisation by Asiedu et al. (2017)

The same study conducted a second iteration to be able to use the device in women with severely tilted uteri, which affects 20% of women. The main modification was the addition of an angled curvature of 30 degrees to the tip as shown in figure 25.

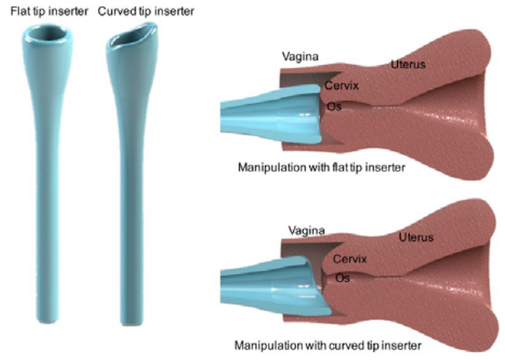


Fig. 25: Second test modification by Asiedu et al. (2017)

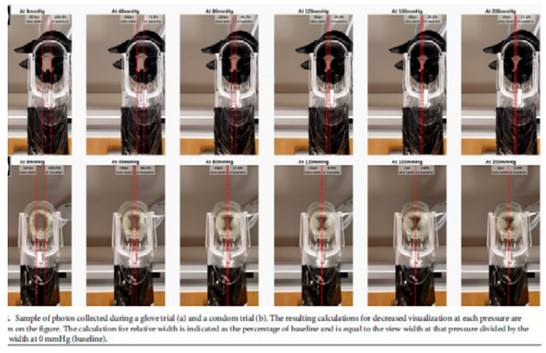
This design variation, besides working better for women with severely tilted uteri, it helps to manipulate the cervix better, as it is both a robust and mobile organ.

Besides Asiedu et al. (2017) other authors like, Taylor et al. (2017) helps to confirm the insights of doctors suggesting as well that the vaginal speculum should have a longer lower bill for a better manipulation and visualisation of the cervix.

2. Number of blades

Some patients, particularly multiparous and obese individuals, experience vaginal wall laxity, a common health issue among women (Coyle Institute, 2023). When using a two-bladed speculum, this laxity can interfere with cervical visualization, as there is no mechanism to retract the lateral walls effectively. This can obstruct the view, complicating the exam and potentially causing discomfort or pinching for the patient (Bouquet et al., 2023).

As mentioned in Chapter 3, the most commonly used method to address vaginal wall collapse in healthcare centres is to utilize readily available supplies, such as gloves or condoms, to cover and support the speculum blades. Yerrabelli et al. (2023) conducted a test to evaluate the effectiveness of this method and determine which material works best for this purpose.



Sample of photos collected during a glove trial (a) and a condom trial (b). The resulting calculations for decreased visualization at each pressure are n on the figure. The calculation for relative width is indicated as the percentage of baseline and is equal to the view width at that pressure divided by the width at 0 mmHg (baseline).

Fig. 26: Test result by Yerrabelli et al. (2023) Using gloves material (first row) and condom (second row) while increasing the pressure due to wall prolapse

The analysis concluded that while condoms are the most commonly used, they offer only a modest benefit in reducing lateral wall collapse. As shown in the image, at a pressure of 40 mm Hg (5.3 kPa), visualization decreases to 40.1% of the total view, and at 120 mm Hg (15KPa), it drops further to just 8.5%, significantly limiting cervical visualization. In contrast, nitrile gloves perform better, reducing visualization to 74% at 40 mm Hg (5.3 kPa) and 35% at 120 mm Hg (15KPa). However, Yerrabelli et al. (2023) note that while nitrite offers better lateral visualization, its mechanical properties make it more difficult to open the speculum.

This finding raises the question of whether the use of a condom truly enhances visualization and whether the traditional two-blade speculum is the best option for cervical examination.

Studies like Bouquet et al. (2023) have explored alternatives, such as a five-blade speculum design (figure 27). Their in vitro evaluation found that the five-blade design offered better cervical visualization and improved patient comfort compared to the traditional two-blade speculum. Bouquet et al. (2023) attribute this to the radial opening of the five-blade design, which distributes forces symmetrically and uniformly, reducing the discomfort caused by the vertical forces of the traditional speculum (figure 28)—an issue highlighted by doctors during interviews in Chapter 1.

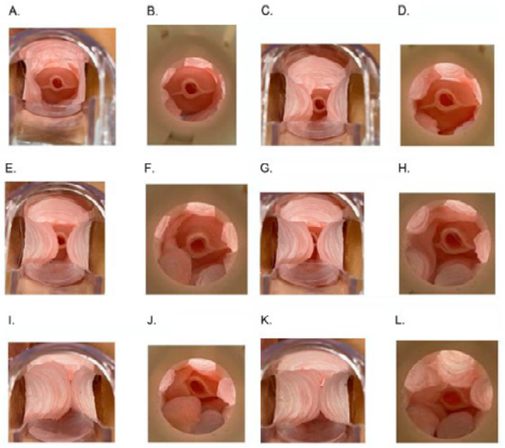


Fig. 27: Visualization Test (A and B): 2-bladed speculum (left) vs Bouquet Speculum (right) at 0.1 cm H20 (10 Pa). (C and D): 2-bladed speculum (left) vs Bouquet Speculum (right) at 4 cm H20 (392 Pa) (E and F): 2-bladed speculum (left) vs Bouquet Speculum (right) at 8 cm H20 (785 Pa). (G and H): 2-bladed speculum (left) vs BouquetSpeculum (right) at 12 cm H20 (1177 Pa) (I and J): 2-bladed speculum (left) vs Bouquet Speculum (right) at 16 cm H20 (1569 Pa) (K and L): 2-bladed speculum (left) vs Bouquet Speculum (right) at 18 cm H20 (1765 Pa). (Bouquet et al. (2023)

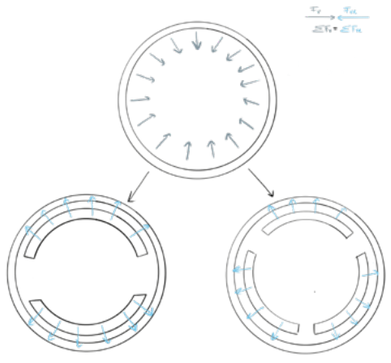


Fig. 28: Forces illustrated

The five-blade speculum can be useful for complex procedures that require extensive visibility and access. However, it may be intimidating for patients due to the big dimensions and shape.

Researchers like Hobart et al. (2017) advocate for a three-blade design, as it provides a clear field of view without the need to open the speculum as widely as a two-blade model, making it less intimidating for patients compared to the five-blade design. Additionally, a three-blade design allows for a reduction in the device's dimensions without compromising blade stability. Using five blades in a small diameter could result in excessively thin individual blades that may struggle to withstand pressure.

Another advantage of the three-blade design is that the blades spread out in a V-shape, which helps prevent the lateral vaginal walls from collapsing, as noted by Hobart et al. (2017). This design also minimizes difficulties in rotating the device.

It is important to mention that there is huge gap of literature regarding this area even vaginal wall laxity is quite popular among patients and more research is needed to test the number of blades on speculum as a method of increasing patient comfort and visualisation.

2.4 The evolution of the relationship between patients and the Speculum

The vaginal speculum is the oldest and most used instrument in obstetrics. However, the device has never been seen just as a medical instrument. In the 19th century, it became a cultural symbol of the relationship between women and physicians, while in the 20th century a symbol for the visualisation and interpretative control of the female body (Sandelowski, 2000).

Before the instrument became an integral part of the pelvic examination, physicians often avoided examining their patients vaginally or rectally (Sandelowski, 2000). Even in the medical field, the female body was the subject of much controversy. To maintain a woman's virtue, the physician would blindly examine the vagina without removing any of the patient's clothing (Sandelowski, 2000). (Figure 29)

The vaginal speculum was designed by J. Marion Sims in 1845. Sim's legacy is based on experiments, without consent, performed on three enslaved women who were loaned to him. During his experiments, he did not use any pain management techniques (Genoff Garzon, 2021). The introduction of the device, in the 19th century, required the assistance of nurses who played an important role in protecting patients and physicians from any improper use of the device (Sandelowski, 2000). The vaginal speculum required physicians not only to touch women's genitals but also to look at them. Some physicians of the time, debated the moral propriety of using the device, considering the device as an instrument for physician corruption.

With the advancements in medical knowledge and professional medicine as well as some cultural shifts caused in the 20th century, the vaginal speculum went from a stigmatised device to a popular tool that contributed to increasing the value of gynaecology specialisation.

In the latest 20th century, the activist Carol Downer used the device to see her vagina and cervix for the first time. This fact started the Women's Health Movement which succeeded in claiming exclusive rights to the instrument and diagnosing women's maladies (Sandelowski, 2000).

Despite advancements in the use of the speculum and societal changes, the device remains a primary reason patients refuse pelvic exams, even though it is one of the most common tools in gynaecology (Arrivillaga et al., 2023).

This underscores the importance of understanding why the speculum is still perceived negatively. It highlights the need to redesign the device with a user-centred approach, considering not only the practitioner's needs but also the patient's comfort and emotional experience to improve overall perception and acceptance.

Fig. 29: Vaginal examination in 1822 without removing any clothes (Sandelowski, 2000)

Fig. 30: Picture in the newspaper of the Los Angeles Women's center from 1973 (Sandelowski, 2000)

Nella speculum invention
2020

Welch Allyn introduced the extra small speculum
2005

Orchid Speculum invention
2000s

Welch Allyn introduced a large size speculum
1999

Different shapes of speculums were created as well as plastic reusable speculum
1990s

Women's reproductive health activists and educators Lorraine Rothman and Carol Downer began teaching other activists how to perform self-examinations using a speculum
1971

Second feminist wave. The speculum become a symbol of female power and bodily autonomy
1960

Activists compared gynaecology with torturing women with devices like the speculum
1970

Graves speculum was invented
1879

Cusco speculum was invented
1870

Meeting in the UK to debate arguments for and against the use of the speculum in gynaecology.
1850

First speculum designed by Marion Sims
1845

Use of medical instruments like the speculum declined in Europe due to social and religious constraints
XVI-XVIII Century

(Embryo Project Encyclopedia, 2019)

2.5 Study of the patient's Experience

Patients are directly affected by the design of the vaginal speculum, and despite being passive stakeholders, their role is crucial. Understanding how the ergonomics of the device impact patient experience is essential, but it is also important to identify other factors that influence their emotional and physical experiences.

To conduct this study, the methodology used in Chapter 1 with practitioners was applied, creating a journey map of the full pelvic exam from the patient's perspective. Eight participants of varying ages were interviewed to identify key factors and pain points throughout the process. Details of the interview method are explained in Appendix B.

2.5.1 Analysis of the journey map

The development of the journey map (figure 31 has provided the following key factors critical to the practitioner's experience during pelvic exams, along with identification of pain points in activities.

A. Key factors

During the analysis of the journey maps it was detected four factors that can make a negative experience for patients: lack of information, relationship with the doctor, vaginal speculum and environmental limitations. It is important to mention, that these factors are not independent from each other, for example, lack of information can be related to the culture or education of the patient and the fear of the device can be related to the lack of information.

1. Lack of information

The most frequently mentioned point among all participants, corroborated by the research of Herzog and Wright (2007), is the lack of knowledge about pelvic exams and their bodies. This, combined with preconceived notions about the test, can make the experience more frightening for patients. Studies have shown that access to information empowers patients and encourages their participation in decision-making regarding their healthcare (Andrist, 1997; Noll-Bader, 2023).

"It is not a topic that I talk about with my friends or that they teach me in school"

"I was scared because I don't know how much you can open my vagina"

"I was lying waiting for the doctor, naked, without knowing what was going to happen"

Even participants expressed fear when they saw the speculum due to its aesthetics, they still preferred to understand its appearance and functionality. Understanding the device and the procedure will relax the patient and improve the trust of the practitioners.

"Maybe if I know what is going to happen I can anticipate"

Some participants suggested that better explanations, such as using models or pictures and reducing technical vocabulary, would improve their experience. In addition, they expressed their interest in having the doctor describe what she was doing and finding, as they could not see what was going on.

One of the participants of the journey map interview expressed that after learning more about the device during the interview, her subsequent gynaecological test felt more familiar and less frightening. This highlights that increased knowledge about the device can significantly influence how the test is perceived, reducing fear and anxiety.

2. Relationship between doctor and patient

The doctor-patient relationship is crucial to the success of the examination. Poor relationships can increase patient stress and reduce communication, which may result in inaccurate answers or reluctance to answer questions during the initial phase.

During the interviews, all participants highlighted their preference for a female doctor, with a calm and empathetic attitude.

"I have the same doctor who saw me born, so she is quite old. I feel she can not understand me. Sometimes is quite old-fashioned mind"

"I appreciate the professionalism of my doctor. She is very calm and makes me feel respected"

"I always ask for a woman"

Patients suggested that they would like to hear calm and positive sentences during examinations, specifically during the moment of the bimanual exam and the insertion of the speculum.

3. Vaginal speculum

The vaginal speculum has a big influence on the pelvic examination experience, as found in studies conducted by Herzog and Wright (2007) and Rinko et al. (2018). These studies found that the device can cause some pain in patients, which was confirmed during the interviews.

In the interviews, two patients indicated that they felt pain during the insertion attributed to the shape of the device. However, one of them also noted pain during the removal as well.

Participants in menopause experienced higher pain during insertion due to the vaginal dryness associated with menopause. In some cases, menopausal patients can bleed during the exam. Practitioners confirmed that the shape and the lack of lubrication are most of the time the cause of discomfort among patients.

"With the menopause, I am more dry. It feels very cold"

"I feel the stretch while they open"

"The longer it's taking the more painful it becomes"

Beyond causing physical discomfort, the device also causes psychological stress. Two of the patient participants mentioned that when the doctor showed them the device, they got very nervous and as a consequence, their vagina walls tightened. This tightness can increase the pain of the insertion, and in some cases, it is not possible to conduct the exam.

"I was really scared when I saw the thing... and my pelvic area and everything became tight and, she (the doctor) was telling me that I was tight"

"I'm so stressed that everything is very tight"

4. Environmental limitations

The last point that all the participants mentioned was the stress generated by environmental factors.

4.1 Time

Two patients mentioned that they did not have enough time to relax and prepare themselves for the test. However, the most common need for more time was at the end of the exam. Six out of eight patients felt pressured to put their clothes back and needed more time to recuperate their bodies after the exam. One mentioned that she did not have time to think about questions at the end of the session.

However, they understand that the doctor needs to see other patients.

"I didn't have time to ask questions to the doctor"

"I feel I need more time to recuperate my body before getting the results"

During the interviews, it was found that the duration of a pelvic exam can vary between countries and healthcare systems, for example in the Netherlands (GP) is about 20 minutes, while in Italy, it is about one hour.

This time difference reflects the time pressure that the patient can perceive increasing discomfort during the exam.

4.2 Culture

Cultural factors and perceptions of the body and women's sexuality play a vital role in the exam. Those patients who have no problem talking about their sexual organs rated better on the phase of the questions and the visualisation while the speculum is inserted. However, those patients who have more tabu in this area rated more negatively on these two steps.

"I don't care, I do not have any secrets"

"I do not feel very comfortable talking about my intimacy"

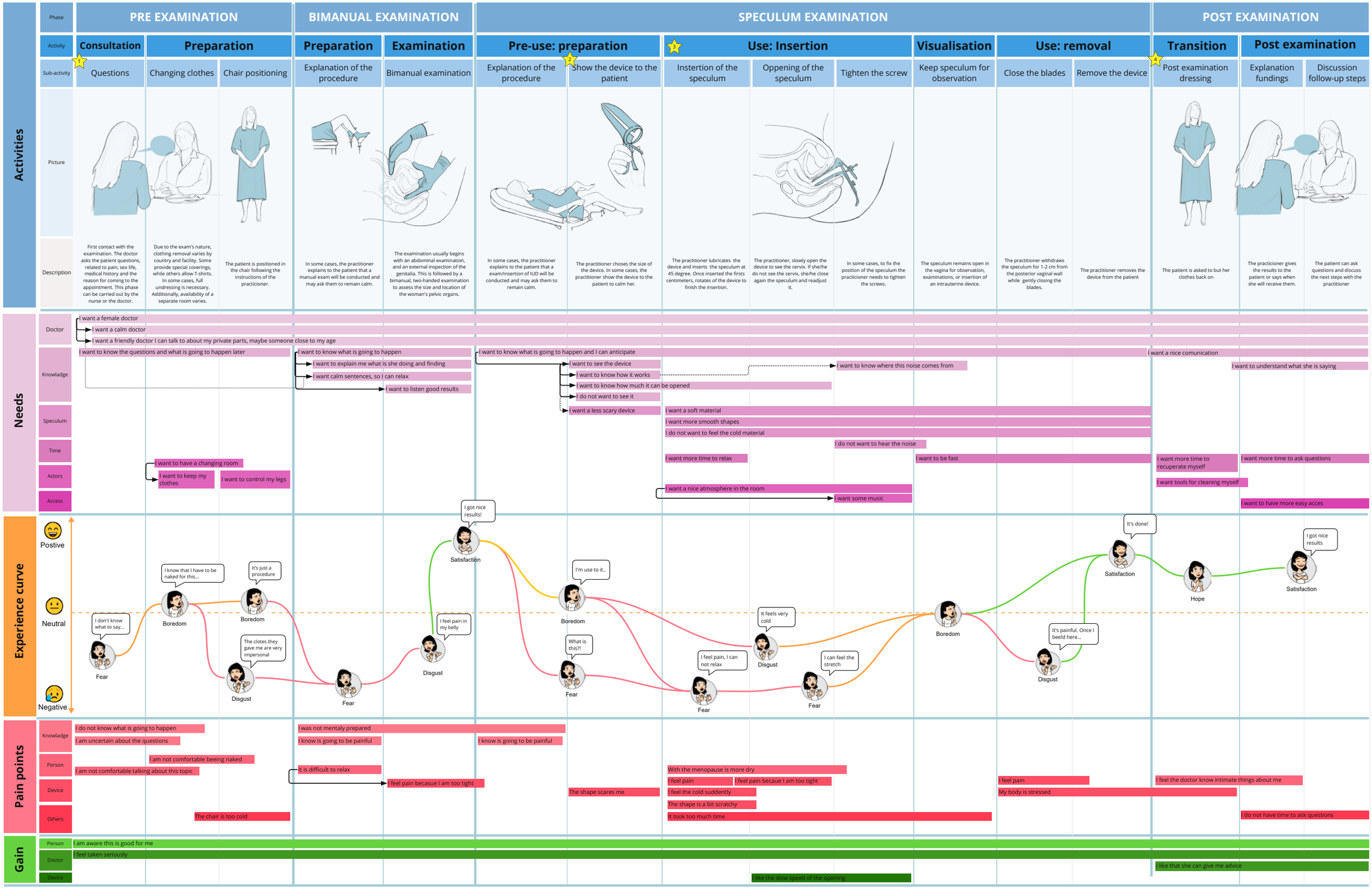


Fig. 31: Patient Journey map

Cultural factors combined with the lack of information, increase the nervousness and stress of the exam. One of the participants mentioned that despite undergoing the test annually, she experiences significant stress. As a consequence her vagina walls tightened, making the insertion of the speculum painful, and sometimes the test is not possible to perform.

"And every year she (the doctor) gets not mad, but frustrated by me because she cannot do it because I'm so stressed that I'm contracting everything"

4.3 Room:

The design and facilities of the room where the exam is conducted have an impact on the patients. In the case of changing clothes, those patients who did not have a spare room expressed their willingness to have one to have more privacy. Two of the participants mentioned that they would like to have more tools to clean themselves after the test, like pads or humid paper.

"I would like to have a changing room, so I do not have to take off my clothes in front of the doctor"

The room, in general, is very cold for the majority of the participants, some of them suggested that having a more friendly decoration would help them to be relaxed, as well as having some music during the test.

"Maybe it would be nice to have some music to distract me"

"I think changing the way how the atmosphere was of the room can make the exam more comfortable"

Pain point activities

Finding pain points using the journey map method helps to identify specific activities where the patient's experience is negative. Throughout the analysis of the interviews, the following activities are considered pain points:

1. Questions

The initial contact with the doctor and patient is crucial, as it sets the relationship for the entire experience. During this phase, factors mentioned before such as the knowledge of the test, environmental factors and relationship with the doctor, interact creating potentially negative feelings during the questioning phase.

2. See the device:

In some cases, the aesthetics of the device can be intimidating for the patient. Some doctors may not show the device to the patient increasing the lack of information and resulting in fear. In other cases when the speculum is shown, it can increase the patient's stress.

3. Insertion of the speculum:

The insertion of the speculum is described as a painful step for the patient. The factors deceived by the patients are the temperature, the roughness, and the lack of round features of the device.

This may also be due to the dimensions of the device seen on the page 50. Most speculum dimensions are larger than the diameter of the introitus. In addition, it is important to note that when the body is stressed, the walls of the vagina tighten (Rose, 2023), reducing the diameter and making it difficult for the device to enter.

4. Post Examination

In some cases, time constraints during the exam have negative effects. Some patients expressed that they needed more time to change and recover mentally and physically after the test. If this part is inadequately performed, the post-examination can have negative feelings, affecting the follow-up steps.

2.6 How do patients envision the device?

During the interviews, participants were asked to describe how they would like to see the vaginal speculum and which features would make them less scared of it.

Less scary:

A recurring theme among responses was the desire for a change in material while still prioritizing sustainability because most of the patients perceive the metal as scary. Additionally, the use of the metal increase the feelings among patients to compare the device as a "torture instrument". Metal was often perceived by patients as aggressive and impersonal. This perception is supported by material-user interaction studies, which attribute the term "aggressive" to materials that are hard, strong, and metallic (Karana et al., 2009).

Besides the material, most participants do not like the shape. Delving into the reason, it was found that some patients associate the shape with a gun, perceiving it as an intimidating instrument (figure 32). Emotional design theory refers to this phenomenon as negative transfer in perception, where previous knowledge interferes with new learning.

Fig. 32: Speculum is perceived as an aggressive instrument due to the negative transfer in perception from objects like guns

This phenomenon can also explain why most participants perceived discomfort and fear due to the visible screws on the device. Visible mechanisms are often associated with industrial instruments rather than objects intended for insertion into the vaginal canal.

As shown in figure 33 there is a comparison between current objects that patients are familiar with for vaginal insertion and objects that may have visible mechanisms. The speculum has more similarities to the objects on the left than the right ones.

Fig. 33: Where the vaginal speculum fits?

More rounded and colourful:

Patients emphasised the wish of see the device with more rounded shapes and colourful aesthetics similar to menstrual cups or sexual toys, which they believed it would make the speculum appear less intimidating.

Fig. 34: Patient's vision

Since menstrual cups were frequently mentioned during the interviews as a comparison with the vaginal speculum, a detailed study was conducted to understand why menstrual cups are perceived positively by users and which features contribute to this positive experience. The goal was to apply these insights to the redesign of the speculum. This study involved a questionnaire with a total of 20 participants. The complete methodology can be found in Appendix C.

The participants were asked the following question:

"On a scale from 1 to 5, how much do the following aspects of the menstrual cup make it feel more user-friendly for you? Scale: 1 (Very friendly), 5 (Extremely intimidating)."

The results indicated that aspects such as the possibility of self-insertion, size, sustainability, and familiarity contribute to the menstrual cup being perceived as user-friendly.

Less cold:

The cold temperature of the current devices is a significant concern for most patients. They envision a device made of a material that maintains body temperature, so they do not suddenly feel the cold during use.

Clean:

Safety and cleanliness were also emphasized, with some participants expressing a preference for single-use devices for added safety or to retain the metal device for sustainability purposes but use a silicone cover to protect it.

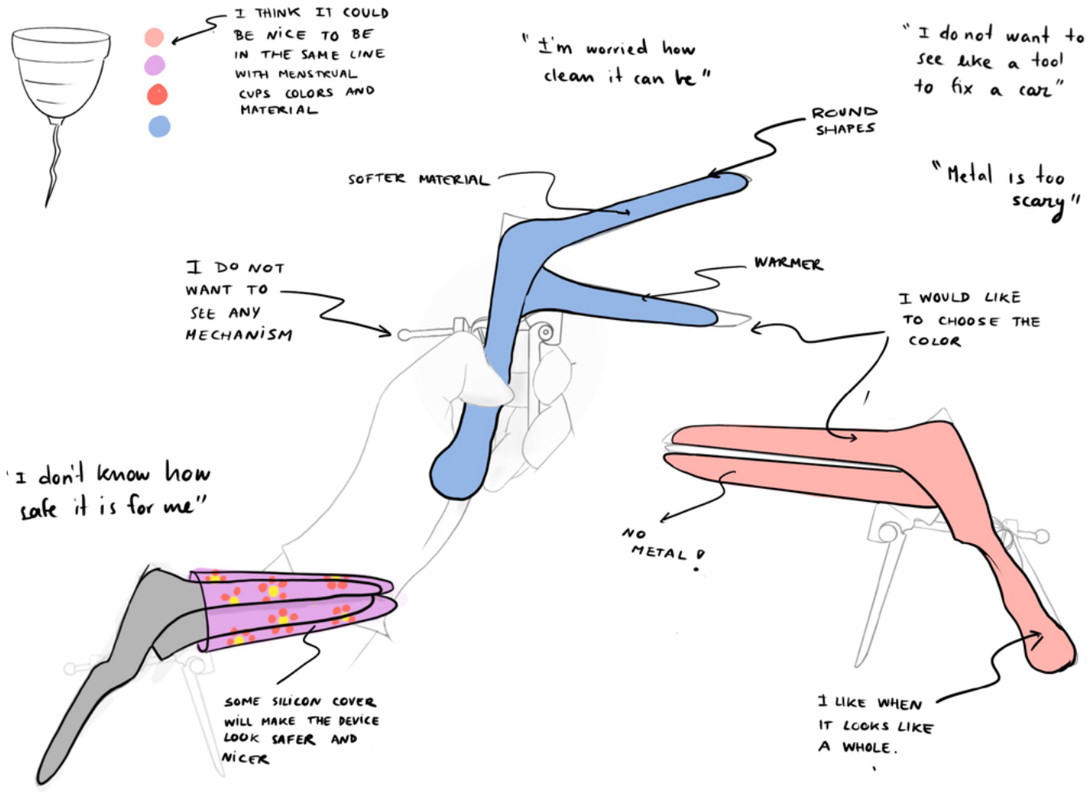


Fig. 35: Sketch of patients vision with some quotes

2.7 Discussion and takeaways chapter 2

This chapter compiled important insights about the vaginal speculum from the patient's perspective. Understanding why this widely used medical device continues to evoke fear, despite its commonality, and considering patient opinions alongside anatomical factors, is crucial for the success of the new design. Through desk research and interviews, the questions posed at the beginning of the chapter have been addressed.

