

# Designing the instructional materials of fabricating a vesicovaginal fistula repair clinical task trainer

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# Acknowledgements

I am pleased to present my graduation thesis for the Master's degree in Design for Interaction at the Faculty of Industrial Design Engineering at TU Delft. This report presents the work accomplished during my graduation project. Throughout this process, I not only learned a lot about the subject itself, but also about independently leading and organizing a project.

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I am grateful to have completed this graduation project. Enjoy reading!

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# Abbreviations

BME = Biomedical Engineering

LMICs = Low- and Middle- Income Countries

MOOC = Massive Open Online Course

VVF = vesicovagina fistula

# Abstract

This thesis explores the design of instructional materials for the independent fabrication of a vesicovaginal fistula (VVF) repair clinical task trainer in low-resource settings. The clinical task trainer, developed by Biomedical Engineering for Global Health at TU Delft, aims to support surgical education by enabling local and affordable production through 3D printing, silicone casting, and assembly techniques. However, the existing instructional materials were found to be complex and difficult to follow independently.

To better understand the challenges makers experience during fabrication, the existing fabrication process was analyzed through user research and process evaluation. From this analysis, four key themes were identified, forming the starting point for the design phase. These themes focused on improving guidance throughout the fabrication process, reducing complexity, supporting independent fabrication, and creating clearer and more accessible instructional materials.

Based on these findings, three iterative design sprints were conducted. The first sprint focused on designing the overall maker journey, mapping how makers interact with the fabrication process from preparation to completion. The second sprint focused on redesigning the silicone casting instructions, while the third sprint addressed the assembly instructions. Throughout the design process, principles from instructional design and human-centered design were applied to improve clarity, usability, and engagement.

The developed concepts and prototypes were evaluated with users to assess comprehensibility, usability, and the level of support provided during fabrication. Insights from these evaluations informed the final design. The resulting solution consists of a website containing step-by-step instructional materials that guide makers throughout the complete fabrication process, including sourcing materials, preparing components, silicone casting, and assembly.

The final design supports makers in fabricating the VVF clinical task trainer more independently and confidently. In addition, this thesis contributes broader insights into the design of instructional materials for fabricating the clinical task trainer where accessibility, and usability are essential.



# Introduction

This chapter introduces the context and scope of the project. It outlines the global challenge of vesicovaginal fistulas (VVF) and the need for accessible surgical training. In addition, it introduces BME for Global Health, the client of this project. The chapter further defines the problem addressed in this project, presents the research question and describes the project approach.

- 1.1 Background
- 1.2 BME for Global Health
- 1.3 Problem Definition
- 1.4 Project Approach

# 01

## 1.1 Background

Globally, at least 3 million women, predominantly in Africa and South Asia, live with untreated vesicovaginal fistulas (VVF), with an estimated 30,000 to 130,000 new cases arising annually in Africa alone (El-Azab et al., 2019). A VVF is an abnormal connection between the bladder and vagina, typically caused by obstructed labour. This condition can result in urine leakage and lead to significant physical and psychological consequences; a more detailed description is provided in Chapter 2.2.1. Most cases require surgical repair; however, many medical professionals in low-resource settings lack both the experience and the necessary tools to perform or practice the procedure (Chinthakanan et al., 2023). Consequently, patients often must travel to specialized clinics for treatment, even though many cases could be successfully addressed with relatively simple surgical interventions. To address this issue, a clinical task trainer was developed by Tink Voskamp in collaboration with BME for Global Health (Voskamp et al., 2022). This clinical task trainer enables medical professionals to practice the surgical procedure, improve their skills, and provide effective treatment despite resource constraints (Voskamp et al., 2022).

## 1.2 BME for Global Health

Biomedical Engineering for Global Health Lab is a global initiative within TU Delft that focuses on developing medical innovations to improve global health and increase universal healthcare. The initiative is part of the Biomechanical Engineering department at TU Delft and functions as a research laboratory dedicated to tackling challenges in the field of access to medical technology worldwide. Through research and design projects, BME for Global Health aims to increase the availability of medical devices, collaborating with international partners to investigate current usage patterns and barriers in hospitals around the world. In addition to developing new solutions, the laboratory offers education and training both within TU Delft and to external stakeholders, thereby promoting global capacity building in the field of healthcare innovation.

This graduation opportunity was framed by BME for Global Health as a contribution to the development of an online platform for creating DIY 3D-printed and silicone clinical task trainers for surgical procedures. These task trainers are designed to support medical professionals in low- and middle-income countries in performing surgical procedures. The platform aimed to disseminate designs for three specific training phantoms: vesicovaginal fistula (VVF) repair surgery, vacuum delivery and caesarean section. The goal of this project was to define the fabrication process of the VVF clinical task trainer and to design the instruction materials.

## 1.3 Problem Definition

BME for Global Health develops clinical task trainers and phantoms to enhance surgical education in low-resource settings. The vesicovaginal fistula (VVF) repair clinical task trainer, as seen in Figure 1, is designed to train medical professionals in the transvaginal approach to VVF repair. This task trainer is constructed using 3D-printed PLA components and silicone parts, allowing for local production in low resource settings at a low cost. It enables the practice of all procedural steps involved in VVF repair, addressing the scarcity of training opportunities in regions where the condition is prevalent.



Figure 1: Vesicovaginal Clinical Task Trainer. Left: three-quarter view. Middle: front view. Right: side view.

The primary objective of this project is to ensure that the VVF clinical task trainer can be successfully fabricated by the maker. Through this project, two key factors have been identified as essential to achieving this goal:

- 1 clear and comprehensive fabrication instructions, and
- 2 access to the appropriate equipment, tools, and materials.

The focus of this project is the development of clear and complete instructions, enabling the maker to successfully fabricate the VVF clinical task trainer. Although the main focus of the project is on the development of the instruction materials, the project also introduces an approach for accessing the necessary materials.

The following main question was formulated to guide the project:

**“How should instructional materials be designed to enable independent fabrication of the VVF clinical task trainer in low-resource settings?”**

To provide clarity, it is important to distinguish between the individual who fabricates the task trainer and the individual who uses it for surgical training. In this project, the first user referred to the ‘Maker’ is the person responsible for fabricating the task trainer. While the end user, referred to as the ‘Trainee’ is the person who uses the clinical task trainer to practice surgical procedures (e.g. the surgeon in training).

In the overall scenario, the task trainer is fabricated by the maker using 3D printing, silicone casting and assembly. The maker operates the 3D printer and works with printing materials, silicone, and the associated tools throughout the process. Fabrication takes place locally in a low- to middle-income country, which is not specifically defined. Once the task trainer has been produced, it is used by the trainee to perform the surgical procedure. After use, the task trainer may be reused until the degradation of the silicone’s properties becomes unacceptable (Voskamp et al., 2022), with the number of potential reuse cycles to be determined through further investigation. When the task trainer is no longer usable, it is returned to the maker for repair or the fabrication of new components. This implies that the maker is not only responsible for the initial fabrication, but also for the maintenance and repair of the task trainer throughout its lifecycle.

The scope of this project focused on the development of the silicone casting and assembly instructions. Instructions for 3D printing and repair were not developed within this project. However, recommendations for these instructions were formulated. Figure 2 provides a visual overview of the first user and the end user in relation to the clinical task trainer and highlights the scope of the project.

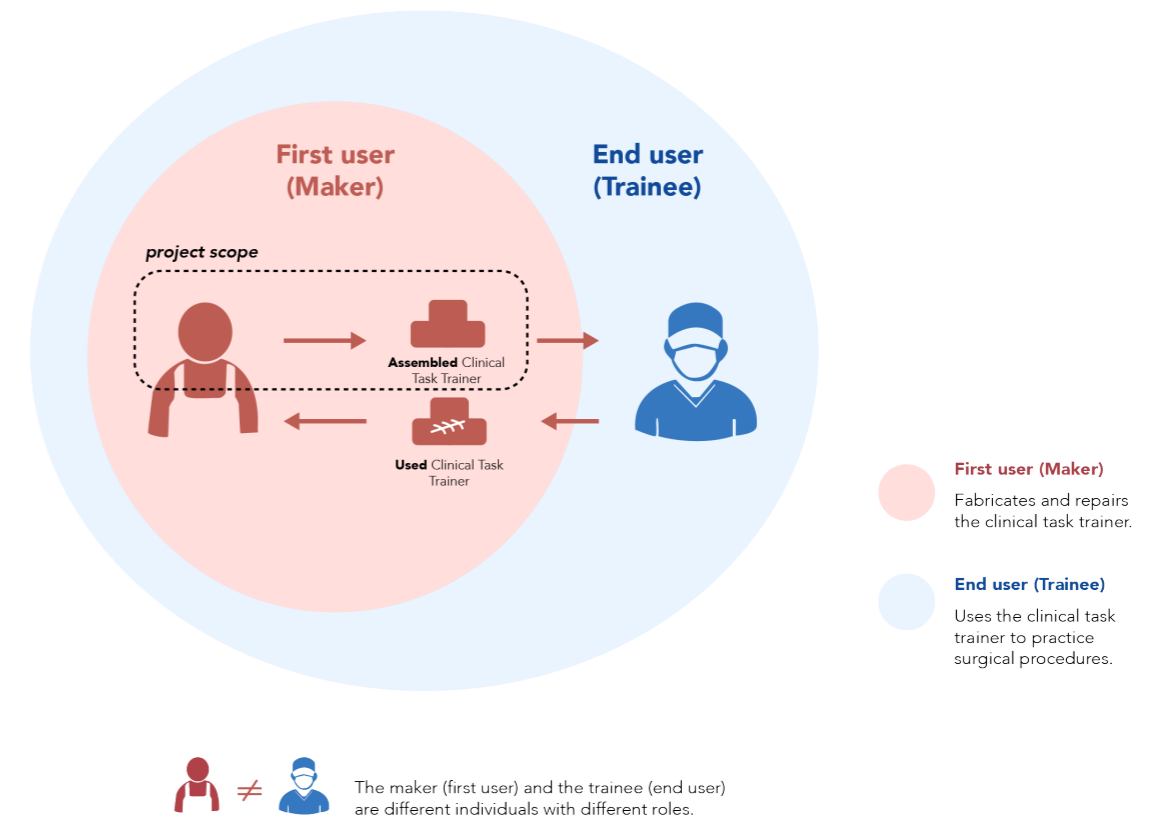


Figure 2: Visual overview of the first user, end user, and project scope

# 1.4 Project Approach

This project adopts a Research through Design (RtD) approach, in which knowledge is generated through the iterative process of designing, prototyping and evaluating (Godin & Zahedi, 2014).

To structure this process, the Double Diamond design framework is employed, consisting of four phases: Discover, Define, Develop and Deliver. This framework supports guiding the exploration of the problem space and the development of solutions by diverging and converging.

The main research question guiding this project is: "How should the instruction materials be designed to enable fabrication of the VVF clinical task trainer in low-resource settings?"

## Discover

The first phase is Discover, which focuses on diverging, aiming to explore and understand the problem space. The context is explored through hands-on fabrication of the task trainer using the existing instructional materials, complemented by desk research and interviews with experts involved in the design of the task trainer. In addition, the following sub question is addressed: "What challenges occur when using the current instruction materials to fabricate the VVF clinical task trainer?"

## Define

The second phase is Define, which focuses on converging. Insights gathered during the Discover phase are analysed and translated into a set of requirements. Based on these findings, a design goal is formulated, and interaction qualities are defined to describe the intended experience of the maker and guide the design process.

The design goal is defined as:

"Develop an instruction manual that enables users to successfully fabricate the clinical task trainer for vesicovaginal fistula repair while feeling guided and confident throughout the process."

## Develop

In the Develop phase, the process diverges again to generate potential solutions. This phase is structured into three design sprints. The design sprints are performed sequential from each other.

Through iterative cycles of ideation, prototyping and user-testing and co-creation, new insights are generated. These insights lead to the refinement of existing requirements and the formulation of new ones, which inform the subsequent iterations.

## Deliver

The final phase is Deliver, which focuses on refining and presenting the final design. The final design integrates the insights from the previous phases into a design that guides an independent and successful fabrication process of the clinical task trainer. The final design is evaluated against the requirements and interaction qualities.

Figure 3 provides a visual overview of the project structure, indicating how each chapter corresponds to the phases of the design process.

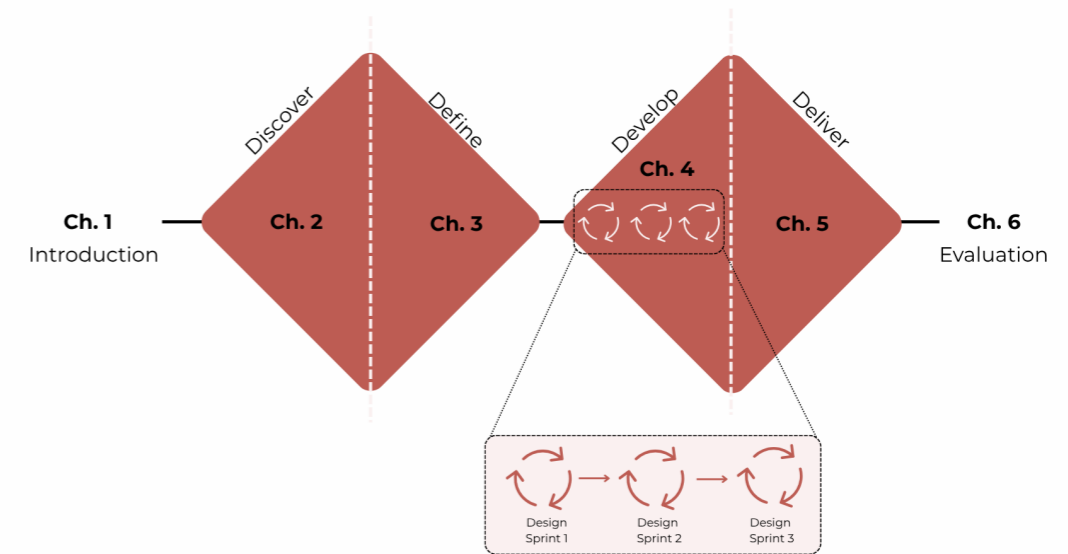


Figure 3: Visualisation of project approach

# Discover

This chapter presents the Discover phase of the project. The aim of this phase is to gain a clear understanding of the clinical task trainer and its context. First, the medical background of vesicovaginal fistula and the role of medical training is discussed. Next, the anatomy of the clinical task trainer is explained, followed by its use in surgical training. Subsequently, the existing fabrication workflow is presented and analysed to answer the sub question: “What challenges occur when using the current instruction materials to fabricate the clinical task trainer?”. The four leading themes that emerged from this analysis are presented and combined with insights from the literature.

## 2.1 Medical Background

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### 2.1.2 Medical Training

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## 2.5 Key Takeaways

# 02

## 2.1 Medical Background

This section provides context on a vesicovaginal fistula and its impact, highlighting the relevance of simulation-based training. It then introduces medical training and the role of task trainers, with a focus on application in low-resource settings.

### 2.1.1 Vesicovaginal Fistula

A vesicovaginal fistula (VVF) is an abnormal connection between the bladder (vesico) and the vagina, resulting in continuous urinary leakage through the vagina (Wall, 2006).

VVF occurs most frequently in low-and middle-income countries (LMICs), primarily due to obstructed childbirth, especially in parts of Africa, where early marriage and poor socioeconomic conditions are major contributing factors (Lee & Zimmern, 2019).

Obstructed labour occurs when the fetus cannot pass through the birth canal due to a mismatch between fetal size and the mother’s pelvic dimensions. This condition is more common in regions where girls experience malnutrition, early marriage, and pregnancy before full pelvic development (Wall, 2006).

VVF caused by obstructed labour develops when the fetal head puts prolonged pressure on the soft tissue between the bladder and the vagina, cutting off blood flow. Without enough oxygen, the tissue becomes damaged, breaks down, and eventually forms a hole (fistula) between the two organs (Wall, 2006). Figure 4 shows the fistula between the bladder and vagina.

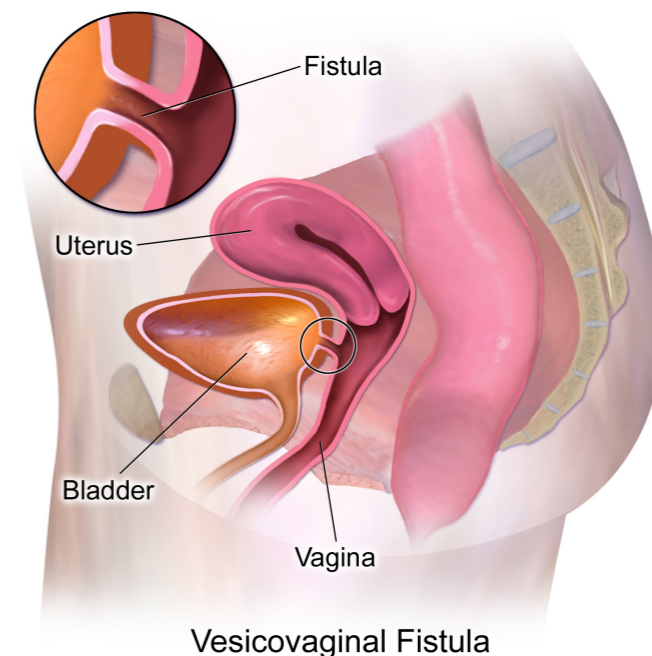


Figure 4: Female reproductive organs with typical location of a vesicovaginal fistula.

The consequences for women living with a VVF are not only physical but also psychological and social. Chronic incontinence often leads to social isolation, loss of social support, divorce, worsening poverty, malnutrition, and other illnesses, especially in traditional cultural settings (Wall, 2006). These severe consequences highlight the importance of treatment.

The high prevalence of VVF in LMICs is linked to poor access to quality healthcare and inadequate obstetric services (Wall, 2006). Although rare, VVF can also occur in high-income countries, usually because of surgical complications, radiation therapy or cancer (Wall, 2006).

VVFs can be simple or complex, and the surgical approach depends on the type of fistula. Repair can be performed either through a transvaginal or abdominal approach, depending on the complexity of the fistula. Complex fistulas may require an abdominal approach. However, the transvaginal approach is preferred for simpler cases, as it is minimally invasive, causes less blood loss, and allows for a shorter recovery time. (Lee & Zimmern, 2019).

## 2.1.2 Medical Training

Medical training is the structured educational process designed to develop the knowledge, skills, and professional competencies required to provide effective and safe medical care. A component of this training involves practical surgical procedures. Those often rely on specialized models to simulate the human body and clinical conditions to practice. Among these models, simulation-based training is a way to train surgical procedures. Such training utilizes a variety of tools, ranging from virtual reality systems to physical anatomical models. The following sections describe simulation-based models, including phantoms and task trainers and discusses the challenges of implementing simulation-based training in low-resource settings.

### 2.1.2.1 Simulation-Based Training

Simulation-based medical training refers to the use of engineered models and technologies that recreate clinical scenarios for hands-on practice. This approach allows learners to repeatedly perform surgical techniques, make decisions, and refine their skills without posing any risk to real patients. A category within simulation models includes task trainers and phantoms. A phantom is a physical model that replicates human anatomy and tissue properties, primarily used for imaging training and procedural practice. Phantoms range from simple tissue-mimicking blocks to complex anatomical replicas utilized in ultrasound, MRI, or CT imaging training (Keenan et al., 2024). Task trainers, in contrast, are designed to represent a particular body part or task, allowing learners to focus on practicing a specific surgical skill. They enable repeated, hands-on practice, which enhances confidence and proficiency for real-world application. The primary advantage of task trainers lies in providing opportunities for deliberate, focused repetition, supporting the development of both competence and assurance (Task Trainers, n.d.).

### 2.1.2.2 Simulation- Based Training in Low-Resource Settings

Simulation-based training in low-resource settings encounters several barriers, including limited infrastructure, time constraints, and the absence of an established simulation culture (Del Castillo Miranda et al., 2025). The high cost of commercial manikins, software, and high-fidelity models further limits accessibility, as many low-resource settings lack the financial resources to acquire these tools. Alternatives such as task trainers and low-tech manikins have proven effective in addressing these cost-related challenges (Del Castillo Miranda et al., 2025)

In addition, challenges such as limited access to commercial models and scarce training infrastructure hinder the widespread adoption of simulation-based training in low-resource contexts. Practical solutions include constructing task trainers locally from affordable materials and adapting them to meet regional healthcare needs (Del Castillo Miranda et al., 2025). These innovations allow surgical skills to be acquired despite resource constraints, thereby improving the quality and safety of healthcare. Consequently, it is advantageous that the VVF clinical task trainer is designed to be fabricated locally and independently. When producing the clinical task trainer locally, dependence on international supply chains is reduced. These supply chains may be unreliable, slow, or inaccessible in low-resource settings, so local production also facilitates easier maintenance and replacement.

## 2.2 Introducing the vesicovaginal clinical task trainer

This section introduces the vesicovaginal clinical task trainer used in this project. First, the relevant anatomy is outlined. Finally, the use of the task trainer in surgical training is explained.

### 2.2.1 Relevant Anatomy

The vesicovaginal clinical task trainer used in this project was originally developed as part of a thesis project by Tink Voskamp (Voskamp et al., 2022). Aiming to provide an accessible and locally reproducible surgical training tool in low-resource settings.

The vesicovaginal clinical task trainer is a simplified simulation model designed to train the surgical repair of simple vesicovaginal fistulas, defined as singular fistulas with a diameter smaller than 4 cm and performed through a transvaginal approach (Voskamp et al., 2022). During training, users practice identifying the fistula and performing suturing techniques, including watertightness of the closure.

The task trainer mimics pelvic anatomical structures relevant to the surgical procedure. This includes, the vulva, vaginal canal, bladder, urethra, and cervix, as well as the pelvic bone and a part of the pubic bone (see figure 5).

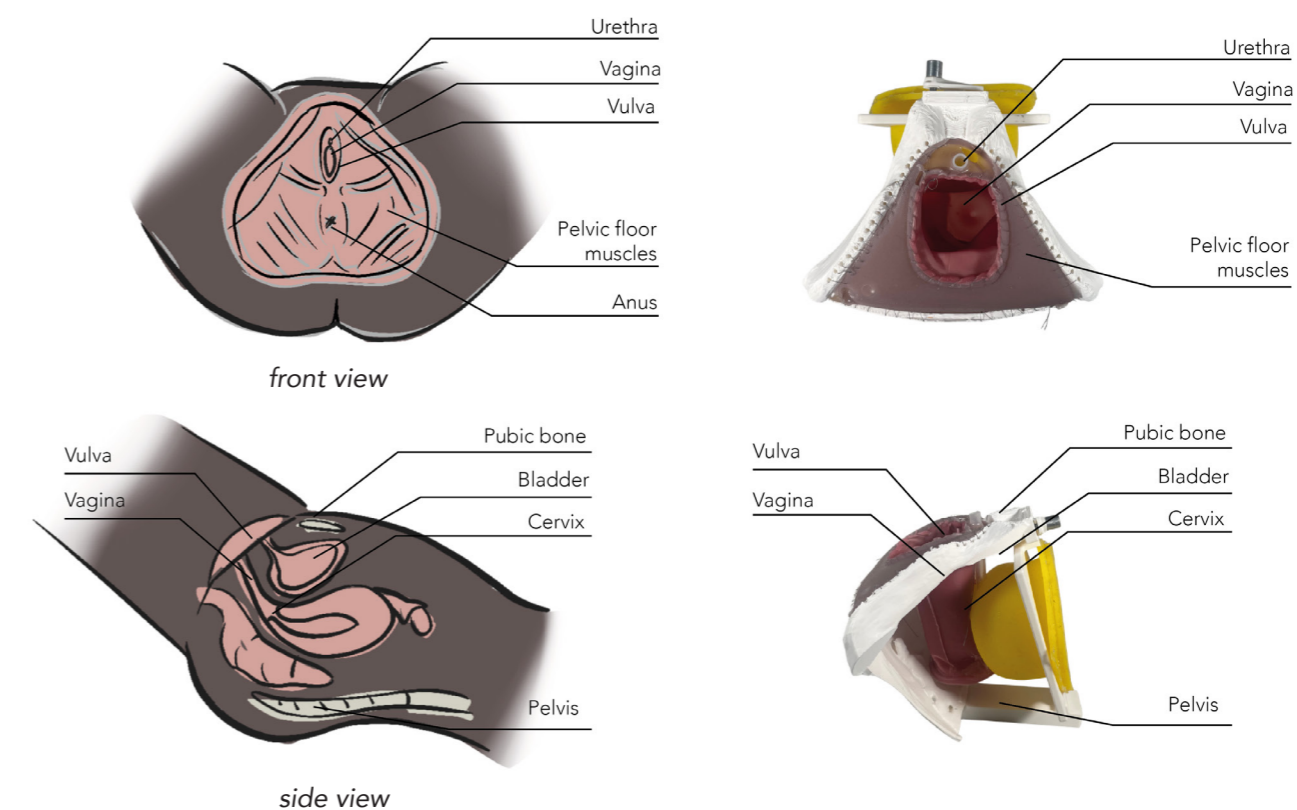


Figure 5: Representation of female anatomy and its corresponding components of the clinical task trainer.

The vulva component is intentionally simplified and does not aim to be fully anatomically realistic, as detailed external anatomy is not essential for training objectives of the surgical procedure. The vulva is presented in an opened position, representing the situation in which a vaginal speculum has already been inserted, allowing direct access to the vaginal canal during training.

The fistula itself is represented by a small circular opening in both the bladder wall and the vaginal wall. During the assembly of the model, these openings are aligned forming the fistula. The fistula opening in the vaginal wall features a thickened edge, which mimics the presence of scar tissue.

The task trainer was designed to enable local production in low- and middle-income countries (LMICs). For this reason, simple materials and simplified components are used in the design, allowing the task trainer to remain affordable and reproducible in local contexts.

## 2.2.2 Use of Clinical Task Trainer

Several techniques exist for performing a vesicovaginal fistula (VVF) repair using a transvaginal approach. Figure 6 illustrates one possible method of performing the surgical procedure on the clinical task trainer.

The procedure starts with identifying the fistula through the vagina and placing traction sutures. An incision is then made around the fistula in the vaginal wall. The fibrous ring, representing scar tissue obstructing the area, is excised and removed, exposing the bladder wall. The defect in the bladder is subsequently closed with a suture. The closure is tested for watertightness by inserting a catheter through the urethra and filling the bladder with liquid. Inside the vagina, a gauze is used to check for any leakage. Once the suture in the bladder wall is performed correctly, the vaginal wall is sutured and closed, thereby completing the procedure (Voskamp et al., 2022).

The photographs used in the figure were originally taken from the report by Tink Voskamp. The task trainer depicted in these images is one of the earlier versions, which is why its appearance differs from the most recent version introduced in this project.

The demonstrated surgical procedure shows that incision and suturing take place within the vaginal wall and the bladder wall, in an area of approximately 2 cm surrounding the fistula. In addition, a watertightness test is performed, highlighting the importance of a secure connection between the urethra and the bladder cup. Ensuring the suture in the bladder wall can be assessed accurately.



Figure 6: Demonstration of performed surgery on the task trainer.

## 2.3 Fabrication Process

This section presents the fabrication process of the clinical task trainer. The fabrication of the task trainer consists of a multi-stage process. This process includes 3D printing, silicone casting and assembly. After use by the trainee, the task trainer can be returned to the maker for repair. Figure 7 provides a visual overview of the stages the maker goes through.

In the 3D printing stage, all structural components of the task trainer are produced, along with the moulds required for silicone casting. After printing, the parts require post-processing, including the removal of support material and clearing of ventholes and injection holes.

In the silicone casting stage, the printed moulds are used to produce the silicone components. First, the parts of the mould are assembled and secured using bolts and nuts, after which the liquid silicone is injected into the mould. After curing of several hours, the mould components are removed resulting in a silicone component.

During the assembly stage, all 3D-printed and silicone components are combined to fabricate the task trainer. In addition to the fabricated components, the urethra (rubber tube) is necessary as well. The 3D-printed parts that form the framework are assembled using superglue, while silicone components are assembled using silicone glue. The urethra is attached to the silicone with superglue, and the silicone components are secured to the framework using a needle and thread.

After assembly, the task trainer is ready for use by trainees. After use, the fistula hole is closed with sutures, making the vagina and bladder cup components unusable. These components must therefore be replaced during the repair stage. The used silicone components are removed and reproduced in the silicone casting phase. The remaining components can be reused, after which the task trainer can be reassembled and used again.

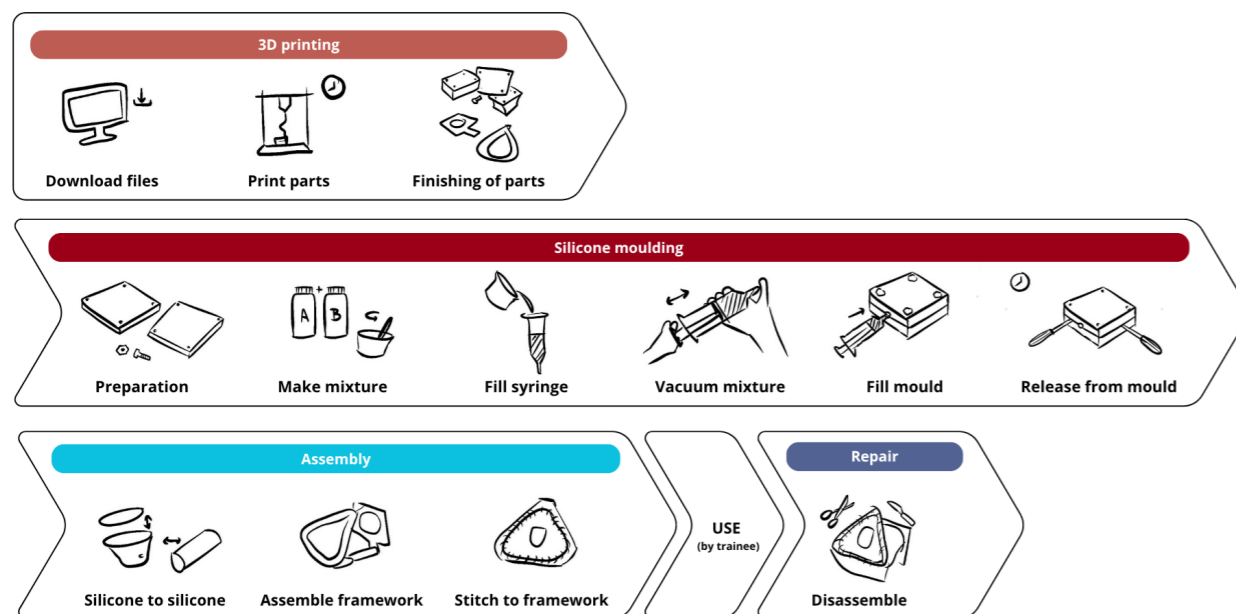


Figure 7: Fabrication Process

To provide a more detailed overview of the fabrication outputs of each stage, Figure 8 illustrates the components produced during the 3D printing, silicone casting and assembly stages.

The 3D printed framework components and the 3D printed moulds are produced during the 3D printing stage. During the silicone stage, the silicone components are made using the 3D printed moulds. The urethra is a component which is not made but necessary to fabricate the task trainer.

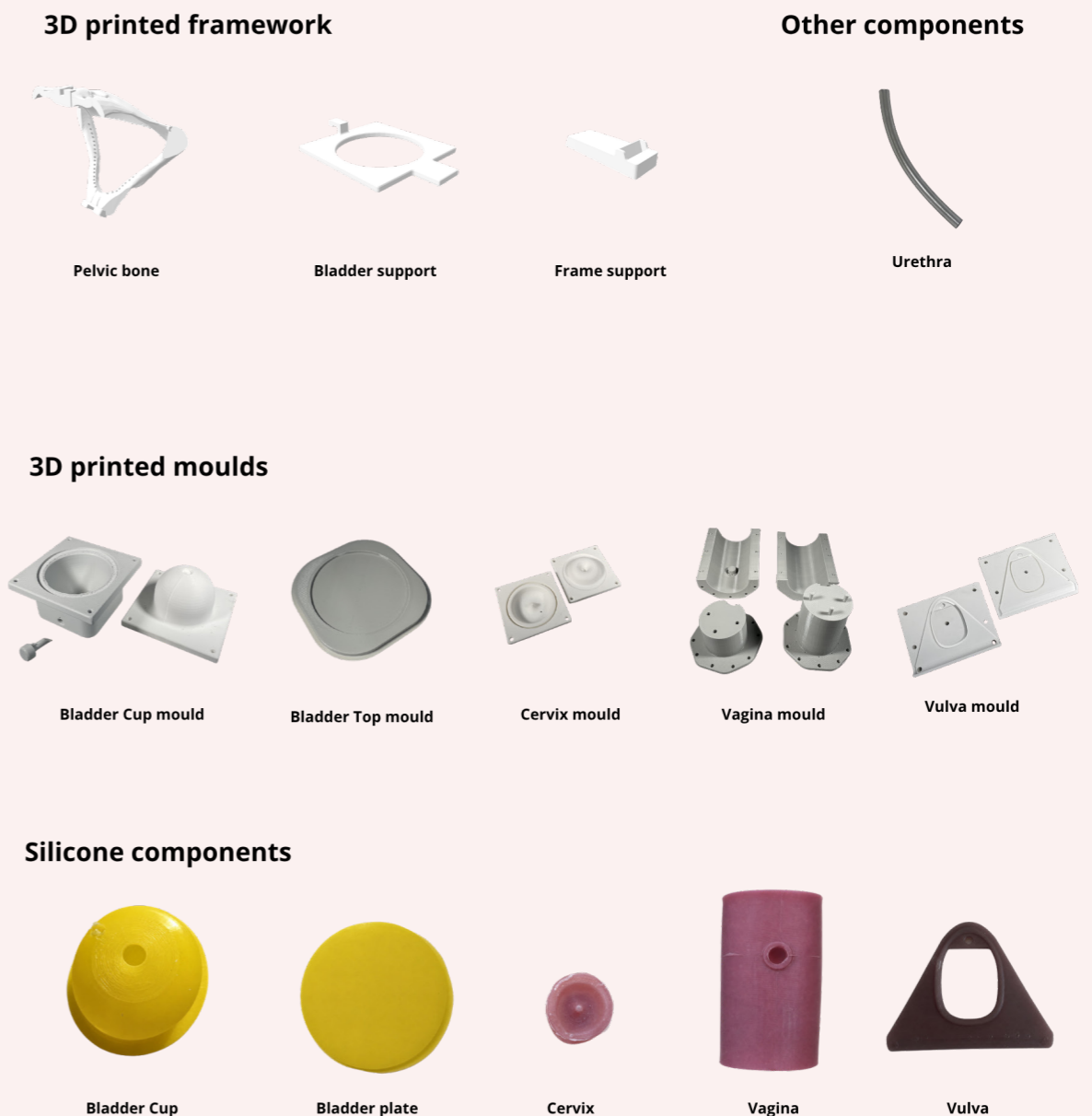


Figure 8 - Overview of the produced and necessary components to fabricate the task trainer

## 2.4 Insights from the Fabrication Process

This chapter provides an in-depth analysis of the fabrication process of the clinical task trainer. The insights presented are based on a first-hand exploration of the process, in which the researcher performed each stage of the fabrication. From this exploration, four key themes emerged. The first theme addresses the fabrication process, focusing on the overall journey of the maker. The second and third themes relate to the content and quality of the provided instructions. The final theme explores the differences between experienced makers and first-time makers.

Within each theme, specific issues that encountered during the process are discussed and supported with relevant literature. Together, these insights contribute to answering sub-question 1: What challenges occur when using the current instruction materials to fabricate the VVF clinical task trainer?

### 2.4.1 Theme 1: Fabrication Process as a Learning Journey

Based on practical experience, the fabrication process can be understood as a time-intensive procedure consisting of numerous stages and substages that must be executed in a specific sequence. In addition, the actions involved represent practical skills that the maker develops over time. This suggests that the fabrication process can be approached as a structured learning experience for the maker. To better understand this, the process is analysed using principles from instructional design and learning experience design, supported by relevant theoretical frameworks and practical applications.

#### 2.4.1.1 Instructional Design and Learning Experience Design

It was observed that the fabrication process is extensive, with waiting periods between the different stages and numerous components involved. Completing the process cannot be achieved in a single day. Consequently, it is essential that the maker remains motivated throughout, receives appropriate guidance, and is aware of what to expect during the process. Adequate preparation in advance regarding the workflow is important. Due to the prolonged and complex process, it is beneficial to structure it. Approaches such as Instructional Design and Learning Experience Design provide established frameworks for organizing learning processes, which can be applied to support the maker throughout the fabrication journey.

Instructional Design (ID) and Learning Experience Design (LXD) are often regarded as two related yet distinct approaches to the design of learning environments. ID focuses on the systematic design of instruction with an emphasis on measurable learning objectives, effectiveness, and reproducibility. Historically, it has been associated with a teacher-centered paradigm, emphasizing the transmission of knowledge and the control of learning outcomes. In contrast, learning experience design emerged from the design domain and focuses on creating meaningful, human-centered, and experiential learning processes that begin from the learner's perspective (Reigeluth & An, 2023). From the perspective of ID, classical models such as those developed by Robert Gagné and David Merrill form an important foundation. Gagné developed the Nine Events of Instruction, a framework describing the sequence in which information should best be presented to support effective learning. Each of these nine steps corresponds to internal cognitive processes that occur during learning (Kruse, 2008). The steps include gaining attention, informing the learner of the objective, activating prior knowledge, presenting new information, providing guidance, practice, feedback, assessing performance and promoting transfer to real-world contexts. This systematic approach, derived from behaviourism, emphasizes that learning builds on repetition, feedback, and the development of skills toward an autonomous, error-free level (Lin et al., 2024). Another influential theory within ID is Merrill's First Principles of Instruction. Merrill (1966) argues that effective instruction is based on five fundamental principles: activation of prior knowledge,

demonstration of new knowledge, application by the learner, integration of what has been learned into realistic contexts, and a task-centered approach to learning (Truong et al., 2019). These principles emphasize that learning is most effective when learners are actively engaged in solving meaningful tasks and when new knowledge can be applied immediately.

Whereas ID provides structure, clarity, and measurability, LXD introduces an empathetic and experiential dimension to the design process. LXD is described as a human-centered, iterative design approach that focuses not only on what must be learned but also on how that learning is experienced (Reigeluth & An, 2023).

According to Reigeluth and An (2023), a well-designed learning experience is characterized by several recurring principles. These include a learner-centered approach, goal-oriented design, the creation of cognitive dissonance and aha moments, and the use of multi-sensory and contextual elements. In this context, cognitive dissonance refers to the moment when the learner is confronted with a situation that does not immediately align with existing knowledge or expectations. It represents a temporary sense of confusion or tension that arises when new information does not fit within an existing mental framework. This tension stimulates the learner to think critically, reconsider assumptions, and integrate new knowledge (Miller et al., 2015). When the learner subsequently understands how the new information complements or corrects previous understanding, an epiphany occurs, a sudden sense of insight or comprehension that results in a meaningful change in knowledge (Reigeluth & An, 2023).

By deliberately integrating such moments of confusion and insight into the design process, learning becomes more active, meaningful, and enduring. This aligns with Kolb's (1984) experiential learning cycle, in which learning occurs through a continuous interaction between concrete experience, reflective observation, abstract conceptualization, and active experimentation. Instructions that allow room for mistakes, exploration, and reflection promote this cycle and enhance the learners' intrinsic motivation.

For the design of a learning experience that guides users through the fabrication of the phantom, this means that not only the what and how of the process should be defined, but also the why and how it feels to learn through making. The principles of ID and LXD therefore provide both structure and inspiration for the design process.

#### 2.4.1.2 Contemporary Applications of Learning Experiences

The frameworks of Gagné and Merrill are still applied today in modern contexts such as Massive Open Online Courses (MOOCs) and e-learning. Such approaches could also be considered for guiding the fabrication process of the phantom, presenting the process on an online platform. Contemporary applications of learning experiences are e-learning and MOOCs. E-learning involves the use of information and communication technology (ICT) tools to facilitate, support, and improve the processes of teaching and learning (Gachanja et al., 2021).

A MOOC is a form of technology-supported learning that offers large-scale, freely accessible education via online platforms. MOOCs are typically developed by universities or academic institutions and enable participants to engage with structured educational content, such as lectures, readings, assessments and discussion forums, without restrictions on time or location. In healthcare, MOOCs have become increasingly relevant as a means of supporting the continuing professional development of doctors by offering flexible, cost-effective and scalable training opportunities (Schettino & Capone, 2022).

The main advantages of MOOCs are their accessibility, affordability, and ability to provide high-quality education to a global audience, thereby promoting lifelong learning and professional growth (Schettino & Capone, 2022). This makes them an interesting tool to integrate into the fabrication process of clinical task trainers, particularly in low-resource settings, where access to traditional training opportunities may be limited. However, several limitations have also been identified,

including high dropout rates, limited opportunities for interaction between learners and instructors, language and digital literacy barriers, and inconsistencies in pedagogical quality. Despite these challenges, MOOCs represent a promising educational model with the potential to enhance knowledge dissemination and skill development across diverse professional contexts.

Since the maker's journey in the current fabrication process begins online, by downloading 3D print files, this presents an opportunity to implement e-learning or MOOCs.

### **Challenges of E-learning in LRS**

However, e-learning implementation in low-resource settings reveal several challenges that need to be addressed.

O'Flynn et al. (2024) emphasize that no two low-resource settings (LRSs) are the same. Each context differs in terms of healthcare infrastructure, available resources, disease patterns, and training systems. Nevertheless, they note that many shared challenges exist across these diverse settings, which broadly shape the effectiveness of e-learning.

Common challenges identified include limited internet connectivity, high data costs, and insufficient access to appropriate digital devices. Learners often face difficulties in finding suitable resources due to the overwhelming and scattered nature of available materials. The quality of e-learning content also varies widely, with frequent issues such as a lack of peer review, limited transparency regarding authorship and reliability, and insufficient use of learner-centered educational principles. Additionally, the content is often incomplete or repetitive, with some topics being overrepresented while others receive little to no coverage. Many materials are not adapted to the local context or integrated into formal training curricula, reducing their practical relevance. Finally, sustainability remains a major issue, as developing and maintaining high-quality e-learning platforms requires substantial time, funding, and ongoing administrative support, which are often lacking (O'Flynn et al., 2024).

O'Flynn et al. (2024) conclude that while local contexts differ, the focus for improving e-learning in LRSs should be on enhancing the findability, quality, and contextual appropriateness of resources, with a strong emphasis on sustainability and local ownership.

Although these challenges relate to e-learning, several aspects are relevant for the fabrication journey. Firstly, issues concerning incomplete content are apparent, which will be further addressed in Section 2.4.2. To account for limited internet connectivity, providing instructions is a practical solution, as it ensures that the process is not interrupted by connectivity issues. Furthermore, it highlights the importance of presenting the process and instruction material in a clear and manageable way, and available in one central location.

#### **2.4.1.3 Onboarding**

Observations during the fabrication process revealed that makers are not properly introduced, indicating a lack of preparatory guidance. In literature, this type of introduction is commonly referred to as onboarding.

The term onboarding is mostly used in a business context, where it refers to the process through which new employees transition from being external to the organization to becoming integrated and effective members, acquiring the knowledge, skills, and behaviors necessary for success (Bauer & Erdogan, 2011). In this project, the concept of onboarding is adapted to introduce the maker and provide them with the knowledge and skills required to successfully fabricate the clinical task trainer. Similarly, in the context of online applications, user onboarding is understood as the process of increasing the likelihood that new users become successful when adopting a product (Chiappetta, 2020). During the fabrication of the clinical task trainer, the maker is not properly introduced to the process they are about to face. From a holistic learning journey perspective, the fabrication journey currently begins when the maker downloads the 3D print files and instructions, leaving an important gap in preparation.

Implementing a structured onboarding step could address this gap by providing clear guidance, contextual explanations, and step-by-step support before the maker begins the fabrication process. This could include checklists, illustrative examples, or short tutorials that help the maker understand the purpose of each component, the overall workflow, and potential challenges. Based on insights from customer onboarding software (Dock, 2025), such an approach would make the process more repeatable, reduce uncertainty, and increase the likelihood of a successful outcome. By guiding makers through an initial orientation phase, similar to how digital products guide new users through complex features, the overall learning journey becomes smoother, more engaging, and better aligned with the goal of independent and confident fabrication.

## 2.4.2 Theme 2 : Content is Incomplete

Another theme identified from the insights is that the instructional materials are not comprehensive, with multiple stages of the fabrication process incompletely covered.

This insight concerns the entire fabrication process, which starts with 3D printing, followed by silicone moulding, and finally assembly. However, the provided instruction manual only includes information about the silicone moulding and assembly stages.

A first-time user, however, also requires information regarding the 3D printing process. Although this project assumes that the maker has basic knowledge of 3D printing, printer operation, and general printing procedures, it is still important to specify which print settings are used and what the optimal orientation of the parts on the print bed is.

The quality of the printed moulds directly influences both the surface texture of the silicone components and the durability and reusability of the moulds.

An important advantage of the VVF task trainer is that it can be used multiple times to train the surgical procedure. However, after a certain number of uses, some components, specifically the bladder cup and the vagina, need to be remade, while the remaining components can still be used if they are not damaged, as they are not directly involved in the surgical training. Therefore, it is essential for a first-time user to understand how to successfully disassemble the clinical task trainer to replace these components. Therefore, instead of consisting of three stages, the fabrication process should be described as consisting of four stages.

Another observation is that the instructions were designed for general use and are not tailored to each individual mould. From personal experience, it was found that each mould for the silicone components differs sufficiently to require separate instructions. While the preparation of the silicone mixture is largely consistent across the silicone components, the processes of filling the mould and demoulding vary for each mould.

## 2.4.3 Theme 3: Content is Unclear

In addition to ensuring that all instructions are complete for makers, it is equally important that the instructions for each stage are clear, enabling the maker to successfully complete the tasks. Based on personal experience, several aspects of the fabrication process were identified as unclear. These issues can be discussed for each fabrication stage.

To begin, there is no clear overview of the steps that need to be taken. It is essential that the information is presented to the maker in manageable, well-structured segments. According to the cognitive load theory of Sweller (1994), the working memory has a limited capacity, meaning that processing new information can quickly overwhelm cognitive resources. Cognitive load refers to the amount of mental effort required to process information within the working memory. High cognitive load can impede learning and performance, especially when a task is complex or unfamiliar. When the maker fabricates the task trainer for the first time, detailed, step-by-step instructions are essential. These instructions help manage the intrinsic cognitive load, which is determined by the complexity of the task itself, and reduce extraneous load, which arises from poorly organized or unnecessary information (Sweller, 2010). By following structured guidance, the learner can focus on the critical elements of the fabrication process without overloading the working memory.

Based on personal experience during the fabrication process, findings were identified for each stage, and opportunities were developed, partly informed by expert input and literature. Figure X maps the stages and substages that the maker progresses through. Using this overview, each substage is briefly described in terms of the activities the maker is expected to perform, followed by the questions and uncertainties that arose. Finally, potential opportunities to address these uncertainties are presented.

### 2.4.3.1 3D Printing Stage

The process begins with the 3D printing stage, as shown in in Figure 9.

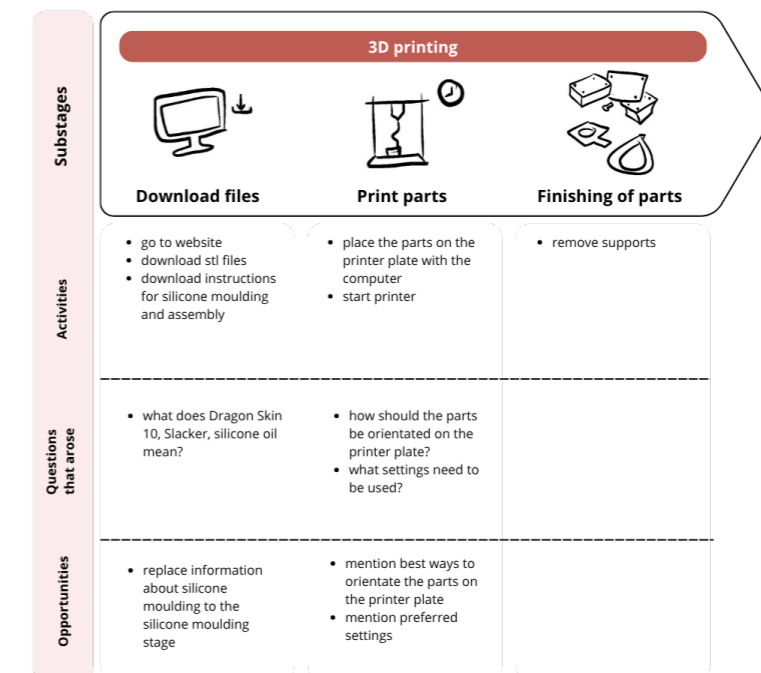


Figure 9 – Map of 3D printing stage

Most uncertainties arose during the fabrication of the components, particularly regarding the required print settings and the optimal orientation of each part on the print plate. On the website where the files are downloaded, a brief text is provided. This text includes a short introduction mentioning the necessary 3D printing material and explains that some prints serve as a framework for the 3D printed bone structure, while others function as moulds for silicone moulding. The required materials for silicone moulding are also briefly listed, but the instructions use technical jargon, which may make the information less accessible and reduce its likelihood of being read thoroughly. Once the maker begins the silicone moulding process, they rely primarily on the paper instructions and no longer refer to the website. As a result, any information about silicone moulding available online is often overlooked. Therefore, it is important to include all relevant information directly within the silicone instructions for that stage. Presenting information at the point of use aligns with a principle from the cognitive load theory, the split attention effect. Consequently, this information would be more effective if presented at the point in the process where it is relevant to the maker.

### 2.4.3.2 Silicone Casting Stage

Figure 10 shows the second stage, the silicone casting stage. Photographs illustrating this process are provided in Appendix A. The figure presents the substages along with the questions that arose, followed by potential opportunities to address these issues.

After the silicone casting process, it was observed that this stage can be divided into six substages. Silicone casting is the most time-consuming and demanding stage, as it must be performed for all five silicone components: the bladder cup, bladder plate, cervix, vagina, and vulva. Furthermore, it is a technique that involves numerous steps that must be executed in a specific sequence and within a limited timeframe, since the silicone hardens after a certain time. Without prior knowledge or experience, this process can be complex to perform. Therefore, it is useful to divide this stage into manageable substages and to provide clear instructions to guide the maker effectively.

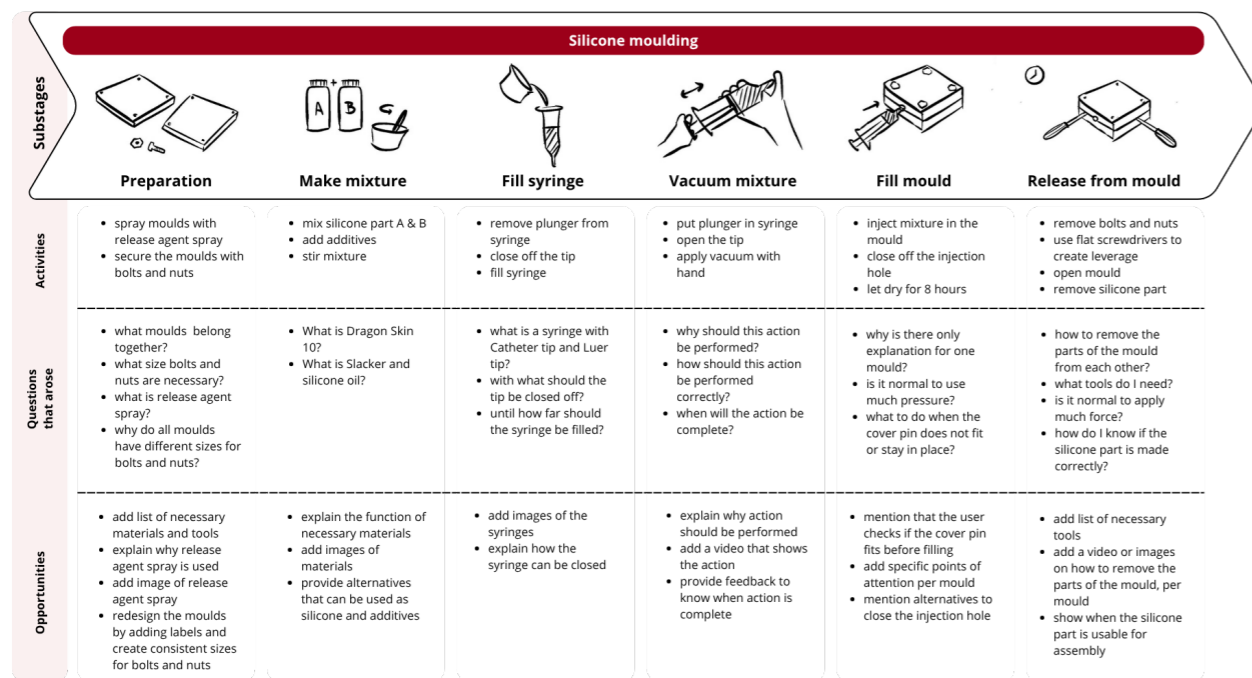


Figure 10 – Map of silicone moulding stage

What can be concluded from this stage is that the maker needs a list of necessary materials and tools prior to each substage. They also need images or illustrations and explanations of the function of materials such as silicone, additives, and syringes, as well as clear images or video tutorials demonstrating complex procedures, combined with opportunities to receive feedback. However, adding more steps and information can increase cognitive load for the maker. According to Sweller's cognitive load theory, it is important to avoid overloading the learner's working memory. Therefore, a minimalist instruction approach could be considered. According to Carroll and Van der Meij (1996), the most important principle of this approach is task orientation. Task orientation refers to the degree to which a learner understands a task and focuses on performing the correct steps in the right order to complete it successfully.

