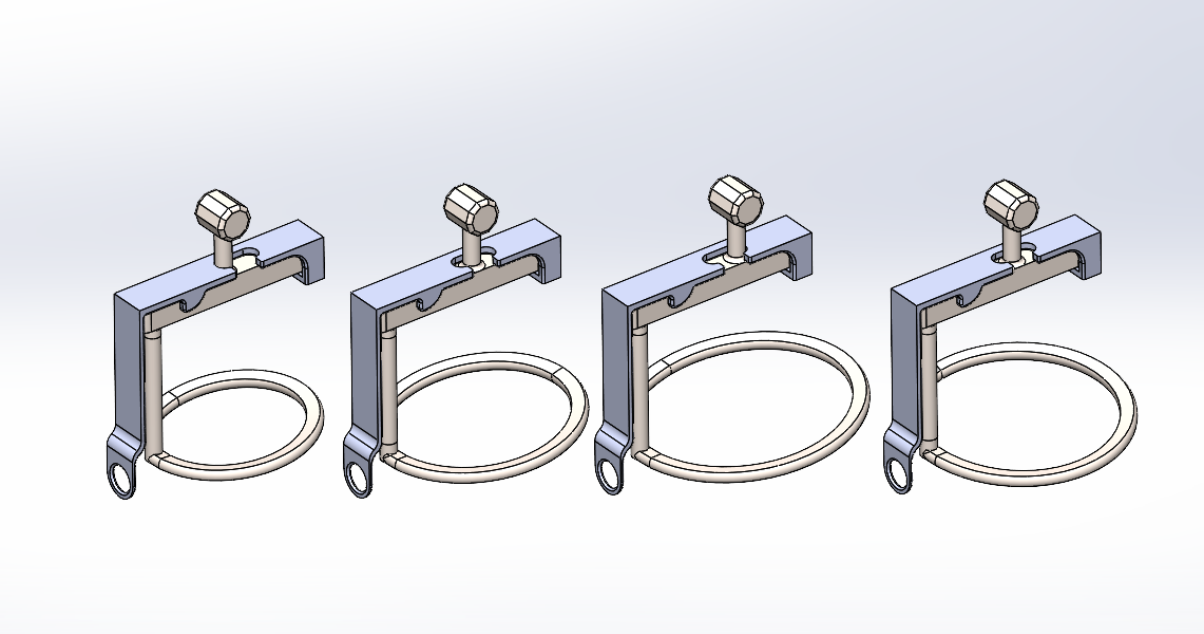
EMPOWERING HEALTHCARE BEYOND BOUNDARIES

INTRODUCING A FRUGAL LAPAROSCOPIC CAMERA HOLDER FOR LOW RESOURCE SETTINGS IN INDIA



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TU Delft

MIT

Frugal laparoscopic camera holder

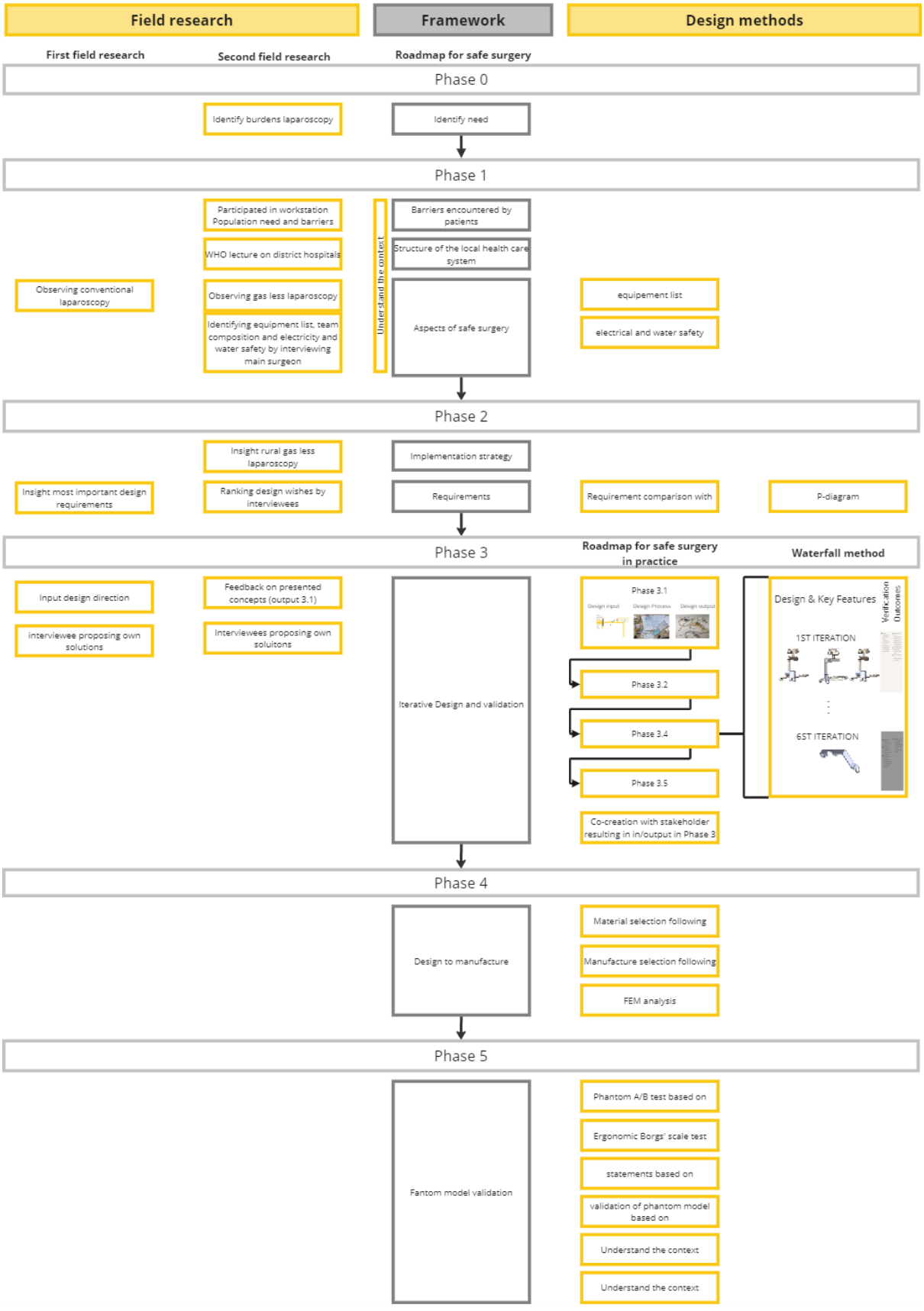

Field research
Framework
Design methods
First field research
Second field research
Roadmap for safe surgery
Phase 0
Identify burdens laparoscopy
Identify need
Phase 1
Participated in workstation Population need and barriers
WHO lecture on district hospitals
Observing conventional laparoscopy
Observing gas less laparoscopy
Identifying equipment list, team composition and electricity and water safety by interviewing main surgeon
Understand the context
Barriers encountered by patients
Structure of the local health care system
Aspects of safe surgery
equipement list
electrical and water safety
Phase 2
Insight rural gas less laparoscopy
Insight most important design requirements
Ranking design wishes by interviewees
Implementation strategy
Requirements
Requirement comparison with
P-diagram
Phase 3
Roadmap for safe surgery in practice
Waterfall method
Input design direction
interviewee proposing own solutions
Feedback on presented concepts (output 3.1)
Interviewees proposing own soluitons
Iterative Design and validation
Phase 3.1
Design input
Design Process
Design output
Phase 3.2
Phase 3.4
Phase 3.5
Co-creation with stakeholder resulting in in/output in Phase 3
Design & Key Features
Verification
Outcomes
1ST ITERATION
6ST ITERATION
Phase 4
Design to manufacture
Material selection following
Manufacture selection following
FEM analysis
Phase 5
Fantom model validation
Phantom A/B test based on
Ergonomic Borgs' scale test
statements based on
validation of phantom model based on
Understand the context
Understand the context

Table of Contents

TIME LINE

Timeline 150 days of graduation

Phase 3
Act

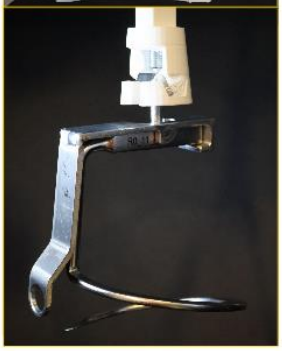
3.1

3.2

3.3

3.4

3.5



May 24 — **Phase 0**
Identify need

3 June — **Phase 1**
Understanding of the context

July 16 — **Phase 2**
Determining design requirements

field study

July 17

September 28

field study

October 7 — **Phase 0-2**
Update with field study findings

3 November — **Phase 4**
Refine through design to manufacture

November 20/21 — **Phase 5**
Phantom validation

December 12

SUMMARY

Recently, the world population has crossed 8 million people and it is estimated that out of every three persons two cannot afford surgery (Meara et al., 2015a). Surgery is the primary treatment for one-third of the diseases (Quene et al., 2022), but since 6 percent of all procedures are performed in the poorest countries, where more than one third of the world's population lives (Meara et al., 2015). This creates a need for accessible surgery.

Laparoscopic surgery is a commonly used surgery technique to replace open surgery on the abdominal region. Research shows that this method gas multiple benefits over conventional laparoscopy , including: lower infection rates, shorter hospital stay, faster return to normal activity, improved cosmetics, reduced postoperative pain and medication use (2013; Chao et al., 2016; Epstein et al., 2013; Kalser, 1993; Murphy et al., 1992; Solomon Bekele & Hagos Biluts, 2012; Straub et al., 2011; Udwadia, 2001; Zadey et al., 2023). However, in low resource countries, without advanced technology like robot arms, laparoscopes are hold by healthcare assistants. A field study showed that these healthcare assistants need to hold and manoeuvre the laparoscope in the abdominal without support. Resulting in fatigue that hinders the movement of the laparoscopic instruments and vision on the operation area. Therefore, the goal of this study is to

'Design a product to improve the ergonomics for healthcare personnel that holds a laparoscope during surgery in low resource settings'.

To provide a thorough solution for this design goal incorporating the local context, a framework is chosen. The first four steps follow a Roadmap for safe (Oosting, 2019), covering: 0) identify need 1) understanding of the local context, 2) determine design requirements, 3) concept development and validation. Two following steps are added based on (Webb et al., 2022) 4) refine through design to manufacture 5) clinical validation. In this study, the last step is modified by a phantom test.

Step 0 concludes the reason for this study, the ergonomics of the healthcare assistants needs to be improved. Followed by gaining contextual insight though field studies in India. This results in preliminary design requirements that will updated during the study. This field study showed that it is desirable to have a holder that supports the laparoscope during surgery. The ideal location is below the RAIS abdominal ring (top of the incision) and above the laparoscopic instruments (placed at the bottom of the incision) and connected to the RAIS device. A second field study for Phase 3 at a WHO conference and rural hospitals in India is used to iterate and validate the concepts. In this step, an ideal design is made that form fits easily on the abdominal ring of the RAIS device and that provides a stable support for the laparoscope. In the fourth step, this design is refined for manufacturing. A medical grade material selection is performed which resulted into AISI 316L stainless steel that is able to be manipulated by cold forming and welding if needed. With this material and production method in mind, the holder is designed according to ISO 7153-1 to make sure the holder remains hygienic. An Indian manufacturer can produce the holder for around 200 Indian Rupees, meaning just above two euro, which is within the requirement of 5 Euros per piece.

A phantom test with an Indian surgeon is conducted to test the performance of the holder. The vertical force on the holder during surgery is measured and used for a final FEM analysis. The FEM analysis shows a stress well below the fatigue stress for 1e7 cycles. The phantom test concluded that the holder is suitable to support the laparoscope reducing the stress on the laparoscopic assistant. Secondly, the holder is suitable for implementation in low resource settings.

To conclude, the designed holder improves the ergonomics for the healthcare assistants during operation, its price to produce is well below 5 Euros and is therefore suitable for low resource settings. Initially it was desired to make a holder that could fix the laparoscope by a surgeon during single surgery, this demand was deemed unnecessary because the field study showed that enough personnel was available. However, introducing this option could also improve the ergonomics, but at the cost of complexity.

Technology innovation is crucial in surgery, as it can save lives. Developers should focus on creating accessible medical equipment for low and medium-income countries, a market worth billions, and billions of lives.

INTRODUCTION/RELATED WORK

Laparoscopic surgery has revolutionized abdominal and pelvic operations by utilizing small incisions and a laparoscope, a slender rod with a camera for visualization. This technique offers several advantages over open surgery, including reduced blood loss, lower infection rates, shorter hospital stay, faster return to normal activity, improved cosmetics, reduced postoperative pain and medication use compared to laparotomy (Adisa et al., 2013; Chao et al., 2016; Epstein et al., 2013; Kalser, 1993; Murphy et al., 1992; Solomon Bekele & Hagos Biluts, 2012; Straub et al., 2011; Udwadia, 2001; Zadey et al., 2023) as have been shown in a significant amount of clinical studies (Berguer et al., 1999; Matsuhira et al., 2001; Narvaez C et al., 2020; Vereczkei et al., 2003; Wichert et al., 2004).

By introducing laparoscopy, a new task had to be carried out, the positioning and stabilization of the laparoscopic camera. This makes the operation a two persons job, controlling the camera and performing the surgery by the assistant and the surgeon respectively. However, one significant barrier in low- and middle-income countries (LMICs) is the scarcity of qualified healthcare personnel to operate the laparoscopic camera during procedures - amongst others. The WHO still recognizes shortages of health workers in rural areas despite local and global efforts to recruit health workers. Adjusting the laparoscope is a skill-intensive task that requires precision and coordination, and almost continuous adjusting. Surgeries can take up to several hours, imposing fatigue and ergonomic issues on the assistant making it harder to maintain a stable camera position and precise manoeuvring.

To address this issue, laparoscopic camera holders have been introduced to perform the task of assistants, ideally to enable solo surgery. A laparoscopic camera holder typically consists of a mechanical arm or a frame with adjustable joints, designed to hold and position the laparoscopic camera securely. The camera holder is attached to the operating table or another stable surface.

The camera's position, angle, and focus, ensure an optimal view of the surgical area on a television monitor. Holders improve stability, reduce dependence on personnel, and reduce surgeon fatigue by eliminating the need of constant communication with the camera assistant. Additionally, holders enhance depth perception (Amin et al., 2021), (Bogdanova et al., 2016), precise control over camera movements and improved ergonomics, minimizing the risk of musculoskeletal injuries for surgeons (Athanasiadis et al., 2021).

Despite their potential benefits, many of these camera holders face certain limitations, such as high purchasing costs, maintenance expenses, reliance on stable energy sources, and bulky design, rendering them unsuitable for deployment in rural areas. Given that numerous rural regions lack a consistent energy supply, water, and essential medical resources, a frugal design approach becomes essential. Frugality entails three primary conditions: i) emphasis on core functionalities, ii) significant cost reduction, and iii) shared sustainable engagement. The third point, shared sustainable engagement, focuses on the collaboration of local partnerships in the design process to maximize resource efficiency, optimize the outcome of integrating the business environment, and create shared value for every stakeholder in the project while embracing open innovation as a way to achieve frugal innovation (Rossetto et al., 2023).

In addition to frugality, the ideal design of a laparoscopic camera holder should be characterized by simplicity to ensure robustness, ease of repair using locally available materials, and minimal training requirements. Moreover, the design must allow for easy cleaning and sterilization using commonly

available resources autoclave and rubbing alcohol (Webb et al., 2022) which are typically accessible in rural hospitals.

The successful development of a frugal and sustainable laparoscopic camera holder could significantly enhance the availability of laparoscopy in rural areas, making crucial healthcare services are more accessible to a substantial portion of society. An interest has grown to develop products for the countries in the Global South, especially in medical devices. Since, the developing world's aggregate GDP has overgrown the developed nations' aggregate GDP in 2007, the developing world is big market. However, designing for the developing world market brings forth unique challenges not encountered elsewhere. The unmistakable proof of these challenges lies in the current failures, with the WHO estimating that a staggering 70% of medical equipment originating from the most developed nations fails to function effectively in developing world hospitals (WHO, 2000) and a market penetration for most medical devices close to zero.

Current efforts to increase access to medical devices in low resource settings have let to the development of the six crucial components: Availability, Affordability, Accessibility, Appropriateness, Acceptability and Quality (WHO, 2012b). Focussing on these aspect, the methods have been chosen accordingly. One example is the STAAN and RAIS device,

STAAN and RAIS device

The need for laparoscopy in rural settings present, the initiator of this project worked with rural surgeons to make a gas insufflation-less abdominal lift device suitable for low resource setting. The outcome was the STAAN device (WHO, 2016). After a few years a newer model was developed in collaboration with the University of Leeds, the Retractor for Abdominal Insufflation-less Surgery (RAIS) device (Webb et al., 2022). Some of the main improvements of this new model is that is allows to fix the abdominal wall in various angles due to the octagonal profile on the abdominal hook. Unlike the STAAN device, the RAIS device can be taken apart and fits therefore in an autoclave and suitcase for easy cleaning and transport/storage.