1. **What are the optimal device dimensions and structure to improve patient comfort?**

There are no universally optimal dimensions; however, this chapter has developed a guideline approximation and provided recommendations for small, medium, and large models of the Graves, Cusco, Pederson, and Collins speculum.

Beyond achieving the optimal dimensions, other factors can enhance visualization while improving comfort. For example, incorporating a 30-degree angle at the end of the device, with a longer lower blade compared to the upper blade, can improve cervix fixation and visualization. Additionally, using a three-blade speculum instead of the traditional two-blade model can offer several advantages. A three-blade design enhances visualization by better managing wall prolapse and increases comfort through improved force distribution and reduced need for opening compared to a bivalve speculum. This design also allows for the use of smaller blades, as the three-blade speculum can better manage wall retraction on its own.

2. **Why are most patients scared of the vaginal speculum but not of menstrual cups or tampons?**

Extensive research through literature reviews and interviews has sought to uncover why the vaginal speculum, despite being a common gynaecological device, evokes considerable fear among patients compared to menstrual cups or tampons. Several factors contribute to this fear, as identified in the chapter.

The primary concern stems from the negative perception of the speculum design. Its visible screws and metallic appearance can be intimidating. Additionally, the way the speculum is handled and presented can resemble a threatening object to some patients, akin to a gun, which is perceived as aggressive.

In contrast, menstrual cups and tampons are more familiar and less intimidating. They are designed to be inserted into the vagina but do not evoke the same level of fear because they lack the speculum's mechanical and metallic features.

3. **Are there factors other than physical ones that cause patients to perceive pelvic exams negatively?**

Yes, there are factors beyond the physical aspects of the device that contribute to patients' negative perceptions of pelvic exams. The most significant one founded in this chapter is the lack of knowledge about women's sexual health and the reproductive system. This gap in understanding can leave patients feeling uncertain and out of control, which heightens their fear and anxiety about the procedure.

Chapter 2 takeaways and its relevance for the design are summarised in the following figures:

1. **Dimensions:**

- Use the smallest width that permits adequate visualization for each patient to ensure optimal comfort.
- All patients reported experiencing slight pain during insertion, attributed to the width of most models except for the Pederson small size.
- Maintain a minimum width of 40 mm for patients who have given birth multiple times or are obese, ensuring better visualization.
- Explore alternatives like lateral blades or a three blades speculum to balance reduced width with effective visualization.

2. **Visualisation**

- Three or five-blade designs offer better visualization by effectively holding back vaginal wall prolapse.
- A three-blade design opens like a "V," reducing the possibility of the device rotating once inside the vagina.
- A longer lower blade facilitates finding the cervix and helps in fixing the device securely.

3. **Material**

- Temperature of the device and material were primary complaints during interviews.
- Redesign should consider the thermal conductivity of the chosen material.
- Explore material alternatives to metal, like plastic or semi-transparent plastic.
- Consider surface texture preferences; most patients prefer a smooth device.

4. **Aesthetics:**

- Hide mechanisms in the redesign to alleviate patient fear and aversion.
- Focus on the look and feel of the product, emphasizing uniformity of design and CMF (Colour, Material, Finish) aesthetics.
- Consider inspiration from feminine hygiene products for design cues.
- Balance patient preference for round shapes with practitioners' concerns, prioritizing patient comfort.
- Avoid shapes that evoke negative perceptions or associations, such as those resembling guns or torture instruments.
- Use familiar shapes for patients to reduce the fear perceived from the device.
- Aim for the speculum to be perceived as clean, sustainable, and warm based on patient feedback.

5. **External to the physical design**

- Lack of information about the vaginal speculum contributes to fear and reluctance among patients.
- It is crucial to provide knowledge and information about the device and the female reproductive system to patients.
- Increased knowledge can help calm and empower patients.
- Consider options to share information with patients through various media channels to improve understanding and comfort.

Chapter 3

The vaginal speculum and sustainability

This chapter addresses the final area of focus in this project: sustainability. Throughout this chapter, we explore the importance of applying circular strategies in the healthcare sector and specifically how these strategies can be implemented for the vaginal speculum.

Questions addressed in this chapter:

1. Why is sustainability crucial for this project?
2. What is the environmental impact of the current vaginal speculum?
3. Which circular strategies can be effectively applied to improve the sustainability of the vaginal speculum?

Methods used:

- Literature review
- Circular Design Approach
- Product Journey Map

3.1 Environment impact of healthcare

The healthcare sector is known to be a large contributor to environmental pollution, with approximately 4,4% of global net greenhouse emissions. This figure is twice the aviation industry's impact (Serres, 2024). In the Netherlands, the contribution of the national footprint is above the global average, standing at 7%, among which waste generation is 4,2 % and material extraction is 13%. Zooming in on the waste category, this consists of 15% hazardous materials and 85% general hospital waste, of which 55% is plastic (Steenmeijer et al., 2022).

However, in recent years, healthcare centres have increased the use of disposable instruments such as plastic speculums, which are incinerated after a single use, contributing to waste and environmental impact (Buuren et al., 2023).

This paradox of healthcare having indirect adverse effects on public health calls for action to improve the environmental performance of the healthcare sector through energy savings as well as pollution and waste reduction (Friedericy et al., 2021). For this reason, the European Union has created a package of activities as part of the EU climate law aiming to achieve a 55% reduction in greenhouse emissions by 2030. This initiative, known as the Green Deal, has as its main objective the reduction of medical waste streams.

To achieve this goal, healthcare systems can adopt different measures, such as transitioning to circular practices and utilizing the 10R strategies (Reike et al. 2018), which enhance the sustainability and circularity of products.

3.2 Circular economy and 10R strategies for the HC sector

According to the Ellen MacArthur Foundation (2019), circularity is a system where materials never become waste and nature is regenerated. In this system, the economic and environmental value of materials are maintained for as long as possible by continually reintegrating them into the economic cycle.

The circular economy (CE) seeks to diverge from the linear economy model, where products become waste once they lose their perceived value or reach their end-of-life. For CE, waste is considered non-existent, and obsolescence does not mean waste (Kane et al., 2018). Instead, methods of "recovery" are used to change or remove the status of obsolescence.

The 10R strategies framework inside CE approach classifies strategies under three categories according to the length of the waste loop each represents, with longer loops being the least preferred. (Figure 36).

Due to the strict safety and hygienic standards of medical products the 10R strategies have to be adapted (Samenjo et al., 2023). This aspect will be further explored on page 78.

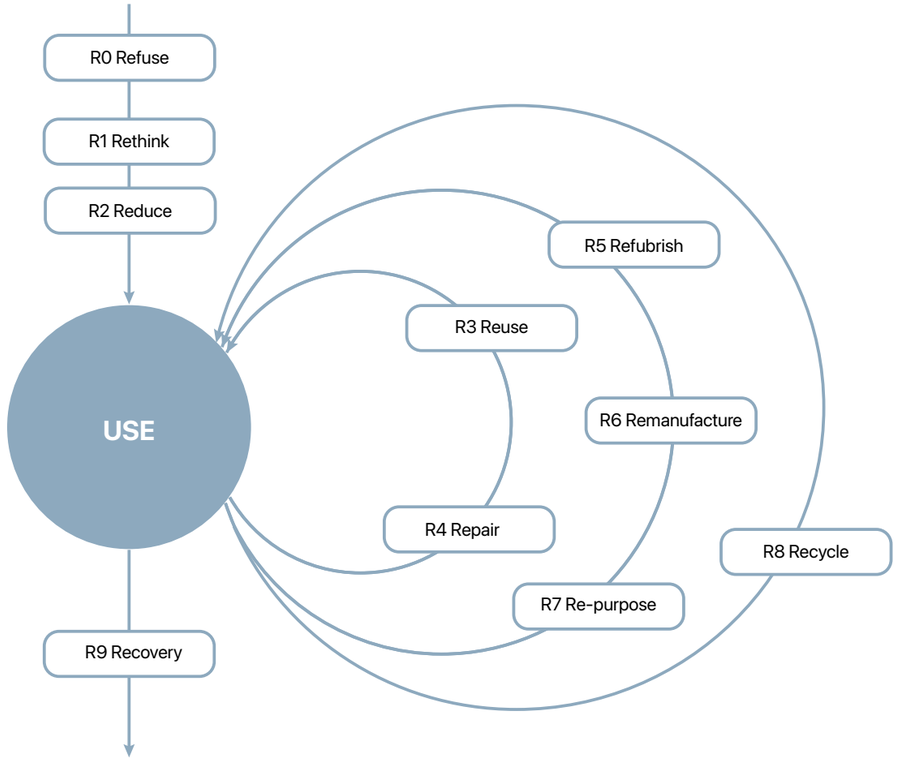


Fig. 36: 10R strategies representation. Adaptation from Netherlands environmental assessment agency (2023).

Short loop: Eliminate waste by tackling the design phase (Circularise, 2023).

R0 Refuse: Prevent the use of products and raw materials by questioning if there is a more sustainable function or if this can be eliminated.
R1 Rethink: Reconsidering ownership, use, and maintenance of the products by making a product use more intensive
R2 Reduce: Decrease the use of raw materials by increasing the efficiency of product manufacturing or use

Medium loop: Lengthen a product's lifespan (Circularise, 2023 , Hoveling et al., 2024b).

R3 Reuse: Use the product with the original working condition by another user or the same user after cleaning
R4 Repair: Repair and maintenance of a defective product so it can be used again with the same working condition
R5 Refurbish: Restoring an old product to a satisfactory condition for a new use
R6 Re-manufacture: integrating product components that are still perfectly intact into new products with the same function.
R7 Re-purpose: Incorporates discarded components into a completely different product for a unique benefit or alternative purpose.

Long loop: The least preferred option. Focused on the recovery of the material and energy (Circularise, 2023).

R8 Recycle: Process waste or materials from products that can not be used anymore to create new products
R9 (Energy) recovery: Process the waste to recover energy

3.3 Environmental impact of the current vaginal speculum

The vaginal speculum is a ubiquitous instrument. It is versatile in shapes and materials and it can be used in primary care as well as in surgical procedures. This versatility affects the impact that has its life cycle on the environment.

To analyse the complete product flow within pelvic exams and assess the impact on sustainability and circularity of current vaginal speculum, a product journey map has been conducted, followed by an analysis of two Life Cycle Assessments (LCAs).

3.3.1 Product journey map

The product journey map (figure 37) highlights a notable difference in circularity based on whether reusable or single-use vaginal speculums are utilized. Reusable devices generally offer a more sustainable option, as they can be sterilized and used multiple times, reducing the overall material waste. However, single-use devices, while convenient and hygienic, contribute significantly to medical waste, which poses a challenge for circularity.

Regardless of the type of speculum used, a considerable amount of waste is generated from supplementary materials such as condoms, packaging, and lubricants. These materials are typically disposed of after a single use, following a completely linear path with no established strategies for recovery, recycling, or reuse. This linear consumption pattern contributes to the environmental impact of pelvic exams, underscoring the need for innovative approaches to reduce waste and improve the sustainability of the entire procedure. Furthermore, as mentioned in the decontamination analysis in chapter 1, the disassembly and reassembly of current vaginal speculums require time and additional tools. This necessity not only complicates the process but also impacts circularity by increasing the demand for other materials and resources to maintain the device's usability.

3.3.2 Current LCA

To quantify the footprint that single-use and reusable speculum have, two different LCA conducted by Snijder & Broeren (2022), and Donahue et al (2020) have been studied (Figure 38 and 39). The following insights have been obtained:

1. Impact of reused frequency:

The number of times a speculum is reused determines its climate impact. For example, according to the LCA, the impact of using a metal speculum twice is nearly double that of a single-use fossil plastic and four times higher than the bioplastic. However, if a reusable speculum is used more than seven times, its environmental impact becomes lower than a single-use fossil plastic speculum. The analysis suggests that if reusable speculums are used 500 times, the climate impact is approximately 50% lower compared to a fossil plastic speculum, and it becomes slightly lower than a bioplastic one.

2. Difference in weight:

Plastic speculums are considerably lighter, weighing approximately 35-40, compared to metal speculums which weigh around 180 grams. Additionally, there is no relevant weight difference between stainless steel 316, commonly used in surgical speculums and stainless steel 304.

3. Impact of sterilisation:

If steam sterilisation is considered medically no longer necessary, the climate impact of reusable specula is reduced by about 40%. As the speculum does not need to be used sterile, the modification or removal of the CSA packaging could also be considered a factor in reducing the environmental impact

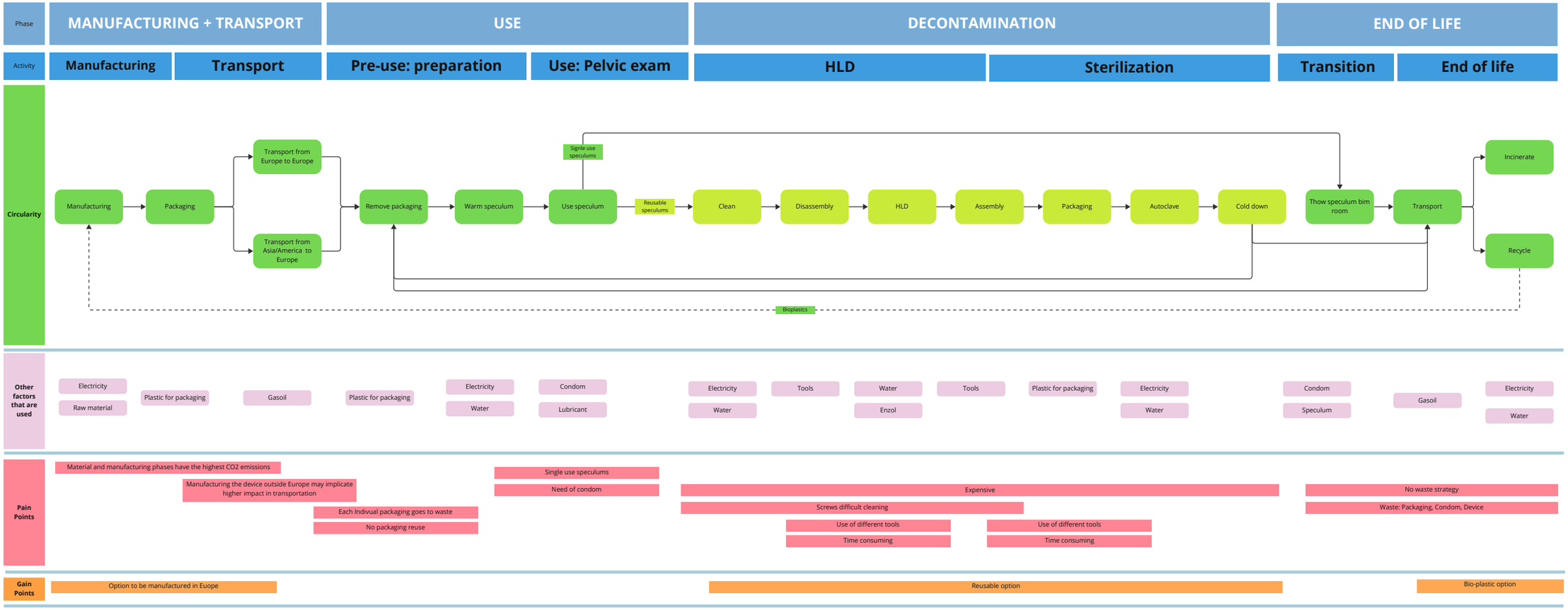


Fig. 37: Product Journey map

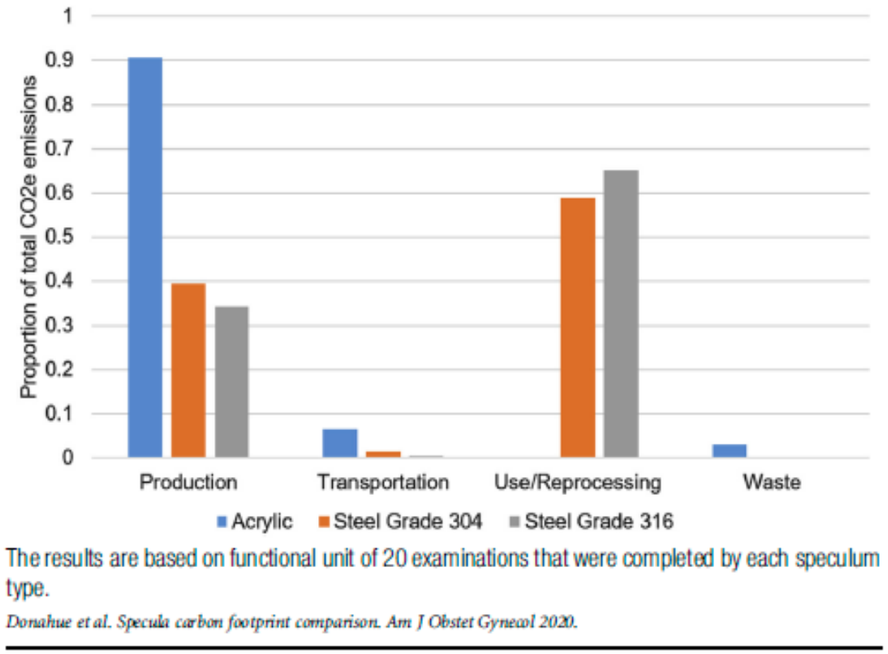


Fig. 38: Results LCA Donahue et al (2020)

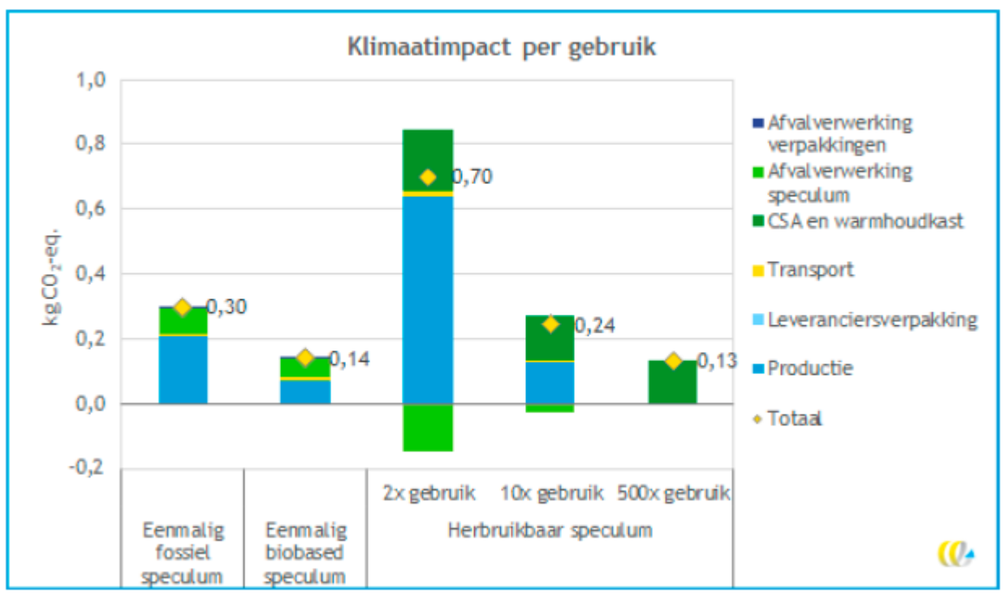


Fig. 39: Results LCA Snijder & Broeren (2022)

4. **CO2 Emissions from Material and Manufacturing:**

When compared to a one-to-one number of reuses, material and manufacturing phases have the highest CO2 emissions for both single-use and reusable speculum. According to the studies, this issue can be addressed by transitioning to sustainable electricity supplies. For example, using electric boilers for steam supply could reduce the impact by about 20%.

5. **CO2 Emissions for waste disposal:**

For single-use speculum, waste disposal of both the instrument and packaging leads to CO2 emissions. Although energy is recovered here, net CO2 is released.

The metals of the reusable speculum produce no CO2 emissions in the incinerator and can be filtered out of the bottom ash to be reused. This provides an environmental benefit.

6. **Bio-based plastic (PLA) vs fossil plastic (ABS) impact:**

Fossil plastic speculum emit twice as CO2 emissions as bio-based ones. Despite both types having the same manufacturing process, moulding injection, the raw materials differ significantly. While fossil plastic is derived from petroleum, bio-based is derived from sugar cane. However, fossil plastics are produced locally in Europe, while bio-based plastics are manufactured in Thailand and transported to Europe by ship. So the main difference in environmental impact comes from the raw material used.

7. **Surgical stainless steel grade 316 vs Stainless steel grade 304:**

Compared to a one-to-one number of reuses, the 316 SS speculum emits twice the CO2 emissions of the 304 SS speculum, primarily due to 316 SS being more carbon-intensive to produce. However, after 50 uses, the impact becomes nearly equivalent between the two.

3.4 Circular strategies for the vaginal speculum

One of the main objectives of redesigning the vaginal speculum is to integrate the circular strategies mentioned above. However, due to the semi-critical nature and low economic value of the vaginal speculum, some R strategies are considered not relevant for this product adn some of them due to t safety and hygienic standards of medical products the have to be adapted (Samenjo et al., 2023).

The following is an evaluation of which and how of the 10R strategies can be applied to the vaginal speculum

R0 Refuse:

There are specific situations where the use of a vaginal speculum can be avoided. For example, vaginal infections like candidiasis or trichomoniasis can be adequately diagnosed without using a speculum in young patients (Buchanan, 2000), pregnant patients (Audisio et al., 2005), and older patients (Landy et al., 2021). However, when test results are uncertain, the use of a speculum becomes necessary. The case of diagnosing HPV without a speculum has not yet been studied (Landy et al., 2021). There are products on the market that can conduct these tests without a speculum. In some countries, such as the Netherlands, cervical cancer screening programs allow women to perform self-tests at home without using a speculum, although this may not always be the most sustainable option (National Institute for Public Health and the Environment, 2024).

Despite these specific cases, avoiding the use of a speculum is not feasible in other gynaecological procedures where it is necessary to open the vaginal walls or visualize them and the cervix . For this reasons this strategy is not suitable for the device.

"Even though the device has a bad reputation, I think it is a good and necessary design. Without it, there is no way to see the cervix"

R1 Rethink:

Reconsidering device ownership may be a viable design strategy. In the interviews (see page FIXME), participants were asked whether they would prefer own their device. Three out of eight participants expressed interest in this option, stating that owning the device could alleviate their fear of the speculum. However, while this option has advantages, it also has disadvantages such as loss of control over cleaning, proper disposal, and increased production and distribution demands. Additionally, there would need to be systemic changes, and the question of who would bear the cost—hospitals, individuals, or the government—would need to be addressed. For these reasons this strategy is not suitable for the device.

R2 Reduce:

The second strategy can be applied to the vaginal speculum. However, the regulations and standards mentioned before, limit the reduction of materials or components. This limitation comes from the need to ensure that the speculum can resist degradation even after multiple decontaminations, thus maintaining functionality and safety. (Samenjo et al., 2023).

Reduce strategy can be applied in different ways:

- **Reduce number of sizes options:** Currently, the device is designed to come in different sizes, which implies greater production demands. Designing the speculum with a one-size-fits-all approach can significantly impact the production phase, reducing the quantity of material needed as well as the energy consumed. This approach has been already used in some redesigns of the speculum, as it can be seen in page FIXME.
- **Reducing the number of components**: As seen in the decontamination analysis, see page FIXME, current devices have numerous (small) components that can be integrated or eliminated. Additionally, reducing some components would also reduce the number of tools needed for disassembly and assembly. This option would not only impact production by reducing material and energy use but also improve the efficiency of the decontamination process.
- **Reduce dimensions of the product:** The final approach involves reducing the overall size of the device, which directly reduces the quantity of material used. However, it is crucial to ensure that the speculum maintains its functionality and safety even after multiple decontaminations (Samenjo et al., 2023). This approach aims to achieve sustainability through material reduction while maintaining the integrity and usability of the device.

R3 Reuse:

Reuse of medical devices is mostly related to the recovery through the level of decontamination required (Kane et al., 2018, Samenjo et al., 2023). In this case, the vaginal speculum will require high-level decontamination or sterilisation to be reused. However, as it is a low-value device the main limitation of this strategy is, whether it is more financially viable to recover the product or to discard and replace it (Kane et al., 2018). Considerations like material choose will determine the process of decontamination of the product.

R4 Repair, R5 Refurbish, R6 Remanufacture, R7 Re-purpose:

Repair in the healthcare sector can be both costly and risky due to the critical nature of medical equipment (Kane et al., 2018). Maintenance practices, such as part replacement and regular cleaning, are generally preferred but may not be feasible for low-cost devices like the vaginal speculum. Instead, the focus should be on designing a durable device that minimizes the need for repairs over its lifetime, aligning with a reuse strategy.

Refurbishing, remanufacturing, and repurposing are commonly applied to high-cost medical equipment such as imaging systems, patient monitors, and anaesthesia machines (Kane et al., 2018). These strategies are less suitable for low-cost and low-value devices like the vaginal speculum due to their cost-effectiveness and practicality considerations for end-users.

Given the low cost of the vaginal speculum, these four strategies—repair, refurbish, remanufacture, and repurpose—are not suitable for it.