To minimize unnecessary information when conveying instructions, it is important to consider the cognitive load that a person can handle. The concept of minimalist instruction emerged from empirical research conducted by Carroll et al. (1987), in which they observed word processor trainees to identify common issues with traditional training manuals. They found that learners often experienced information overload, felt overwhelmed, and preferred hands-on engagement over lengthy explanations. Many skipped between sections rather than following the prescribed sequence, guided by their own goals. Learners also tended to rely on personal assumptions, disregarding information that conflicted with their mental models, and sometimes focused too heavily on the manual instead of interacting with the system itself. Additionally, traditional manuals failed to account for user errors or unexpected system behaviour, leaving trainees struggling to recover. Finally, many learners demonstrated impatience, desiring to engage in meaningful, real tasks as quickly as possible.

Additionally, the readability of the current instructions for tasks such as filling the syringe and applying the vacuum is overwhelming. While the steps are explained correctly during performance, a first-time user is faced with a large amount of information and must remember to repeat these steps accurately (Figure 11). In the literature on cognitive load theory, this challenge is referred to as the split-attention effect. The split-attention effect occurs when learners must divide their attention between multiple sources of information, which can increase cognitive load and reduce learning efficiency.

diameter about 7 mm)

NOTE: For the bladder, first fill the syringe with halve of the silicone mixture, perform step 7, 8 and 9 and repeat when the syringe is empty with the other halve of the mixture. For the cervix, if there are multiple moulds available and step 1 to 3 are performed on all moulds, it is easier to mix the amount for 2, 3 or 4 cervixes at the same time, this amount still fits in the syringe.



Figure 11 - Example of split attention effect in current instructions.

Another observation is that each step in the instructions consists of multiple sub steps, resulting in long blocks of text (Figure 12). This presentation is overwhelming, making the instructions difficult to read and execute. Literature on cognitive load theory also highlights that excessive information within a single instructional unit can increase cognitive load, reduce comprehension, and impair task performance.

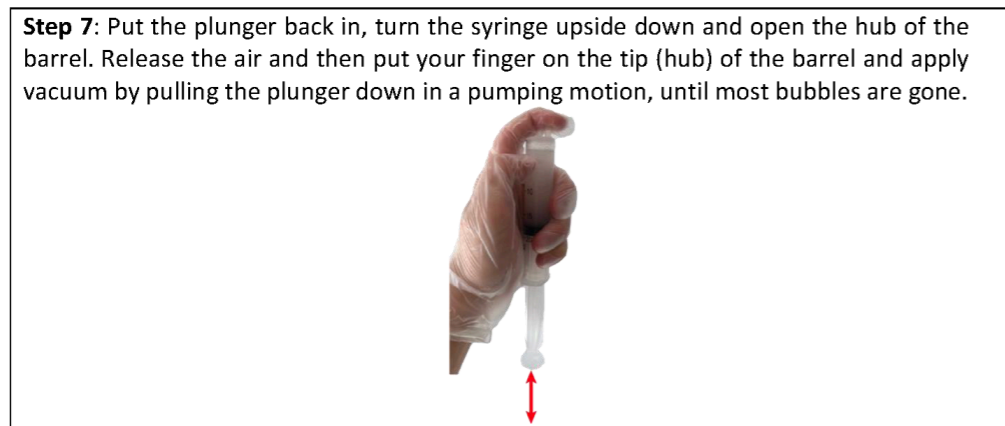


Figure 12: Example of too many activities described in 1 step

According to Norman (2013), well-designed products should be intuitive to use, making manuals unnecessary. When a manual is needed, it should be short, clear, visual, and support the user step by step. Norman also introduces the concept of affordances, which means that the design should communicate function through the object itself, minimizing reliance on manuals or external instructions. In a later study, he presents the concept of signifiers, which are visual or physical cues that indicate where and how actions should take place. For all substages of the silicone moulding process, the actions are too complex to fully apply Norman's principles. However, there is an opportunity to redesign the 3D printed moulds to make them more intuitive. After interviews with one of the founders of the clinical task trainer, it was suggested standardizing the sizes of holes for bolts and nuts, which ensures consistency and reduces the amount of information required in the instructions. Additionally, a PhD researcher at UMC, mentioned adding markings and labels on the prints. This leads to more intuitive use, as Norman describes, and allows less redundant information to be included in the instructions.

### 2.4.3.3 Assembly and Repair Stage

Figure 13 illustrates the assembly and repair stage.

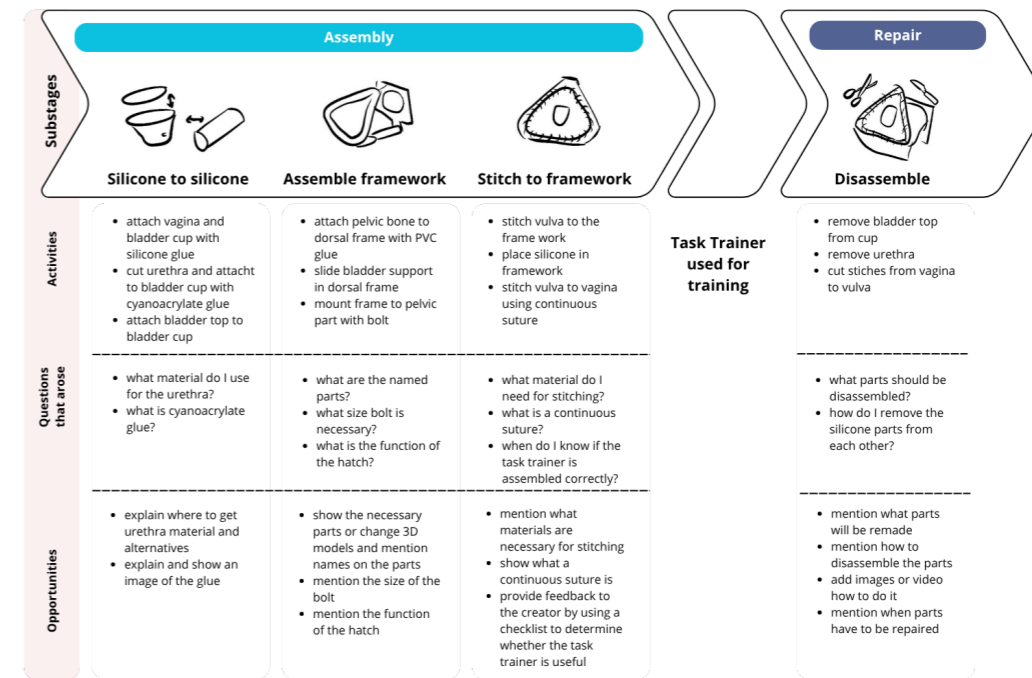


Figure 13 - Map of assembly and repair stage

The assembly stage requires clear explanations of the materials used, such as the glue and the urethra, as well as explicit guidance on which silicone and 3D-printed components should be used. In addition, technical terminology, such as continuous suture technique, may need to be clarified to support users without prior knowledge. Most importantly, at the end of the assembly stage, the maker requires feedback to determine whether the task trainer has been assembled correctly and is suitable for successful use by trainees. As described in the nine events of Gagné, feedback reinforces learning by providing learners with immediate corrections and evaluations, along with advice and explanations to make their actions more accurate (Higgins et al., 1982). This emphasizes the need for feedback to the maker. The repair stage is important to provide the maker with information regarding which silicone or 3D printed components need to be remade and the correct procedure for disassembling. It should specify when components are no longer in the right condition and require replacement.

## 2.4.4 Theme 4: Level of experience

The fourth finding relates to the varying levels of experience among makers. There is a noticeable difference between a first-time user and someone who has produced a silicone component multiple times. As makers gain experience, the amount of guidance required to successfully complete the process gradually decreases.

Based on personal experience, it is evident that creating the task trainer can be an overwhelming process without having prior knowledge, as many aspects of the fabrication are unfamiliar. The current manual provides insufficient information and guidance for first-time users, which can increase cognitive load and make the initial process more challenging.

In contrast, for experienced makers, the instructions on silicone moulding provided in the manual are generally adequate. After repeatedly producing a silicone component, the procedures become familiar, and only specific details remain necessary.

For example, experienced users primarily need information regarding the precise quantities of silicone and additives, as well as specific mould-related procedures.

These observations illustrate that different guidance is required depending on the user's experience, with the first-time maker benefiting from detailed, step-by-step instructions, while frequent users can operate effectively with concise, targeted guidance.

According to the cognitive load theory of Sweller (1994), with repeated practice, learners begin to develop schemas, which are organized mental structures stored in the long-term memory that represent the key steps and relationships involved in the task. Schemas allow learners to chunk information, reducing the number of separate elements that the working memory must handle at any given moment. As a result, the fabrication process becomes more automated, and learners can execute the procedure with less reliance on explicit instructions.

This has practical implications for designing the instructions, first-time makers require comprehensive guidance, whereas experienced makers can rely on abbreviated instructions. Therefore, tailoring instruction materials to the learner's level of experience, ensures that cognitive resources are used efficiently.

One way to achieve this is by applying the principles of adaptive learning, in which instructions can be tailored to the maker's level of experience and personal preferences. Adaptivity recognizes that not all learners have the same background or prior knowledge (Martin et al., 2020). For example, makers can be offered different options for how to proceed with their learning experience, depending on their experience level and individual preferences.

## 2.5 Key Takeaways

The key takeaways from the Discover phase are summarized in the following bullet points:

- In healthcare, MOOCs have become increasingly relevant by offering flexible, cost-effective, and scalable training opportunities (Schettino & Capone, 2022).
- Common challenges regarding the effectiveness of e-learning have been identified. Learners often face difficulties due to the overwhelming and scattered nature of available materials. Content is frequently incomplete or repetitive, and many materials are not adapted to the local context, reducing their practical relevance (O'Flynn et al., 2024)
- The study by Carroll et al. (1987) identified common issues with traditional manuals. Learners often experienced information overload, felt overwhelmed, and preferred hands-on engagement over lengthy explanations. Many skipped between sections rather than following the prescribed sequence, guided instead by their own goals.
- In addition, the study by Carroll et al. (1987) found that learners tended to rely on personal assumptions and sometimes focused too heavily on the manual instead of interacting with the system itself. Furthermore, manuals failed to account for user errors, leaving learners struggling to recover from mistakes.
- According to Norman (2013), well-designed products should be intuitive to use, making manuals unnecessary. The use of affordances, which communicate function through design, should minimize reliance on manuals.
- As described in Gagné's Nine Events of Instruction, feedback reinforces learning by providing learners with immediate corrections and evaluations (Higgins et al., 1982).
- According to Sweller's Cognitive Load Theory (1994), repeated practice enables learners to develop schemas, which are organized mental structures stored in long-term memory. Schemas allow learners to chunk information, reducing the number of separate elements that working memory must process.

# Define

This phase defines the design direction and forms the start for the Develop phase. During the analysis in the Discover phase, many insights were gathered. In this chapter, the target group is presented, followed by the requirements derived from these insights, the design goal, and the interaction qualities.

- 3.1 Requirements
- 3.2 Target Group
- 3.3 Design Goal
- 3.4 Interaction Qualities

# 03

## 3.1 Requirements

The requirements are gathered throughout the Discover phase and the MoSCoW method was used to prioritize the requirements. This method categorizes requirements into four groups: Must have, Should have, Could have, and Won't have, providing a structured approach to determine which elements are essential and which are optional or lower priority.

The requirements can be grouped into five clusters and are listed below: fundamental requirement, requirements for the maker's journey, requirements for the content of the instructions, general requirements for instructional materials, including specific requirements for silicone casting and assembly, and requirements for the 3D-printed parts.

<b>Fundamental Requirements</b>	<b>Requirement</b>
The maker must have clear and comprehensive fabrication instructions to successfully fabricate the VVF clinical task trainer.	0.1
The maker should have access to the appropriate equipment, tools, and materials.	0.2

<b>Maker's Journey</b>	<b>Requirement</b>
The maker should be feeling guided throughout the entire fabrication process.	1.1
The maker must feel invited to start and continue the fabrication process.	1.2
An instructional design framework must be used to structure the fabrication process.	1.3
The instructional materials must not feel overwhelming.	1.4
At the start of the fabrication process, the maker should go through an onboarding step.	1.5
The maker must receive feedback during the process.	1.6
For experienced makers, only information on precise quantities and specific mould-related procedures could be provided.	1.7
The instructions could be adaptable to the maker's level of experience.	1.8

<b>Content of Instructions</b>	<b>Requirement</b>
The maker must be provided with an overview of the process in advance, including time indications.	1.9
All stages of the fabrication process must be covered.	1.10
3D printing information must be included in the content.	1.11
Repair information must be included in the content.	1.12
The instructions could be modular.	1.13

<b>Instruction material</b>	<b>Requirement</b>
<b>General</b>	
The instructions must be presented in manageable, well-structured segments.	1.14
The instructions must be presented in detail, with step-by-step instructions.	1.15
Technical jargon should be avoided or clearly explained when used.	1.16
A list of items necessary to perform each step must be provided.	1.17

The function of all materials and tools should be explained.	1.18
The instructions should follow the principle of task orientation.	1.19
The split-attention principle should be considered in the design of the instructional materials.	1.120
Each step in the instructions must require only one activity.	1.21
The manual must be concise and not contain unnecessary information.	1.22
The manual must be clear and easy to understand.	1.23
The manual must combine text with visual representations.	1.24

### Silicone casting

Instructions for demoulding silicone must be available.	1.25
Separate instruction materials must be provided for each silicone component.	1.26

### 3D printed parts

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The 3D parts should be intuitive to use.	1.29
The 3D printed parts could include visual or physical cues to support usability.	1.30
The 3D printed mould parts could have consistent hole sizes for bolts and nuts.	1.31

## 3.2 Target Group

The target group of the final design are first-time makers of the clinical task trainer, referred to as “novice makers”. These are individuals with no experience in fabricating the task trainer or working with silicone casting techniques. However, it is assumed that novice makers are familiar with 3D printing.

## 3.3 Design Goal

Based on the requirements and the gathered insights during the Discover phase, the following design was developed:

**“Develop an instruction manual that enables novice makers to successfully fabricate the clinical task trainer for vesicovaginal fistula repair while feeling guided and confident throughout the process.”**

## 3.3 Interaction Qualities

To support this design goal, the desired interaction between the maker and the final design is defined with interaction qualities. Interaction qualities originate from the Vision in Product Design method (ViP), which is a design approach that translates a future-oriented vision into design decisions (Hekkert & Van, 2016).

The ViP method focuses on the interaction between the user and the product, based on a formulated future vision. Within this method, interaction qualities are used to describe how this interaction should be experienced by the user and to support design decisions during the design process.

In this project, interaction qualities are used to define and guide the desired interaction between the maker and the final design. For the client, BME for Global Health, it is important that makers can fabricate the clinical task trainer independently. Therefore, the design should not only be functional, but also accessible. The fabrication process should feel inviting to start, be clear and understandable, and support the maker in feeling guided and confident throughout the process.

While the ViP method typically derives interaction qualities from a formulated interaction vision, the full method is not applied in this project, as this project primarily follows a Research through Design approach. Instead, only interaction qualities were used to guide the design process towards the desired interaction.

Based on these considerations, the following interaction qualities were defined. These qualities are used to guide design decisions during the design process and help shape how the interaction between the maker and the final design should feel:

- Accessible
- Inviting
- Guiding
- Clear
- Understandable

# Develop

This phase explores the solution space based on the Define phase and is structured into three sequential design sprints. The first design sprint focuses on designing the overall fabrication journey, based on the requirements gathered during the Define phase, and concludes with an updated set of requirements that serve as input for the subsequent sprints. The second design sprint focuses on the design of the silicone instructions. It builds on both the requirements from the Define phase and the insights gained from the first sprint. The third design sprint uses the requirements from the Define phase, along with the updated requirements and insights from the previous sprints, to develop the final assembly instructions.

## 4.1 Design Sprint 1 - Design the Maker's Journey

### 4.1.1 Design the Journey

### 4.1.2 Concept Development

### 4.1.3 New Requirements

## 4.2 Design Sprint 2 - Development of Silicone Casting Instructions

### 4.2.1 Determine the Content

### 4.2.2 Design the Silicone Casting Instructions

#### 4.2.2.1 Silicone Casting Instructions 1.0

#### 4.2.2.2 Silicone Casting Instructions 2.0

#### 4.2.2.3 Silicone Casting Instructions 3.0

#### 4.2.2.4 Silicone Casting Instructions 4.0

### 4.2.3 New Requirements

## 4.3 Design Sprint 3 - Development of Assembly Instructions

### 4.3.1 Determine the Content

### 4.3.2 Design the Assembly Instructions

#### 4.3.2.1 Assembly Instructions 1.0

#### 4.3.2.2 Assembly Instructions 2.0

### 4.3.3 New Requirements

# 04

## 4.1 Design sprint 1 – Design the Maker's Journey

This design sprint focuses on the maker's journey, interpreted as a learning process based on Theme 1 identified during the discover phase.

Two key factors are essential to successfully fabricate the task trainer:

1. Clear and comprehensive fabrication instructions tailored to the needs of a novice maker.
2. Access to the appropriate equipment, tools, and materials

During this sprint, multiple ideas and design decisions are made, resulting in a final concept and updated requirements.

### 4.1.1 Design the Journey

Given that the fabrication process can be understood as a learning journey, contemporary learning approaches such as e-learning platforms and MOOCs were explored as initial design directions.

To structure this learning journey, an instructional framework was required (Requirement 1.3). Therefore, the choice was made between the five principles of Merrill or Gagné's Nine Events of Instruction. The principles of Merrill are more focused on open and explorative learning, whereas Gagné's nine events are more structured and guided. For the task trainer it is important that everyone makes the same final product, there is no room for self-exploring. Therefore, the instructional framework of Gagné was selected to structure the maker's journey.

The framework consists of the following nine events and a visual overview can be found in Figure 14:

1. Gain attention
2. Inform about objective
3. Stimulate prior knowledge
4. Present content
5. Provide guidance
6. Practice
7. Provide feedback
8. Assess performance
9. Enhance retention and transfer



Figure 14 - Visualisation of Gagné's Nine Events of Instruction (CourseArc, n.d.)

After selecting the instructional framework, the maker's journey was visualised, and it was examined how the nine events are distributed throughout the fabrication process. This journey is visualised in Figure 15.

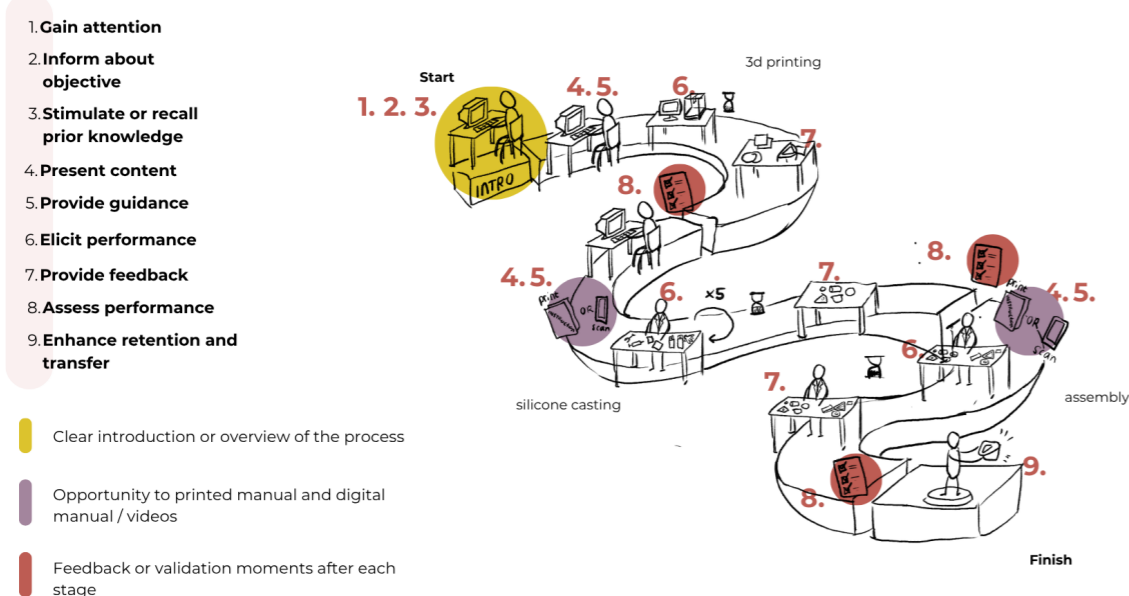


Figure 15 - Visualised journey including the nine events of instruction.

This visualisation led to one key insight: the instructions must be portable. The visualisation showed that the different stages do not take place while working at a computer, as 3D printing and silicone casting typically occur in workshop environments or laboratory settings.

Therefore, it was concluded that the instructions and guidance should be portable, allowing the maker to carry them throughout the process, either digitally or physically. If digital instructions are used, it was agreed with the client that these should be optimized for a phone screen, since a phone is most accessible in LMICs, rather than a laptop or tablet.

To continue the design process, a decision had to be made between digital or paper-based instructions. Analysis of the fabrication process showed that working with silicone takes place in a laboratory setting where gloves are likely to be worn. The process can be messy, and silicone often spills, making the use of a phone possible but inconvenient, as devices can become dirty and are harder to operate with gloves or messy hands.

Therefore, the design choice was made to develop physical paper-based instructions, which will be further developed in sprint 2 and 3.

To retain the benefits of a digital platform, makers will be able to download and print the instructions as PDFs. Based on a conversation with the client, it is assumed that in low- and middle-income countries printing is often limited to black-and-white ink. This constraint should therefore be considered in the development of the instructions to ensure they remain clear and easy to follow when printed in grayscale.

Although the instructions are intended for physical use, a digital platform remains essential. This is necessary not only for downloading STL files for 3D printing but also because a website provides accessible distribution to a wide audience.

This led to the concept of an online platform featuring a landing page with all relevant information and downloadable instruction manuals, to meet the requirement of providing a central location for all necessary information.

## 4.1.2 Concept Development

To improve the design and the features of the landing page, a set of interaction qualities was defined to guide the design process towards developing the desired interaction between the maker and the final design. As stated in Chapter 3.2, the interaction between the maker and the design should be accessible, inviting, clear, understandable, and guiding.

Ideation was conducted for each interaction quality to generate possible features for the website. Several ideas were generated using "How Might We" questions, such as How might we make the platform inviting?.

Combined with Requirements 0.1 and 0.2, which focus on providing clear instructions and supporting access to materials, this resulted in website features. These features include guidance for sourcing materials through either self-sourcing or an optional starter kit, as well as an introductory onboarding to prepare makers before starting the fabrication process.

## 4.1.3 New Requirements

This design sprint resulted in the refinement of existing requirements as well as the formulation of new ones.

The requirement "the maker must receive feedback during the process (1.6)" has been revised to: "the maker must perform a self-check after each substage (1.6)."

The following new requirements have been established:

- Instruction materials must be usable when printed in grayscale. (2.1)
- A website must be provided that contains all necessary instructional materials, information and material specifications required to fabricate the clinical task trainer. (2.2)
- Instructional materials must be designed for paper-based use. (2.3)

### Key takeaways

- The instructional materials should be portable and paper-based.
- The website should provide onboarding, support material sourcing, and offer printable instructional materials.

## 4.2 Design sprint 2 – Development of Silicone Casting Instructions

This design sprint focuses on the development of the instructional materials for producing the silicone components: the vagina, vulva, bladder cup, bladder top and cervix. Gagne's events 4-8 from the instructional framework will be incorporated in the design of the instructional materials for silicone casting.

The goal of this sprint is to further develop and refine the instructional content by defining the required content (Theme 2), improving clarity and structure (Theme 3), and addressing varying levels of makers experience (Theme 4). In addition, insights from sprint 1 highlighted the need for a self-check after each substage, requiring clear definitions of quality criteria for the silicone components.

Four versions of the silicone casting instructions were developed, of which three versions were evaluated with participants. Through a research-through-design approach, prototypes were iteratively developed and evaluated. Key insights were identified leading to the final version of the silicone instructions. The design sprint concludes with a set of gathered requirements.

### 4.2.1 Determine the Content

To address Theme 2, which emphasized the importance of complete instructional content for novice makers, the design sprint started with a detailed documentation of the silicone casting procedure. This was conducted by maintaining a logbook during self-fabrication and by consulting the designers of the clinical task trainer to gather additional explanations of the required steps.

The content was determined using the current instructions (see Appendix A for the full instructions). An important insight was that each step contained many different actions, making it overwhelming for a maker. To address this and meet the requirement that each step requires only one activity (req. 1.12), the process for making the silicone parts was broken down into single-action steps. An example is shown in Figure 16, illustrating a step from the current instruction manual.

**Step 7:** Put the plunger back in, turn the syringe upside down and open the hub of the barrel. Release the air and then put your finger on the tip (hub) of the barrel and apply vacuum by pulling the plunger down in a pumping motion, until most bubbles are gone.



Figure 16 - Example of step 7 of current instructions

Step 7; Changed into:

- Put the plunger back in
- Turn the syringe upside down
- Open the hub of the barrel
- Release the air
- Put your finger on the tip (hub) of the barrel
- Apply vacuum by pulling the plunger down in a pumping motion, until most bubbles are gone.

In addition, an insight was found that the production of a silicone part can be divided into six substages. Structuring the information by organizing it into these substages and smaller steps contributes to requirement 1.14: the instructions must be presented in manageable, well-structured segments. The substages are as followed:

1. Prepare the mould
2. Make the mixture
3. Fill the syringe
4. Vacuum the syringe
5. Fill the mould
6. Release from mould

Another insight that emerged during the detailed documentation of the silicone casting process is that all silicone components follow the same six substages. While there is significant overlap in the techniques used within these substages, differences arise in how their application due to variations in required quantities and additives. However, the primary source of variation lies in the difference between the moulds. This indicates that a single set of general instructions is insufficient to support the production of all silicone components effectively for novice makers. Therefore, a design choice was made to develop separate instructions for each silicone component.

### Key takeaways

- The steps in the current instruction manual can be broken down into smaller, single-action steps to reduce cognitive load for novice makers.
- The silicone casting process can be structured into six recurring substages to create a more manageable and organized fabrication workflow.
- Although the silicone components share similar fabrication techniques, variations between the moulds require component-specific instructions for novice makers.

## 4.2.2 Design the Silicone Casting Instructions

With the content clear, the translation was made to the development of the instructions. The following sections describe the iterative design process, in which each prototype is presented, followed by its evaluation results and the resulting improvements. This phase specifically addresses Theme 3 from the Discover phase, which highlights that the content is not presented clearly. The main challenge is to balance cognitive load by providing sufficient information without overwhelming the maker.

### 4.2.2.1 Silicone Casting Instructions 1.0

The first prototype, Silicone Casting Instructions 1.0, is designed as a single, comprehensive instruction booklet that covers all stages of the fabrication process: 3D printing, silicone casting, assembly, and disassembly (repair) (req. 1.10).

For this prototype, only the silicone casting chapter was developed in detail. This chapter is structured into multiple subchapters. Within the prototype, Chapter 2 provides information on how to work with silicone, including an explanation of different additives and their functions (req.1.18). Chapter 3 contains step-by-step instructions for producing each individual silicone component, divided into Sections 3.1 to 3.5, covering the bladder cup, bladder top, cervix, vagina, and vulva.

During the discovery phase, it became clear that certain steps, particularly vacuuming the mixture (removing air bubbles by hand) and filling the syringe, were perceived as difficult and required additional explanation. Therefore, these techniques are explained separately in Chapter 2. For these specific steps, supporting visual illustrations were included to enhance understanding.

Figure 17 illustrates a section of the instructional materials describing the vacuuming process of the silicone mixture. The complete instructions are provided in Appendix B.1.

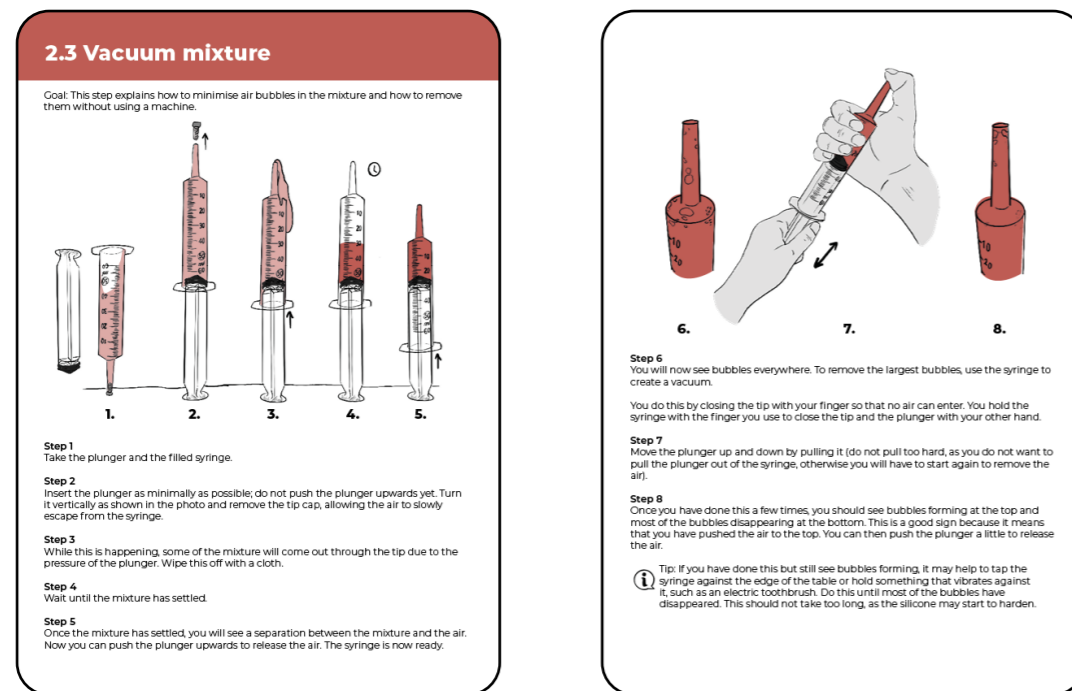


Figure 17: Section 2.3 from silicone instructions 1.0, explaining vacuum pumping by hand

## Evaluation

The prototype was printed in grayscale and tested with two participants who were novices in silicone casting. The full test plan can be found in Appendix B.2 The evaluation focused on the interaction of the participant with the prototype and whether the steps were performed correctly.

Each participant was asked to produce the bladder cup silicone component using the instructions. The results showed that several requirements were not met.

Most important findings of the test were that participants experienced the material as overwhelming, containing too much text and unnecessary information. They did not follow the booklet sequentially, which resulted in missed information. When opening the booklet both participants felt overwhelmed, indicating the interaction of the maker with the instructions did not feel inviting.

Additionally, having the techniques of filling the syringe and vacuuming the mixture were explained in a different chapter, participants had to flip through the booklet. This increased the split-attention effect, as participants had to divide their attention between their current page and the pages where the techniques were explained. The increase of the split-attention effect increases the cognitive load, making the instructions harder to follow.

The vacuuming step was by both participants not performed as intended. This step took the most time, the researcher provided a hint about the time left before the mixture started to cure. Both participants showed signs of stress during this step as they felt the silicone was already starting to cure.

The requirement of combining text with visual representations was not fully met, as visuals were only used to explain more complex techniques such as filling the syringe and vacuuming the mixture. Within these explanations, the split-attention still occurred since the images were spatially distant from the corresponding explanation, as can be seen in Figure 17..

Both participants frequently questioned whether they were performing steps correctly, indicating that the requirement for providing feedback to the maker was not met (req. 1.6).

These findings indicate that the interaction between the maker and the instructions should be improved through making less overwhelming, a clearer structure, better integration of visuals, and more feedback during production. Nevertheless, both participants succeeded in producing a usable final product, suggesting that the written procedural steps were understandable.

### Key Takeaways

- The written procedural steps were sufficiently clear for novice makers to successfully produce the bladder cup component.
- The instructional materials were experienced as overwhelming and insufficiently guiding, indicating that the interaction between the maker and the instructions should be improved.
- Separating technique explanations from the procedural steps increased the split-attention effect and cognitive load, making the instructions harder to follow.

## 4.2.2.2 Silicone Casting Instructions 2.0

Based on the insights gained from testing instruction manual 1.0, an ideation was conducted to explore how to make the instructions less overwhelming, reduce split-attention effect, and incorporate a self-check. This resulted in the following improvements:

### Make instructions less overwhelming

The initial idea was to reduce the number of pages to make the manual less overwhelming and more structured, while still using the six stages to segment the information. Therefore, the concept shifted from a single comprehensive book to separate sheets for each silicone component, with the aim of physically segmenting the instructions and reducing their perceived complexity. Figure 18 shows an overview of the ideation. However, in practice, it became evident that the amount of information for novice makers did not fit on a single sheet. This resulted in information-dense pages, which, according to cognitive load theory, may increase cognitive load rather than reduce it.

Therefore, a trade-off was made: instead of loose sheets, the silicone instructions 2.0 consists of separate booklets for each silicone component. This maintains the benefit of segmenting the instructions into manageable parts, while allowing to present the necessary information in a clear and structured way. Reducing cognitive load by presenting information in smaller, and well-structured segments.

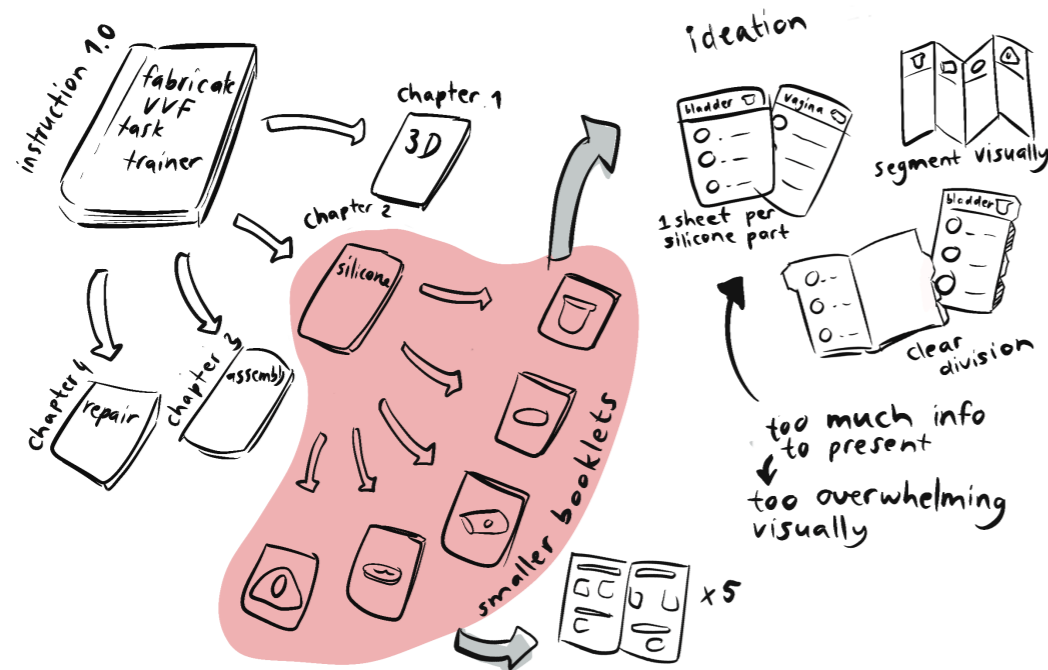


Figure 18: Ideation for making instructions less overwhelming

### Reduce the split-attention effect

To minimize the split-attention effect, instructions for techniques such as filling the syringe and vacuuming the silicone mixture are not placed on separate pages. Instead, they are integrated into each individual instruction booklet for each silicone component, allowing the maker to access all necessary information in one place without needing to switch between pages.

Additionally, to meet the requirement of combining text with visual representation and to further minimize the split-attention effect, each step includes both an illustration and text (Figure 19).

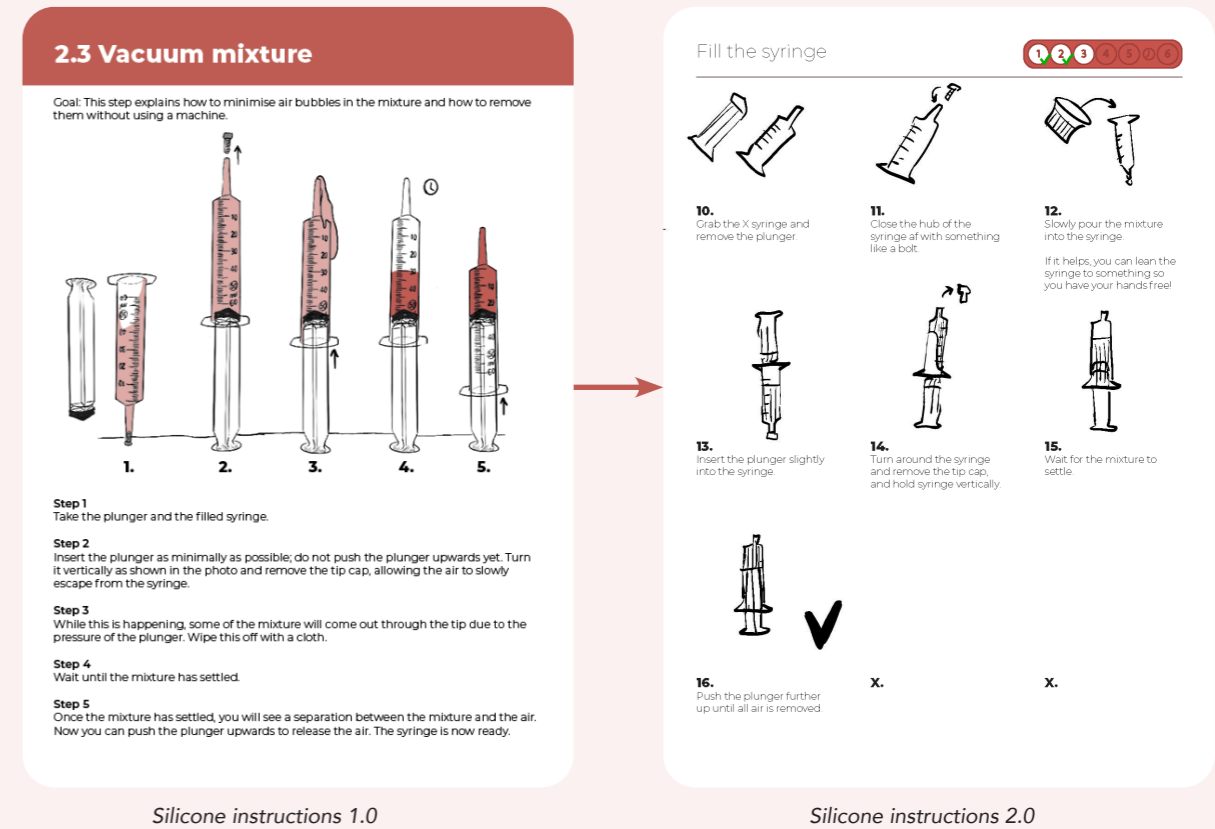


Figure 19: Improvement of split-attention effect instructions 1.0 vs instructions 2.0

### Feedback during process

To increase the maker's confidence and provide feedback during the process, self-checks were incorporated throughout the instructions (Figure 20). These include checks after each substage (e.g. after preparation, after making mixture, etc), as well as a final quality check to assess the produced silicone component (Figure 21).

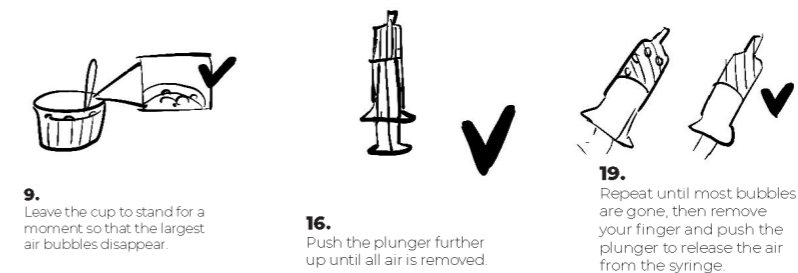


Figure 20: Added self-check after each substage

### Final Check

Once all checkboxes can be ticked, your silicone part is complete

- Mold Separation – The mold parts came apart without tearing the silicone
- No Air Bubbles – Most visible air bubbles have been removed
- Complete Fill – Silicone has reached all vent holes and filled the mold completely

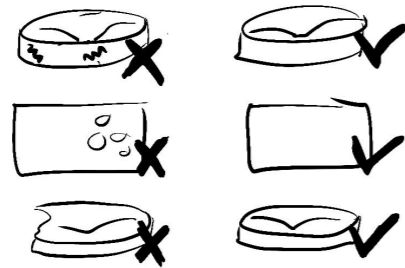


Figure 21: Added quality check to assess produced silicone part

### Evaluation

The instruction manual for producing the cervix component was evaluated with nine participants at the faculty of Industrial Design. The goal was to evaluate whether the instructions were perceived as overwhelming and whether the text and illustrations were understood correctly. Participants were asked to think aloud while explaining what they believed they needed to do, while observations were made by the researcher if the steps were explained correctly. The full silicone instructions 2.0 and the test-setup can be found in Appendix C.2.

A limitation of this test is that participants did not actually produce a silicone component. As a result, their responses are based on expectations rather than hands-on experience. Therefore, no conclusions can be drawn about the effectiveness of the instructions in when producing the silicone part. However, perceptions of clarity, structure and presentation could be evaluated.

The results show that the overall presentation of the instructions is clear and well-structured. Eight out of nine participant rated the presentation with a score of 4 or higher (on a 5-point scale), and none of the participants experienced the instructions as visually overwhelming. Appendix C.2 shows more results of the test.

However, several areas for improvement were identified. Participants indicated that the illustrations were visually appealing but lack sufficient detail and consistency with the actual components, making some steps harder to interpret. In addition, some textual instructions require better explanation on specific actions and terminology.

Furthermore, multiple participants found the self-check for assessing the quality of the silicone component unclear. Participants mentioned they were unsure how to evaluate a produced part.

#### Key takeaways

- The segmented booklet structure and step-by-step presentation were perceived as clear and not visually overwhelming.
- The self-checks required more detailed explanations to support participants in assessing the quality of the produced silicone component.
- The illustrations should contain more detail and better correspond visually to the actual silicone components to improve interpretation of the steps.

### 4.2.2.3 Silicone Casting Instructions 3.0

Based on the insights from the evaluation of silicone casting instructions 2.0, the main focus of the improvements was on clarifying the self-check by defining clear boundary conditions for the final silicone component. In addition, the illustrations were redesigned into more realistic and detailed visuals to improve clarity.

#### Determination of quality of silicone components

To establish the boundary conditions for the quality check, it is important that each silicone part is fully filled. Ideally, when producing silicone parts, it is required that no air bubbles are present. To ensure this, a vacuum chamber is used to remove air bubbles from the mixture.

However, since this task trainer is intended for fabrication in LMICs, it is assumed that not all makers have access to a vacuum chamber. Instead, air removal is performed manually using pumping movements. This method is less effective, meaning that some air bubbles may remain after curing. Therefore, it is necessary to define the acceptable boundary conditions under which a silicone component is considered usable.

As discussed in chapter 2.2, the surgery is performed within approximately 2 cm around the fistula. In this area, incisions and sutures are made. Therefore, this region is critical for the functionality. The other silicone parts, cervix, bladder top and vulva are not directly involved in surgery.

This information led to the following boundary conditions:

- All silicone components must be completely filled.
- The vulva, cervix and bladder plate may contain air bubbles
- The vagina and bladder cup must not contain air bubbles larger than 1 mm within an area of 2 cm around the fistula (see Figure 21)

No air bubbles larger than 1 mm within the marked areas:



Figure 22: Indication of boundary conditions of airbubbles on bladder cup and vagina.

While the previous iteration focused on the cervix component, this iteration shifts to the silicone vagina component. This decision was made to better evaluate the self-check and because self-production showed that the vagina component is the most challenging part to produce, particularly in filling the mould and releasing it after curing, making it important to evaluate whether these instructions are clear.

This is how the final check is incorporated in the instructions 3.0, compared to 2.0.

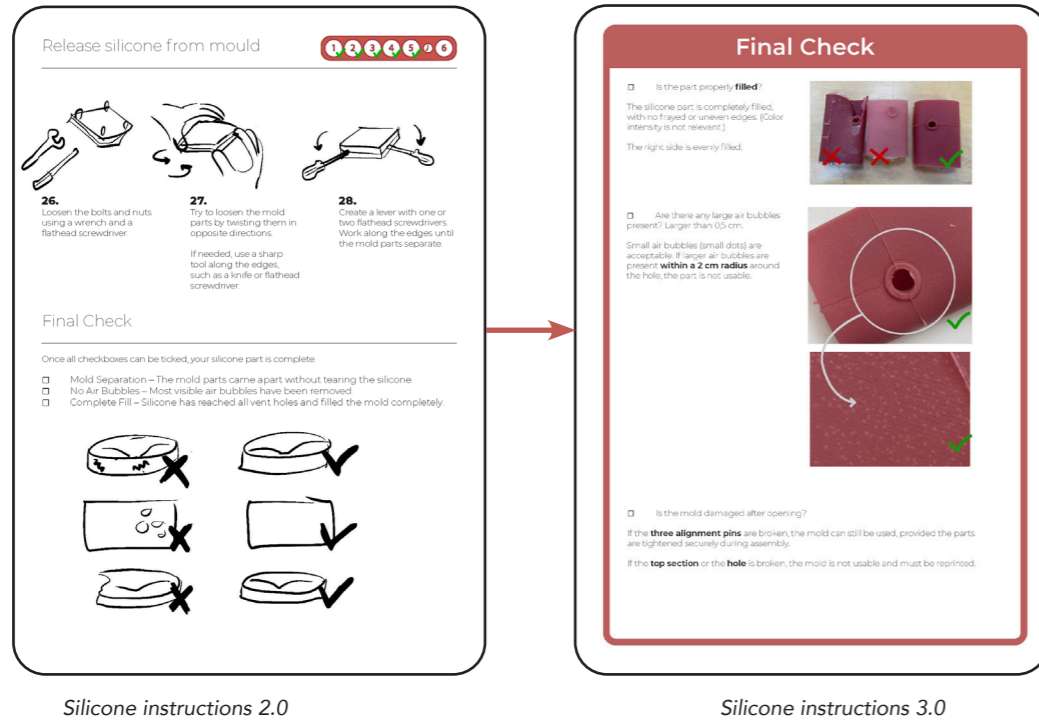


Figure 23: Improvement of final check in instructions.

### Illustrations

In addition, all illustrations were redesigned into more realistic and detailed visuals. Figure 24 shows an example of an improved illustration compared to the previous version.

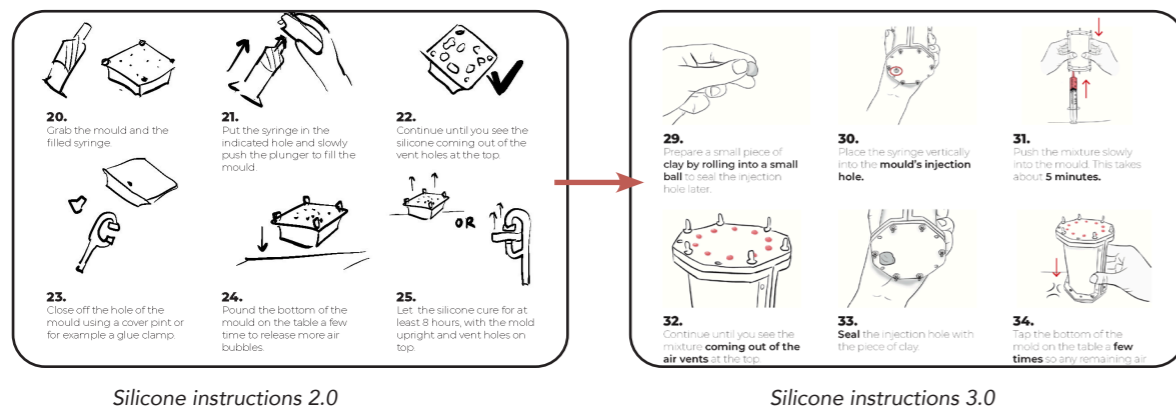


Figure 24: Improvement of illustrations of filling the mould

### Additional improvements

In addition to the main changes, several smaller improvements were implemented in this version. A process overview was added to the front page to address requirement 1.9, which had not yet been met. Furthermore, the term 'pot life' was introduced and explained, referring to the time available to work with the silicone before it starts curing. This was done to increase the maker's awareness of time constraints and to reduce stress observed in earlier tests, where participants experienced unexpected time pressure.

### Evaluation

Based on the improvements, the silicone casting instructions 3.0 were developed (see Appendix D.1). A usability test was conducted with two novice participants. The evaluation focused on how clearly each step was understood and executed, and whether the self-check supported them in assessing the quality of the produced component. The full evaluation plan can be found in Appendix D.2)

Several issues occurred during the production of the silicone vagina component. All observations of the test can be found in Appendix D.2.

The most important issues are discussed below:

In Step 2, where the maker must apply a thin layer of release agent to the moulds, the term "thin layer" was not clearly defined. Both participants were unsure how much release agent should be sprayed. This issue was also identified during the evaluation of Silicone Instructions 1.0, indicating that the required amount should be explained more clearly.

In Step 17 (Figure 25) makers were instructed to set a timer for 20 minutes. This timer indicated the remaining working time before the silicone would become too thick to pour. However, both participants misinterpreted this instruction and believed they had to wait 20 minutes before continuing with the next steps. The researcher provided a hint to clarify that the 20 minutes referred to the time available to complete the remaining steps, rather than a waiting period. After this clarification, both participants shifted from a calm working pace to a more stressed and hurried approach.

This is a crucial step in the process, as waiting for 20 minutes would have caused the silicone to thicken too much. This indicates that this step should be revised.

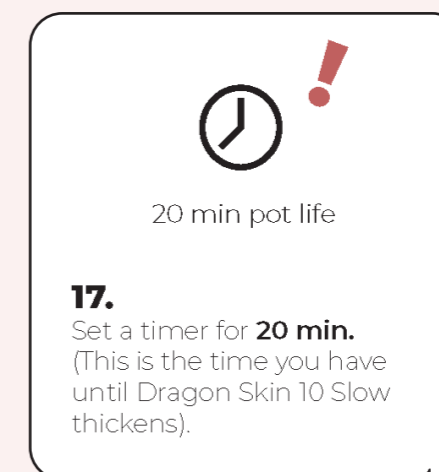


Figure 25: Step 17 of silicone instructions 3.0

Another issue was identified in the step describing how to release air bubbles from the silicone mixture. Both participants struggled to execute the step correctly and expressed uncertainty about whether they had performed the process properly.

Through observations and the think-aloud method, it became clear that the amount of information on the page was overwhelming for the participants. During the post-test discussion, both participants mentioned that they had skipped or overlooked parts of the page because the information lacked visual hierarchy and contained too much text. This indicates that the section should be redesigned with less information and a more structured layout.

Both participants proceeded to fill the mould while large air bubbles were still visibly present in the syringe. However, very few air bubbles were observed in the final silicone parts. This suggests that the presence of these air bubbles during the filling process did not significantly affect the final result. Therefore, this may indicate that the air bubble removal step is unnecessary or less critical than initially expected.



Figure 26: Left: fill mould with large amount of air. Right: produced silicone part

During Step V, Filling the Mould, Participant 1 did not observe the silicone mixture coming out of the air vents. This made her feel uncertain and gave her the impression that she had failed. However, after releasing the silicone part from the mould the next day, she was surprised by how well the final result turned out.

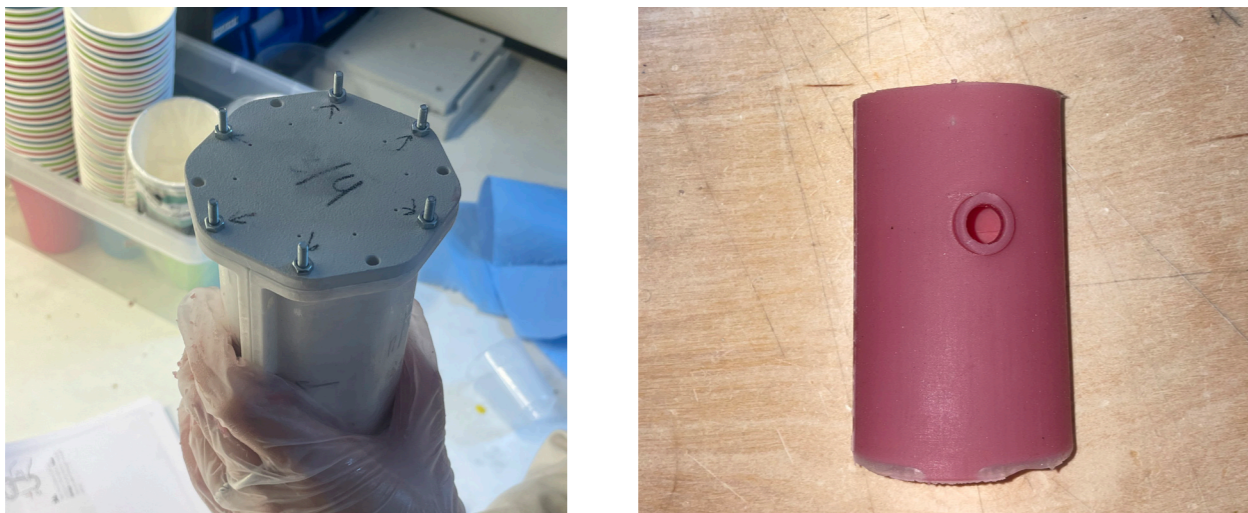


Figure 27: Left: no silicone out of air vents. Right: produced silicone part

According to the final self-check, the part was considered not completely filled. However, both the participant and the researcher agreed that the silicone part was usable. This indicated that the self-check instructions did not clearly define when a part should be considered sufficiently filled. Therefore, more precise boundaries should be described in the self-check section.