Figure 1 The STAAN (left) and RAIS (right) device based on (Bridges et al., 2021)

METHODS

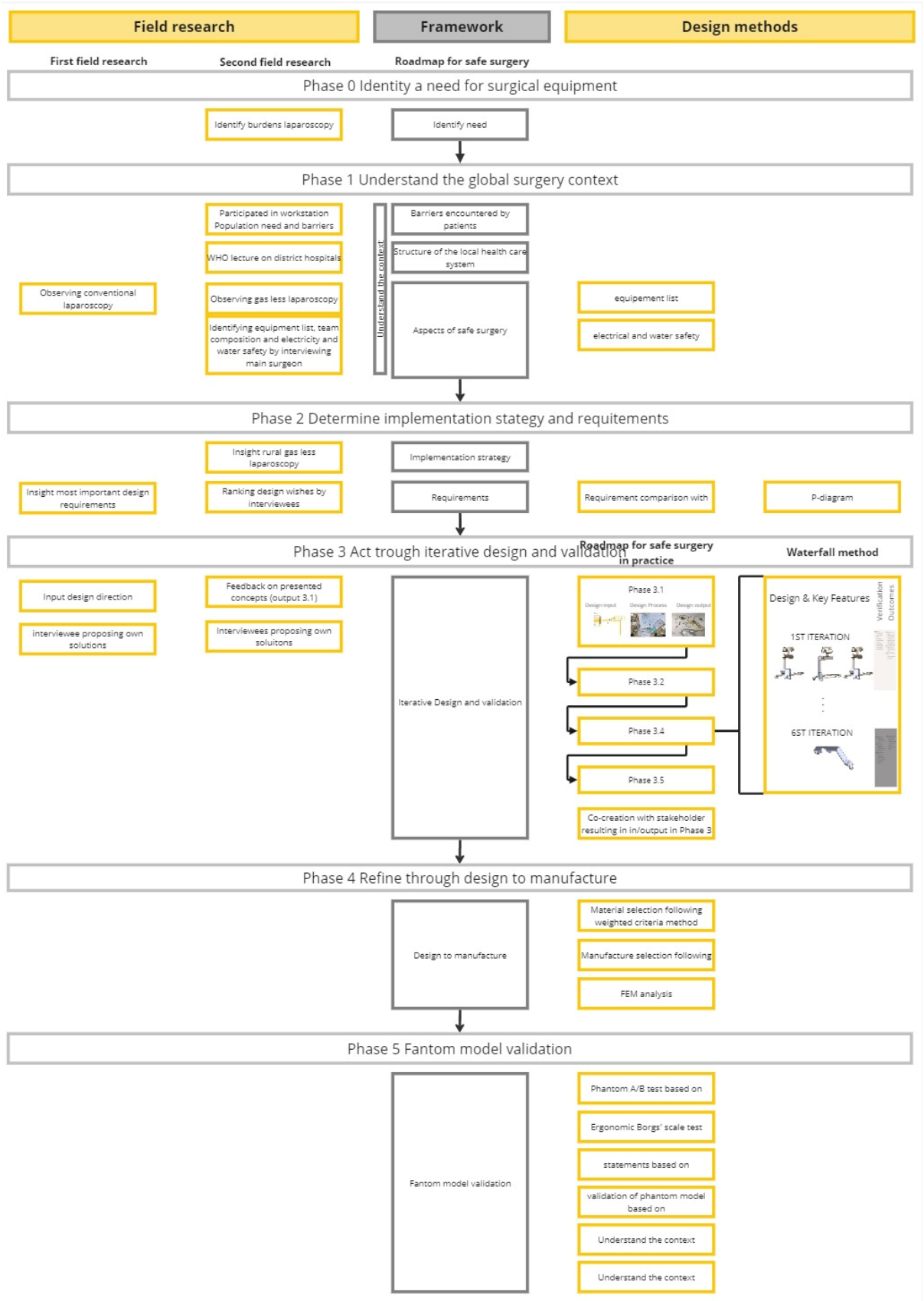


Figure 2 Overview of the 5 design phases and the contribution from the field studies and methods used

Medical device design frameworks are still strongly focussed on high-resource settings and therefore an design approach to cover the entire development process was necessary to construct. This was done by incorporating methods described in previous work that identified the need and gained understanding of local context (Oosting, 2019),(Di Pietro et al., 2020), systematic design iteration incorporating local stakeholder and its visualization (Marriott Webb et al., 2021). Furthermore, two field researches were planned to get gain insights on the problem, local context and its limitations, and to incorporate the end users in the design process to "extract the ranking of the requirements and to find out what they think is important to use that as input on the choice of design direction.

Guided by the framework 'Roadmap for Design of Surgical Equipment for Safe Surgery Worldwide' (referred herein as the `Design for Safe Surgery Roadmap') (Oosting, 2019), the initial phases of the development focusses on the understanding and nuances of the needs of local end users to innovate on appropriate prototype solutions. The framework describes a detailed structure of the pre-defined content and is implemented in the only real-life scenario to develop the RAIS device (Webb et al., 2022). Their interpretation of the framework is used for inspiration to source on with similar methods data for the different phases in the Roadmap for safe surgery. Furthermore, their addition of phase 4 is taken over in this project and phase 5 is altered to fantom validation due to time and resource limitations.

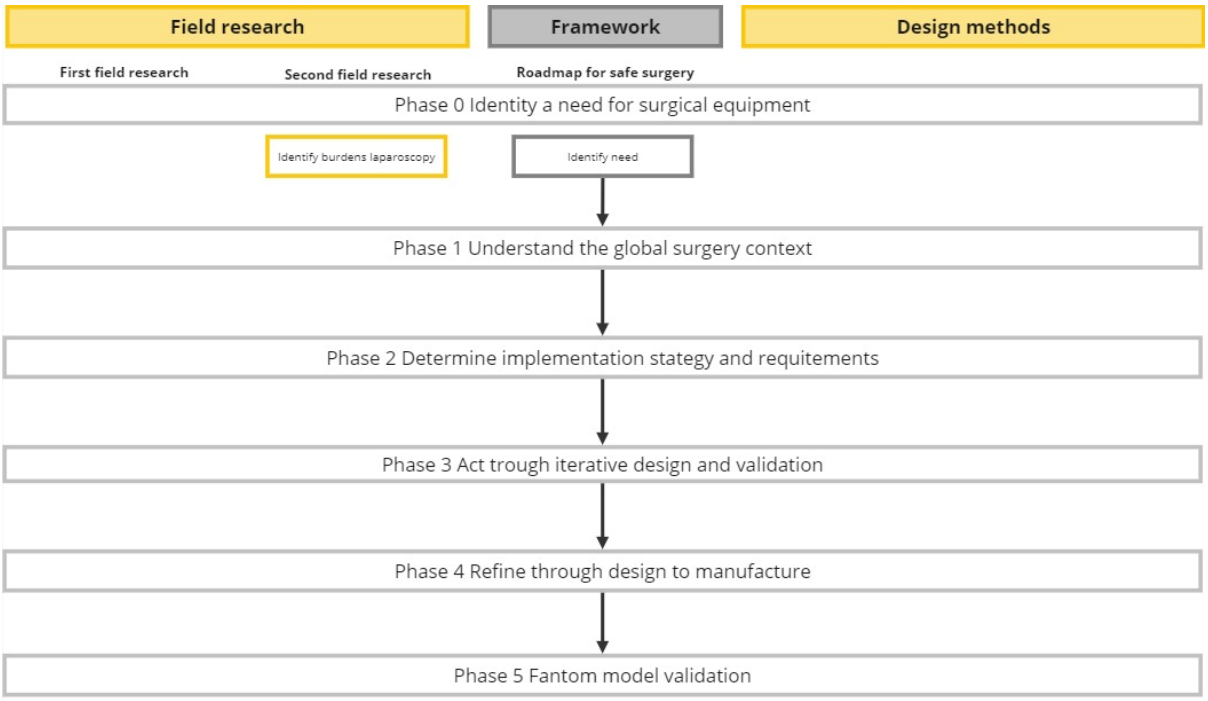
To inform the activities conducted within this hybrid design framework, the definition of frugality explained by Rossetto (2023 was selected as the driving force due to the wide use in medical design for low resource settings and alignment with the project aims (Marriott Webb et al., 2021). Frugality entails three primary conditions: i) emphasis on core functionalities, ii) significant cost reduction, and iii) shared sustainable engagement which focuses on the collaboration of local partnerships in the design process to maximize resource efficiency, optimize the outcome of integrating the business environment, and create shared value for every stakeholder in the project while embracing open innovation as a way to achieve frugal innovation (Rossetto et al., 2023). Frugal design aims to find elegant design solutions which use less resource while achieving comparable performance by promoting solutions which avoid extraneous features and focus on key needs (Park et al., 2018), (Weyrauch & Herstatt, 2016). The consequent outcomes are recognized to support disruptive improvements in global healthcare (WHO, n.d.). For a general overview; The design orientation is determined by frugality, directed by the six components of the WHO, and the product development journey is shaped by the Roadmap. Methods for extracting or displaying data are described in depth in the next section.

Roadmap for Safe Surgery

The following sections describe the implementation of this approach as a series of interconnected activities aligned to phases defined in the `Design for Safe Surgery Roadmap' and expanded with the commercialization and clinical validation phases to map the entire design process to structure these processes. The complete description of the Roadmap can be found in X and is summarized here for contextual understanding.

Phase 0: Identify need

The Roadmap starts with investigating the need for surgical equipment. Through a literature research and speaking to local end users a preliminary and final need got established.



This project started with a call to the Delft University of Technology by a rural Indian surgeon who had worked his entire life in different rural areas of India and Africa. From a point of product relevance, it is an essential that there is a need for designing expressed by the end users. This need for surgical equipment got investigated by performing a literature review on existing laparoscopic cameras, explaining the problem from a wider context. This resulted in identifying a gap between existing laparoscopic camera holders and their unsuitability for rural settings. Passive laparoscopic holders show potential to be implemented in low resource settings but not for solo-surgery but relative affordable. On the other hand active holders can perform solo-surgery but unsuitable for implementation in low resource settings due to their bulkiness, high purchasing cost and resources needed to maintain the device.

The surgeon's work includes a training program of gas insufflation-less laparoscopic surgery in low resource settings using previously the STAAN and now the RAIS device developed in collaboration with the University of Leeds, England. In combination to the numerous benefits of minimal invasiveness compared to gas insufflation-less laparoscopy, lower cost and no need for most of the single use products is gas insufflation-less laparoscopy a good alternative for gas insufflation-less laparoscopy. However, both methods need a laparoscopic camera assistant who can impact the quality of the surgery since the assistant is the eyes of the surgeon. As the operation progresses the laparoscopic assistant who needs to hold the laparoscopic camera in the air experience fatigue. This can lead to instable camera movements. The tip of the laparoscopic camera needs to be positioned above and behind the tips of the laparoscopic instruments, to make the movement of the tips of the instruments visible. The least invasive method is called single incision laparoscopic surgery (SILS) that uses only one incision

to insert the laparoscopic camera and the two laparoscopic instruments through a ~1 cm in diameter incision, see Figure 3. Especially, in this technique is the placement of the laparoscopic camera above the instruments challenging. For the laparoscopic assistant it is more convenient due to fatigue to rest the laparoscopic camera on the bottom of the incision in the abdominal wall. This has the consequence that the laparoscopic instruments fight with the laparoscopic camera and movement with the instruments are less fluent and the camera view get more disrupt.

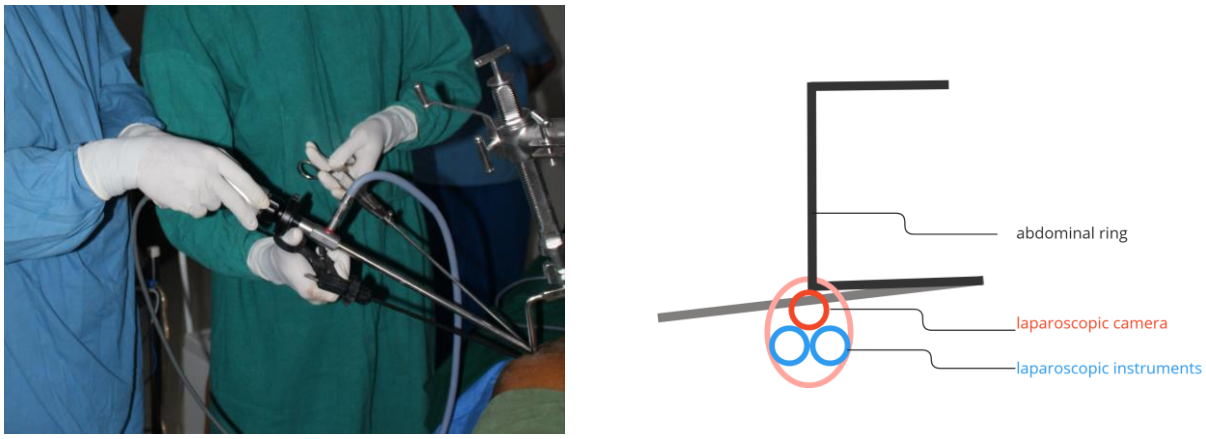


Figure 3 Performance of SILS cholecystectomy(left), and the configuration of the laparoscopic equipment during SILS(right)

This problem was later rephrased as the primary clinical need: “A laparoscopic camera holder that can hold and manoeuvre the laparoscope is needed to improve the accessibility to gas insufflation-less laparoscopy by facilitating solo operations.” This need was based on the understanding that laparoscopic assistants are scarce in low resource settings. Gas insufflation-less laparoscopy is a frugal technique but due to the need of an extra healthcare personnel to hold and manoeuvre the camera it lays a burden on the hospitals and becoming an obstacle to implement laparoscopy on frequent treatments. After the second field research the clinical need was revised as enough trained but uncertified healthcare personnel was available to hold the laparoscopic camera into:

“To improve the stability and position of the laparoscopic camara a laparoscopic holder is introduced to improve the assistants ergonomics and provide enough workspace for the surgical instruments to be smoothly manoeuvred during the surgery.”

Securing enough workspace for the surgical instruments was found to be the major challenge, since there is limited room to implement a holder.

Phase 1: Understanding of the context

To gain a high contextual understanding, Phase 1 gains insights from two field researches and existing literature on the: i) barriers encountered by patients, ii) structure of the local healthcare system, iii) aspects of save surgery.

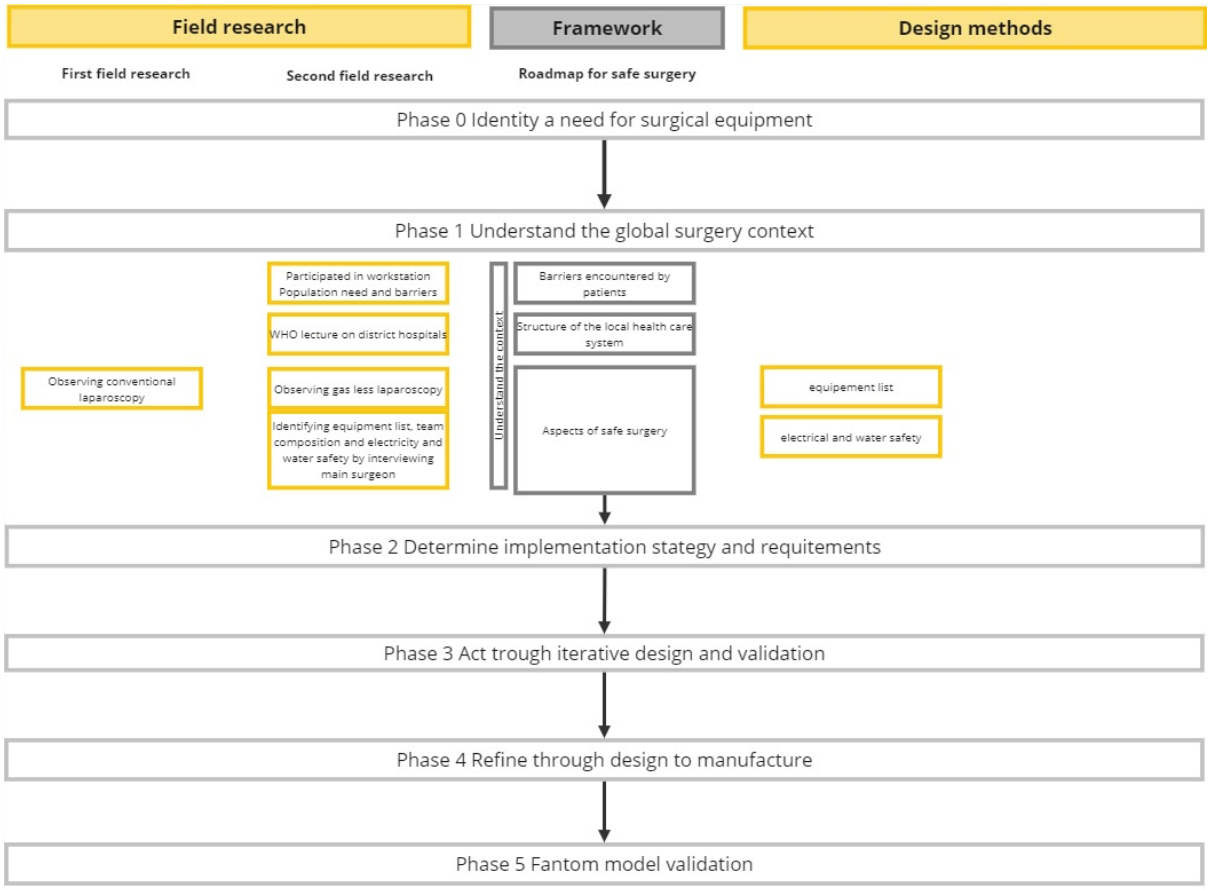


Figure 4 The 3 steps in Phase 1 of the Roadmap for Safe Surgery

The two field studies in India were dominated by the following activities:

1) A semi-structured interview with a surgeon of a Higher level Hospital in Delhi who has experience in rural laparoscopic surgery and observing a conventional laparoscopic surgery.

2) Attending the WHO symposium on district hospitals in Delhi and two training programs at rural hospitals(West-Bengal and Tamil Nadu) for rural surgeon in gas insufflation-less laparoscopy to obtain a clear user problem, understanding of rural surgery, low resource setting and to involve clinical stakeholders in the project.

The involvement of local stakeholders started before the field research with video calls with rural surgeons, including the initiator of this project, and project members of the RAIS device of the University of Leeds. The research process was predominately qualitative, involving semi-structured interviews, observations of surgical practise using the RAIS and STAAN device and group discussions with rural surgeons to understand the limitations of those devices and potential barriers to them using gas insufflation-less techniques in the future.

i) Patient barriers

This phase benefited primarily from the second field research were the design team participated in the WHO symposium on district hospitals 2023 and visited two rural hospitals in West-Bengal and Tamil Nadu. The WHO symposium entailed low cost training methods to teach healthcare personnel in rural and low resource setting various healthcare practises. Prearranged teams of 6 participants, comprising of 1 or 2 proposers of the new training method, and 4 or 5 participants with limited prior knowledge of the workstation. Two participants were assignment as reviewers to save the feedback/made changes of the group in an online form.

In total collaborated for a duration of 4 days, working on 2 workstations each day. One workstation "Population needs and barriers" was participated by the design team, WHO member, and rural surgeons over India and Liberia. A suitable teaching method needed to be found to teach the following learning goals:

1. Identify the various types of delays in 3 delay model
2. Enumerate the barriers at each level of delay
3. Formulate at least 3 solutions to the barriers for the 3 levels of delays with a group discussion (starting with the most prevalent barriers or the most actionable solution)

The outcome of this workshop resulted in a visual representation of the 3 types of delays including the barriers at each level of delay.

ii) Structure of the health care system

Furthermore, a lecture was given on First level hospitals in the Indian healthcare system. This combined with found literature forms the basis of this section. The outcome can be found in Results Phase 1.2 Structure of health care system.

iii) The aspects of safe surgery

The aspects of safe surgery are split up in 4 categories:

a. Operating theatre process
   By observing various laparoscopic procedures at rural surgery training camps, an understanding of the whole operation process was noted down, including the steps before and after the operation. Layouts were drawn of the operating theatre, including the position of the active healthcare staff(surgeon, first assistant, second assistant and anaesthetist), both can be found in APPENDIX A: Lay out OT of rural hospitals.
b. Team
   To gain information about the surgical team, the head of surgery was interviewed to give an indication about the composition of the surgical team.
c. Surgical equipment
   The same was done for to get an indication of the availability of equipment since both hospitals did not keep a record.
d. Infrastructure on water and electricity
   Lastly, the interview contained questions regarding the electrical and water safety in the hospital based on (Di Pietro et al., 2020).

Phase 2 Determine design requirements

Now an understanding of the local context is gained, a suitable implementation strategy and requirements can be determined. Through discussion with clinical stakeholders a preliminary implementation was drawn up that later for refined once the final products was established. The initial set of requirements was based on insights from the first field study and frugal approach. After the second field study the requirement were updated based on the gained insights and new found literature on ranking of requirement for low resource settings(Piaggio et al., 2021).