R8 Recycling:

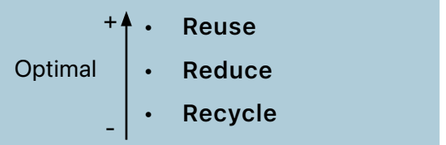
Even recycling is the least preferred option because it creates waste and destroys the product integrity, it can be applied to the vaginal speculum in different ways:

- **Assembly and disassembly of the product**: Designing the vaginal speculum for easy assembly and disassembly, using minimal materials, can facilitate efficient recycling processes
- **Recycling strategy (out of scope)**: Developing a comprehensive recycling strategy for the device could significantly reduce its environmental impact. Currently, hospitals typically dispose of the device (single-use) mixed with other plastic instruments, making recycling challenging.
- **Material:** Use materials which can be returned to simple molecules through processes such as incineration and biodegradability, as these processes do not contribute fossil carbon dioxide (CO2) to the atmosphere.

R9: Recovery:

Recovery strategies are considered not applicable for this device, as they involve incinerating materials for energy recovery. Hoveling et al. (2024) argue that this approach is not feasible for designing specific strategies, as virtually any material can be incinerated.

Potential R Strategies for the vaginal speculum:



3.5 Discussion and takeaways chapter 3

This chapter compiled important insights about the vaginal speculum from the sustainable perspective. Understanding why is important to considere circular strategies and which one works better for the vaginal speculum is crucial for the new design. Through desk research, the questions posed at the beginning of the chapter have been addressed.

1. **Why is sustainability crucial for this project?**

Sustainability is crucial for this project because the healthcare sector, despite its mission to improve health, significantly contributes to environmental pollution, with an impact nearly twice that of aviation. This chapter highlights the paradox of healthcare, where increasing reliance on single-use products for hygiene reasons worsens the sector's environmental footprint.

Moreover, new EU regulations, to reduce the impact of this sector, are pushing hospitals to prioritize sustainable products. Incorporating sustainability into this project not only reduces its environmental impact but also increases its appeal to hospitals aiming to comply with these regulations.

2. **What is the environmental impact of the current vaginal speculum?**

The environmental impact of the current vaginal speculum varies depending on whether it is reusable or single-use. Single-use speculums generally have a higher environmental impact, though they are less expensive, while reusable speculums become more sustainable after being used more than seven times. For both types, the production phase has the most significant environmental footprint, with sterilization also contributing substantially to the impact of reusable devices. Therefore, the new speculum design should focus on minimizing production and decontamination impacts, with an emphasis on creating a more sustainable, reusable device.

3. **Which circular strategies can be effectively applied to improve the sustainability of the vaginal speculum?**

In Chapter 1, the vaginal speculum was identified as a low-value device due to its low economic price and as a semicritical device due to its role in medical procedures. These attributes impact the 10R strategies used to apply circular principles to products, resulting in three possible strategies for this device: reuse, reduce, and recycle. As discussed in this chapter, reuse will be prioritized as a design requirement for a more sustainable device. Insights from Chapter 1 suggest that this strategy can be effective by reducing the number of design features or improving process efficiency. The reduce strategy can be applied by minimizing the number of sizes, potentially adopting a one-size-fits-all approach. Lastly, recycling, while less favoured, can be considered a requirement for the material.

Chapter3 takeaways and its relevance for the design are summarised in the following figures:

1. **Circularity**

- The most potential 10R Strategies for the vaginal speculum are reuse, reduce to and recycle.
- Ensure the product is designed to be more cost-effective to reuse it than disposal.

2. **Use**

- For procedures aimed solely at detecting vaginal infections like Candidiasis or Trichomonas vaginalis, using a speculum may not always be necessary. This approach can be beneficial for young patients, those experiencing strong pain during speculum insertion, or individuals who are very scared.
- However, a speculum is still required to visualize the cervix and vaginal walls accurately during examinations.

3. One-size-fits-all

- Chapters 1 and 2 discussed the need for different sizes of speculums to accommodate all types of vaginas. However, for sustainability, explore the possibility of a single speculum that fits all sizes.
- A single adaptable speculum can reduce the number of instruments that need to be manufactured.
- This approach can lower inventory costs for hospitals

4. Reusable option

- Single-use devices may have a lower initial economic cost but incur a significantly higher environmental cost due to waste generation.
- To mitigate environmental impact, prioritize reusable options in the redesign.
- Ensure the material chosen can withstand at least 7 cycles of decontamination.

Chapter 4

Converging healthcare sector, patient and sustainable needs

This chapter addresses the final area of focus in this project: sustainability. Throughout this chapter, we explore the importance of applying circular strategies in the healthcare sector and specifically how these strategies can be implemented for the vaginal speculum.

Questions addressed in this chapter:

1. What are the primary requirements for the new device?
2. Which requirements conflict among the different perspectives?
3. What is the shared vision of the problem?

Methods used:

- Requirements definition
- Visual vision

4.1 Requirements

Throughout the discovery phase, insightful information was gathered from three key areas: the healthcare sector, patient perspectives, and sustainability. This information has been translated into specific requirements for each stakeholder, guiding the development of a product that meets the necessary functionalities, capabilities, and characteristics to address their needs. These requirements are classified as either Wishes or Demands and are prioritized according to their importance within each sector. Due to the different wished of the sectors it is also noted which requirements conflicts between each other.

Requirements for the Healthcare sector:

The main requirement for this sector is to be able to fulfil the function, benign able to provide good visualisation from the walls and the cervix and at the same time the device need to be feasible for hospitals, making it more cost efficient to reuse than to thought away. The requirements for this sectors are described below:

1.1 The device needs to have good visualisation of the cervix and the walls

- **1.1.1** The device needs to allow the doctor to see the cervix *(Demand)*
- **1.1.2** The design of the device needs to allow proper visualisation holding the wall prolapse, so the condom is not needed *(Demand)*
- **1.1.3** The design needs to allow the doctor to see the walls *(Demand)*
- **1.1.4** The design of the introitus opening must match or exceed the viewing range of the Cusco design. *(Demand)*
- **1.1.5** If the blades are narrower than 40 mm, a design feature for handling vaginal wall prolapse must be incorporated. *(Demand)*
- **1.1.6** The device should have minimal rounded features to facilitate easy fixation. *(Wish)* ***(Conflicts with patient requirement 2.1.7)***
- **1.1.7** The doctor needs to be able to control the opening of the blades *(Demand)*
- **1.1.8** The device should be able to fit different sizes of vaginas *(Demand)*

1.2 Design a device easy to use for HC staff

- **1.2.1** The design should be more cost-efficient to reuse than to throw away. *(Demand)*
- **1.2.2** The design of the blades must incorporate the minimum number of inner curves to ensure they can withstand a fast decontamination process *(Demand)*
- **1.2.3** The device shall be designed to allow disassembly or assembly in less than 30 seconds *(Wish)*
- **1.2.4** The device must be designed to require no more than one tool for disassembly or assembly *(Wish)*
- **1.2.5** The device shall be designed to minimize the number of areas that staff need to touch during assembly and disassembly *(Wish)*
- **1.2.6** The device must have the minimum number of joins possible *(Demand)*
- **1.2.7** The device must be designed to ensure that the assembly and disassembly process is intuitive for the user *(Demand)*
- **1.2.8** The device should not include small parts that are difficult to manipulate *(Demand)*. ***(Conflicts with patient requirement 2.1.2)***
- **1.2.9** If the handle is not designed for sterilization, it shall be independent from the device *(Wish)*
- **1.2.10** The material used in the device must be capable of withstanding decontamination procedures *(Demand)*
- **1.2.11** The material used in the device should be biocompatible and with a medical grade *(Demand)*

1.3 The device should be ergonomic for the doctor

- **1.3.1** The device must be equally efficient and comfortable for both left-handed and right-handed users *(Demand)*
- **1.3.2** The device must be operable with only one hand *(Demand)*
- **1.3.3** The handle must be ergonomically designed for doctors, accommodating small hands *(Demand)*
- **1.3.4** The device, if it exists in different sizes, must be accompanied by clear instructions specifying suitable user demographics *(Wish)*
- **1.3.5** The handle angle should be between 105 and 135 degrees *(Demand)*
- **1.3.6** The device need to be intuitive for the practitioner *(Demand)*

Requirements for the Patients:

For this sector, the main requirement is to design a device that patients perceive as friendly while still fulfilling its intended function. Prioritizing patient comfort involves considering friendly shapes and avoiding the use of metal, which are primary concerns for this group. Additionally, the design will aim to use the smallest possible dimensions to enhance comfort and reduce intimidation. The specific requirements for this sector are outlined below:

2.1 The device should be patient-friendly

- **2.1.1** The device must not be made of metal *(Wish)*
- **2.1.2** The device should have minimal visible mechanisms or joints. *(Demand)* ***(Conflicts with HC requirement 1.2.8)***
- **2.1.3** The device may include small visible mechanisms. *(Demand)*
- **2.1.4** The device should look compact *(Demand)*
- **2.1.5** The device should be designed with friendly colours *(Demand)*
- **2.1.6** The material must be soft and smooth *(Wish)*
- **2.1.7** The device should have a rounded look and feel *(Wish)* ***(Conflicts with HC requirement 1.1.6)***
- **2.1.8** The device needs to be familiar for the user *(Demand)*
- **2.1.9** The device should operate silently *(Demand)*
- **2.1.10** The device needs to have a clean look and feel *(Demand)*

2.2 The device needs to be ergonomic for the patient

- **2.2.1** The opening of the blades needs to be slowly *(Demand)*
- **2.2.2** The dimension in the extreme of the blades (insertion) needs to be smaller than 13 mm *(Demand)*
- **2.2.3** The device should have the minimum dimensions as possible *(Demand)*
- **2.2.4** The device should feature small gaps between the blades to mitigate the risk of pinching *(Demand)*

2.3 The design should include informative media about pelvic exams and speculum.

- **2.3.1** The information must be understandable regardless of educational background *(Demand)*
- **2.3.2** The language must be inclusive *(Demand)*
- **2.3.3** The language must be gender neutral *(Demand)*

Requirements for Sustainability:

Incorporating circular strategies is essential to achieving a truly sustainable product. Sustainability will be a key factor in ensuring the product's reusability, which in turn will influence the requirements of the other sectors. Based on these sustainability requirements, material choices will be made to ensure that the device can meet the circularity expectations of this stakeholder. The specific requirements for this sector are outlined below:

3.1 Design a more circular device

- **3.1.1** The design should be reusable *(Demand)*
- **3.1.2** The device should be designed with standard, easily replaceable parts *(Demand)*
- **3.1.3** The material must have a minimum lifespan of 7 cycles *(Demand)*
- **3.1.4** The device should reduce the impact of it production *(Wish)*
- **3.1.5** The device should have the fewest possible components.*(Demand)*
- **3.1.6** The device should offer a one-size-fits-all solution *(Wish)*
- **3.1.7** The device should reduce the time of decontamination *(Demand)*
- **3.1.8** The device should need the minimum tools for assembly and disassembly *(Demand)*
- **3.1.9** The device should reduce the number of other objects needed to fulfil the function (condom, lubricant) *(Demand)*

3.2 The device should have a lowest impact while recycling

- **3.2.1** The device should be easy disassembly *(Demand)*
- **3.2.2** The device should be made by one material *(Wish)*
- **3.2.3** The design should facilitate the separation of different materials, in cases where there are multiple components *(Wish)*
- **3.2.4** The material should be recyclable or have a low impact *(Demand)*

4.2 Main requirements

As seen in the section below, some requirements from different areas conflict with each other. For example, patients prefer smaller components for comfort, whereas decontamination staff prefer fewer small components to simplify cleaning.

To find an equilibrium and establish a methodology for developing the product that considers the three main areas as much as possible, four primary requirements have been established to prioritize these areas.

The main requirements are as follows:

1. **Functionality**: As a medical device, it is crucial for the speculum to perform its functions effectively—allowing visualization of the cervix and vaginal walls and opening the vaginal canal for the use of other instruments. The new device must perform these functions as well as, or better than, the current device and be cost-effective for hospitals.
2. **Re-usability**: To promote sustainability in the medical sector and align with the preferences of patients and doctors, designing the device for re-usability is essential.
3. **Comfort:** Ensuring comfort for both the patient during use and the practitioner is a primary requirement.
4. **User-Friendliness**: The perception and acceptance of the device by users are crucial. The design must be intuitive and acceptable to both patients and doctors to enhance its adoption and use.

By prioritizing these requirements, the design process can better balance the needs and constraints of different stakeholders, leading to a more effective and widely accepted vaginal speculum.

4.3 Vision

Once the requirements are established, a vision is created. Defining a vision helps to articulate what the design aims to deliver to people in a future context before determining how the design can achieve this goal (Van Boeijen et al., 2020).

The research identified a gap in the market: no device currently exists that fulfils its function, is liked by patients and is sustainable. furthermore, surprisingly, the design of the vaginal speculum has remained unchanged since 1845, despite its origins in experiments on enslaved women without anaesthesia.

To express this vision, instead of using a sentence, it will be represented by a drawing. This illustration (figure 40) aims to convey the designer's ambition to evolve the speculum from its original 1845 design to a version that meets the standards of 2024. Achieving this transformation requires the healthcare sector, sustainability, and patient needs to work together harmoniously, enhancing the functionality, reusability, comfort, and user-friendliness of the new product.

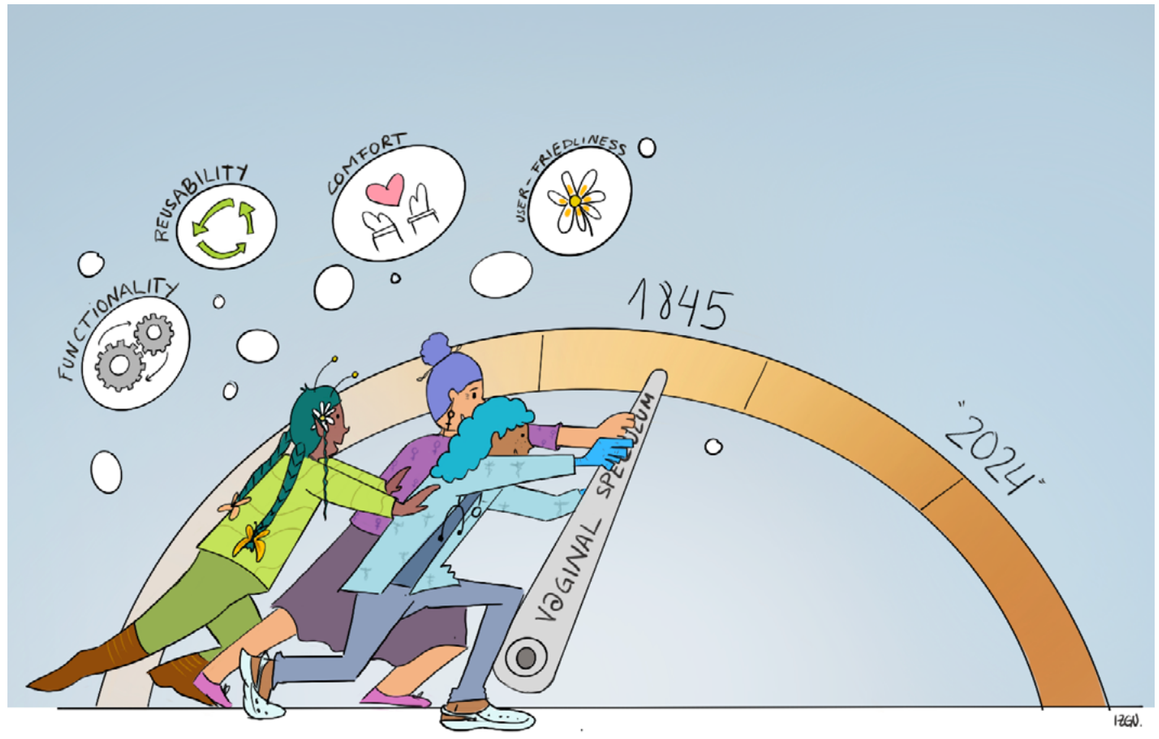


Fig. 40: Visual vision

Chapter 5

Concept exploration

This chapter transforms the requirements and insights gathered during the discovery and definition phases into tangible concepts. The first part focuses on ideation, where various methods are employed to generate ideas. The second part transitions into the conceptualization phase, where these ideas are refined and merged to create the final concept.

> Questions addressed in this chapter:
>
> 1. How can the requirements and literature insight be transformed into a product?
>
> Methods used:
>
> - Brainstorming
> - Co-creation sessions
> - Analogue
> - Harries profile

5.1 Individual preliminary brainstorming

The ideation phase began with individual brainstorming through sketching, generating preliminary ideas alongside the ongoing literature review. As new insights emerged, such as the number of blades or the need to eliminate the handle to counteract the "gun" perception, the concepts evolved.

o develop the initial ideas, the requirements were grouped according to the parts of the device they impacted, with an initial focus on the blades and methods for opening the vaginal walls. This approach generated various concepts, which were then evaluated against the established requirements and literature findings.

As shown in figure 41 certain attributes from different concepts inspired the final design. For example, one early concept presented the speculum as a modular item, where the blades could be given to the patient for self-insertion, with the doctor assembling the device afterward. This idea highlighted that users preferred a design without a handle during the co-creation session, as it avoided the "gun" shape associated with traditional speculum. Another concept explored the use of an exaggerated gap between the blades to prevent wall pinching, which was incorporated into the final design.

However, some ideas were discarded during this process due to their failure to meet the requirements. For instance, a "cylindrical design that expands" was rejected because it expanded parallel rather than gradually, and the vagina's conical shape made this design uncomfortable and inadequate for ensuring a gradual aperture. Similarly, the concept of a silicone "condom" to make the device appear more friendly was dismissed because it retained the same unsuitable shape, failed to address the need for a simple and user-friendly mechanism, and added more material, reducing sustainability.

5.2 Co-creation sessions

To involve patients in the development of the new device and explore a range of options beyond the preliminary brainstorming, a co-creation session was conducted. This session allowed participants to collaboratively generate and refine ideas, particularly concerning the device's insertion and visualization functions.

The co-creation session was organized into two distinct groups: one consisting of female participants and the other of male participants. Conducting a separate session with male participants aimed to gather unbiased insights from a different user perspective. During the co-creation session, the radical empathy method was employed to ensure a thorough understanding of user needs and perspectives (Lubana, 2021). The method and results of the co-creation session are detailed in Appendix D.

The co-creation session revealed that participants frequently referred to the vaginal speculum as "a tampon applicator". This observation prompted further investigation into what aspects of the tampon applicator are beneficial to users. During previous interviews in the menstrual cup research phase, participants noted that the self-insertion option, a feature shared with tampon applicators, is one of their preferred attributes of the product.

Exploration of this idea led to the proposal to incorporate self-insertion into the new speculum design, which could significantly improve the user experience. The shift from 'passive patient' to 'active patient' medical consumer behaviour underscores the importance of involving patients more in their care and empowering them to make informed decisions (Mullaney et al., 2012).

In the case of the vaginal speculum, allowing patients to self-insert the device offers several advantages. Many women are already used to inserting tampons and know their own bodies well. Allowing them to control the insertion process can alleviate discomfort during the procedure, one of the main pain points identified in the patient journey map conducted in chapter 2. This approach is especially valuable for women with past experiences of abuse or discomfort. Research shows that patient participation in medical procedures can increase relaxation and overall satisfaction with the technology (Mullaney et al., 2012).

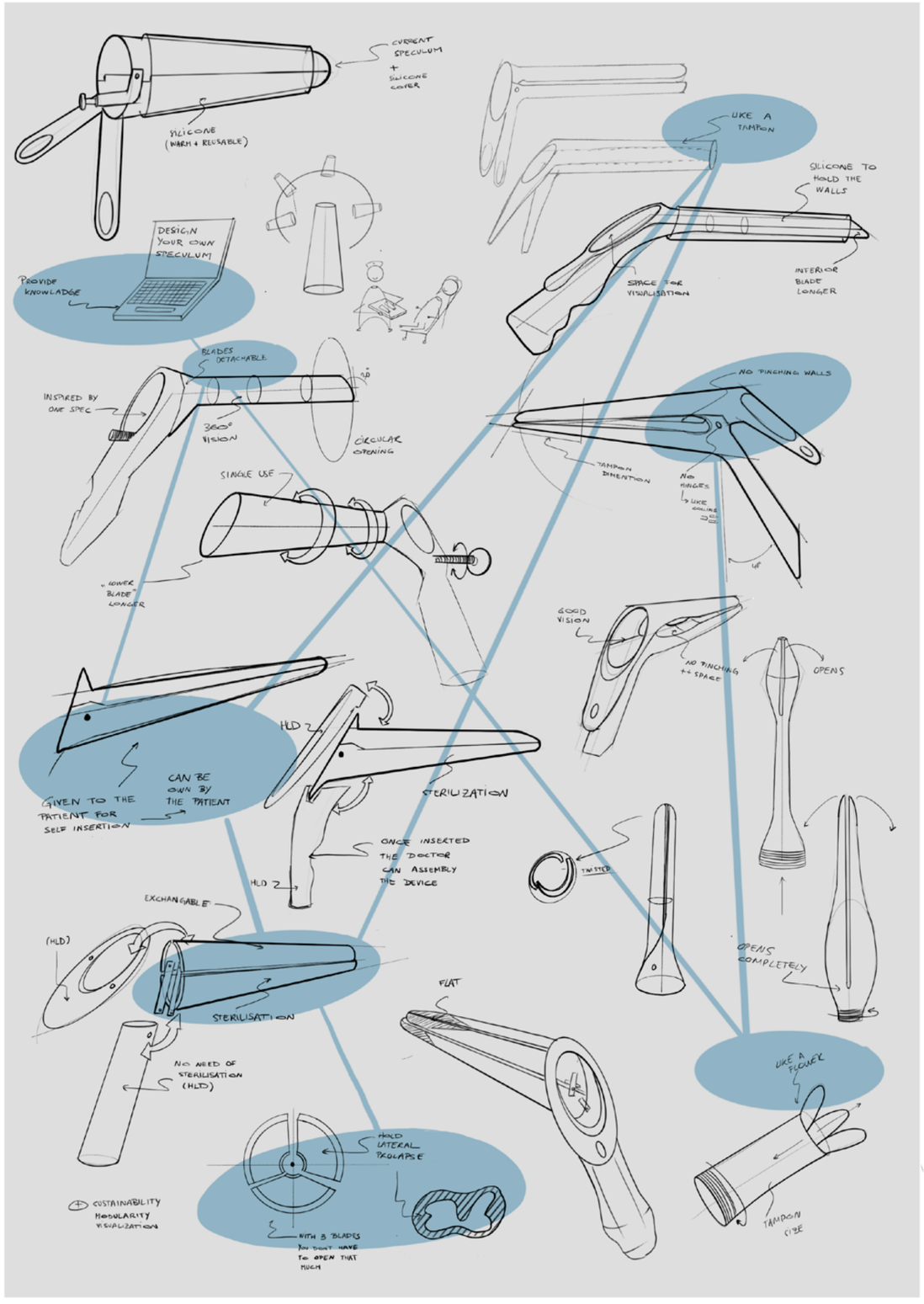


Fig. 41: Preliminary ideas generated with İndividual brainstorming through sketching

5.3 Analogy and biomimicry

Another aspect highlighted during the co-creation session was the aggressive shape of the device, a concern also raised during patient interviews in the research phase. To address this, two methods were employed: Ideation Based on Analogies and a Biomimicry Approach.

Ideation based on analogies is a method that develops solutions for design problems by mapping attributes shared by different products (Dam & Siang, 2024). Meanwhile, the Biomimicry Approach studies and applies principles found in natural environments and species (Verma, 2024). For both methods, the selected attribute to study was the opening mechanism. Mixing this two methods will allow to identify everyday objects or natural species with similar attributes to the vaginal speculum, which could feel familiar and appealing to users.

As a result the following mind map with different objects and natural species that have a similar opening to the vaginal speculum was obtained (figure 42)

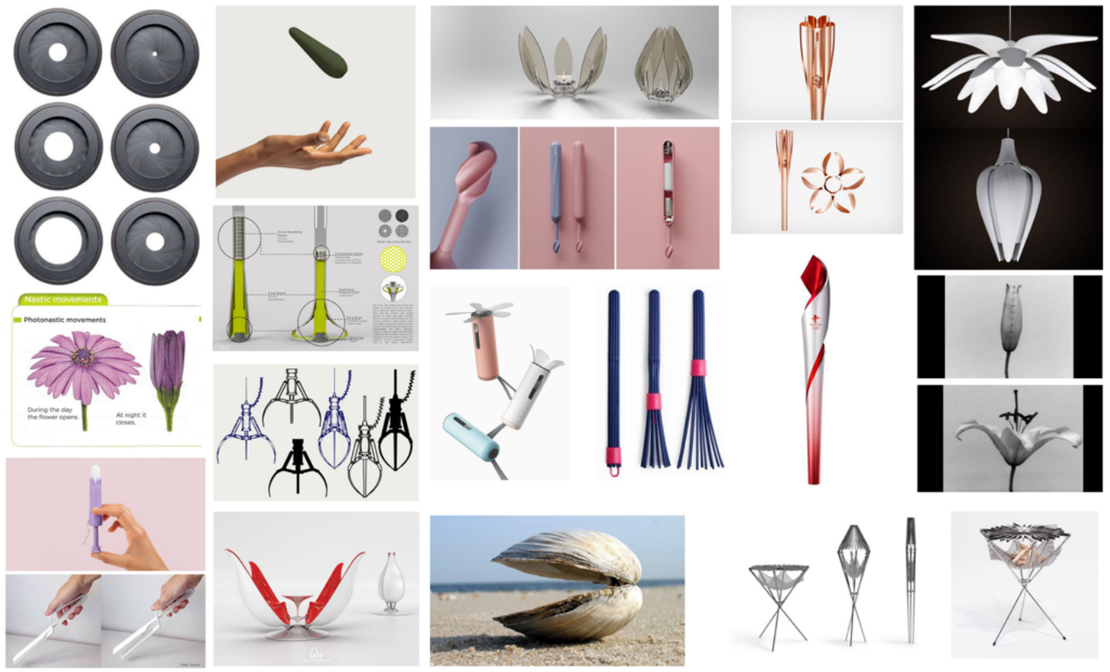


Fig. 42: Analogies and biomimicry exploration

5.4 Conceptualisation

To converge the ideas obtained from the individual brainstorming the analogies method and the insights of the co-creation session a last individual brainstorming was conducted. For this step the ideas were based on the following design drivers:

- **Easy insertion like a tampon**
- **The familiar shape of the device**

5.4.1 Concept 1: Smart materials

This concept is inspired by Vinciane Van den Dwey's master's thesis (2022). It involves the use of smart materials embedded in silicone. When the speculum is inserted via an applicator similar to those used for tampons, the silicone expands due to the activation of the shape-morphing material. This material responds to body temperature, causing it to expand and maintain a stable shape. The removal mechanism of the device is similar to that of a menstrual cup.