#### Additional Insight

An additional observation emerged after the usability test of Silicone Instructions 3.0. After completing the test, one participant independently produced another silicone component, the vulva, without using the detailed instructions. Before starting, she only requested a limited set of information, including the required moulds, material quantities, syringe size, bolt and nut sizes, and the locations of the air vents and injection opening. The participant also indicated that most fabrication steps, including the vacuum pumping process, could now be performed without additional guidance.

A similar observation was previously made during the evaluation of Silicone Instructions 1.0, where another participant independently produced a silicone component after the usability test and indicated that only limited information, such as quantities and dimensions, was still necessary. Although these observations are too limited to draw definitive conclusions, they do align with Theme 4: Level of Experience, identified during the Discover phase, which described how the amount of guidance required decreases as makers gain familiarity with the fabrication process.

#### Key takeaways

- Overall, the fabrication steps and actions were understood clearly; however, several minor adjustments are needed to further improve clarity.
- The self-check criteria and quality boundaries should be described in more detail.
- The visual hierarchy of the instructions in 'Section V.' should be improved to better emphasize important information and feedback moments.
- After gaining hands-on experience with the fabrication process, makers required less detailed instructional guidance and primarily relied on concise reference information.

#### 4.2.2.4 Silicone Casting Instructions 4.0

Based on the insights from the evaluation of silicone casting instructions 3.0, the following improvements are made, leading to the final instructions for producing the vagina part (Appendix G.1)

##### Clarity of steps

Step 2 was revised by replacing the unclear description "thin layer" with a more specific description of the required amount of release agent. Instead of using the term "thin layer," the instruction now specifies applying 2–3 sprays to each highlighted mould area.

Step 17 was revised by changing both the wording and the timer icon. The original static timer icon unintentionally suggested that participants had to wait for 20 minutes. Therefore, it was replaced with a more dynamic timer icon to better communicate that the timer represents the remaining working time available to complete the next steps.

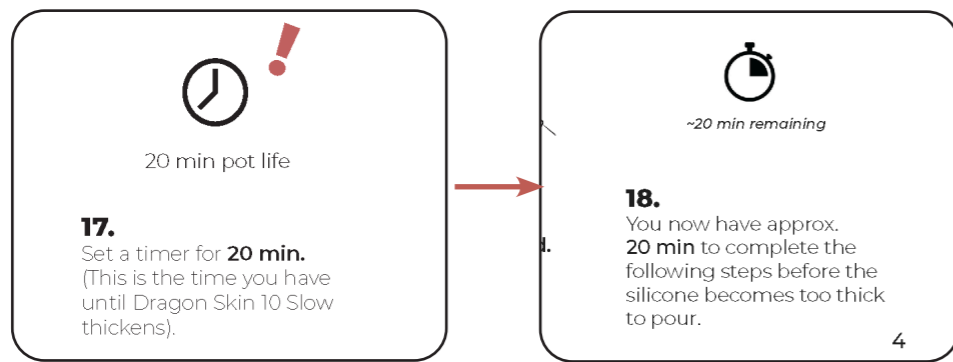


Figure 28: Improvement of step 17

##### Improvement of page

Section IV was revised with a calmer and more structured layout to reduce information overload. In addition, the description of several steps was adjusted to improve clarity (Figure 29)

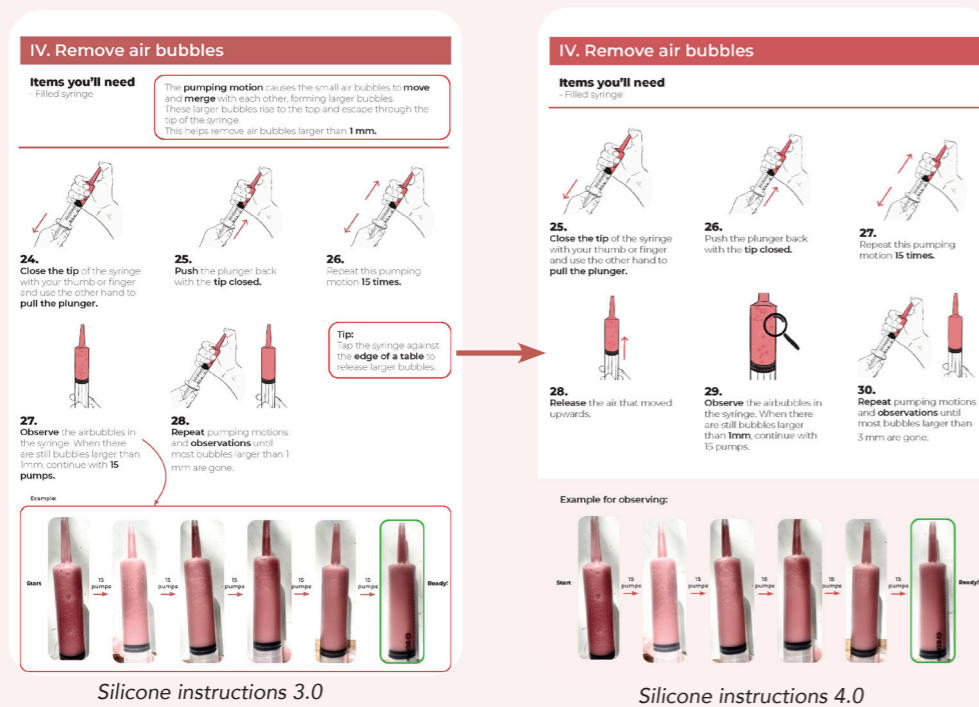


Figure 29: Improvement of Section IV.

The final self-check was revised to provide clearer definitions and a more structured layout with improved visual hierarchy (Figure 30). In addition, tips were added to explain what makers can do when a silicone part is considered unusable.

For this version, a height deviation greater than 1 cm is defined as unacceptable, and air bubbles larger than 0.5 cm. However, these boundaries are not yet based on material or assembly research, but rather on assumptions of what appears acceptable in practice. Therefore, further research is required to determine the actual impact of these deviations on the performance of the silicone parts.

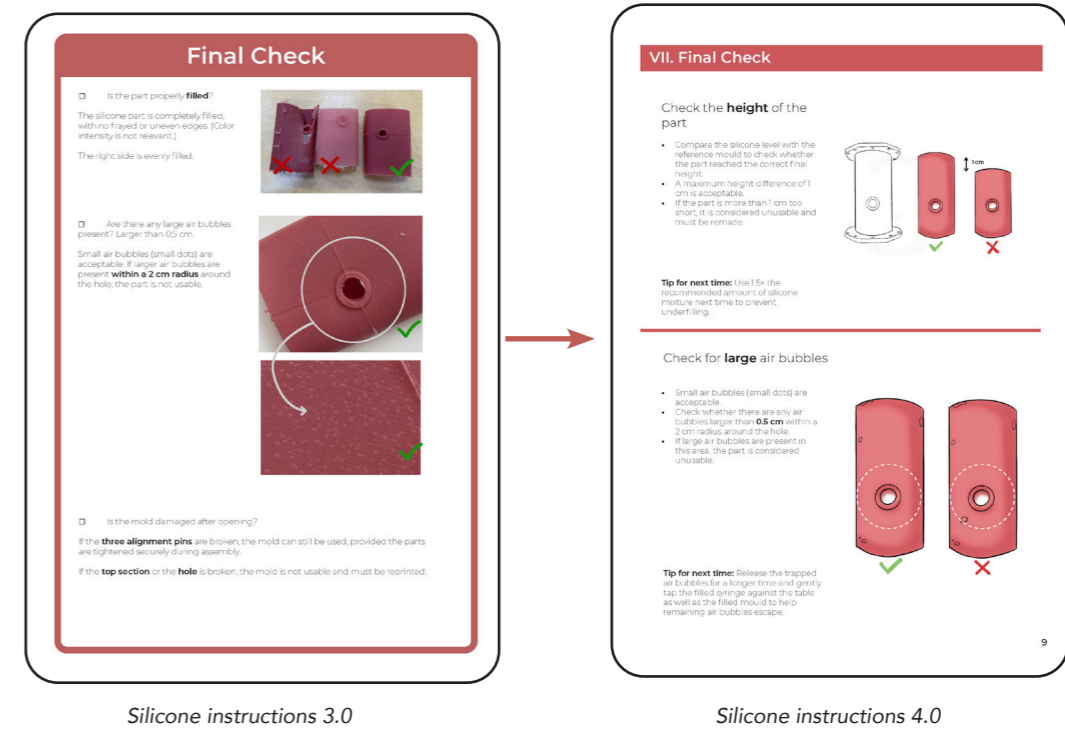


Figure 30: Improved final check section

Based on the insight that experienced makers require less detailed guidance, quick-reference sheets were developed for the vulva, bladder cup, bladder plate, and cervix components as an exploration of how instructional support could be adapted for more experienced makers (Figure 31). Full-size versions can be found in Appendix G.2.

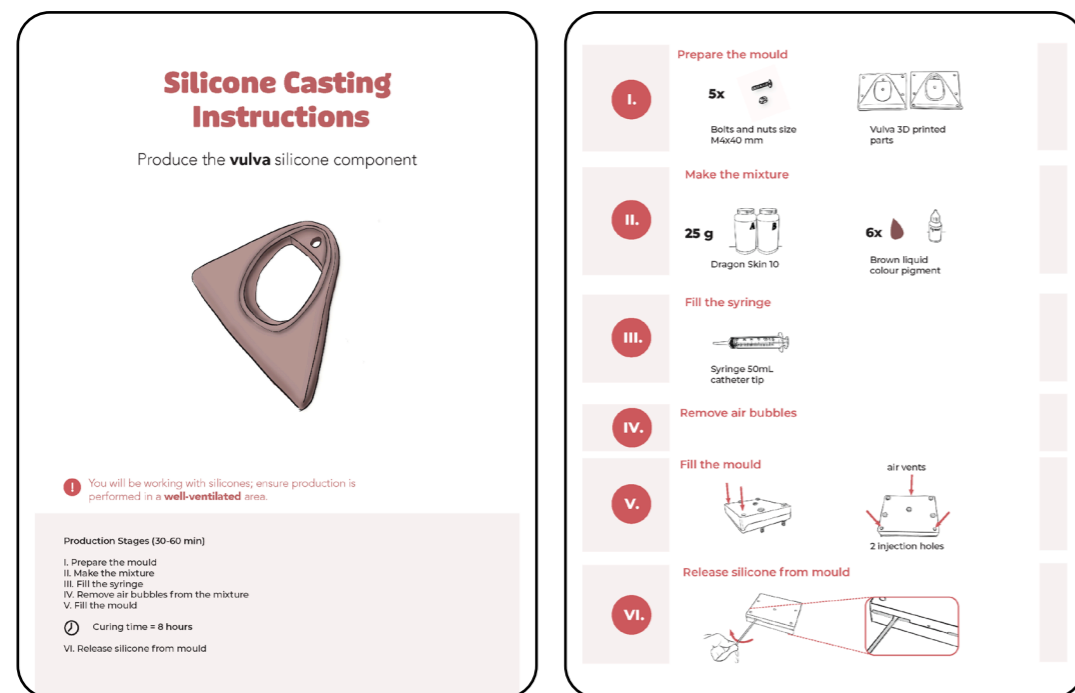


Figure 31: Quick-reference sheet of vulva

All insights gained throughout the iterative design sprint informed the development of the final silicone instructional design. The final instructions were no longer evaluated within this project and are presented in Chapter 5.

#### 4.2.2 New requirements

This design sprint resulted in the refinement of existing requirements as well as the formulation of new ones.

The requirement "Separate instruction materials must be provided for each silicone component (1.26)" has been refined to: "Separate instruction materials must be provided in the form of individual booklets for each silicone component (1.26)".

The requirement "The manual must combine text with visual representations (1.24)" has been revised to: "The manual must include visual representations for each step, accompanied by explanatory text (1.24)"

The following new requirements have been established for the quality of the silicone components:

- All silicone components must be completely filled to be usable. (2.4)
- The vulva, cervix, and bladder plate may contain air bubbles (2.5)
- The vagina and bladder cup must not contain air bubbles larger than 1 mm within a 2-cm radius around the fistula. (2.6)

## 4.3 Design Sprint 3 – Development of Assembly Instructions

This design sprint focuses on the development of the instructional materials for the assembly of all components into the final clinical task trainer. Design sprint 2 already gave a starting point in how the instruction manual will be structured in ways of formatting and created new requirements.

Two versions of the assembly instructions were developed, which were both tested with participants. The prototypes were iteratively developed and evaluated. Key insights were identified leading to the final version of the assembly instructions. The sprint concludes with an updated list of requirements. The final design of the assembly instructions will be presented in Chapter 5.

### 4.3.1 Determine the Content

Similar to the approach used for the silicone instructions, it was necessary to determine what information novice makers require for the assembly instructions as well (Theme 2). To achieve this, the steps of the existing assembly instruction were broken down into smaller actions. Like the production of the silicone parts, the assembly can be divided into substages as well:

- I. Assemble Framework
- II. Assemble Blader Cup to Vagina
- III. Assemble Cervix to Vagina
- IV. Assemble Urethra
- V. Assemble Bladder Top to Bladder Cup
- VI. Assemble Vulva to Framework
- VII. Assemble Vagina to Vulva

This provided a strong starting point for presenting the instructions in manageable and well-structured segments, supporting Requirement 1.14.

### 4.3.2 Design the Assembly Instructions

With the content clear, the translation was made to the development of the instructions. The following sections describe the iterative design process, in which each prototype is presented, followed by its evaluation results and the resulting improvements. This phase specifically addresses Theme 3 from the Discover phase, which highlights that the content is not presented clearly. The main challenge is to balance cognitive load by providing sufficient information without overwhelming the maker.

#### 4.3.2.1 Assembly Instructions 1.0

Based on insights gained during Design Sprint 2, the assembly instructions 1.0 used the same visual layout of text and images as the silicone casting instructions. The assembly instructions 1.0 can be found in Appendix E.1.

Before developing the first version of the assembly instructions, a conversation was held with one of the designers of the task trainer. During this conversation, it became clear that correctly assembling the bladder cup to the vagina component, as well as connecting the urethra to the bladder cup, is essential for the task trainer to function properly during surgical training.

Therefore, it was important to determine the specific requirements for assembling these critical connections. Chapter 2.2.2 describes how the surgical procedure is performed on the task trainer and provided insight into the functional requirements of the assembly. Based on this information, it was established that the bladder cup and vagina components must have at least 2 cm of contact area surrounding the fistula connection. In addition, it can be concluded that the connection of the urethra with the bladder cup must be assembled in a watertight manner.

To standardize the assembly of the bladder cup and vagina during the gluing process, the designer introduced a simple solution: a 3D-printed cylinder, further referred to as the 'glue support'. This component is placed inside the vagina part and indicates the surface area where the glue should be applied and where the bladder component should be attached (Figure 32)

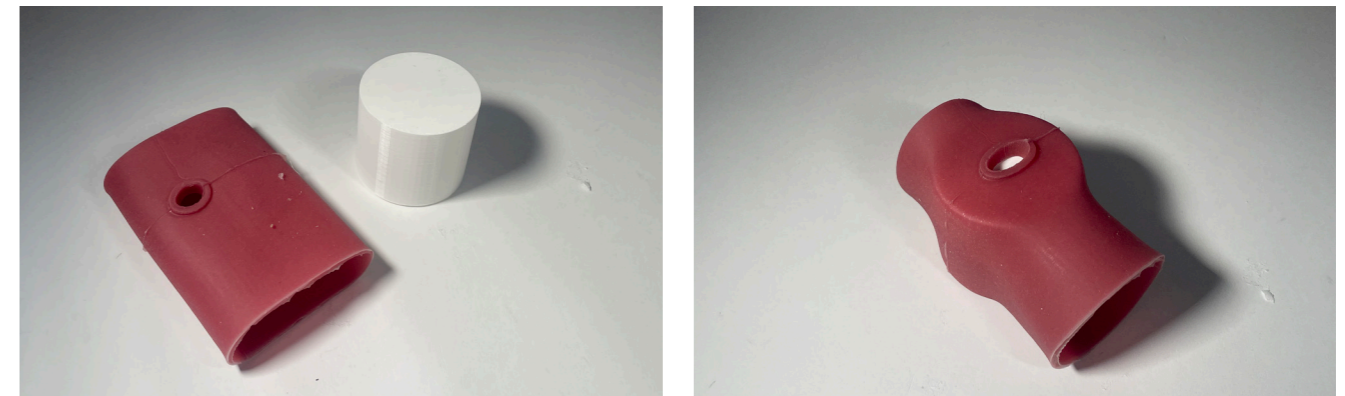


Figure 32: Left: Silicone vagina and glue support. Right: Glue support in vagina

#### Test set-up

A user test was conducted with three participants. The participants assembled the clinical task training using the provided assembly instruction 1.0 to evaluate the usability and clarity. In addition, the assembled task trainers were evaluated based on predefined criteria. After the assembly, a co-creation session was conducted to identify and prioritize the issues and generate improvements. These improvements included rewriting steps, adjusting images and improving layouts. Finally, the participant listed the issues on priority, to emphasize what had the biggest priority to improve. A detailed description of the test setup and evaluation criteria can be found in Appendix E.2.

The instructions are designed in colour but were given in grayscale. To test whether the illustrations remain understandable without colour, in accordance to requirement 2.1: instruction materials must be usable when printed in grayscale. Each assembly took about 2,5 to 3 hours.

The goal of the test was to evaluate both the product quality, referring to the quality of the assembled task trainer, and the process quality, referring to how participants experienced the assembly process and interpreted the instructions.

Since the design goal focuses on supporting maker confidence, participants were also asked to rate how well they believed they had assembled the task trainer on a 5-point Likert scale, referred to as the confidence score. These scores were later compared to the actual quality assessment of the assembled task trainers to explore whether the instructions supported both successful assembly and maker's confidence. Appendix E.2 shows the predefined criteria. If all criteria were met per section, the task trainer was marked as usable for a trainee.

## Product quality evaluation results

Each criterion per substage was assessed for each participant. The participants received a score of 1 when their assembled part did not meet a criterion and a score of 5 when the criterion was met.

None of the participants met all predefined criteria, meaning that all assembled task trainers were classified as unusable. Figure 33 provides an overview of the product scores and the confidence scores.

Section	P1	P2	P3
I. Assemble framework	-	-	-
II. Bladder cup to vagina	5	1	1
III. Cervix to vagina	1	5	5
IV. Urethra into bladder hole	5	5	5
V. Bladder top to cup	5	5	1
VI. Vulva to framework	5	1	5
VII. Vagina to vulva	5	1	5
Means (product score)	4.3	3	3.7
Confidence score	4	2	3
Usable task trainer	No	No	No

Figure 33: Results of the assembled task trainer of each participant.

Although all participants recognized that errors had occurred during the assembly process, they continued with the subsequent steps instead of correcting these mistakes.

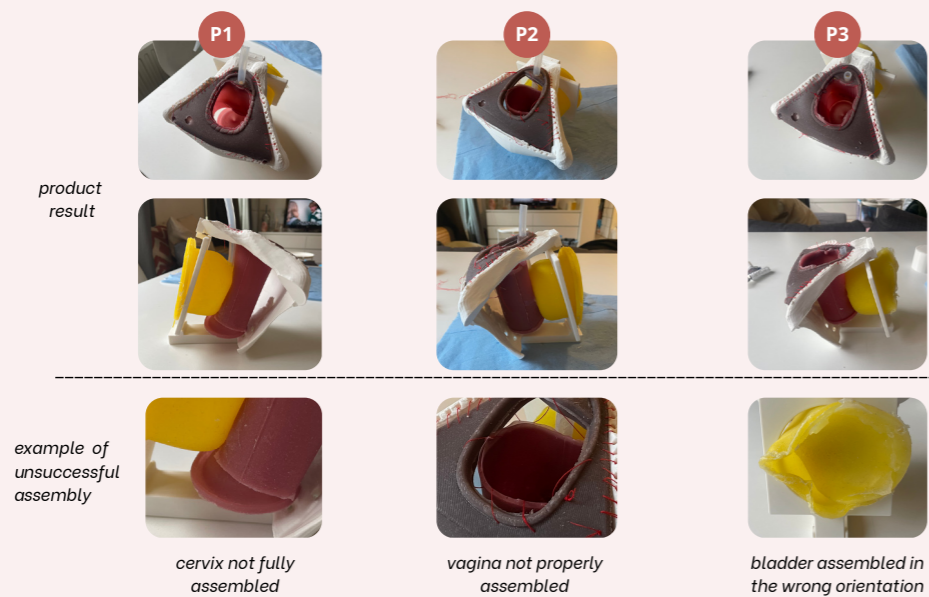


Figure 34: Errors of all participants in assembled task trainer

The low product score and the fact that no participant assembled a usable task trainer indicates that the instructions contain errors and should be improved.

## Process quality evaluation results

During the assembly process, multiple issues, uncertainties, and frustrations were observed, even in cases where the final assembly outcome was considered usable. The complete overview of all observations, impacts, priorities, and co-creation outcomes can be found in Appendix X.X. The most important findings observed during the usability test are discussed below and formed the starting point for the next iteration of the assembly manual.

### General Observations

All participants indicated that several illustrations were difficult to read in grayscale. All participants experienced frustration with the waiting times required for glue curing. Participants often relied more heavily on illustrations than on textual explanations.

### Assemble Bladder Cup to Vagina

Two out of three participants did not assemble the bladder cup to the vagina correctly because the glue was not spread evenly and the components were positioned at an angle. The third participant assembled the bladder cup in the wrong orientation, see Figure X. These findings indicated that the instructions did not sufficiently communicate the correct positioning and alignment of the components.

### Assemble Cervix to Vagina

All participants struggled with the assembly of the cervix to the vagina. The instructions showed to keep the glue support in the cervix and glue the cervix to the vagina. However, this glue support made the action way more complex than it actually is. Therefore, the step to remove the glue support was replaced to an earlier step.

### Assemble Urethra

All participants struggled with gluing the urethra. The rubber tube did not fit properly making it difficult to glue in the right position. It was also observed that participants struggles with this step.

### Assemble vulva to framework and vulva to vagina

All participants mentioned that too little explanation about the sewing steps were present and that it was assumed that the user had sewing experience. P2 and P3 felt really frustrated while sewing. P2 rushed the task, lost patience, and therefore did not perform the sewing correctly.

The main reason P2 and P3 felt inconfident is because of the sewing steps. It was clear that P1 had prior sewing experience, in contrast to the other two participants.

An additional observation was that all participants experienced moments of impatience or frustration during the process. Participants indicated that the assembly took long, which negatively affected their motivation. Two participants reported increased frustration during the assembly of the vulva to the framework and the vagina to the vulva, as these steps involved sewing techniques with which they were not familiar. The third participant experienced frustration during the gluing process, expressing impatience with required drying time, which led to components detaching. A full overview of all results from the test can be found in Appendix E.2.

The results indicate that the current instructions are insufficient to guide makers to successfully fabricate the task trainer. Based on the test results, five key insights emerged.

#### **Error Prevention**

First, there is a clear need to emphasize error recovery and improvements of the self-checks. The maker should receive clear guidance on how to correct the mistakes that were made. A possible explanation for why makers continued the assembly despite recognizing errors may be related to the testing context, in which participants were aware that the task trainer would not be used by a trainee after completion. However, this observation still emphasizes the need to provide clear guiding and incorporating error-recovery.

In addition, the self-checks should be highlighted more clearly, as these steps were not recognized as self-check and the accompanying text was not read. This can be done by visually emphasizing the self-check to grab the attention.

#### **Assume Prior Knowledge on Sewing**

Second, the instructions assume prior knowledge on sewing. Not all participants had experience with sewing. Therefore additional explanation is necessary to make the instructions understandable to makers.

#### **Illustrations**

Third, some illustrations require improvements. As all participants mostly relied on the illustrations rather than the text, icons should be added. Such like time indications to know how long to apply pressure and let glue dry. Some steps are not visually clear enough, resulting in doubt and incorrect assembly. Including close-up and more realistic illustrations would enhance clarity. In addition, for some illustrations the contrast should be higher to make it more clear when printed in grayscale.

#### **Efficient Workflow**

Finally, since the assembly currently takes up to 2,5-3 hours, the workflow can be made more efficient by organizing the sequence of the steps differently. This will reduce the waiting times and improves the maker's experience.

#### **Urethra Self-check**

Another insight is that the self-check for verifying whether the urethra connection is watertight, is currently based on visual inspection. However, this method does not technically confirm whether the connection is watertight. Therefore, an addition watertightness test should be introduced in the self-check to ensure quality.

#### **Key takeaways**

- Assembly Instructions 1.0 did not provide sufficient guidance and support for novice makers to successfully assemble the clinical task trainer. Improvements are needed regarding error prevention and recovery, sewing guidance, illustration clarity, and self-checks.
- The assembly sequence for attaching the cervix to the vagina should be revised to simplify the assembly process.
- The assembly of the urethra and bladder cup should be improved to ensure correct positioning and a watertight connection.

### 4.3.2.2 Assembly Instructions 2.0

Based on the insights, improvements are made. The final Assembly Instructions 2.0 can be found in Appendix F.1. The main improvements are shown below.

#### Assemble vulva to framework

The steps for this assembly are broken down into smaller substeps and presented on two pages. In addition, a QR code to a video for providing help with tying a knot.

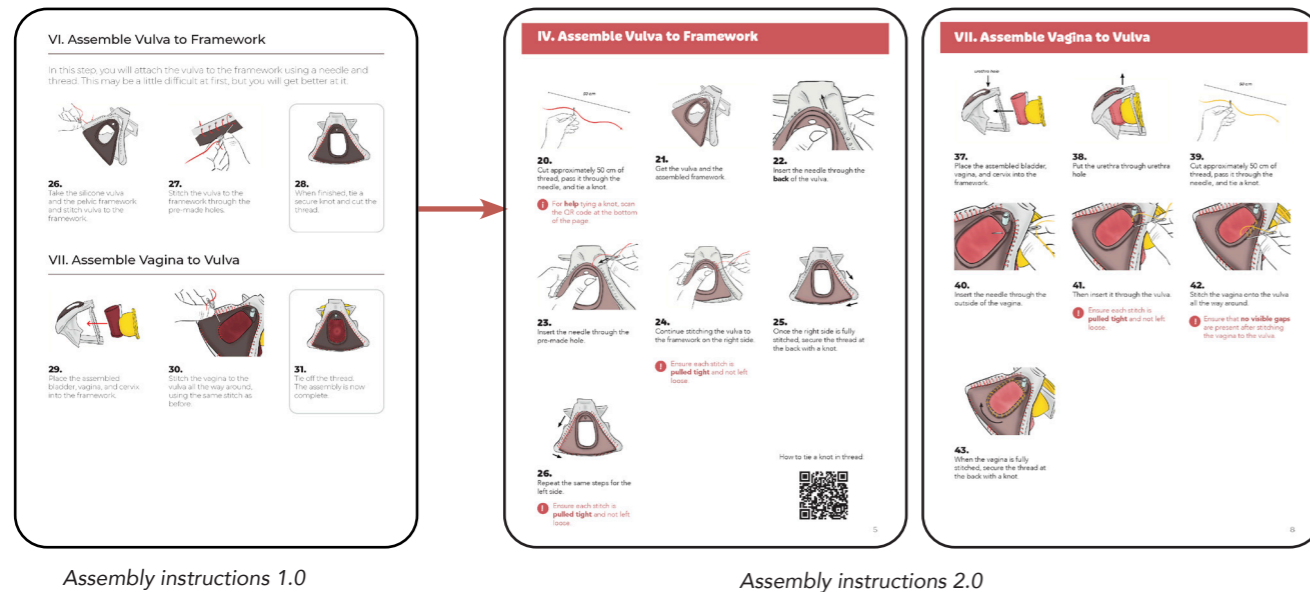


Figure 35: Improved sewing instructions

#### Assembly of cervix

The sequence of the steps is improved (Figure 36). The glue support is taken out of the vagina before assembling the cervix part.

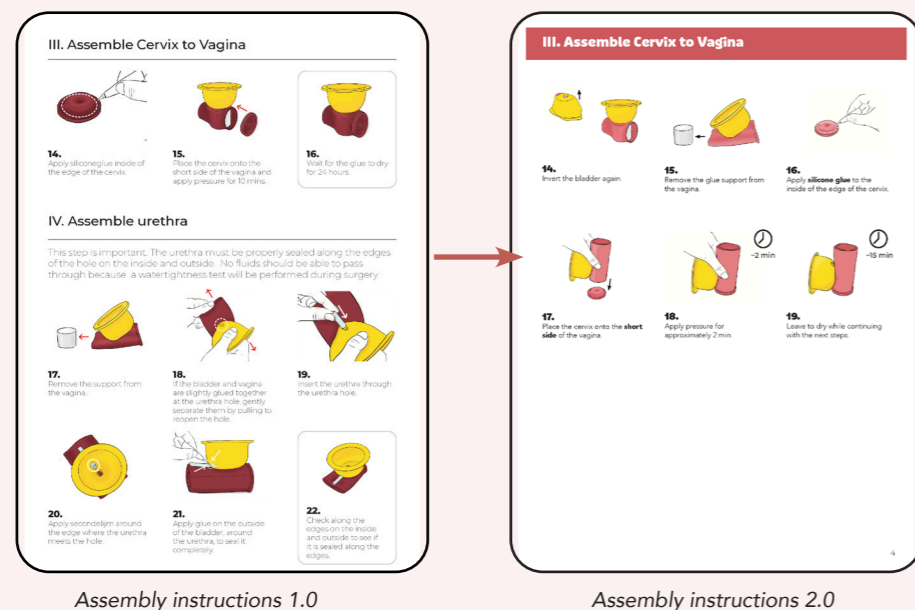


Figure 36: Improved instructions for assembly of cervix

#### Assembly of Urethra

For the assembly of the urethra, a rubber tube with a wider diameter was used to make the connection more firm.

#### Product quality evaluation results

The Assembly Instructions 2.0 were evaluated with two participants using the same test setup as for the evaluation of Assembly Instructions 1.0. A complete overview of all results can be found in Appendix F.2; the most important findings are discussed below.

None of the participants assembled a clinical task trainer that was assessed as usable for training according to the predefined criteria. Figure 37 presents the scores per assembly section for each participant, including the participants' self-reported confidence scores.

Section	P4	P5
I. Assemble framework	-	-
II. Bladder cup to vagina	1	1
III. Cervix to vagina	5	5
IV. Urethra into bladder hole	5	5
V. Bladder top to cup	5	5
VI. Vulva to framework	5	5
VII. Vagina to vulva	5	5
Means (product score)	4.3	4,3
Confidence score	4	3
Usable task trainer	No	No

Figure 37 - Product scores and confidence scores per participant for Assembly Instructions 2.0.

Participant 4 rated the assembly performance with a confidence score of 4 out of 5. This corresponded relatively well with the product assessment, as most assembly sections were considered usable. However, the assembly of the bladder cup to the vagina did not meet the predefined criteria. Although only one section failed, this connection is one of the most critical requirements for the functionality of the task trainer. This suggests that the importance of this assembly step was not sufficiently communicated to the maker.

Participant 5 rated the assembly performance with a score of 3 out of 5 and stated: "It is not completely correct, but I think it will still work." However, the urethra was assembled in the wrong orientation, resulting in incorrect anatomy and limited accessibility of the vaginal fistula during surgical training. This indicates that participants struggled to assess the actual usability of the assembled task trainer, despite the inclusion of self-checks within the instructions.

## Process quality evaluation results

Appendix F.2 provides a complete overview of all results from the assembly process. The most important findings are summarized below.

### Assemble bladder cup to vagina

Both participants incorrectly assembled the bladder cup to the vagina during the early assembly steps. The mistake only became visible later when the assembled components were placed into the framework and the urethra no longer aligned correctly.



Figure 38: Incorrect orientation of the bladder cup assembly for both participants.

In addition, both participants became impatient during the curing process and continued with the next assembly steps before the glue had sufficiently cured. This resulted in a loose connection between the bladder fistula opening and the vaginal fistula opening. This connection is the most critical assembly of the task trainer, as it directly forms the surgical area on which the fistula repair procedure is performed. Therefore, it is essential that this connection is firmly bonded.

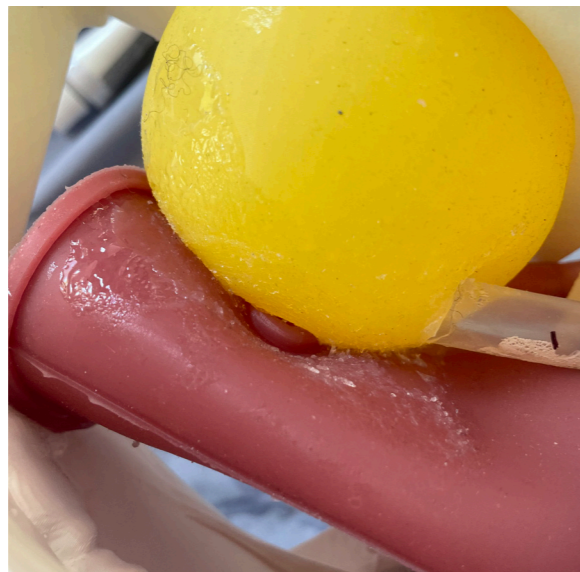


Figure 39: Incorrect assembly of bladder cup to vagina

### Assemble cervix

The revised assembly sequence for attaching the cervix to the vagina significantly reduced participant struggles compared to Assembly Instructions 1.0, where all participants experienced major difficulties during this step. During the evaluation of Assembly Instructions 2.0, no major struggles were observed, indicating that the revised sequence of instructions improved the assembly process.

### Assemble urethra

Replacing the urethra tube with a rubber tube with a larger diameter improved the watertight connection and simplified the assembly process. The larger diameter created tension within the urethra opening, helping the tube remain in position more easily. In the previous evaluation, the urethra tube was too narrow, making it difficult to fill the remaining gaps with superglue and achieve a watertight connection. As a result, creating a watertight assembly became significantly easier in Assembly Instructions 2.0.

### Assemble vulva to framework

Sewing the vulva to the framework was experienced as highly time-intensive by both participants. Although additional sewing explanations and intermediate steps were added in Assembly Instructions 2.0 compared to Assembly Instructions 1.0, both participants still struggled with sewing techniques.

On average, sewing the vulva to the framework required approximately 50 minutes across all usability tests, indicating that sewing forms a substantial part of the total assembly time for novice makers.

These findings provide important directions for further improvements of the instructional materials and will be further discussed in the Recommendations section.

#### Key takeaways

- Makers were not aware of the functional importance of critical assembly steps or the consequences of incorrect assembly for the usability of the task trainer.
- Participants struggled to assess whether the assembled task trainer was actually usable, despite the inclusion of self-checks in the instructions.
- Sewing the vulva to the framework was experienced as highly time-intensive and still difficult for novice makers.

### 3.3.2 New requirements

This design sprint resulted in new requirements for the assembly instructions. The following new requirements have been established:

- The self-check must be visually emphasized to attract attention to ensure makers notice them. (2.7)
- The instructions must provide clear instructions on how to correct errors during assembly. (2.8)
- All assembly steps must clearly communicate orientation, alignment, insertion depth, and positioning through both text and visuals. (2.9)
- Material application (e.g. glue) must clearly specify type, placement, amount, and timing. (2.10)
- Illustrations must accurately represent real components and include hand positioning where relevant. (2.11)
- The assembly sequence should be organized to create an efficient workflow. (2.12)
- The manual could provide additional support (e.g. video) for makers without prior sewing knowledge. (2.13)
- A watertightness test should be included in a self-check to verify the connection between the urethra, and the bladder cup is watertight. (2.14)
- The bladder cup and vagina components must be assembled to each other with approximately 2 cm of contact area around the fistula. (2.15)

# Deliver

This chapter presents the final design of the instructional materials for fabricating the VVF clinical task trainer. The final design consists of evaluated and non-evaluated components. The silicone casting and assembly instructions were iteratively developed and evaluated throughout the project, although the final refinements of the silicone instructions were not re-evaluated. The website, starter kit concept, sourcing flow, and quick-reference sheets were developed as research-informed design proposals but were not evaluated with users within the scope of this project.

## 5.1 Final Design

## 5.2 Website

## 5.3 Instructions

### 5.3.1 Silicone Casting Instructions

#### 5.2.1.1 Quick Reference Sheets

### 5.3.2 Assembly Instructions

## 5.4 Maker's Journey

# 05

## 5.1 Final Design

The final design consists of two main elements (Figure 40). A website (A) and a set of printable instructional materials (B). These elements support novice makers throughout the fabrication process of the vesicovaginal fistula (VVF) clinical task trainer. The design aims to reduce cognitive load, guide makers during fabrication, support preparation and provide quality control during the process.

The website functions as a central location where makers can access all necessary information related to the fabrication of the clinical task trainer. The printable instructional materials support makers during the hands-on fabrication process in laboratory or workshop environments.

Appendix I provides an overview of which requirements were met, partially met, or not met within the final design.

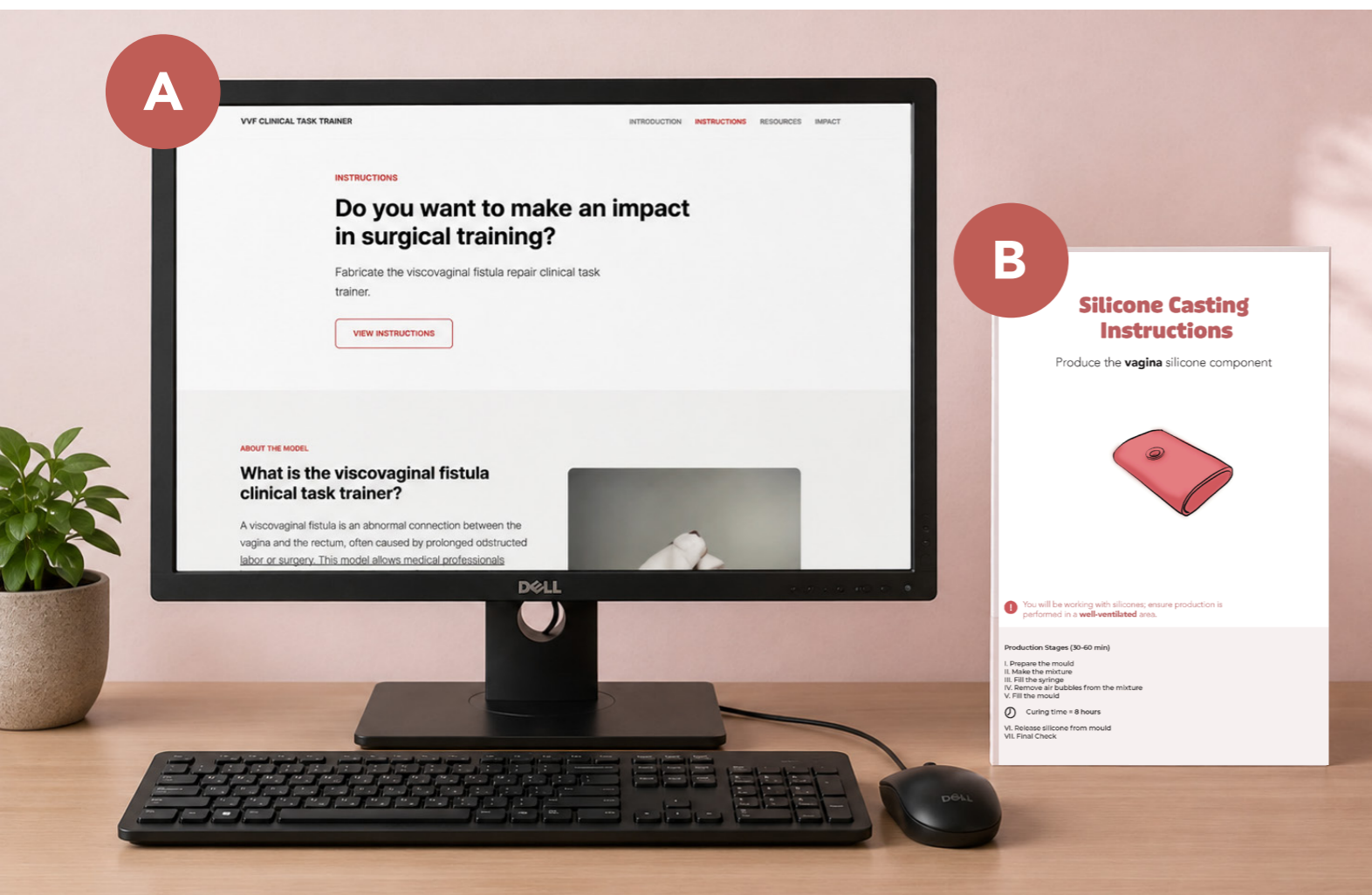


Figure 40: Screenshots of the information presented in the introduction

## 5.2 Website

The website consists of four main sections: Introduction, Materials, Fabricate, and Repair. The website will be accessible through a link provided on the BME for Global Health website.

### Introduction

The introduction page functions as onboarding for novice makers. Figure 41, shows screenshots of the introduction, full size images of the website can be found in Appendix H. The design captures the maker's attention through the use of an inviting sentence: Do you want to make an impact in surgical training? (A). It explains the purpose of the VVF clinical task trainer (B), it shows who this project is intended for and what skills are required (C). In addition, it introduces the fabrication process, and provides an overview of the required skills and estimated fabrication time (D).

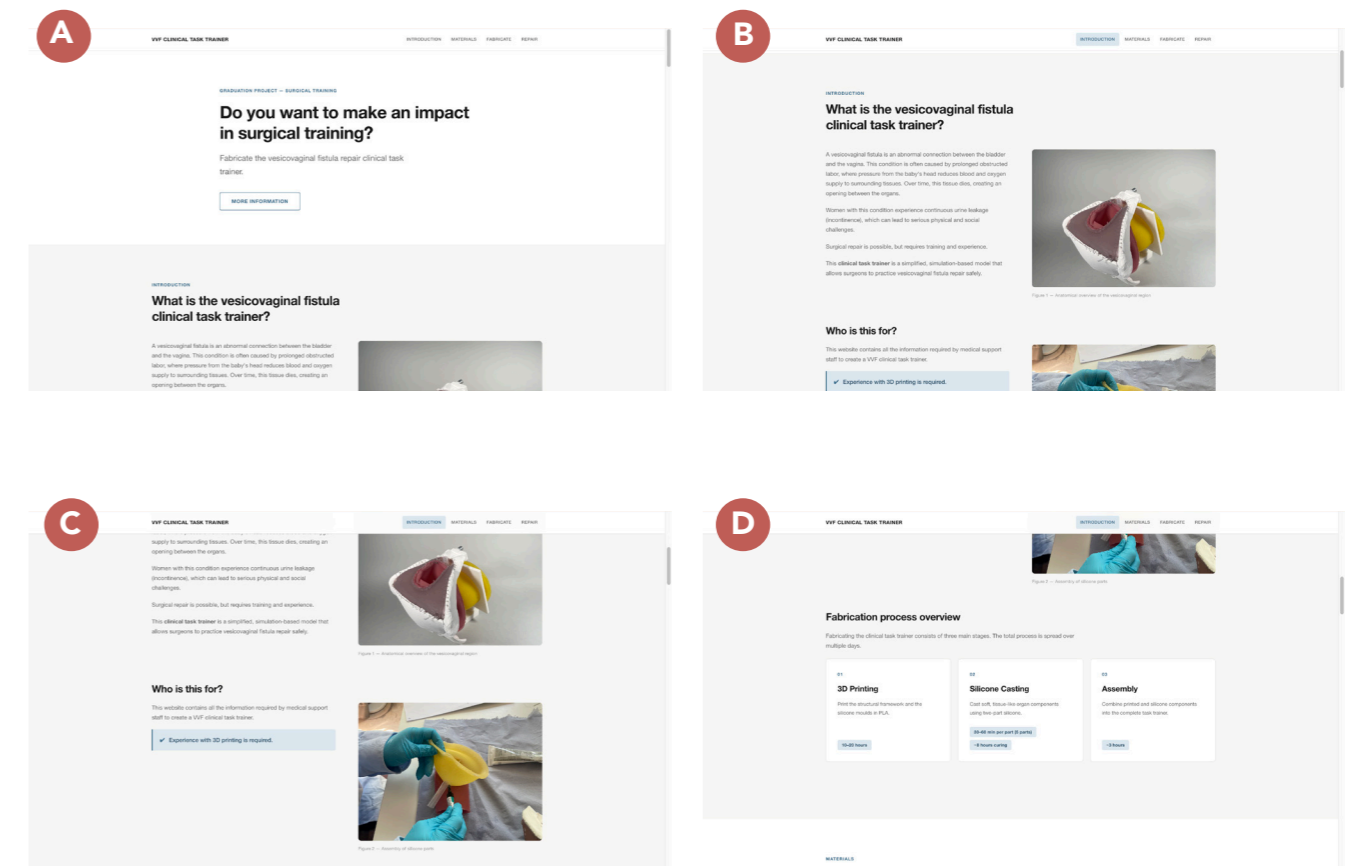


Figure 41: Screenshots of the information presented in the introduction

## Materials

The materials section supports makers in preparing for fabrication by guiding the sourcing of required materials and tools (Figure 42). Two sourcing options are provided: self-sourcing materials and ordering a starter kit. Figure 42, shows screenshots, full size images of the website can be found in Appendix H.

The self-sourcing option (A) provides an overview of the required materials per fabrication stage. Each material includes a 'details' section (B) with additional information about its function, specifications, possible alternatives, and supplier links.

The second option is ordering a starter kit (C). The starter kit includes the necessary materials to fabricate one complete clinical task trainer and perform nine repairs of the bladder cup and vagina component. Providing a starter kit aims to lower the barrier to start the fabrication process by reducing the need and time to source materials from multiple suppliers. The starter kit can be ordered through an order portal by pressing the button (D).

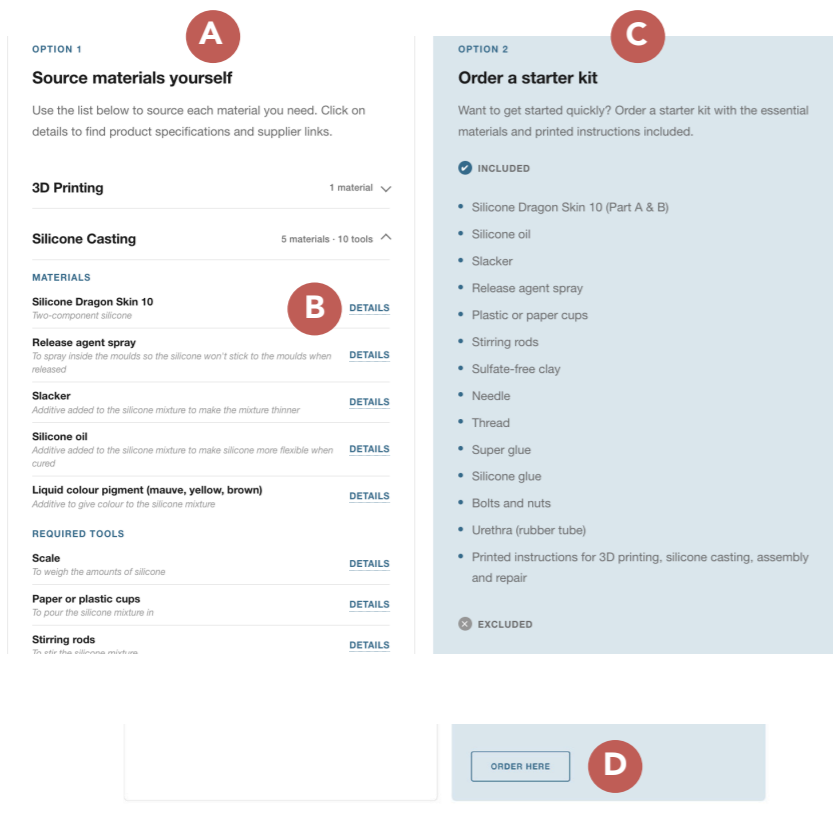


Figure 42: Screenshots of the materials sourcing options presented

The estimated cost of the starter kit is approximately €286.50. This estimation is based on producing one complete clinical task trainer and performing nine repairs. Assuming the task trainer can be used for ten training sessions in total, the estimated material cost per training is approximately €28.65. A complete overview of the estimated costs can be found in Appendix J.

## Fabricate

The fabricate section supports makers when the correct materials and tools are sourced. The fabrication process is divided into three substages; 3D printing (A), silicone casting (B) and assembly (C). For each stage a short introduction is provided (D), including supporting images and a download section (E) to download STL-files or the instructions. Figure 42, shows screenshots, full size images of the website can be found in Appendix H.

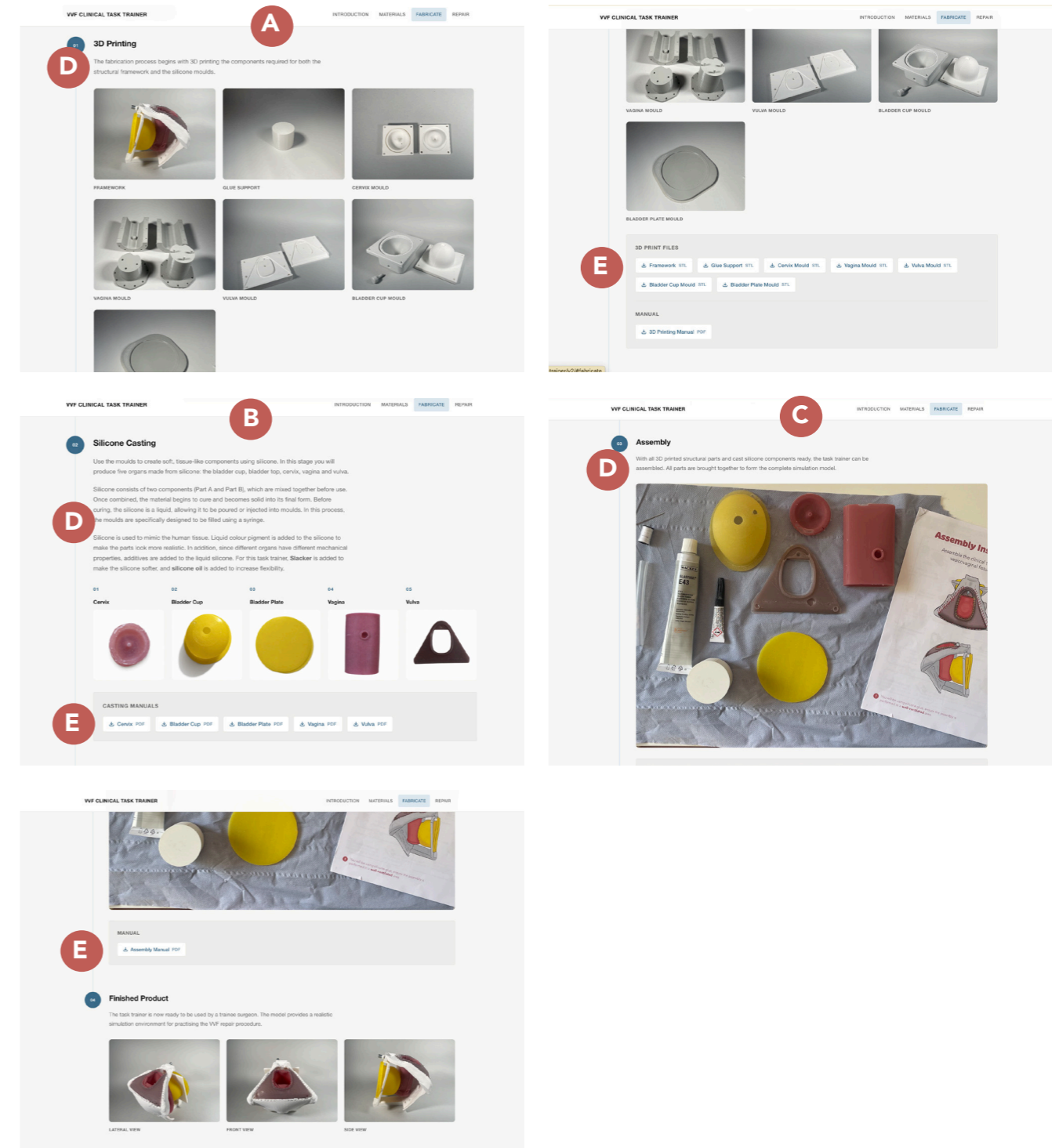


Figure 43: Screenshots of fabrication process information

## Repair

The repair section provides guidance and printable instructions for replacing the used silicone components after training. Figure 42, shows screenshots, full size images of the website can be found in Appendix H. An overview of the repair process is provided including time indications (A) and downloadable instructions are presented (B). Although repair instructions were not developed within the scope of this project, the website structure proposes the idea.