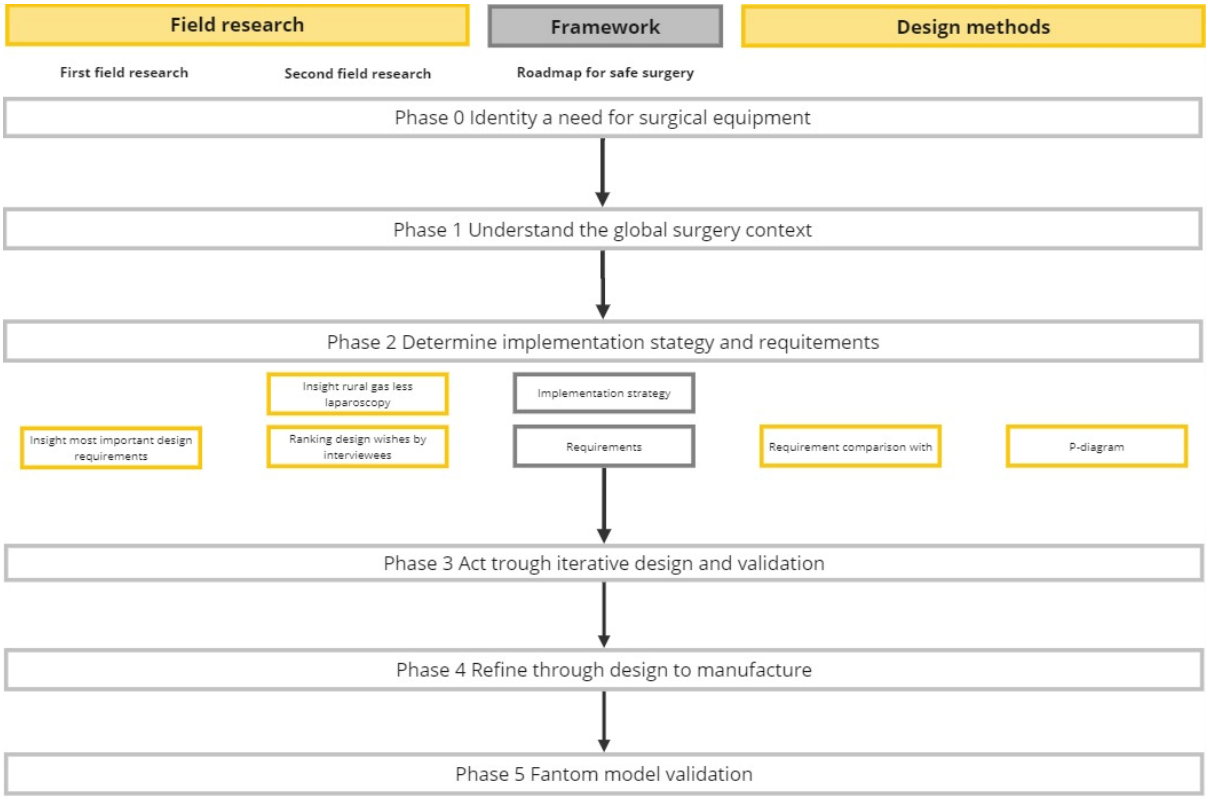


Figure 5 Framework highlighting the details of Phase 2

Implementation strategy

By listing possible implementation strategies, a wide range of possibilities was considered. By interviewing healthcare workers especially experienced nurses contributed to the implementation strategy, since they are often in control of the prepping and cleaning of the equipment. Based on these insights an implementation was first established. During the last visit of the project initiator the implementation strategy got refined.

Requirements

Before the field researches an initial set of requirements was established with feedback from rural surgeons and a project member of the RAIS device via online meetings. A preliminary P-Diagram was established, see Figure 6.

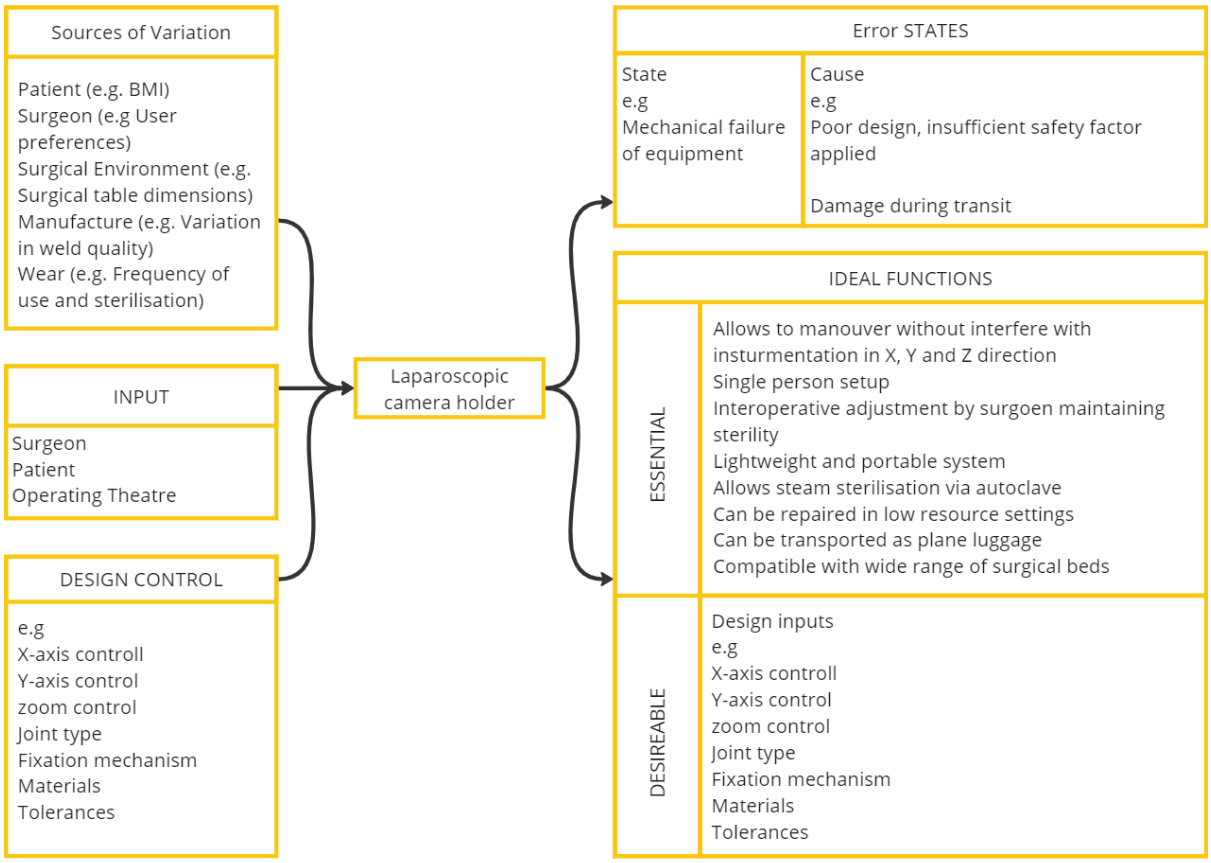


Figure 6 Preliminary P-diagram, shown for context

This diagram reflects the design spectrum specified by functions, and makes you aware of frequent failures by integration errors state and its causes. P-diagrams are a tool used in "Six-Sigma" design to capture and define the essential details of a system, such as inputs, desired functions, "Error States," and variations in the environment/context. In this situation, it offers a way to succinctly yet firmly record and share this important information with the entire team (Yang & El-Haik, 2003). During the second field research the aim was to interview participants with experience in rural settings and preferably with laparoscopy as well. The goal of the semi structured interviews was to get:

- Insights in rural laparoscopy
- Identify the existing need
- Feedback on the functionality of the presented concepts to choose a suitable design direction

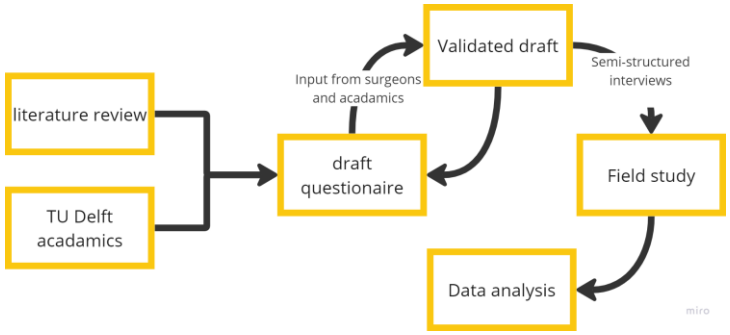


Figure 7 Process on obtaining the semi structured interview for the second field research based on (Di Pietro et al., 2020)

A draft questionnaire got written based on i) the earlier performed literature review, ii) literature on systematic reviewing of rural hospitals on the available equipment and electrical safety (Di Pietro et al., 2020). This draft got refined by input form the rural surgeon (initiator of the project) and with TU Delft academics, including the project team. The validated questionnaire got used in the second field study. The obtained data analysis can be found in

R Phase 2.

The structure of the semi structured interview is split up in three parts and can be found in full length in Appendix C Interview guide.

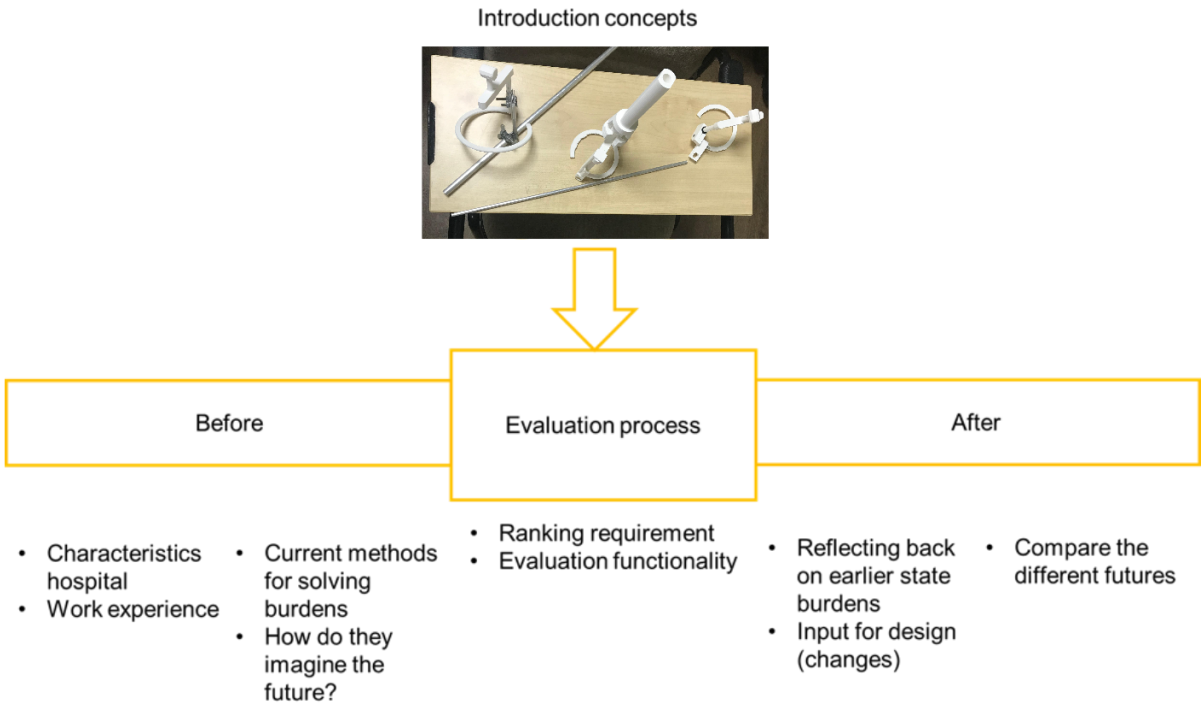


Figure 8 Phases of the semi structured interview

1. Before

   Gathering information on the background of the interviewee and earlier experiences in low resource settings with laparoscopic surgery. Secondly, identify the burdens in (gas less) laparoscopy and how these burdens are currently solved or should be solved with there daily influence on the overall accessibility of laparoscopy. The outcome of these questions resulted in defined user needs which were later used to adjust the design goal.

2. Evaluation process

   Here, the concepts got introduced for the participants were asked to lay out the wish card while thinking out loud in order from most important to least important. Secondly, the functionality of the presented concepts got evaluated.

3. After

   The interviewee was asked if the concepts would solve the earlier stated burdens in the phase “Before” and if not what should be changed about the design. These changes could be drawn in the booklet or new concepts could be drawn. The booklet contained of each presented concept different orientations and a picture of the RAIS device.

Figure 9 Schematic of the interview process during the group discussion

During the second field research 13 participants were interviewed, 6 individually, 5 during a group discussion and 2 via an online questionnaire.

During the field researches, group discussions and semi-structured interviews with Indian surgeons let among other things to the ranking of a preliminary list of 8 most important design wishes. The wishes were printed on cards to make discussion and rearranging more convenient. The ranked wishes were compared with ranks of requirements for low-resource settings found in literature.

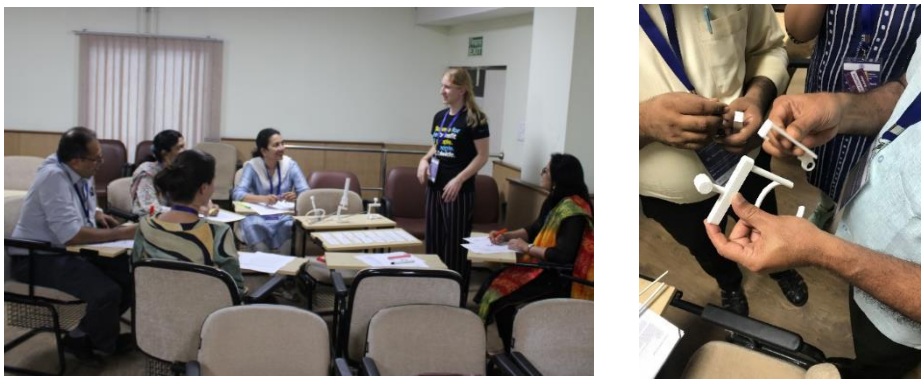
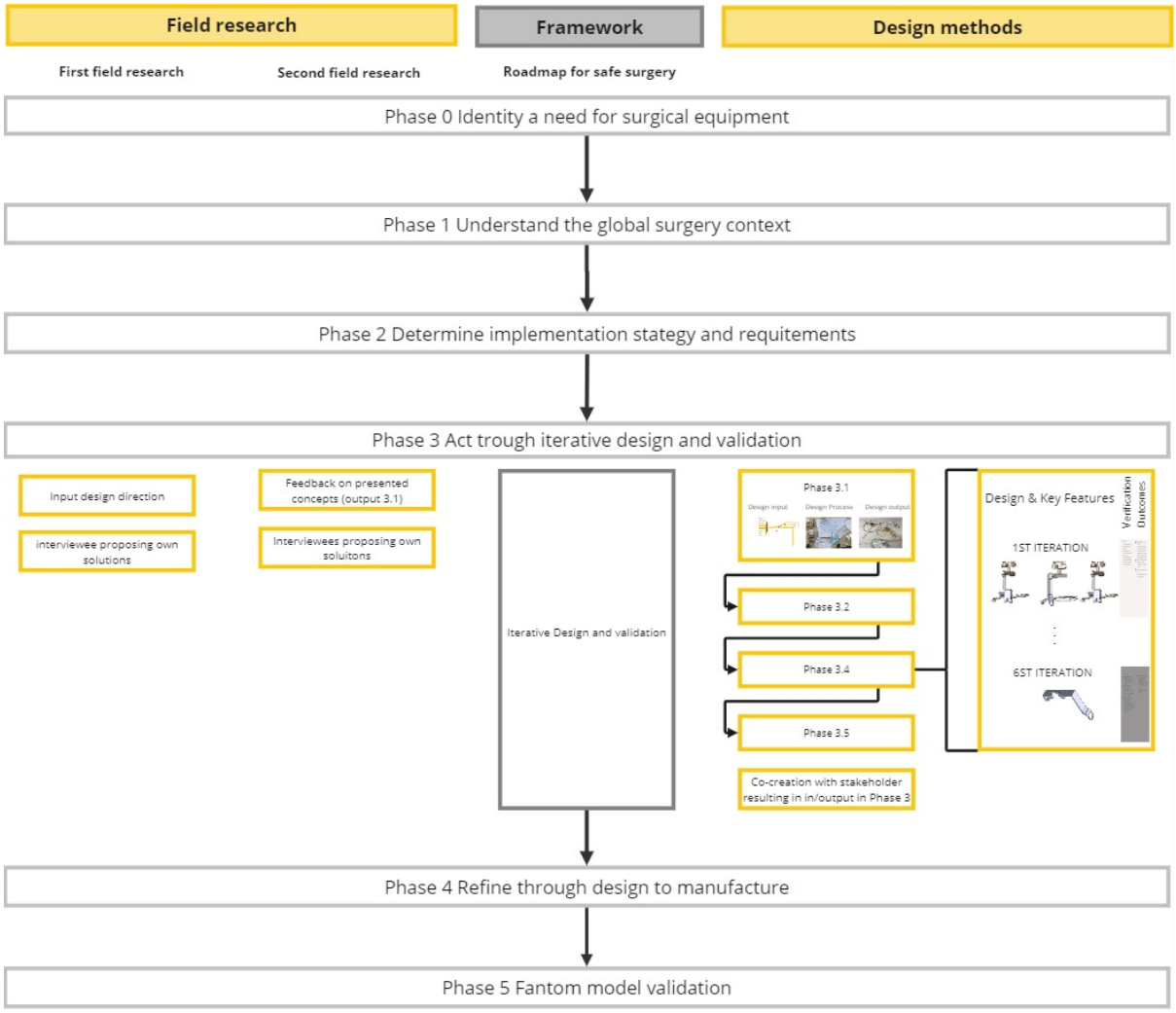


Figure 10 Discussion group (left), the 8 most important design wishes printed on cards with explanation (right)

Phase 3: Concept development and validation

The last phase of the Roadmap for safe Surgery focuses on developing a solution to the problem derived in Phase 1 through iterative cycles of co-creation with end-users, and limiting the design space in Phase 2. While the aim of this phase is clear, it lacks the methods to guide you through this process. The *Roadmap in practice* (Marriott Webb et al., 2021) was used as a red line to structure and visualize the design input, process, and output in a similar systematic way.



The design process started with exploring the design space and structure the different possibilities in a tree map. The most potential concepts got prototyped to get an indication of their size and working principle. The 3 most potential concepts can be found in the outcome of Phase 3.1. These 3 design directions got refined and evaluated in Phase 3.2 and Phase 3.3 in context. The feedback of the field research got implemented in the design in Phase 3.4 which got covered in six iterations. Lastly in Phase 3.5 the design got evaluated by a group discussion and phantom test in Phase 3.5 which led to the final design and recommendations for further improvements, see Appendix.

For the final iteration, phase 3.4 the waterfall method was used to visualize the intermediate design alterations based on the input of the second field research to specify the need and outcome for each

design iteration. The choice for the Waterfall method was derived from the United States Food and Drug Administration that adopted the framework for the development of medical devices. In every design cycle in Phase 3, marked by Phase 3.1 to Phase 3.5, input from stakeholders was used to start a new design cycle and their feedback about the new iteration noted down and called output in the Roadmap in practice. Since the design output was not satisfied a new cycle started.