This technology is currently used in some medical applications, such as catheters that expand like a balloon once in place, using a smart Nitinol shape-morphing material (Bengisu & Ferrara, 2018).

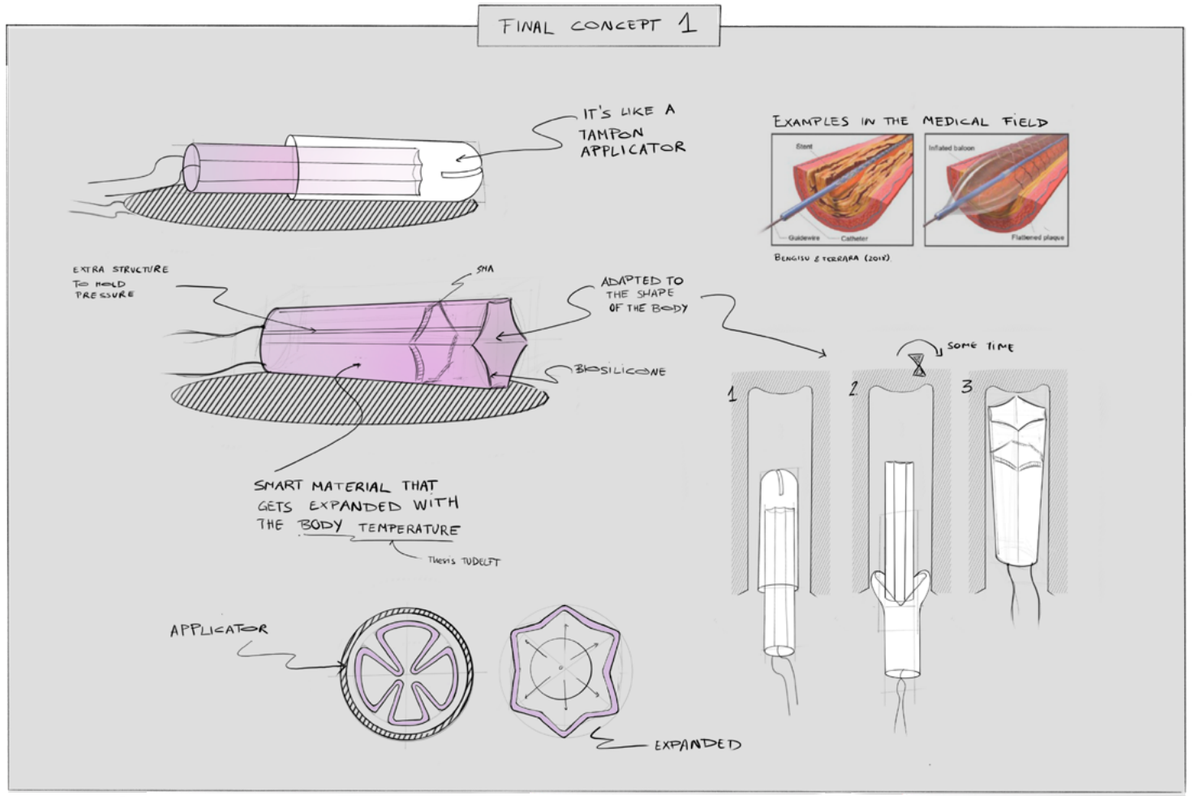


Fig. 43: Digital sketch of the final concept 1.

5.4.2 Concept 2: Flower

This concept is the result of the use of analogue methods and biomimicry research. It is inspired by the natural mechanism and shape of flowers as they open, a shape that is familiar and intuitive to users. The design incorporates three leaves to enhance visualisation. The insertion mechanism works similarly to a tampon inserter. An inner part of the device expands the "leaves" once inserted, mimicking the blooming process of a flower.

The concept of the flower not only inspires the shape of the product but also a service. During the interviews and literature review, it was noted that a lack of information significantly influences how users perceive the device. For this reason, the flower is also used in a possible app where users can access all the information related to reproductive system care.

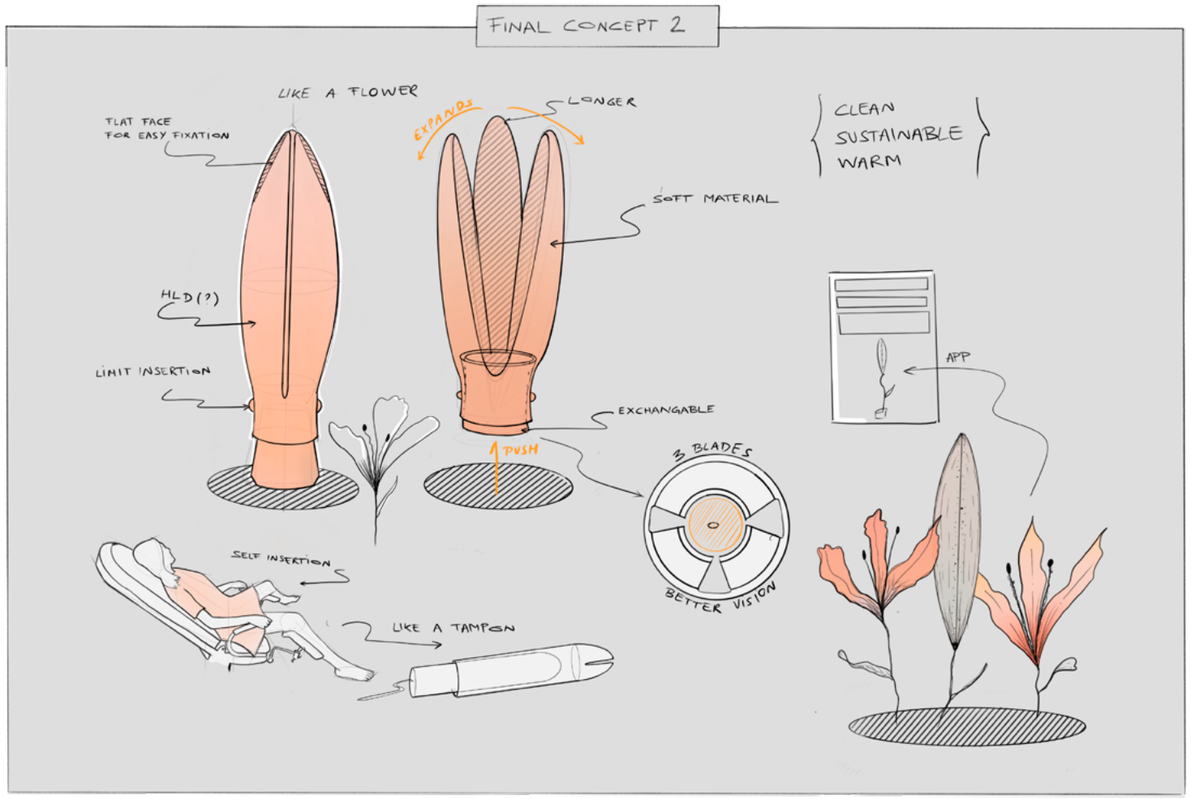


Fig. 44: Digital sketch of the final concept 2.

5.5 Final concept

To converge the ideas and select the best concept for further development, a concept selection process was conducted. Two methods were chosen for this exercise: first, evaluating the advantages and disadvantages of each concept within the project's three main areas—patient, healthcare sector, and sustainability—and then using the Harris profile.

The first method provides a general overview of which concept aligns better with the requirements for each chapter in a qualitative manner. This qualitative assessment helps identify which concept offers more advantages in relation to the specific needs of each area. Following this, the Harris profile is used to provide quantitative data, allowing for a more objective comparison and guiding the final decision on which concept to pursue.

Following the results of the advantages and disadvantages evaluation:

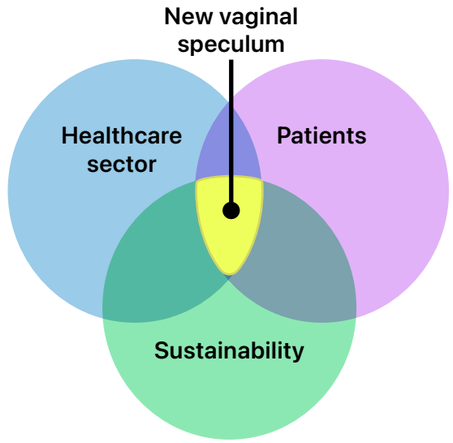


Fig. 45: Framework of the project

<u>Healthcare sector:</u>

Advantages Concept 1: Smart materials

- No need for multiple sizes,
- Smart morphing materials can provide a more personalized fit for each patient
- Innovative solution
- Provide a 360 vision of the walls

Disadvantages Concept 1: Smart materials

- No control over the opening
- Long activation time
- Expansion is still somewhat unpredictable, technology still in development
- Unclear removal process
- Unclear interaction with other gynaecological instruments
- High cost

Advantages Concept 2: Flower

- 3 blades allows better visualization
- Support for vaginal prolapse
- Control of the opening
- Feasible to interact with other instruments
- One size fits all, no need for multiple sizes

Disadvantages Concept 2: Flower

- Unclear locking system
- Unfamiliar mechanism for doctors

Patients:

Advantages Concept 1: Smart materials

- No difference from the tampon inserter - intuitive.
- The expansion of the speculum adapts to the vagina.
- The gradual expansion of morphing materials can reduce the discomfort.
- Friendly appearance (soft and without screws).
- Extremely silent movements.

Disadvantages Concept 1: Smart materials

- It requires a long activation time (6s-10s), requiring the patient to wait.
- It requires a temperature difference to activate the material, which means that or the device needs to be very cold or to be activated using electricity.
- Unclear removal process
- Unclear positioning of the doctor during self-insertion.

Advantages Concept 2: Flower

- Familiar shape
- Familiar mechanism – self-insertion possibility
- Three blades allow visualization of the cervix with less opening
- Warm material
- Friendly appearance (soft and without screws).

Disadvantages Concept 2: Flower

- No user-clues
- Unclear positioning of the doctor during self-insertion

Sustainability:

Advantages Concept 1: Smart materials

- SMA can withstand the sterilization process.
- One-size-fits-all.
- No need of extra instruments to hold lateral walls or for disassembly and assembly
- **N**o small components that are easy to lose

Disadvantages Concept 1: Smart materials

- Can lose properties over time.
- To avoid temperature difference, the SMA cable must be inside a non-thermal conductor material.
- The energy required to activate the temperature.
- Use of mixed materials.

Advantages Concept 2: Flower

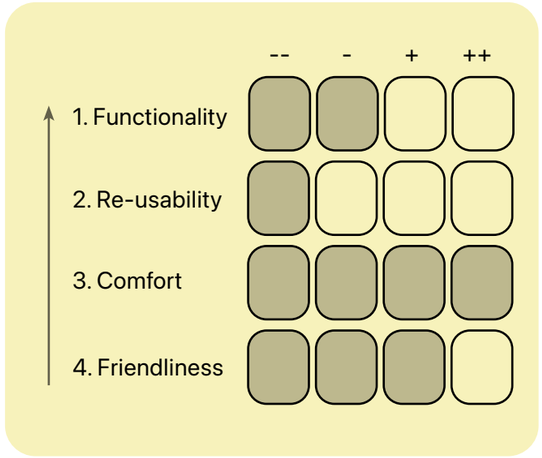
- No complex parts for sterilization
- **N**o small components that are easy to lose
- No tools for disassembly are needed Simple manufacturing process
- Possibility of one size fits all, reducing the need for extra devices
- Possibility of HLD only

Disadvantages Concept 2: Flower

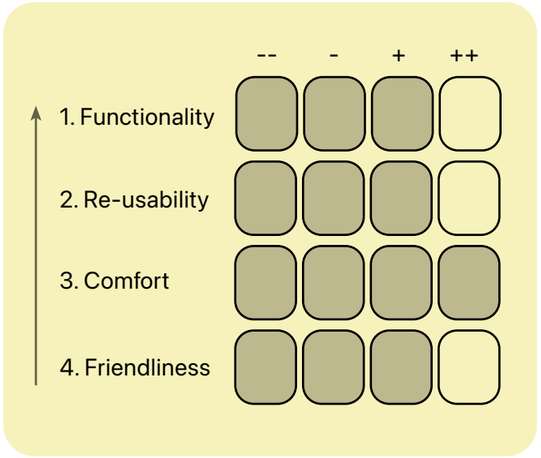
- Unclear material selection

Following the results of the Harries profile:

Concept 1: Smart materials:



Concept 2: Smart materials: Flower



Although both concepts can be self-inserted, following the tampon mechanism and presenting a familiar shape for users, Concept 2 is selected for further development due to its feasibility and functionality. As illustrated in Figure X, the technology used in Concept 1 is still unpredictable because it is under development, making it a less feasible option. Despite having several advantages for patients, Concept 1 has significant drawbacks, such as the required temperature difference and activation time, and the lack of opening control.

Concept 2 is simpler in terms of device complexity compared to Concept 1, making it more sustainable and easier to use and produce. Additionally, it allows the doctor to control both the opening and the speed of the device, enhancing its usability and versatility.

5.6 Discussion and takeaways chapter 5

Chapter five synthesizes all the prior research and insights into a new concept for the vaginal speculum. Co-creation sessions have been crucial in redefining the design and identifying key drivers, with participants expressing a strong preference for a tampon-like design and familiarity. Additionally, the use of analogues as a method encouraged out-of-the-box thinking, ultimately leading to the innovative flower shape.

By combining different methodologies and actively involving users throughout the process, the project has culminated in the final concept. The end of this chapter marks the transition to the next phase, where the concept will need further development to ensure it is fully feasible, usable, and viable.

Through ideation and conceptualisation, the question asked at the beginning of the chapter have been addressed:

How can requirements and literature insights be transformed into a product?

This chapter redefines the importance of using appropriate design methods to effectively transform literature research and insights into a valuable concept for stakeholders. Trusting the design process, maintaining a critical mindset, and having well-defined requirements are crucial steps in this transformation.

Listening to users and giving them a voice significantly influenced the development of the new speculum concept. Some insights from users were not readily available through literature research, highlighting the necessity of focusing not only on functional requirements but also on user feedback. Additionally, employing dynamic and alternative approaches facilitated the development of various concepts

Fig. 46: Current speculums with the new concept analogy

Chapter 6

Embodiment of the new vaginal speculum

Chapter six focuses on the embodiment of the selected concept using an engineering approach. This chapter explores four key areas to address the main requirements: mechanism, dimensions, material, and aesthetics. Additionally, prototyping options are explored.

Questions addressed in this chapter:

1. What are the most effective design features to enhance usability and patient comfort?
2. How can the design ensure compatibility with existing sterilization processes?

Methods used:

- Harries profile
- Granta Edu pack- materials engineering
- Prototyping
- AB test
- Non-linear dynamic simulations SolidWorks
- User interview

6.1 Methodology of the embodiment phase

To transform the concept into a viable device, an engineering phase has been conducted. The methodology in this section addresses the four main requirements of the project from an engineering perspective:

- **Function:** Exploration of different possible mechanisms.
- **Comfort:** Investigating how different device sizes can provide comfort while maintaining optimal functionality.
- **Re-usability:** Understanding the material requirements for different sterilisation processes and ensuring that the mechanical properties meet the standards needed for repeated use.
- **Aesthetics**: Evaluating the final product form with users and studying colour preferences to improve user acceptance and satisfaction.

Each requirement has been addressed using the diamond methodology, a phase of divergence of solutions by brainstorming and a second phase of convergence of ideas by evaluating the concepts using the Harris profile or the AB test.

Although this chapter is divided by requirements, it is important to note that the process has not been linear, but iterative. Therefore, references to design decisions made in later chapters can be included within each requirement.

6.2 Function - Mechanism

The mechanism of the concept is designed with two key parts: an inner component that is inserted and expands the blades of the outer part.

To transition from the concept stage to the product stage, refining this mechanism is crucial to ensure its feasibility. To achieve this, an exploration of everyday products outside the medical field that operate on a similar principle has been conducted (Figure 47). This approach aligns with the requirement that the device should feel as familiar as possible to the patient (requirement 2.1.8). Additionally, the mechanism must remain simple by reducing the number of components and small parts (requirement 3.1.5). The design should also aim to include as few features as possible that might complicate the decontamination process, thereby ensuring ease of use and hygiene.

From the exploration phase, three potential mechanisms were selected: lipstick, tampon applicator, and camera. These mechanisms were chosen because they were frequently mentioned as possible ways to expand the blades by participants during the co-creation session, (see Appendix D).

To determine the most suitable mechanism, the main requirements established on page 86 were used to identify the key drivers for selection using Harris Profile methodology:

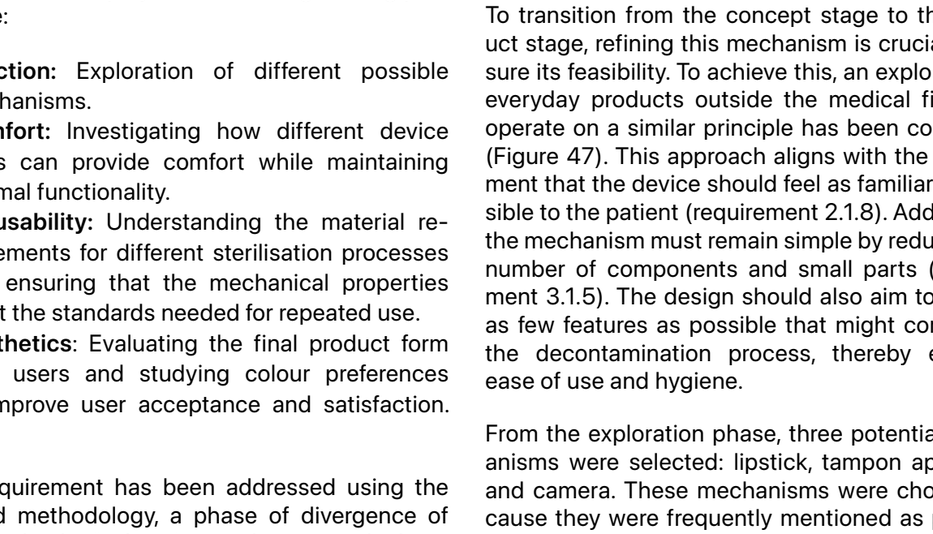


Fig. 47: Exploration of different mechanisms

- **Simplicity**: This driver emphasizes a reduced number of parts and small components that are easy to manipulate, aligning with requirements 3.1.5, 3.1.8, 1.2.5, 1.2.6, 2.1.2
- **Ease of Cleaning**: The mechanism needs to be easy to clean, including straightforward disassembly and assembly processes, adhering to requirements 1.2.1, 1.2.2, 1.2.3. 1.2.4, 3.1.1
- **One-Hand Operation**: The mechanism must be operable with one hand, meeting requirements 1.3.2, 1.3.3.
- **Intuitiveness**: The mechanism needs to be easy for practitioners to use, aligning with requirements 1.3.6

Mechanism evaluation:

1. Applicator

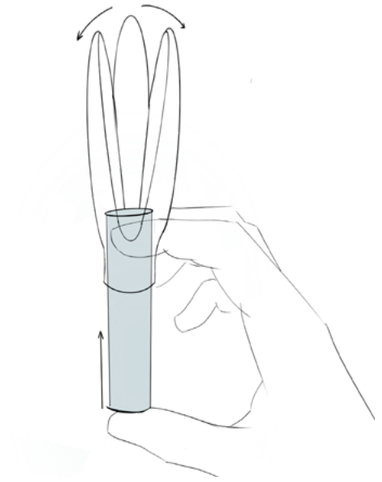


Fig. 48: Sketch of the tampon mechanism

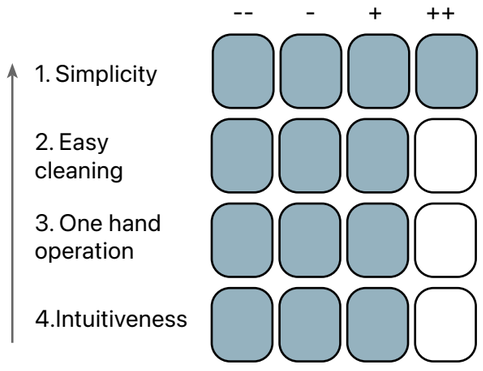


Fig. 49: Harris Profile

The tampon applicator is considered the simplest mechanism among the three options. Its simplicity provides a significant advantage during the decontamination process, as it can be assembled and disassembled quickly and easily compared to the other mechanisms and the current device. This simplicity also extends to the manufacturing process, making it more efficient. However, a key concern with this mechanism is the lack of a locking feature to hold the blades in position. This functionality is essential for doctors to keep the device open independently while conducting exams.

2. Lipstick

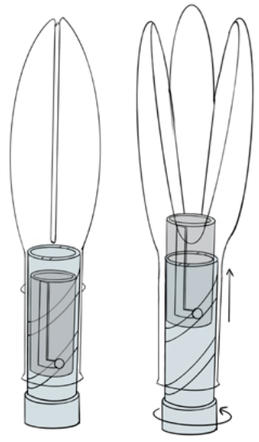


Fig. 50: Sketch of the lipstick mechanism

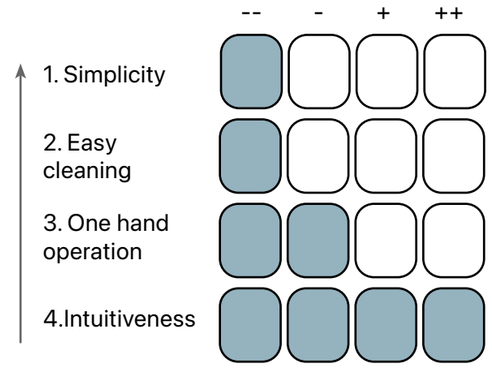


Fig. 51: Harris Profile

The second mechanism offers a high level of patient familiarity due to its intuitive design and its similarity to a lipstick mechanism. In addition, unlike the other two options, it limits the speed of opening through its threaded system. This feature could mitigate human error, potentially making the

opening process more comfortable for the patient. However, this option is ultimately discarded as too complex. Its design, with numerous critical features such as guides and holes, complicates the cleaning process, making it less practical to use.

3. Camera

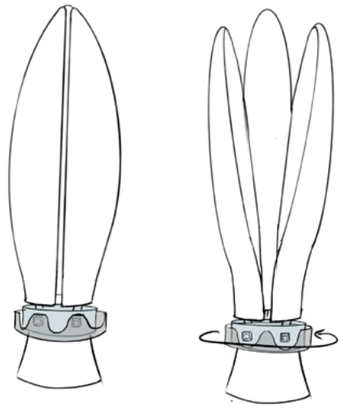


Fig. 52: Sketch of the camera mechanism

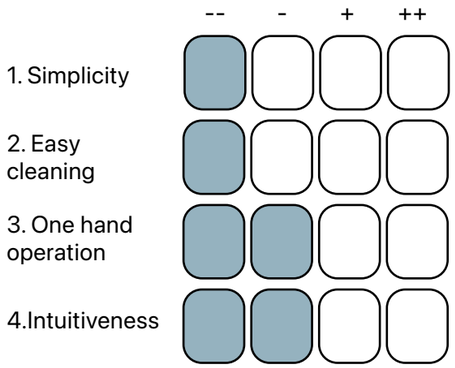


Fig. 53: Harris Profile

The last mechanism is the least suitable of the three options studied. Although it is intuitive and can be operated with one hand once inserted, it is composed of too many parts. The complexity of having multiple components complicates the decontamination process, as it increases the time required for assembly, disassembly and cleaning. Each part would have to be cleaned individually, making the process more time-consuming and less efficient. While the mechanism may appear compact and patient-friendly, it is ultimately not a suitable option for this design.

Mechanism:

The tampon applicator is considered the best mechanism for the final product due to its simplicity and familiarity. This mechanism was frequently mentioned by participants during interviews and co-creation sessions, making it the most favoured option. It allows for a design without visible screws, which reduces the number of small parts and improves the patient's perception of the speculum. In addition, the simplicity of the mechanism offers a significant advantage for the decontamination process, allowing for quick and easy assembly and disassembly compared to other mechanisms and the current device.

Apart from material considerations which will be explored in next pages , another concern is the familiarity that physicians will have with the mechanism. The new design proposal lacks a handle, unlike traditional speculum, which could cause confusion among clinicians due to lack of familiarity, especially since this medical product can be used by both specialists and general practitioners. It is therefore essential that the device remains intuitive and easy to use for both groups. To address this concern, it is necessary to integrate, whenever possible, a form or mechanism that is common in the medical sector. This led to the creation of an analogue inspired by the injection mechanism, a very common device in healthcare that works in a similar way to the proposed design. The integration of this inspiration, especially in the way the device is held and pushed (Figure 61)

6.2.1 Locking mechanism

To facilitate the work flow of practitioners, it is important that the device includes an effective locking mechanism. The appropriate locking mechanism was selected using the same methodology applied to the main mechanism, by exploring locking systems found in everyday products and evaluating them against key criteria: simplicity, ease of cleaning, one-hand operation, and intuitiveness. Three options were tested:

Locking system 1: Thumb snap fit

Fig. 54: Prototype locking system

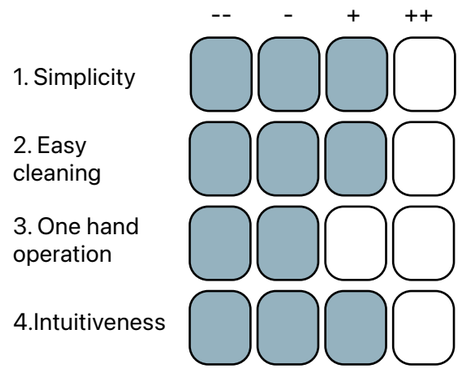


Fig. 55: Harris Profile

The thumb mechanism offers a simple and efficient method for locking the blades in place. Its primary advantage lies in the ease it provides during the cleaning phase; the critical design features, such as holes, are located on the exterior surface, making them easily accessible for cleaning with a brush. Additionally, since this part of the device never enters the vagina, maintenance is further simplified, ensuring hygiene. Moreover, this mechanism can be operated with one hand, enhancing its practicality.