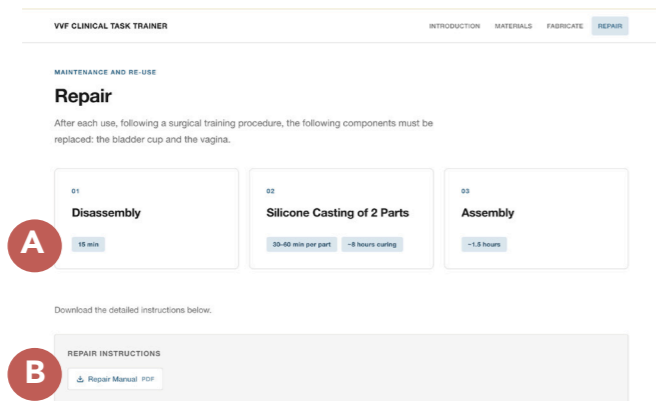


Figure 44: Screenshots of repair information

## 5.3 Instructions

The printable instructional materials were designed for use during fabrication in laboratory or workshop settings. The instructions combine visuals and explanatory text to guide novice makers throughout the fabrication process.

### 5.3.1 Silicone Casting Instructions

The silicone casting instructions consist of separate instructions for each silicone component. This segmentation reduces information density and supports novice makers by presenting the process in smaller and more manageable sections. The instructions are designed in a way that it is also readable and understandable when printed in grayscale.

The detailed instruction of the vagina silicone component starts with an overview of the required materials and tools. Followed by step-by-step instructions supported by illustrations and explanatory text. In addition, a final quality check is included to support makers in evaluating the produced silicone components.

The instructions for the vagina component are the most detailed, indicating that novice makers should start with this booklet. The full set of silicone instructions can be found in Appendix G. Figure 45 shows a mock-up of these instructions.



Figure 45: Mock-up of silicone casting instructions

### 5.3.1.1 Quick-Reference Sheets

The instructional materials were developed for novice makers. However, throughout the process of producing the silicone components, makers gradually become more experienced and require less guidance. Based on this insight, quick-reference sheets were developed for the vulva, bladder cup, bladder plate, and cervix components.

These sheets provide a compact overview of the six silicone casting substages, including the required materials and quantities, assuming that the maker is already familiar with the fabrication techniques. Figure 46 shows an example of a quick-reference sheet for the vulva component.



Figure 46: Mock-up of vulva quick reference sheet



Figure 47: Mock-up of assembly instructions

### 5.3.2 Assembly Instructions

The assembly instructions are designed as a printable booklet divided into substages. Similar to the silicone instructions, the assembly instructions combine visuals with explanatory text to guide makers through the assembly process.

Critical assembly steps are highlighted visually using warning indicators and color accents (Figure 48) to attract attention and support error prevention. In addition, self-checks are integrated throughout the assembly process to support makers in assessing the quality of the assembled task trainer.

The complete assembly instructions can be found in Appendix F.1.

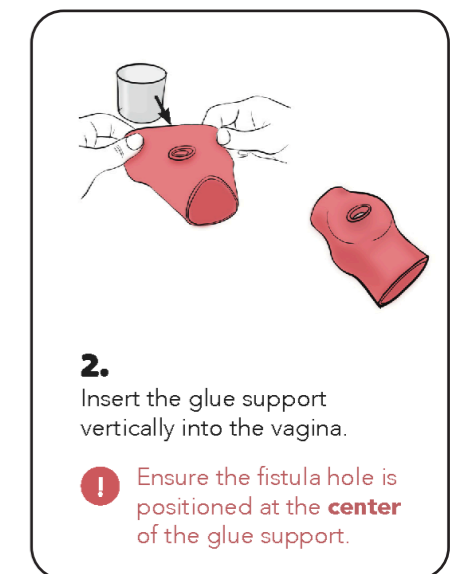


Figure 48: Example of warning indicators

## 5.4 Maker's Journey

The maker's journey consists of two possible routes:

1. self-sourcing materials and printing the instructions, or
2. ordering a starter kit with the required materials and printed instructions.

Figure 49 visualizes the starter kit journey. The journey starts with the website, which aims to attract the maker's attention and introduce the fabrication process, corresponding to Gagne's first event of instruction. The website supports the preparation phase by providing onboarding information. Including, material guidance, and access to the instructional materials, corresponding to Events 2 and 3 of Gagné's Nine Events of Instruction.

After this introduction, the maker proceeds through the different fabrication stages: 3D printing, silicone casting, and assembly. Throughout these stages, the maker is guided using printable instructions supported by self-check moments, corresponding to events 4-8 of Gagné.

After completing the assembly process, the fabricated clinical task trainer can be used for surgical training. When components become damaged through repeated use, the maker can return to the repair stage to replace silicone components.

The journey in which the maker self-sources the materials is largely similar. The main difference occurs in the preparation phase, where the maker must collect the materials and print the instructions themselves instead of receiving a box containing materials and printed instructions.

# Evaluation

This chapter concludes the project by answering the research question and reflecting on the extent to which the design goal was achieved. The findings are further discussed in the Discussion section, including the limitations of the project and recommendations for future research.

In addition, the Recommendations section presents design directions and insights that emerged during the project but fell outside the scope of this graduation project, while still being relevant for the further development of the clinical task trainer and its instructional materials.

Finally, the chapter concludes with a personal reflection on the project process, including notable experiences, challenges, and personal learning outcomes encountered throughout this project.

6.1 Conclusion

6.2 Discussion

6.2.1 Limitations

6.2.2 Future Research

6.3 Recommendations

6.4 Personal Reflection

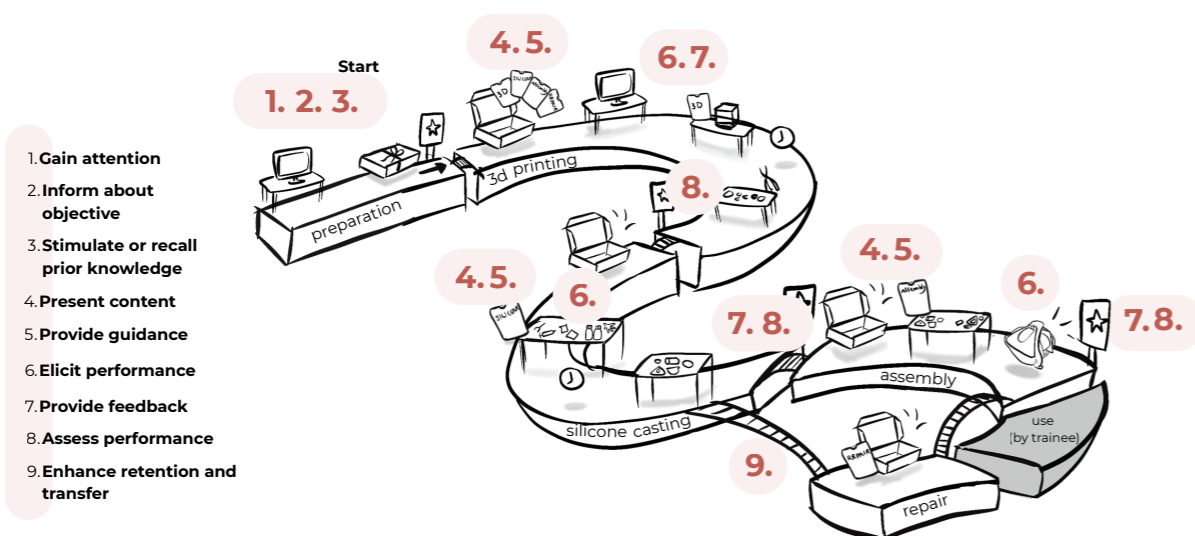


Figure 49: Maker's journey using a starter kit, structured according to Gagné's Nine Events of Instruction

# 06

## 6.1 Conclusion

This project investigated how the instructional materials should be designed to enable the fabrication of the vesicovaginal fistula clinical task trainer in low-resource settings. The project was conducted using a Research through Design approach, structured according to the Double Diamond framework. Through hands-on fabrication, desk research, expert input, the current fabrication process was analyzed and translated through iterative prototyping and user evaluations into a set of instructional materials.

The research question guiding this project was:

“How should the instruction materials be designed to enable fabrication of the VVF clinical task trainer in low-resource settings?”

The findings show that the instructional materials should not only explain the steps of fabrication, but should guide the maker through the fabrication process as a structured learning journey. The fabrication of the VVF clinical task trainer consists of multiple stages, including 3D printing, silicone casting, assembly and repair. For novice makers, this process can be overwhelming when instructions are incomplete, unclear or not supporting.

The Discover phase identified challenges that were clustered into four themes. First, the fabrication process is a long and multi-stage journey that requires structure and preparation. Second, the content of the existing instructions is incomplete for novice makers who require information about the full workflow, materials, tools and quality criteria. Third, the content is unclear in several places, due to missing visuals, unclear terminology and insufficient guidance during critical steps. Fourth, the level of experience of the maker strongly influences the type and amount of guidance required. Novice makers need detailed step-by-step support, while experienced makers can work with more concise information. Within the silicone production, the maker produces five components and with each production gets more experienced and needs less guidance.

Based on these insights, the final design proposes instruction materials that are portable, printable, visually supported and divided into manageable sections. The silicone casting instructions were redesigned into separate booklets of which only the silicone casting instructions of the vagina is fully developed and evaluated. The booklets should follow the same six substages: preparing the mould, making the mixture, filling the syringe, vacuuming the syringe, filling the mould and releasing the component from the mould. This structure helps makers process the information in manageable steps.

The assembly instructions were also redesigned. The evaluation of the assembly process showed that certain steps, such as attaching the bladder cup to the vagina, attaching and orienting the urethra and sewing the vulva to the framework, are critical for the final functionality of the task trainer. These steps require clear communication of orientation, alignment and quality criteria.

The design goal was partially achieved: the silicone casting instructions for the vagina component successfully supported novice maker in independently producing the part, while the assembly instructions still require further refinement and validation.

Overall, this project concludes that instructional materials for the VVF clinical task trainer should be designed for novice makers as guided, step-by-step instructions that include feedback moments. These instructional materials should not only provide clear and complete procedural information, but also support the maker experience throughout the fabrication process.

## 6.2 Discussion

A central insight from this project is that the fabrication process can be approached as a learning journey. The use of Gagne’s Nine Events of Instruction helped structure this journey by emphasizing the importance of preparation, guidance, practice, feedback and assessment. In the context of the VVF clinical task trainer, this means that makers should be introduced to the overall workflow before starting and supported during each fabrication stage. In addition, makers should be provided with quality criteria and self-check moments to enhance correct reproducibility.

The iterative development of the silicone casting instructions illustrates the importance of balancing completeness of the information and cognitive load. The silicone casting instructions 1.0 contained much of the necessary information, but were experienced as overwhelming by participants. This showed that providing more information does not automatically lead to better support. Instead, the information should be divided into smaller, task-oriented steps. Segmenting the instructions into separate booklets for each silicone component contributes to reducing information density, making the fabrication process more manageable for novice makers.

The evaluations also showed that visual instructions are essential, but that visuals alone are not always sufficient. In several tests, participants relied on illustrations and skipped explanatory texts. This led to mistakes in critical silicone casting and assembly steps. This especially highlights that instructions should use both text and visuals. Visuals can quickly communicate shape, position and sequence but text remains necessary to emphasize critical details.

Another important insight is the role of feedback. During both silicone casting and assembly, makers frequently questioned whether they were performing steps correctly. This indicates that self-checks are necessary design elements. However, the project also showed that self-checks must be clearly visible and specific. When feedback moments were subtly integrated into the steps, participant sometimes overlooked them which negatively influenced the quality of the assembled task trainer.

The evaluations further showed that novice makers were not always aware of the functional importance of critical assembly steps. Several participants believed their assembled task trainer was still usable, while critical assembly mistakes were present that made the trainer unusable for surgical training. This indicates that the maker’s perception of quality does not necessarily correspond to the actual functional quality of the task trainer. Self-check moments were integrated throughout the instructions, but participants sometimes overlooked these checks or underestimated the consequences of incorrect assembly. At the same time, providing extensive quality criteria upfront may increase cognitive load for novice makers. Therefore, a balance is needed between supporting quality control and maintaining a manageable instruction flow. One possible direction could be to better explain the function and importance of critical assembly connections before the assembly process starts.

The assembly evaluations revealed that some fabrication problems cannot be solved through instructional design alone. For example, attaching the bladder cup to the vagina requires patience and stable positioning while the glue cures. Participants struggled with this step even when they understood what they were supposed to do. Similarly, sewing the vulva to the framework was time-consuming and required practical skill. These findings suggest that there is a limit to what instruction materials can achieve when the design of the clinical task trainer remains difficult to fabricate and be reproducible by a wider audience.

The results of this project show that the usability of fabricating the VVF clinical task trainer not only depends on the quality of the instructional materials but also on the design of the task trainer itself.

The VVF clinical task trainer was designed to be affordable, locally producible, and suitable for low-resource settings. However, this project showed that local reproducibility cannot be achieved through accessible instructional materials alone. Makers also require support in accessing the correct tools, materials, and components necessary for fabrication.

Throughout the project, it became clear that the large number of required materials, tools, and separately sourced components can form a barrier for novice makers to start the fabrication process. With the final design the maker has the opportunity to self-source the materials or to order a starter kit. A conversation with a student who completed an internship in Eldoret, Kenya, highlighted practical challenges related to ordering and transporting materials in low-resource settings. These challenges included long delivery times and uncertainty regarding whether materials arrive at the correct location. Since the fabrication process requires many different materials sourced from multiple suppliers, a starter kit could provide a more convenient solution by supplying the required materials in one package. However, this insight was based on one shared experience and should therefore be further investigated across different low-resource contexts.

At the same time, implementing a starter kit introduces logistical challenges related to storage, transportation, distribution, and production. Assuming that starter kits would initially be distributed from the Netherlands, several approaches for transportation could be explored. One possible approach could involve collaboration with international volunteer, educational, or global health organizations that already organize training activities or travel to low-resource settings. These existing travel networks could potentially support the transportation of starter kits or material packages to the correct locations.

Another possible direction could involve investigating whether transporting starter kits as personal luggage during travel would reduce shipping times and improve delivery reliability compared to conventional shipping methods. However, further research is needed regarding logistics, regulations, costs, and scalability.

## 6.2.1 Limitations

Although the project provided valuable insights into the design of instructional materials for the VVF clinical task trainer, several limitations should be considered when interpreting the findings and evaluating the outcomes of the project.

- A relatively small sample size was used throughout the evaluations. Although the findings provided valuable insights into the usability and clarity of the instructional materials, the results cannot be generalized.
- Not all components of the final design were evaluated. The website, sourcing flow, starter kit concept, and experienced-maker support were developed as research-informed design proposals but were not tested with users.
- Small adjustments were made to the final instructional materials after the last evaluations to improve clarity and consistency. However, these final refinements were not evaluated anymore.
- Within the silicone casting instructions, only the instructions for the vagina component were extensively developed and evaluated. The remaining silicone components were not fully developed or validated within this project.
- Variations in materials influenced parts of the evaluation process. For example, different types of silicone glue with different curing times were used during the evaluations of assembly instructions 1.0 and 2.0, which may have affected participant experiences and assembly outcomes.
- The self-check criteria and quality boundaries for both silicone casting and assembly were practically determined within the context of this project, but were not clinically or materially validated.

## 6.2.2 Future Research

Although this project provided valuable insights into the design of instructional materials for the VVF clinical task trainer, several aspects require further investigation in future research.

During the develop phase, the design choice was made to create paper-based instructions rather than digital instructions. This decision was based on practical considerations, as silicone fabrication takes place in a laboratory setting where makers are likely to wear gloves, making interaction with a phone inconvenient. However, when makers do not order the proposed starter kit, they are dependent on printing the instructions themselves. This assumes the availability of a printer, which may not be the case in all low-resource contexts. Therefore, further research is needed to investigate whether the instructional materials could also be adapted for mobile phone use.

One possible direction could involve voice-guided interaction to reduce the need for physical interaction with the screen during fabrication. However, further research is needed to determine how complex fabrication instructions can be effectively communicated on small screens while maintaining manageable cognitive load.

Although initial ideas were explored regarding the logistics and distribution of starter kits, further research is needed to investigate how starter kits could be practically organized, transported, and distributed within low-resource contexts.

In addition, the assembly evaluations assessed the quality of the assembled clinical task trainer using predefined criteria developed within the context of this project. These criteria were based on insights gathered throughout the design process but were not clinically or materially validated by medical professionals or surgical trainees. As a result, the influence of incorrect assembly on actual surgical performance is unknown. Future research should therefore investigate which assembly criteria are clinically relevant for surgical training and how these criteria influence the reproducibility and functional quality of the task trainer.

The estimated cost price of the starter kit currently assumes sufficient materials to fabricate one complete clinical task trainer and perform nine repairs. However, additional research is needed to determine how often the task trainer can realistically be repaired and how durable the remaining components, such as the cervix, bladder plate, and vulva, are over repeated use.

Finally, future research should investigate how air bubbles in silicone component influence the final functionality of the clinical task trainer. For example, it is unclear how incomplete filled vagina components influence the final assembly and usability of the task trainer. In addition, the effect of air bubbles within silicone components on surgical performance should be further explored.

## 6.3 Recommendations

Based on the outcomes, limitations and future research of this project, several recommendations can be made for the further development of the instructional materials and the VVF clinical task trainer.

### Instructional Materials

Future work should focus on evaluating the complete fabrication journey as one continuous process. This project primarily focused on the silicone casting and assembly stages, while 3D printing and repair instructions were not developed or evaluated. Since 3D print quality, part orientation on the 3D printer, and repair procedures are important parts of the fabrication workflow, these stages should also be further developed and tested.

In addition, onboarding materials are recommended to prepare makers before starting the fabrication process. Such onboarding could explain the purpose and functionality of the clinical task trainer, introduce critical assembly connections, and clarify why specific assembly steps are important for the final usability of the task trainer.

The latest version of the silicone casting instructions (Version 4.0) included several final adjustments to improve clarity. These refinements should still be evaluated to determine whether the intended improvements were achieved. Furthermore, the quick-reference sheets developed for more experienced makers should be tested to determine whether they provide sufficient information while reducing unnecessary guidance.

For the assembly instructions, several additional improvements are recommended. During the evaluation of Assembly Instructions 2.0, both participants assembled the bladder cup in the wrong orientation. Therefore, clearer emphasis should be added stating that the urethra opening must remain parallel to the long side of the vagina. In addition, a practical solution should be explored to stabilize the bladder cup and vagina assembly during glue curing.

The evaluations also showed that integrating self-checks throughout the instructions was insufficient to fully support quality assessment. Therefore, it is recommended to introduce a final checklist containing critical assembly and quality criteria. This checklist could help makers better understand which connections and assembly steps are essential for the final functionality of the task trainer and what the consequences are of incorrect assembly.

Although the instructional materials were designed for novice makers rather than specifically for makers in low-resource settings, future evaluations should investigate how the instructions function within the intended context of use. Factors such as language, cultural context, material availability, and working conditions may influence usability and accessibility.

In addition, the website currently exists as an interactive mockup and has not yet been evaluated with users. Future work should therefore investigate whether the navigation, onboarding, and material sourcing support are effective for makers.

## Clinical Task Trainer and Mould Design

The assembly evaluations showed that sewing the vulva to the framework was experienced as difficult and highly time-intensive, especially for participants without sewing experience. On average, this step required approximately 40–50 minutes.

In addition, repeated sewing caused tearing of the vulva component over time. Therefore, future development should investigate alternative connection methods that are more user-friendly, durable, and less dependent on sewing skills.

The project currently provides makers with the option to self-source materials using specified material references. However, future versions should also include validated alternative materials to reduce dependency on specific suppliers or brands. Additionally, opportunities should be explored to reduce the total number of required materials and assembly actions. For example, some connections that currently require sewing or gluing could potentially be redesigned as single integrated silicone parts.

The connection between the urethra and bladder cup is especially important, as creating a watertight glued connection was sometimes difficult during the evaluations.

Since the task trainer is intended for low-resource settings, reducing material waste and consumable costs is also recommended. Currently, new syringes are required during silicone fabrication. Future development could investigate mould designs that eliminate the need for syringe injection or allow multiple components to be produced simultaneously.

Several improvements to the mould design itself are also recommended. The use of many bolts and nuts increases preparation time and having different sizes for each mould is inconvenient. Making consistent bolt sizes in each mould or replacing them with clamps could simplify mould preparation and improve usability.

In addition, removing silicone components from the moulds sometimes required significant force, negatively affecting the user experience and increasing the risk of damaging the moulds. The vulva mould already contains an indentation that allows a screwdriver to be inserted for easier release of the silicone component. Applying similar release features to the other moulds is recommended.

The air vent openings within the moulds should also be enlarged to improve airflow during silicone injection. Furthermore, the vulva mould currently lacks an air vent and should be redesigned to include one.

The opening for the urethra tube in the bladder cup mould could be reduced in diameter to increase tension when the urethra tube is inserted. This may improve the watertightness of the connection between the urethra and bladder cup.

Finally, physical signifiers should be added directly onto the 3D-printed moulds, such as labels, arrows, top/bottom indicators, and markings for injection and vent holes. These additions could improve orientation and reduce instruction steps.

## 6.4 Personal Reflection

This section reflects on the project from a personal perspective, including both reflections on the design process and personal development throughout the graduation project.

### Reflection on the project

One of the main challenges during this project was defining the target group. At the start of the project, the focus was strongly placed on low-resource settings. However, throughout the process it became clear that low-resource settings are highly diverse and cannot be approached as one uniform context. Therefore, the focus shifted toward designing for novice makers instead. Even this remained a broad target group, since people differ greatly in prior knowledge, learning preferences, and ways of interpreting instructions. This became visible throughout the usability tests, where participants approached the instructions and fabrication process in very different ways.

Another challenge was maintaining focus within the scope of the project. During the process, several side directions emerged, which sometimes made it difficult to prioritize. Especially during the final phase of the project, I learned the importance of narrowing focus and accepting that not every idea can be fully explored within the available time.

The project also highlighted how subjective instructional design can be. Actions that seemed clear from my perspective were sometimes interpreted completely differently by participants. It was particularly interesting to observe how one misunderstood step early in the process could significantly influence the final fabricated result.

At the same time, working on instructional materials for a medical training device for low-resource settings made the project feel meaningful. I especially enjoyed designing the instructional materials and creating the illustrations. In addition, gaining hands-on experience with silicone fabrication and working in the phantom lab provided valuable practical experience throughout the project.

### Personal development

Besides the design outcomes, this project also contributed to my personal development. At the start of the project, academic writing, independently leading a project, and communicating with stakeholders felt challenging and unfamiliar. Throughout the graduation process, I learned how to structure and manage a long-term project more independently and gained more confidence in presenting my work and trusting my own decisions.

Although the process was sometimes difficult and overwhelming, this graduation project provided valuable experience in both design practice and independent project management.

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# Appendices

## Appendix A - Current Instruction Materials

The fabrication journey starts on a website including a short introduction and a place where all STL-files for 3D printing and the instruction manual is presented and can be downloaded.

### A.1 Platform

Currently the information needed is presented on the website 4TU Research data. Figure A.1 provides an image of the website and the information it provides.

It provides a short introduction and a list of STL-files for 3d printing and an instruction manual, which is presented in Appendix A.2.

The screenshot displays the 4TU ResearchData website interface. At the top, there is a search bar and a navigation menu with options like 'About your Data', '4TU.ResearchData', 'Our Community', 'Training', 'Collaborations', 'News & Resources', and 'Log in & Upload D'. The main content area features a dataset titled 'Data underlying the publication: A training phantom for a vesicovaginal fistula repair with the transvaginal approach'. Below the title, the DOI is listed as '10.4121/f487e16e-c4f5-4f62-84a8-4650807c9004.v1'. A 'Cite' button is visible. The dataset is attributed to 'Theo Wiggers, Tink Voskamp, J. (Jenny) Dankelman, Roos Oosting'. A description of the dataset is provided, along with a list of materials required: PLA for the bone structures, Dragon Skin 10 with and without additives, 11% silicone oil and Slacker, natural rubber, and silicone glue. Usage statistics show 158 views and 538 downloads. Categories include 'Expanding Knowledge', 'Health And Support Services', and 'Other Manufacturing'. A 'History' section notes the dataset was first online on 2024-07-10. The publisher is also listed. At the bottom of the dataset page, there are buttons for 'RefWorks', 'BibTeX', 'Reference Manager', 'Endnote', 'DataCite', 'NLN', 'DC', and 'CFF'. Below this, a 'DATA' section lists 21 files for download, including 'Bladder cover part 1.STL', 'Bladder cover part 2.STL', 'Bladder cover pin.STL', 'Bladder inner mold.STL', 'Bladder outer mold.STL', 'Bladder support frame.stl', 'Bladder urethra locking pin.STL', 'Cervix locking pin.STL', 'Cervix mold 1.STL', 'Cervix mold 2.STL', 'Frame support dorsal.stl', 'Hatch bladder support.stl', 'Moulding instructions April 2024.pdf', 'Pelvic bone vesicovaginal fistula.stl', 'Vagina inner mold 1.STL', 'Vagina inner mold 2.STL', 'Vagina locking pin.STL', 'Vagina outer mold 1.STL', 'Vagina outer mold 2.STL', 'Vulva mold 1.stl', and 'Vulva mold 2.stl'. A 'download all files (zip)' button is also present, indicating 19,271,798 bytes unzipped. The footer of the website includes logos for TU Delft, TU/e, and the University of Twente, along with a link to the 'Getting started' page and other policies.

Figure A.1: Website where instructional materials are currently placed

## A.1 Silicone and Assembly Instructions 0.0

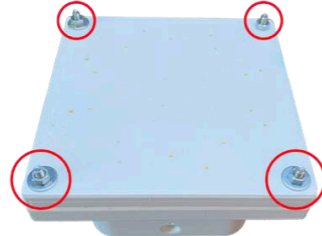
### MOULDING STEPS

**Step 1:** Make sure the parts of the mould are clean. If not, clean with soap and let it dry.

**Step 2:** Spray release agent on the surfaces that will be in contact with the silicone.



**Step 3:** Connect the parts of the mould with bolts and nuts.



**Step 4:** Pour the silicone in the paper cup according to the required ratio and amount as given in the table.

Part	Amount
Bladder	34 g Dragon Skin 10 part A 34 g Dragon Skin 10 part B 17 g Slacker App. 6 drops of yellow liquid pigment
Bladder plate	20 g Dragon Skin 10 part A 20 g Dragon Skin 10 part B App. 4 drops of yellow liquid pigment
Vagina	25 g Dragon Skin 10 part A 25 g Dragon Skin 10 part B 5.5 g silicone oil App. 6 drops of mauve liquid pigment
Cervix	5.5 g Dragon Skin 10 part A 5.5 g Dragon Skin 10 part B App. 1 drop of mauve liquid pigment
Vulva	25 g Dragon Skin 10 part A 25 g Dragon Skin 10 part B App. 6 drops of brown liquid pigment

NOTE: For the vagina, first stir the A and B parts a few times before adding the silicone oil and the colour pigment.



**Step 5:** Stir the silicone mixture for about 2-3 minutes.



**Step 6:** Pull the plunger out of the syringe and close off the hub of the barrel, then fill the syringe with the silicone mixture where the plunger is normally placed. The table provides an overview of the used syringe for each mould.

Part	Used syringe
Bladder	50 mL catheter tip (tip diameter about 7 mm)
Bladder plate	50 mL catheter tip (tip diameter about 7 mm)
Vagina	50 mL catheter tip (tip diameter about 7 mm)
Cervix	20 mL Luer tip (tip diameter about 4 mm)
Vulva	50 mL catheter tip (tip diameter about 7 mm)

NOTE: For the bladder, first fill the syringe with halve of the silicone mixture, perform step 7, 8 and 9 and repeat when the syringe is empty with the other halve of the mixture. For the cervix, if there are multiple moulds available and step 1 to 3 are performed on all moulds, it is easier to mix the amount for 2, 3 or 4 cervixes at the same time, this amount still fits in the syringe.

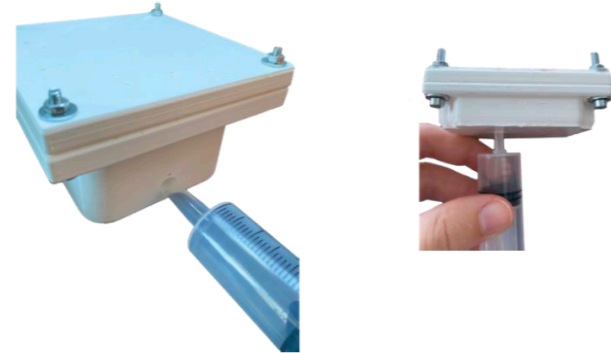


**Step 7:** Put the plunger back in, turn the syringe upside down and open the hub of the barrel. Release the air and then put your finger on the tip (hub) of the barrel and apply vacuum by pulling the plunger down in a pumping motion, until most bubbles are gone.

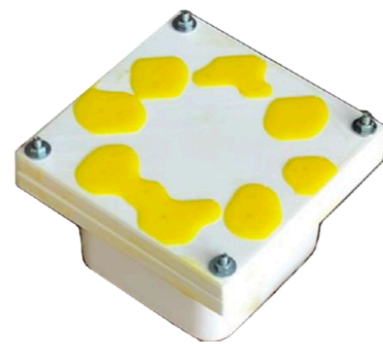


**Step 8:** Remove the finger and release the air out of syringe by pushing the plunger.

**Step 9:** Put the syringe in the indicated hole in the mould and slowly push the plunger to fill the mould with silicone.



**Step 10:** Make sure to fill the mould entirely, keep pushing after the silicone comes out of the air holes, to make sure when trapped air is released there is still enough silicone inside the mould, so there will be no air bubbles present in the silicone.



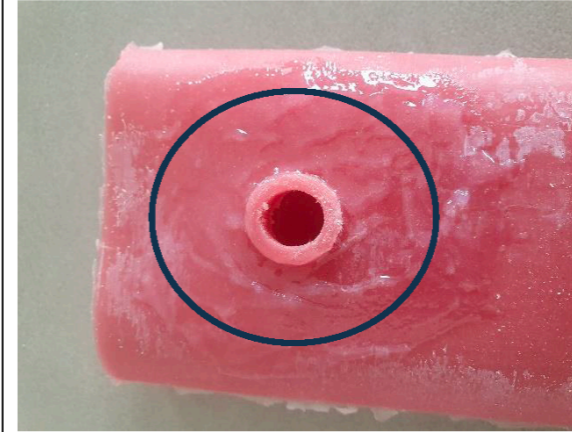
**Step 11:** Close off the hole for the syringe in the mould and pound the bottom of the mould on the table a few times to release air bubbles.



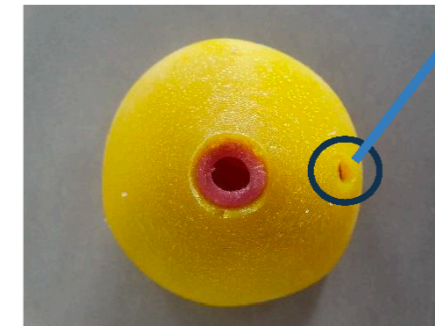
**Step 12:** Let the silicone cure for at least 8 hours and release the silicone parts out of the moulds.

### FABRICATION STEPS SILICONE PARTS

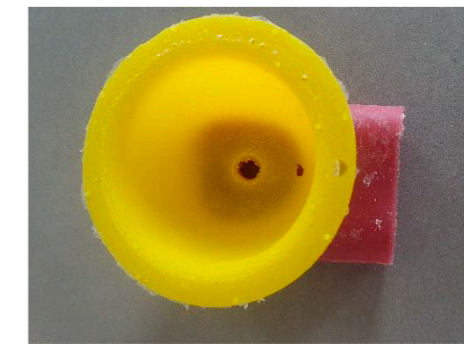
**Step 1:** Apply a thin layer of silicone glue over the entire area about 2 cm around the fistulas hole, at the thickened edge the glue layer must be a bit thicker.



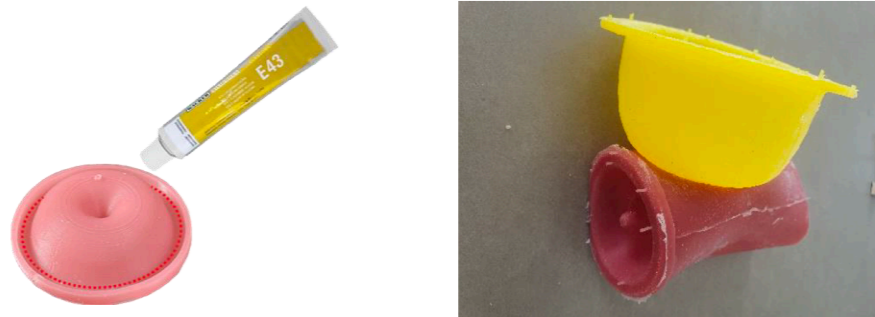
**Step 2:** Evert the bladder and stretch the bladder's hole for the fistula over the thickened edge of the vagina and apply pressure. Keep the orientation of the urethra opening parallel to the length direction of the most lengthy part of the vagina.



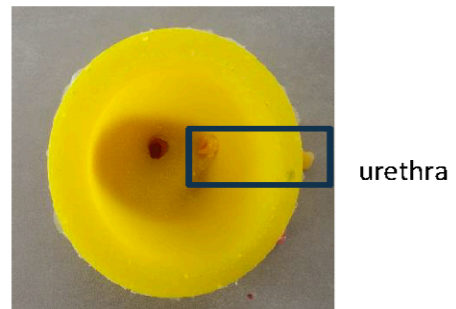
**Step 3:** Fold the vagina in the everted bladder ( keep it if necessary in position using an elastic band). Let it dry for a few hours and unfold the bladder.



**Step 4:** Apply silicone glue in the edge of the cervix and place the vagina in the edge. Let it dry for a few hours.



**Step 5:** Cut the urethra to 5 cm and apply a layer of cyanoacrylate glue around it, then place in the indicated location in the bladder. Add a bit more glue around the inner and outer edges, and let it dry for 10 minutes.



**Step 6:** Apply glue on the circular edge of the bladder, place the bladder plate on top of this and lay it flat on the side of the plate to be able to apply pressure for about 10 minutes. Let it dry for a few hours.

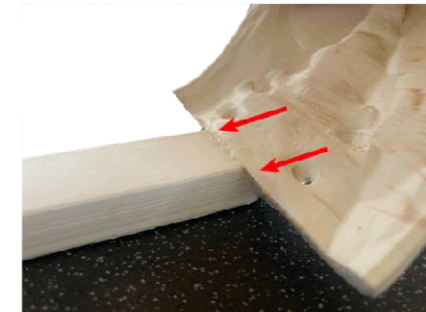


### FABRICATION STEPS FRAMEWORK

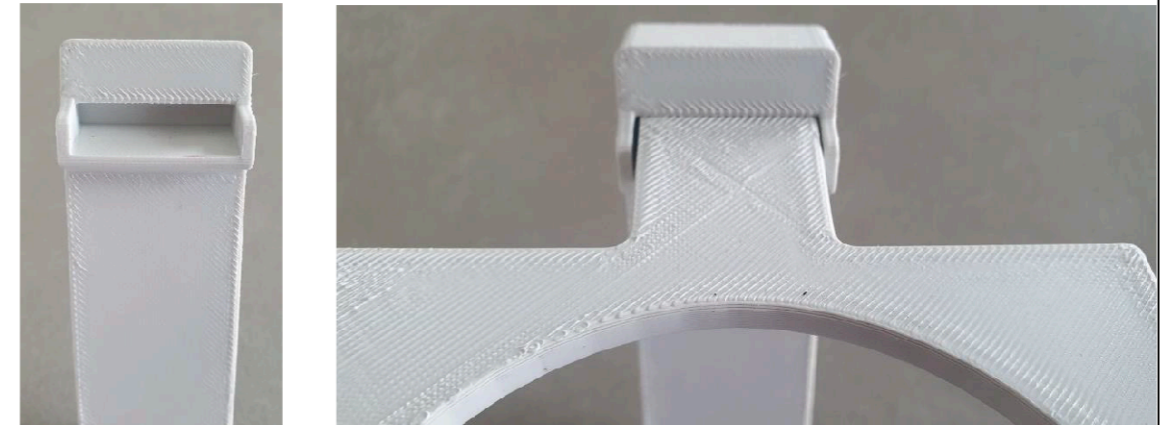
**Step 1:** Clamp dorsal frame part of the framework at the table and apply hard PVC glue.



**Step 2:** Push the 3D printed bone part against dorsal frame part and apply pressure for 10 minutes.



**Step 3:** Slide bladder support frame in dorsal frame part.

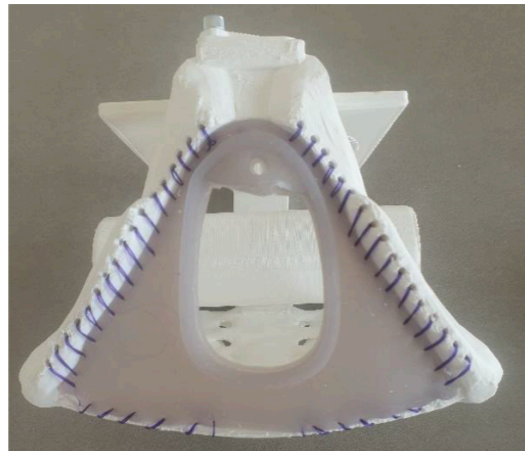


**Step 4:** Mount frame to pelvic part to using the hatch (fixed with a bolt to the pelvic part)



## PLACING SILICONE PARTS IN FRAMEWORK

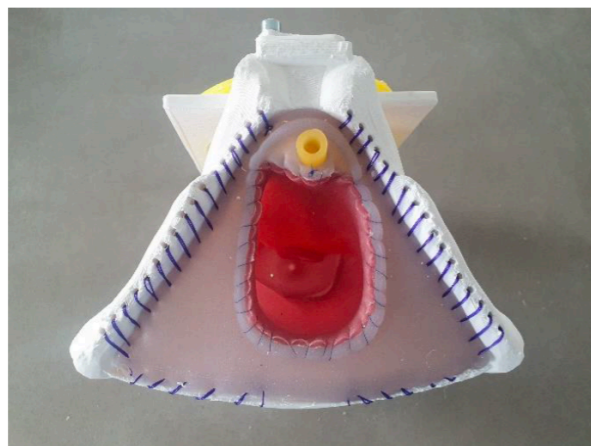
**Step 1:** Stich the vulva to the pelvic fram using the preprinted holes.



**Step 2:** Place the bladder with the urethra and vagina in the framework and push the urethra through the indicated hole in the vulva.



**Step 3:** Stich the vagina to the vulva using a continuous suture.



**END RESULT:**



# Appendix B – Silicone Casting Instructions 1.0

## B1 Silicone Casting Instructions 1.0

The first version of the instruction manual was a book with multiple chapters for; 3D printing, silicone moulding basics and silicone instructions per part, assembly and disassembly (repair). The basics of the silicone moulding were worked out in detail as well as the instructions of the bladder cup, those are shown in this appendix.

Figure B.1 shows an overview of all chapters in the instruction book.

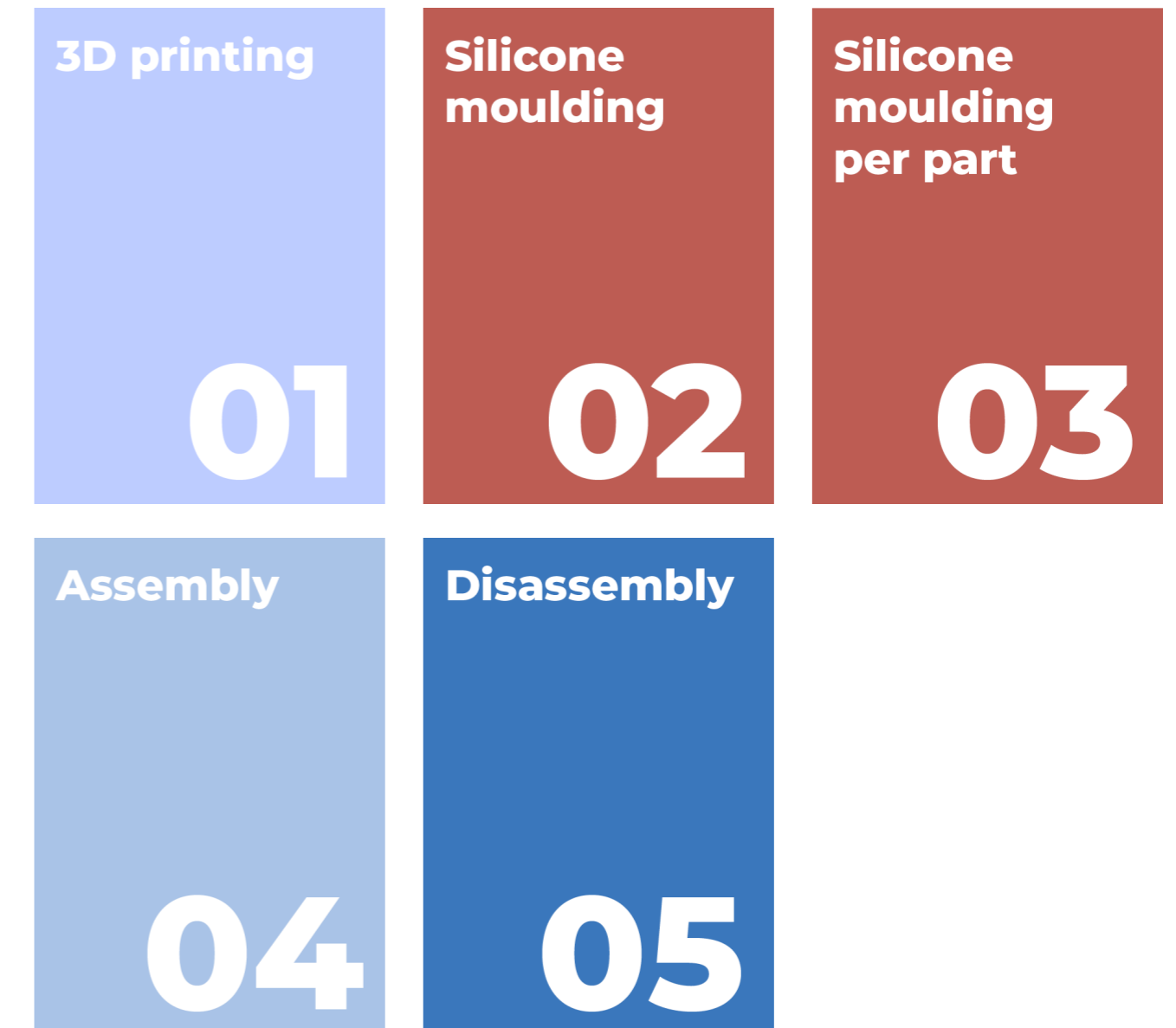


Figure B.1: Overview of all chapters covered in the instruction book.

## Introduction

### What are silicones and why do you use them?

Silicones consist of two components:

Part A: the silicone itself

Part B: the hardener

These two must be mixed in the correct ratio so that the mixture hardens into a flexible, rubber-like form.

For this phantom, you will use Dragon Skin 10. Sometimes additional substances are added:

- Slacker: makes the silicone softer and more flesh-like → used for the bladder.
- Silicone oil: makes the mixture more fluid and flexible → used for the vagina.
- Pigment colours: to give the material a realistic shade.

These additives allow the silicone material to better mimic human tissue.

### What do you need?

Chapter 2.1 shows the items and materials you will need when casting this phantom in silicone.

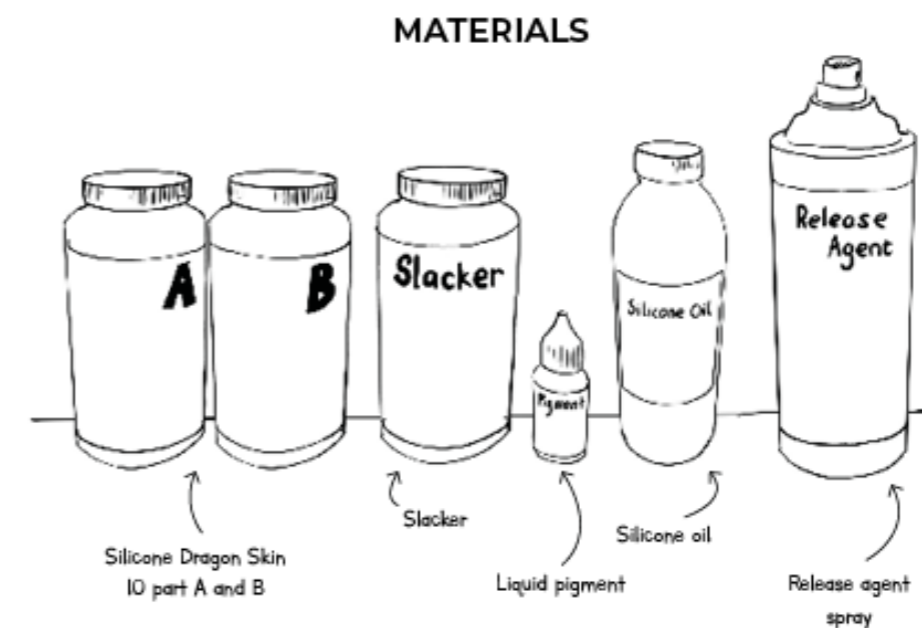
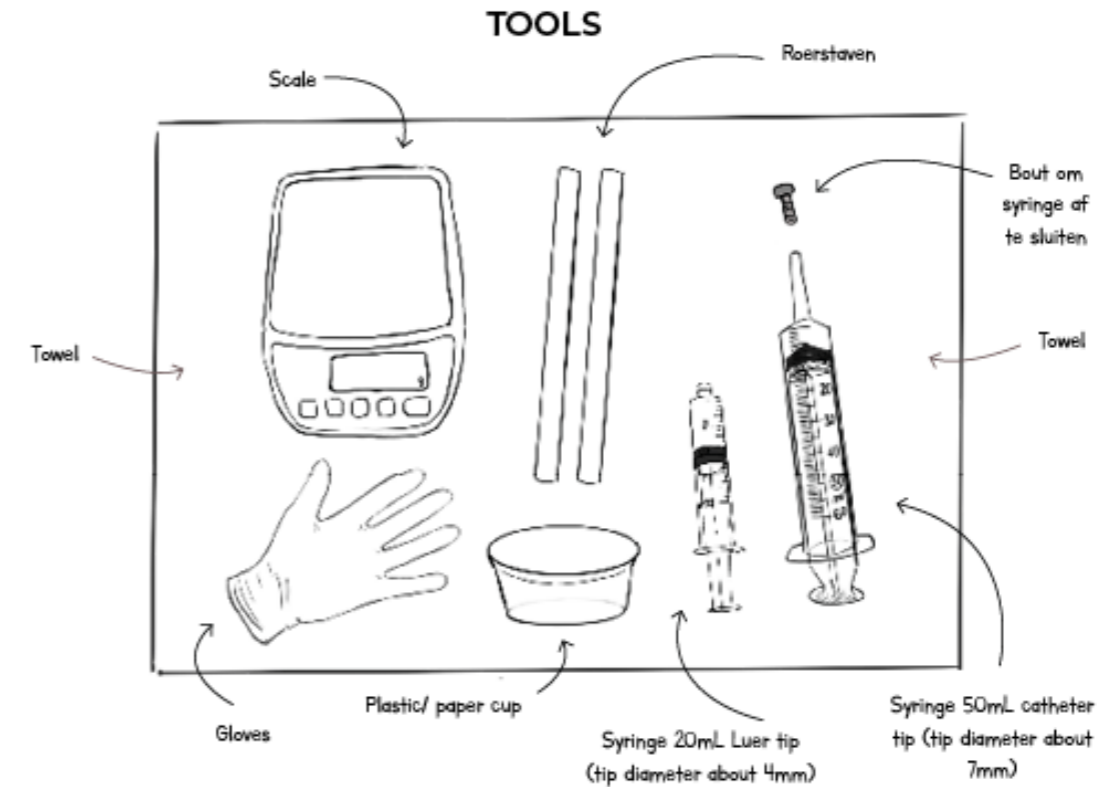
### What steps do you take?

1. Make the silicone mixture
2. Fill a syringe with the mixture
3. Remove air from the filled syringe
4. Fill the 3D printed mould

This chapter will elaborate on the techniques you need to practice step 2. fill the syringe, and step 3, remove air from the syringe.

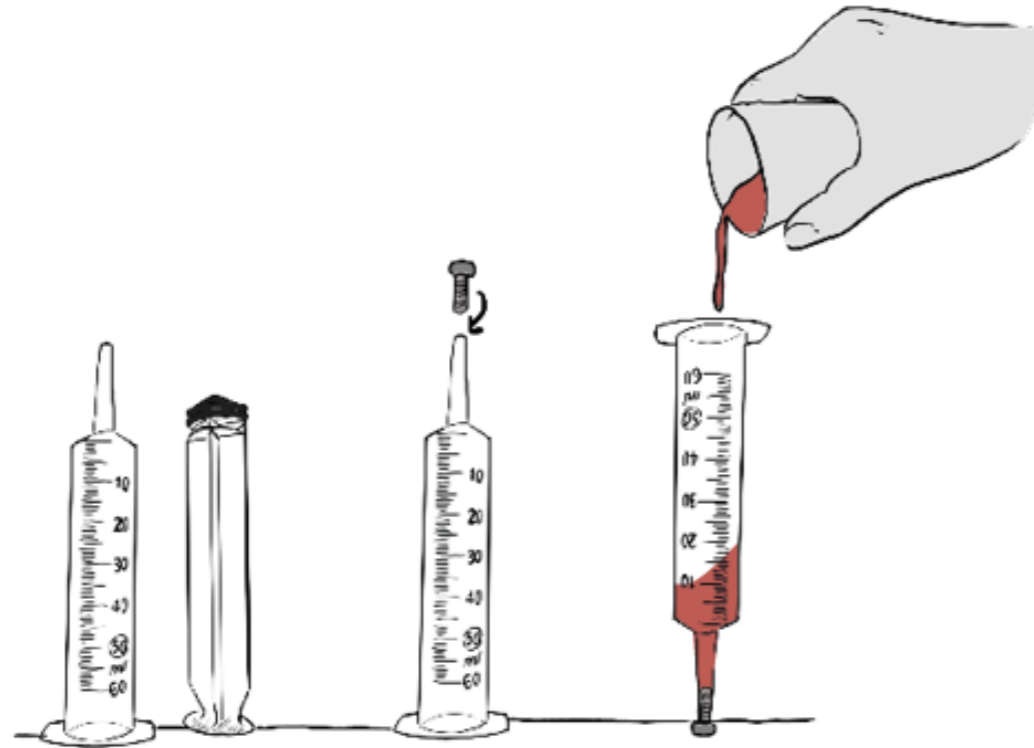
These can be found in chapter 2.2 and 2.3.

## 2.1 Item Checklist



## 2.2 Fill syringe

Goal: In this step, you will fill the syringe with the silicone mixture, because you will ultimately use this syringe to inject the mixture into the mould via the injection point.



### ITEMS YOU NEED

- Syringe
- Bolt to close syringe
- Something to lean the syringe against so that it remains upright while filling the syringe

#### Step 1


Remove the plunger from the syringe.

#### Step 2

Insert the bolt into the tip at the bottom to close it. Place the syringe vertically with the tip pointing downwards against something so that you can fill it.

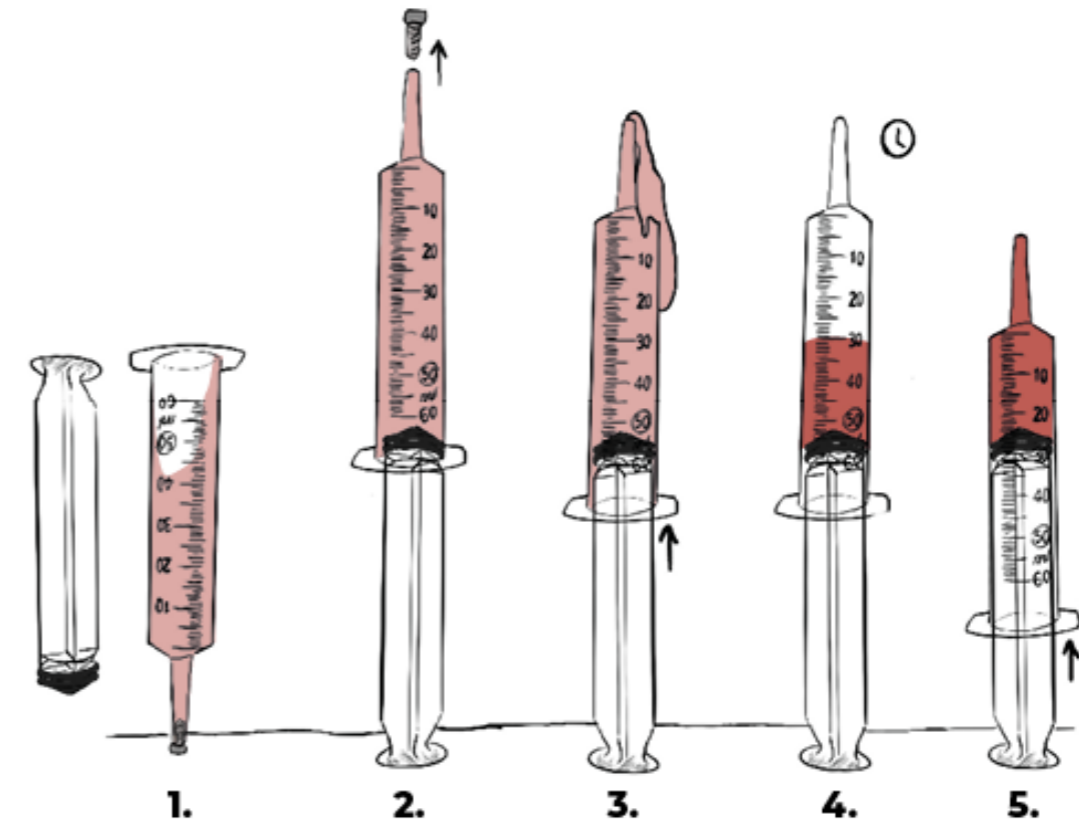
#### Step 3

Pour the mixture into the syringe, holding the container slightly higher so that the mixture can fall in properly and does not spill out. A high, thin stream also reduces the risk of air bubbles.