Phase 4: Refine through design to manufacture

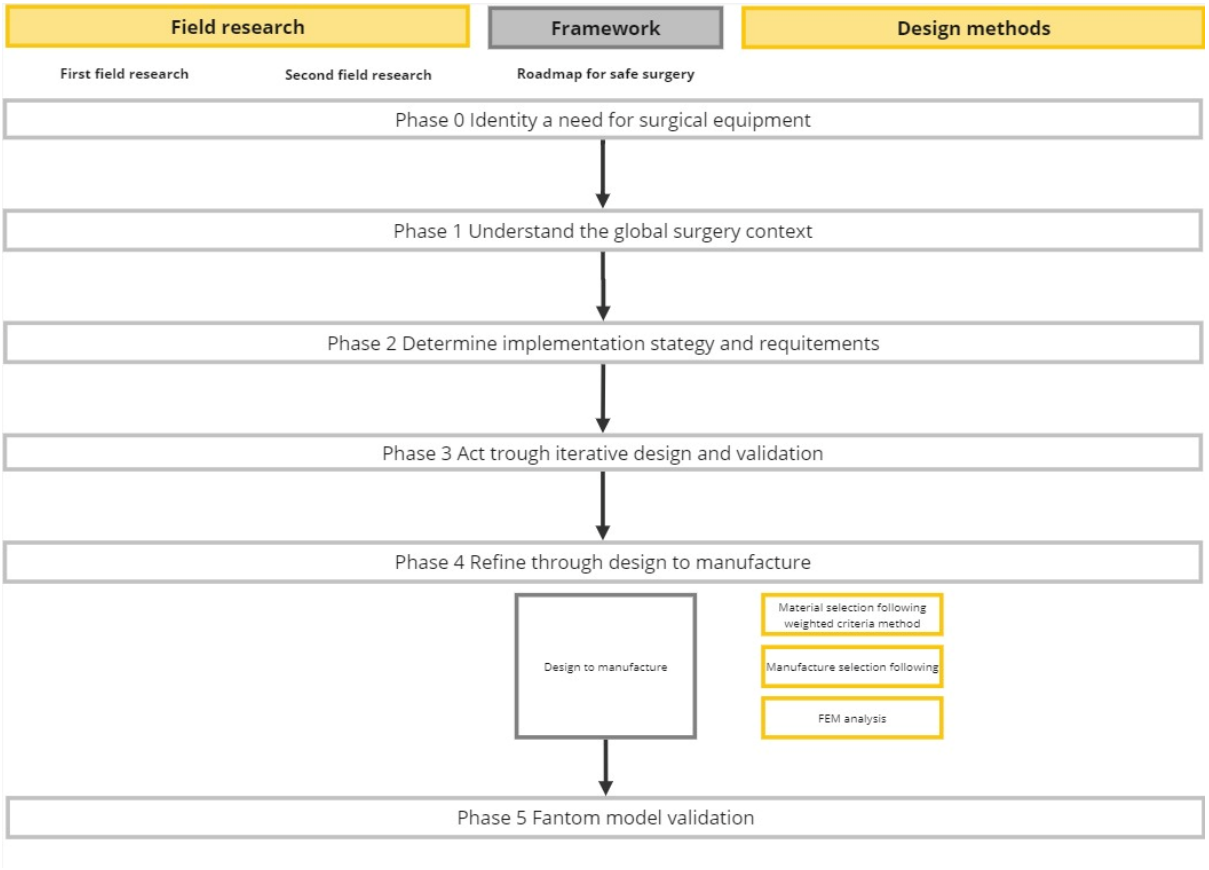
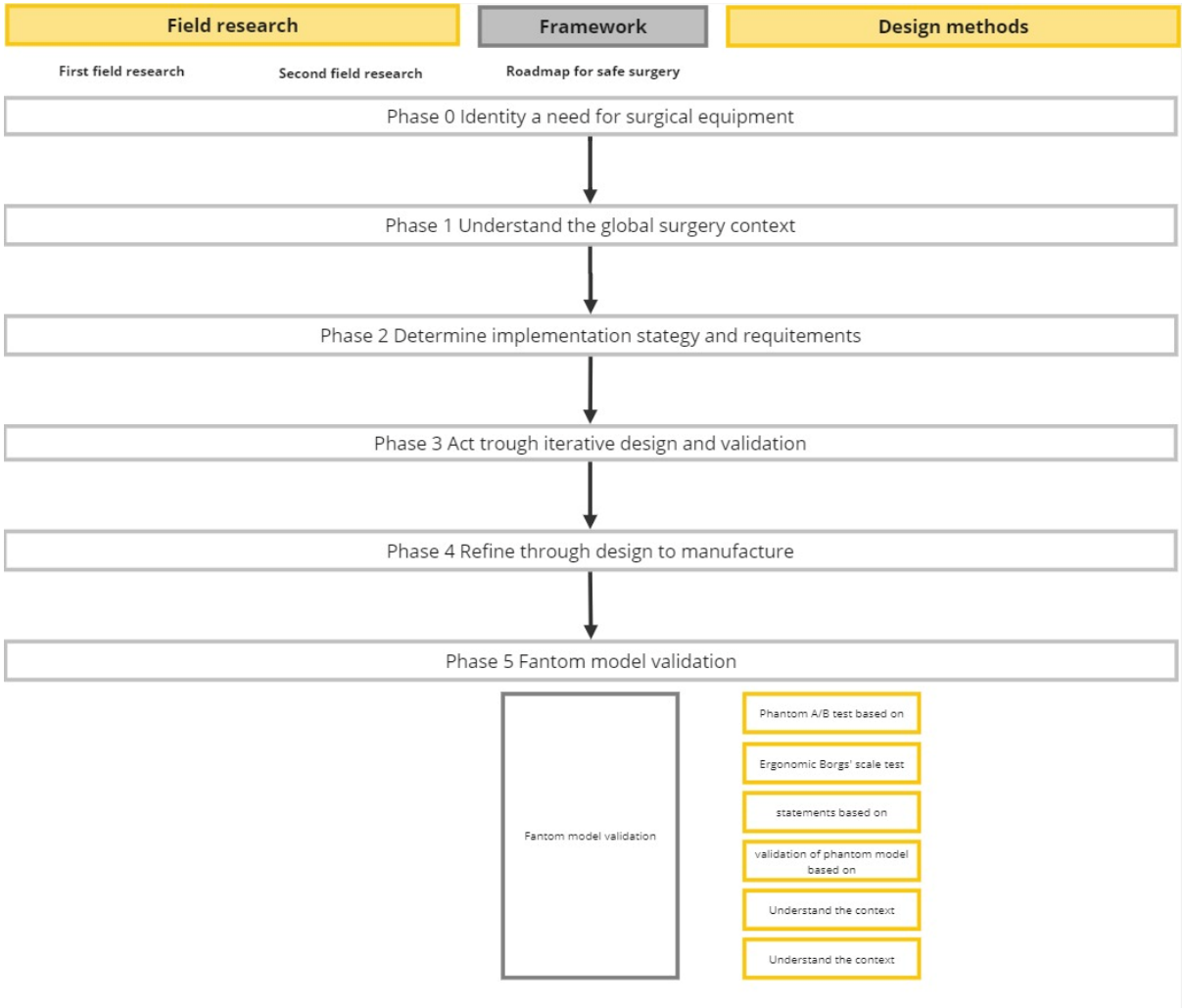


Figure 11 Detailed breakdown of Phase 4

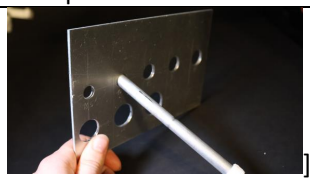
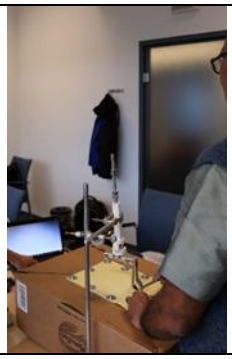
This stage of the project focusses on refining the design to meet the selected manufacture process. To start this process an material selection in CES EDUPACK is performed to anlayse all suitable materials. By applying the weighted critia method, the most suitable material was selected by filtering down the materials through the material demands and later select the most suitable material based on the material wishes. Based on the requirements set for the production process, for example a batch size of 20 was required a range of suitable manufacture process could be established based on the manufacture demands and selected based on the wishes. After, establishing the material and manufacture process a manufacturer needed to be found to produce the product. A local manufacturer was desired to fulfil the wish for the products to be local manufactured and able to be repaired locally. Since and in-country manufacturer has knowledge about these aspects in his community, a higher chance this wish will be met. Moreover, domestic manufacturers promote long-term sustainable solutions, assisting in the mitigation of global supply-chain problems and integrating in-depth understanding of regional regulatory needs and procedures (Shipley et al., 2021). Against the projects aim, a local manufacturer was not found in the earlier stages of the project. The reason was that contact with the RAIS device manufacturer was

still intact, was suggested a natural choice to choose the same manufacturer, since their pre-knowledge of the RAIS device and setting of the implementation. Unfortunately, the RAIS manufacture was not interest in producing, since the focus of the company lays in large batch sizes. At the end of the project a former employee who worked on the RAIS device, before it denied the RAIS manufacturing, started his own company. Agreeing to small batch sizes, the design team worked the last week with the manufacturer to gain input on the manufacture process to refine the design of the holder for low cost production and estimating production cost.

Phase 5 Phantom model validation



The last step is this design process is to validate the final product with the end users. The initiator of this project planned a visit to The Netherlands in November 2023. This opportunity was used for a final evaluation moment. The following activities and tests were conducted:

	Test / Activities	Set up	Equipment
	Establish same field of view, determine which size hole results to a comparable field of view of a gas insufflation-less laparoscopic cholecystectomy	]	- Laboratory stand with clamp - Counterweight - 3D printed arm of RAIS system - 12 mm thread + 2 bolts - Abdominal ring - Laptop cystoscope - Laparoscopic holder - Phantom box - Metal board with hole sizes - 3 metal holders -
	Discussion about the integration method with stakeholder and maximum purchase price		
	Force component test, determine the maximum horizontal force component exerted by the laparoscopic assistant on the holder		- scale - Laboratory stand with clamp - Counterweight - 3D printed arm of RAIS system - 12 mm thread + 2 bolts - Abdominal ring - Laptop cystoscope - Laparoscopic holder
	Phantom cholecystectomy A/B test, determine influence of the holder on the performance of the surgery.		- Laboratory stand with clamp - Counterweight - 3D printed arm of RAIS system - 12 mm thread + 2 bolts - Abdominal ring - Phantom box - Stop watch
	Holder attachment, determine if the attachment of the holder is a one person job and how initiative attaching the holder is		- Laboratory stand with clamp - Counterweight - 3D printed arm of RAIS system - 12 mm thread + 2 bolts - Abdominal ring
	Evaluation of laparoscopic holder	Appendix	Filled in questionnaire “Statements low resource

	statements, determine how suitable the holder is in low resource settings		settings", see Appendix
	Validation phantom test, determine the validity of the phantom test	Appendix	Filled in questionnaire "Validation Phantom test", see Appendix

Force component test

Furthermore, the maximum vertical force component on the holder was measured, in the following set up. By asking the rural surgeon to exert with the laptop cystoscope the maximum vertical force on the holder, via a scale, the maximum horizontal force could be calculated by:

$$F_{maxhor} = m_{measured} * g$$

Resulting from multiplying the maximum measured weight by the gravitational constant, g. This result was used for input for the horizontal force component in the FEM analysis including a safety factor (SF) of 10.

$$F_{FEMhor} = F_{maxhor} * SF$$

Figure 12 Set up Force component test

Phantom test

The final validation for the laparoscopic holder carried out by performing a phantom cholecystectomy, removal of the gallbladder, to simulate the holder in a clinical environment. This phantom model was built with available materials by the project team and is based on (Nagyné Elek & Haidegger, 2022). The phantom model simulates a cholecystectomy, since this type of surgery was found to be the most common procedure during the field study.

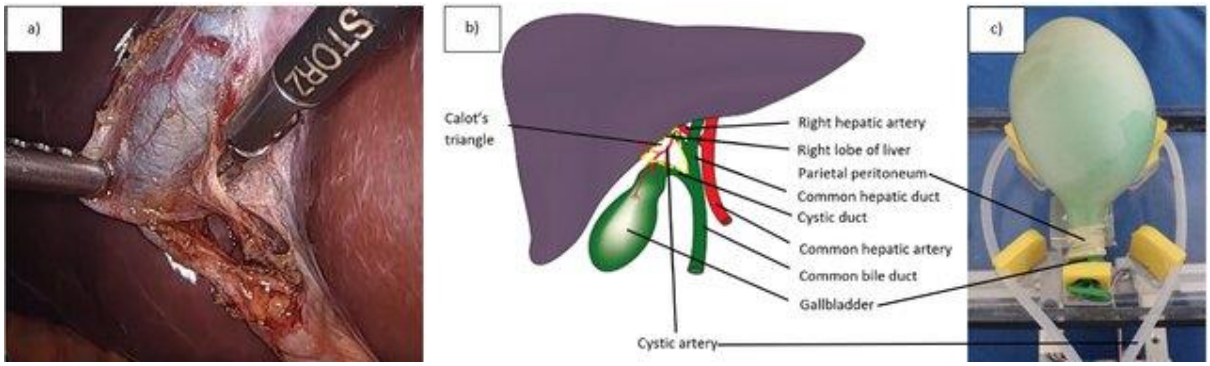


Figure 13 Laparoscopic Cholecystectomy (LC) anatomy and the proposed phantom; (a) Laparoscopic Cholecystectomy surgical scene, after the exploration of the Calot's triangle, which is a critical task in patient safety; (b) Anatomy of the gallbladder and its environment; c) Surgical phantom created for LC with the peritoneum, gallbladder and the cystic artery, which provides the option for abrupt bleeding, intending to mimic a stressful surgical situation (Nagyné Elek & Haidegger, 2022).

The simulations was carried out by an Indian rural surgeon, the initiator of the project. Furthermore, the laptop cystoscope, a zero degree laparoscope which can be directly plugged into a laptop, and several

laparoscopic instruments were made available by the Department of Mechanical Engineering to carry out the fantom surgery. The box contained a replica of the most important atomical reference points of the inside of the abdominal based on (Nagyné Elek & Haidegger, 2022). To simulate a Gas Insufflation Less Laparoscopic Surgery (GILLS), a box with synthetic skin was placed over the cholecystectomy phantom and secured with additional counterweights. The surgeon was given instructions on how to perform the phantom, which can be found in Appendix D Phantom Instructions. The aim was to simulate the movements needed to perform the cholecystectomy while evaluating the field of view, perceived fatigue of the laparoscopic assistant and surgeon.

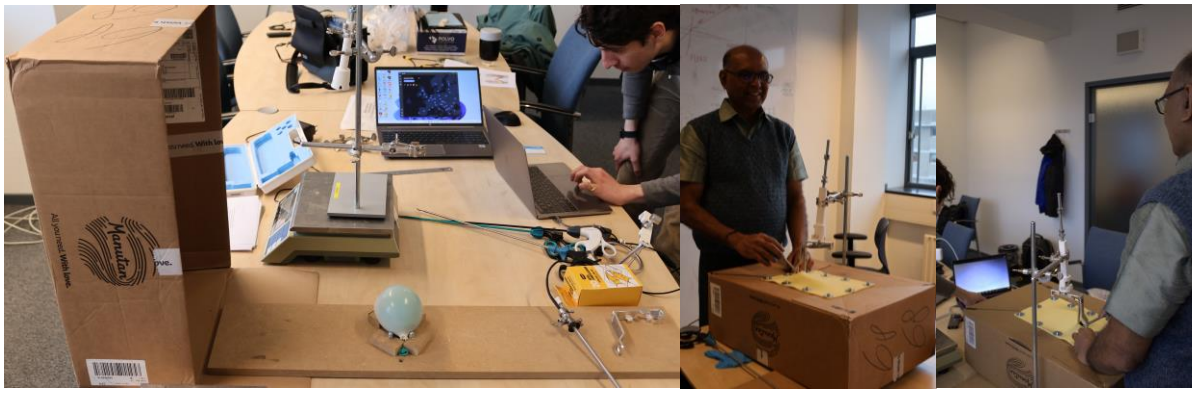


Figure 14 Set up of the phantom cholecystectomy.

RESULTS

Since the project makes use of a fusion of design methods and co-creation is continuously being applied a layout is made to indicate for each phase the used methods, contributors and specific outcomes based on (Piaggio et al., 2021), see **Error! Reference source not found.**. The camera holder was successfully

manufactured as described in Section

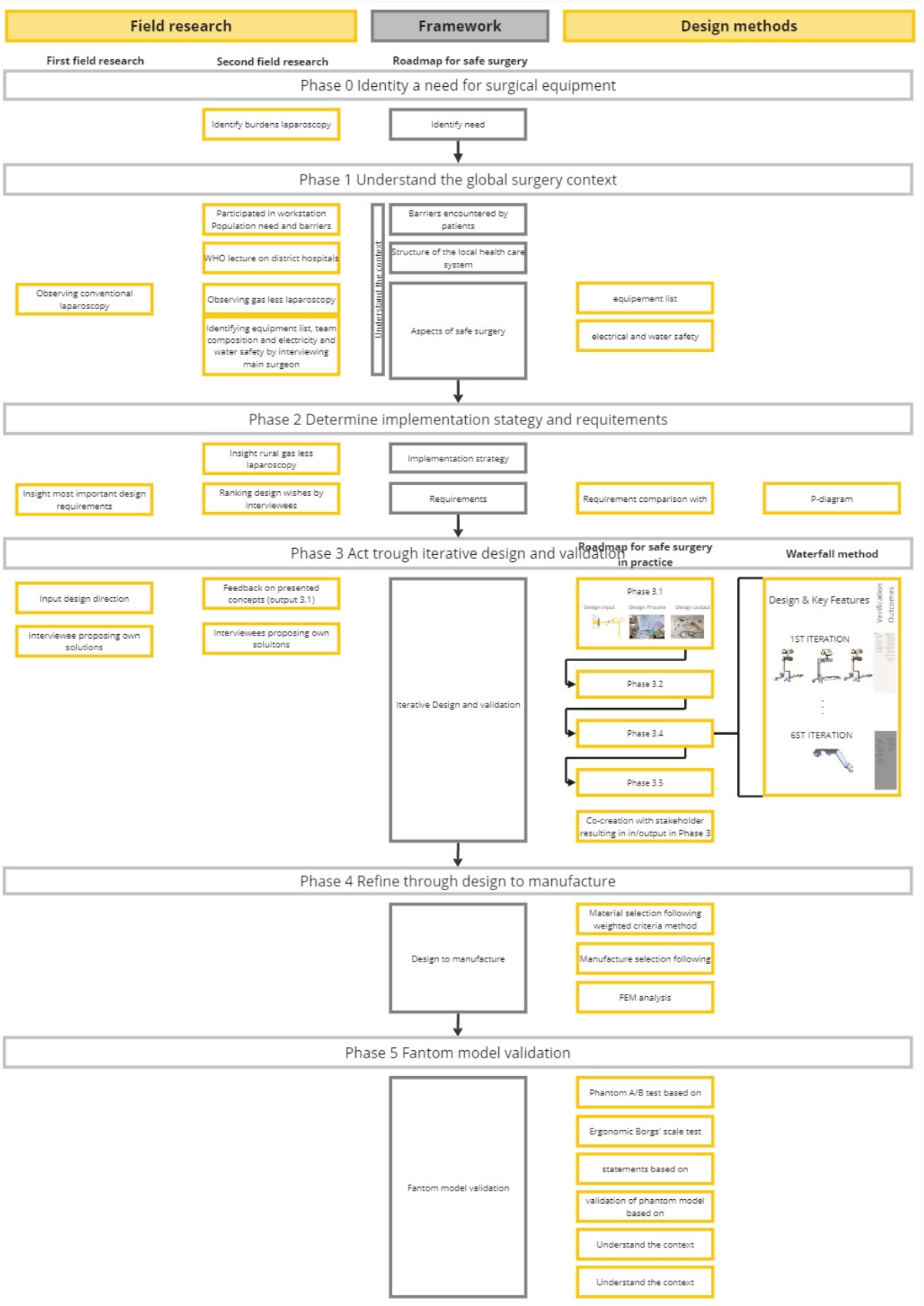


Figure 2 Overview of the 5 design phases and the contribution from the field studies and methods used

.