Locking system 2: Bottle

Fig. 56: Prototype locking system

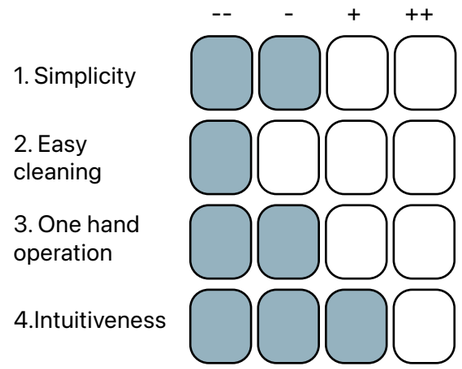


Fig. 57: Harris Profile

The second mechanism also allows for easy locking of the blade position and helps control the speed of insertion, making the procedure more comfortable for patients. However, this mechanism presents significant cleaning challenges due to the small and deep holes located on the inner surfaces of the device, which complicate the cleaning process before sterilization. Additionally, these intricate features may pose challenges during manufacturing, further complicating its implementation.

Locking system 3: Bayonet

Fig. 58: Prototype locking system

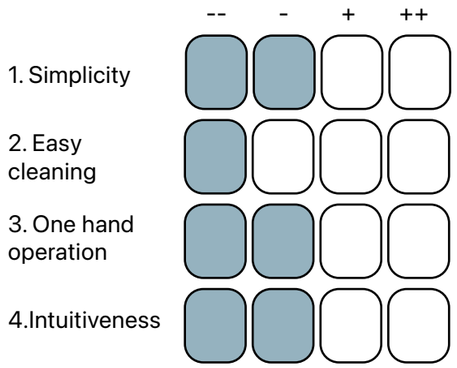


Fig. 59: Harris Profile

The last mechanism, despite being one of the most popular locking systems, is not suitable for this product. Like the second option, it has too many small design features on the inner surface, which complicate the cleaning process. Additionally, this mechanism is not as intuitive as the other two options.

According to the Harris profiles, the best option is the thumb snap-fit locking system. With the mechanism and locking system now designed, the final working principle of the device can be seen in Figure 60.

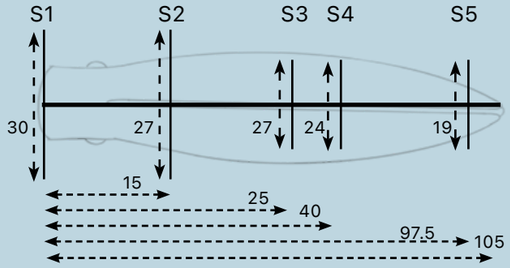
Fig. 60: Sketch of the complete mechanism

6.3 Comfort - Dimensions

Once the mechanism is chosen, the aperture of the blades will be explored through the dimensions of the device. The main objective is the following:

"Use the smallest dimensions to obtain the maximum aperture."

To study how the shape and dimensions affect the aperture, different designs were obtained using parametric design. The variables that differentiate the devices, based on the main structure of the device shown in the image 61 are as follows:



- Section shape P1: circular or ellipse
- Section shape P2: circular or ellipse
- Section shape P3: circular or ellipse
- Section shape P4: circular or ellipse

Fig. 61: Scheme of the sections, dimensions (mm) and variables used

To simplify the number of tests, the following restrictions were applied:

- Section S1 will always be circular for optimal visualization.
- Sections S3 and S4 will be the same for aesthetic preferences.

AB test:

The main goal of this test is to verify or discard the following hypotheses:

H1: When S5 has an elliptical shape, it enters more smoothly than when it is circular.

H2: When S4 and S5 have an elliptical transition section, there is more opening than when they are circular.

Test 1: Insertion (H1)

For this test, the shape of the tip is evaluated. Two identical testing devices were designed with shapes S1, S2, S3, and S4, while Option 1 features a completely rounded S5, and Option 2 has an elliptical shape. According to the literature review, the introitus has a cross-section resembling a "I," suggesting that an elliptical shape might be smoother than a circular one, despite tampon applicators typically using a circular shape.

To test this hypothesis, a silicone model was developed due to project limitations on testing methods.

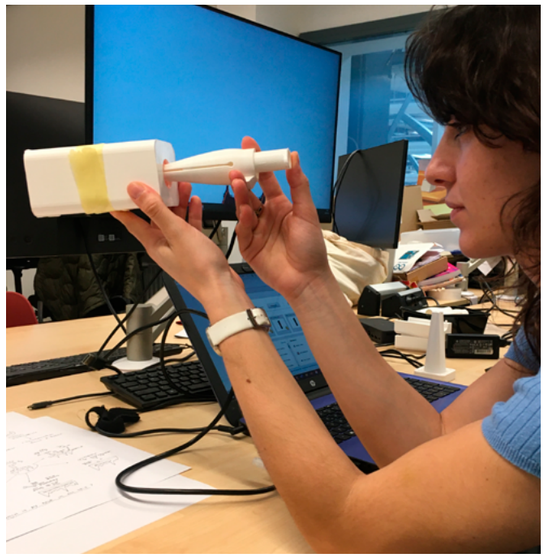


Fig. 62: Picture of the test 1

The results concluded that having an elliptical shape at the tip of the device facilitates insertion. This finding differs somewhat from tampon applicators, which have a completely circular tip.

Test 2: Opening (H2)

With the results of the test 1 another restriction as been applied to the models further tested:

- Section S5 will be with an ellipse shape.

This section of the test evaluates which shape allows for a better opening with the same dimensions. Two models were designed with identical dimensions. Option 1 has a circular shape in sections S3 and S4, while Option 2 has an elliptical shape in these sections.

Fig. 63: Picture of the test 2

The results demonstrated a significant difference in aperture, with Option 2 achieving a much larger opening at the same depth of insertion compared to Option 1. This improvement is attributed to the fact that curved faces resist deformation better than flat faces due to the number of contact points. As a result, although both options end with a similar aperture at full insertion, Option 2 is noticeably smoother and more effective in expanding the opening compared to Option 1.

Due to the limitations of the material of the prototypes the real aperture has not been taken into account. After conducting research of the material (page 117) and modify slightly the design due to material constrictions the aperture of the device is the following one:

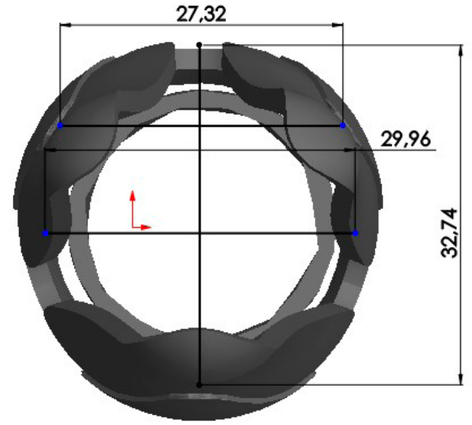


Fig. 64: Opening with the material TPV

The results indicated that under maximum pressure, the device opens between 32-27mm, which falls within the typical range for most current devices (30mm). However, the inner part of the device restricts the visible diameter to 26.5mm, making it too small for some procedures. During the evaluation with doctors, as discussed in Chapter 7, they suggested either increasing the dimensions of the inner part or designing the device in different sizes to accommodate various needs.

6.4 Re-usability-Decontamination process and material

Re-usability is a crucial requirement for the new design due to sustainability concerns, meaning that the product must be adaptable to decontamination processes. During the design of the mechanism, several features, such as inner curves and screws, were carefully considered to ensure effective and efficient decontamination.

However, the choice of material plays a crucial role, as it influences not only the mechanical properties of the device, but also the decontamination process. The choice of material will determine whether the final device can be sterilised and which sterilisation methods are compatible (Sastri, 2021). This section will delve into the material considerations essential for optimal functionality and safety in reuse and sterilisation.

During material selection, efforts will focus on minimising the use of metal due to its "aggressive" perception among patients and professionals. This perception is a major reason why many patients fear the device, often describing it as an "element of torture" or "gun", as discussed in page FIXME. Consequently, plastics will be primarily explored as the material of choice.

As detailed on page 32 many high-risk infections can be eliminated without sterilization; however, sterilization is considered necessary for the speculum due to specific use cases such as with pregnant women or potential contact with blood. Plastics can withstand various sterilization processes, but each method requires specific material properties. The most common sterilization methods include:

1. **Ethylene oxide (EtO) sterilisation:**

   One of the most commonly used methods for sterilization, employed by approximately 50% of medical devices during manufacturing and pre-sterilised methods (AdvaMed, 2023). It consists in the exposure of devices into EtO gas at specified humidities and times in a sealed chamber. This process is suitable for temperature and radiation-sensitive materials like polyvinyl chloride (PVC), polyethylene, polypropylene (PP) and Polyethylene terephthalate glycol (PETG) (Sastri, 2021). This process uses temperature around 40C and 60C during 8-16h.
   However, EtO is both flammable and highly reactive. Repetitive exposure to EtO gas can result in respiratory irritation and lung injury, as well as symptoms such as headache, nausea, vomiting, diarrhoea, shortness of breath, and cyanosis (Agency for Toxic Substances and Disease Registry , 2022).

2. **Gamma sterilization:**

   This method utilizes gamma rays from Cobalt-60. It is only suitable for plastics that do not degrade under radiation exposure (Sastri, 2021).

3. **Electro-beam sterilization:**

   It is another type of radiation sterilization, but applying high-energy electrons to the instrument. Only plastics that withstand electron beam exposure without degradation can be sterilized using this technique (Sastri, 2021).

4. **Autoclave (steam) sterilisation:**

   This method employs high temperature and pressurized steam, making it very popular in hospitals due to its high effectiveness (Sterility, 2021). The processing time ranges from 10 to 60 minutes at temperatures between 121°C and 134°C, with longer exposure times required at lower temperatures. This method is suitable for plastics that can endure high heat and moisture without compromising their function (Sastri, 2021). However, plastics with lower softening points, such as polycarbonate, polyester, and polyamides, may not be suitable due to the high possibility of deformation, despite their ability to withstand high temperatures. Most plastics will survive around 1-5 cycles of this method, however for the reusable instruments that needs to stand 100 cycles plastics like polysulfonse, polyether, polyetherminides, PEEK can be used.

Due to the requirement 1.2.1, prioritising cost-effective sterilisation over recycling the device for hospitals is essential. Autoclaving will be the preferred option whenever feasible, primarily because it incurs lower initial setup costs, it is notoxic to the patients, staff and enviroment, the cycle is easy to control and monitor, offers rapid operation, and is widely adopted in hospital settings (Dickinson, 2022).

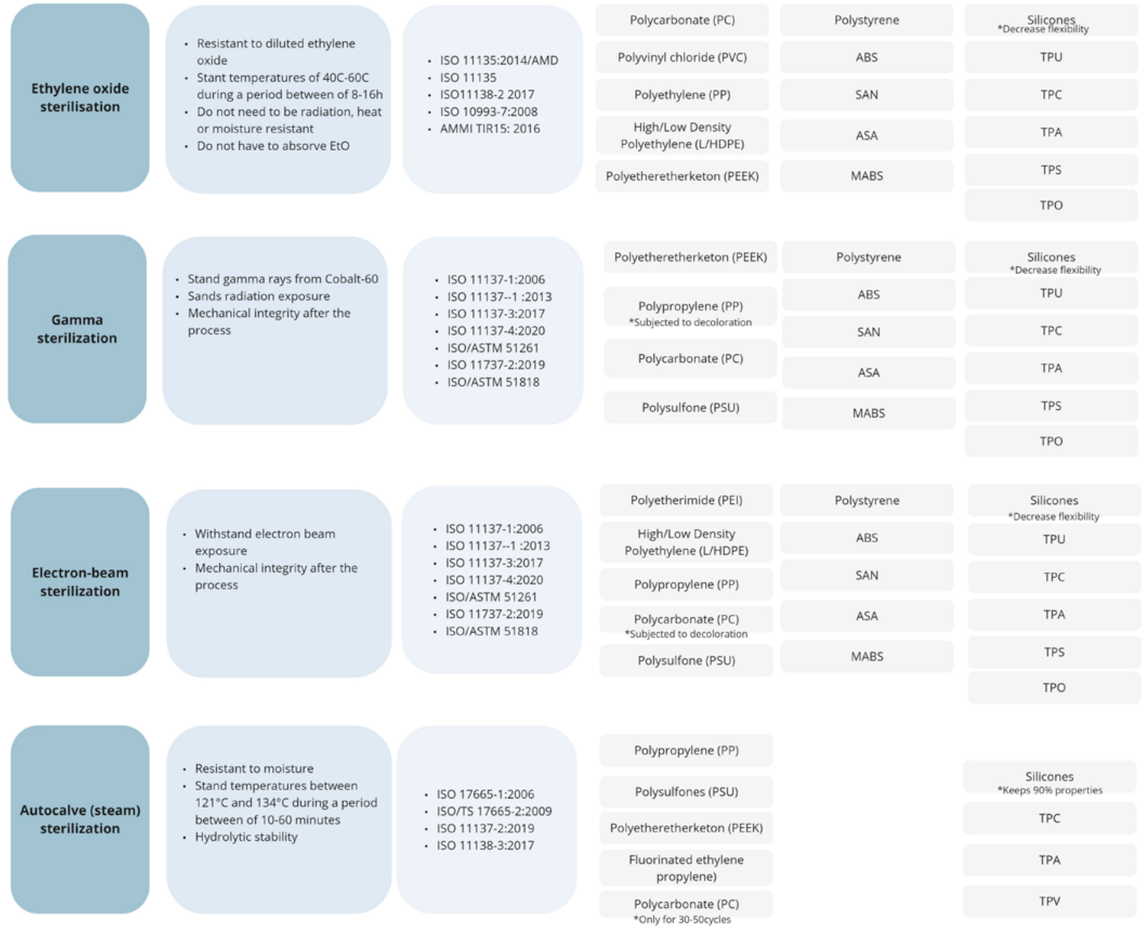


Fig. 65: Scheme with different plastics for each sterilization method, along with corresponding legislative considerations for these processes.

Material selection

Besides meeting the requirements for beam sterilisation, the material must fulfil other functional criteria as per the design specifications. In order to choose the adequate material for this application it has been used to Software *Granta EduPack* with the Advance bioengineering database, with a filter of "polymer and elastomer".

The parameters established to determine the material and used in the software are derived from the primary requirements of the product to fulfil its function, decontamination and sustainability:

1. Function:

- **Medical Grade material**
- **Flexible material** enough to be deformed when the inserter part push the blades.
- *Parameter to consider in the software Young's modulus (Low)*
- **Strength materia**l to hold the vagina wall pressures without breaking (9.81 Pa to 1185.20 Pa) *Parameter to consider in the software: Yields strength*

2. Decontamination:

- **Resistant to steam temperatures** (121C during 8-30 minutes). *Parameter to consider in the software: Maximum service temperatures: 130C, Excellent/Good resistance to sterilisation*
- **Resistant to water and soft acids:** During the decontamination the device will be submerged in water and in enzymatic detergent with a pH of 7 (neutral). *Parameter to consider in the software: Durability in water, durability in weak acids*

3. Sustainability:

- **Recyclable:** *Parameter to consider for the software: Recyclable*

After applying all these parameters to the software to identify possible materials that fulfil all the requirements, the following graph was generated. (Figure 66). While the properties of the potential materials are summarized in the table (68).

The full comparative table can be found in Appendix I.

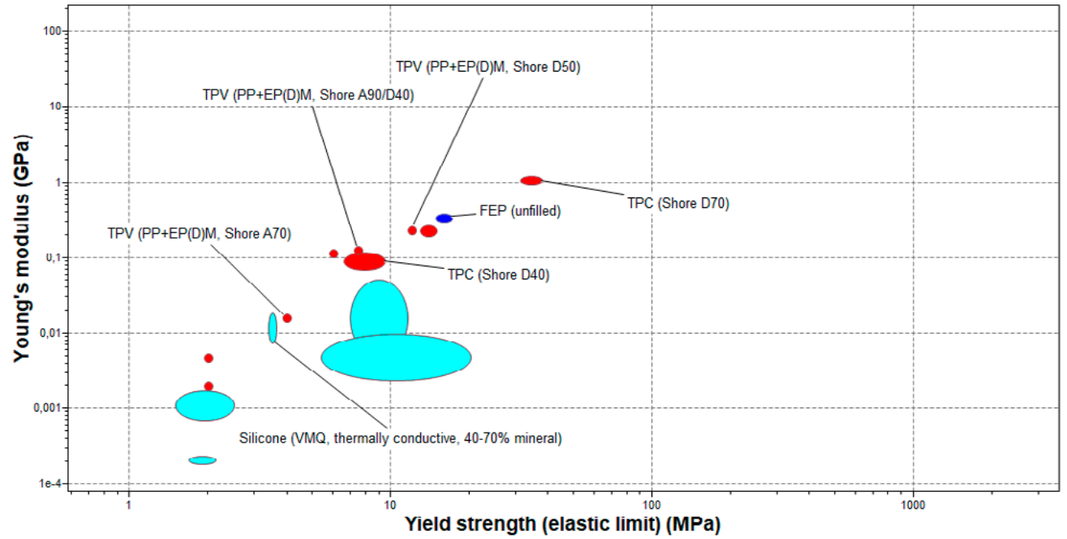


Fig. 66: Plastics that full fill the requirements except recycling. Imported from Granta Cesedu Pack

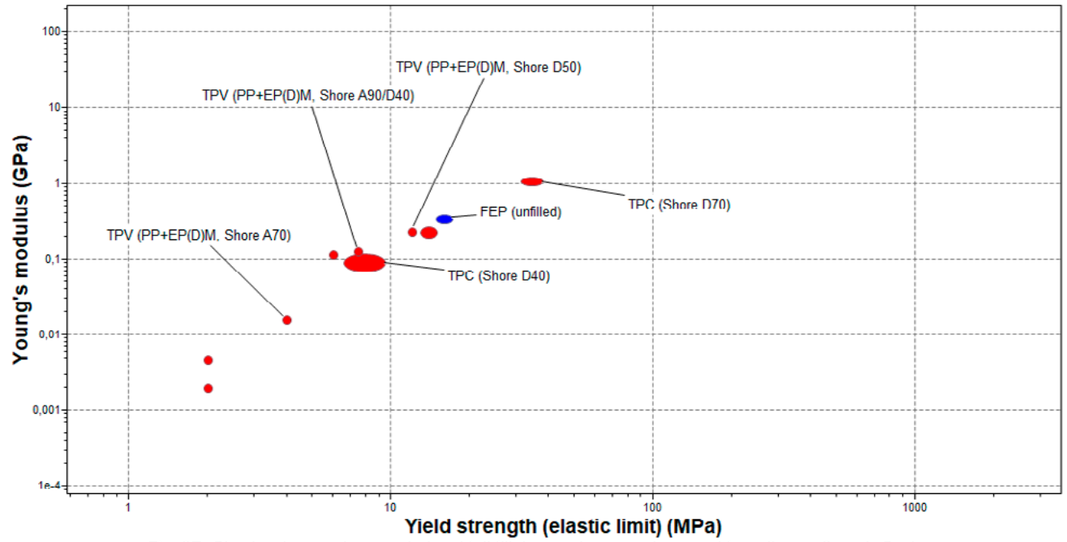


Fig. 67: Plastics that can be recycled and full fill the requirements. Imported from Granta Cesedu Pack

	Silicone (VMQ, thermally conductive, 40-70% mineral)	TPC (Shore D40)	TPC (Shore D70)	TPV (PP+FP(D)M, Shore A90/D40)	TPV (PP+FP(D)M, Shore D50)	FFP (unfilled)
General information						
Biomedical materials	✓	✓	✓	✓	✓	✓
Price						
Price (EUR/kg)	2,68	6,78	6,78	2,04	2,04	8,67
Mechanical properties						
Young's modulus (GPa)	0,0116	0,0904	1,07	0,125	0,235	0,344
Yield strength (elastic limit) (MPa)	3,5	7,94	34,5	7,5	12	16
Hardness - Vickers (HV)	2	2,45	9,95	2	3,46	5
Thermal properties						
Maximum service temperature (°C)	255	131	161	135	135	205
Healthcare & food						
Medical grades? (USP Class VI, ISO 10993)	✓	✓	✓	✓	✓	✓
Sterilizability (steam autoclave)	Good	Good	Good	Good	Good	Good
Durability						
Water (fresh)	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent
Weak acids	Excellent	Acceptable	Acceptable	Excellent	Excellent	Excellent
Recycling and end of life						
Recycle	✗	✓	✓	✓	✓	✓
Downcycle	✓	✓	✓	✓	✓	✓
Combust for energy recovery	✓	✓	✓	✓	✓	✓

Fig. 68: Comparative table with the mechanical properties needed to select the material

First iteration: Silicone

To understand the behaviour of the forces applied to the device and identify the critical points in the design, a preliminary non-linear simulation was conducted using silicone material in *SolidWorks*.

Even Silicone it is not a recyclable material it was selected due to the preference during user interviews in chapter 2.

The simulation reply the minimal wall pressure with a force of 9.5 Pa. To optimize memory usage and reduce simulation time, the model was streamlined to include only the essential functional components.

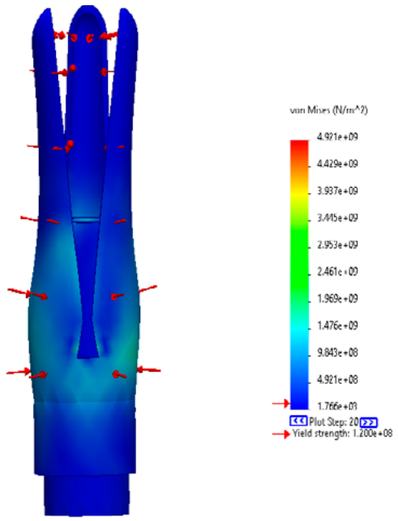


Fig. 69: Strain results Silicon medical grade. Imported from Solidworks

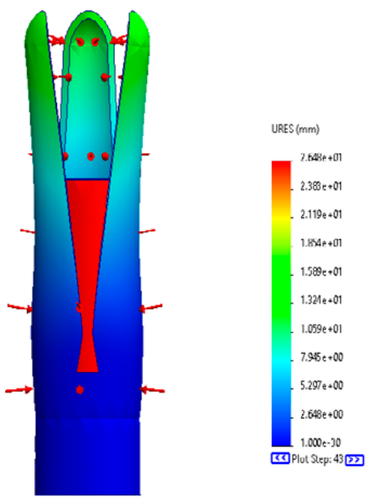


Fig. 70: Deformation results Silicon medical grade. Imported from Solidworks

As shown in the simulations under minimal pressure, silicone's Young's modulus is suitable for the expansion of the blades. However, its low yield strength leads to plastic deformation rather than elastic, indicating that the final material needs a yield strength exceeding 3.5 MPa. Additionally, the current design, where the blades converge, is not optimal due to stress concentration. Mechanically, areas with sharp angle changes are more susceptible to high stress points, which can be alleviated by incorporating rounded sections to distribute stress more evenly.

Second Iteration. TPV D40

As silicone was found to be unsuitable due to its insufficient yield strength, alternative materials need to be evaluated. The silicone simulation indicated that the material requires a yield strength greater than 3.5 MPa. According to the data in figure 68, all other potential materials exceed this yield strength.

In order to select the most suitable material among the possible options, price has been used as a selection parameter. For the product to be feasible, the material should be as inexpensive as possible, with a target cost of less than €5/kg.

As shown in figure 68, materials like TPC and FEP are significantly more expensive compared to others. Consequently, Thermoplastic Vulcanizates (TPV) D40 has been selected for the second iteration due to its favourable price and suitable yield strength.

For this second iteration, several design changes have been applied based on insights gained from the first iteration:

- **Rounded Opening:** The point were blades converge have rounded features to reduce stress concentration.
- **Increased Distance**: The distance from the S1 to S3 (figure 61) has been increased. This change will help to distribute the stress more evenly and reduce tension were the blades converge.
- **Added Material**: Additional material has been added to the blades to enhance their structural integrity and increase the yield strength

The procedure to evaluate the material was the same as in the first iteration, using *SolidWorks*. The evaluation was conducted by applying the minimum force of the walls, 9.5 Pa

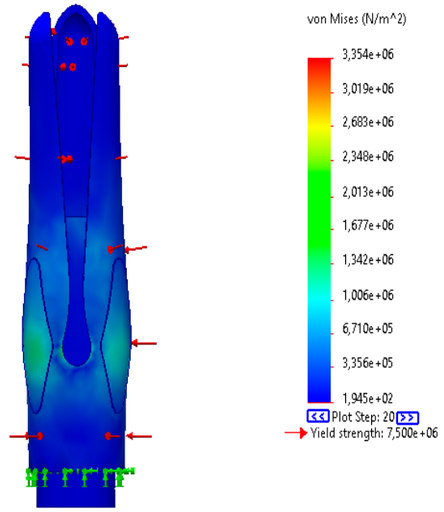


Fig. 71: Strain results TPV D40. Imported from Solidworks

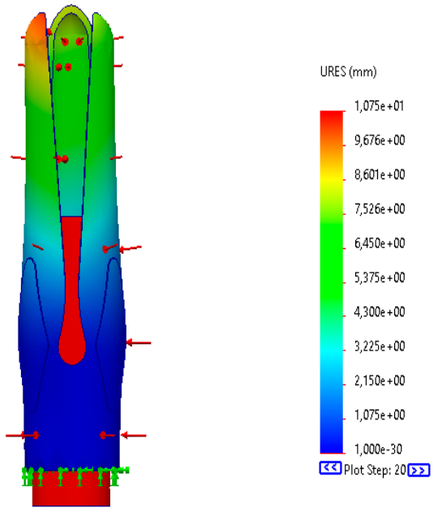


Fig. 72: Deformation results TPV D40.Imported from Solidworks

As the tests were positive using the minimum values found in the literature, the material was further tested under the maximum values, which were 1185 Pa. The simulation was successful (figure 73 and 74) obtaining positive results with the TPV.