 Tip: pour slowly, otherwise the syringe will overflow.

## 2.3 Vacuum mixture

Goal: This step explains how to minimise air bubbles in the mixture and how to remove them without using a machine.



#### Step 1

Take the plunger and the filled syringe.

#### Step 2

Insert the plunger as minimally as possible; do not push the plunger upwards yet. Turn it vertically as shown in the photo and remove the tip cap, allowing the air to slowly escape from the syringe.

#### Step 3

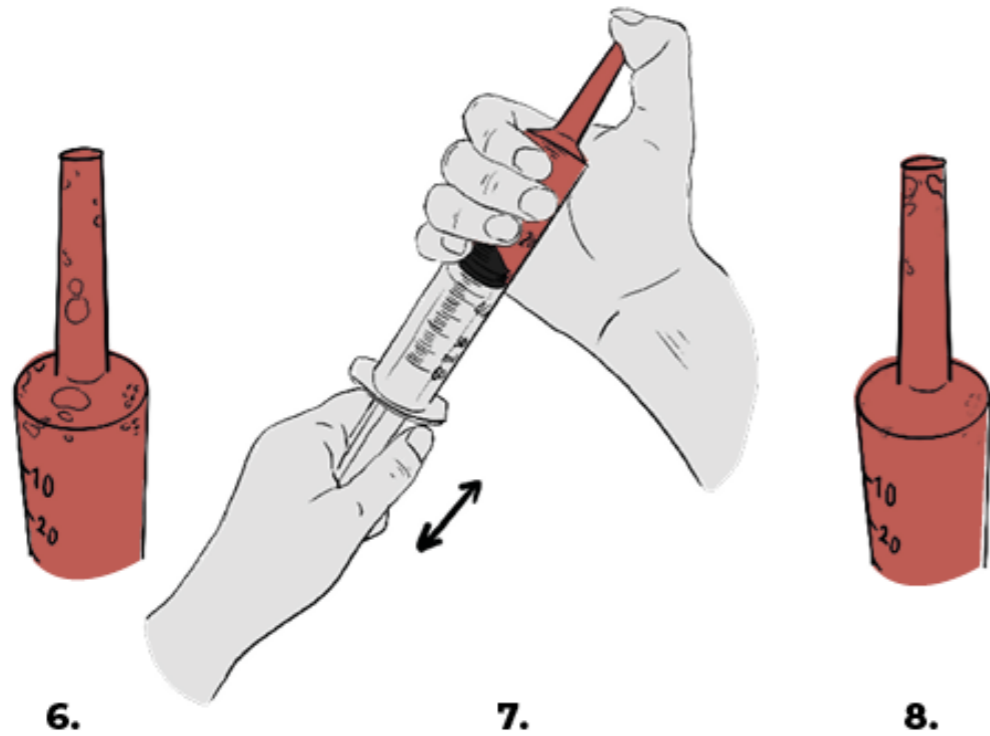
While this is happening, some of the mixture will come out through the tip due to the pressure of the plunger. Wipe this off with a cloth.

#### Step 4

Wait until the mixture has settled.

#### Step 5

Once the mixture has settled, you will see a separation between the mixture and the air. Now you can push the plunger upwards to release the air. The syringe is now ready.



#### Step 6

You will now see bubbles everywhere. To remove the largest bubbles, use the syringe to create a vacuum.

You do this by closing the tip with your finger so that no air can enter. You hold the syringe with the finger you use to close the tip and the plunger with your other hand.

#### Step 7

Move the plunger up and down by pulling it (do not pull too hard, as you do not want to pull the plunger out of the syringe, otherwise you will have to start again to remove the air).

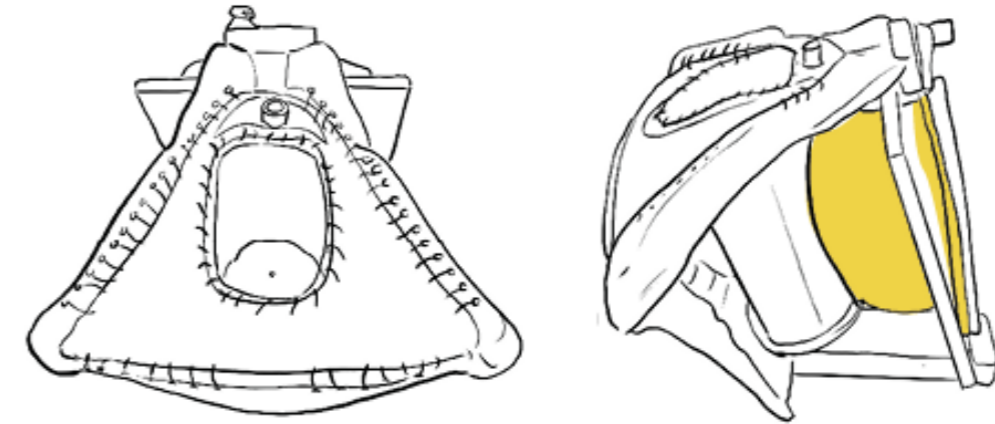
#### Step 8

Once you have done this a few times, you should see bubbles forming at the top and most of the bubbles disappearing at the bottom. This is a good sign because it means that you have pushed the air to the top. You can then push the plunger a little to release the air.

**i** Tip: If you have done this but still see bubbles forming, it may help to tap the syringe against the edge of the table or hold something that vibrates against it, such as an electric toothbrush. Do this until most of the bubbles have disappeared. This should not take too long, as the silicone may start to harden.

## 3.1 Bladder cup

### What will you make?



### How will you make it?

#### 1.0 Preparation

#### ITEMS YOU NEED

- 3D printed parts: Bladder inner mould, bladder outer mould
- Release agent spray
- 4 bolts and nuts size M4x40mm
- 8 washers size M4
- Spanner
- Flat screwdriver

#### Insert plaatje

### Step 1.1

Take the 3D printed parts that will form the mould.

### Step 1.2

Spray a thin layer of release agent on the edges where the silicone will be applied.

### Step 1.3

Fasten the 3D printed parts together with bolts, nuts and washers. Use washers both above and below. Tighten all bolts and nuts securely with a spanner and flat-head screwdriver.

*the washers increase the surface area, so the mould is more securely closed and you will not damage the mould when tightening the bolts and nuts.*

## 2.0 Making the silicone mixture

### ITEMS YOU NEED


- 5.5 g Dragon Skin part A
- 5.5 g Dragon Skin part B
- 1 drop of mauve liquid pigment
- Plastic or paper cup
- Stirring rods
- Scale
- Gloves


### Step 2.1

Put on gloves.

### Step 2.2


Place the cup on the scales and pour 5.5 g of part A into the cup, followed by the same amount of part B.

 It does not matter if you spill a little, but make sure that the ratio of A to B is 1:1. (This depends on which silicone you are using. For dragon skin, it is 1:1.)

 Be careful to pour the silicone slowly into the cup, as it can sometimes come out very quickly in thick drops, resulting in too much.

### Step 2.3

Stir the mixture thoroughly but slowly with the stirring rod for approximately 30 seconds to 1 minute.

 Do this slowly, as stirring too quickly can create extra air bubbles, and you want as few air bubbles as possible in the mixture, because you ultimately want as few air bubbles as possible in your final product.

### Step 2.4

Shake the bottle of liquid pigment briefly and then add 1 drop of mauve pigment to the cup. Stir slowly again until the colour is well mixed.

### Step 2.5

The mixture is now ready. Leave the cup to stand for a moment so that the largest air bubbles disappear.

## 3.0 Filling the syringe

### ITEMS YOU NEED

- Syringe 50 mL Catheter tip (diameter about 7mm)
- Bolt to close syringe (diameter approx. 7 mm)
- Chapter 2.2 that shows how to fill a syringe

### Step 3.1

Go to chapter 2.2 to see how to fill the syringe.

## 4.0 Vacuum the mixture

### ITEMS YOU NEED

- Filled syringe
- Plunger of syringe

### Step 4.1

Go to chapter 2.3 to how to vacuum the mixture in the syringe.

## 5.0 Fill the mould

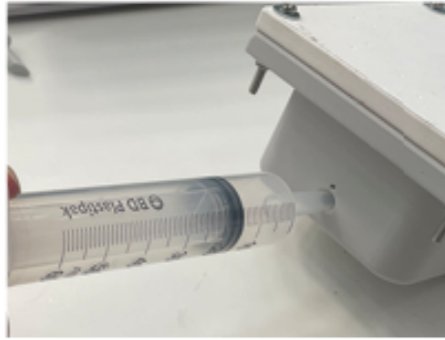
In this step, you will fill the mould with the syringe via the injection point in the mould.

### ITEMS YOU NEED

- Fixed mould
- Bladder cup cover pin
- Filled syringe

**Step 5.1**

Place the syringe against the injection hole on the side and slowly press the plunger to fill the mould.



**i** Suggestion: fill the mould when it is horizontal, as this ensures the silicone is distributed evenly.

**Step 5.2**

Continue injecting the mixture until you see it coming out of the air holes on top of the silicone, or when nothing more can fit into the mould and it comes out of the injection point.

**Step 5.3**

Close the injection hole with the bladder cover pin.

**Step 5.4**

To remove any remaining air bubbles, you can tap/drop the filled mould on the table a few times.

**Step 5.5**

Leave the filled mould to dry for approximately 8 hours.

## 6.0 Remove silicone from mall

In deze stap ga je het siliconen eindproduct uit de mal halen

**ITEMS YOU NEED**

- The filled mould
- Spanner
- Flat screwdriver
- Knife (use blunt side)

**Step 6.1**

Loosen all bolts and nuts using a spanner and flat-head screwdriver.

**Step 6.2**

Try to loosen the mould by first moving it back and forth (see picture). Turn and move in opposite directions until it comes loose. If necessary, use the blunt side of a knife or a flat screwdriver to create a lever between the two moulds and then move around.

picture:...

**Step 6.3**

Apply considerable force and create leverage.

**Step 6.4**

Once the mould is loose, carefully remove the silicone.

Final product: ...

## B.2 Evaluation

### B.2.1 Purpose of the test

This test evaluates whether novice makers can successfully produce the silicone component of the bladder cup using the provided instructions, and how they experience the production process.

Therefore, the evaluation focuses on:

- Clarity of the instructions
- Perceived confidence in task performance

### B.2.2 Test Objectives

- Assess clarity of the instructions
- Identify usability issues in the production workflow using the instructions

### B.2.3 Participants

Two participants (aged 25-27) from TU Delft with no prior experience in silicone casting were recruited.

This small sample size is considered sufficient for exploratory usability testing, where the goal is to identify major usability issues.

### B.2.4 Task and Context

Participants are instructed to produce the bladder cup silicone component using the provided instructions and materials. All required materials and tools are provided. The test is conducted in a well-ventilated lab environment for working with silicones.

### B.2.5 Equipment

Instructions

- Silicone casting instructions 1.0

Materials for silicone casting

- Dragon Skin 10 (part A&B)
- Additives: Slacker
- Yellow colour pigment
- Release agent spray

Tools

- 3D printed moulds for bladder cup
- 4 Bolts and nuts to close the mould (size M4x20)
- Towels
- Gloves
- Syringe 50mL with Catheter tip
- Plastic or paper cup
- Stirring rods
- 2 Flat screwdrivers
- Wrench size 6
- Sharp knife
- Scale

### B.2.6 Procedure

The test takes place in a well-ventilated lab environment suitable for silicone production. Participants perform the production process while following the instructions (approx. 30-60 minutes).

During the task, the think-aloud method is used: participants verbalize their thoughts while performing the task. The researcher records observations, issues and quotes. After completing the production, a short semi-structured interview is conducted, with the researcher and participant. During this session, the participant is asked to identify the most significant issues they encountered during the production process.

### B.2.7 Evaluation Measures


The evaluation focuses on observed performance, interpretation of instructions, and perceived confidence. Measures are based on direct observations and post-task self-report.


Participants' ability to correctly interpret and execute each step is assessed through observation and think-aloud data of confusion, hesitation, frustration, questions and misinterpretation. These observations provide insight into which steps are difficult to understand or perform.

## B.3 Results

The key findings were as follows.


- Both participants managed to make a useful bladder cup component.
- The frequent need to flip through pages was inconvenient.
- The clear images were found to be helpful.
- The amount of text was sometimes overwhelming.
- Participants showed different ways of reading the instructions: one participant read ahead, while the other did not, resulting in warnings and remarks sometimes being overlooked.
- One participant appreciated the inclusion of **warnings and remarks**, as they helped reduce uncertainty. The other participant considered them unnecessary and preferred to figure things out independently.

 It does not matter if you spill a little, but make sure that the ratio of A to B is 1:1. (This depends on which silicone you are using. For dragon skin, it is 1:1.)

 Be careful to pour the silicone slowly into the cup, as it can sometimes come out very quickly in thick drops, resulting in too much.

#### Step 2.3

Stir the mixture thoroughly but slowly with the stirring rod for approximately 30 seconds to 1 minute.

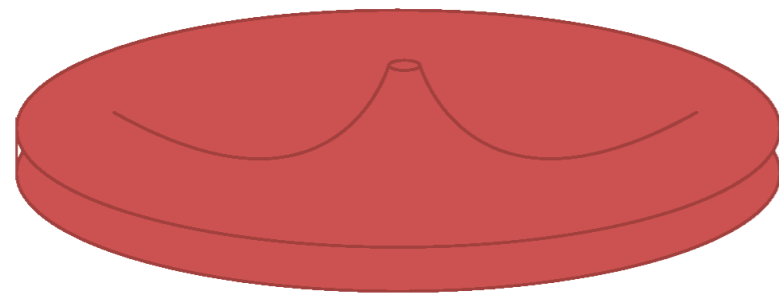
 Do this slowly, as stirring too quickly can create extra air bubbles, and you want as few air bubbles as possible in the mixture, because you ultimately want as few air bubbles as possible in your final product.

- Both participants skipped the introduction and general explanation, choosing instead to proceed directly to the practical steps.
- The inclusion of a materials list and the division of the silicone moulding process into six components were perceived as helpful and very clear by both participants. Allowing them to perform the production in manageable segments.

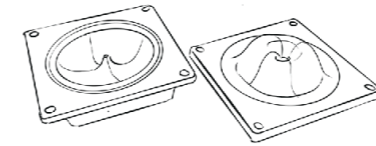
# Appendix C – Silicone Casting Instructions 2.0

## C.1 Silicone Casting Instructions 2.0

make the  
**Cervix**



### Items you'll need



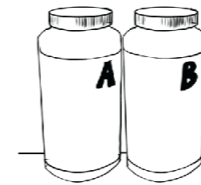
Cervix mould 1 & 2



4x bolts and nuts  
size Mx mm



Syringe with Luer tip



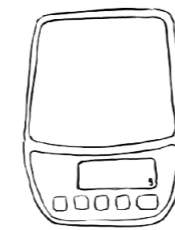
Silicone part A and B  
(Dragon Skin 10)



Liquid colour  
pigment mauve



Release agent spray



Scale



Stirring rods



Plastic or paper cup



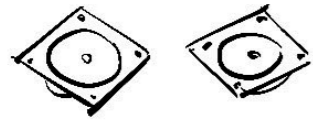
Gloves

Paper towels

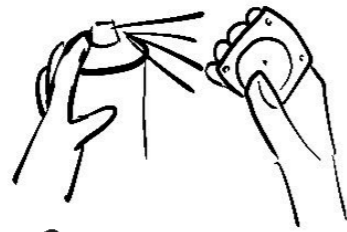
# Instructions



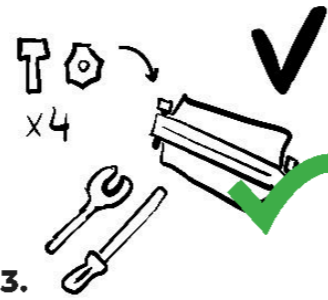
## Prepare the mould



**1.** Take the 3D printed parts.



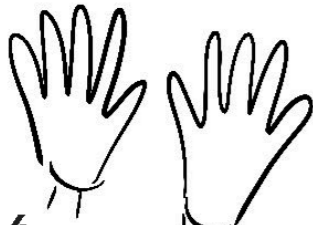
**2.** Spray release agent spray on the insides that will touch the silicone.



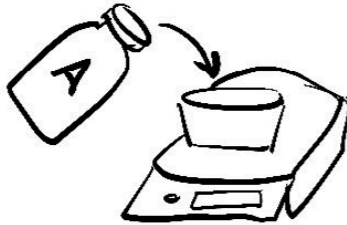
**3.** Fasten the parts with bolts and nuts.

Tighten all bolts and nuts securely with a spanner and flat-head screwdriver

## Make the mixture



**4.** Put on gloves.



**5.** Place the cup on the scale. Pour Xg of part A in the cup.



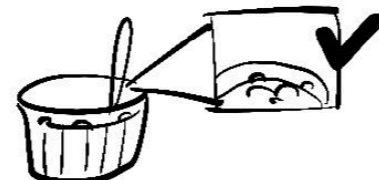
**6.** Pour Xg of part B in the cup.



**7.** Stir with a stirring rod for approx. 30 seconds.

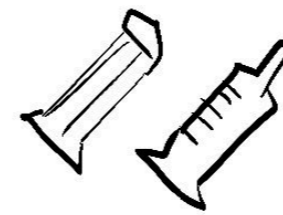


**8.** Add X drops of color pigment into the mixture and mix until the color is



**9.** Leave the cup to stand for a moment so that the largest air bubbles disappear.

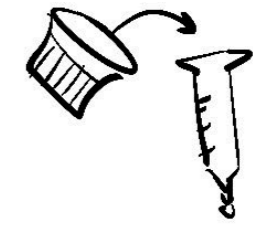
## Fill the syringe



**10.** Grab the X syringe and remove the plunger.



**11.** Close the hub of the syringe af with something like a bolt.



**12.** Slowly pour the mixture into the syringe.  
If it helps, you can lean the syringe to something so you have your hands free!



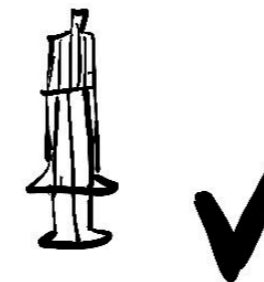
**13.** Insert the plunger slightly into the syringe.



**14.** Turn around the syringe and remove the tip cap, and hold syringe vertically.



**15.** Wait for the mixture to settle.

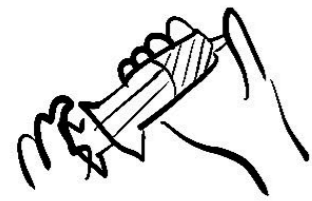


**16.** Push the plunger further up until all air is removed.

X.

X.

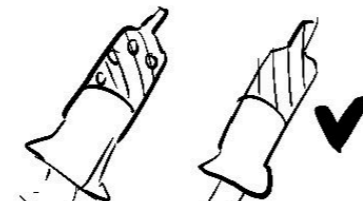
## Vacuum the mixture



**17.**  
Close the tip of the syringe with your thumb or finger.

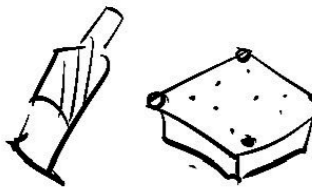


**18.**  
Pull the plunger to draw the mixture into the syringe under vacuum, then release.



**19.**  
Repeat until most bubbles are gone, then remove your finger and push the plunger to release the air from the syringe.

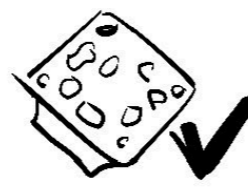
## Fill the mould



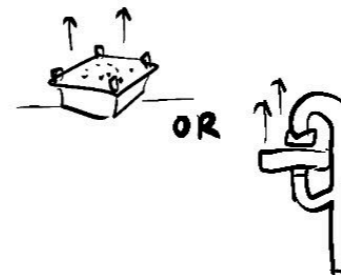
**20.**  
Grab the mould and the filled syringe.



**21.**  
Put the syringe in the indicated hole and slowly push the plunger to fill the mould.



**22.**  
Continue until you see the silicone coming out of the vent holes at the top.

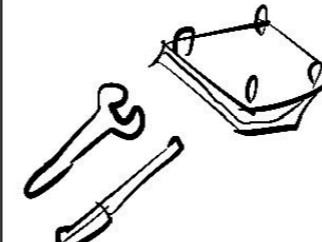


**24.**  
Pound the bottom of the mould on the table a few times to release more air bubbles.

**23.**  
Close off the hole of the mould using a cover pint or for example a glue clamp.

**25.**  
Let the silicone cure for at least 8 hours, with the mold upright and vent holes on top.

## Release silicone from mould

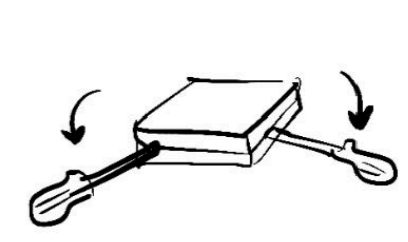


**26.**  
Loosen the bolts and nuts using a wrench and a flathead screwdriver.



**27.**  
Try to loosen the mold parts by twisting them in opposite directions.

If needed, use a sharp tool along the edges, such as a knife or flathead screwdriver.

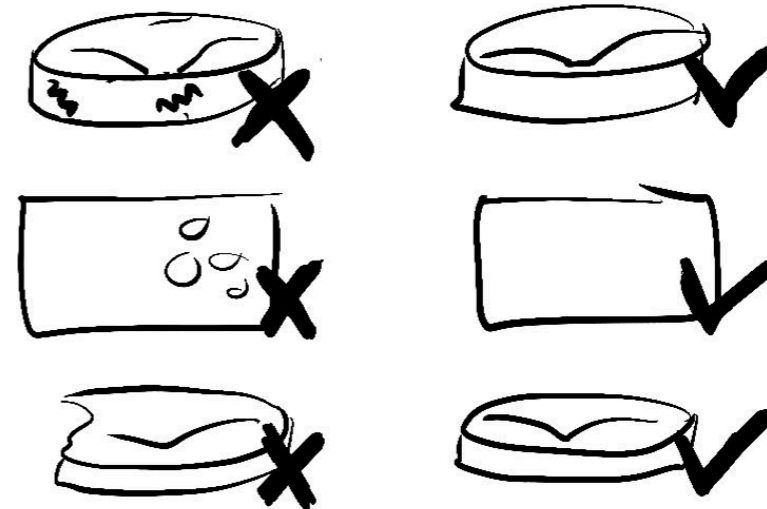


**28.**  
Create a lever with one or two flathead screwdrivers. Work along the edges until the mold parts separate.

## Final Check

Once all checkboxes can be ticked, your silicone part is complete.

- Mold Separation – The mold parts came apart without tearing the silicone.
- No Air Bubbles – Most visible air bubbles have been removed.
- Complete Fill – Silicone has reached all vent holes and filled the mold completely.



## C.2 Evaluation of Silicone Casting Instructions 2.0

### C.2.1 Purpose of the test

This test evaluates whether the instructions were perceived as overwhelming and whether they were easy to understand for novice makers.

### C.2.2 Test Objectives

- Assess perceived clarity of the instructions
- Assess perceived confidence of the instructions
- Identify if instructions are perceived as overwhelming

### C.2.3 Participants

Nine participants from TU Delft on the faculty Industrial Design Engineering, with no prior experience in silicone casting were recruited. effectiveness of the instructions. However, perceptions of clarity and presentation could be evaluated.

### C.2.4 Task and Context

Participants are asked to think aloud while explaining what they believe they need to do to produce the cervix silicone parts, while observations are made by the researcher. A limitation of this test is that participants do not actually produce a silicone component. As a result, their responses are based on expectations.

### C.2.5 Equipment

Instructions  
- Silicone casting instruction manual 2.0

Materials for silicone casting  
- 3D printed moulds  
- Sheet with post-task questions

### C.2.6 Procedure

During the task, the think-aloud method is used: participants verbalize their thoughts while performing the task. The researcher records observations, issues and quotes. After completing the production, a structured interview is conducted, with the researcher and participant. During this session, the participant is asked to identify the most significant issues they encountered during the production process.

### C.2.7 Evaluation Measures

The evaluation focuses on observed performance, interpretation of instructions, and perceived confidence. Measures are based on direct observations and post-task questions.

#### Clarity of instructions

Participants' ability to correctly interpret and execute each step is assessed through observation and think-aloud data of confusion, hesitation, frustration, questions and misinterpretation. These observations provide insight into which steps are difficult to understand or perform.

### C.2.3 Test Results

The key findings were as follows.

Based on the test with nine participants, the results of the post-task questions and observations are as follows;

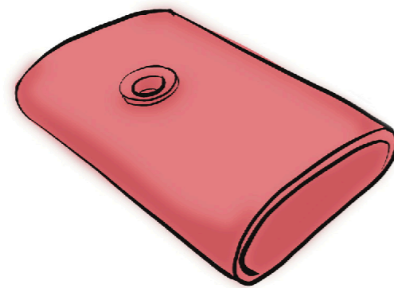
	not clear					very clear
<b>1. How clear are the instructions</b>	1	2	3	4	4,2	5
	not structured					very well-structured
<b>2. How well-structured did you find the instructions?</b>	1	2	3	4	4,2	5
	not at all					completely
<b>3. To what extent do you think these instructions enable you to produce the product?</b>	1	2	3	4	4,5	5
	not complex					very complex
<b>4. How complex do you perceive this task to be?</b>	1	2	2,3	3	4	5
	not pleasant at all					very pleasant
<b>5. How pleasant do you find the way the information is presented?</b>	1	2	3	4	4,4	5

- Instructions are perceived as clear and well-structured
- Steps are well divided into manageable sections
- Limited amount of text improves the readability
- Visuals support understanding, but can be improved and made more clear.
- Instructions were not perceived as overwhelming, due to the short length of the booklet and the distribution of the content.
- Some steps require more detailed explanations
- Certain illustrations are unclear (e.g., filling the syringe, vacuum steps)
- Lack of clarity on specific terms (e.g., vent holes, air bubbles, release agent spray)
- Participants want to understand the purpose of the use of materials and steps
- The final check is unclear.
- Progress bar was received as unnecessary by some participants, while other considered it as useful.

# Appendix D – Silicone Casting Instructions 3.0


## D.1 Silicone Casting Instructions 3.0

### Instruction Manual Producing the silicone vagina



#### Process overview

- I. Prepare the mould
- II. Make the mixture
- III. Fill the syringe
- IV. Remove air bubbles from mixture
- V. Fill the mould

 Curing time at least 8 hours

- VI. Release silicone from mould
- VII. Final Check

Silicone terms:

**Pot life:** time the silicone has before it thickens.

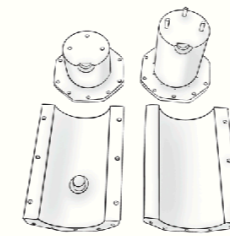
**Curing time:** time the silicone needs before it is fully cured

For Dragon Skin 10 Slow:

Pot life = 20 min

Curing time = 8 hours

### Items you'll need



Vagina moulds



Syringe 50mL catheter tip

14x bolts and nuts size M3x20 mm

Piece of sulfate free clay (1cm x 1cm)



Silicone part A and B (Dragon Skin 10)



Mauve liquid colour pigment



Release agent spray



Silicone oil



Scale



Stirring rods



Cup



Gloves

Paper towels

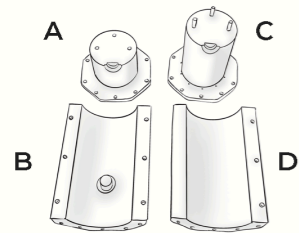
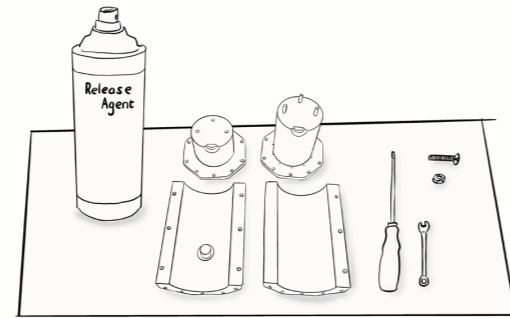
Steeksleutel size 5.5

Flat screwdriver

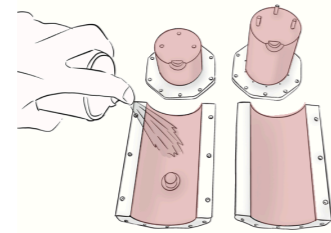
## I. Prepare the mould

### Items you'll need

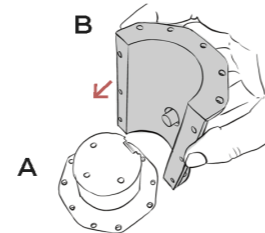
- 3d printed parts for vagina
- release agent spray
- 14 bolts and nuts size M3x20mm
- spanner size 5,5
- flat screwdriver



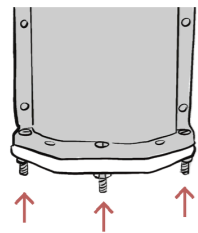
- 1.** Take the **four** 3D printed moulds for the vagina



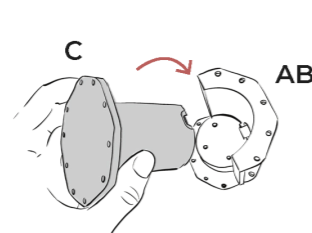
- 2.** Spray a **thin layer** of release agent onto the areas indicated in color.



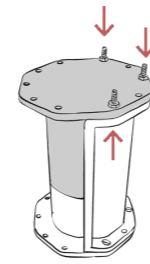
- 3.** Place **part B** onto **part A**.



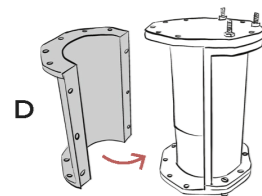
- 4.** Connect part A to part B using **3 bolts and nuts** using spanner and screwdriver



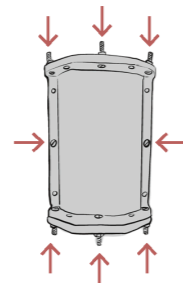
- 5.** Take **part C** and place onto **AB**.



- 6.** Connect **part C** to **AB** with **3 bolts and nuts**.



- 7.** Place **part D** onto ABC.



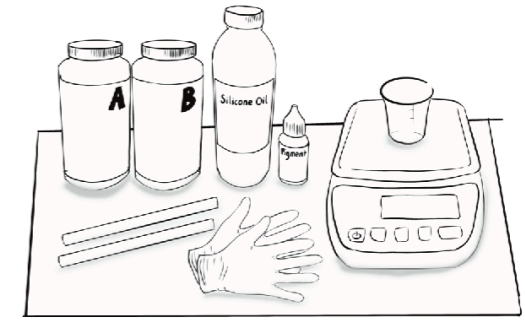
- 8.** Connect with **8 bolts and nuts**.

3

## II. Make the mixture

### Items you'll need

- Dragon Skin 10 A + B
- Colour pigment 'Mauve'
- Silicone oil
- Towels
- Cup
- Gloves
- Scale
- Stirring rods



- 9.** Put on the **gloves**.



- 10.** Pour **30 g** of part **A** in the cup.



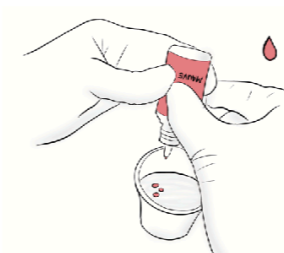
- 11.** Pour **30 g** of part **B** in the cup. Ratio A:B 1:1.



- 13.** Add **5.5 g** of **silicone oil** into the mixture.

- 12.** Stir the mixture for approximately **20 seconds**.

- 14.** Stir the mixture for approximately **20 seconds**.



- 15.** Add **6 drops** of mauve color pigment into the mixture.

- 16.** Stir the mixture until the color is **evenly distributed**.



20 min pot life

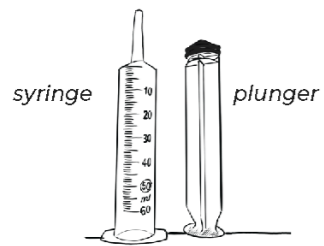
- 17.** Set a timer for **20 min**. (This is the time you have until Dragon Skin 10 Slow thickens).

4

### III. Fill the syringe

#### Items you'll need

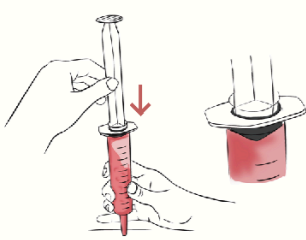
- 50mL syringe with catheter tip.
- Mixture



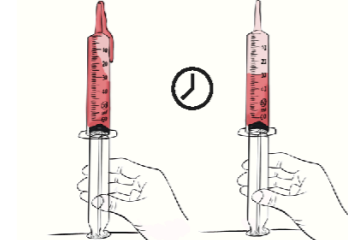
**18.** Grab the syringe and **remove** the plunger from the syringe.

**19.** Place the syringe with the **tip on the table**, this closes the tip during filling.

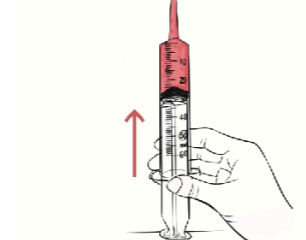
**20.** Slowly **pour all** of the mixture in the syringe.



**21.** Put the plunger into the syringe, make sure to only **put the tip in**.



**22.** Turn the syringe around and **wait for the mixture to settle**.



**23.** Push the plunger further until **all air is removed**.

### IV. Remove air bubbles

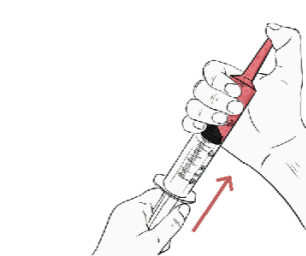
#### Items you'll need

- Filled syringe

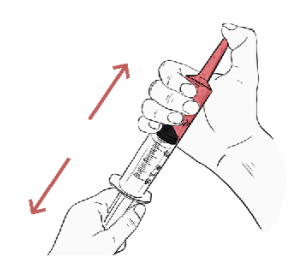
The **pumping motion** causes the small air bubbles to **move** and **merge** with each other, forming larger bubbles. These larger bubbles rise to the top and escape through the tip of the syringe. This helps remove air bubbles larger than **1 mm**.



**24.** **Close the tip** of the syringe with your thumb or finger and use the other hand to **pull the plunger**.



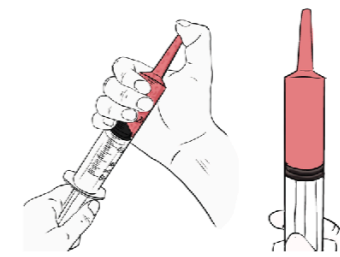
**25.** **Push** the plunger back with the **tip closed**.



**26.** Repeat this pumping motion **15 times**.



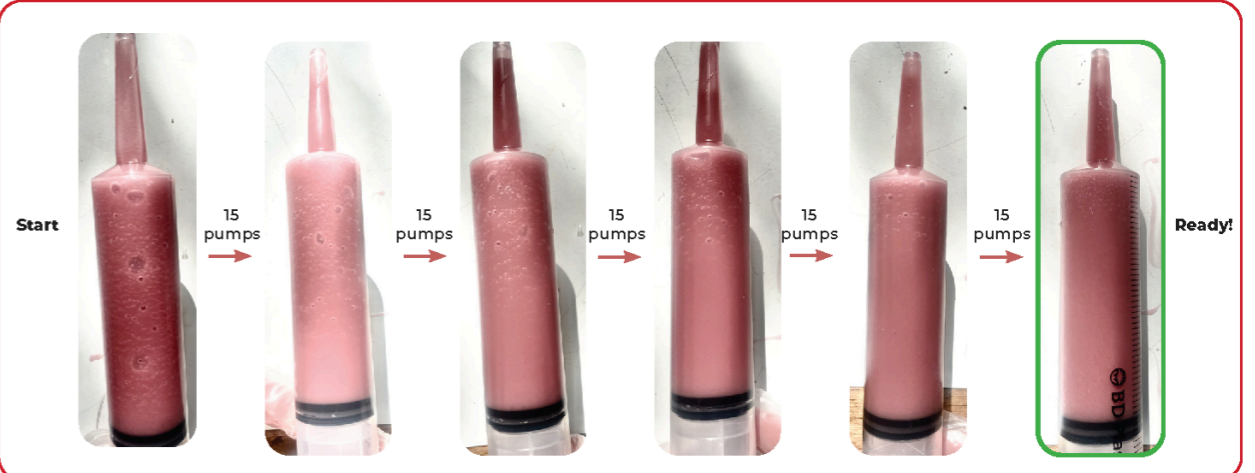
**27.** **Observe** the airbubbles in the syringe. When there are still bubbles larger than 1mm, continue with **15 pumps**.



**28.** **Repeat** pumping motions and **observations** until most bubbles larger than 1 mm are gone.

**Tip:** Tap the syringe against the **edge of a table** to release larger bubbles..

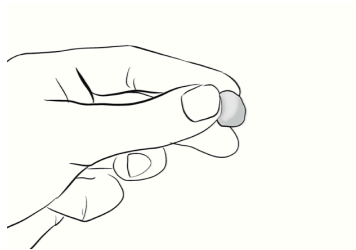
Example:



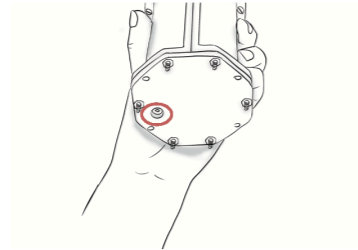
## V. Fill the mould

### Items you'll need

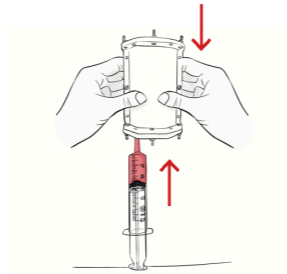
- Filled syringe
- Prepared mould
- Piece of sulfat free clay (1cm x 1cm)



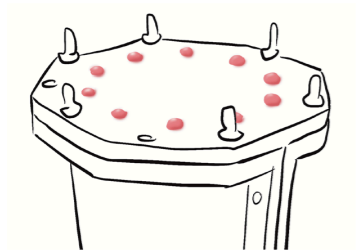
**29.** Prepare a small piece of clay by rolling into a small ball to seal the injection hole later.



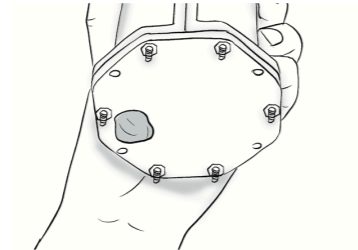
**30.** Place the syringe vertically into the mould's injection hole.



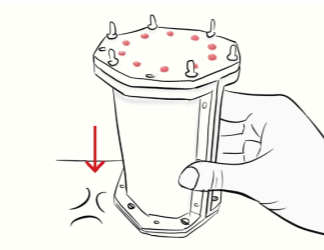
**31.** Push the mixture slowly into the mould. This takes about 5 minutes.



**32.** Continue until you see the mixture coming out of the air vents at the top. This indicates that the mold is full.



**33.** Seal the injection hole with the piece of clay.



**34.** Tap the bottom of the mold on the table a few times so any remaining air can escape through the air vents.



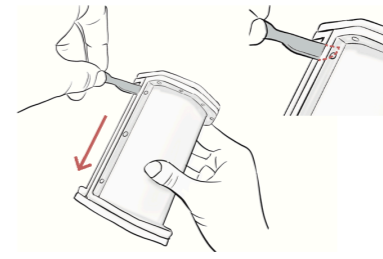
**35.** Let the silicone cure for at least 8 hours, with the mold upright and vent holes on top.

7

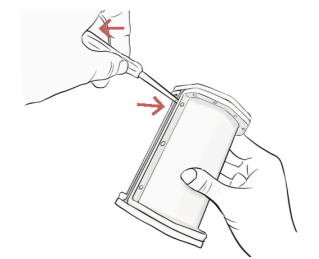
## VI. Release silicone from mould

### Items you'll need

- Filled mould
- Steeksleutel size 5,5
- Platte schroevendraaier
- Knife

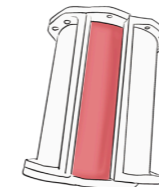


**36.** Loosen the bolts and nuts using a wrench and a flathead screwdriver.

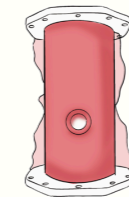


**38.** Use a flathead screwdriver to insert between the molds and create leverage.

Do not cut too deep, or you may cut into the silicone.



**39.** Once the outer parts are loose, remove the outer sections.



**40.** Peel the silicone off the other parts.

**41.** Trim off any remaining edges.

**42.** The silicone vagina is finished! Now do the self-check.

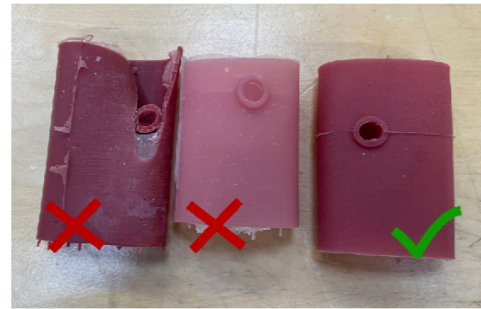
8

## Final Check

- Is the part properly **filled**?

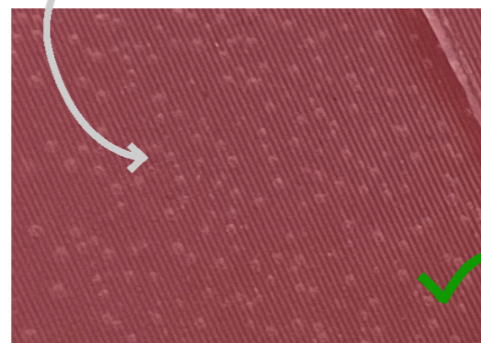
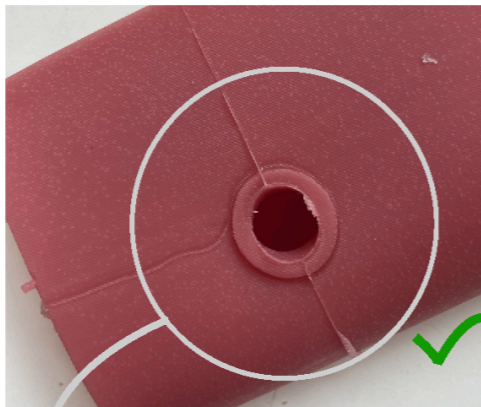
The silicone part is completely filled, with no frayed or uneven edges. (Color intensity is not relevant.)

The right side is evenly filled.



- Are there any large air bubbles present? Larger than 0,5 cm.

Small air bubbles (small dots) are acceptable. If larger air bubbles are present **within a 2 cm radius** around the hole, the part is not usable.



- Is the mold damaged after opening?

If the **three alignment pins** are broken, the mold can still be used, provided the parts are tightened securely during assembly.

If the **top section** or the **hole** is broken, the mold is not usable and must be reprinted.

## D.2 Evaluation of Silicone Casting Instructions 3.0

### D.2.1 Purpose of the test

This test evaluates whether novice makers can successfully produce the silicone component of the vagina using the provided instructions, and how they experience the production process.

Therefore, the evaluation focuses on:

- Clarity of the instructions
- Ability to assess the quality of the produced silicone component
- Perceived confidence in task performance

### D.2.2 Test Objectives

- Assess clarity of the instructions (text and illustrations)
- Identify usability issues in the production workflow
- Assess participants' ability to perform a quality check
- Evaluate perceived confidence during the process.

### D.2.3 Participants

Two participants (aged 24-26) from TU Delft with no prior experience in silicone casting were recruited.

This small sample size is considered sufficient for exploratory usability testing, where the goal is to identify major usability issues.

### D.2.4 Task and Context

Participants are instructed to produce the vagina silicone component using the provided instructions and materials. All required materials and tools are provided. The test is conducted in a well-ventilated lab environment for working with silicones.

### D.2.5 Equipment

Instructions

- Silicone casting instructions 3.0 for vagina (see Appendix X for tested instructions, version X)

Materials for silicone casting

- Dragon Skin 10 (part A&B)
- Additives: silicone oil
- Mauve colour pigment
- Release agent spray

Tools

- 3D printed vagina moulds
- 14 Bolts and nuts to close the mould (size M3x20)
- Towels
- Gloves
- Syringe 50mL with Catheter tip
- Plastic or paper cup
- Stirring rods
- Flat screwdriver
- Wrench size 5,5
- Piece of sulfat free clay (1cm x 1cm)
- Sharp knife
- Scale

## D.2.6 Procedure

The test takes place in a well-ventilated lab environment suitable for silicone production. Participants perform the production process while following the instructions (approx. 30-60 minutes). During the task, the think-aloud method is used: participants verbalize their thoughts while performing the task. The researcher records observations, issues and quotes.

After completing the production, participants rate their confidence in performing the task and evaluate the quality of the produced silicone component. After completing the production, a short co-creation session is conducted with the researcher and the participant. During this session, the participant is asked to identify the most significant issues they encountered during the production process. Together with the researcher, potential solutions are generated. These include rewriting steps, improving layouts, and adjusting images. Finally, the identified issues are prioritized by the participant.

## D.2.7 Evaluation Measures

The evaluation focuses on observed performance, interpretation of instructions, and perceived confidence. Measures are based on direct observations and post-task self-report.

### D.2.7.1 Clarity of instructions

Participants' ability to correctly interpret and execute each step is assessed through observation and think-aloud data of confusion, hesitation, frustration, questions and misinterpretation. These observations provide insight into which steps are difficult to understand or perform.

Performance is evaluated per step. An issue is defined as:

- Incorrect execution of a step
- Skipping a required step
- Use of incorrect materials or tools

### D.2.7.2 Perceived Performance

Participants assess the quality of their produced silicone vagina using the provided criteria in the self-check in the instructions. This measure indicates whether participants understand what a correct outcome is. After completing the task, participants rate how well they think they performed the task on a scale from 1 (very poorly) to 5 (very well), and provide a short explanation. This measure serves as an indication of perceived confidence in their performance.

## D.2.8 Data processing

The collected data will be structured and analysed per section and step to identify usability issues. The silicone casting instructions are divided into nine sections; front page, items needed, prepare mould, make mixture, fill syringe, remove air bubbles, fill the mould, release silicone from mould, and self-check. Each section consists of multiple steps.

## D.2.9 Results

An overview of the observed issues is provided per page of the instructions. Observations and issues are described for each page, and the blue highlighted areas indicate where the issues occurred. The participants are referred to P1 and P2.

Both participants produced a usable silicone vagina component. Overall, the instructions were perceived as clear, with a few critical usability issues identified in specific steps. Both participants reported a confidence rating of 4/5.

**Instruction Manual**  
**Producing the silicone vagina**

**Process overview**

- I. Prepare the mould
- II. Make the mixture
- III. Fill the syringe
- IV. Remove air bubbles from mixture
- V. Fill the mould

⌚ Curing time at least 8 hours

- VI. Release silicone from mould
- VII. Final Check

Silicone terms:  
**Pot life:** time the silicone has before it thickens.  
**Curing time:** time the silicone needs before it is fully cured

For Dragon Skin 10 Slow:  
Pot life = 20 min  
Curing time = 8 hours

P2 appreciated the process overview, P1 did not read it.

The term pot life was noticed but misinterpreted

- P1 thought it referred to total production time
- P2 initially understood it but later forgot

P1 tend to scan short text and skip longer explanations. P2 read everything.

**I. Prepare the mould**

**Items you'll need**

- 3d printed parts for vagina
- release agent spray
- 14 bolts and nuts size M3x20mm
- spanner size 5.5
- flat screwdriver

1. Take the four 3D printed moulds for the vagina
2. Spray a thin layer of release agent onto the areas indicated in color.
3. Place part B onto part A.
4. Connect part A to part B using 3 bolts and nuts using spanner and screwdriver
5. Take part C and place onto AB.
6. Connect part C to AB with 3 bolts and nuts.
7. Place part D onto ABC.
8. Connect with 8 bolts and nuts.

List of materials was perceived as clear and helpful

Issue step 2:

Both participants applied too much. "Thin layer" was unclear

Assembly issues:

P1 did not use tools (not mentioned explicitly)

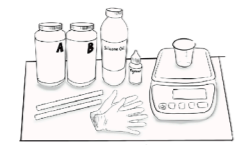
Tightening bolts was unclear for P1

Both found assembly of mould parts time-consuming


### II. Make the mixture

**Items you'll need**

- Dragon Skin 10 A + B
- Colour pigment 'Mauve'
- Silicone oil
- Towels
- Cup
- Gloves
- Scale
- Stirring rods



- Put on the **gloves**.
- Pour **30 g** of part **A** in the cup.
- Pour **30 g** of part **B** in the cup. Ratio A:B 1:1.
- Stir the mixture for approximately **20 seconds**.
- Add **5.5 g** of silicone oil into the mixture.
- Stir the mixture for approximately **20 seconds**.
- Add **6 drops** of mauve color pigment into the mixture.
- Stir the mixture until the color is **evenly distributed**.



20 min pot life

4

Mixing ratio (1:1) helped participants recover mistakes and stirring instructions were clear

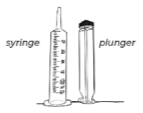
Critical issue:  
Both participants misinterpreted step 17, the 20 min pot life  
Thought they had to wait 20 minutes

Intervention by researcher.  
Participants felt stress and time pressure  
Misinterpretation has high impact on process success.

### III. Fill the syringe

**Items you'll need**

- 50mL syringe with catheter tip.
- Mixture



- Grab the syringe and **remove** the plunger from the syringe.
- Place the syringe with the **tip on the table**, this closes the tip during filling.
- Slowly **pour all** of the mixture in the syringe.
- Put the plunger into the syringe, make sure to only **put the tip in**.
- Turn the syringe around and **wait for the mixture to settle**.
- Push the plunger further until **all air is removed**.

5

Minor issue:  
P1 struggled with handling (no free hands)  
Result: syringe not completely filled

Positive:  
Illustrations showing spillage in step 22 increased confidence.

### IV. Remove air bubbles

**Items you'll need**

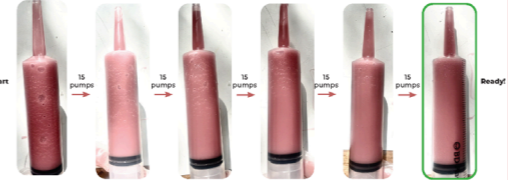
- Filled syringe

The **pumping motion** causes the small air bubbles to **move** and **merge** with each other, forming larger bubbles. These larger bubbles rise to the top and escape through the tip of the syringe. This helps remove air bubbles larger than **1 mm**.

- Close the tip** of the syringe with your thumb or finger and use the other hand to **pull the plunger**.
- Push** the plunger back with the **tip closed**.
- Repeat this pumping motion **15 times**.
- Observe** the air bubbles in the syringe. When there are still bubbles larger than 1mm, continue with **15 pumps**.
- Repeat** pumping motions and **observations** until all bubbles larger than 1mm are gone.

**Tip:** Tap the syringe against the **edge of a table** to release larger bubbles.

**Example:**



Start → 15 pumps → 15 pumps → 15 pumps → 15 pumps → 15 pumps → Ready!

6

Perceived as most difficult and unclear.  
And visually overwhelming

Key issues:  
Instructions unclear on how to perform pumping

Missing step:  
Air must be released after pumping

Observation:  
P1 kept syringe closed the entire time and was unsure how to proceed  
Confusion despite reading instructions (P2)

Both participants saw bubbles changing but did not know what to do next.


Stopped due to time pressure

Layout issues:  
Too much information  
Lack of hierarchy (same colors, boxes, structure)  
Tips not recognized as important


### V. Fill the mould

**Items you'll need**


- Filled syringe
- Prepared mould
- Piece of sulfur free clay (1cm x 1cm)




**29.** Prepare a small piece of clay by rolling into a small ball to seal the injection hole later.



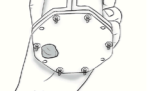
**30.** Hold the syringe vertically into the mould's injection hole.




**31.** Push the mixture slowly into the mould. This takes about 5 minutes.




**32.** Continue until you see the mixture coming out of the air vents at the top. This indicates that the mold is full.



**33.** Seal the injection hole with the piece of clay.



**34.** Tap the bottom of the mould on the table a few times so any remaining air can escape through the air vents.




**35.** Let the silicone cure for at least 8 hours with the mold upright and vent holes on top.


### VI. Release silicone from mould

**Items you'll need**


- Filled mould
- Steckschlutel size 5,5
- Platte schroevendraaier
- Knife




**36.** Loosen the bolts and nuts using a wrench and a flathead screwdriver.




**37.** Cut along the edges of the mould to loosen them slightly. Do not cut too deep, or you may cut into the silicone.




**38.** Use a flathead screwdriver to insert between the moulds and create leverage.




**39.** Once the outer parts are loose, remove the outer sections.



**40.** Peel the silicone off the other parts.



**41.** Trim off any remaining edges.



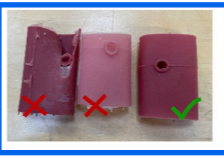
**42.** The silicone vagina is finished! Now do the self-check.

### Final Check

Is the part properly filled?