Roadmap in practice

Phase 0: Identify need

The need for a laparoscopic camera holder was first described by an rural Indian surgeon. This surgeon runs a training program on gas insufflation-less laparoscopy in low resource settings and has implemented successfully gas insufflation-less laparoscopy using the STAAN or RAIS device across rural parts of India and multiple countries in Africa, see Figure 15. The list of hospitals and the specified amount of surgeries performed with the STAAN/RAIS system can be found in Appendix X.

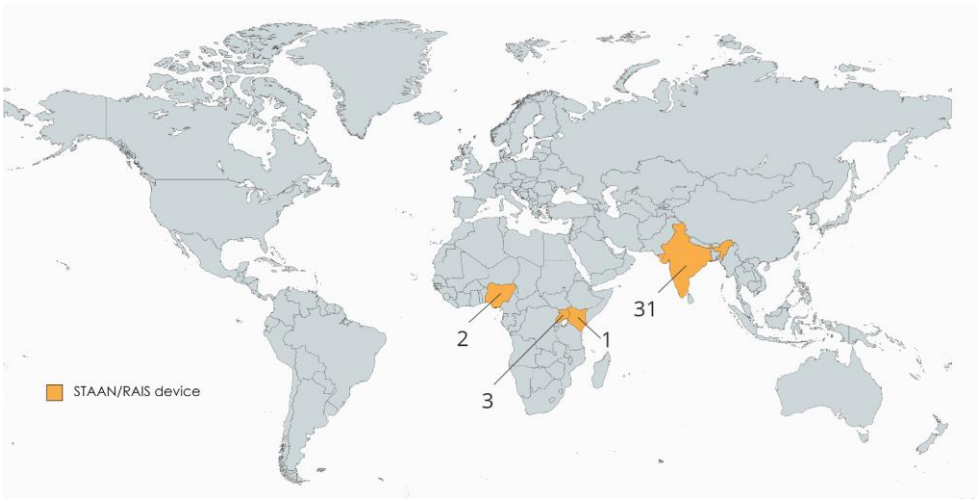
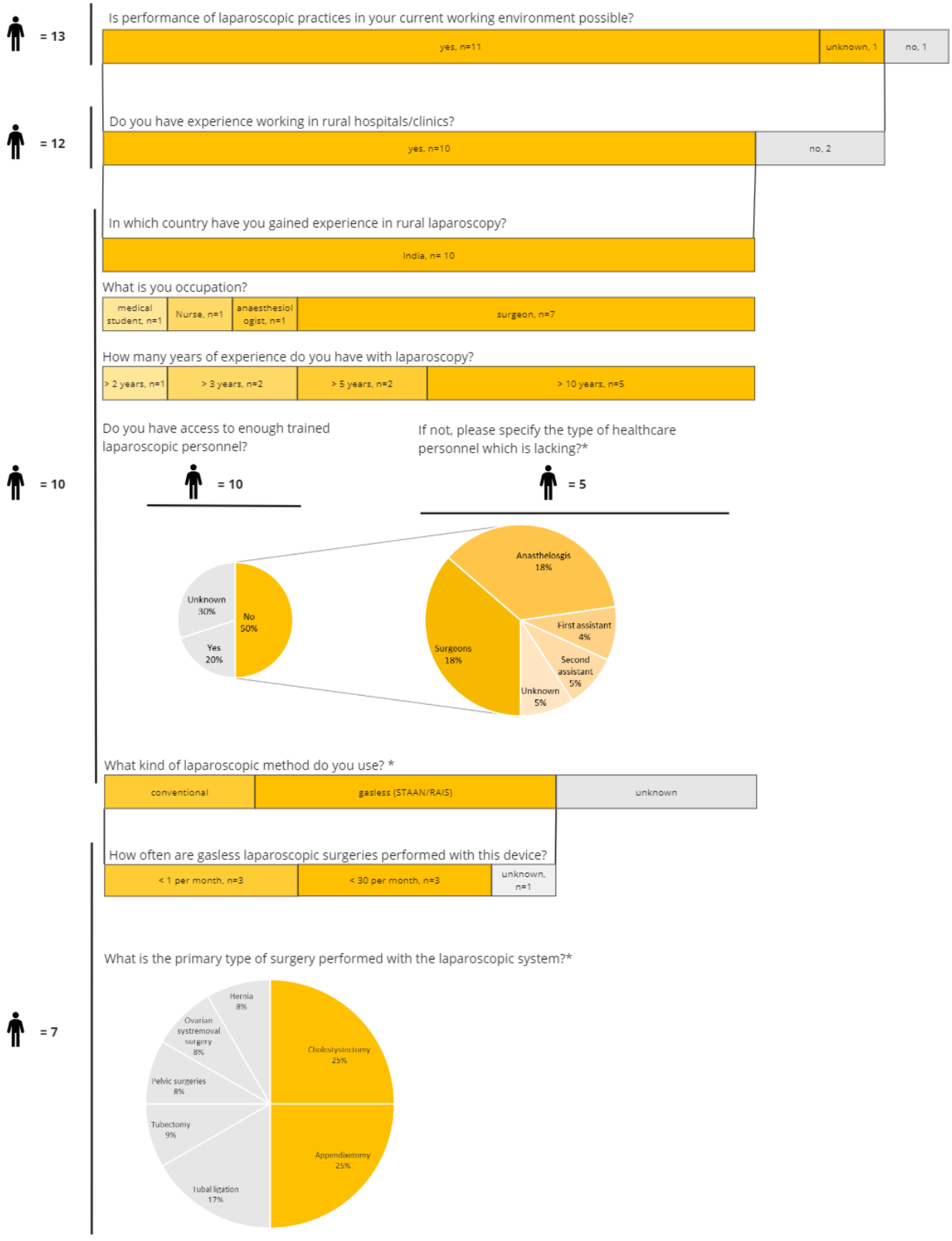


Figure 15 Amount of hospitals per country that use the STAAN/RAIS device or both

The outcome of the second field research resulted in the following result:



*participants could fill in multiple options

As he explained a shortage of trained healthcare personnel and the uncomfortable holding of the camera would result in limited performances of laparoscopic surgery and unstable view and challenging performance of single incision laparoscopy respectfully. Single incision laparoscopy requires that all

instrumentation goes through a single incision, see X. Therefore, it is important to not let the instruments interfere with each other. Especially, creating enough workspace to manoeuvre the instruments but still hold the camera in place. Since space is limited, creating enough workspace by implementing an innovation in a physical space constraint environment is one of the main challenges.

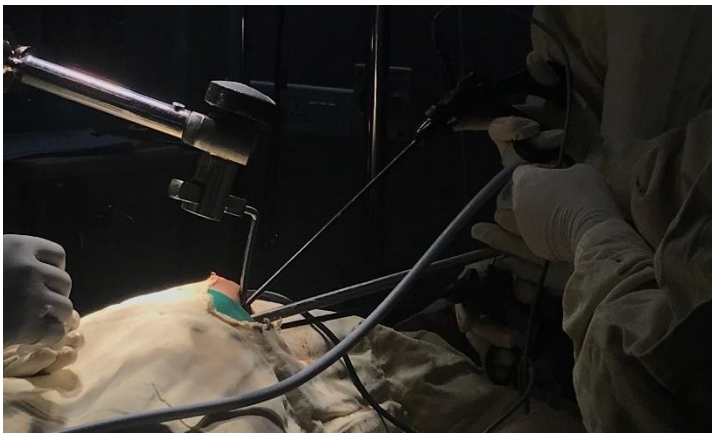


Figure 16 Single incision laparoscopic surgery in H2, second field trip

Phase 1: Understanding of the context

Before patients can access healthcare, The WHO addresses 4 questions that need to be answered with yes before a patient has access to safe surgical care, see Figure 17. In this project we focus on the last 2 phases, Safety and Affordable, by providing a frugal laparoscopic holder. Firstly, by guaranteeing workspace for the laparoscopic instruments without interfering with the laparoscopic camera, a better workflow in terms of time and performance is obtained. Since the surgeon is guaranteed with free space and a stable field of view from above the instruments.

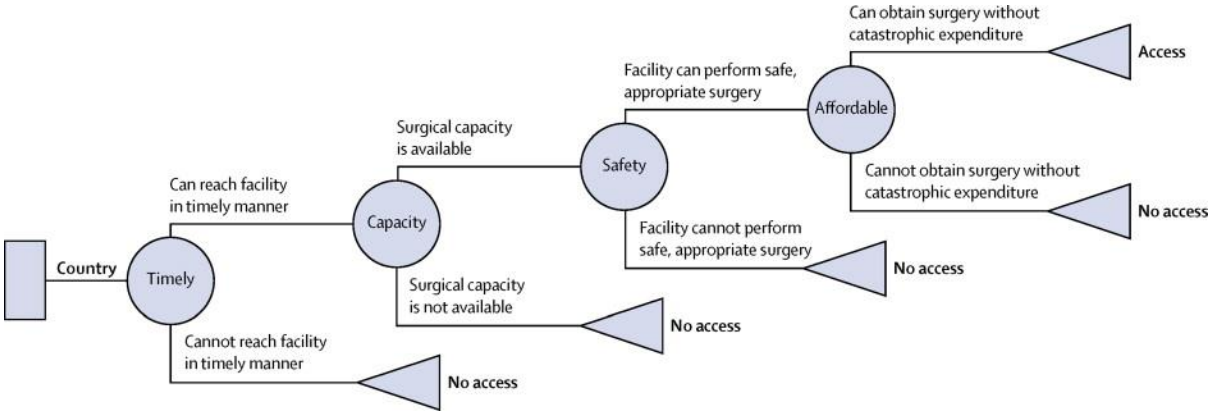


Figure 17 Barries to safe surgical care delivery by (Alkire et al., 2015)

Secondly, by improving the ergonomics of the laparoscopic camera assistant a more stable camera view is obtained. This results in more consistent and precise positioning of the laparoscopic camera. Reducing the likelihood of errors or the need for repeated attempts, potentially decreasing the overall cost associated with procedure time and resource utilization.

By making gas insufflation-less laparoscopy more attractive while this is a frugal technique and is thus less expensive than conventional open or laparoscopy, it is aimed to increase the accessibility of gas insufflation-less laparoscopy.

Phase 1.1 Barriers encountered by patients seeking surgical care

In the workshop Population Needs and Barriers to Operative Care (Gunjan, 2023) method was refined that will teach Indian rural hospitals about patient barriers and start a discussion how they can address them. The following model was obtained:

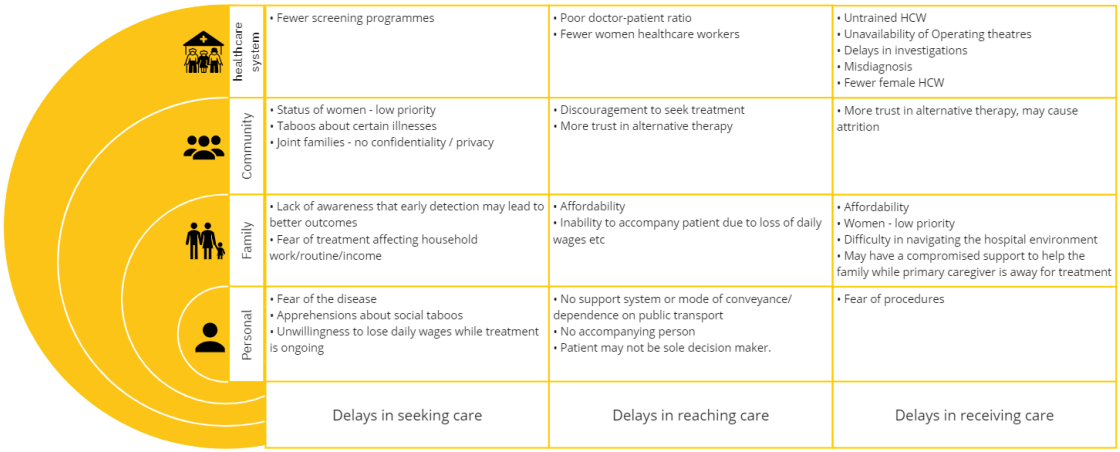


Figure 18 Schematic of barriers faces by patients based on the outcome of the WHO workstation Population Needs and Barriers to Operative Care

Patients seeking surgical care in LMICs face a series of barriers, including: lack of facilities, government corruption and poor health system infrastructure (Grimes et al., 2011). The largest barrier is the financial concern, including both direct and indirect costs. Direct costs are fees for surgery, drugs and supplies, transport and costs for hospital-stays. Indirect costs cover bringing a caregiver to the hospital and loss of income. Health insurance is not yet widely implemented in LMICs, or the insurance does not cover all costs, often resulting in out-of-pocket payments directly to the hospital (Grimes et al., 2011).

Phase 1.2 Structure of health care system

The roots of the surgical system start in the community and primary health centres in Figure 19, where health workers refer patients to the first level hospital or also called district hospitals. District hospitals should provide basic surgical procedures, while more specialized cases should be referred to referral hospitals that also serve as hubs for research and training. In many areas, surgical care is provided by both the public, district and referral hospitals, and the private system (private hospitals). Public hospitals fall under the responsibility of the government, in contrast to the private hospitals and for- and not-for-profit providers (e.g., non-governmental organisations NGO's, mission organisations and traditional healers). The private hospitals are in some areas the largest provider of surgical

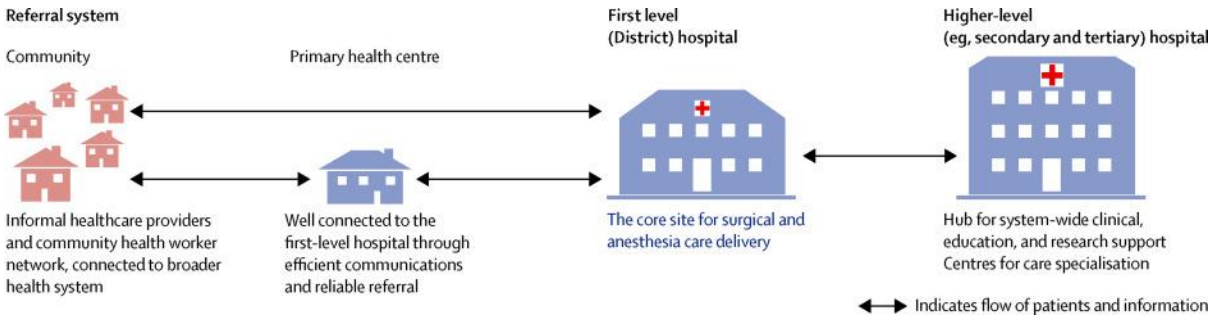


Figure 19 The surgical system: The surgical system is an interdependent network of individuals and institutions that reside within the health system (Meara et al., 2015a)

Since June 2023 India, a lower-middle income country, has the largest worldwide population of 1.4 billion people (United Nations, 2023) and an annual per capita income ranging from $465 (Bihar) to $3788 (Goa).

The governmental healthcare system in India operates across three levels. Primary health centers (PHC), primarily offering outpatient services. Healthcare workers refer patients to first-level hospitals, also known as district hospitals or Primary/Community Hospitals with limited inpatient care of 50-200 beds(WHO, 2023). District hospitals are expected to deliver basic medical services focusing on primary care, while more specialized cases should be directed to higher level hospitals (which also functions as hubs for research and training) .

At the secondary level, community health centers (CHC), 30-bed hospitals with 2–3 doctors, 2–3 nurses, and approximately 20 staff members, are uniformly regulated by the Ministry of Health. Disparities in medical services provided by CHCs are solely based on the income level of the district in which they are located (Chokshi et al., 2016; IPHS, 2011).

In contrast, tertiary centers exhibit significant variations, influenced by national regulatory norms for training program approval, policies established by state and local governments, and the income level of the region. Tertiary centers affiliated with medical schools adhere to higher standards, with those having both medical schools and residency programs offering the highest level of healthcare (Shah et al., 2015).

Public hospitals, under government responsibility, coexist with private hospitals and providers, encompassing for- and not-for-profit entities such as non-governmental organizations (NGOs), mission organizations, and traditional healers. In certain regions, private hospitals emerge as the predominant providers of surgical care (WHO, 2012a).

Phase 1.3 Aspects of safe surgery

During the second field research two rural hospitals were visited, the first rural hospital is a mission hospital in West-Bengal with no prior knowledge of the STAAN or RAIS device. During the week of the project team's observations, the only general surgeon was taught how to use the RAIS device which was brought along by the initiator of this project. During this week multiple gas insufflation-less laparoscopic operations were successfully performed. In the interviews conducted at this hospital special focus was given on the challenges which needed to overcome to start gas insufflation-less laparoscopy and the challenges around the implementation.

The second hospital is a Tribal hospital in Tamil Nadu, which has been using the STAAN device for 5 years. However, on average one patient per three months is operated using the STAAN device due to a shift in focus of the main surgeon who was taught gas insufflation-less laparoscopy with the STAAN device. Therefore, a knowledge gap exist among the new health care workers. The focus was given in the interviews on their previous and day to day challenges.

The main characteristics of the hospitals can be found in Appendix, A. The most important are illustrated below:

Figure 20 The main characteristics of the two rural hospitals visited during the second field study

Both rural hospitals struggled with enough qualitied healthcare personnel. H1 has no in-house anaesthetists, which results on the dependence on the availability of neighbouring anaesthetist. In

practise this means that operations that require and anaesthetist are getting postponed and a special days will be organized for these operations. This is to lower the frequency of hiring an anaesthetist and therefore the overall cost for the patients. Since the hospital has to bare also traveling and cost for the anaesthetist and accommodation if needed. Furthermore, H1 struggled to run the hospital with only one surgeon. H1 facilitates as a nursing school and houses in total 75 nurses in a 3 year program in general nursing and midwifery.
New government rules demanded nurses in H2 to obtain a certificate for most of the procedures they had already been performing in the past, for example giving spinal anaesthesia. The year program to obtain the certificate lead to a lack of first and second assistant in the operation room, since the nurses are following the program for 50% of their time and work the other 50%.