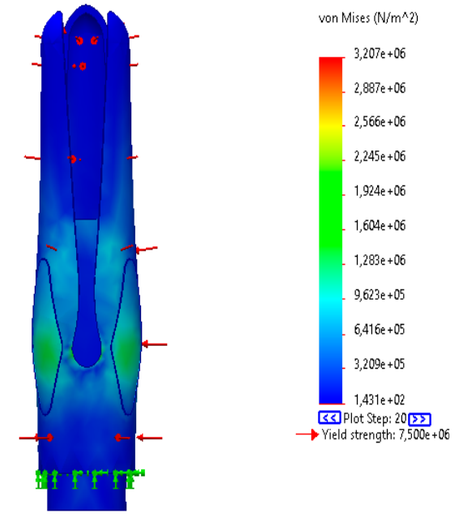


Fig. 73: Strain results TPV D40. Imported from Solidworks

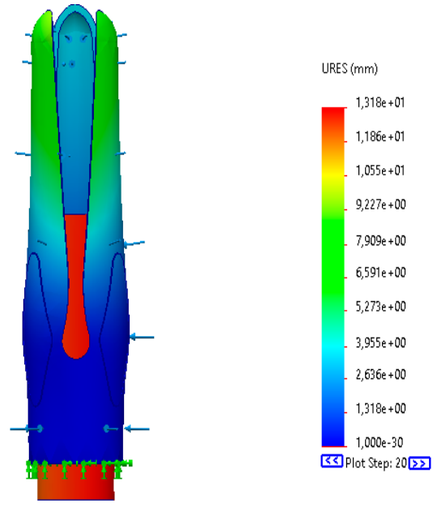


Fig. 74: Deformation results TPV D40.Imported from Solidworks

***Simulation legend:**

Points of pressure applied to the body

Fixed faces

Third iteration. TPV D40 for the blades and TPV D50 for the body

Although TPV D40 is a promising solution for the product, analysis of the figure 74 reveals that the inner part of the speculum experiences the most deformation due to the applied forces. To improve this and maintain the circularity approach and cost-effectiveness while avoiding multiple materials, TPV D50 will be used for the inner part and TPV D40 will be kept for the outer part. TPV D50 with a higher shore hardness and a higher Young modulus, provides greater strength and durability for the inner section making it more stable, while TPV D40 remains suitable for the outer part making it more flexible.

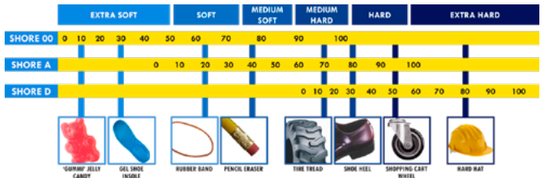


Fig. 75: Shore hardness classification. (Smooth-On, Inc., n.d.)

Based on the results of the second iteration, it is evident that TPVD40 can withstand the minimum pressure, and it is likely that TPVD50 is also capable. Therefore, in the third iteration, the maximum force of 1185 Pa will be directly applied to study the deformation and stress of the inner part.

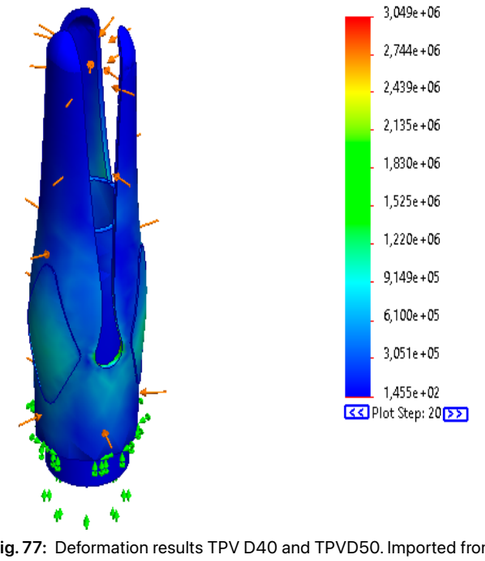


Fig. 77: Deformation results TPV D40 and TPVD50. Imported from Solidworks

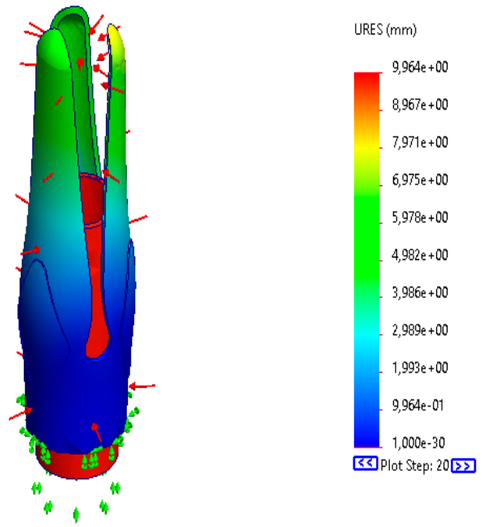


Fig. 76: Deformation results TPV D40 and TPVD50. Imported from Solidworks

As seen in the results of the simulation, using TPV D50 for the inner part reduces deformation by half when maximum pressures are applied, as well as the overall tension on the part. This concludes that the selected materials for the model are TPV D40 and TPV D50.

It is important to note that this selection is based on *SolidWorks* simulations, which provide an approximation to reality. To verify the material's performance, real-world testing is necessary. However, due to the resources and limitations of this project, such testing is not feasible at this time.

6.4.1 TPV material properties

Thermoplastic Vulcanizates (TPVs) are a part of thermoplastic elastomer (TPEs) primarily composed of two main components: polypropylene (PP) and ethylene-propylene-diene (EPDM) rubber. In the blending process, the EPDM phase is vulcanized by mixing the rubber with various additives, which increases the material's strength and elasticity. This process also enhances the material's resistance to abrasion and other forms of damage caused by scraping (Kraiburg TPE, n.d.; Pal et al., 2017).

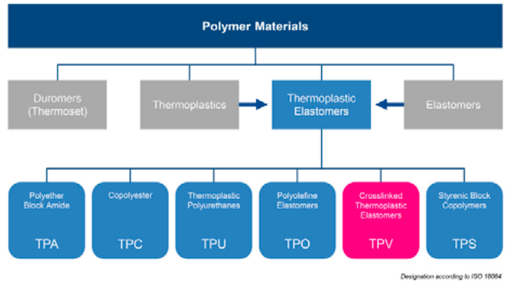


Fig. 78: TPE classification. (Kraiburg TPE, n.d.)

TPEs are widely used in many critical applications in medical devices and pharmaceutical packaging, such as gloves, catheters, syringe tips, drug vial closures, injection sites, tubing, and hoses. Specifically, TPVs, due to their enhanced mechanical properties, are used in applications including syringe plunger, tips and seals, vial and pipette stoppers, surgical cable coatings, filter elements, tubing, bellows, bulbs, and diaphragms (Sree, 2002b).

Fig. 79: Example of medical device with TPV. (Everlon, 2023)

Besides the mechanical properties of the material (Figure 80), TPV can withstand autoclave sterilisation processes up to 100 repeatable sterilisations, depending on the manufacturer (Santopseal, 2022). The average cycle for optimal sterilisation includes a 5-minute rise to 134°C, a 5-minute hold, and a 5-minute cool to ambient (MDDI, n.d.).

	TPV D40	TPV D50
General information		
Biomedical materials	Yes	Yes
Price (€/kg)	2,94	2,94
Mechanical properties		
Young's modulus (GPa)	0,13	0,24
Yield strength (MPa)	7,5	12
Hardness - Vickers (HV)	2	3,46
Thermal properties		
Maximum service temperature (°C)	135	135
Healthcare & food		
Medical grades (USP Class VI, ISO 10993)	Yes	Yes
Steam autoclave	Good	Good
Durability		
Water (fresh)	Excellent	Excellent
Weak acids	Excellent	Excellent
Production footprint (kg/kg)		
Polymer extrusion CO2	0,464	0,465
Primary production CO2	6,03	6,03
Polymer moulding CO2	1,62	1,63
Recycling and end of life		
Recycle	Yes	Yes
CO2 footprint, recycling (kg/kg)	2,07	2,07
Down-cycle	Yes	Yes
Combustion for energy recovery	Yes	Yes
Combustion CO2 (kg/kg)	3,14	3,14
Landfill	Yes	Yes
Biodegradable	No	No

Fig. 80: Comparison table TPVD40 and TPVD50. Imported from Granta EduPack

6.5 User-friendliness - Aesthetics

Once the function, feasibility, and aperture have been achieved, the aesthetics need to be developed due to their important role in the new product. The aim is to achieve the same or a similar perception as menstrual cups, as identified in the literature review. For this section, shape and colouring will be explored through 8 user evaluation interviews (see appendix E for more information about the method), focusing only on the upper body of the device, as the other parts are restricted for the optimal function of the mechanism and manipulation.

Shape evaluation:

For the shape evaluation, the design resulting from the previous section will be evaluated alongside two new designs (dummies). All three shapes incorporate a flower-like form. To evaluate the aesthetics, three adjectives are used: less intimidating shape, trustworthy, used for self-insertion, and smooth. These adjectives were identified as important based on user preferences for menstrual cups, explored through interviews in chapter 2

The results concluded that although the device's shape has a more "medical look," patients preferred it due to its thin neck and resemblance to a flower. This medical appearance also increased their trust in the device. However, patients recommended a few changes, particularly at the tip, suggesting it be closed and slightly more rounded. These suggestions have been incorporated into the final design.

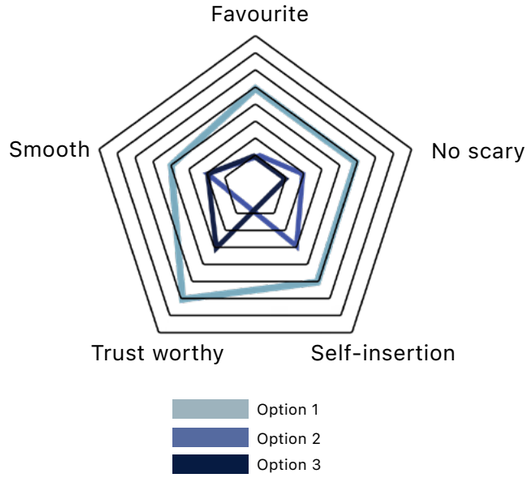


Fig. 84: Results user evaluation interview: shape

Shape 1: Design

Fig. 81: Prototype shape 1

Shape 2: Dummy

Fig. 82: Prototype shape 2

Shape 3: Dummy

Fig. 83: Prototype shape 3

Shape evaluation:

For the colouring, the colours preferred by users during the interviews on menstrual cups were utilized: peach, transparent, cherry, and blue. These colours were chosen based on their ability to create tissue contrast and their capacity to absorb and transmit light, aligning with user preferences as identified in chapter 2.

The methodology used remains consistent with previous evaluation for the shape, although the adjectives assessed are now focused on colour perception: User friendly, sustainable, warm, trustworthy and clean.

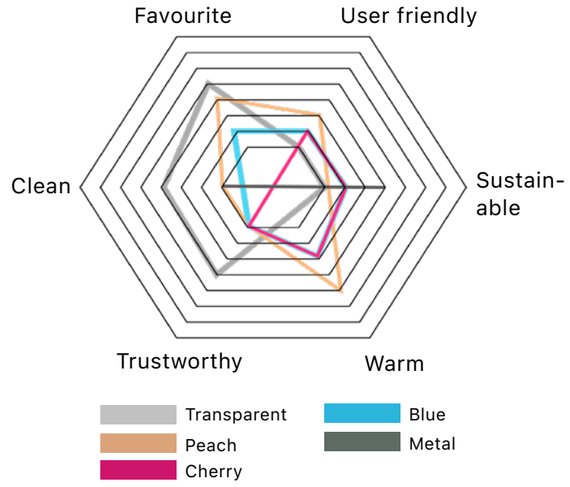


Fig. 85: Results user evaluation interview: colour

While colour can be an attractive design element, participants noted that shape was more important to them. However, two colour options stood out as the most favoured: transparent and peach. Transparent was one of the most preferred options because it allows users to easily see if the device is clean and reliable. Peach was the preferred colour because most participants agreed that it is a very pleasant, calm and warm colour. To determine the final choice, it was necessary to consult with professionals to ensure that the chosen colour would not interfere with the display on the walls. During a product evaluation interview with a nurse, it was suggested that both transparent and semi-transparent colours would not create any problems. In addition, TPV material can be semi-transparent, making it a viable option for the final design (Burger et al., 2022).

Colour options using shape 1:

Fig. 86: Render transparent and peach model

Fig. 87: Render cherry and blue model

Fig. 88: Render metal model

6.6 Prototyping

Prototyping is essential for building and testing ideas, as it allows for the identification of necessary changes that may not be apparent in computer models. Throughout the development of the device, several prototypes were created, particularly to evaluate the shape with users and to test the efficiency of the locking system.

To test the device with doctors, it was necessary to replicate TPV as closely as possible using the technologies available at the faculty. Several iterations were conducted using different methods:

1. **FDM Printing with PLA (Polylactic Acid):**

PLA printing was efficient, cost-effective, and clean, with no need for additional supports. However, the material proved too rigid for functional prototypes, as it tended to break when the inner part was inserted. As shown in the table in Appendix H, PLA has a much higher Young's modulus, making it too difficult to deform, and a higher hardness compared to TPV.

Fig. 89: PLA prototype

2. **FDM Printing with PETG (Polyethylene terephthalate glycol):**

The second iteration used PETG, which provided a less rigid prototype than PLA due to its lower Young's modulus. PETG also offers a transparent option. Despite being less rigid than PLA, the device still broke when the inner part was inserted. However with PETG was the best option aesthetically.

Fig. 90: PETG prototype

3. **FDM Printing with TPU (Thermoplastic polyurethane):**

Printing with TPU presented several challenges, necessitating multiple iterations. Initial prints had poor resolution due to high printing speeds, which were then reduced to 22 mm/s. Adjustments to the infill density and extrusion temperature were made to better approximate the Shore hardness of TPV. TPU has a Shore hardness of A80, while TPV has a Shore hardness of D40, roughly equivalent to A95. Despite these adjustments, including increasing infill density and modifying extrusion temperature, TPU achieved greater rigidity but did not match the rigidity of the optimal TPV material. As shown in the comparative table in Appendix H, TPU has a lower Young's modulus (0.023 GPa) compared to TPV (0.25 GPa for both D50 and D40), making TPU less stiff and more prone to deformation under stress.

Fig. 91: TPU fails prototype with high speed

Fig. 93: TPU prototype correct parameters

4. **FusionJet Printing with a Mix of FLX935 and RDG845:**

The final iteration used FusionJet technology, which allows for mixing materials to obtain different properties. The main disadvantage of this technology is its expense and difficulty in predicting material properties before printing, resulting in multiple iterations. To simulate TPV, two materials, FLX935 and RDG845, were selected. According to experts, this mix should yield a material with a tensile strength of 10-14 MPa and Shore hardness of 85-90. However, the Young's modulus was similar to that of silicone due to the silicone-based nature of these materials. The result was a material that was too flexible and had lower stiffness compared to TPU. Given the time constraints, a full study to create more materials with properties similar to TPV was not feasible.

Fig. 92: Fusion-jet prototype

In conclusion, TPU proved to be the most similar to TPV, proving that TPV can be a good option for the device. Although it is not as rigid as TPV, it was the best option available for demonstrating the concept to practitioners. However, due to time constraints, further research into other options, such as creating new materials using FusionJet technology or change design details like thickness or add ribs, was not possible.

6.7 Discussion

Chapter six focuses on transforming a concept into a tangible product. Exploring mechanisms through analogies of everyday products helped to develop a feasible and familiar mechanism for users. The decontamination and sustainability requirements posed significant challenges in the embodiment of the product, particularly in material selection. Granta EduPack, with its extensive database, proved to be a powerful tool that facilitated the work-flow. However, critical thinking and well-established requirements were still necessary.

Material selection was the biggest challenge in this chapter due to the restrictions and the difficulty in testing TPV in real-life scenarios. Various prototyping and manufacturing techniques were attempted but without success.

Thanks to the literature research on ergonomics in chapter two, the selection of sizes was efficient, resulting in a very ergonomic design for users. Additionally, as seen in chapter six, user feedback on shape and colour was crucial in defining the detailed design of the speculum.

Through a development phase, the questions asked at the beginning of the chapter have been addressed

1.What are the most effective design features to enhance usability and patient comfort?

The most effective design features to enhance usability are not necessarily complex mechanisms or advanced technologies. This chapter demonstrates that simple, existing mechanisms can be highly effective in ensuring usability. Regarding comfort design features, ethical concerns made it challenging to directly test comfort with patients. However, using training models like the Mama U or the specially designed model helped evaluate features such as the shape of the device's tip and the opening mechanism.

2,How can the design ensure compatibility with existing sterilization processes?

Ensuring compatibility with existing sterilization processes requires a thorough understanding of each process's specific requirements. Material selection is crucial, as it must align with the sterilization methods to ensure that the material remains effective and safe. Utilizing extensive databases like Granta CES EduPack can facilitate the workflow by helping identify materials that meet these criteria.

Fig. 94: Picture with some prototypes

Chapter 7

Lilium: the new speculum

This chapter presents the results of the project, Lilium, including an explanation of its use and details. The concept is evaluated through several aspects: desirability is assessed with evaluations from users and doctors; sustainability is examined using a product journey map and an LCA analysis; feasibility is explored by looking into costs, manufacturing processes, and legislation; and viability is determined through a competitor analysis.

Methods used:

- Methods:
- User evaluations
- Journey maps
- LCA analysis
- BoM

7.1 Lilium

Lilium is the final product that integrates the needs of the medical sector, sustainability and patient comfort.

This new device offers patients two insertion options: self-insertion, similar to tampon applicators, or insertion by healthcare professionals. This option empowers patients, transforming them from ‘passive patients’ to ‘active patients’.

Lilium is made of semi-flexible, medical-grade TPV rubber, which has the mechanical strength to withstand the pressure of vaginal walls and the flexibility to open the blades. The device is composed by only two components: a inner part and a exterior part, called petals. The reason behind is due to the similarity of the mechanism with a flower due to when the inner part push the exterior, this one unfolds in a way that resembles the petals of a flower.

This design choice intended to promote patients' psychological comfort when viewing the device, using familiar shapes. . In addition, the symbolism of flowers has long been associated with women, feminism and fertility.

Lilium is designed not only with patients in mind but also with the planet. Its design emphasizes safe reuse and features a simple cleaning process, enabled by its minimal number of components. Lilium is compatible with both high-level disinfection and autoclaving, making it a versatile, sustainable, and hygienic option for gynaecological care.

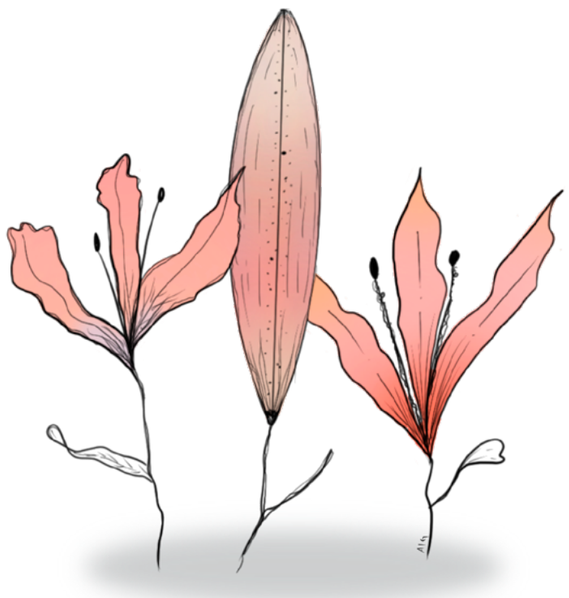


Fig. 95: Lirium sketch

Fig. 96: Render of the final product

Use

The device, Lilium, is designed with a "one-size-fits-all" approach to simplify its use, eliminating the need for doctors to choose different sizes for most patients. However, for cases where a larger tool is necessary or for specific patient ergonomics, a larger model can be used by swapping the inner part with a bigger one.

Insertion Process:

- **Self-Insertion**: If the patient prefers to insert the device herself, the process is similar to using a tampon applicator **(1)**. The practitioner can assist by positioning themselves in front of, beside, or away from the patient, depending on the patient's comfort level.
- **Doctor Insertion (2):** If the patient opts for the doctor to insert the device, the mechanism operates similarly to an injection.
- **Opening the blades**: To open the blades **(4)**, the doctor or patient has to hold the with the thumb against a small tongue where the snap fit is located, simultaneously pushing the inner part inside **(3)**
- **Locating the Cervix:** If the practitioner needs to adjust the position of the device for a better view of the cervix, the inner part can be pushed out slightly, allowing the blades to close partially. Thanks to the ergonomic design and appropriate dimensions, the device can be gently rotated **(5)**, once closed, without causing pain. This feature sets the device apart from current speculum, which often require complete removal and reinsertion to achieve a better view.
- **Visualizing the Walls:** Although not common, certain pathologies can manifest on the walls of the vagina, necessitating examination by the practitioner. To facilitate this, the inner part of the device is designed not to cover the entire length of the exterior part, allowing clear visibility between the blades **(6)**. If the practitioner needs to examine the vaginal walls, they can rotate the device using the same procedure as when locating the cervix, ensuring a comprehensive view without needing to remove and reinsert the device.
- **Orientation and Locking:** The absence of a handle permits the device to be comfortably positioned in any orientation. Once the desired opening is reached, the lever is released, locking the mechanism in place **(7)** to start with the exam **(8)**

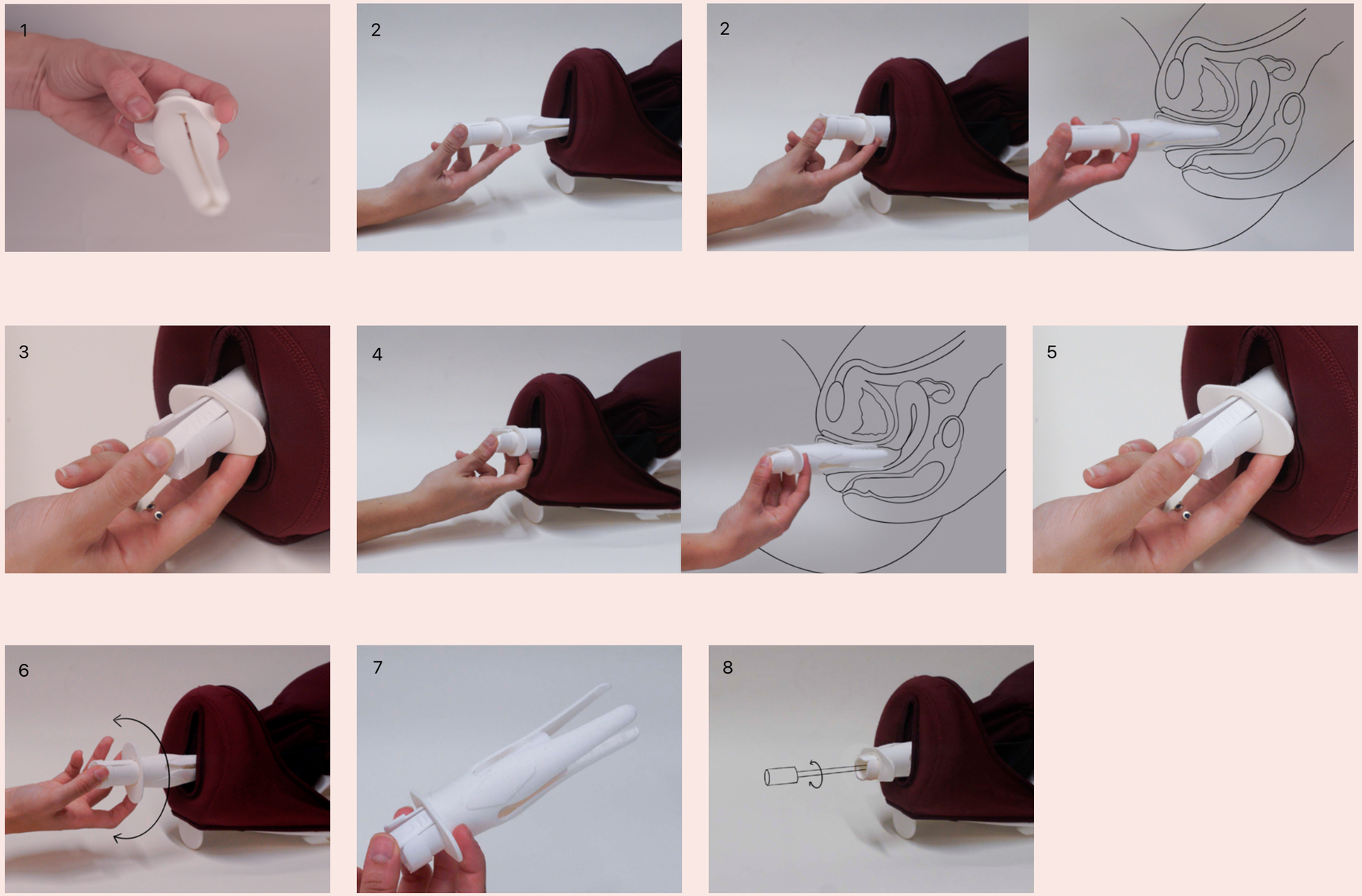


Fig. 97: Pictures done with a prototype of the insertion

Removal:

- **Closing the Blades**: To close the blades, the practitioner first withdraws the device by 2 cm. **(9)**. Then, the practitioner unlocks the device and withdraws the inner part using the same movement as during insertion **(10)**. A visual indicator **(11)**, a line on the inner part, allows the doctor to confirm that the blades are properly closed and that the visible area has not come into contact with the patient's body, making it safer for the doctor to handle the part for the removal.
- **Removal:** To remove the device, the doctor holds the inner part just beyond the visual line and carefully removes it completely (12), placing it directly in the decontamination area (13). This ensures that the doctor avoids any contact with any potential pathogens. After removing the inner part, the doctor can gently remove the exterior part (14) and place it in the decontamination area as well.