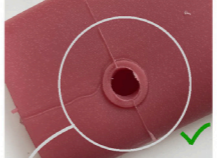
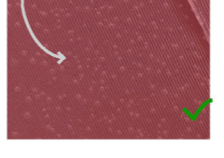
The silicone part is completely filled, with no frayed or uneven edges. (Color intensity is not relevant.)

The right side is evenly filled.



Are there any large air bubbles present? Larger than 0,5 cm.

Small air bubbles (small dots) are acceptable. If larger air bubbles are present within a 2 cm radius around the hole, the part is not usable.

Is the mold damaged after opening?

If the three alignment pins are broken, the mold can still be used, provided the parts are tightened securely during assembly.

If the top section or the hole is broken, the mold is not usable and must be reprinted.

Issues:  
High force required (unexpected)  
Stress due to time constraint

Confusion about:  
Spillage  
Filling duration  
P1 had too little material mould not fully filled, felt insecure.  
P2 had excess material better result, felt confident.

Overestimating material is preferable  
Recommendation: use 1.5x material

Performed correctly by both participants  
Instructions were clear and sufficient.

Quality check was performed correctly by both participants.

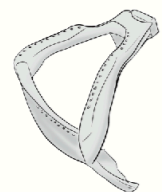
However:  
Unclear what to do if the part is not usable.

Participants need:  
Better reading hierarchy  
Clear decision guidance  
What actions to take after evaluation

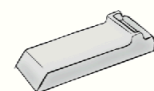
# Appendix E – Assembly Instructions 1.0

## E.1 Assembly Instructions 1.0

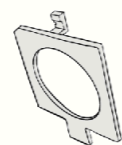
### Items you'll need



3D printed Pelvic bone



3D printed dorsal frame



3D printed bladder frame



3D printed glue support



Vagina



Cervix



Vulva



Bladder cup



Bladder top



Plastic buisje dat fungeert als Urethra (diameter 7mm)



Secondelijm



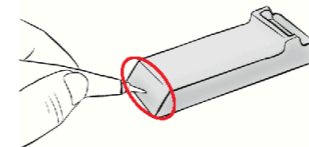
Silicone glue



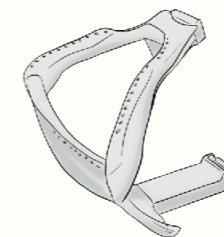
Needle and thread (cotton thread is fine)

### Instructions

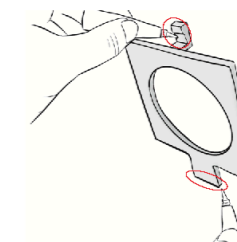
#### I. Assemble framework



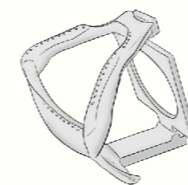
**1.** Apply secondelijm to the dorsal frame.



**2.** Press pelvic bone against dorsal frame and apply pressure for 10 minutes.



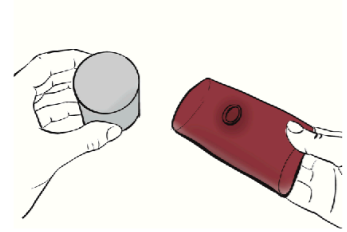
**3.** Apply secondelijm to the bladder frame.



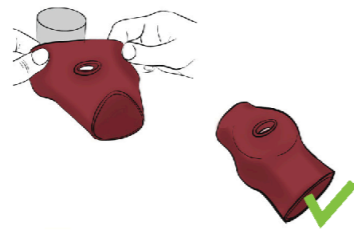
**4.** Place bladder frame into dorsal frame and pelvic bone and apply pressure for 10 minutes.

## II. Assemble Bladder Cup to Vagina

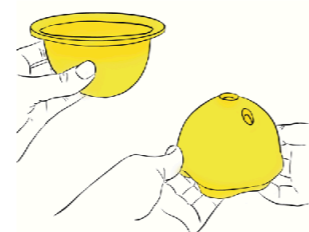
This step affects how realistic the medical procedure will be for the trainee. The bladder cup and vagina must be firmly glued together for 2 cm around the fistula. The cylindric 3D printed glue support will act as a guide for how far to apply the glue.



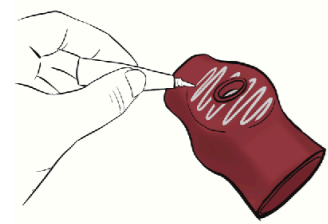
**5.** Get the glue support and de vagina.



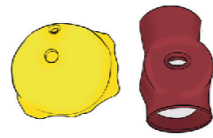
**6.** Place the support into the vagina.



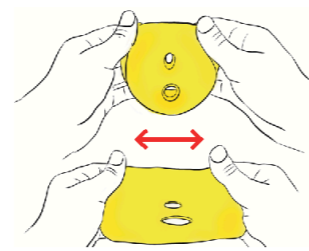
**7.** Evert the bladder.



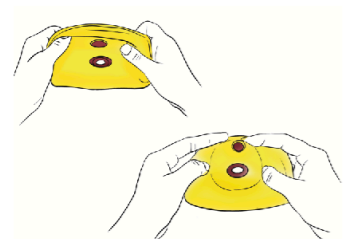
**8.** Apply silicone glue on the circular surface on the vagina.



**9.** Get the everted bladder and vagina, and position as illustrated.



**10.** Stretch the holes of the bladder.



**11.** Place the bladder onto the vagina, over the thickened edge of the fistula on the vagina.

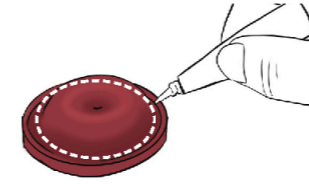


**12.** Apply pressure on the glued surface for 2 minutes and leave to dry for 24 hours.

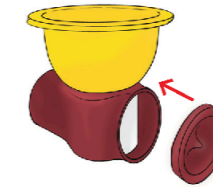


**13.** After 24 hours, check if the bladder and vagina goed vast zitten. If yes, evert the bladder. If no, add glue.

## III. Assemble Cervix to Vagina



**14.** Apply silicone glue inside of the edge of the cervix.



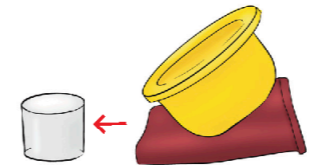
**15.** Place the cervix onto the short side of the vagina and apply pressure for 10 mins.



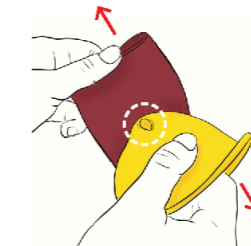
**16.** Wait for the glue to dry for 24 hours.

## IV. Assemble urethra

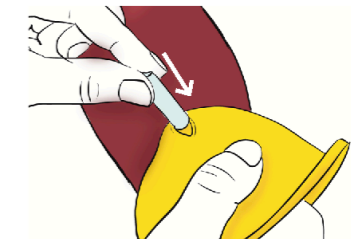
This step is important. The urethra must be properly sealed along the edges of the hole on the inside and outside. No fluids should be able to pass through because a watertightness test will be performed during surgery.



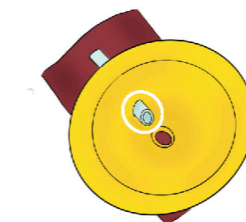
**17.** Remove the support from the vagina.



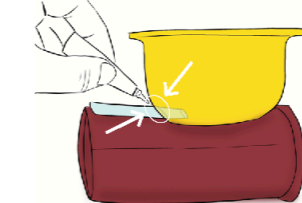
**18.** If the bladder and vagina are slightly glued together at the urethra hole, gently separate them by pulling to reopen the hole.



**19.** Insert the urethra through the urethra hole.



**20.** Apply secondelijm around the edge where the urethra meets the hole.



**21.** Apply glue on the outside of the bladder, around the urethra, to seal it completely.

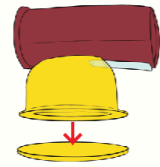


**22.** Check along the edges on the inside and outside to see if it is sealed along the edges.

## V. Assemble Bladder top to Bladder Cup



**23.** Apply silicone glue to the circular edge of the bladder cup.



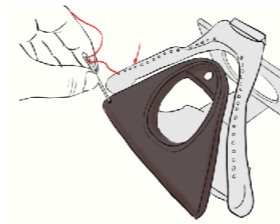
**24.** Place the vagina and bladder cup onto the bladder top plate and apply pressure for 10 minutes.



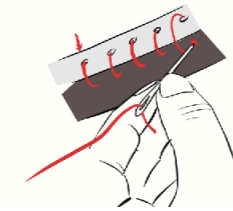
**25.** Let dry for 24 hours.

## VI. Assemble Vulva to Framework

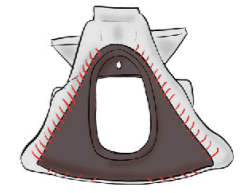
In this step, you will attach the vulva to the framework using a needle and thread. This may be a little difficult at first, but you will get better at it.



**26.** Take the silicone vulva and the pelvic framework and stitch vulva to the framework.

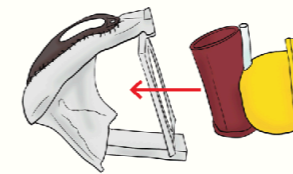


**27.** Stitch the vulva to the framework through the pre-made holes.

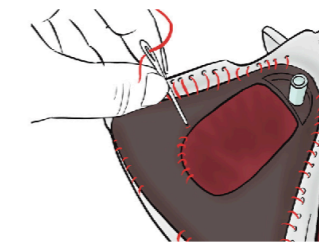


**28.** When finished, tie a secure knot and cut the thread.

## VII. Assemble Vagina to Vulva



**29.** Place the assembled bladder, vagina, and cervix into the framework.



**30.** Stitch the vagina to the vulva all the way around, using the same stitch as before.



**31.** Tie off the thread. The assembly is now complete.

## E.2 Evaluation Assembly Instructions 1.0

This appendix shows the test set up of the evaluation of the assembly instructions and presents an overview of the detailed results. The goal of this evaluation is to determine to what extent the instructions are clear and usable for makers. In addition, the product quality of the final assembled clinical task trainer is assessed.

To achieve this, a user test was conducted with three participants. The results of this test were analysed and resulted in a set of design requirements to improve the assembly instructions.

### E.2.1 Test set-up

This section describes the setup of the user test, including the participants, the test procedure, and the evaluation measures used to assess the assembly instructions.

The goal of the test is to evaluate the usability and clarity of the assembly instructions as well as to evaluate the quality of the assembled clinical task trainer, which assesses the usefulness.

#### E.2.1.1 Participants

The test involves three participants, aged between 25 and 28 years, alle students at TU Delft with no background or experience in design or assembly of the clinical task trainer.

#### E.2.1.2 Equipment

The participants use the following equipment during the test (Figure E.1):

- Assembly instructions printed in greyscale
- 3D-printed framework parts
- 3D printed glue support
- Silicone parts (vulva, vagina, cervix, bladder cup, bladder plate)
- Rubber tube (urethra)
- Silicone glue
- Super glue
- Needle and thread
- Towel



Figure E.1: Materials provided during the test.

#### E.2.1.3 Test procedure

The participant performs the assembly of the clinical task trainer in a well-ventilated room. They follow the assembly instructions and use the provided tools and components.

Each participant is asked to assemble the clinical task trainer using the provided assembly instructions. The assembly process takes approximately two to three hours. During the assembly, the think-aloud method is used, meaning that the participant is asked to verbalize their thoughts while performing the task. The researcher documents observations, quotes and difficulties encountered during each step of the assembly.

After completing the assembly, the participant is asked to rate their confidence of the quality of their assembled task trainer on a five-point scale. Subsequently, the researcher assesses the quality of the assembled task trainer together with the participants.

After the assessing the quality, a short co-creation session is conducted with the researcher and the participant. During this session, the participant is asked to identify the most significant issues they encountered during the assembly process. Together with the researcher, potential solutions are generated. These include rewriting steps, improving layouts, and adjusting images. Finally, the identified issues are prioritized by the participant.

### E.2.2 Evaluation measures

Two main dimensions are assessed during the evaluation: product quality and process quality.

Product quality assesses the correctness and usability of the final assembly of the task trainer, while process quality focuses on the user experience during the assembly, including the clarity of instructions, perceived guidance, confidence during the process and observed issues.

#### Product quality

Product quality is assessed by asking the following question to the participants after the assembly: "How well do you think you assembled the product?"

(1 = very poorly, 5 = very well). As well as by assessing the correctness of each assembled part of the clinical task trainer.

For each section, it is determined whether the assembled component meets the predefined criteria. If the assembled component does not meet the criteria, it is considered not usable and receives a rating of 1. If the component meets the criteria, it is considered usable and receives a rating of 5.

The average score across sections is then calculated for each participant. The clinical task trainer is considered correctly assembled only if all sections receive a rating of 5, indicating that the product is fully functional and ready to be used by trainees. The score is referred to as product score.

Figure E.2 shows the criteria used to assess the assembly of each section.

Section	Criteria
<b>I. Assembling the framework</b>	<ul style="list-style-type: none"> <li>The framework is firmly attached.</li> <li>The bladder frame support is attached on the correct side.</li> </ul>
<b>II. Assemble bladder cup to vagina</b>	<ul style="list-style-type: none"> <li>The bladder cup is glued to the vagina in a ring of approximately 2 cm around the fistula opening.</li> <li>The glue coverage is evenly distributed and fully connects both components.</li> <li>The urethra opening in the bladder cup is oriented towards the long side of the vagina.</li> </ul>
<b>III. Assemble cervix to vagina</b>	<ul style="list-style-type: none"> <li>The cervix is securely attached and does not move when lightly handled.</li> <li>The cervix is positioned on the short side of the vagina.</li> <li>The connection between the cervix and vagina shows no visible gaps.</li> </ul>
<b>IV. Assemble urethra</b>	<ul style="list-style-type: none"> <li>The urethra is attached to the bladder on both the inside and outside, with no gaps.</li> <li>The urethra remains attached when lightly pulled by hand.</li> <li>The urethra does not obstruct or cover the fistula opening.</li> </ul>
<b>V. Assemble vulva to framework</b>	<ul style="list-style-type: none"> <li>The vulva is attached using all pre-printed holes.</li> <li>All stitches are secured with knots that remain tight when handled.</li> <li>The vulva remains firmly attached when lightly pulled by hand.</li> </ul>
<b>VI. Assemble vagina to vulva</b>	<ul style="list-style-type: none"> <li>The stitched seam is fully closed, with no visible openings or gaps.</li> <li>All stitches are secured with knots that do not loosen.</li> <li>The vagina remains firmly attached to the vulva when lightly pulled by hand.</li> </ul>

Figure E.2 – Predefined criteria.

## Process quality

The process quality, focuses on the user experience during the assembly, including the clarity of instructions, perceived guidance, confidence during the process and observed issues. Participants rate their perceived performance using a five-point scale. This score is referred to as the confidence score. The confidence score is later compared with the product score to identify mismatches between perceived and actual performance.

Since part of the design goal is that the maker should feel confident and supported during the process, measuring confidence is considered important. Comparing the product score with the confidence score provides insight into the quality of the instructions.

Confidence level	Product score	Interpretation of instructions
High confidence	High product score	Clear instructions
High confidence	Low product score	Misinterpretation of instructions
Low confidence	High product score	Instructions work but feel unsupported (or personal insecurity)
Low confidence	Low product score	Unclear instructions

## E.2.3 Results

This section presents the results obtained from the user test. First, the results regarding product quality are presented, followed by the results related to process quality.

### 5.2.1 Product quality

To start, none of the participants fabricated a usable task trainer that met all predefined criteria. Figure E.3 presents the assembly section and the corresponding product scores for each participant.

Only participant P1 assembled the framework. The framework was glued using superglue, no materials were available to dissolve the adhesive and disassemble the structure. Additionally, no spare 3D-printed framework components were available. Therefore, participants P2 and P3 were unable to perform this assembly step. For this reason, the framework assembly was not included in the average product score for all participants. However, participant P1 successfully assembled the framework.

Section	P1	P2	P3
I. Assemble framework	-	-	-
II. Bladder cup to vagina	5	1	1
III. Cervix to vagina	1	5	5
IV. Urethra into bladder hole	5	5	5
V. Bladder top to cup	5	5	1
VI. Vulva to framework	5	1	5
VII. Vagina to vulva	5	1	5
Means (product score)	4.3	3	3.7
Confidence score	4	2	3
Usable task trainer	No	No	No

Figure E.3: Product scores of each participant

For each assembly section, the observed issues are summarized in Figure E.4 and includes:

- Step: the corresponding instruction step.
- Observations: objective findings, including participant behaviour, quotes, and occurrence frequency.
- Impact: the effect on product quality, process quality, and participant confidence.
- Priority: issues categorized as low, medium, or high priority based on severity and frequency.
- Improvement: proposed design improvements derived from observations and co-creation sessions.

### Co-creation

During the co-creation sessions, participants were asked to identify the most significant issues they experienced during the assembly process. Based on these discussions, potential improvements to the assembly instructions were generated. Below, the main issues identified by each participant are listed in order of priority.

#### P1: Main issues

1. Gluing components was difficult. It was challenging to position parts, such as the cervix, so that they remained in place during drying. This caused frustration.
2. The urethra did not fit properly, making it difficult to glue in the correct position.
3. Participant wanted to continue working but had to wait a long time for the glue to dry.
4. Some images were too dark, making details difficult to see.
5. A brush for applying the glue would be helpful.

#### P2: Main issues

1. The instructions assume that the user has sewing experience; no preparation or explanation of sewing techniques was provided.
2. Terms such as holes, fistula, or urethra were sometimes introduced without explanation.
3. Gluing the cervix was difficult.
4. Instructions such as "glue evenly" and aligning the fistula opening in the center were important but not described.

#### P3: Main issues

1. The instructions assume sewing experience; preparation and guidance were insufficient.
2. Too little information was provided about the sewing steps.
3. Participant was unsure whether the vagina was assembled in the correct orientation.

## II. Assemble bladder cup to vagina



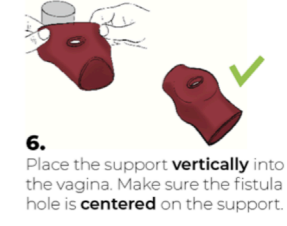





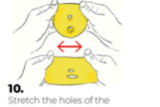
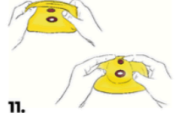
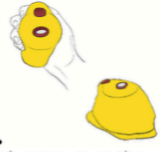


Step	Observations (summarized)	Impact	Priority	Improvement
	-	-	-	-
	<p><b>Orientation:</b> 1/3 placed support incorrectly inside the vagina but corrected it later</p> <p><b>Clarity:</b> 1/3 stated: "I cannot clearly see the check mark."</p>	<p>Validation cue (check mark) is not visually prominent.</p> <p>No lasting product error</p> <p>Low impact</p>	<p>Low</p> <p>1/3 mistake but corrected.</p> <p>Minor visibility issue</p>	<p>Instruct users to place support vertically into vagina.</p> <p>Add sentence stating that fistula opening must be centred on the support to ensure proper alignment.</p> <p>Replace check mark to show clearly.</p> <p>"place the support vertically into the vagina. Ensure that the fistula opening is centered on the support."</p> 
	-	-	-	-
	<p>2/3 grabbed the wrong glue.</p> <p>1/3 stated: "I need something to spread the glue"</p> <p>1/3 did not spread the glue evenly.</p>	<p>Uneven glue distribution compromises realistic tissue simulation.</p> <p>Direct impact on product quality and intended function.</p> <p>High impact</p>	<p>Medium</p> <p>2/3 wrong glue, but corrected themselves.</p> <p>1/3 glue spreading incorrect.</p>	<p>Emphasize that silicone glue should be used.</p> <p>Emphasize that glue must be spread evenly across the entire circular surface.</p> 

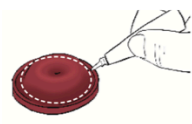
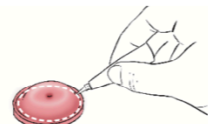

Figure E.4: Results per step for assembly instructions 1.0

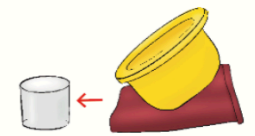


 <p><b>9.</b> Get the everted bladder and vagina, and position as illustrated.</p>	<p>1/3 questioned whether the step was necessary.</p> <p><b>Orientation:</b> 3/3 verbally questioned orientation (short side should be down)</p> <p>1/3 everted the bladder again, resulting in incorrect assembly.</p>	<p>Incorrect assembly occurred in 1 case.</p> <p>High</p>	<p>High</p> <p>3/3 orientation confusion.</p> <p>Correct assembly</p>	<p>Clarify that vagina has a short and long side.</p> <p>Explicitly state that the short side of the vagina should face the maker.</p> <p>Add directional visual cue.</p> <p>“take the everted bladder and vagina. Position the vagina so that the short side faces you.”</p>  <p><b>9.</b> Get the <b>everted bladder</b> and <b>vagina</b>, and position as illustrated.</p>
 <p><b>10.</b> Stretch the holes of the bladder.</p>	-	-	-	-
 <p><b>11.</b> Place the bladder onto the vagina, over the thickened edge of the fistula on the vagina.</p>	<p><b>Anatomy:</b> 3/3 asked “What is the fistula?”</p> <p>3/3 assembled the part correctly</p> <p><b>Timer:</b> 2/3 had no hands free to operate a timer and asked the researcher to track time.</p> <p>1/3 prepared beforehand and started a timer independently.</p>	<p>Anatomy terminology is unclear.</p> <p>Workflow usability issue related to timing.</p> <p>No impact on final product quality.</p> <p>Low to medium impact</p>	<p>Medium</p> <p>3/3 don’t know term fistula</p> <p>Correct assembly</p> <p>Timer usability issue.</p>	<p>Introduce key anatomical terminology (e.g., fistula) before assembly begins.</p> <p>Provide instructions to set a timer.</p> <p>Clarify the exact placement of the bladder’s fistula over the thickened edge of the vaginal fistula by showing a closeup image.</p> <p>“set a timer for 6 minutes, place the bladder onto the vagina, positioning it over the thickened edge of the vaginal fistula.”</p> <p><b>11.</b> Set a timer for 6 minutes and place the bladder onto the vagina, over the thickened edge of the fistula on the vagina.</p>

 <p><b>12.</b> Apply pressure on the glued surface for 2 minutes and leave to dry for 24 hours.</p>	<p><b>Apply pressure:</b> 2/3 did not read the instruction to apply pressure first.</p> <p>1/3 applied pressure by mimicking the image.</p> <p>2/3 applied pressure differently than intended.</p> <p><b>Orientation/ placement:</b> 3/3 were unsure whether placement was correct.</p> <p>One participant asked: “When do I place it like the second illustration?”</p>	<p>Potential risk of incorrect assembly (though all assembled correctly)</p> <p>Unclear instruction sequence.</p> <p>Uncertainty during placement.</p> <p>Medium impact.</p>	<p>Medium (3/3 uncertain)</p> <p>Sequence unclear</p> <p>No final error</p>	<p>Clearly state the working time and curing time of the specific silicone glue used.</p> <p>Add a close-up image showing the correct fistula assembly.</p> <p>Clarify when and how pressure should be applied.</p>  <p><b>12.</b> Apply pressure on the glued surface for 5 minutes.</p> <p><b>X.</b> Leave to dry like this for 12 minutes.</p>
 <p><b>13.</b> After 24 hours, check if the bladder and vagina goe[st] stuck. If yes, evert the bladder. If no, add glue.</p>	<p><b>Time:</b> 2/3 waited for drying of the glue before continuing to the next step and mentioned that the waiting time felt very long.</p> <p>1/3 continued assembling other parts while waiting.</p>	<p>Waiting time affects workflow motivation.</p> <p>One participant identified incorrect fixation but did not correct it.</p> <p>Medium to high impact</p>	<p>Medium</p> <p>Workflow friction</p> <p>1 participant continued despite wrong attachment.</p> <p>Self-validation issue.</p>	<p>Inform makers that they may proceed with next steps during drying time.</p> <p>Change waiting times to match the specific silicone glue used.</p> <p>Include correction guidance if assembly is incorrect.</p> <p>Add self-validation checklist</p> <p><b>Self check</b> Is the bladder securely glued to the vagina? Is the bladder positioned straight (see image)?</p>

	<p><b>Correct assembly:</b> 3/3 checked whether the bladder and vagina were properly attached.</p> <p>2/3 concluded the bladder was assembled properly.</p> <p>1/3 concluded the bladder was not properly attached but continued assembly anyway.</p>			If assembly is incorrect, carefully detach the components and repeat the steps. (specify steps)
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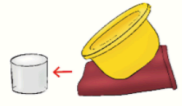
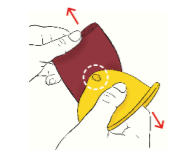
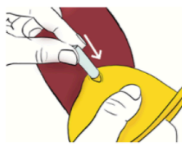

### III. Assemble cervix to vagina


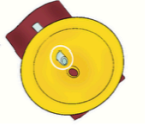


Step	Observations (summarized)	Impact	Priority	Improvement
 <p><b>14.</b> Apply silicone glue inside of the edge of the cervix.</p>	1/3 participant had difficulty seeing the image clearly due to low contrast in black-and-white printing. Despite this, the participant eventually selected the correct silicone component.	Reduced visual clarity caused temporary hesitation.  No product error occurred.  Low impact	Low  Only 1 participant struggled.  No product consequences	Increase image contrast and use lighter, distinguishable tones.   <b>14.</b> Apply <b>silicone glue</b> inside of the edge of the cervix.
 <p><b>15.</b> Place the cervix onto the short side of the vagina and apply pressure for 10 mins.</p>	<b>Placement:</b> 3/3 experienced difficulty and felt insecure while	Image and reality mismatch directly influenced	High  All participants struggled	<b>Placement:</b> Instruct users to remove the 3D support before assembling the cervix.


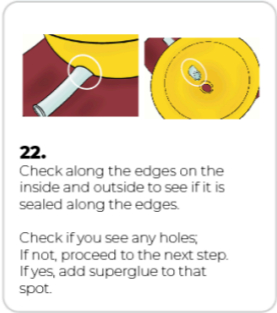
	<p>positioning the cervix because the vagina shape did not match the circular representation shown in the image. This made assembly difficult.</p> <p>1/3 adjusted the internal 3D support to reshape the vagina into a circular form before attaching the cervix.</p> <p><b>Glue drying:</b> 3/3 struggled to apply sufficient pressure while the glue was drying. Uncertainty about hand placement and drying method.</p>	attachment quality.  Product error occurred.  High impact		<p>Ensure the visual representation accurately reflects the actual shape of the vagina during this step.</p>  <p><b>17.</b> Remove the support from the vagina.</p> <p><b>Glue drying:</b> Clearly instruct users to place the short side of the vagina vertically into the edge of the cervix.  Specify: apply gentle, even pressure for 5 minutes.  Include realistic image showing correct hand positioning. (5 min with applied pressure, 7 additional min without holding)</p> 
 <p><b>16.</b> Wait for the glue to dry for 24 hours.</p>	2/3 assembled cervix correctly  1/3 had a loose cervix but continued to the next step without correction.	Product error occurred.  Indicates insufficient self-validation guidance.  Medium to high impact	Not universal, but important for final product.  High	<p>Clearly state the correct curing time: 12 min</p> <p>Add a self-check validation moment after curing.</p> <p>Include a realistic image (without 3D support present) showing correct final attachment.</p> <p>Self-check Users must check is cervix is securely attached along the entire edge.</p>

				<p>No gaps or loose sections are visible.</p> <p>If attachment is incomplete: Apply additional glue to unsecured areas. Apply pressure again for 5 min and wait additional 7 min to cure. Re-check before proceeding.</p>
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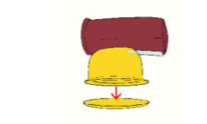
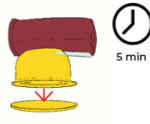
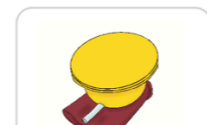

#### IV. Assemble urethra

Step	Observations (summarized)	Impact	Priority	Improvement
 <p><b>17.</b> Remove the support from the vagina.</p>	3/3 completed this step without difficulty.	-	-	Replace to section 'assemble cervix to vagina'
 <p><b>18.</b> If the bladder and vagina are slightly glued together at the urethra hole, gently separate them by pulling to reopen the hole.</p>	3/3 completed this step without difficulty	-	-	-
 <p><b>19.</b> Insert the urethra through the urethra hole.</p>	<p>3/3 questioned how far the urethra should be inserted.</p> <p>Despite this uncertainty, 3/3 completed this step successfully.</p> <p>3/3 stated that their urethra component appeared longer than the one shown in the illustration.</p>	<p>Visual-reality mismatch created hesitation</p> <p>No assembly failure occurred.</p> <p>Medium impact</p>	<p>Low</p> <p>All participants experienced uncertainty.</p> <p>No product failure</p>	<p>Clearly indicate insertion depth in both text and image.</p> <p>Ensure the illustration match real product dimensions.</p>  <p><b>19.</b> Insert the urethra through the urethra hole. Make sure it does not cover the fistula hole.</p>

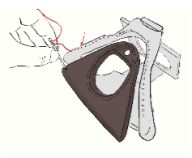
 <p><b>20.</b> Apply secondelijm around the edge where the urethra meets the hole.</p>	<p>3/3 did not know how much glue was required.</p> <p>3/3 struggled with the glue application process and described it as inconvenient.</p>	<p>All participants were confusion about glue quantity and sequence.</p> <p>Inefficient workflow and handling difficulty.</p> <p>Increased risk of assembly failure</p> <p>High impact</p>	<p>High</p> <p>Universal difficulty and risk of assembly failure</p>	 <p><b>20.</b> Apply <b>superglue</b> around the edge where the urethra meets the hole.</p> <p>Restructure the sequence of actions to simplify glue handling.</p> <p>Revised sequence: Apply superglue evenly around the urethra.</p> <p>Insert the urethra into the designated hole and allow it to dry for 1 min.</p> <p>After initial fixation, apply an additional sealing layer on both the insight and outside of the bladder.</p> <p>Clarify recommended glue quantity (e.g., thin, even layer)</p> <p>Add visual example of correct glue coverage.</p>
 <p><b>21.</b> Apply glue on the outside of the bladder, around the urethra, to seal it completely.</p>	<p><b>Illustration:</b> 1/3 stated that the image did not appear realistic.</p> <p><b>Text:</b> 1/3 did not read the instruction 'seal it completely'</p>	<p>Minor visual issue.</p> <p>Risk of incomplete sealing.</p> <p>No immediate failure</p> <p>Medium</p>	<p>Medium</p> <p>Only one participant but relates to sealing completeness.</p>	 <p><b>21.</b> Apply glue on the outside of the bladder, around the urethra, to <b>seal it completely.</b></p> <p>Replace the illustration with a more realistic image that accurately reflects the physical product.</p> <p>Emphasize the phrase "seal completely" visually (e.g., bold text or icon)</p>

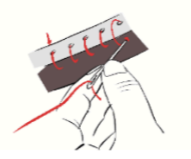

 <p><b>22.</b> Check along the edges on the inside and outside to see if it is sealed along the edges.</p>	<p>1/3 was confident that the urethra was fully sealed and secure, but it later detached.</p> <p>2/3 were uncertain about attachment quality but did not perform a thorough check and proceeded to the next steps.</p>	<p>Structural failure occurred in 1 case.</p> <p>Confidence and accuracy mismatch observed.</p> <p>Lack of self-validation</p> <p>High impact</p>	<p>High</p> <p>Structural issue</p>	<p>Encourage self-validation before proceeding.</p> <p>Introduce self-check with clear criteria:</p> <p>No visible gaps Urethra firmly attached No movement when slightly pulled.</p> <p>“Do not proceed until the urethra is fully secured.”</p> <p>Include corrective guidance is attachment is insufficient (reapply glue, apply pressure, wait 1 min)</p>  <p><b>22.</b> Check along the edges on the inside and outside to see if it is sealed along the edges. Check if you see any holes. If not, proceed to the next step. If yes, add superglue to that spot.</p>
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## V. Assemble bladder top to bladder cup

Step	Observations (summarized)	Impact	Priority	Improvement
 <p><b>23.</b> Apply silicone glue to the circular edge of the bladder cup.</p>	<p>2/3 successfully completed this step without difficulty.</p> <p>1/3 could not complete the step due to an incorrectly assembled bladder cup from a previous step.</p>	<p>Shows dependency on previous steps. However, this step is clear.</p> <p>Medium impact</p>	<p>Low</p>	<p>Add validation in previous steps.</p> <p>Emphasize the correct glue.</p>  <p><b>23.</b> Apply <b>silicone glue</b> to the circular edge of the bladder cup.</p>
 <p><b>24.</b> Place the vagina and bladder cup onto the bladder top plate and apply pressure for 5 minutes.</p>	<p>2/3 successfully completed this step without difficulty.</p>	<p>No structural issue.</p> <p>Low</p>	<p>Low</p>	<p>Add <b>hand</b> to indicate how to apply pressure.</p> <p>Add a clock icon to visually show the required waiting time.</p>  <p><b>24.</b> Place the vagina and bladder cup onto the bladder top plate and apply pressure for 5 minutes.</p>
 <p><b>25.</b> Let dry for 7 more minutes.</p>	<p>2/3 felt the waiting time was too long but continued with the next step.</p> <p>1/3 waited fully for curing before proceeding.</p>	<p>Workflow inefficiency.</p> <p>No product failure.</p> <p>Low impact</p>	<p>Low / medium</p>	<p>Clearly state that users may proceed with subsequent steps while waiting for curing.</p> <p>Clarify which steps can be performed in parallel.</p>  <p><b>25.</b> Let dry for 7 more minutes, in the mean time you can proceed to the next steps.</p>

## VI. Assemble vulva to framework

Step	Observations (summarized)	Impact	Priority	Improvement
 <p><b>26.</b> Take the silicone vulva and the pelvic framework and stitch vulva to the framework.</p>	<p><b>Image;</b> 3/3 stated the image was incorrect (needle shown going through frame before silicone)</p> <p>3/3 struggles with vulva orientation but chose correctly.</p> <p><b>Text</b> 3/3 asked how much thread was needed.</p> <p>2/3 did not know how to start sewing.</p>	<p>All participants were confused.</p> <p>Incorrect visual instruction can cause incorrect execution.</p> <p>High frustration and skill dependency.</p> <p>Risk of improper stitching technique.</p> <p>High impact</p>	High	<p><b>Image:</b> Correct the visual sequence. Improve contrast in illustration to clarify details in black-and-white printing.</p> <p>Add a realistic hand to demonstrate how to hold the components and needle.</p> <p><b>Text:</b> Break the sewing process into smaller, structured steps:</p> <p>“Cut the thread, insert through the needle and tie a knot. “</p> <p>“Start from the backside of the silicone so the knot remains hidden.”</p> <p>“Sew through the pre-printed hole, pull the thread tightly after each stitch.”</p> <p>“Continue until the thread runs out. And get a new thread if you’re not done yet.”</p> <p><b>Additional support</b> Add a QR code linking to a short instructional sewing video.</p>

 <p><b>27.</b> Stitch the vulva to the framework through the pre-made holes.</p>	<p>3/3 stated sewing the framework was difficult due to its large size.</p> <p>2/3 felt that intermediate steps were missing.</p> <p>2/3 needed help to prepare the needle.</p> <p>2/3 expressed clear frustration.</p>	<p>Physical handling difficulty.</p> <p>Perceived lack of procedural guidance.</p> <p>Increased frustration and loss of confidence.</p> <p>High impact</p>	High (usability, frustration)	<p>Move sewing of the vulva to the framework earlier in the process (before full framework assembly) to reduce handling difficulty.</p> <p>Explicitly instruct users to pull the thread tight after each stitch to ensure structural stability.</p>
 <p><b>28.</b> When finished, tie a secure knot and cut the thread.</p>	<p>1/3 did not know how to secure a knot and did not complete the step.</p> <p>1/3 had sewing experience and completed it successfully.</p> <p>2/3 achieved a usable final result.</p>	<p>Risk of structural instability if knot is not secured.</p> <p>Variability based on prior experience.</p> <p>Medium impact</p>	Medium	<p>Include a clear visual step demonstrating how to tie and secure a final knot.</p>

# Appendix F – Assembly Instructions 2.0

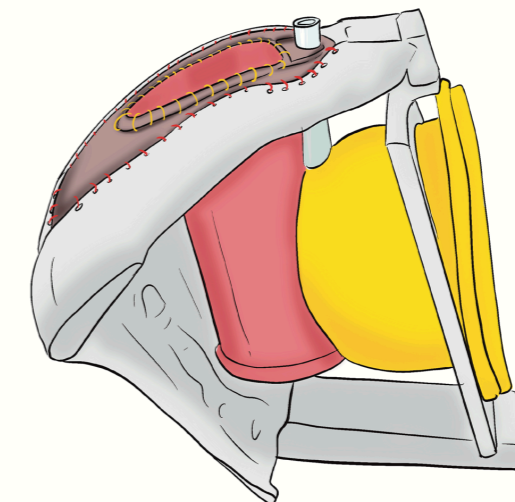
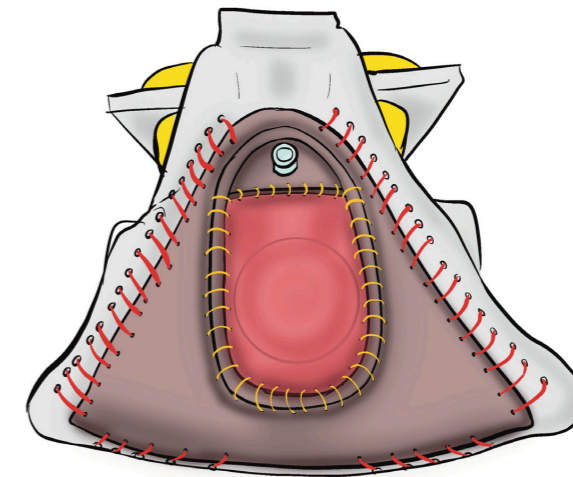
## F.1 Assembly Instructions 2.0

### VII. Assemble vagina to vulva

Step	Observations (summarized)	Impact	Priority	Improvement
 <p><b>29.</b> Place the assembled bladder, vagina, and cervix into the framework.</p>	<p>3/3 asked where the urethra should be positioned. However all successfully completed the step by referencing the next step's image.</p>	<p>Instruction is insufficient, but no product error occurred</p> <p>Low</p>	<p>Low</p>	<p>Add explicit text in instruction: "Place the bladder with the urethra and vagina in the framework and push the urethra through the indicated hole in the vulva."</p> <p>Ensure a visual indication of the indicated hole.</p>
 <p><b>30.</b> Stitch the vagina to the vulva all the way around, using the same stitch as before.</p>	<p>3/3 did not know how far apart stitches should be.</p> <p>2/3 showed reduced motivation and rushed the stitching.</p>	<p>Lack of spacing guidance affects product quality.</p> <p>Decrease of motivation.</p> <p>High</p>	<p>High</p>	<p>Increase visual contrast between vulva and stitches in illustration.</p> <p>Add text guidance: "Space the stitches approximately the same distance apart as in the previous stitching step."</p> <p>Provide realistic visual spacing example.</p>
 <p><b>31.</b> Tie off the thread. The assembly is now complete.</p>	<p>1/3 did not achieve a usable final result.</p> <p>2/3 achieved a usable result.</p> <p>3/3 expressed uncertainty about completion ("okay, so I'm done now?")</p>	<p>Lack of final validation confirmation.</p> <p>No clear end-of-process closure.</p> <p>High</p>	<p>High</p>	<p>Add a self-check step: "Can you see through the stitched opening (add image) If yes, add stitches until fully closed. If no, assembly is complete!"</p> <p>Include a full-page final image of the completed phantom. Add "congratulations" and image of correct final result.</p>

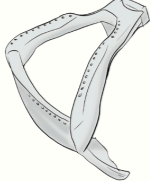
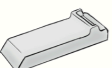
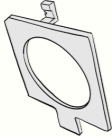

## Assembly Instructions

Assemble the clinical task trainer for vesicovaginal fistula repair





 You will be using silicone glue; ensure the assembly is performed in a **well-ventilated** area.


# Items you'll need

 Pelvic bone  
 Dorsal frame  
 Bladder support frame  
 Glue support

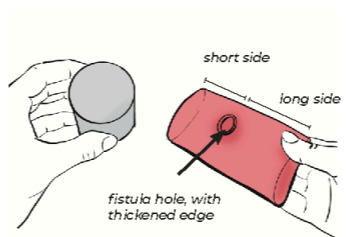
 Silicone part 'vagina'  
 Silicone part 'cervix'  
 Silicone part 'bladder cup'  
 Silicone part 'bladder top'  
 Silicone part 'vulva'  
 Rubber tube as 'Urethra'  
 Ø 7 mm  
 ←→ 6 cm

 Superglue  
 Silicone glue (E43)  

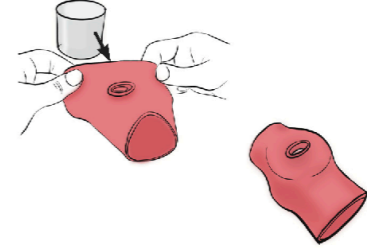
! Time indications in the instructions depend on the specific type of glue used.

 Needle and thread

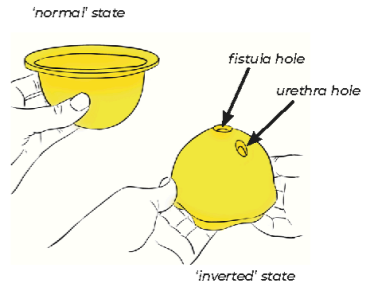
# I. Assemble Bladder Cup to Vagina



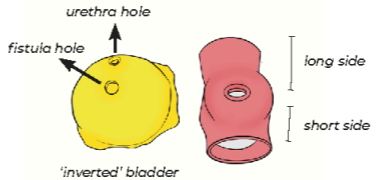
**1.** Get the glue support and the vagina.



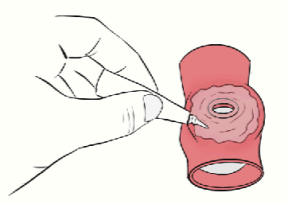
**2.** Insert the glue support vertically into the vagina.  
 ! Ensure the fistula hole is positioned at the **center** of the glue support.



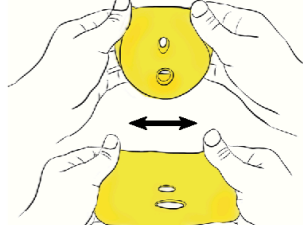
**3.** Invert the bladder cup.



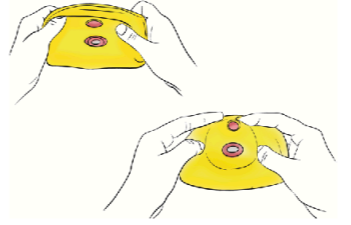
**4.** Position the bladder cup and vagina as illustrated.




**5.** Apply **silicone glue** on the circular surface on the vagina and spread evenly.




**6.** Stretch the holes of the inverted bladder cup.



**7.** Place the stretched bladder cup onto the vagina, over the **thickened edge** of the fistula on the vagina.



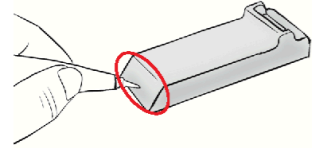
**8.** Apply pressure until the parts no longer move when pressure is released.  
 ~15 min



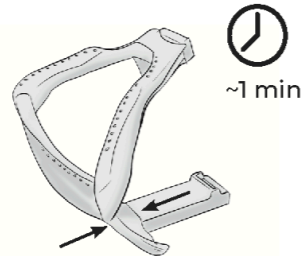
**9.** Leave to dry while continuing with the next steps.  
 ~15 min

! Ensure the bladder's fistula hole remains **around** the vaginal fistula hole.

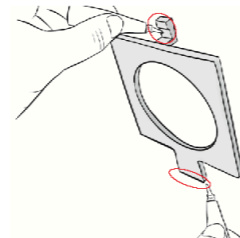
## II. Assemble Framework



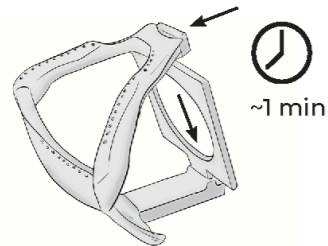
**10.**  
Apply **superglue** to the dorsal frame on the indicated area.



**11.**  
Press the pelvic bone against the dorsal frame and apply pressure for approx. 1 min.



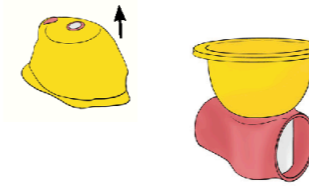
**12.**  
Apply **superglue** on the bladder support frame to the indicated areas in the illustration.



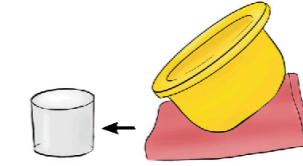
**13.**  
Place the bladder support frame into the dorsal frame and the pelvic bone and apply pressure for approx. 1 min.

3

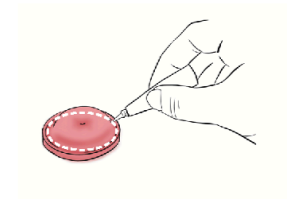
## III. Assemble Cervix to Vagina



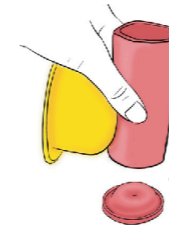
**14.**  
Invert the bladder again.



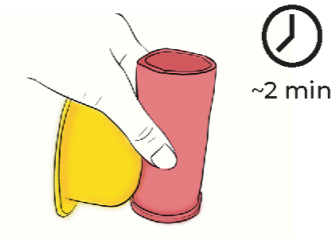
**15.**  
Remove the glue support from the vagina.



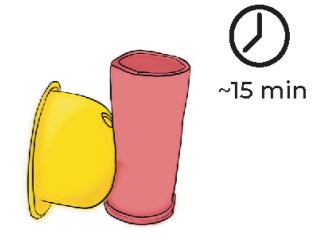
**16.**  
Apply **silicone glue** to the inside of the edge of the cervix.



**17.**  
Place the cervix onto the **short side** of the vagina.



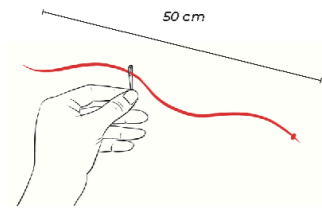
**18.**  
Apply pressure for approximately 2 min.



**19.**  
Leave to dry while continuing with the next steps.

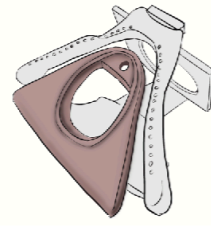
4

## IV. Assemble Vulva to Framework

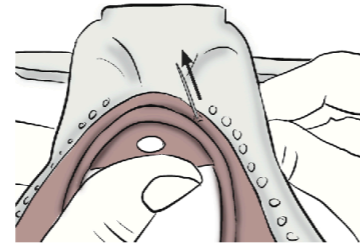


**20.** Cut approximately 50 cm of thread, pass it through the needle, and tie a knot.

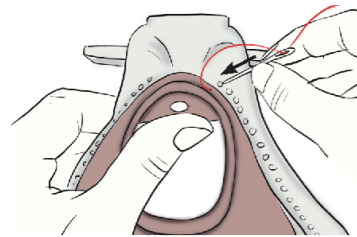
**i** For **help** tying a knot, scan the QR code at the bottom of the page.



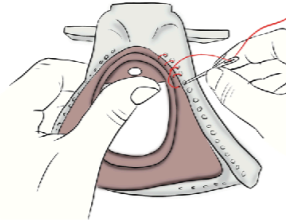
**21.** Get the vulva and the assembled framework.



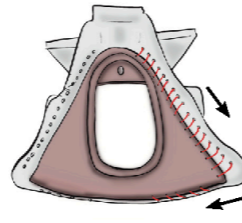
**22.** Insert the needle through the **back** of the vulva.



**23.** Insert the needle through the pre-made hole.

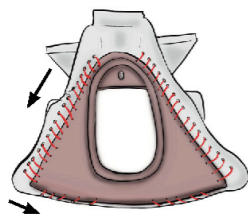


**24.** Continue stitching the vulva to the framework on the right side.



**25.** Once the right side is fully stitched, secure the thread at the back with a knot.

**i** Ensure each stitch is **pulled tight** and not left loose.



**26.** Repeat the same steps for the left side.

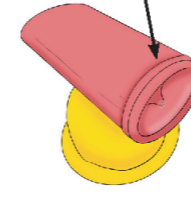
**i** Ensure each stitch is **pulled tight** and not left loose.

How to tie a knot in thread:

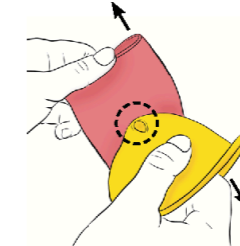


5

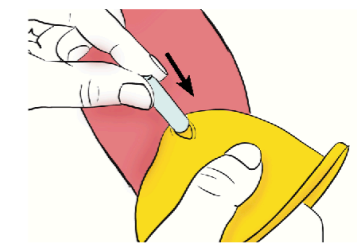
## V. Assemble urethra



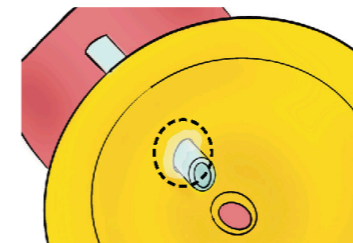
**27.** Check if the cervix is fully attached **all around**.  
If not, apply additional glue to any loose areas.



**28.** If the bladder and vagina are slightly glued together at the urethra hole, gently separate them by pulling to reopen the hole.

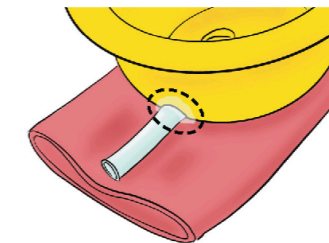


**29.** Insert the urethra through the urethra hole.  
**i** Ensure the urethra does not cover the fistula hole.

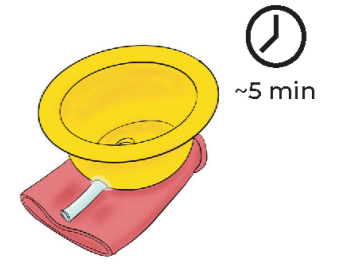


**30.** Apply **superglue** around the edge where the urethra meets the hole.

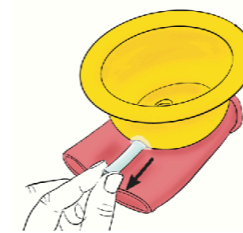
**i** Ensure it is **fully sealed** all around to make it watertight.



**31.** Apply **superglue** around the urethra on the outside of the bladder to fully seal it.



**32.** Leave it to dry for approximately 5 min.



**33.** Gently pull the urethra to check if it is securely attached.

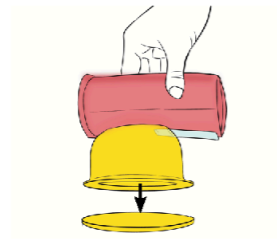
If not, apply an additional layer of superglue to the inside and outside.

6

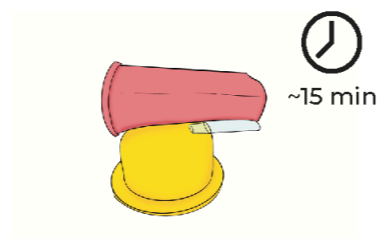
## VI. Assemble Bladder Top to Bladder Cup



**34.** Apply **silicone glue** to the circular edge of the bladder cup.



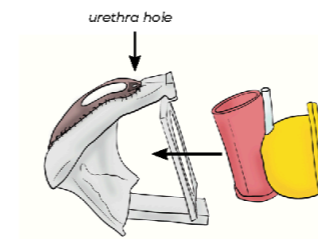
**35.** Place the vagina and bladder cup onto the bladder top.



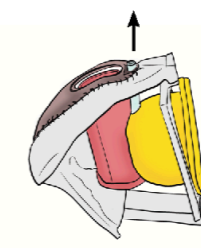
**36.** Leave to dry for approximately 15 min while continuing with the next steps.

7

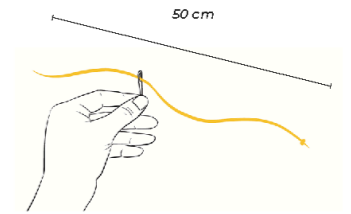
## VII. Assemble Vagina to Vulva



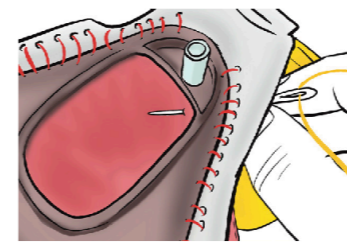
**37.** Place the assembled bladder, vagina, and cervix into the framework.



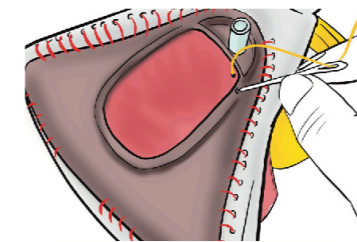
**38.** Put the urethra through urethra hole



**39.** Cut approximately 50 cm of thread, pass it through the needle, and tie a knot.

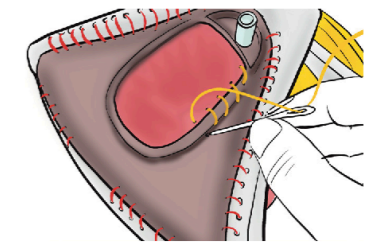


**40.** Insert the needle through the outside of the vagina.



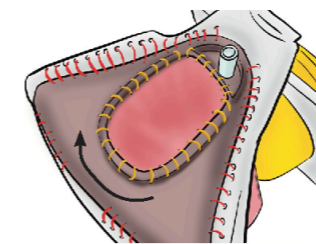
**41.** Then insert it through the vulva.