To show the hospitals level of rurality an overview of the available essential medical devices and services is made as indication based on the existing framework of Di Pietro et al., 2020, see Figure 21.

Country	India	
State	West-Bengal	Tamil Nadua
Colonoscope	0	0
Mammograph	0	0
CT-scanner	0	0
Gastroscope	0	1
Infant reanimation centre	1	0
X-Ray Machine	1	1
Ambulance	1	1
Defibrillator	0	1
Ventilator ICU	1	1
Hemocytometer	1	1
Ultrasound machine	1	1
Oxygen systems/cylinders	10	25
Syring pump	1	4
Autoclave for sterilisation	2	2
Operating theatre with basic equipment	2	2
Suction pump	5	7
Infant warmer	5	5
Anasthetic machine	1	3
Fetal monitor	1	0
Neonatal incubator	0	0
ECG machine	2	3
Patient monitor	5	11
Scale for adult	1	3
Scale for newborns	1	1
Pulsoximeter	5	6
Thermometer	10	5
Blood pressure machine/cuff	7	6

Figure 21 The distribution of essential MDs and services within the 2 hospitals. The ranges were substituted with the average value. Red circles individuate a low availability of the MD, yellow circles a medium availability, and green circles a high availability

The study's findings regarding the limited availability of surgical equipment and the factors contributing to this scarcity underscore a pressing need for future research in the field of surgical equipment in rural parts of India. Despite these limitations, this study emphasizes the existing gap between the requirements of hospitals to ensure safe surgical procedures and the resources at their disposal. The availability of surgical equipment is not only crucial for a hospital's capacity to deliver safe surgery but also pivotal in enhancing the job satisfaction of surgical and anaesthesia providers, as the quality of their work depends on the availability of this essential equipment.

D. Infrastructure

A further insight in the infrastructure of the two rural hospitals was gained to address how pressing the infrastructure influenced their ability to provide safe and affordable surgery. From every hospital the main performing surgeon was asked during a semi structured interview to provide input on the status of the hospital's electricity. During an online following up the status of the hospitals water infrastructure got ranked on scale from very good, good, acceptable, poor and very poor.

Table 1 Summary of the information and the ratings of the electrical access, reliability, and safety

Hospital	Average power outages **hours per day**	Rating of the access to the main source of electricity	Rating of the quality and reliability of the electricity of the facility	Available and functional systems for electrical safety	Rating of the electrical safety in the facility
H1	1	Good	Acceptable	EG, IT	Poor
H2	> 1	Acceptable	Very Poor	Very Poor	Good

EG electrical grounding, EN equipotential node, IT isolation transformer

Both Hospitals mentioned the very poor of quality and reliable of the main source of electricity. Accesing the main source of electricity is often no problem. However, both hospitals experience many powercuts during the day, especially in raining season and thunder makes the facility cut of the power beforehand. H1 has installed a back- up generator that can facilitate the operation theater from electricity. However, it can take several minutes for the backup generator to turn on, which can have problematic consequences during challenging operations where fast were quick action is needed. H2 has installed solorpannels to take a first step in making herself independent from the existing grid.

Table 2 Summary of the information and the ratings of the water access, reliability, and safety

Hospital	Water outages(in case running water is available) **hours per day**	Rating of the access to the main source of water	Rating of the quality and reliability of the water of the facility	Available and functional systems for water safety	Rating of the water safety in the facility
H1	< 1	Good	Poor	RH, W	Poor
H2	Unknown	Unknown	Unknown	Unknown	unknown

RH rainwater harvesting, UA underground aquifers, W wells, HWT home water-treatment(such as filters, solar disinfection, flocculants), - none of the systems are available

Water is especially scare in the dry season explained the general surgeon at H1. They have access to a well and during the rainy season they collect water through an underground rainwater harvest system. However, this is insufficient to sustain them throughout the year.

Phase 2: Determine design requirements

Phase 2.1 Implementation strategy

Prior to the first field research, it was established that the RAIS system is packaged in a specific box suitable for autoclaving. Recognizing the available space within the box and the imperative for pre-use cleaning of the holder, it seems a logical progression to incorporate the holder as an integral component

of the RAIS system. After the second research, several participants expressed concerns regarding the lack of suitable equipment. Especially, nurses faced challenges in maintaining sterility of multiple operations over the day that required a the same equipment, when only one piece was available. Consequently, a participant articulated the desire for multiple pieces of the same equipment, as autoclaving takes several hours and will not be ready before the next surgery.

Taking into account the STAAN and RAIS devices which are already in use, an offer would be made to them to purchase 2 or 3 low cost frugal laparoscopic holders. Depending on the final price, the amount of holders can be decided. Since the investment was a grant, no interest is present to make profit, but instead making the RAIS device suitable for wider implementation.

Phase 2.2 Design requirements

A preliminary set of X requirements in X different categories was made based on available literature on frugal innovations (Rossetto et al., 2023), designing for medical devices in low resource settings (Webb et al., 2022) and wishes of the project initiator. During the first field research semi structured interviews with surgeons knowledge about rural laparoscopic surgery let to the identification of 4 major design requirements. To this list 4 additional requirements got added to form the 8 most important design wishes:

		Dr 1	Dr 2	Dr 3
		Rural surgeon	First level surgeon with experience rural surgery	Project member RAIS
1. (later split up into 3 different requirements)	Frugal, 3 conditions: i. focus on core functionalities: Laparoscopic camera holder enables performance of laparoscopic solo surgery ii. substantial cost reduction: The product must cost less than 60% of available alternatives on the market iii. shared sustainable engagement: A minimum of 80% of product weight must be recyclable and uses no single products in usage	x	x	x
2.	Simplicity, Minimizing amount and moving parts	x	x	
3.	Robustness, A lifetime of >10 years			**x**
4.	Local maintenance and repairs, Easy to maintain and spare parts readily available / repair possible in rural setting	x		**x**
5.	Training time, Product must be usable by Product must be usable by personnel with limited training			**x**
6.	Cleaning, Can be cleaned and sterilized in a rural hospital with CIDEX, alcohol rub, autoclave			x

This was evaluated during multiple online meetings with a rural Indian surgeon and a project member of the RAIS device. This 8 design wishes list was used during the second field study to rank the importance of the different wishes against each other. Since, the second field study included semi structured interviews and one group discussion, the results will be shown separately for clarity.

Comparison Ranking literature vs context

After returning from the second field study, literature was found on the ranking of requirements for medical devices for low resource settings across 5 continents. It was decided to compare the results of Piaggio et al. 2021 with the ranking of the individual interviews and the group discussion to get an insight how well our local design requirement rankings would align with a broader/the global perceived importance. This give an indication how well our design might be suitable for implementation globally.

In the global study requirement for the design of medical devices for low income settings was rated by 29 participants, with various expertise areas such as Biomedical engineering 9/29 (31.0%), Clinical engineering 6/29 (20.7%), Medical devices & Instrumentation design 7/29 (24.1%), Life cycle management of MDs 4/29 (13.8%), Health technology assessment 2/29 (6.9%), other 1/29 (3.5%). The assessment was based on a series of nested closed loops involving the relevant scholars and experts from 5 continents. It is unclear whether the participants had experience working in low income settings. If we compare the outcomes, these are the results:

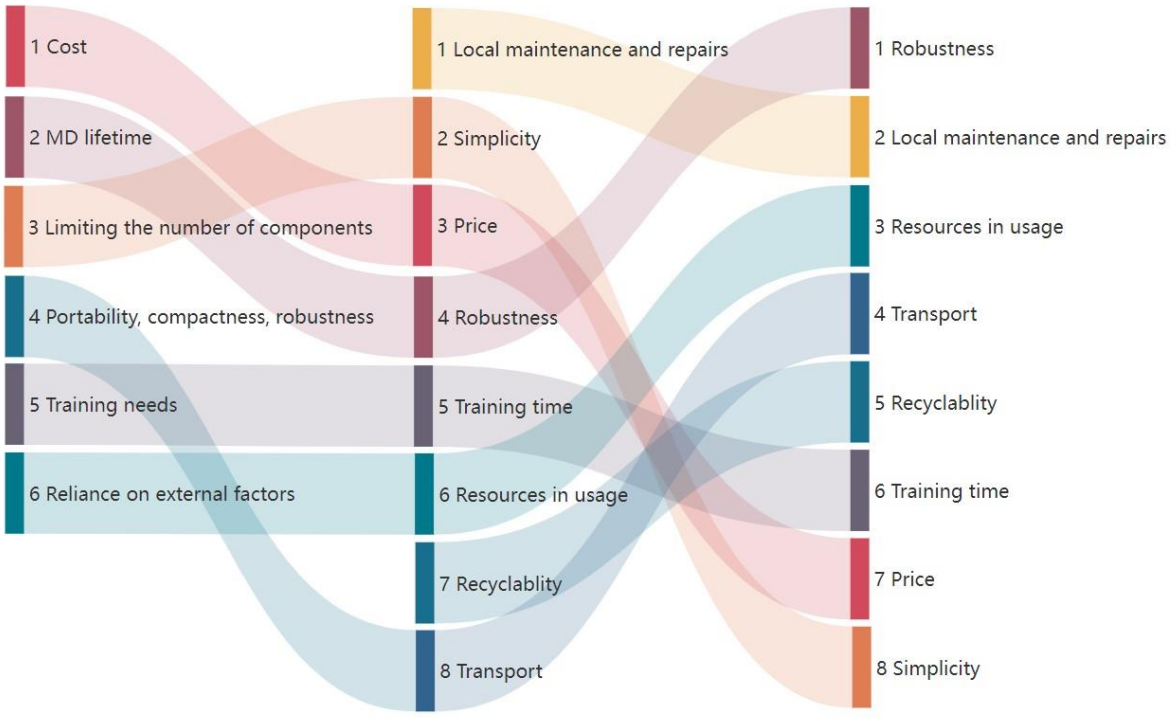


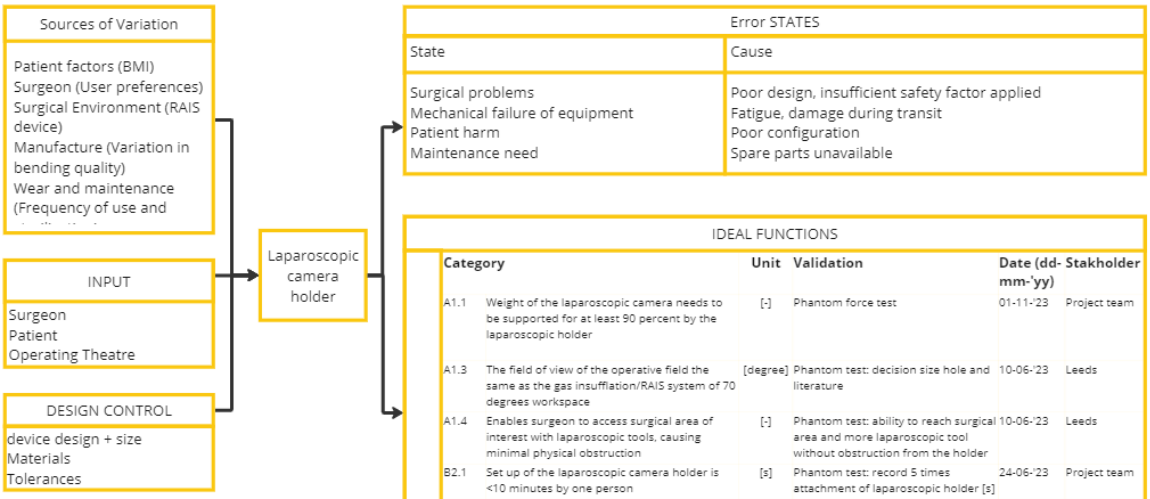
Figure 22 Comparison among requirement rankings from Piaggio et al. 2021 (left), individual interviews (middle) and group discussion (right)

The ranked requirements in Piaggio et al., 2021 have been best fitted with the requirement in this study for comparability. Complete explanation about the mapping of the requirements can be found in Appendix E Requirements.

Several observations can be made:

- Both requirements cost and simplicity are ranked less important in the group discussion than in the found literature and individual interviews.
- Transport is ranked similar except in during the individual interviews. The diversity of the group discussion might have stressed the importance of this requirement, acknowledging the participants of the group discussion were working in two different continents.
- Training time has received an overall similar importance.
- Only in the group discussion is the requirement resources ranked more important on average
- The new introduced requirement 'Local maintenance and repairs' is ranked very important in both individual and group discussion, however this requirement was not included in the found literature.

Based on the new insights, the demands and whishes got more specified to avoid multi-interpretations. The final review happened after the last design iteration Phase 3.5 where the most important requirements are included in the P-diagram, see Figure 23.



Error STATES	
State	Cause
Surgical problems Mechanical failure of equipment Patient harm Maintenance need	Poor design, insufficient safety factor applied Fatigue, damage during transit Poor configuration Spare parts unavailable

IDEAL FUNCTIONS

		Category		Unit	Validation	Date (dd-mm-'yy)	Stakholder
ESSENTIAL	A1.1	Weight of the laparoscopic camera needs to be supported for at least 90 percent by the laparoscopic holder		[-]	Phantom force test	01-11-'23	Project team
	A1.3	The field of view of the operative field the same as the gas insufflation/RAIS system of 70 degrees workspace		[degree]	Phantom test: decision size hole and literature	10-06-'23	Leeds
	A1.4	Enables surgeon to access surgical area of interest with laparoscopic tools, causing minimal physical obstruction		[-]	Phantom test: ability to reach surgical area and more laparoscopic tool without obstruction from the holder	10-06-'23	Leeds
	B2.1	Set up of the laparoscopic camera holder is <10 minutes by one person		[s]	Phantom test: record 5 times attachment of laparoscopic holder [s]	24-06-'23	Project team
	C3.1	Lifetime of >10 years		[years]	Design follows the infinity life design cycles approach/ Maximum occuring stress during operation is below 10 percent of the materials yield stress.	24-06-'23	Project team
	C3.2	The maximum movement of the laparoscopic holder in x,y and z direction attached to the abdominal ring is less than 3mm		[mm]	FEM analysis, maximum displacement is 0.03mm	1-12-'23	Project team
	C3.3	Product must be able to sustain 25N vertical/down force		[N]	FEM analysis; maximum Von Misses stress is below fatique stress model at 1e7 cycles	10-06-'23	Project team
	D4.1	Product must be compatible with the all the sizes of abdominal rings of the LEEDS and field research version of the RAIS device		[-]	Holder fits all abdominal rings	24-06-'23	Gnanaraj
	D4.2	Product must adapt to an abdominal wall thickness corresponing to a person with a BMI up to 25.		[-]	Test holder with different abdominal wall thicknesses	14-10-'23	Gnanaraj
	D4.3	Product must be compatible with 0 and 30 degree laparoscopic camera during surgery		[-]	Phantom test perfomed with largest workspace needed by persoming the test with a 0 degree laparoscope	14-10-'23	Gnanaraj
	E5.1	Laparoscopic holder is autoclavable in a rural hospital		[-]	CES EDUPACK, AISI 316L is excellent autoblavable	24-06-'23	Gnanaraj
	E5.3	Material is alcohol resistance so laparoscopic holder is able to be able to be cleaned by alcohol rub in a rural hospital		[-]	Good resistance against rubbing alcohol(Alcohol, Isopropy) 112	27-11-'23	Leeds
	F6.1	Easy to maintain and spare parts readily available / repair possible in rural setting		[-]	Phantom test: statement check. No medical grade material or bending/welding is possible in rural settings	24-06-'23	Project team
	F6.2	Local maintaince and production of spare parts is possible		[-]	Phantom test: requirment check	24-06-'23	Project team
	F6.3	Material has to be medical grade, suitable for medical application		[-]	Medical graded materials in CES EDUPACK	27-11-'23	Norms
	G7.1	The laparoscopic camera holder uses no single products in usage		[-]	No single used producst are needed during usage	24-06-'23	Project team
	G7.2	Product must cost less than 5 euros		[Euro]	cost analysis	21-11-'23	Gnanaraj
	G7.3	A minimum of 80% product weight must be recyclable		[-]	CES EDUPACK, AISI 316L is recyclable	24-06-'23	Project team
	I8.1	Placing and using camera holder can't damage tissue(no sharp edges and max applied forze per m^2 is __N)		[N/m^2]	All edges are rounded and holder does not come in contact with tissue during operation	10-06-'23	Leeds
DESIREABLE	W1.3	Laparoscope holder enhances the percieved stability of the laparoscopic camera		[-]	Phantom test	24-06-'23	Project team
	W2.1	The product must be usable by personnel with as little training time as possible		[-]		24-06-'23	Project team
	W2.2	The holder should be as light and compact as possible (for transporation and storage)		[-]		24-06-'23	Project team
	W7.1	The laparoscopic camera should be as cheap as possible		[Euro]		24-06-'23	Project team
	W7.2	Minimizing the amount and moving parts		[-]	Holder exist out of 1 part	24-06-'23	Project team
	W7.3	Can be maintained and repaired using as much as possible local resources		[-]		24-06-'23	Project team
	W7.4	Uses as little as possible resources during usage(electricity, water, etc.)		[-]	Holder does not require additional resources during usage	21-07-'23	Project team
	W7.5	As much of the product can be recycled		[-]	CES EDUPACK, AISI 316L is recyclable	24-06-'23	Project team

Figure 23 Final P-diagram

Phase 3: Concept Development and validation

This Phase started by evaluating the existing laparoscopic holder found in literature. It was concluded that both passive system as active systems were unsuitable for low resource settings due to the purchasing price and resources needed for maintenance.
After an initial set of concepts was developed a categorization was made during a project group workshop. The reason was to identify all possible design directions, see Figure 24. Three of the most promising concepts got low fidelity prototyped, to get an indication about the space the concept required, this was the outcome of Phase 3.1

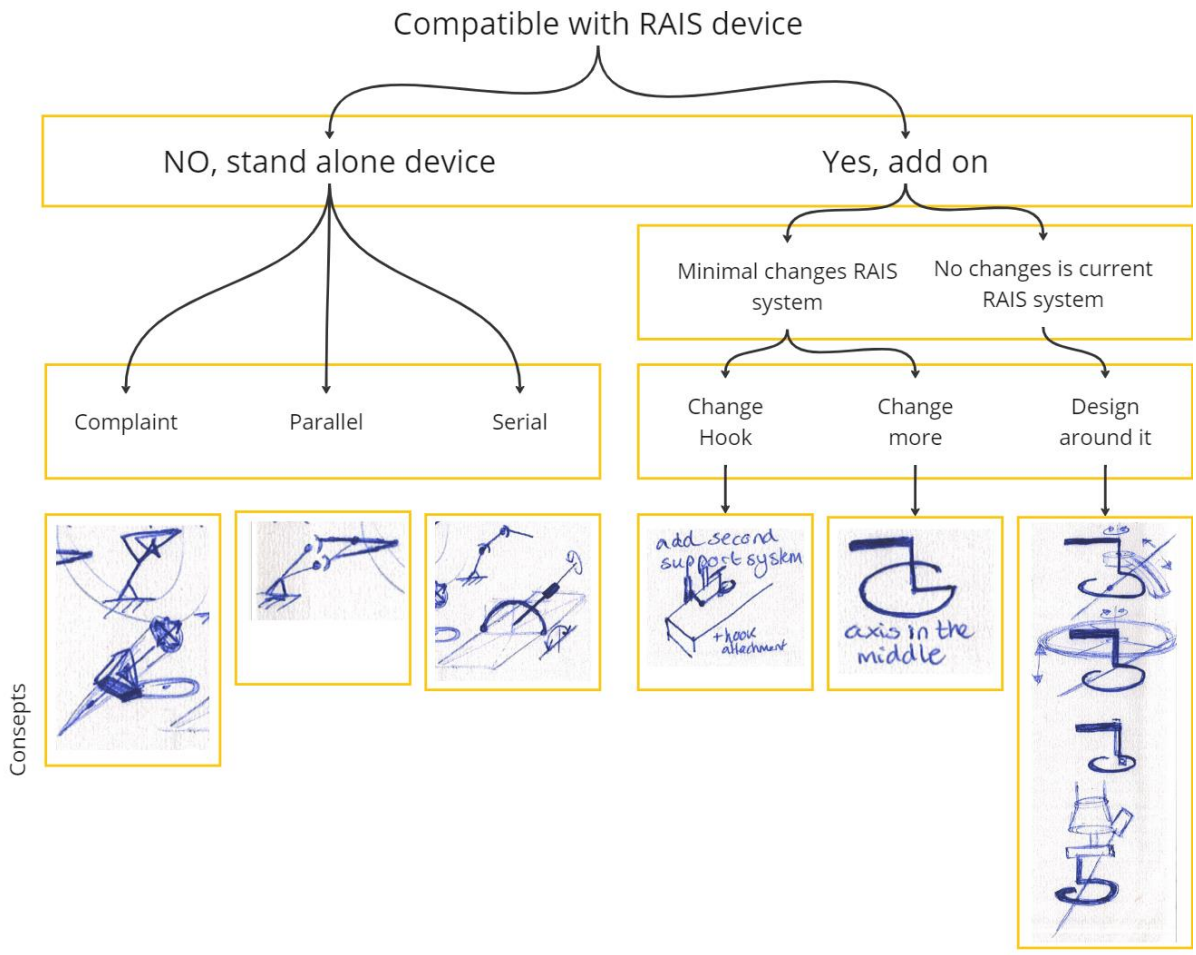


Figure 24 Overview of the different design directions

In this phase, 5 complete design iterations are made, as summarized in Figure 25. After, the establishment of the new design problem during the second field study, the focus shifted in Phase 3.3 to

'Design a product to improve the ergonomics for healthcare personnel that holds a laparoscope during surgery in low resource settings'.