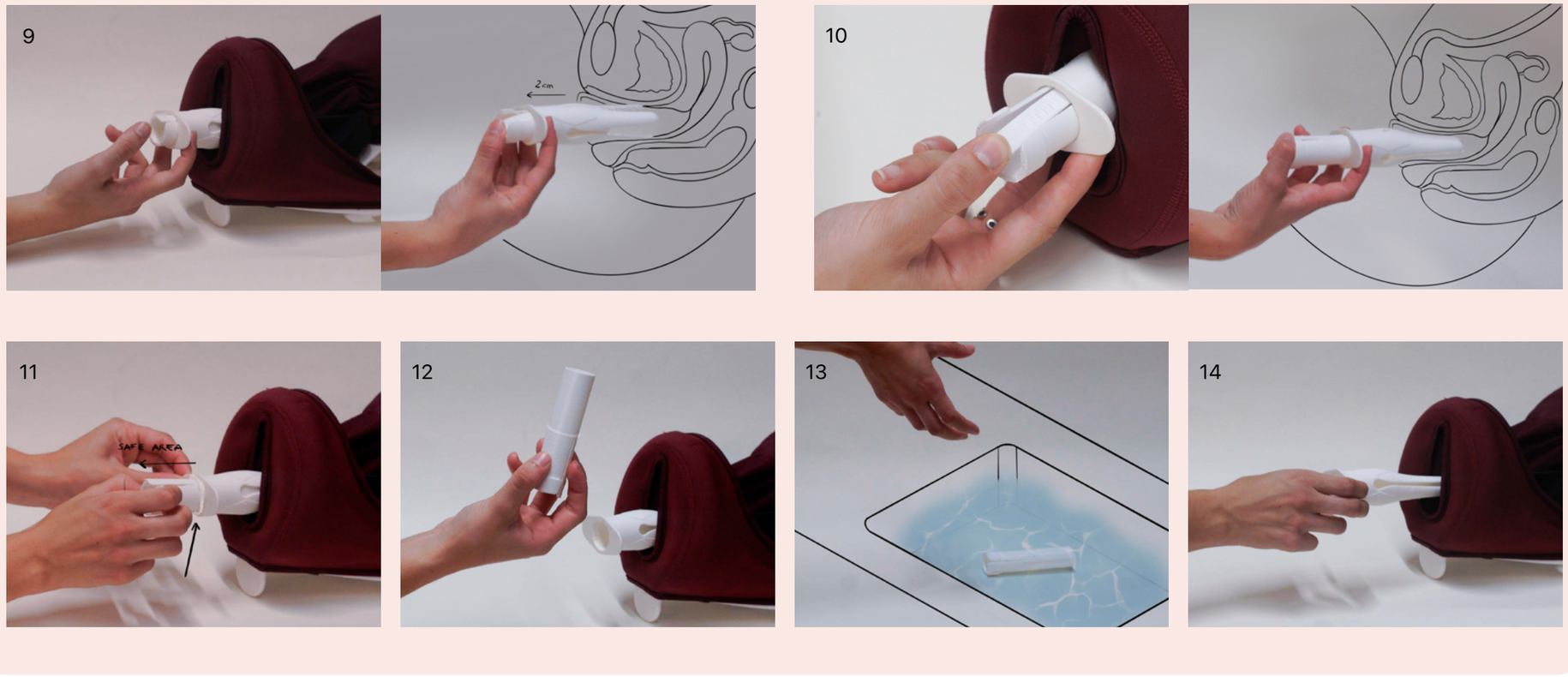


Fig. 98: Pictures done with a prototype of the removal

Decontamination:

- **No Need for Disassembly**: Since the device is removed from the body in separate parts, there is no need for an additional disassembly process, streamlining the cleaning procedure **(15**).
- **Manual Cleaning**: Lilium is designed without screws or small joints that are difficult to clean such components, making the process less time-consuming **(16)**.
- **Easy Assembly:** The device can be easily reassembled without the need for extra tools, simplifying the process and ensuring it is ready for the next use **(17)**
- **Autoclave Sterilization**: The device undergoes a standard autoclave cycle at 132°C for 10 minutes **(18)**.
- **Cool Down:** After sterilization, the device is cooled down for 10 minutes before being handled or stored.

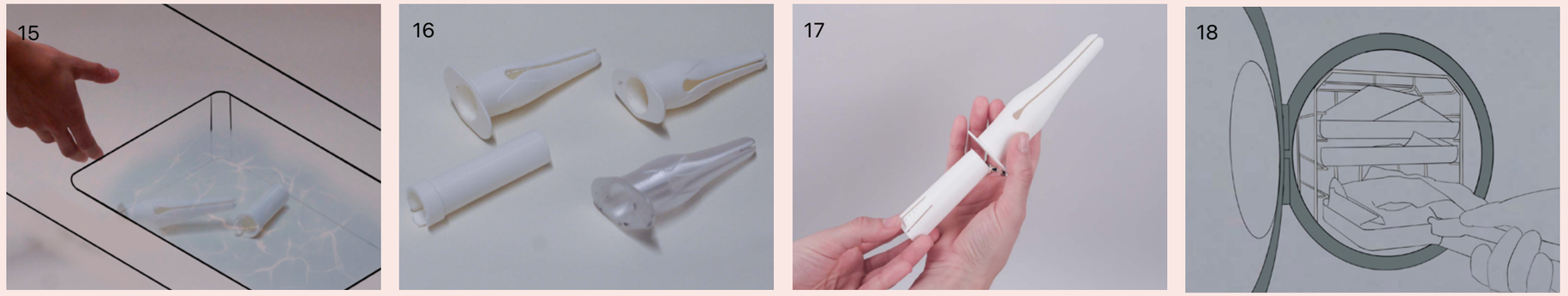


Fig. 99: Pictures done with a prototype of the decontamination

7.1.1 Lilium's details

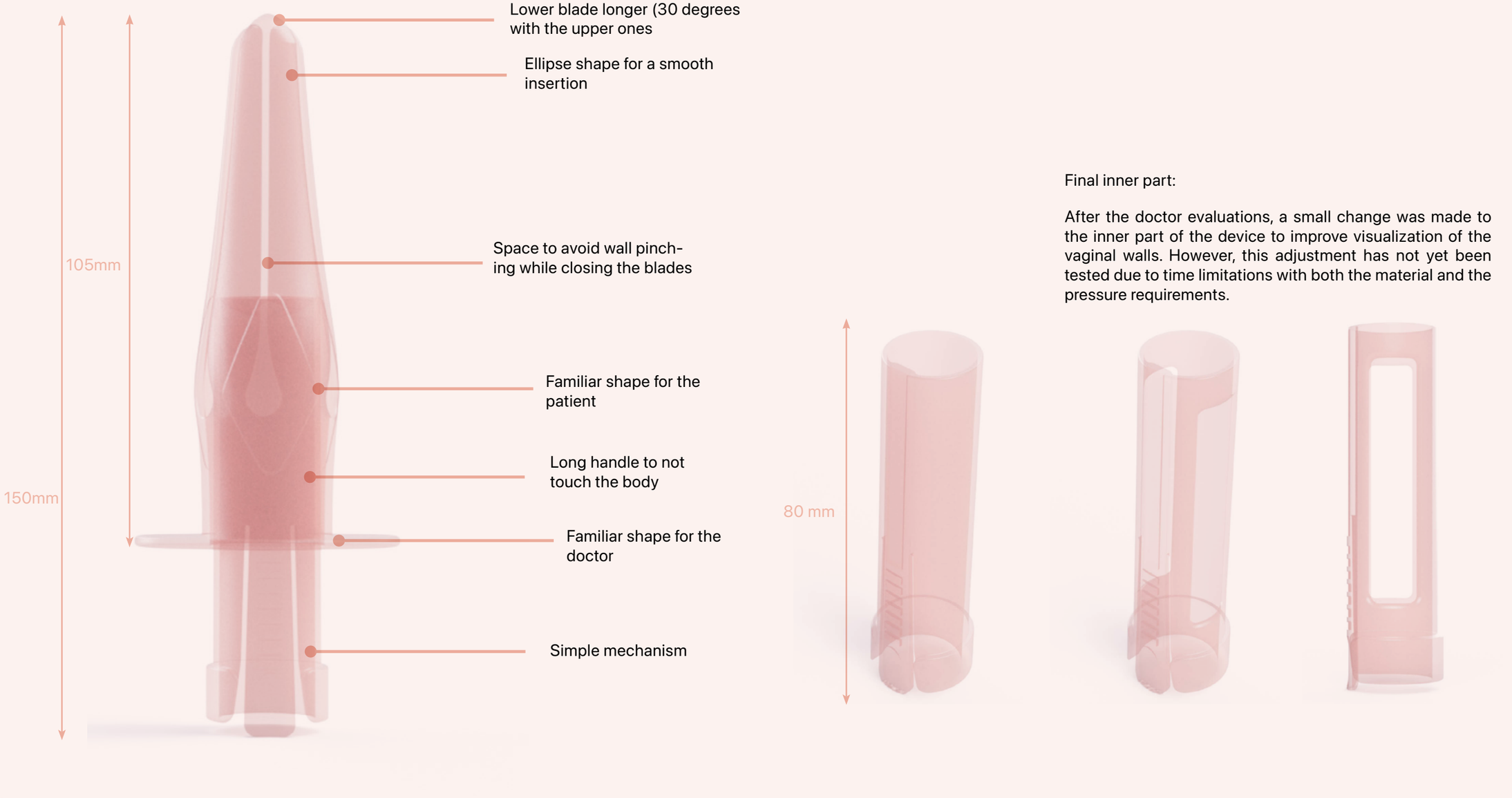


Fig. 100: Renders Lilium

7.2 Desirability

Lilium's desirability refers to the extent to which people want the product and whether it effectively meets their needs and desires. To evaluate this, two validation tests were conducted: one with practitioners and another with patients.

7.2.1 Doctor's validation test

The doctor's validation test was conducted through an informal conversation with five nurses and two doctors at Reinier de Graaf Hospital in Delft. During the discussion, participants were able to try a TPU prototype of Lilium using a pelvic training model available at the hospital. The main objectives were to gather opinions on the new device and evaluate its interaction and usability. The main insights are as follows:

1. Improved cervix visualisation

During the conversation doctor's agree that the wall prolapse is a huge issue for cervix visualisation, specially for obese patients. They appreciate the three blades solution since it will help them in the work-flow.

"it's very useful obese woman, they also have the prolapsing wall and with the ones that we have we can not see anything"

"I can also imagine that you have less prolapse when you have three blades instead of two blades, even if they are small"

2. Enhanced insertion and usability for doctors

Nurses and doctors explained that with the current speculum, they need to insert their fingers into the introitus to slightly open the vaginal walls and reduce patient discomfort (figure 101). However, after using Lilium with the pelvic training model, they agree that this technique is no longer necessary with Lilium because the shape of blades of the new device are very smooth (figure 102).

Fig. 101: Practitioners need to place a finger inside to slightly separate the walls to make the insertion process smoother.

Fig. 102: Practitioners do not need to place a finger inside when inserting Lilium.

Additionally, they noted that the shape of the new device allows it to rotate easily within the vagina without causing pain to patients during the insertion

"For some women this position is painful and maybe this is not so painful,I if I insert the device diagonal then I have to rotate it again, and with yours always is going to be the same shape like even if you rotate it a bit. So I can inserter it and find the best position better"

"It's like more soft and easier the insertion for me"

"As a woman, You don't feel it rotating so much (Lilium) as this one (current). I think this one is much more perceptible (current)"

Another point they highlighted is that the small tip of Lilium minimizes the risk of damaging the urethra during insertion. With the current device, they need to rotate it 45 degrees to avoid contacting the urethra, but this adjustment is not required with Lilium.

3. Potential use for young patients and balloon insertion when giving birth

During the conversation, it was suggested that Lilium could be particularly suitable for patients who have never had sexual intercourse due to its dimensions and friendly shape. Additionally, it was noted that Lilium might be useful for balloon insertion during labour. Practitioners explained that during labour, patients are often highly dilated and may experience wall prolapse, which complicates the visualization of the cervix. In such cases, where condoms are not used and there is no mechanism to hold the walls, Lilium's design could offer practical benefits.

The first thought I have when I see it is that it's good for when you want to place a balloon and vagina walls are prolapsed.

4. General impression and Improvements

Both nurses and doctors viewed Lilium positively, highlighting its potential, especially with the three-blade option and the perceived comfort for both practitioners and patients. They also appreciated the aesthetics and noted how different it looks compared to current devices.

"I think this is brilliant"

"I think it's really innovative, and friendly"

They suggested a few changes:

- Increase the diameter to 30 mm.
- Add holes in the inner part to improve visibility of the vaginal walls.
- Design different sizes, considering both diameter and length.

"Like more versatile, you can use a bigger one in the case that you need more expand or a longer one, because everyone is different"

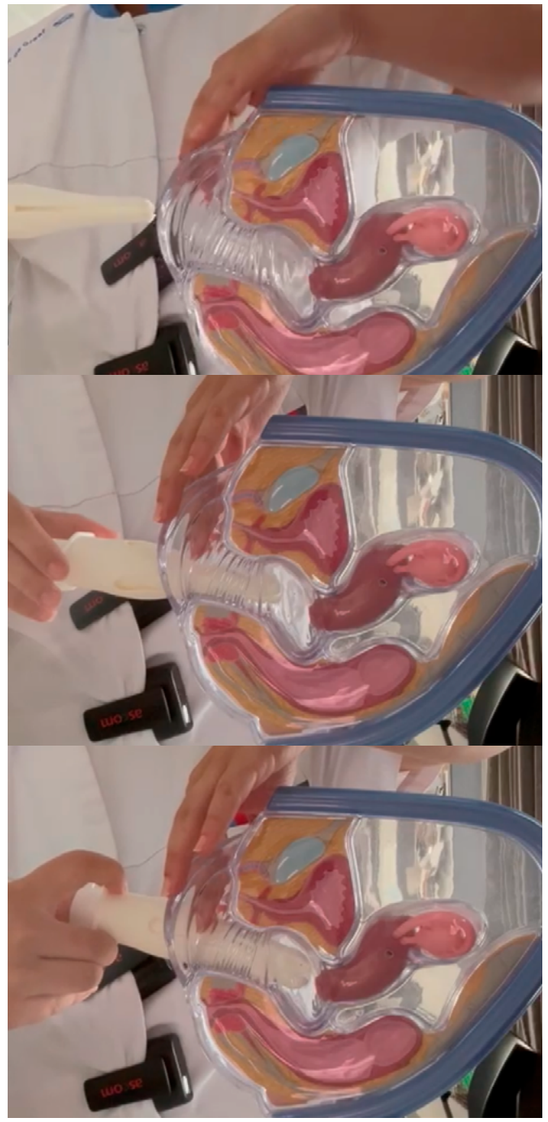


Fig. 103: Nurse trying Lilium prototype

Fig. 104: Liliium with the single-use speculum that they use in the Hospital

7.2.2 Patient's validation test

The validation with patients aimed to gather their opinions and insights on two aspects of the device: their thoughts on the possibility of self-insertion and self-removal, and how they perceived Lilium compared to the current speculum.

The user validation test was conducted simultaneously with the shape evaluation interview mentioned in Chapter 6, involving interviews with 8 participants. The results are as follows:

Self-Insertion and Self-Removal

Most participants agreed that having the option to choose between self-insertion and a traditional method would make them feel less stressed during the exam. When asked which option they preferred, 6 out of 8 participants chose self-insertion, responding very positively to having this possibility.

"I feel very uncomfortable when the doctor touch me. I am very shy with this things. To know that I can do it by myself it make me feel more invested"

"I think I am in control of my body. I am putting something in myself voluntary and I can feel if it is painful I can go slowly. It will be more gentle"

"Because if it's work the same way as a temp tampon, it's really easy to do it by yourself. Once you understood it"

While self-insertion was viewed as a potentially preferred option by some patients, self-removal was less favoured. This is because the removal phase is generally not as critical or invasive as insertion. Additionally, knowing that removal is the final step in the process helps patients feel more relaxed.

General opinion

Overall, like the doctors, patients seemed very excited about the new design and expressed eagerness for the product's market launch. When asked which device they would prefer between the current speculum and Lilium, all participants chose Lilium. This makes Lilium a highly desirable product, especially for patients, due to its shape and dimensions.

"The form seems more like it's kind of curvy and in my head it's more it's it feels like it's more fluid like it would"

"Like the metal and the whole like screw and everything makes it really look like a torture instrument"

"So it seems to be something more logic to put in my vagina than a screw like, because it's something that I would use also by myself on other occasion"

"It seems more familiar and make more sense to put it inside than the current one"

Fig. 105: Render of Lilium with the current device

7.3 Sustainability

Lilium's sustainability is evaluated using the same methods that have been used to evaluate the current devices: LCA and Product Journey map.

LCA Analysis

To evaluate the footprint of Lilium, an Eco Audit was conducted using Granta EduPack. This ensures consistency in material information, as the same database and software were used for both material selection and sustainability assessment. Given that the product is still in the early stages of development, the Eco Audit serves as an approximation of the sustainability impact, with some assumptions made regarding transport and manufacturing location.

- Material, Manufacture, and End of Life:

  Flower:

  - Material: TPV D40
  - Mass: 0.27 kg
  - Primary Process: Polymer injection
  - End of Life: Reuse

  Inner:

  - Material: TPV D50
  - Mass: 0.13 kg
  - Primary Process: Polymer injection
  - End of Life: Reuse

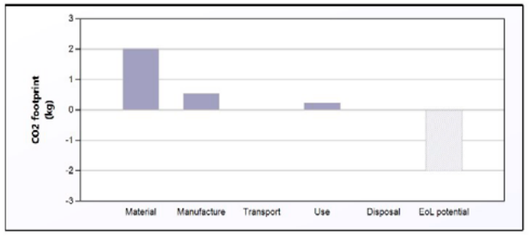
- Country of Manufacture: Europe
- Package Dimensions: 0.1 x 0.1 x 0.1
- Transport:

  - Supplier: Celanese (provides TPV molding injection material, specifically SANTOPRENE® TPV, used in both material analysis and Eco Audit)
  - Location: Germany (assumed for transport calculations)
  - Transport Type: Small truck
  - Distance: Approximately 200 km

- Use:

  - Life cycle: The TPV material can withstand 100 cycles of sterilization. Assuming one cycle per day, the product lifespan is approximately 4 months.
  - Energy Use: While the software cannot directly calculate the impact of sterilization, it does include the energy consumption of the device. To estimate this, the energy used for autoclave sterilization per cycle, based on the study by Snijder & Broeren (2022), was included as the energy consumed for the device.

The results of the eco audit are as follows. The full report can be found in Appendix F.



	CO2 (kg/year)
Equivalent annual environmental burden (averaged over 0,5 year product life):	5,59

Phase	Energy (MJ)	Energy (%)	CO2 footprint (kg)	CO2 footprint (%)	Cost (EUR)	Cost (%)
Material	40,5	78,7	2,01	72,0	1,09	55,8
Manufacture	7,23	14,0	0,542	19,4	0,774	39,6
Transport	0,1	0,2	0,00721	0,3	0,0156	0,798
Use	3,56	6,9	0,229	8,2	0,0719	3,68
Disposal	0,0667	0,1	0,00467	0,2	0,00183	0,0935
Total (for first life)	51,5	100	2,79	100	1,95	100
End of life potential	-40,5		-2,01			

Fig. 106: Results LCA. Imported from Granta EduPack

The Eco Audit results provide an initial understanding of Lilium's environmental footprint, particularly in terms of CO2 emissions:

- **Footprint**: Lilium has a carbon footprint similar than stainless steel grade 316 model, with an estimated 2.48 Kg CO2. for the first use, wich is still higer than single-use PP model (0,88kg CO2)
- **Limitations**: The software is unable to calculate the environmental impact of the device when reused. So, even in the first use of the device the footprint is higer it can be that after several reuses the impact is reduced as happens with the SS model
- **Durability Consideration:** It is important to note that while stainless steel can withstand over 500 sterilization cycles, TPV can only withstand around 100 cycles. This significant difference in durability will impact the overall footprint of the device, potentially leading to a higher environmental impact for TPV over its shorter life cycle compared to stainless steel.

Product Journey Map

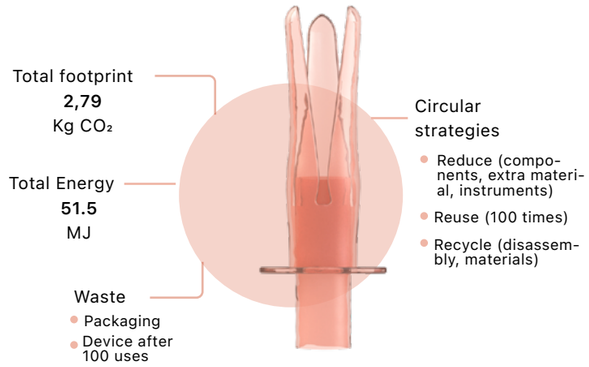
The LCA analysis calculated above does not take into account the larger environmental impact associated with the waste generated together with the equipment or the use of additional products necessary to complete the function of the device. To include this in the analysis a product journey map has been conducted.

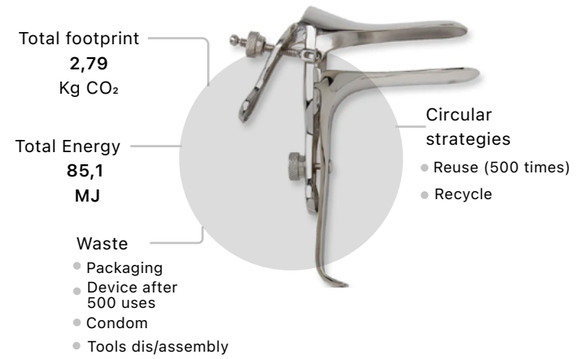
If the two journey maps are compared (Figure 37 and Figure 107), the following key differences are observed:

- **Reduction of Steps**: The new Lilium speculum eliminates several steps that are typically part of the current product journey, such as warming the device, adding a condom, and disassembly. In terms of sustainability, these changes can be translate into the following impact:

  - **Reduction of Warm Water Use**: The elimination of the need to warm the device reduces the use of warm water, leading to energy savings.
  - **Elimination of Extra Materials**: By removing the need for a condom and additional tools for assembly or disassembly, Lilium reduces the consumption of extra materials and tools, contributing to a decrease in overall waste.

- **No Single-Use Option:** Unlike traditional speculums, which often include single-use components, Lilium is designed for reuse. This design choice reduces the generation of medical waste and lessens the environmental burden associated with the production and disposal of single-use items.





**One cycle

Fig. 108: Comparison Lilum vs current reusable speculum

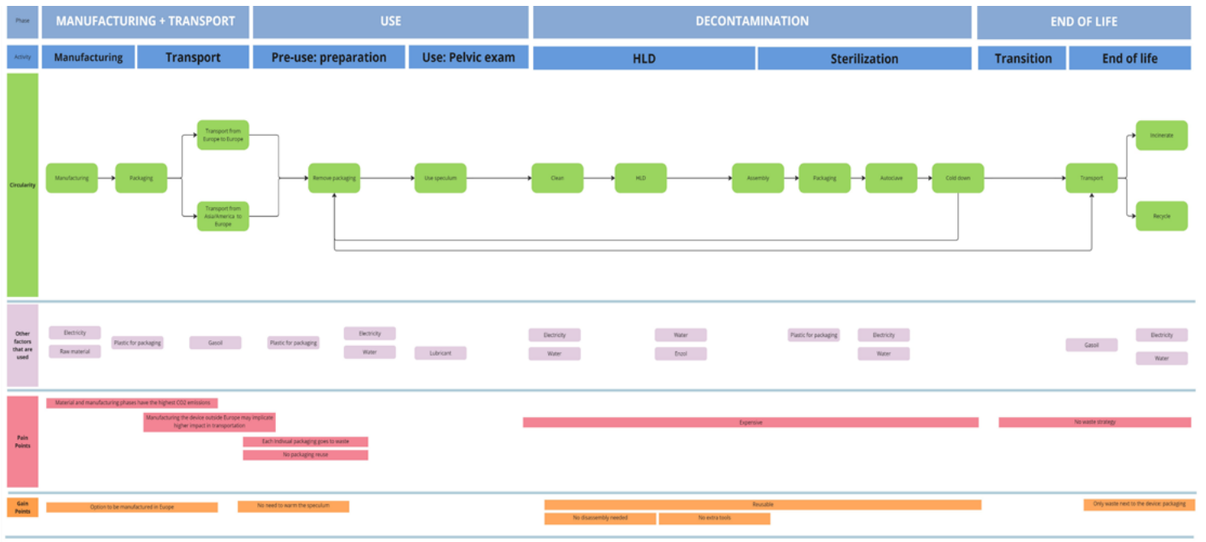


Fig. 107: Lilium journey map

7.4 Feasibility

Lilium's feasibility refers to the practicality and possibility of developing the product given the available resources, technology, time and constraints. To evaluate it, three different areas have been explored:

Technical Feasibility:

Studying the technical feasibility of Lilium will provide an approximation of whether it is possible to manufacture the product. At this design stage, the device is not yet ready for manufacturing, and material testing needs to be completed before finalizing the design for production. Given the current material and shape, the manufacturing process will likely be injection moulding (figure 110). This choice may lead to design changes, such as adding draft angles or addressing aesthetic aspects like parting lines and extrusion marks.