! Ensure each stitch is **pulled tight** and not left loose.



**42.** Stitch the vagina onto the vulva all the way around.

! Ensure that **no visible gaps** are present after stitching the vagina to the vulva.



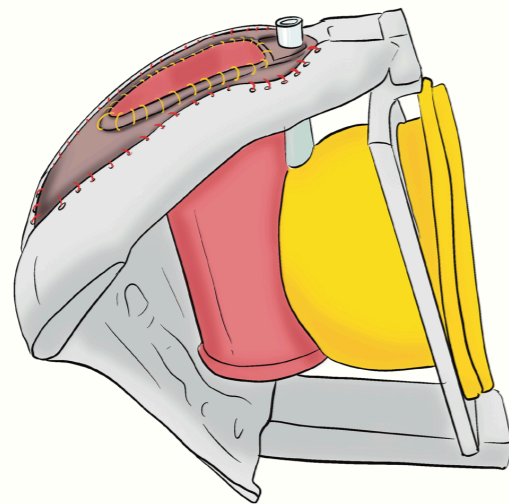
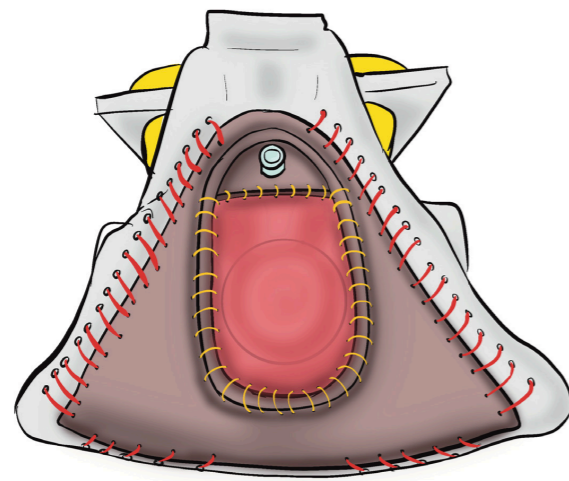
**43.** When the vagina is fully stitched, secure the thread at the back with a knot.

8

# Congratulations!

You have **successfully** assembled the clinical task trainer.

It is now **ready for use** by a trainee.



## F.2 Evaluation

The same test plan is used for testing assembly instructions 1.0. The test involves two participants, aged between 25 and 28 years, with no background or experience in design or assembly of the clinical task trainer.

### Results Product Quality

Section	P4	P5
I. Assemble framework	-	-
II. Bladder cup to vagina	1	1
III. Cervix to vagina	5	5
IV. Urethra into bladder hole	5	5
V. Bladder top to cup	5	5
VI. Vulva to framework	5	5
VII. Vagina to vulva	5	5
Means (product score)	4.3	4,3
Confidence score	4	4
Usable task trainer	No	No

### Results Process Quality

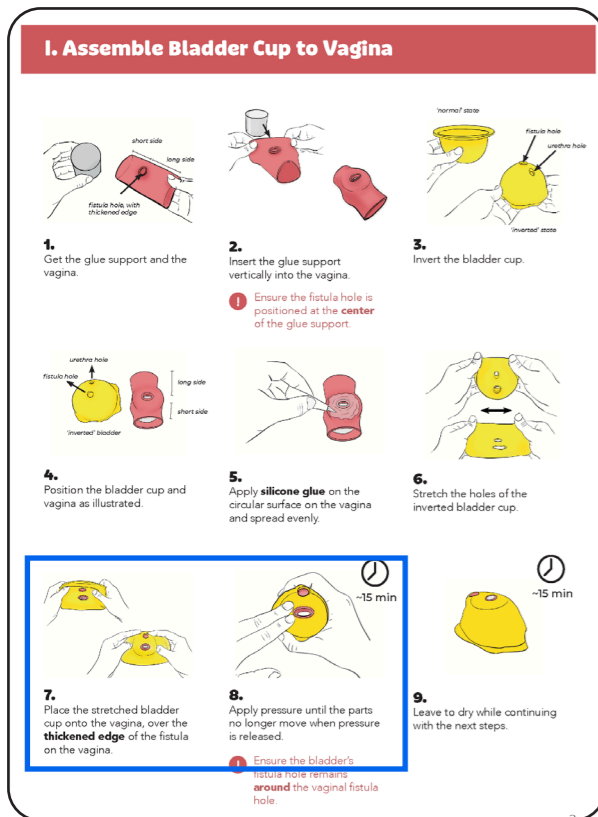
The visualization of the results is less detailed than that of Assembly Instructions 1.0 and only includes the most important observations, quotes, and issues. The blue boxes indicate the steps in which issues occurred.

#### General observations

In general, Participant 1 carefully read the front page, including the required materials and warning information. She checked whether all necessary items were available before starting the process. The results are presented per section below.

Participant 2, in contrast, barely read the textual instructions throughout the test and relied primarily on the illustrations.

Participant 1 mentioned that the warning texts were particularly helpful during the fabrication process.

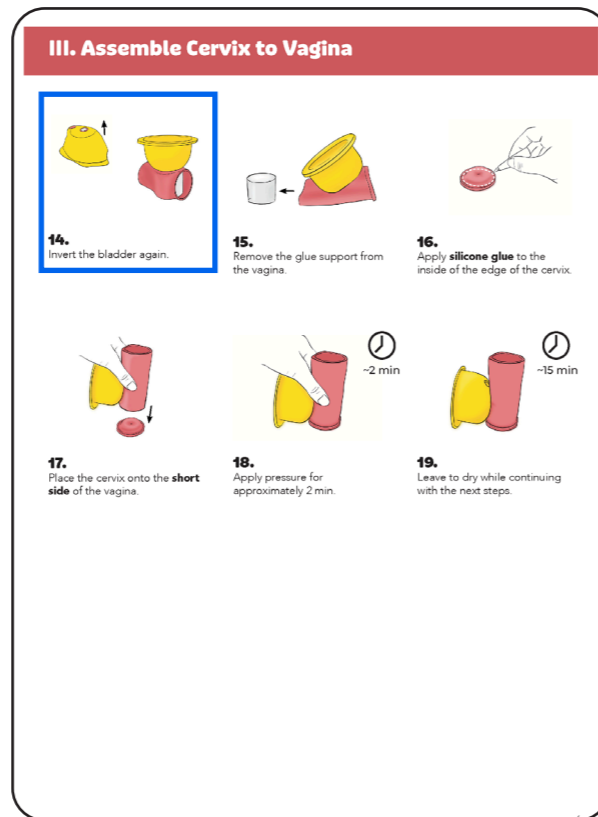


### Insights

In Section 1, Both participants mentioned that adding terms such as “short side” and “long side” was helpful for understanding the orientation of the components. Similar feedback was given for Step 3.

Participant 1 performed the assembly steps as intended until Step 7, where an issue occurred without her noticing it. In this step, the urethra opening needed to be positioned parallel to the long side of the vagina.

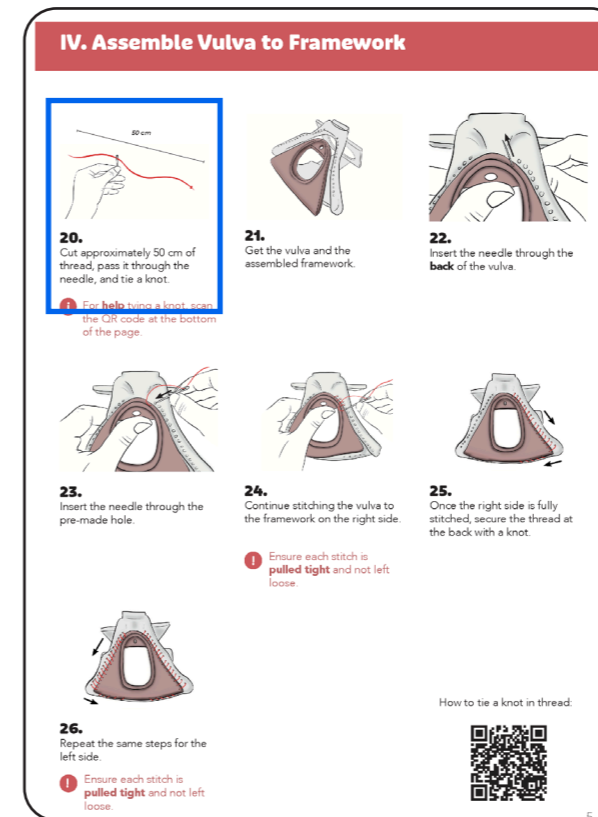
Step 7, This step proved to be critical, as both participants assembled the bladder cup onto the vagina in the wrong orientation. Participant 1 stated: “I don’t think it matters where the urethra hole should be placed, the focus is mainly on the fistula hole and the thickened edge,” indicating that the functional importance of this orientation was not fully understood. Both participants understood that the fistula opening needed to remain positioned around the thickened edge and continuously applied pressure to keep the parts aligned correctly. However, the glue required a long curing time, causing both participants to lose patience at a certain moment, release the pressure too early, and continue with the next assembly step.



### Insights

When inverting the bladder assembly, it became visible that the urethra opening was incorrectly positioned for both participants. In addition, the bladder cup was not evenly attached to the vagina, as the required 2 cm distance around the fistula opening was not maintained consistently.

The assembly of the cervix was completed easily by both participants. Removing the glue support before attaching the cervix positively improved the assembly process.



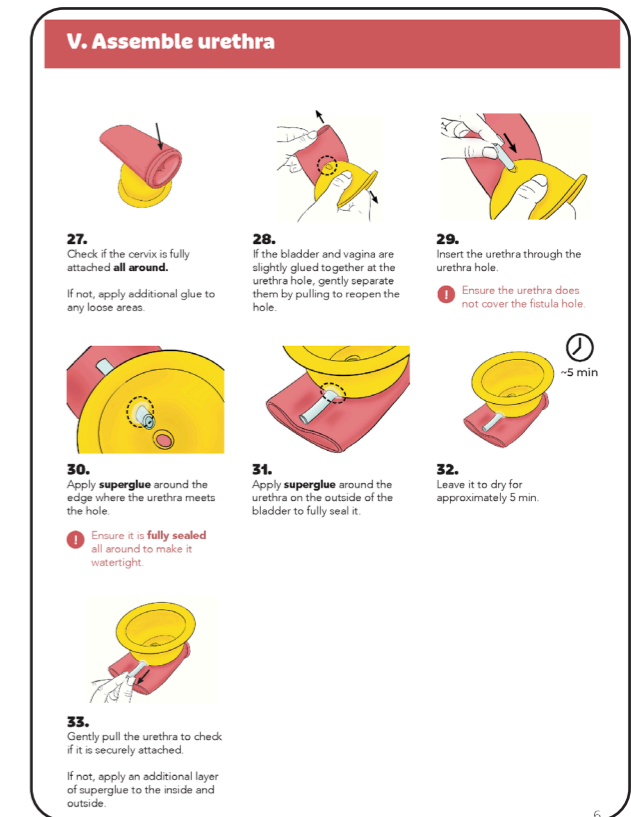
### Insights

The amount of thread suggested in the instructions was considered too short by both participants. Both participants preferred to sew using one continuous piece of thread rather than multiple shorter sections, as repeatedly creating knots and rethreading the needle was experienced as inconvenient and time-consuming.

Participant 1 and Participant 2 both indicated that the instructional video was not particularly helpful. Instead, both participants developed their own sewing technique during the process, which became more effective over time.

Both participants were ultimately able to complete the sewing successfully. Participant 1 had some prior sewing experience, while Participant 2 did not. Although neither participant described the process as frustrating, both mentioned that the sewing process was highly time-intensive and required precise manual work.

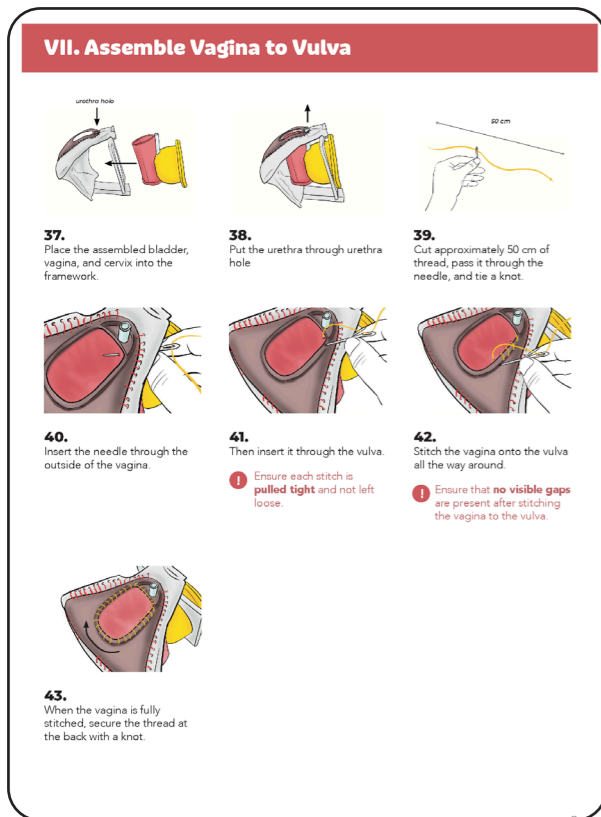
On average, this assembly step required approximately 40–50 minutes per participant



### Insights

This assembly step was completed easily by both participants. Both participants successfully achieved a watertight connection.

Afterwards, the researcher performed an additional watertightness test to verify the quality of the connection.

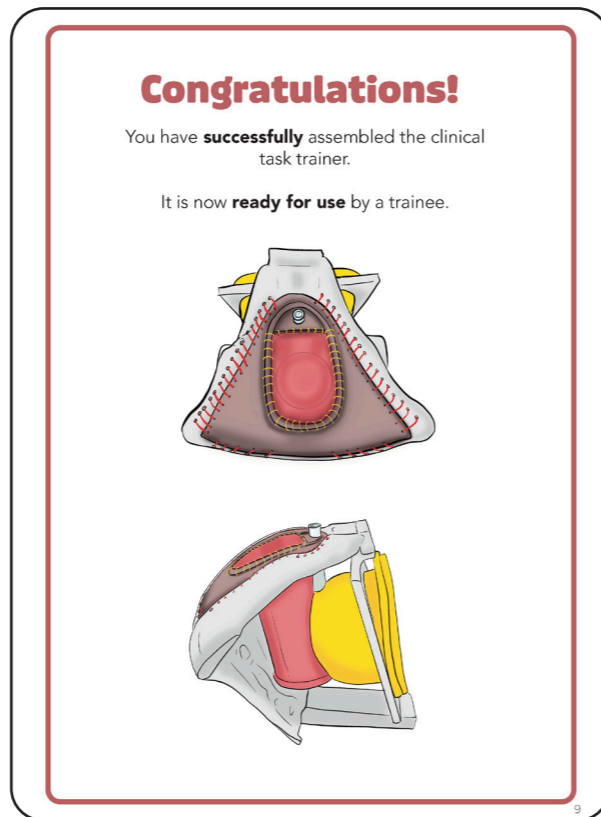


**Insights**

While placing the assembly into the framework, both participants discovered that the orientation of the urethra was incorrect.

In addition, Participant 1 noticed that the glue connection was starting to detach, causing the fistula connection to become unstable.

During the sewing process, both participants showed signs of losing patience. However, both participants ultimately succeeded in attaching the components correctly.



**Insights**

Both participants expressed satisfaction after completing the assembly process and rated their own performance with a score of 4 out of 5.

However, it was observed that neither participant fully understood the impact that the incorrect assembly had on the surgical procedure for which the task trainer is intended.

# Appendix G – Final Instructions

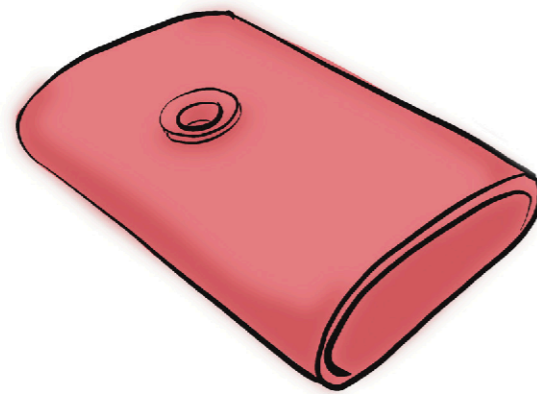
This Appendix presents the full-size final instructions for Silicone Casting.

## G.1 Silicone Casting Instructions 4.0

This sections provides the final design of the silicone casting instructions for the vagina part. In addition, the designed reference sheets for the vulva, bladder cup, bladder plate and cervix component.

# Silicone Casting Instructions


Produce the **vagina** silicone component



 You will be working with silicones; ensure production is performed in a **well-ventilated** area.

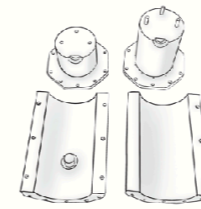
## Production Stages (30-60 min)

- I. Prepare the mould
- II. Make the mixture
- III. Fill the syringe
- IV. Remove air bubbles from the mixture
- V. Fill the mould

 Curing time = 8 hours

- VI. Release silicone from mould
- VII. Final Check

## Items you'll need



3D printed vagina moulds



Syringe 50mL catheter tip



14x bolts and nuts size M3x20 mm



Piece of sulfate free clay (1cm x 1cm)



Silicone part A and B (Dragon Skin 10)



Release agent spray



Silicone oil



Mauve liquid colour pigment



Scale



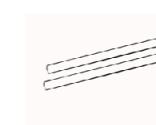
Wrench size 5.5



Flat screwdriver



Plastic or paper cup



Stirring rods



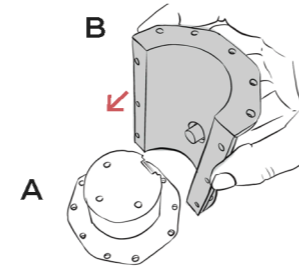
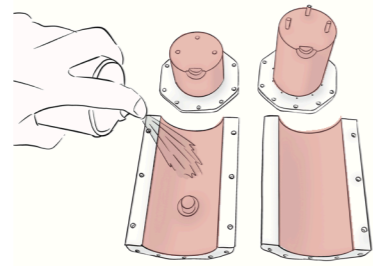
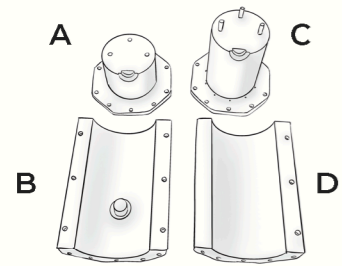
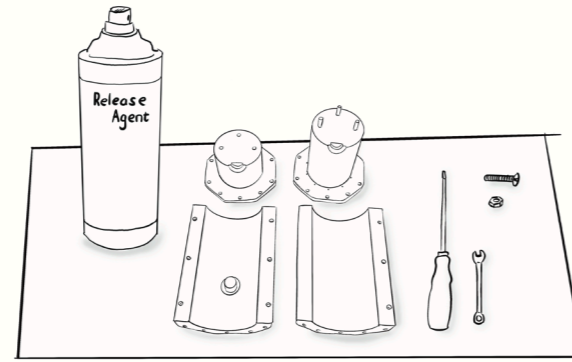
Gloves

Paper towels

# I. Prepare the mould

## Items you'll need

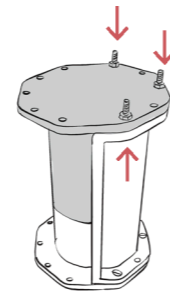
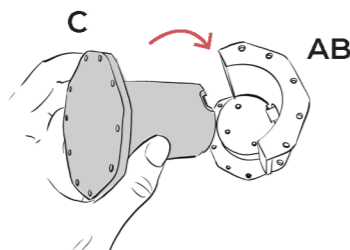
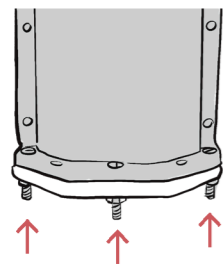
- 3d printed parts for vagina
- release agent spray
- 14 bolts and nuts size M3x20mm
- spanner size 5,5
- flat screwdriver



**1.** Take the **four** 3D printed moulds for the vagina

**2.** Apply **2-3 sprays** of release agent to each highlighted component area.

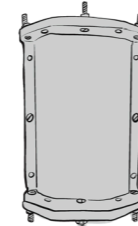
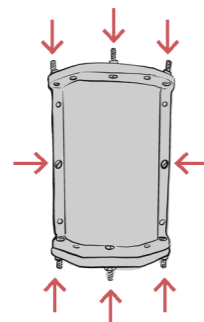
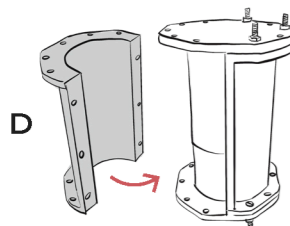
**3.** Place **part B** onto **part A**.



**4.** Connect part A to part B using **3 bolts and nuts** using spanner and screwdriver

**5.** Take **part C** and place onto **AB**.

**6.** Connect **part C** to **AB** with **3 bolts and nuts**.



**7.** Place **part D** onto ABC.

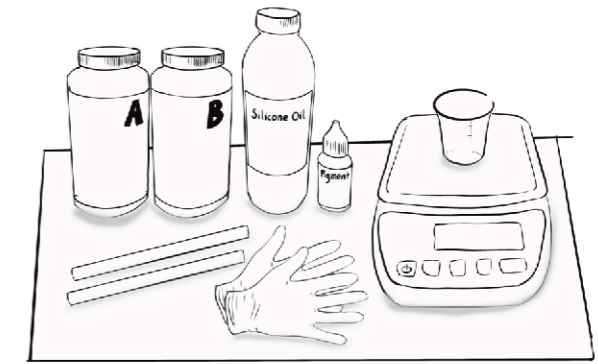
**8.** Connect with **8 bolts and nuts**.

**9.** **Tighten** all bolts and nuts with a spanner and/or screwdriver.

# II. Make the mixture

## Items you'll need

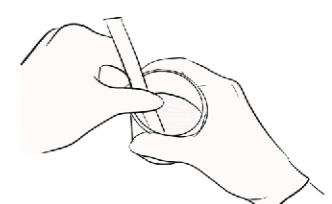
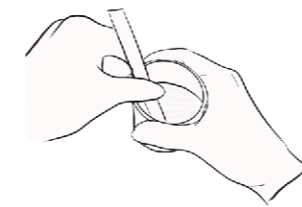
- Dragon Skin 10 A + B
- Colour pigment 'Mauve'
- Silicone oil
- Towels
- Cup
- Gloves
- Scale
- Stirring rods



**10.** Put on the **gloves**.

**11.** Pour **30 g** of part **A** in the cup.

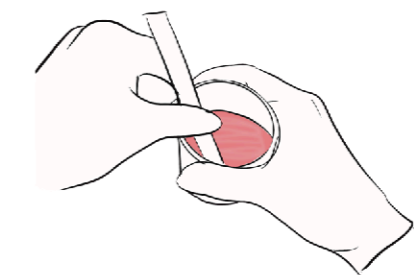
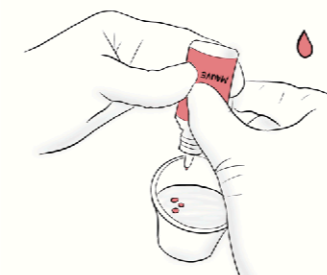
**12.** Pour **30 g** of part **B** in the cup. Ratio A:B 1:1.



**13.** Stir the mixture for approx. **30 seconds**.

**14.** Add **5.5 g** of **silicone oil** into the mixture.

**15.** Stir the mixture for approx. **30 seconds**.



**16.** Add **6 drops** of mauve color pigment into the mixture.

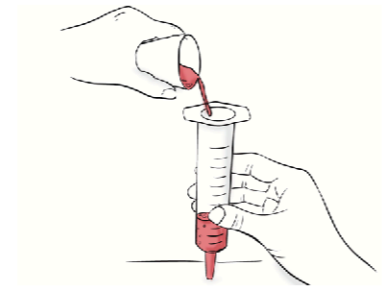
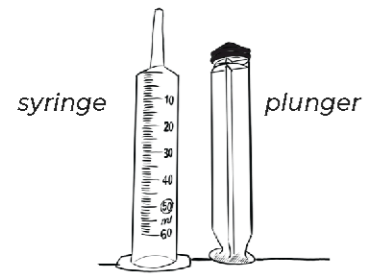
**17.** Stir the mixture until the color is **evenly distributed**.

**18.** You now have approx. **20 min** to complete the following steps before the silicone becomes too thick to pour.

### III. Fill the syringe

#### Items you'll need

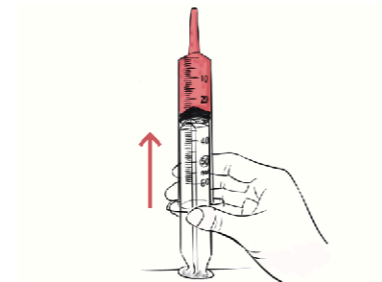
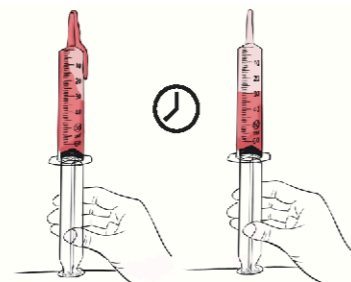
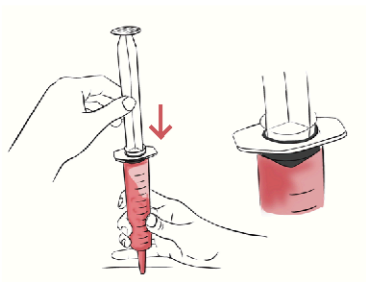
- 50mL syringe with catheter tip.
- Mixture



**19.** Grab the syringe and **remove** the plunger from the syringe.

**20.** Place the syringe with the **tip on the table**, this closes the tip during filling.

**21.** Slowly **pour all** of the mixture in the syringe.



**22.** Put the plunger into the syringe, make sure to only **put the tip in**.

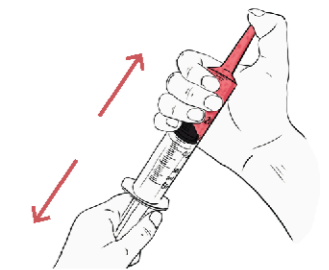
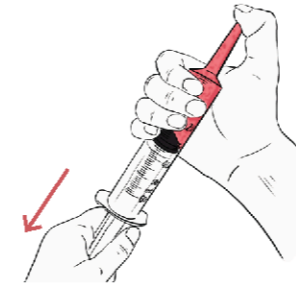
**23.** Turn the syringe around and **wait for the mixture to settle**.

**24.** Push the plunger further until all **air is removed**.

### IV. Remove air bubbles

#### Items you'll need

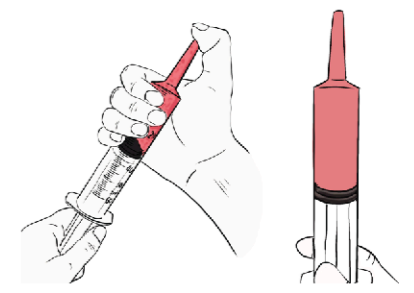
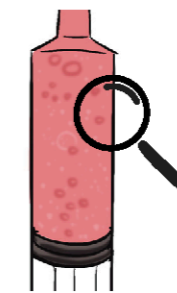
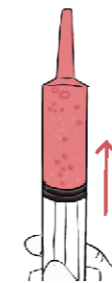
- Filled syringe



**25.** **Close the tip** of the syringe with your thumb or finger and use the other hand to **pull the plunger**.

**26.** Push the plunger back with the **tip closed**.

**27.** Repeat this pumping motion **15 times**.

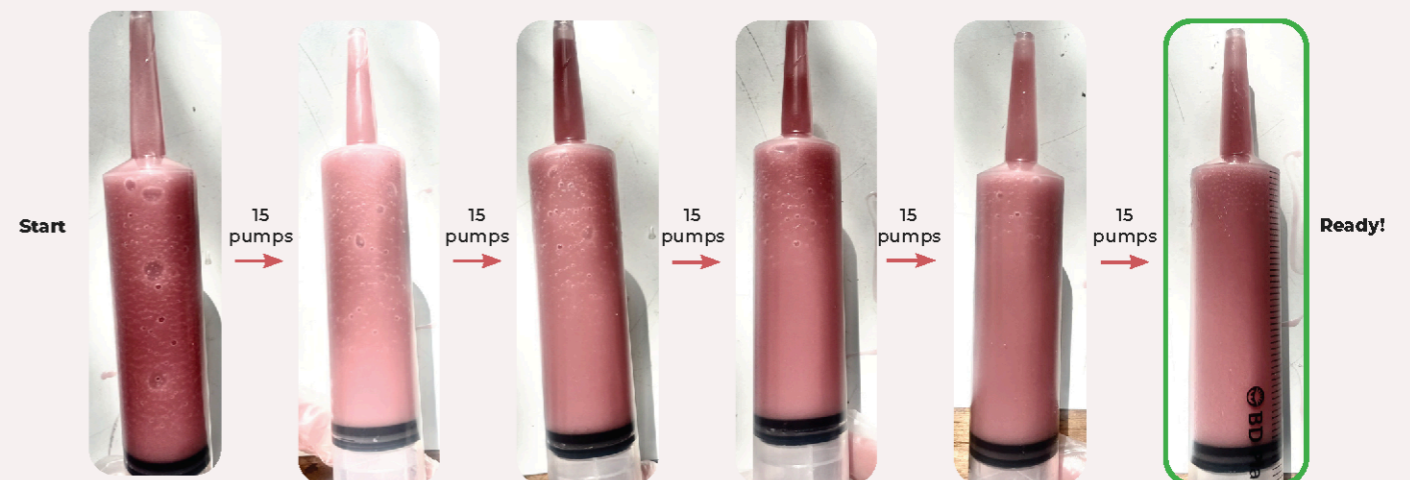


**28.** **Release** the air that moved upwards.

**29.** **Observe** the airbubbles in the syringe. When there are still bubbles larger than **1mm**, continue with 15 pumps.

**30.** **Repeat** pumping motions and **observations** until most bubbles larger than 3 mm are gone.

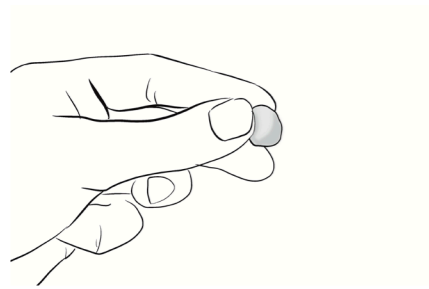
#### Example for observing:



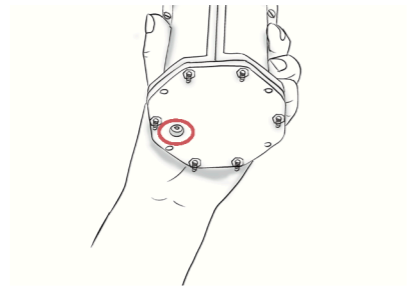
## V. Fill the mould

### Items you'll need

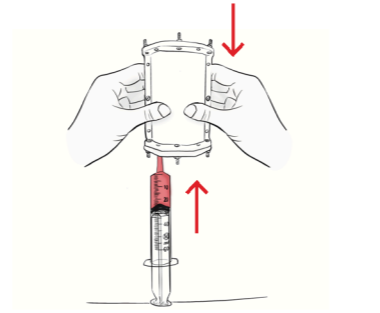
- Filled syringe
- Prepared mould
- Piece of sulfat free clay (1cm x 1cm)



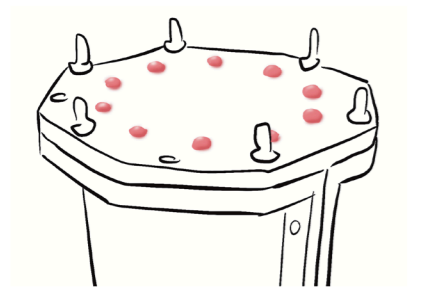
**31.** Prepare a small piece of clay by rolling into a small ball to seal the injection hole later.



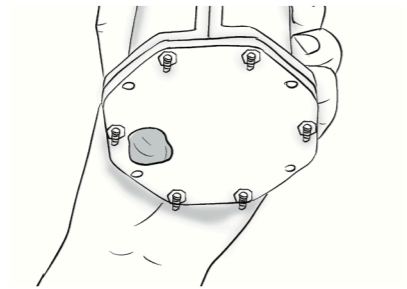
**32.** Place the syringe vertically into the mould's injection hole.



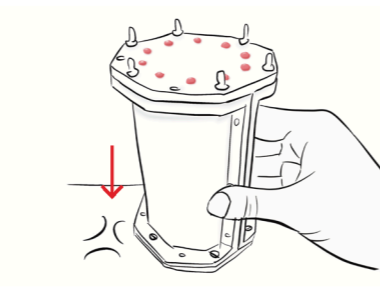
**33.** Push the mixture slowly into the mould. This takes about 5 minutes.



**34.** Continue until you see the mixture coming out of the air vents at the top. This indicates that the mold is full.



**35.** Seal the injection hole with the piece of clay.



**36.** Tap the bottom of the mold on the table a few times so any remaining air can escape through the air vents.

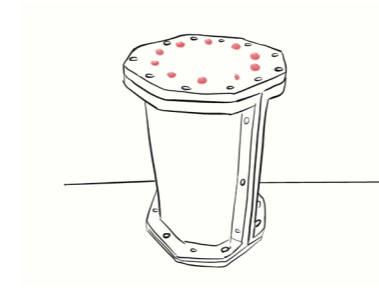


**37.** Let the silicone cure for at least 8 hours, with the mold upright and vent holes on top.

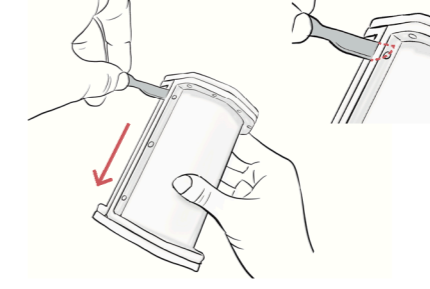
## VI. Release silicone from mould

### Items you'll need

- Filled mould
- Steeksleutel size 5,5
- Platte schroevendraaier
- Knife

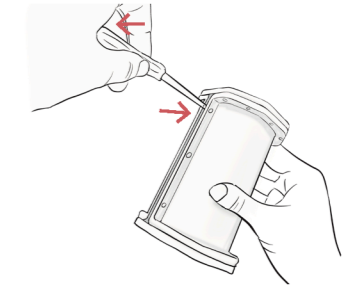


**38.** Loosen the bolts and nuts using a wrench and a flathead screwdriver.

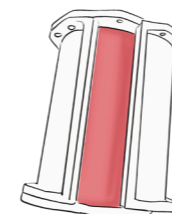


**39.** Cut along the edges of the molds to loosen them slightly.

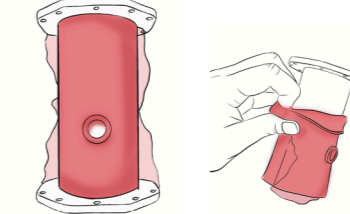
Do not cut too deep, or you may cut into the silicone.



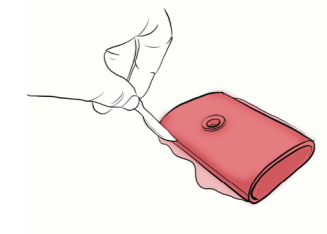
**40.** Use a flathead screwdriver to insert between the molds and create leverage.



**41.** Once the outer parts are loose, remove the outer sections.



**42.** Peel the silicone off the other parts.



**43.** Trim off any remaining edges with a knife.

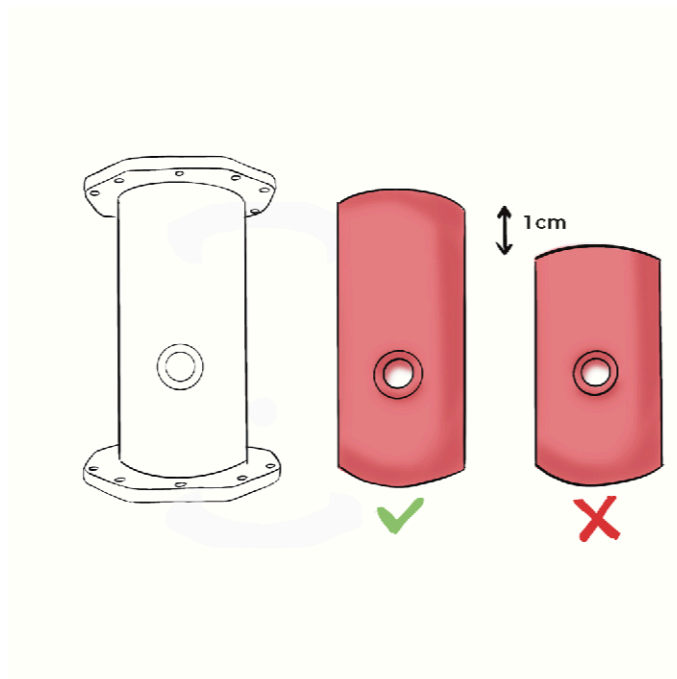


**42.** The silicone vagina is finished! Now do the final check!

## VII. Final Check

### Check the **height** of the part

- Compare the silicone level with the reference mould to check whether the part reached the correct final height.
- A maximum height difference of 1 cm is acceptable.
- If the part is more than 1 cm too short, it is considered unusable and must be remade.



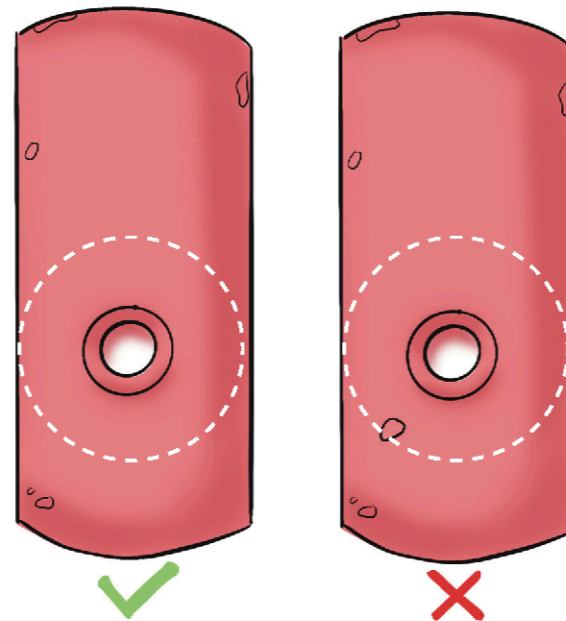
**Tip for next time:** Use 1.5× the recommended amount of silicone mixture next time to prevent underfilling.

## G.2 Quick Reference Sheets

This section provides the final design of the silicone casting instructions for the vagina part. In addition, the designed reference sheets for the vulva, bladder cup, bladder plate and cervix component.

### Check for **large** air bubbles

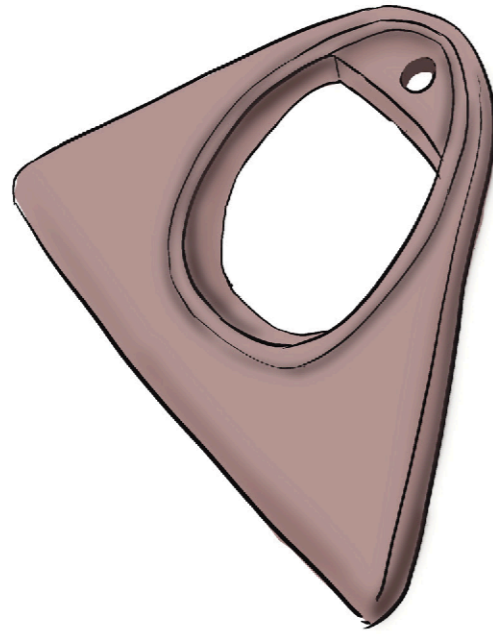
- Small air bubbles (small dots) are acceptable.
- Check whether there are any air bubbles larger than **0.5 cm** within a 2 cm radius around the hole.
- If large air bubbles are present in this area, the part is considered unusable.



**Tip for next time:** Release the trapped air bubbles for a longer time and gently tap the filled syringe against the table as well as the filled mould to help remaining air bubbles escape.

# Silicone Casting Instructions

Produce the **vulva** silicone component



**!** You will be working with silicones; ensure production is performed in a **well-ventilated** area.

## Production Stages (30-60 min)

- I. Prepare the mould
- II. Make the mixture
- III. Fill the syringe
- IV. Remove air bubbles from the mixture
- V. Fill the mould

 Curing time = 8 hours

- VI. Release silicone from mould

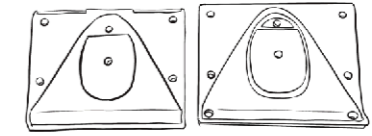
I.

## Prepare the mould

5x



Bolts and nuts size M6x40 mm



Vulva 3D printed parts

II.

25 g



Dragon Skin 10

6x



Brown liquid colour pigment

III.

## Fill the syringe



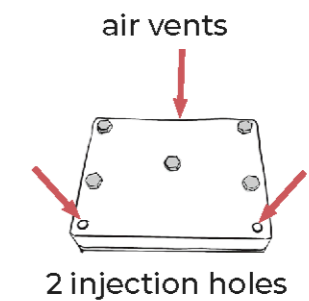
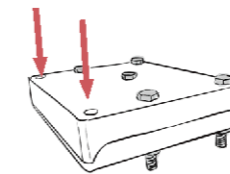
Syringe 50mL catheter tip

IV.

## Remove air bubbles

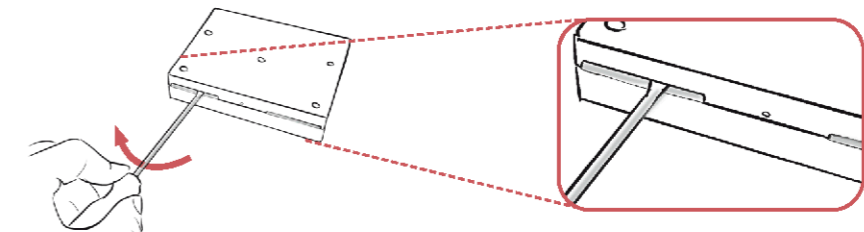
V.

## Fill the mould



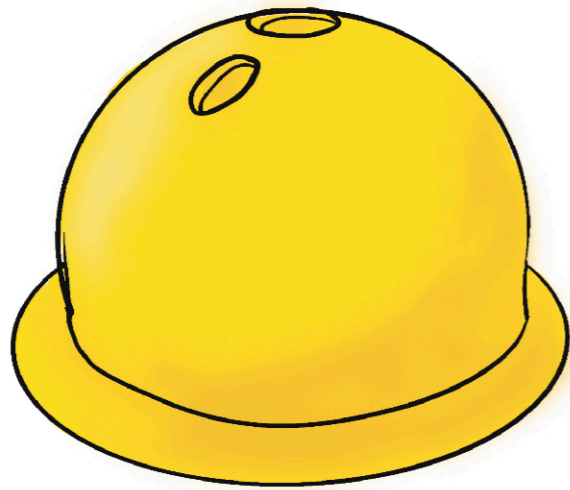
VI.

## Release silicone from mould



# Silicone Casting Instructions

Produce the **bladder cup** silicone component



! You will be working with silicones; ensure production is performed in a **well-ventilated** area.

## Production Stages (30-60 min)

- I. Prepare the mould
- II. Make the mixture
- III. Fill the syringe
- IV. Remove air bubbles from the mixture
- V. Fill the mould

🕒 Curing time = 8 hours

- VI. Release silicone from mould

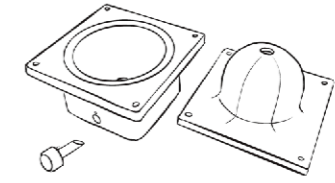
I.

## Prepare the mould

4x



Bolts and nuts size M4x40 mm



Bladder cup and cover pin  
3D printed parts

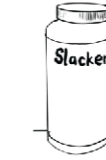
II.

25 g



Dragon Skin 10

17 g



Slacker

6x



Yellow liquid colour pigment

III.

## Fill the syringe



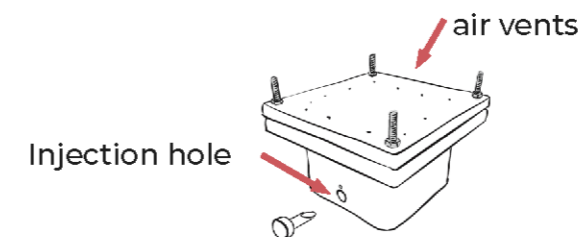
Syringe 50mL  
catheter tip

IV.

## Remove air bubbles

V.

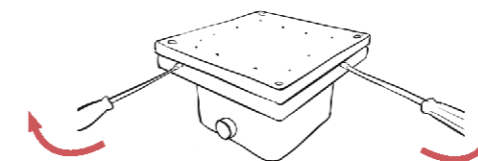
## Fill the mould



Two syringe fills  
required

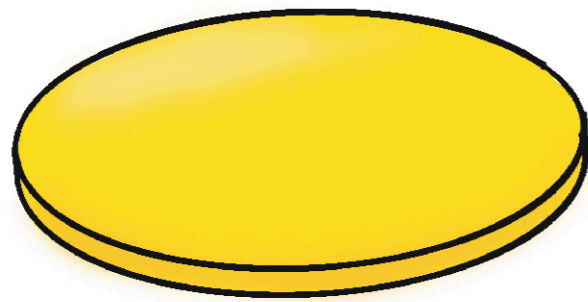
VI.

## Release silicone from mould



# Silicone Casting Instructions


Produce the **bladder plate** silicone component



**!** You will be working with silicones; ensure production is performed in a **well-ventilated** area.

## Production Stages (30-60 min)

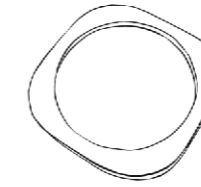
- I. Prepare the mould
- II. Make the mixture
- III. Fill the syringe
- IV. Remove air bubbles from the mixture
- V. Fill the mould

 Curing time = 8 hours

- VI. Release silicone from mould

I.

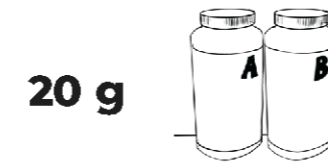
## Prepare the mould



Bladder plate 3D printed parts

II.

## Make the mixture



20 g

Dragon Skin 10



4x

Yellow liquid colour pigment

III.

## Fill the syringe

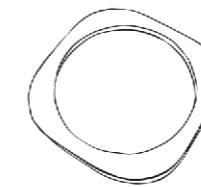
No syringe needed

IV.

## Remove air bubbles

V.

## Fill the mould



Pour mixture in

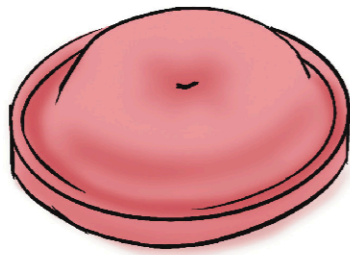
VI.

## Release silicone from mould

No tools needed

# Silicone Casting Instructions

Produce the **cervix** silicone component



! You will be working with silicones; ensure production is performed in a **well-ventilated** area.

## Production Stages (30-60 min)

- I. Prepare the mould
- II. Make the mixture
- III. Fill the syringe
- IV. Remove air bubbles from the mixture
- V. Fill the mould

🕒 Curing time = 8 hours

- VI. Release silicone from mould

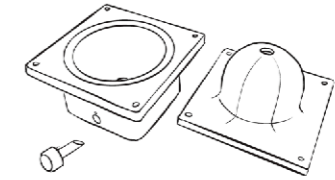
I.

## Prepare the mould

4x



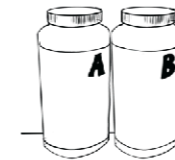
Bolts and nuts size M3x20 mm



Bladder cup and cover pin  
3D printed parts

II.

5.5 g



Dragon Skin 10

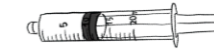
1x



Muave liquid  
colour pigment

III.

## Fill the syringe



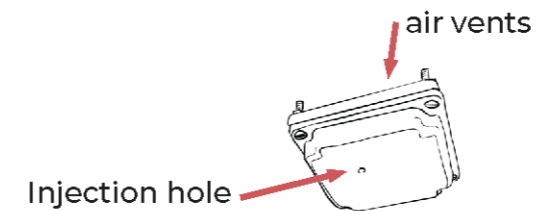
Syringe 20mL  
Luer tip

IV.

## Remove air bubbles

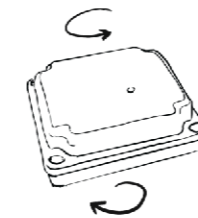
V.

## Fill the mould



VI.

## Release silicone from mould



# Appendix H – Website

This Appendix shows screenshots of the mock-up of the interactive website that was developed.

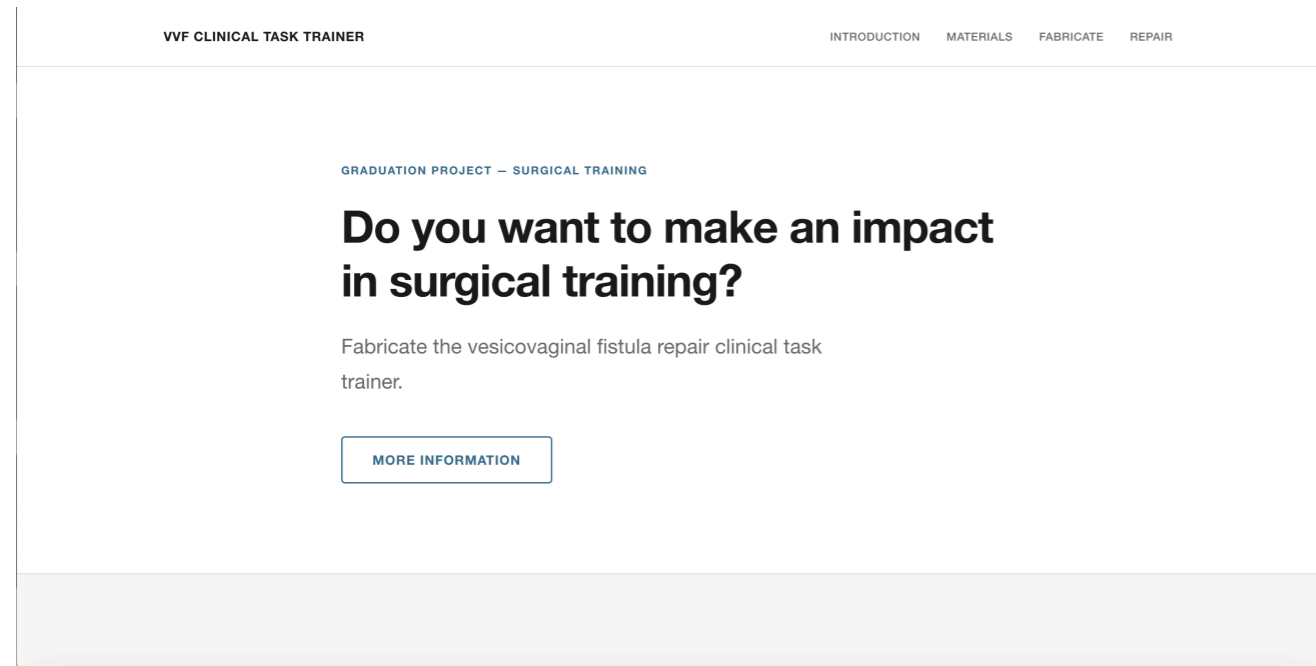


Figure H.1: Homescreen of website mockup

## Introduction tab

Figure H.1, H.2, H.3 and H.4 provide images of the information available under the introduction section.