Phases 0 -1

- Literature study
- In-country contextual research
- Forming of collaboration and partnerships (feedback group)

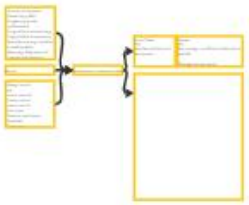
Phases 2

- Requirements and P- Diagram
- Evaluation of requirements through feedback group

Phase 3.1

Design input

- Requirements
- P- Diagram



Design Process

- Frugal innovation
- Interdisciplinaire goup workshop

Design output

- Low-fidelity prototypes

Phase 3.2

Design input

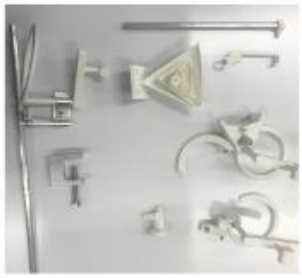
- Evaluation University Leeds (presentation to Dr Culmer)and Indian surgeon(zoom meeting with Dr

Design Process

- 3D printing

Design output

- Low-fidelity prototypes



Phase 3.3

Design input

- WHO symposium in Delhi, India
- Research at rural hosipitals at Calcutta and Sittling, India
- Functional feasability confirmed usign semi structured feedback from end-users (rural surgeons() and assistants())

Design Process

- Concept selection
- 3D printing

Design output (India)

- Medium-fidiality prototype

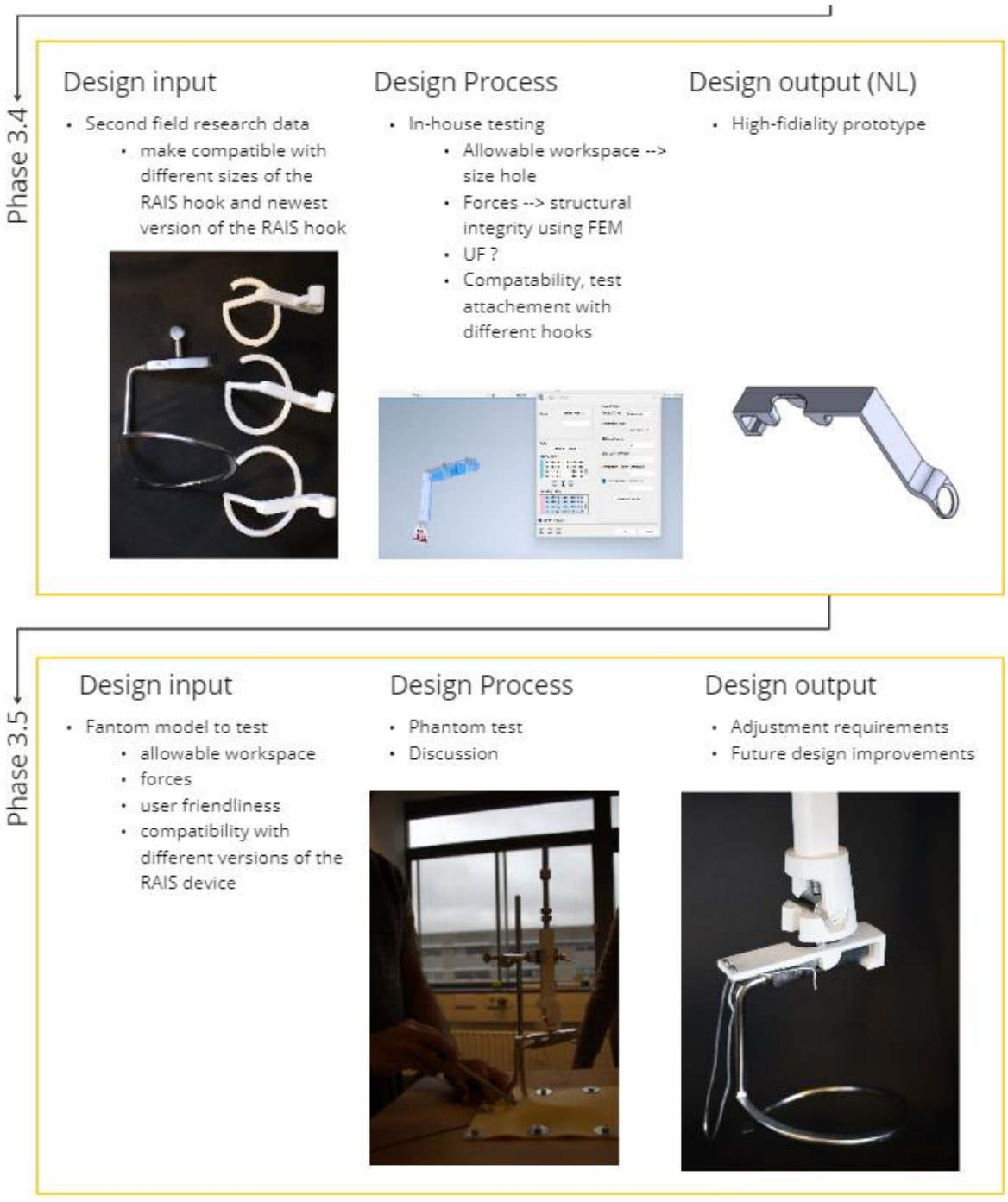


Figure 25 Roadmap in Practice illustrating the 5 iteration cycles of Phase 3 in detail

In Figure 26 the design input, process and output are explained to give a detailed overview of the iteration cycles. Phase 3.1 and 3.2 describes the design iterations that resulted in the evaluated concepts during the second field study. Phase 3.3 describes the design iteration during the second field study. Nine out of 13 participants preferred Concept B over the other concepts, naming simplicity and robustness as most often factors. Phase 3.4 describes the iteration process with the gained input from the second field study resulting in the concept used for testing in the Phantom study which resulted in future design improvements in Phase 3.5. To provide details of iteration process 3.4 the waterfall is applied and

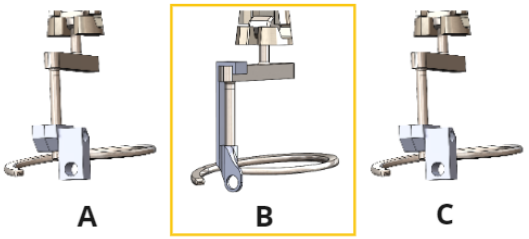
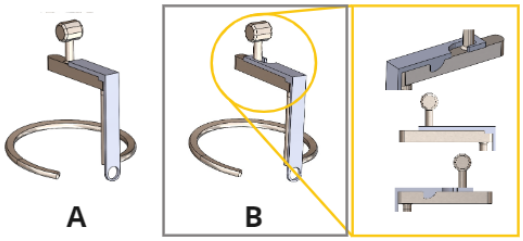
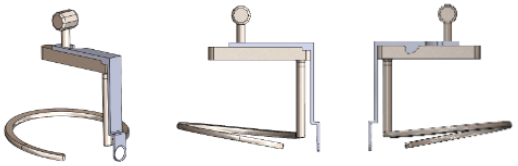
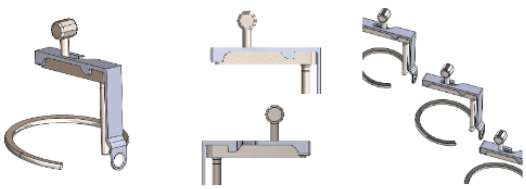
Figure 26 position of the 4 i profiles of the different abdominal rings (top view)

shown in. Figure 28.

The waterfall method shows in 6 iteration how the feedback from the second field study is processed. New problems arose and were addressed, for example the compatibility with all the RAIS abdominal rings. Due to the slight variation of position of the i profile on the rings a long sloth had to be introduced since it was not possible to make individual sloths, see Figure 27. This resulted in an extra degree of freedom since the horizontal direction was not constraint, see 3rd iteration. Therefore, a back support needed to be introduced, see 4th iteration that extended to the end of the horizontal part of the abdominal ring.

Figure 27 Tilting problem occurring in medium size abdominal ring in iteration 4

The medium sized abdominal ring tilted during the tests, resulting in extending the support till the bottom of the abdominal ring, see iteration 5. Combining this solution with optimization on the shape of the sloth, shape of support to reduce manufacture complexability and configuration of the side wings, the design in iteration 6 is obtained. For each iteration the verification method and outcome is stated:

	Design & Key Features	Verification	Outcomes
1ST ITERATION		• Semi structured interviews with surgeons, nurses (end users) evaluating low-fidelity 3D printed prototypes	• Designs do not incorporate thickness of abdominal wall, current attachment damage skin. • Concept B in favour for being single part • First interest in manufacturing shown
2ND ITERATION		• Low fidelity 3D printed prototype evaluated by local expert	• Attachement B found to be sufficient • Hole size to small to allow for whole camera workspace • Bottom of hook limits instrument workspace by covering incision
3RD ITERATION		• Low fidelity 3D printed prototype evaluated by local expert	• Hole size still too small, further testing required in The Netherlands • Design not compatible with other hook sizes and RAIS versions
4TH ITERATION		• Low fidelity 3D printed prototype evaluated by "in-house" project team	• Holder fitted RAIS version Leeds but not to RAIS version B due to thicker i base • Tilt problem detected with medium size hook of RAIS version Leeds due to sloth at the top

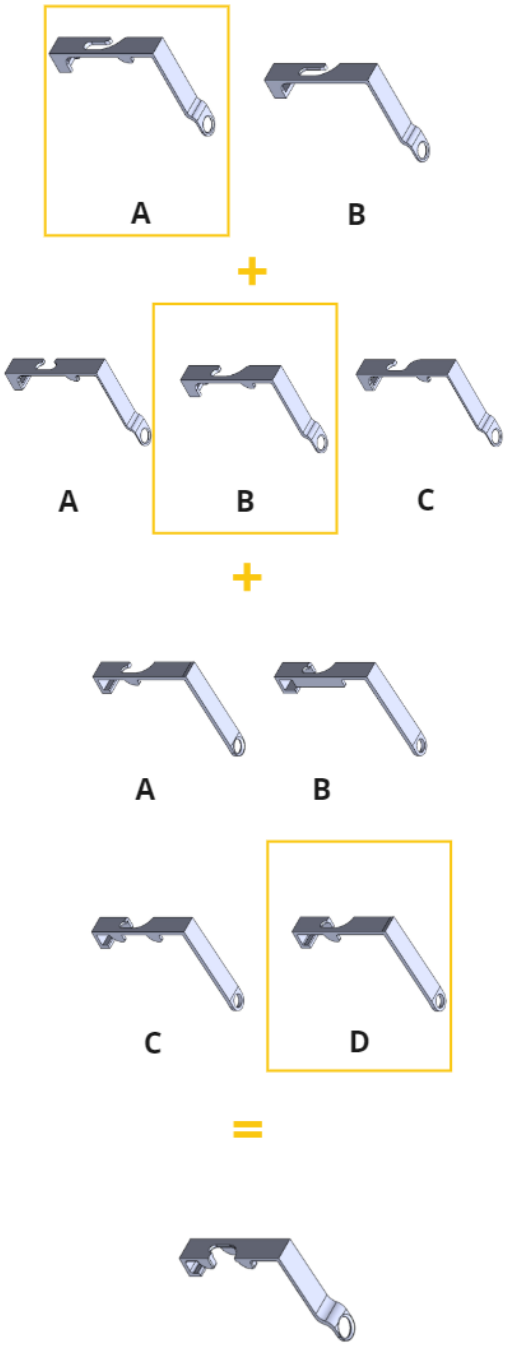
	Design & Key Features	Verification	Outcomes
5TH ITERATION		• In house tilting problem solved by introducing base under horizontal bar of RAIS hook	• not easy to attach holder to abdominal ring due to limited sloth opening
		• Minimalizing material and optimizing for easy (de)attachment of holder to RAIS hook by opening up the sloth. Three configurations were tested	• Inclosure at the back complex to manufacture
		• Integrated angle into design to make compatible for newest version of the RAIS hook (metal version) • Combinations of different shape locking configurations of the side wings to optimize stability and easiness of (de)attachement	• (De)attachment is found easy by project team • Stability of holder to the different abdominal rings have been found sufficient • Final dimension of the hole needs to be determined • Holder is easier to operate for people with left hand dexterity • 3D printed protoypes do not fulfill behaviour of metal material
6TH ITERATION		• Metal holder with different hole sizes 14,5-16,5,18,5 mm were made • Mirrored design to better suit right handed persons • Aluminium version prototype evaluated by rural surgeon in fantom study	• Prefered hole size: 16.5 mm to obtain similair FOV • Stability of holder is find suitable for its purpose • (De) attachment "very easy" by rural surgeon • Expressed flexability so holder can be adjusted to different incision positions

Figure 28 Waterfall method describing Phase 3.4 in detail

Phase 4: Refine through design to manufacture

This phase focusses on finding a first a suitable production technique and material to manufacture the proposed solution in Phase 3. Secondly, knowing the material, a FEM analysis is made to investigate the holders behaviour under the found forces during the user test. Thirdly, the design of the holder is adapt to fit the found production technique.

Material and Production selection

According to ISO 10993-18 of a medical device that will come into direct contact with the human body a chemical characterization of the material is needed . Due to time constraints, only materials that are already certified for medial application are included in the material selection.

To find a suitable process technique the most relevant demands and wishes have been listed below, for the complete list see Appendix E Requirements.

Table 3 Demands and wishes regarding material selection

		Unit	Validation	Date	Stakeholder
F6.1	Easy to maintain and spare parts readily available/repair possible in rural setting	[-]	Phantom test: requirements check	xx-xx-'xx	Project team
F6.2	Local maintenance and production of spare parts is possible	[-]	Phantom test: requirements check		Project team
F.6.3	Material has to be medical grade, suitable for medical application		Medical graded materials in CES EDUPACK		Norms and regulations
F6.4	Optimize production technique for a batch size of 20 pieces				Gnanaraj
E.5.1	Laparoscopic holder is autoclavable in a rural hospital	[-]	CES EDUPACK, temperature tolerance needs to lay above 132 degrees Celsius		Gnanaraj
E5.2	laparoscopic holder is able to be able to be cleaned and sterilized with CIDEX in a rural hospital		CES EDUPACK		Leeds
E5.3	Material is alcohol resistance so laparoscopic holder is able to be able to be cleaned by alcohol rub in a rural hospital		CES EDUPACK		Leeds
E5.4	Surface roughness, according to ISO 1672:2020 the surface roughness is maximum 0.8 um	[um]			
W7.1	The price of the laparoscopic camera should be as cheap as possible	[Euro]			Project team
W5.2	Material has a strong acids resistance				
W5.3	Stress corrosion cracking				

W6.1	Weldability	[-]	CES EDUPACK, AISI is weldable and no post and pre heating is required	27-11-‘23	Norms

The above wishes have been ranked on their importance and given a weight to define their relative importance. This is needed to choose, via the Weighted Criteria method, the most suitable material out of the materials that have met the above described demands and found production technique.

Table 4 Ranking of the different material wishes and given weight

	Wishes material selection	Weight
1	The price of the laparoscopic camera should be as cheap as possible	10
2	Strong acids resistance	7
3	Stress corrosion handling	4
4	Weldability	3

In 5 steps the most suitable production technique, according to the material requirements defined in Table 3, is selected.