In the future, it will be important to study how the manufacturing process affects both aesthetics and material properties. Injection moulding of elastomer is a common and feasible technology for this device.

As mentioned, Lilium is a simple product composed of only two components and the Bill of material is the following one.

Bill of Materials - Lilium			
Q	**Part**	**Material**	**Manufacturing**
1	Exterior	TPV D40	Moulding injection
1	Inner	TPV D50	Moulding injection
1	Packaging	NA	NA

Fig. 109: BOM Lilium

Processing properties

Polymer injection molding	Acceptable			
Polymer extrusion	Excellent			
Polymer thermoforming	Acceptable			
Linear mold shrinkage	1,4	-	2,1	%
Melt temperature	188	-	198	°C
Mold temperature	8	-	50	°C
Molding pressure range	76,4	-	135	MPa

Fig. 110: Process properties TPV. Imported from Granta Edupack

Economic Feasibility:

Economic feasibility will provide an estimate of the cost to develop the product and use. Since the product is still in the early stages, decisions regarding material suppliers, manufacturing companies, and material finishes will significantly impact the final cost. However, a cost estimation has been conducted to evaluate the economic feasibility.

Costs Lilium		
Part	**Q**	**Cost (€)**
Raw material TPV D40	0.27 Kg	
Raw material TPV D50	0.15 Kg	
Moulding injection exterior part[1]	1	9.270
Moulding injection inner part[1]	1	13.445,85
Exterior part injection[1]	1	2,63
Inner part injection[1]	1	5,85
Manufacturing cost	-	NA
Personal cost	-	NA
Packaging	-	NA
Purchase of autoclave[2]	-	800
Training staff[2]	-	100
Reprocessing time[3]	-	6000
Annual cleaning solution[2]	-	600

Fig. 111: Approximation of the list of cost

[1]The cost calculation for the mould was obtained through a quotation from Potolabs. While injection moulding has a high initial cost, the cost per unit decreases with larger production volumes. As illustrated in the figure 112, the cost impact reduces significantly with increased batch sizes.

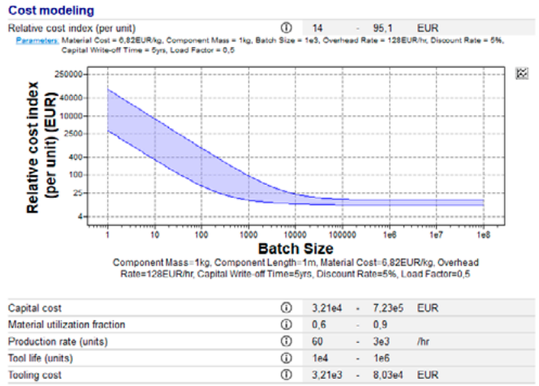


Fig. 112: Cost moulding. Imported from Granta Edupack

[2]Data obtained from the cost analysis for a reusable metal speculum from the manufacturer Welch Allyn in 2018.

[3]Since Lilium requires less time for reprocessing compared to the metal speculum—due to fewer steps involved (no disassembly, faster brush cleaning owing to the lack of critical design features)—the estimated reprocessing cost of 12,000€ provided by Welch Allyn has been reduced by half for Lilium.

Legal Feasibility:

According to the EU Medical Devices Directive 93/42/EEC, the vaginal speculum is classified as a Class I risk device (UNICEF, n.d.). This classification means that before the device can be launched and marketed within the EU, it must comply with several legal requirements.

Given the complexity of medical legislation, the most general procedures are outlined below:

- **Medical Device Regulation (MDR)**: Lilium must adhere to the Medical Device Regulation (Regulation (EU) 2017/745), which outlines the safety and performance requirements (EMA, n.d.).
- **Clinical Evaluation Report (CER)**: Lilium will need to undergo clinical evaluation tests to assess its performance in clinical settings. A full clinical evaluation is required before the device can be launched on the market (VDR, 2023).
- **Quality Management System (QMS):** A Quality Management System must be established in compliance with ISO 13485, an international standard for medical device quality management. This is essential for marketing, distributing, or servicing Lilium in regulated markets such as the EU and the US (PTC, 2024).
- **Conformity Assessment**: This process includes an audit of the manufacturer's quality system and a review of technical documentation on the safety and performance of the device, depending on its type (EMA, n.d.).
- **CE (Conformité Européenne) Mark**: Lilium will receive the CE mark after successfully passing the conformity assessment (EMA, n.d.).

7.5 Viability

The viability of Lilium refers to its business potential and its ability to sustain itself in the long term.

To evaluate this at the current stage of the product, a competitor analysis has been conducted with the result of the market research done in page 19 to assess Lilium's potential positioning in the market. Additionally, a SWOT analysis is used to further understand the strengths, weaknesses, opportunities, and threats related to the device.

Lilium's positioning in the market

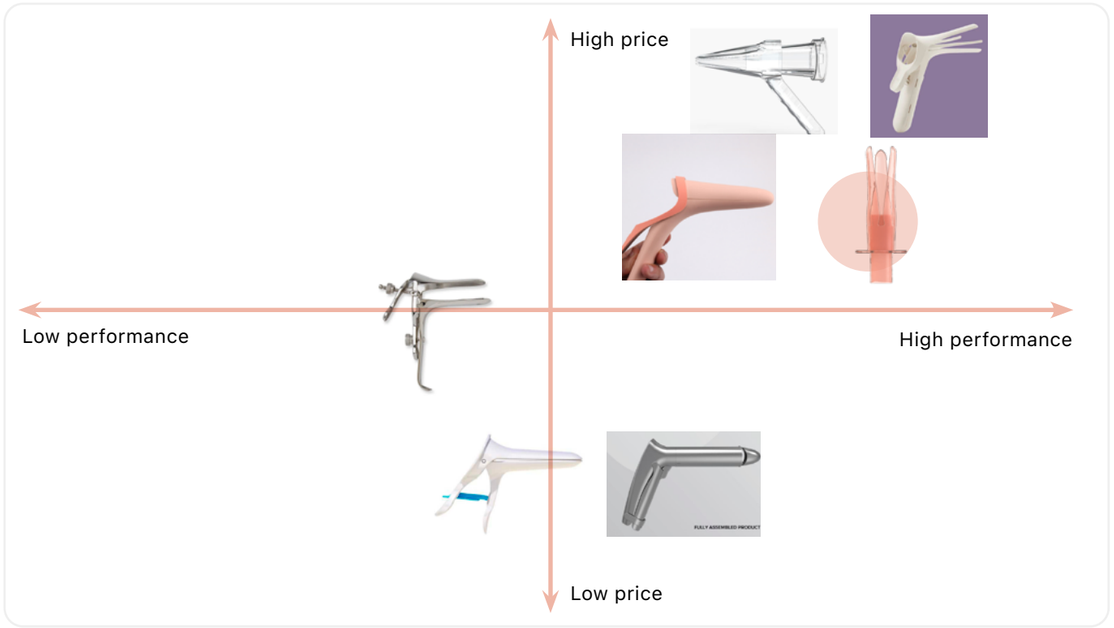


Fig. 113: Price vs performance market positioning

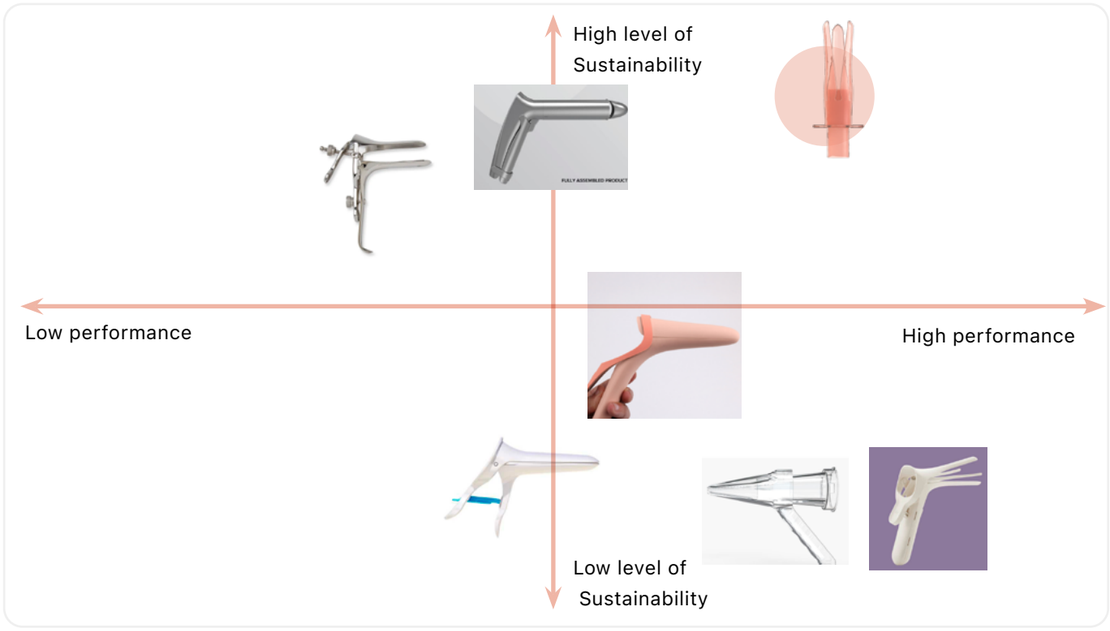


Fig. 114: Sustainability vs performance market positioning

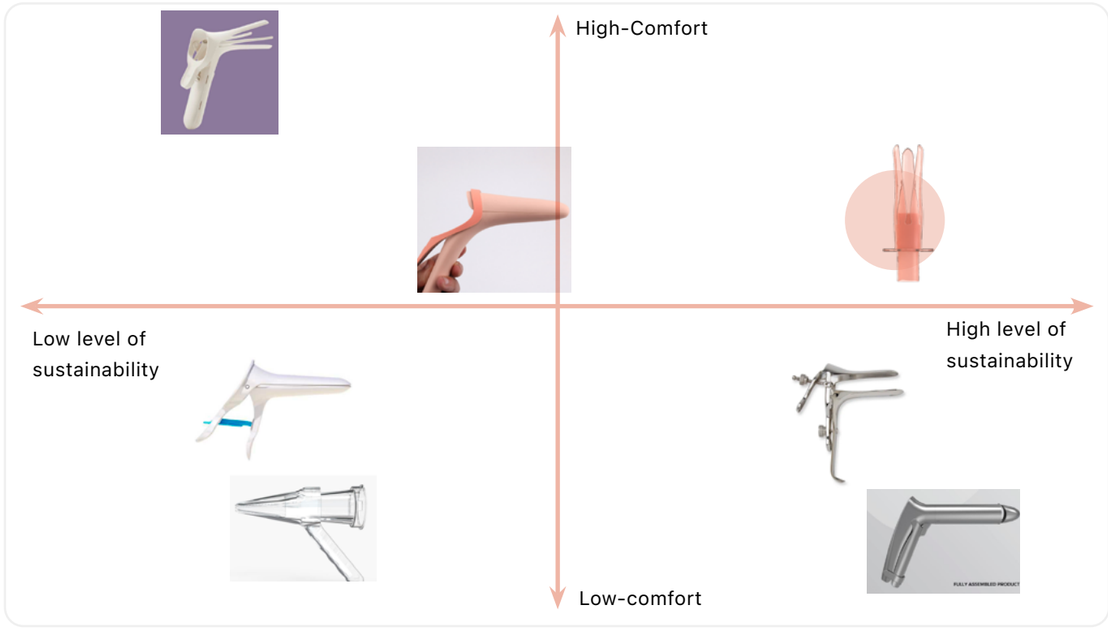


Fig. 115: Sustainability vs performance market positioning

SWOT Analysis

STRENGTHS

- **Enhanced Visualization**: The three-blade design offers better cervix visibility.
- **Improved Rotation**: The shape allows easier rotation to locate the cervix.
- **Minimized Urethral Contact**: The design reduces the risk of touching the urethra.
- **Efficient Decontamination**: The speculum is easy to clean and sterilize.
- **User-Friendly:** Its ergonomic shape is easy to handle and use.

WEAKNESSES

- **Concept Stage**: The Lilium is currently a concept and must undergo regulatory approval and testing.
- **Limited Use:** It is not yet suitable for surgical procedures.
- **Sterilization Limit**: The TPV material can only withstand 100 sterilization cycles.
- **Performance Issues**: It has difficulty functioning with a prolapsed uterus.

OPPORTUNITIES

- **User-Friendly Design**: The Lilium is easier to use compared to current market options, offering a more intuitive experience for practitioners.
- **Sustainable Option**: It provides a sustainable solution for hospitals, potentially reducing waste and costs associated with disposable speculums.
- **No Additional Accessories Needed**: Unlike other devices, the Lilium doesn't require condoms or other techniques to hold vaginal walls during examinations.

THREATS

- **Higher Cost**: Lilium may be more expensive for hospitals, which could limit its adoption.
- **Competitors**: There are existing competitors, such as Orchid Spec that offer similar performance, posing a challenge to Lilium's market entry.
- **Adoption Challenge:** Introducing the new shape and mechanism to doctors could be difficult, as it requires training and acceptance of the new design.

Chapter 8

Discussion

This final chapter discusses the contributions and added value of the project. Additionally, it includes recommendations and explores the project's limitations.

8.1 Contributions

This project aimed to redesign the vaginal speculum by considering not only the physiological and psychological needs of the patient but also the requirements of practitioners, the healthcare system, and circularity. Although these three areas have distinct design requirements, which can sometimes conflict, the challenge was to find a balance between them. This balance was achieved through detailed research and careful prioritization of requirements.

This project not only introduces an innovative vaginal speculum but also reaffirms the importance of a user-centered design approach. It moves beyond the famous "form follows function" principle by emphasizing the significance of incorporating user thoughts and needs into the process. Additionally, it explores how form, when shaped by function, can impact the user experience, and highlights the lack of research on emotional user experience through aesthetics in healthcare products. Moreover, it highlights the significant gap in current research regarding women's ergonomics, an area that remains under explored.

Contribution to the Healthcare Sector:

This project explores alternatives to the traditional two-blade design through a literature review, proposing a new three-blade device to enhance visualization and workflow. By applying circular strategies and offering a reusable option, the project also contributes to the healthcare sector by providing more sustainable solutions that align with the EU's new regulations, such as the Green Deal.

Contribution to Patients:

Throughout this project, special attention has been given to ergonomics, comfort, and aesthetics. By adopting a patient-centred design approach, the resulting speculum differs significantly from the current design, which was historically developed using enslaved women without their consent and without considering their voices.

Contribution to Sustainability:

This project not only challenges traditional medical device design and user-centered approaches but also emphasizes sustainability. What differentiates this project from other speculum redesigns is the application of circular strategies. For example, it reduces the number of steps required for decontamination, which also lowers costs, making the reuse option more attractive to hospitals. Additionally, the project minimizes the quantity of other components needed alongside the device and proposes a material selection methodology that considers decontamination requirements.

Contributions for Future Projects:

During the development of this project, an unexpected challenge arose: prototyping. Due to the sustainable and product requirements, TPV was chosen as the material after analyzing various options. However, verifying the material and the mechanism required prototyping, which proved challenging since TPV is not commonly used in 3D printing. Several alternative technologies and materials were tested, including TPU, PETG, PLA, and material blends. This project opens up a research opportunity to explore how accessible technologies can simulate final manufacturing materials like TPV, and to develop a material guideline for similar cases.

8.2 Limitations

Time Limitations

Medical devices are highly complex products that require extensive time for development. This project was completed within a limited time frame of 100 days, which restricted the depth of exploration in certain research areas, such as high-risk infections, other medical procedures where the device might be used, and additional prototyping. Additionally, during the patient journey mapping study, it was observed that the lack of information about the device and the examination process negatively impacts the patient experience. The initial idea for Lilium included an app or service that would provide information to users before their appointment. However, due to time constraints, this aspect of the project could not be developed.

Final Validation of the Product

a. Material

Although the material, TPV, has been validated through SolidWorks simulations and reviewed by experts, there remains a possibility that it may not perform as expected in real-life applications. Components often behave differently in practice than in simulations.

b. Testing

Testing was a known limitation of this project. Due to medical and ethical regulations, as well as the current phase of development, Lilium has not been tested with real patients. However, patient validation efforts focused on the aesthetics and emotional experience of the product and doctors were able to test a prototype using medical pelvic training models available at Reinier de Graaf Hospital.

8.3 Recommendations

More Sizes (Diameter and Length)

During the final evaluation with doctors and nurses, it was noted that the device needs to be available in different sizes to accommodate all patients. For future work, it is recommended to explore not only varying diameters but also different lengths.

Materials exploration

Further investigation into alternative materials is recommended to ensure the device meets all functional, safety, and sustainability requirements.

Legislation

It is essential to review and comply with the latest medical device regulations, both locally and globally, to ensure the product's market readiness.

Design for Manufacturing

Future iterations should focus on optimizing the design for manufacturing, considering factors such as cost, ease of production, and scalability.

Scalability of the Product

While this project was based on the context of the Netherlands, it is recommended to explore the potential for global expansion, adapting the product to different markets and healthcare systems.

Education Strategy

Knowledge and information are powerful tools. Even if the device is highly ergonomic and visually appealing, some patients may still feel apprehensive. It is recommended to develop education strategies that hospitals can use to provide patients with clear, understandable information about exams and female reproductive healthcare.

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Appendix

IDE Master Graduation Project

Project team, procedural checks and Personal Project Brief

In this document the agreements made between student and supervisory team about the student's IDE Master Graduation Project are set out. This document may also include involvement of an external client, however does not cover any legal matters student and client (might) agree upon. Next to that, this document facilitates the required procedural checks:

- Student defines the team, what the student is going to do/deliver and how that will come about
- Chair of the supervisory team signs, to formally approve the project's setup / Project brief
- SSC E&SA (Shared Service Centre, Education & Student Affairs) report on the student's registration and study progress
- IDE's Board of Examiners confirms the proposed supervisory team on their eligibility, and whether the student is allowed to start the Graduation Project

STUDENT DATA & MASTER PROGRAMME

Complete all fields and indicate which master(s) you are in

Family name	Izcara Gual
Initials	AIG
Given name	Ariadna

IDE master(s) IPD ✓ DfI SPD

2nd non-IDE master

Individual programme *(date of approval)*

Medisign

HPM

SUPERVISORY TEAM

Fill in he required information of supervisory team members. If applicable, company mentor is added as 2nd mentor

Chair	Jan-Carel Diehl	dept./section	Sustainable Design Engineering
mentor	Anna Ruiter	dept./section	Ergonomics Department
2nd mentor			
client:	Tamara Hoveling		
city:	Delft	country:	The Netherlands
optional comments			

! Ensure a heterogeneous team. In case you wish to include team members from the same section, explain why.

! Chair should request the IDE Board of Examiners for approval when a non-IDE mentor is proposed. Include CV and motivation letter.

! 2nd mentor only applies when a client is involved.

APPROVAL OF CHAIR on PROJECT PROPOSAL / PROJECT BRIEF -> to be filled in **by the Chair** of the supervisory team

Sign for approval (Chair)

Name _____ Date _____ Signature _____

Personal Project Brief – IDE Master Graduation Project

Name student Ariadna Izcara Gual

PROJECT TITLE, INTRODUCTION, PROBLEM DEFINITION and ASSIGNMENT

Complete all fields, keep information clear, specific and concise

Project title Enhancing Women's Healthcare: Redesigning the Vaginal Speculum for modern society

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

Introduction

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

The vaginal speculum - derived from the Latin *'specere,'* meaning 'to look' - is a popular device in women's healthcare. It is commonly used in pelvic examinations and procedures such as IUD insertions, helping practitioners in visualizing or accessing the cervix by retracting the vaginal walls.

This device was designed by J. Marion Sims in 1845. Its historical usage, particularly with the experimentation on slave women without consent or anesthesia, combined with the historical taboo surrounding women's bodies and sexuality, has led to a challenging legacy for this device whose design has almost remained unchanged until now.
Furthermore, the original design process was geared towards meeting the needs of the practitioner, with little regard for the comfort and well-being of patients undergoing the examinations (Arrivillaga et al. ,2023). The discomfort caused by the tool is one of the reasons why people with vaginas may avoid participating in examinations, a problem that is aggravated, for example, in the case of obese or menopausal patients. In addition, insufficient attention has been paid to the environmental impact of speculum production and disposal.

The main opportunity of this project is to improve the experience of using the vaginal speculum for twenty-first-century society. This will be achieved through the redesign of the device, taking into account the needs and preferences of both patients and practitioners, while also considering the principles of the circular economy for the product. As the main product is a medical device, the project will have certain limitations to consider, for instance, the real-life testing due to regulatory requirements.

Arrivillaga, M., Bermúdez, P. C., García-Cifuentes, J. P., Rodríguez--López, M., Neira, D., & Vargas-Cardona, H. D. (2023). Women's critical experiences with the pap smear for the development of cervical cancer screening devices. Heliyon, 9(3), e14289. https://doi.org/10.1016/j.heliyon.2023.e14289

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introduction (continued): space for images

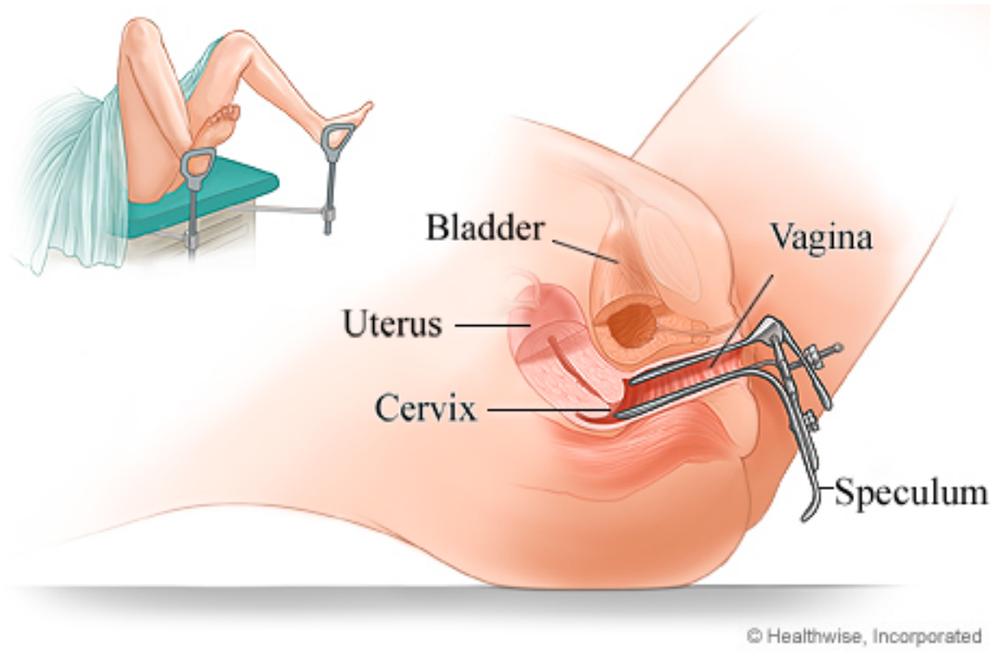

image / figure 1 Pelvic exam. Pelvic exam with speculum. (n.d.). https://myhealth.alberta.ca/Health/pages/conditions.aspx

image / figure 2 Speculum. Graves Vaginal speculum | MPM Medical supply. (n.d.). MPM Medical Supply. https://www.mp

Problem Definition

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

According to the introduction, the main research question for this project is the following one:

Is it possible to improve the vaginal speculum considering the physiological and psychological needs of patients, as well as the requirements of practitioners and the healthcare system and circularity?

The redesign of this tool widely used in gynaecology with the main objective of improving the physical and psychological comfort with the use of the product, will improve the experience for the professional and the patient. The redesign of this tool can change the current perception of going for gynaecological check-ups, motivating more patients to access this test and as a consequence saving costs to the Health Systems.

Furthermore, using a circular design approach to validate design decisions within this project can benefit stakeholders by reducing environmental impact, improving product durability and safety, and contributing to cost savings in healthcare.

Assignment

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

Redesign and prototype the vaginal speculum to improve the expereince of it use for patients and practitioners in Europe.

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

The project will consist of two main phases: Research and Development.

During the research phase, the project will focus on studying three main areas: patients, the medical sector, and circularity in the healthcare sector. The objective of this phase is to define and understand the needs and preferences of these three groups. To achieve this, a variety of methods will be employed, including interviews, observations, and co-creation sessions. Additionally, a thorough examination of the speculum, including its physical operation and historical context, will be conducted. Once insights have been gathered, a definition phase will follow, during which requirements and vision for the project will be established to start the redesign of the product.For the development phase, an engineering approach will be used, fcuing in the materials, modelling mechanism and aesthetics. The project will finish with a validation phase.

Project planning and key moments

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

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

Kick off meeting 5 Mar 2024

Mid-term evaluation 3 May 2024

Green light meeting 10 Jul 2024

Graduation ceremony 7 Aug 2024

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

Part of project scheduled part-time	
For how many project weeks	
Number of project days per week	

Comments:

Motivation and personal ambitions

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

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

The motivation for this project comes from my interest in learning and gaining expertise in the development of medical devices for the women's healthcare sector. Throughout it, I want to learn more about physical and cognitive ergonomics and explore new design methods that can contribute to achieving the project's objectives.

I also want to develop my ability to manage a complex project independently, fostering critical thinking and refining my working methodology.

With this project I also want to develop my ability to manage a complex project like this independently. Enhancing critical thinking mind and redefining my working methodology. I want to be able to delve into the most design engineering approach while remining mindful of current and future social contexts and learn how to critically evaluate not only the design themselves but also their impacts and meanings.

Finally, my motivation for this project is to successfully do an ambitious project with good results and conclude the masters with being proud of myself and my work.