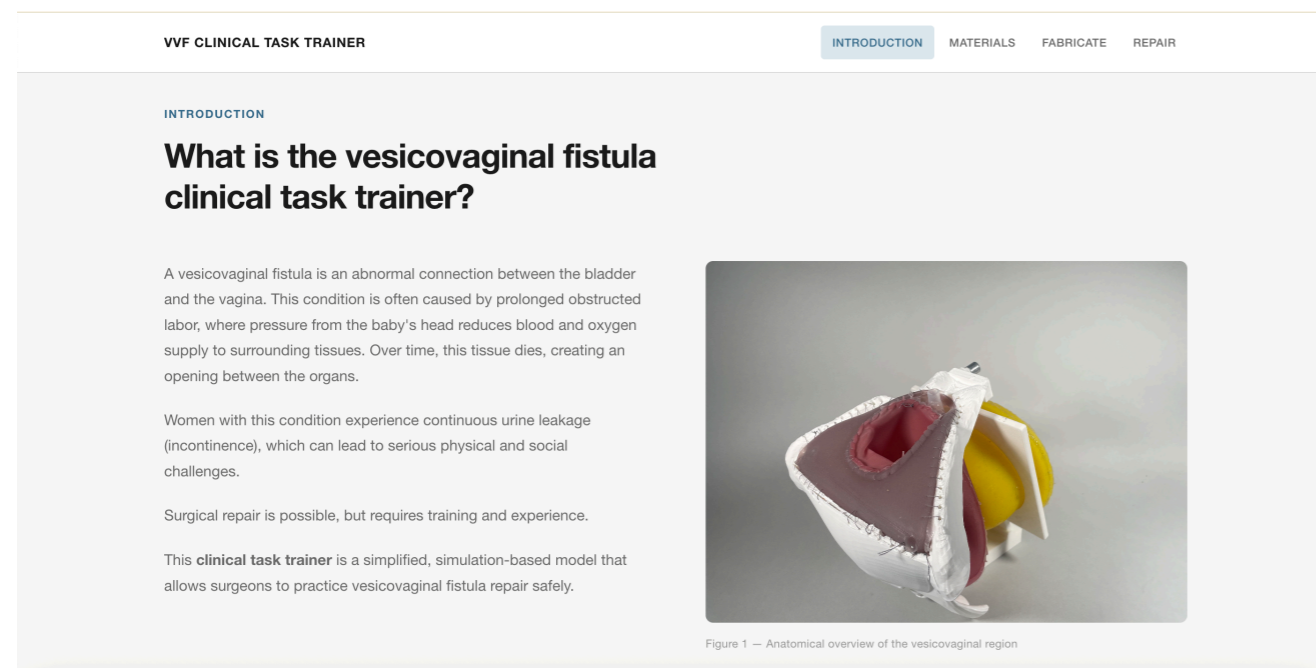


Figure H.2: Introduction about task trainer

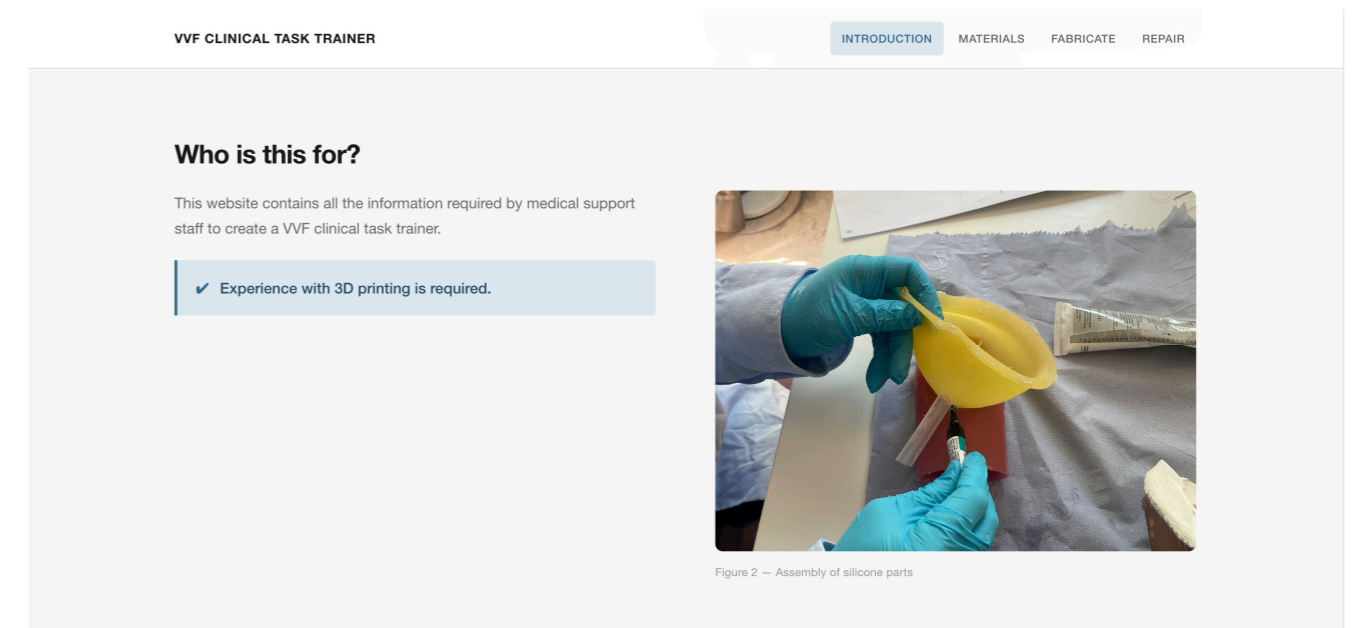


Figure H.3: Who is this for

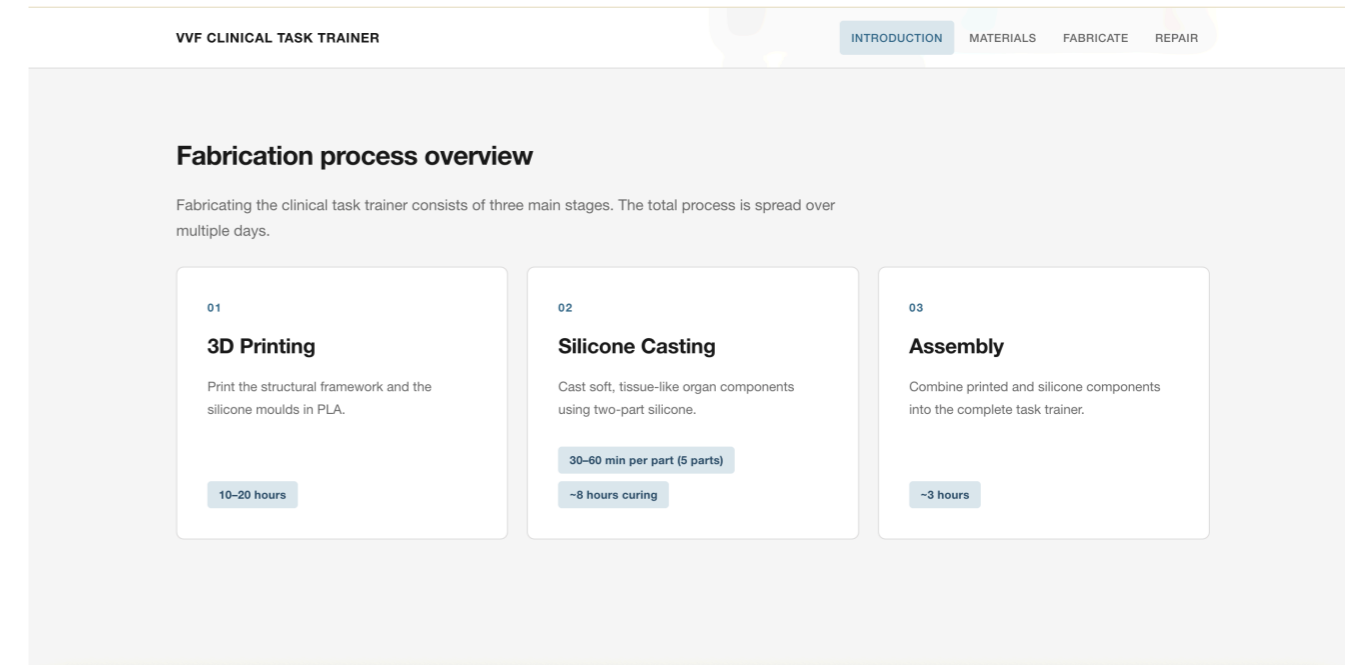


Figure H.3: Fabrication process overview including time indications

## Materials tab

Figure H.4 and H.5 provide images of the materials sourcing options. Option 1 provides links to material specifications, alternative materials and supplier links.

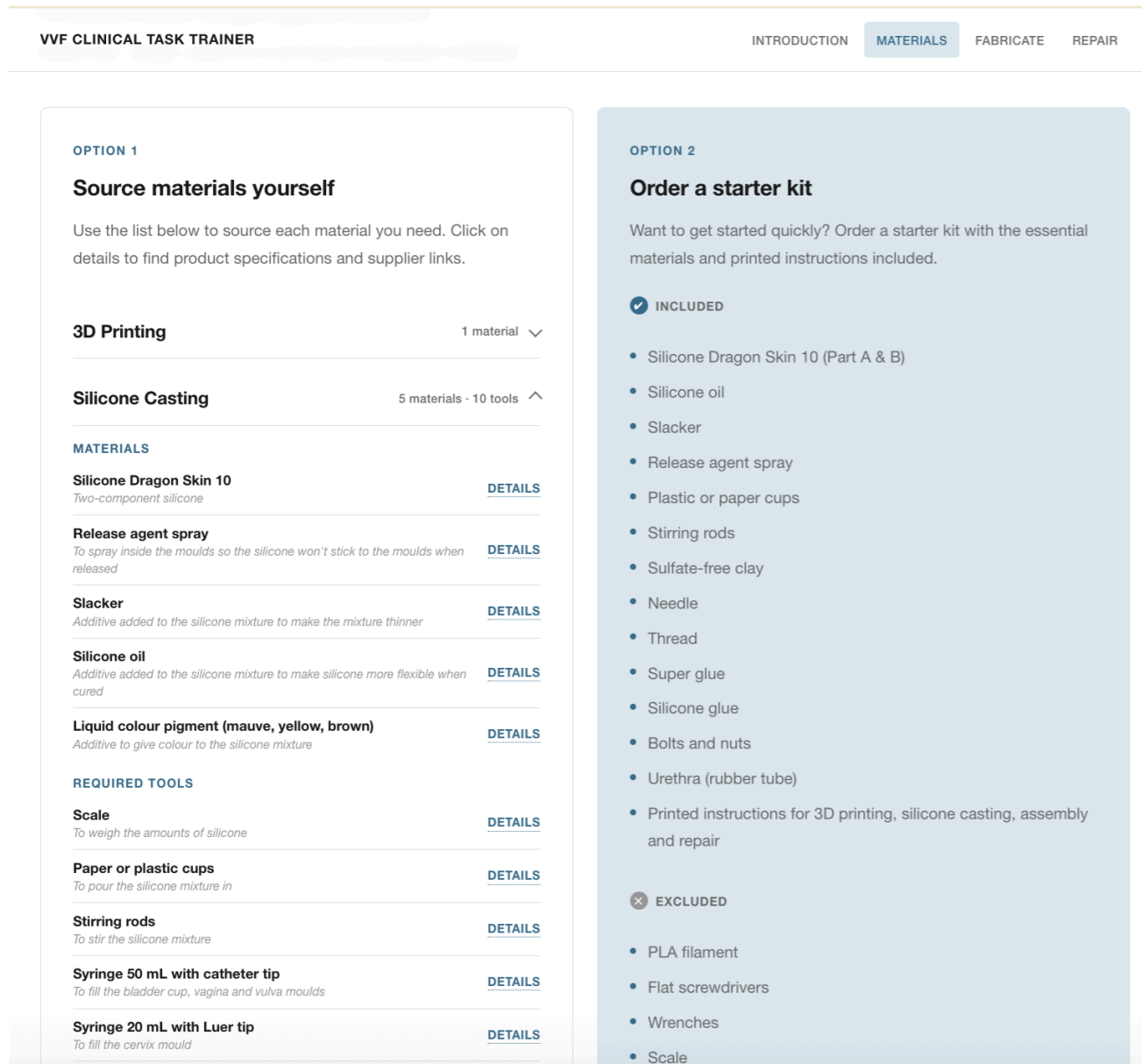


Figure H.4: Options to source correct materials. Left: self-sourcing. Right: order a starter kit.

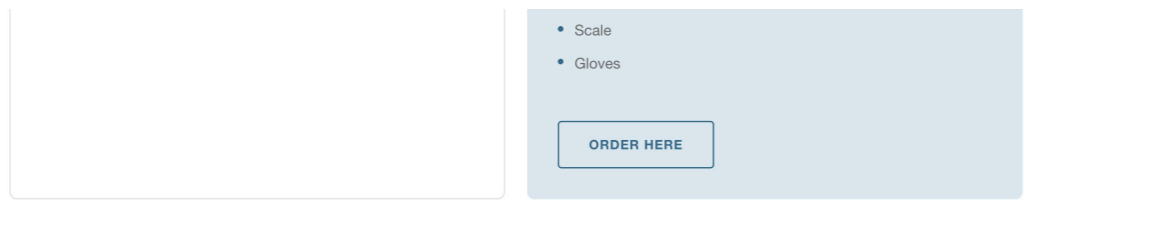


Figure H.5: Option to order the starter kit

## Fabricate tab

Figure H.6, H.7 H.8 and H.9 provide an images of how the fabrication process is guided. Including a short introducton, photo's and printable instructions.

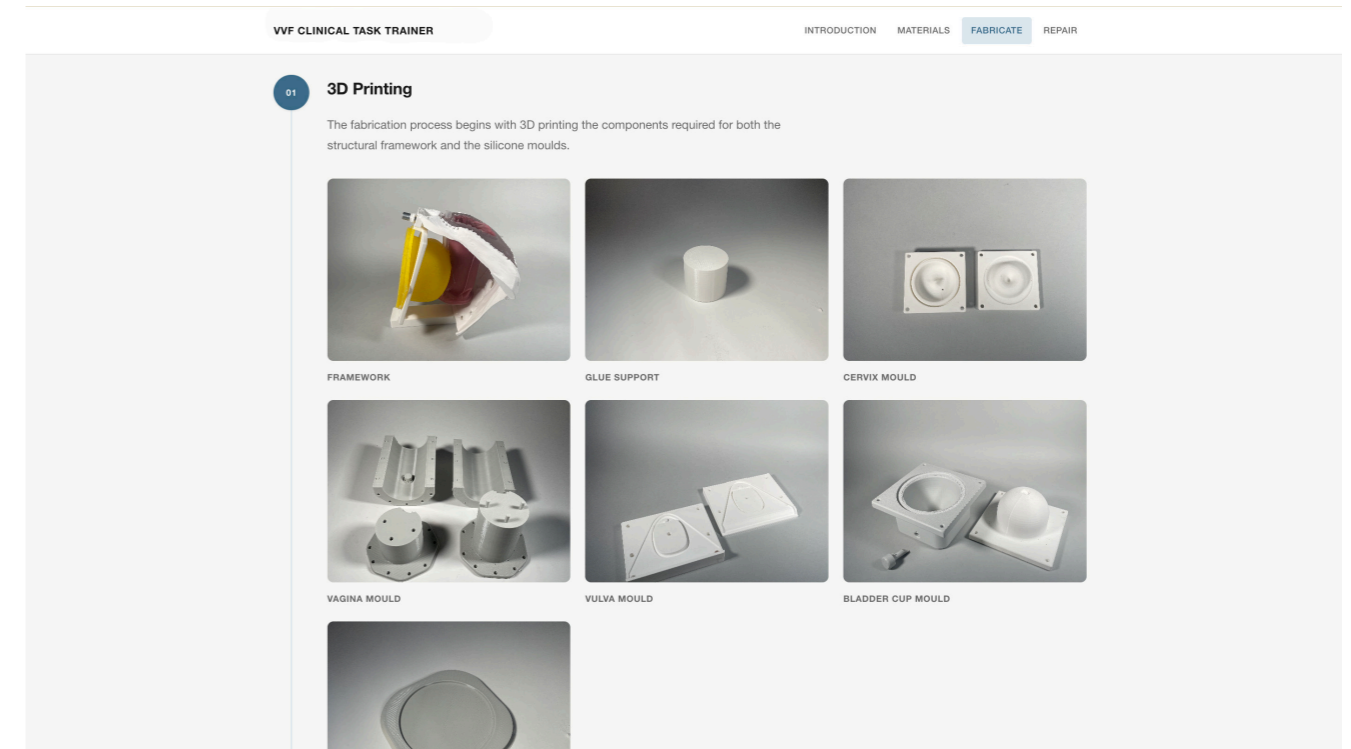


Figure H.6: Introduction of 3D printing and what parts will be printed.

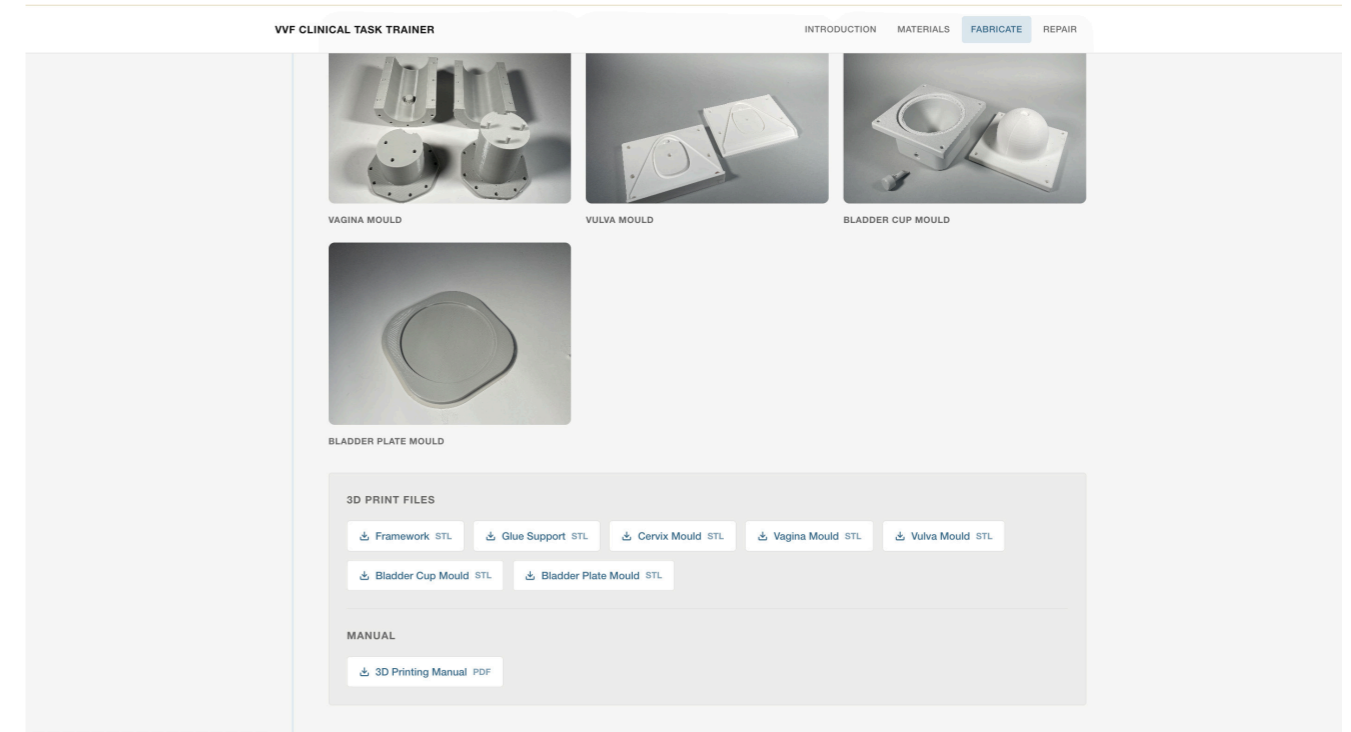


Figure H.7: Downloadable 3D print files and instructions.

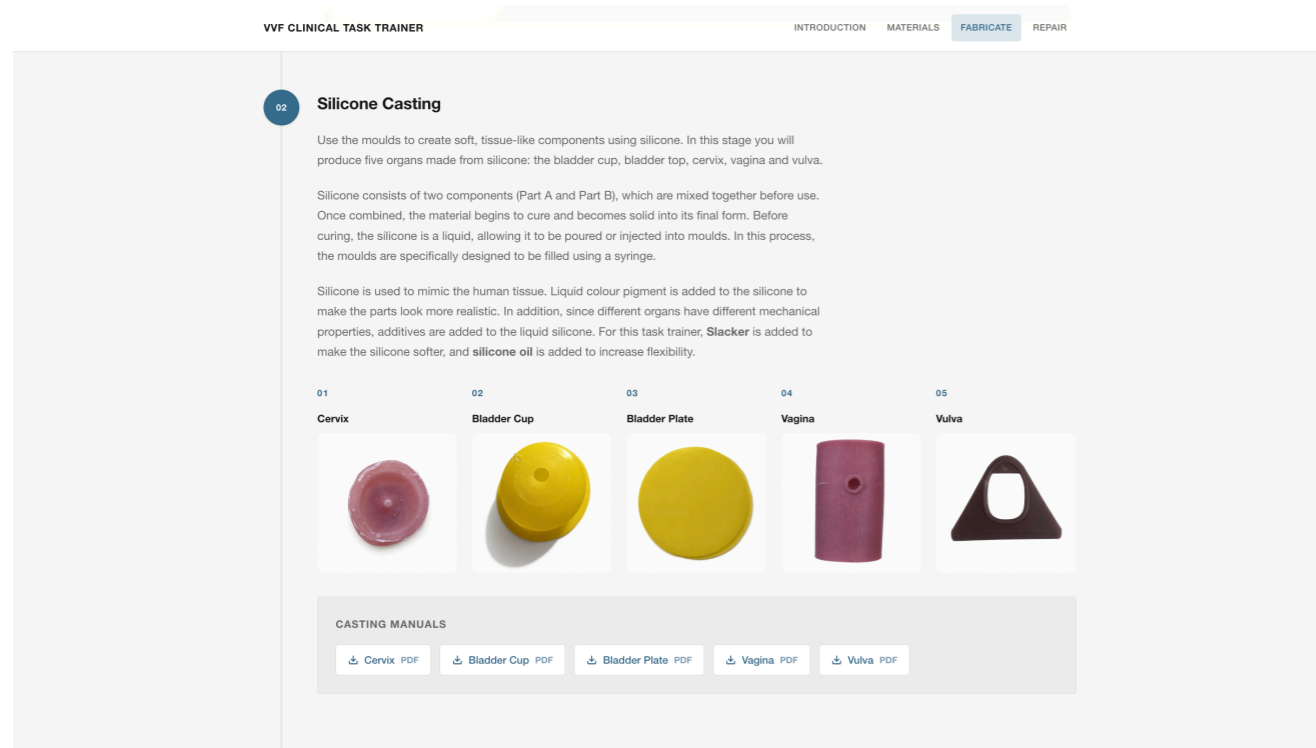


Figure H.7: Introduction of silicone casting, what parts will be produced and a download section to download instructions for each component

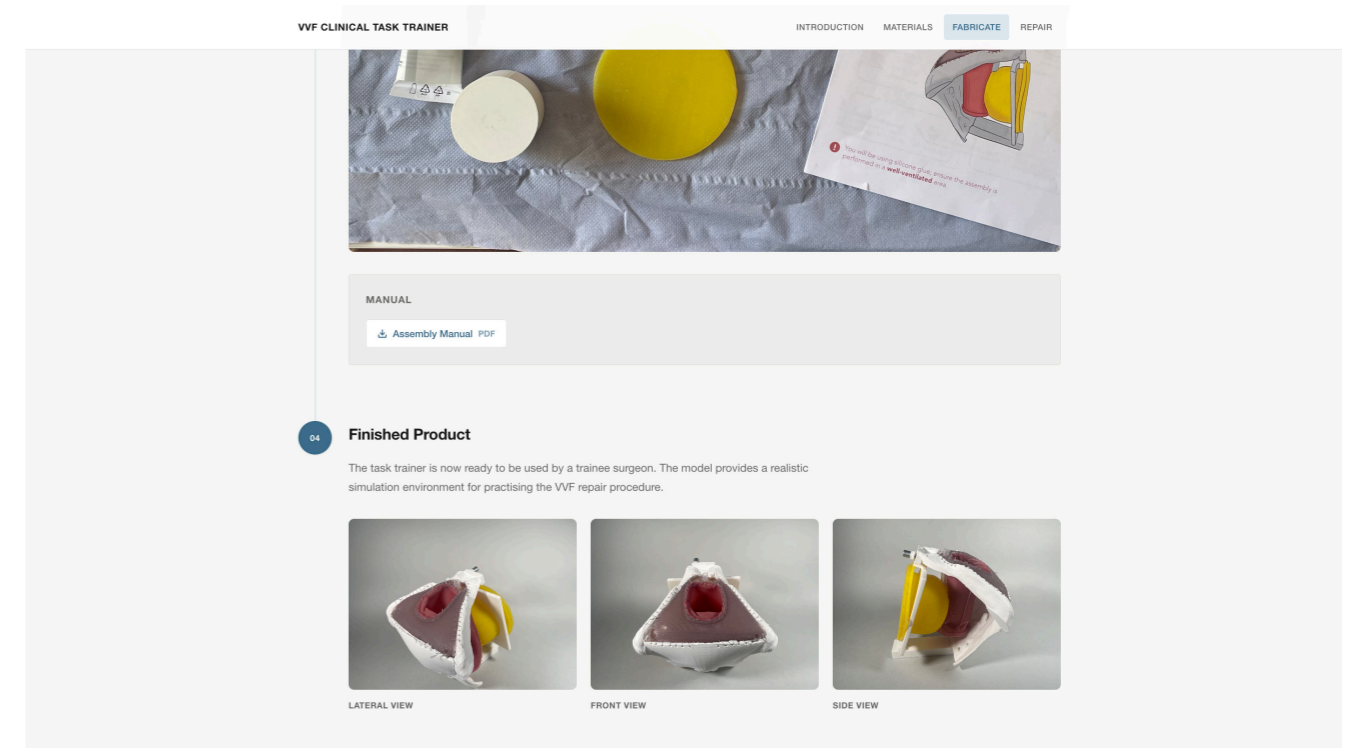


Figure H.9: Downloadable instructions for the assembly and an overview with images to show what will be made

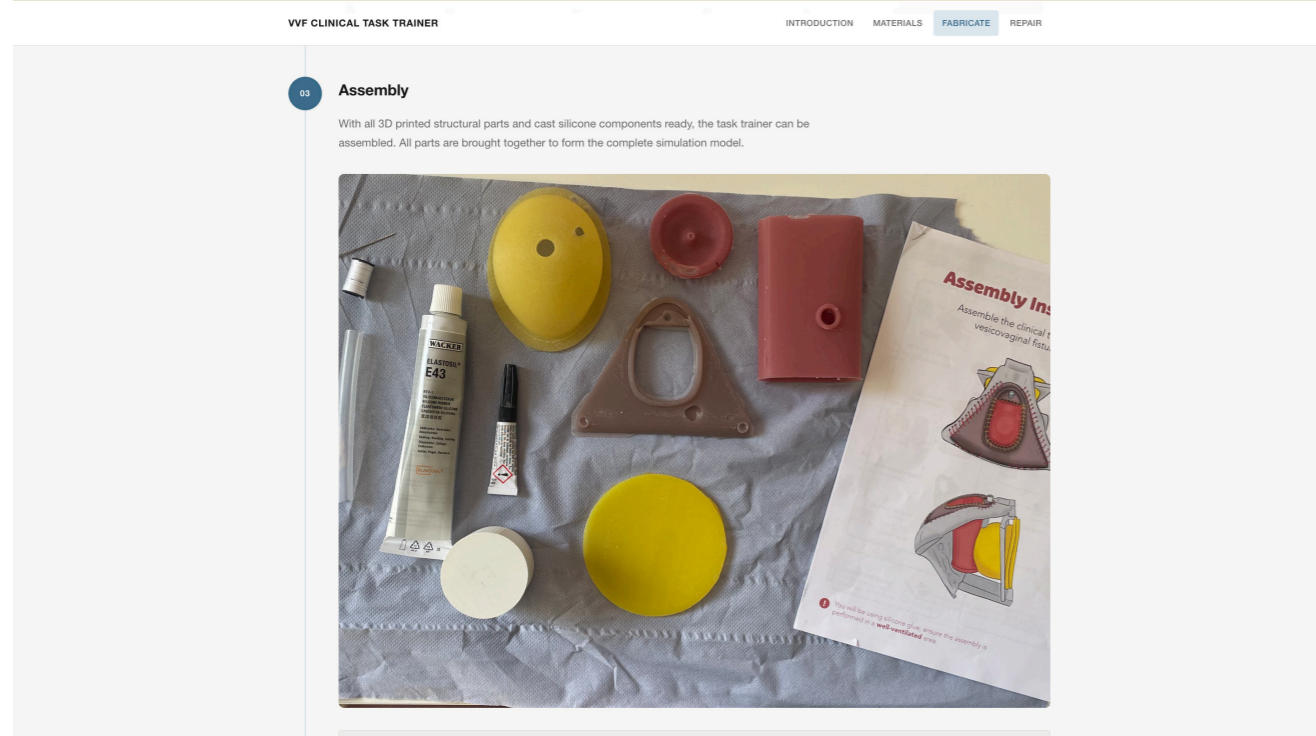


Figure H.8: Introduction of the assembly stage, including a short introduction and image of assembly setting

## Fabricate tab

Figure H.10 shows the repair stage.

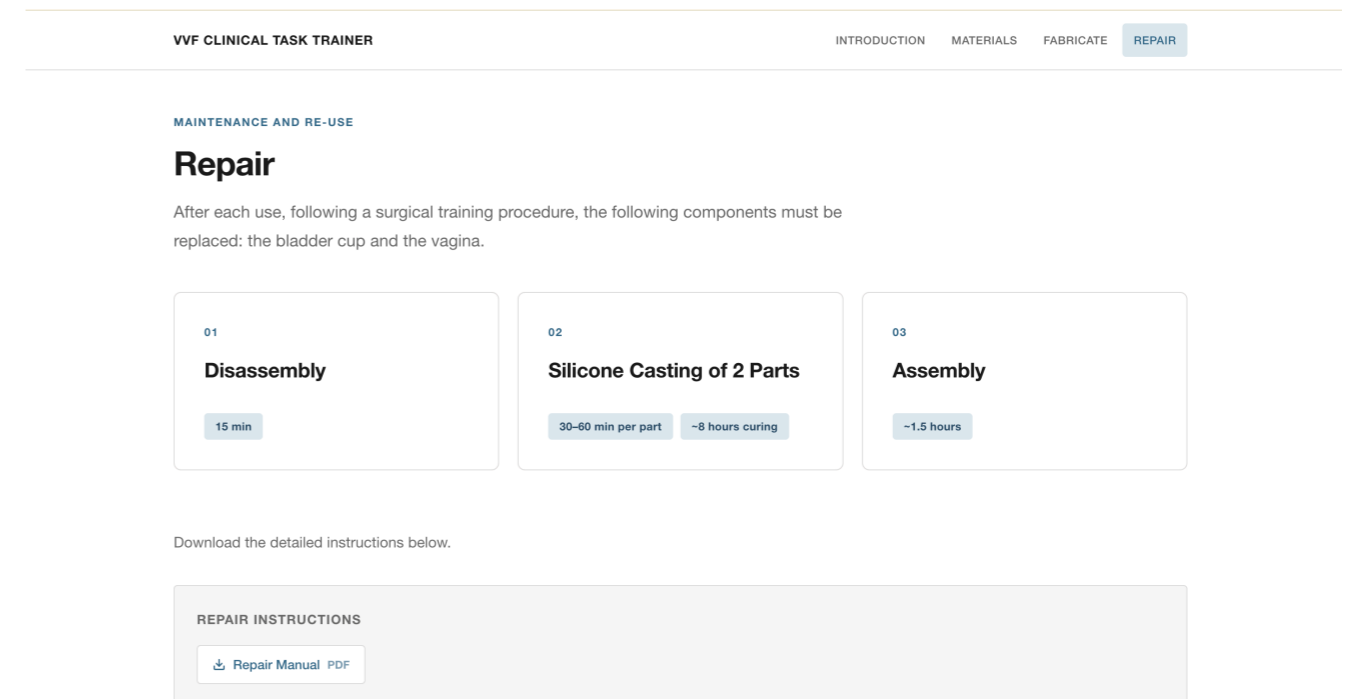


Figure H.9: Repair stage with an overview of the process including time indications and downloadable instructions.

# Appendix I - Requirements

This appendix provides an overview of which requirements were met within the final design. The requirements that were gathered or improved during the design sprints are also included. Red indicates not met, orange indicates partially met or uncertain, and green indicates met.

<b>Fundamental Requirements</b>	<b>Requirement</b>
The maker must have clear and comprehensive fabrication instructions to successfully fabricate the VVF clinical task trainer.	0.1
The maker should have access to the appropriate equipment, tools, and materials.	0.2
<b>Maker's Journey</b>	<b>Requirement</b>
The maker should be feeling guided throughout the entire fabrication process.	1.1
The maker must feel invited to start and continue the fabrication process.	1.2
An instructional design framework must be used to structure the fabrication process.	1.3
The instructional materials must not feel overwhelming.	1.4
At the start of the fabrication process, the maker should go through an onboarding step.	1.5
The maker must perform a self-check after each substage	1.6
For experienced makers, only information on precise quantities and specific mould-related procedures could be provided.	1.7
The instructions could be adaptable to the maker's level of experience.	1.8
A website must be provided that contains all necessary instructional materials, information and material specifications required to fabricate the clinical task trainer.	2.2
<b>Content of Instructions</b>	<b>Requirement</b>
The maker must be provided with an overview of the process in advance, including time indications.	1.9
All stages of the fabrication process must be covered.	1.10
3D printing information must be included in the content.	1.11
Repair information must be included in the content.	1.12
The instructions could be modular.	1.13
<b>Instruction material</b>	<b>Requirement</b>
<b>General</b>	
The instructions must be presented in manageable, well-structured segments.	1.14
The instructions must be presented in detail, with step-by-step instructions.	1.15
Technical jargon should be avoided or clearly explained when used.	1.16
A list of items necessary to perform each step must be provided.	1.17
The function of all materials and tools should be explained.	1.18
The instructions should follow the principle of task orientation.	1.19

The split-attention principle should be considered in the design of the instructional materials.	1.120
Each step in the instructions must require only one activity.	1.21
The manual must be concise and not contain unnecessary information.	1.22
The manual must be clear and easy to understand.	1.23
The manual must include visual representations for each step, accompanied by explanatory text	1.24
Instruction materials must be usable when printed in grayscale	2.1
Instructional materials must be designed for paper-based use.	2.3
The self-check must be visually emphasized to attract attention to ensure makers notice them.	2.7
The instructions must provide clear instructions on how to correct errors during assembly.	2.8
All assembly steps must clearly communicate orientation, alignment, insertion depth, and positioning through both text and visuals.	2.9
Material application (e.g. glue) must clearly specify type, placement, amount, and timing.	2.10
Illustrations must accurately represent real components and include hand positioning where relevant.	2.11
The assembly sequence should be organized to create an efficient workflow	2.12
The manual could provide additional support (e.g. video) for makers without prior sewing knowledge.	2.13
A watertightness test should be included in a self-check to verify the connection between the urethra, and the bladder cup is watertight.	2.14
The instructions must communicate that the bladder cup and vagina components must be assembled to each other with approximately 2 cm of contact area around the fistula.	2.15
<b>Silicone casting</b>	
Instructions for demoulding silicone must be available.	1.25
Separate instruction materials must be provided in the form of individual booklets for each silicone component.	1.26
The instructions must communicate that all silicone components must be completely filled to be usable.	2.4
The instructions must communicate that the vulva, cervix, and bladder plate may contain air bubbles.	2.5
The instructions must communicate that the vagina and bladder cup must not contain air bubbles larger than 1 mm within a 2-cm radius around the fistula.	2.6
<b>3D printed parts</b>	
The 3D parts should be intuitive to use.	1.29
The 3D printed parts could include visual or physical cues to support usability.	1.30
The 3D printed mould parts could have consistent hole sizes for bolts and nuts.	1.31

The requirements marked in red were not met. These requirements emerged during the design process but were ultimately considered outside the scope of this project.

The requirements marked in orange indicate that the evaluation results showed that these requirements were not fully met. Requirements 0.1, 1.23, 2.8, and 2.9 relate to the clear and understandable communication of information. Although the instructional materials improved clarity, the evaluation results showed that certain steps and information were still not interpreted clearly by all participants. Therefore, these requirements were considered only partially met.

Requirement 1.18 relates to explaining the required tools and materials. This information is not included within the instructional materials. However, the website proposes a sourcing section containing a list of materials and their functions. This also partially contributes to Requirement 0.2, which states that makers should have access to the required materials. Although access itself was not achieved within the scope of this project, a concept to support this was proposed.

Requirements 1.1 and 1.2 relate to makers feeling guided and invited throughout the fabrication process. Since the complete fabrication journey was not fully evaluated as one continuous process, it cannot yet be determined whether these requirements were fully met.

## Appendix J – Starter Kit Cost Estimation

This cost estimation provides an indication of the products that could be included in the starter kit. The listed prices are indicative and are partly based on the assumption that certain materials can be repackaged into smaller volumes where possible.

The estimated total cost of the starter kit would be approximately €286.50, taking into account the complete fabrication of one clinical task trainer and nine repairs. These repairs assume that only the bladder cup and vagina components need to be replaced.

Assuming that the task trainer can be used for ten training sessions in total, this results in an estimated material cost of approximately €28.65 per training setup, based on the materials included in the starter kit.

Material	Usage initial task trainer (including ca. 40% loss due to spillage)	Usage for (max.) 9 repairs	Total usage	Amount in starterkit	Indicate price excl VAT	Source (Example)
Silicone Dragon Skin 10 (part A & B) Per part in grams	154					
<b>Per component</b>						
Bladder cup: 34g A, 34 g B, 17 g Slacker, 6 drops yellow	48	432				
Bladder plate: 20 g A, 20 g B, 4 drops yellow	28	N/A	900	2 Sets each of 450 gram A and 450 gram B = total 900 of each type	€ 65,00	<a href="https://www.formx.nl/products/silicone1/dragon-skin-series/dragon-skin-10-very-fast---09-kgs.php">https://www.formx.nl/products/silicone1/dragon-skin-series/dragon-skin-10-very-fast---09-kgs.php</a>
Vagina: 25g A, 25g B, 5.5 g silicone oils, 6 drops mauve	35	315				
Cervix: 5.5 g A, 5,5 g B, 1 drop mauve	8	N/A				
Vulva: 25 g A, 25 g B, 6 drops brown	35	N/A				
Slacker 17g (for Bladdercup only)	24	216	240	Flask 450 gram	€ 18,00	<a href="https://www.formx.nl/accessories/silicon-miscellaneous/slacker/slacker---500ml.php">https://www.formx.nl/accessories/silicon-miscellaneous/slacker/slacker---500ml.php</a>
Silicone oil 5,5g (for Vagina only)	8	72	80	Flask 250 ml	€ 10,00	<a href="https://polyestershoppen.nl/siliconenrubber/siliconenolie-295.html">https://polyestershoppen.nl/siliconenrubber/siliconenolie-295.html</a>
Release agent spray (1 fles)	N/A	N/A	N/A	Spray can 400 ml	€ 16,50	<a href="https://www.benam.co.uk/products/releases-sealers/release-agents-for-mouldmaking-and-casting">https://www.benam.co.uk/products/releases-sealers/release-agents-for-mouldmaking-and-casting</a>
Colour pigments mauve	7	54	61	Pot 110 ml	€ 29,00	<a href="https://www.formx.nl/pigments/silcpig/index.php">https://www.formx.nl/pigments/silcpig/index.php</a>
Colour pigments brown	6	0	6	Pot 110 ml	€ 23,00	<a href="https://www.formx.nl/pigments/silcpig/index.php">https://www.formx.nl/pigments/silcpig/index.php</a>
Colour pigments yellow	10	54	64	Pot 110 ml	€ 26,00	<a href="https://www.formx.nl/pigments/silcpig/index.php">https://www.formx.nl/pigments/silcpig/index.php</a>
Plastic or paper cups	5	18	23	30 pieces	€ 1,00	<a href="https://www.disposablelidscounter.nl/coffee-to-go-espresso-koffiebeker-120ml-4oz-wit?">https://www.disposablelidscounter.nl/coffee-to-go-espresso-koffiebeker-120ml-4oz-wit?</a>
Stirring rods	5	18	23	30 pieces	€ 0,10	<a href="https://www.disposablelidscounter.nl/bio-roerstaafje-bamboe-">https://www.disposablelidscounter.nl/bio-roerstaafje-bamboe-</a>
Sulfate-free clay	small cube 1cm * 2			1 bloc *450gr	€ 7,50	<a href="https://syntechshop.com/en/poly-plasteline-klie-450-gram-blok">https://syntechshop.com/en/poly-plasteline-klie-450-gram-blok</a>
Needle				10 pieces	€ 5,00	
Thread nylon				1 spool	€ 4,00	
Super glue				4 tubes á 3 gram	€ 16,00	<a href="https://www.toolstation.nl/bison-secondelijm-gel/p94229">https://www.toolstation.nl/bison-secondelijm-gel/p94229</a>
Silicone glue				1 x tube 90 ml	€ 17,50	<a href="https://www.greendaleerubber.nl/siliconelijm-elastosil-e41-90ml">https://www.greendaleerubber.nl/siliconelijm-elastosil-e41-90ml</a>
Syringe 50 ml catheter tip used for Bladdercup, Vagina and Vulva	3	18	21	22 pieces	€ 23,00	<a href="https://www.medschevakhandel.nl/nl/bd-plastipak-injectiespuiten-50ml-3-delig-katheter-tip-60-">https://www.medschevakhandel.nl/nl/bd-plastipak-injectiespuiten-50ml-3-delig-katheter-tip-60-</a>
Syringe 20 ml luer tip used for Cervix	1	14	15	16 pieces	€ 4,00	<a href="https://www.medschevakhandel.nl/nl/medware-werwerspuiten-20-ml-3-4-oz">https://www.medschevakhandel.nl/nl/medware-werwerspuiten-20-ml-3-4-oz</a>
For fixing moulds: Bladder cup: 4x M4x40; Cervix: 4x M3x20; Vagina: 14x M3x20; Vulva: 5x M6x40						
Bolts M6x40	5		5	7 bolts	€ 1,50	<a href="https://www.rvspaleis.nl/bouten/buitenzeskant/din-6921/din-6921-f-1-a2-f-1-m6/6921-2-6x40_200">https://www.rvspaleis.nl/bouten/buitenzeskant/din-6921/din-6921-f-1-a2-f-1-m6/6921-2-6x40_200</a>
Nuts M6	5		5	7 bolts	€ 1,50	<a href="https://www.rvspaleis.nl/voeren/zeskant-moeren/din-934/din-934-f-1-a2/din-934-f-1-a2-f-1-m6">https://www.rvspaleis.nl/voeren/zeskant-moeren/din-934/din-934-f-1-a2/din-934-f-1-a2-f-1-m6</a>
Bolts M3 x 20	18		18	24 bolts	€ 4,50	<a href="https://www.rvspaleis.nl/bouten/zaaggeul/din-84/din-84-f-1-a2-f-1-m3/84-2-3x20_1">https://www.rvspaleis.nl/bouten/zaaggeul/din-84/din-84-f-1-a2-f-1-m3/84-2-3x20_1</a>
Nuts M3	18		18	24	€ 6,00	<a href="https://www.rvspaleis.nl/voeren/zeskant-moeren/din-934/din-934-f-1-a2/din-934-f-1-a2-f-1-m3/934-2-3_1">https://www.rvspaleis.nl/voeren/zeskant-moeren/din-934/din-934-f-1-a2/din-934-f-1-a2-f-1-m3/934-2-3_1</a>
Bolts M4 x 40	5		5	8 bolts	€ 2,00	<a href="https://www.rvspaleis.nl/bouten/buitenzeskant/din-933/din-933-f-1-a2/din-933-f-1-a2-f-1-m4/933-2-4x40_1">https://www.rvspaleis.nl/bouten/buitenzeskant/din-933/din-933-f-1-a2/din-933-f-1-a2-f-1-m4/933-2-4x40_1</a>
Nuts M4	5		5	8 nuts	€ 2,00	<a href="https://www.rvspaleis.nl/voeren/zeskant-moeren/din-934/din-934-f-1-a2/din-934-f-1-a2-f-1-m4/934-2-4_1">https://www.rvspaleis.nl/voeren/zeskant-moeren/din-934/din-934-f-1-a2/din-934-f-1-a2-f-1-m4/934-2-4_1</a>
Rubber tube (urethra) length 6cm, 7mm diameter	1		1	1 piece	€ 3,40	<a href="https://www.rubberwebshop.nl/siliconen-slang-siliconen-slang-diameter-7mm-inwendig">https://www.rubberwebshop.nl/siliconen-slang-siliconen-slang-diameter-7mm-inwendig</a>
Printed instruction books on A4 in colour						
Cost of a starter kit for manufacturing 1 task trainer and 9 repairs to it					€ 286,50	

N/A = Not applicable | Prices are indicative and are partly based on repackaging into smaller volumes

# Appendix K – Graduation Brief





## Personal Project Brief – IDE Master Graduation Project

Name student \_\_\_\_\_
Student number \_\_\_\_\_

### PROJECT TITLE, INTRODUCTION, PROBLEM DEFINITION and ASSIGNMENT

Complete all fields, keep information clear, specific and concise

**Project title** *Develop an online platform for production & use of surgical training phantoms in Low and Middle Income Countries*

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

#### Introduction

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

In many low- and middle-income countries (LMICs) there is limited access to high-quality surgical training and tools. To address this, the TU Delft Biomedical Engineering for Global Health Lab has developed a ranged of surgical training phantoms, which are models that allow surgeons to practice surgical procedures. These phantoms follow a do-it-yourself (DIY) approach, to make it easy to produce and use locally. They are affordable, easy to produce, and can be reused several times. They consist of 3D-printed parts that form the bony structures in combination with silicone components that mimic human tissue.

The specific training phantom that will be focused on in this project is a phantom developed for a medical condition called as vesicovaginal fistula (VVF). A VVF is an abnormal connection between the vagina and the bladder, which causes urine leakage through the vagina [1]. In many LMICs, women develop VVFs as a result of prolonged obstructed labour. Treating this condition requires a complex surgical procedure that can be challenging to learn [1].

The files and instruction manual to create and use this training phantom are currently available through an open-access publication. However, there lies an opportunity to make the instructions to produce the phantom more accessible for the target group, the makers and users of the phantom. A potential target group could be local makerspace members, hospital technicians, or small local companies. By providing clearer instructions and support, a broader audience can make the phantoms and the end-users (surgeons) can practice the procedure effectively. This could lead to more surgeries being carried out and, ultimately, more women receiving the care they need.

[1] Voskamp, T., Khisa, W. W., Oosting, R. M., Wiggers, T., & Dankelman, J. (2024). A training phantom for a vesicovaginal fistula repair with the transvaginal approach. *Current Problems in Surgery*, 61(8), 101550. <https://doi.org/10.1016/j.cpsurg.2024.101550>

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introduction (continued): space for images

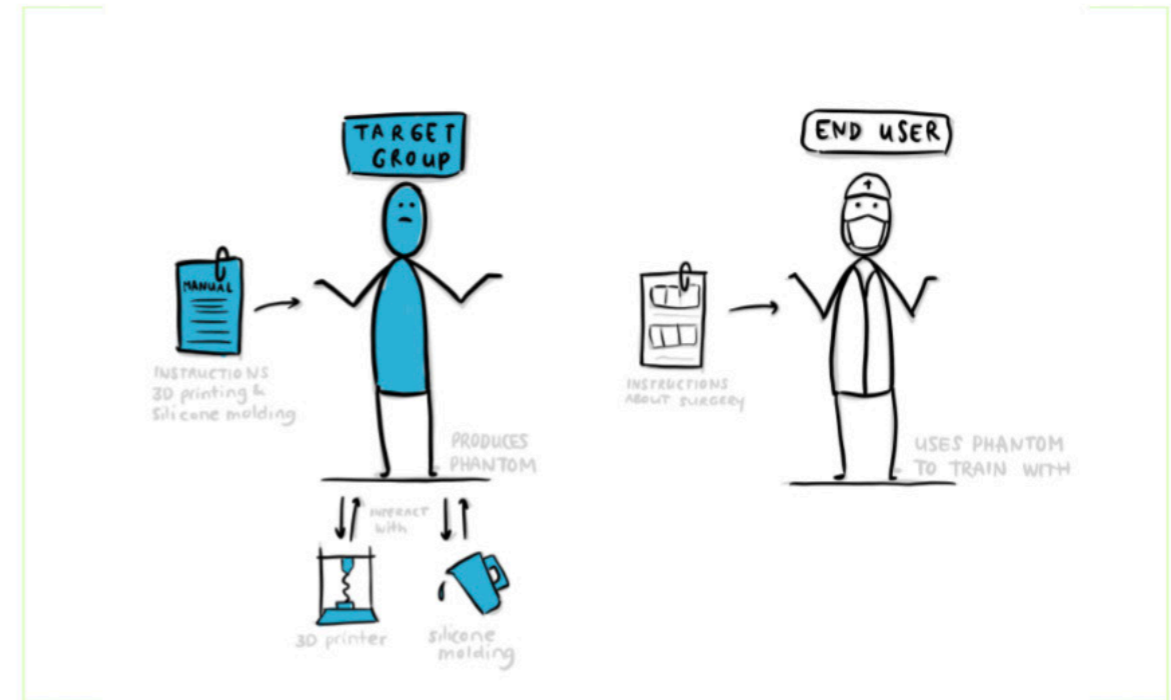


image / figure 1 *Current situation. Blue shows the focus of the project.*

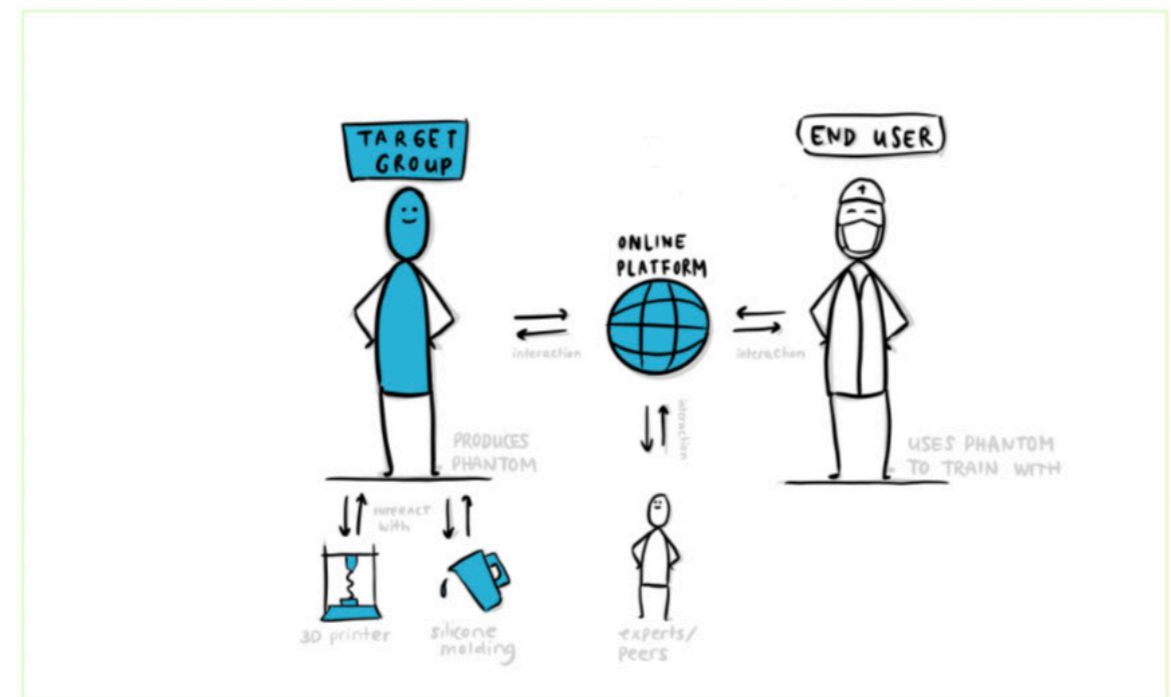


image / figure 2 *Desired situation. Blue shows the focus of the project.*

Personal Project Brief – IDE Master Graduation Project

**Problem Definition**

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

Currently, the makers of the phantom follow an online instruction manual. However, this manual is incomplete and makers need guidance and support from others, which are not present, making it even more difficult to make the phantom. The process is already challenging since producing the phantom involves both 3D printing and silicone molding, requiring the right materials and equipment. It also includes many steps that must be done in the correct order. For that reason, it is important that the maker has background knowledge about the purpose for which the phantom will eventually be used.

Through an online platform, it would be possible to provide training, guidance and support to the makers, offering clear steps and explanations tailored to the target group. This could lower the barrier for them to produce the phantoms, leading to more production and widespread use and ultimately a greater impact. The platform could also enable interaction not only between the makers and the platform itself, but also between makers and end-users, and among end users themselves. However, this project will mainly focus on the makers. Additionally, it can enable interaction with experts or peers in the field, allowing more knowledge to be shared.

Figure 1 shows the current situation, figure 2 shows the desired situation when an online platform is incorporated.

**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:

Create an online platform to guide users for producing the surgical training phantoms in low- and middle-income countries.

✖ 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)

In this project, I will follow the Double Diamond process, half of the project will be focused on research and the other half on designing. During the discover phase, I will map out possible current problems, causes and effects by doing literature research and interviews with stakeholders and experts. In the define phase I will determine the key issues and I will come up with an interaction vision and a final design goal.

This will be the starting point for the third phase, develop, where designing begins. I will brainstorm, experiment with prototypes and test with prototypes. Finally, in the deliver phase, I will refine and narrow down the ideas to a final idea which then will be tested.

**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 13 juni 2025

Mid-term evaluation 26 aug 2025

Green light meeting 6 nov 2025

Graduation ceremony 5 dec 2025

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

Part of project scheduled part-time	<input checked="" type="checkbox"/>
For how many project weeks	<u>25</u>
Number of project days per week	<u>4</u>

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)

I have always found medical topics interesting, even though I don't have the background or expertise in the field. What I like about this project is that it feels like a meaningful way to contribute to global health. Despite lacking medical knowledge, I'm curious to see how I can still make an impact through my role as a Design for Interaction student.

On a personal level, I also hope to become more confident in taking the lead on a project and to develop my skills in that area. Additionally, I want to learn how to keep my perfectionism from becoming an obstacle in projects like this.