Step 1: Possible machining methods

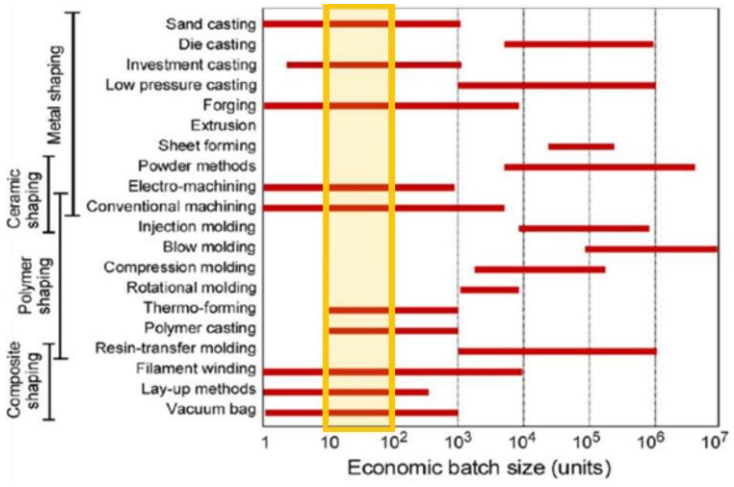


Figure 29 Economic viable methods highlighted for production of a batch size of 20 pieces based on (Proxom, 2023)

The required batch size is 20 pieces, according to requirement . This means, a batch size between 10 until 10^2. From Figure 23 the economic viable production methods can be derived, and are listed below categorized by which material type is used:

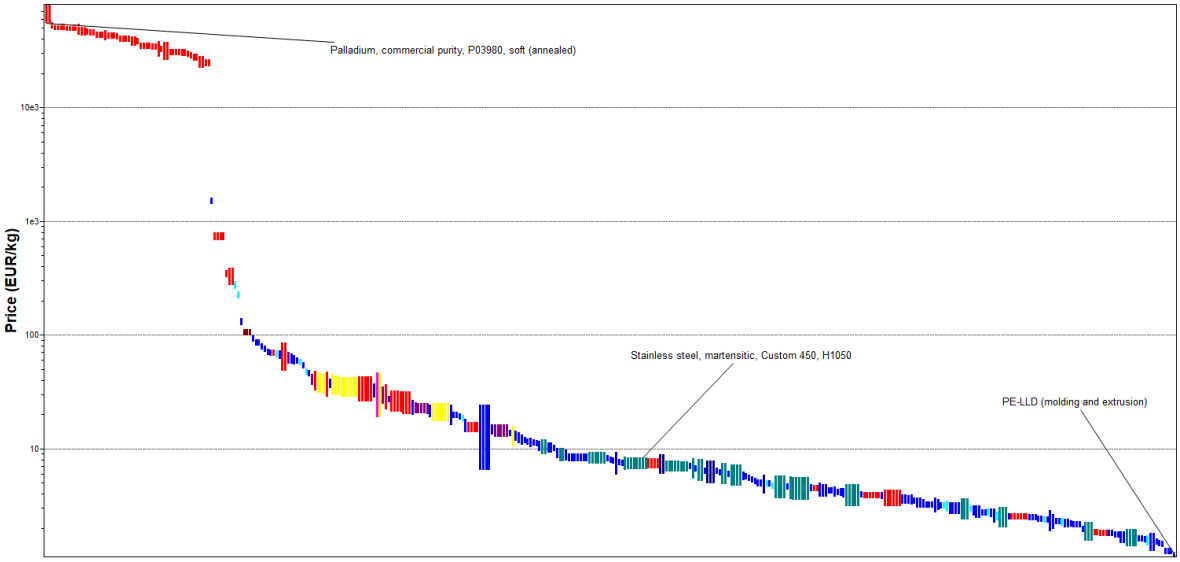
Table 5 Economic viable production methods considering a batch size of 20 pieces

Material	Production technique
Metal	Sand casting
Metal	Investment casting
Metal	Forging
Metal	Electro-machining
Metal	Conventional machining
Polymer	Thermo-forming
Polymer	Polymer casting

Composite shaping	Filament winding
Composite shaping	Lay-up methods
Composite shaping	Vacuum bag

Step 2: Possible materials for medical surgery

All materials in the library Medical graded materials in CES EDUPACK are considered and the details can be found in Appendix G CES EDUCPACK material selection.



The second demand is autoclavable, only materials that have excellent sterilizability using autoclave have been considered in the next step. Since, both rural hospitals that were visited during the second field research had access to autoclaves, it is considered a suitable cleaning method for low resource settings.

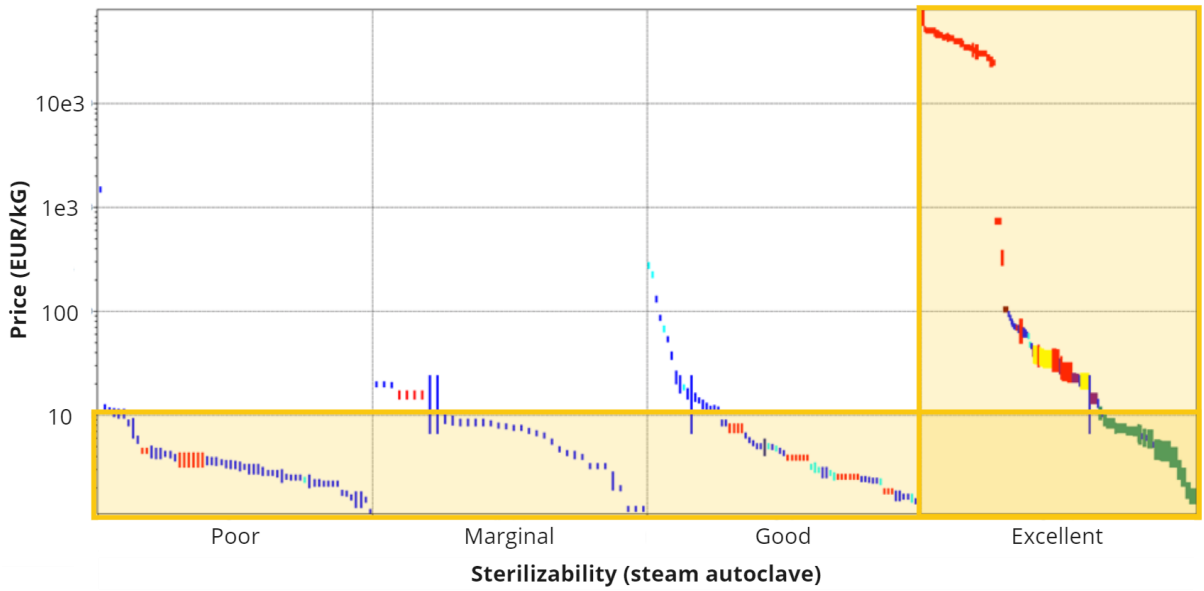


Figure 30 Highlighting the materials with a maximum price of 10 euros/kg and excellent sterilizability by autoclaving

Looking into the price of the materials, a max price of 10 euro per Kg is chosen to ensure the material cost does not exceed the total price of 5 euros, set in Requirement G7.2, as the maximum weight is estimated at 0,5 kg.

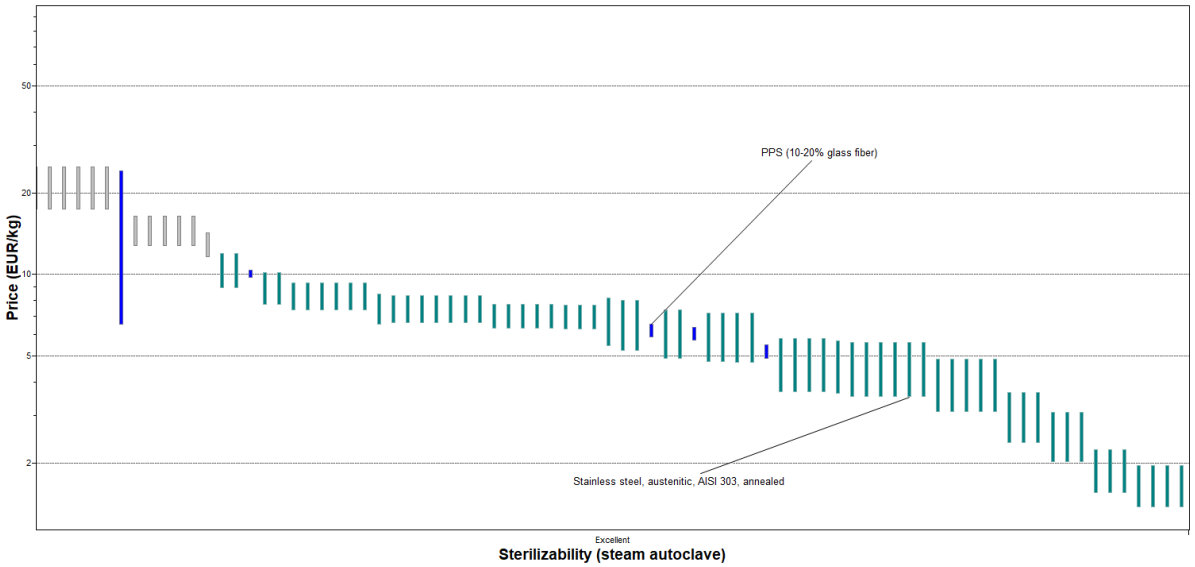


Figure 31 Available materials after applying initial set of material demands (CES EDUPACK)

Based on Figure 31, two material categories can be chosen: Polyphenylene Sulpfide (PPS's) or Stainless steels. However, Requirement G7.3: A minimum of 80% product weight must be recyclable and PPS's are not recyclable. Therefore, it is known that the laparoscopic holder will be made from a stainless steel. This narrows the economic viable production processes listed in Table 5 down to: Sand casting, Investment casting, Forging, Electro-machining and Conventional machining.

Metal	Sand casting
Metal	Investment casting
Metal	Forging
Metal	Electro-machining
Metal	Conventional machining

Step 3:

The last demand is have a surface roughness of maximum 0.8 um. For the 5 remaining production techniques, highlighted in Figure 32, finishing is needed to ensure the maximum surface roughness of 0.8 um.

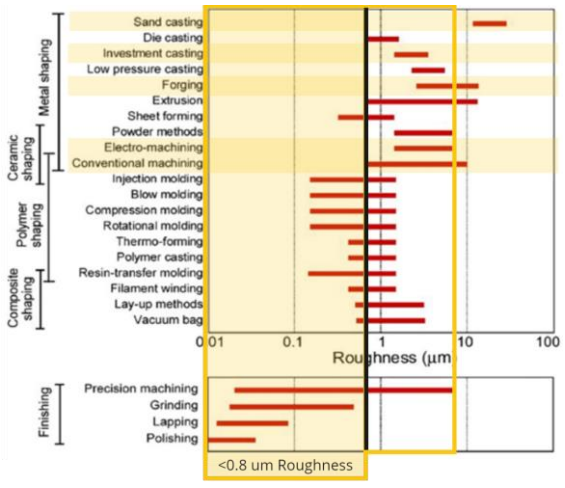


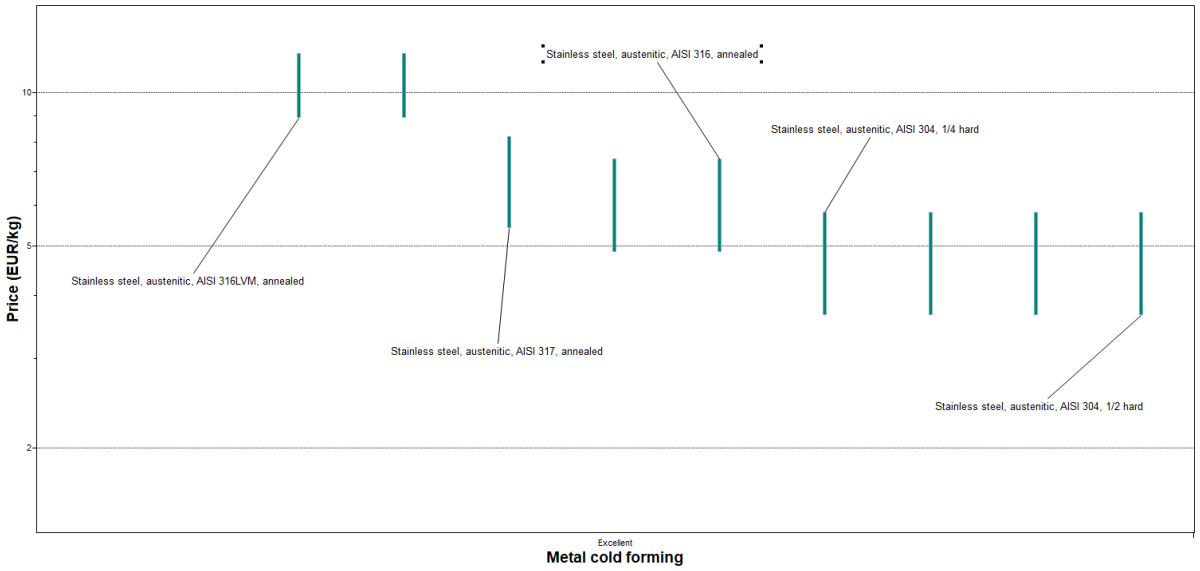
Figure 32 Production techniques with a surface roughness between 0.2 and 0.8 um based on (Proxom, 2023)

Although, several other production techniques than conventional machining can be brought down by finishing to a surface roughness of maximum 0.8 um, it requires more advance tool and production steps. Therefore, based on demand DD wish WW: Product process should have the least amount of production steps, this leaves conventional machining as the most suitable production method that fulfils the batch size and surface roughness demands.

Part 4: selecting the stainless steel

Now various types of stainless steel are available. Based on step three it is chosen that the stainless steel needs to be processed by metal sheet forming. This means bending etc. of a metal sheet. This results in two demands: the stainless steel has to be able to be processed by sheet forming and it needs to be forged to get to a sheet.

Only materials that can handle sheet forming excellent are selected.



This leaves 9 possible materials consisting of three categories, AISI 317, AISI 316 and AISI 304. These three categories will be compared in GRANT EDUPACK. All materials are biomedical materials, medical grasde ISO 10993 used for surgical instruments.

Table 6 Properties of the 3 possible material categories

category	AISI 317	AISI 316L	AISI 304
Price [Eur/kg]	5.4-8.2	4.8-7.4	3.65-5.81
Strong acids	Acceptable	Excellent	acceptable
Stress corrosion cracking	Slightly susceptible	Slightly susceptible	Susceptible
Weldability	No post and pre heating required	No post and pre heating required	Post and pre heating required

AISI 316L shows excellent properties for acid environments. As cleaning may also happen with strong acids, this material might suit better. However, it is more expensive than AISI 304. 316L is also better

weldable if needed. To make a decision, the Weighted Criteria method is continued where for each material wish the materials suitability compared to each other is listed down based on Table 6.

Table 7 Outcome of the Weighted Criteria method, ranking the wishes from 1 = least suitable to 3 = most suitable

Property	AISI 317		AISI 316L		AISI 304	
Price	1	1*10 = 10	2	2*10 = 20	3	3*10 = 30
Strong acids	1	1*7 = 7	3	3*7 = 21	1	1*7 = 7
Stress corrosion	2	2*4 = 9	2	2*4 = 8	1	1*4 = 4
Weldability	3	3*3 = 9	3	3*3 = 9	1	1*3 = 3
total		35		58		44

Based on Table 7 the material AISI 316L is chosen. The L stands for low in carbon, which makes it better resistance against acids.

Changes in design to suit manufacture and hygienic standards

In the previous section it is concluded that the most suitable production method is conventional machining. Making use of SOLIDWORKS environment Sheet Metal, the design is reconstructed from a plate with a thickness of 3mm. The design was modified to meet the ISO 1672:2020 for cleanability, the NORM and respective part drawings can be found in Appendix H Part drawing metal sheet.

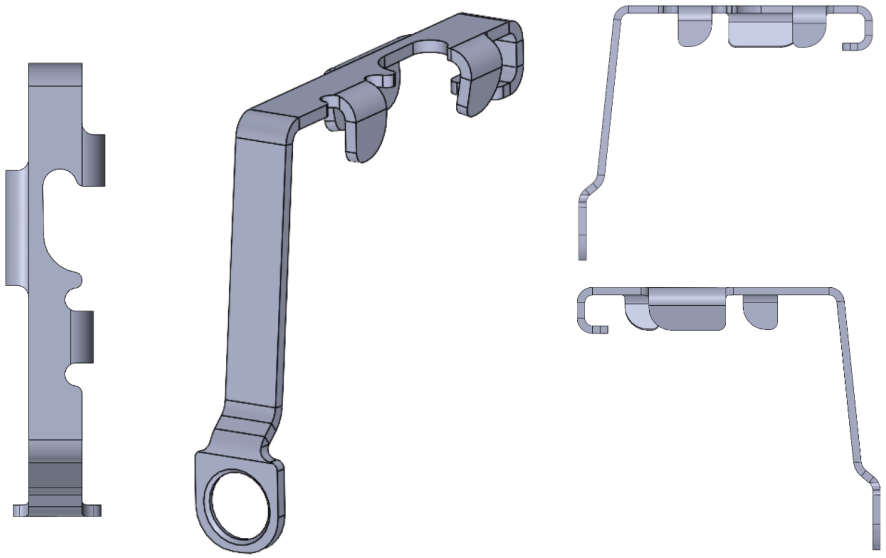


Figure 33 The design of the laparoscopic holder suitable for metal sheet forming, top (left), in perspective (middle) and sides (right)

The norm ISO 1672:2020 advices further to design with at least components as possible for a cheap production process and robust design. Ince the holder exist out of one part a robust design is obtained which is 100 percent recyclable.

The design in Figure 33 was sent to the Indian manufacturer for validation on the manufacturing process, available material and production price. He explained that he is aware of companies that could laser cut the holder to later bend it as proposed. An initial batch of max 15 holders would cost around 600 rupees per piece. Once the design is final he states*:*

"Once the design is frozen and final, this part can definitely be made below 500(5,55 Euros) or even below 200 Rs(2,22 Euros)." ~ Indian manufacturer

This indicates that the final holder can with reasonable evidence be sold below the set purchasing price, meeting demand G7.2: Product must cost less than 5 Euros.

FEM analyses

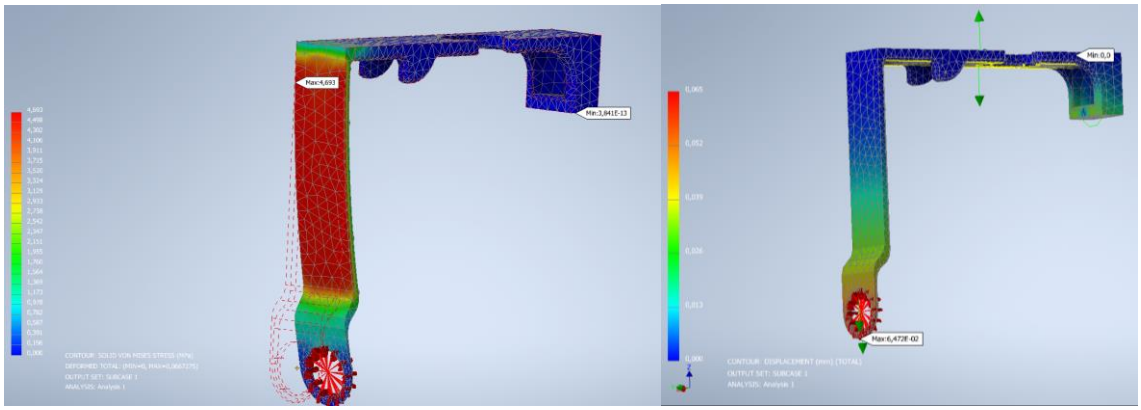


Figure 34 FEM analysis showing the displacements on the designed laparoscopic camera holder

After a preliminary Finite Element Method (FEM) analysis it was concluded that the holder was suitable to withstand the expected load. This is based on the stresses of the holder that all lay below the Yield stress of 450 MPA where plastic deformation would occur in steel AISI 316L. A maximum displacement of 0,06 mm at the bottom of the holder, see Figure 34.

This preliminary result got refined by performing a FEM analysis on the laparoscopic holder suitable for production by bending sheet metal. The horizontal load used in the FEM analysis is based on the maximum horizontal load, found in Phase 5, including a safety factor of 10. The complete report can be found in **Error! Reference source not found.**.

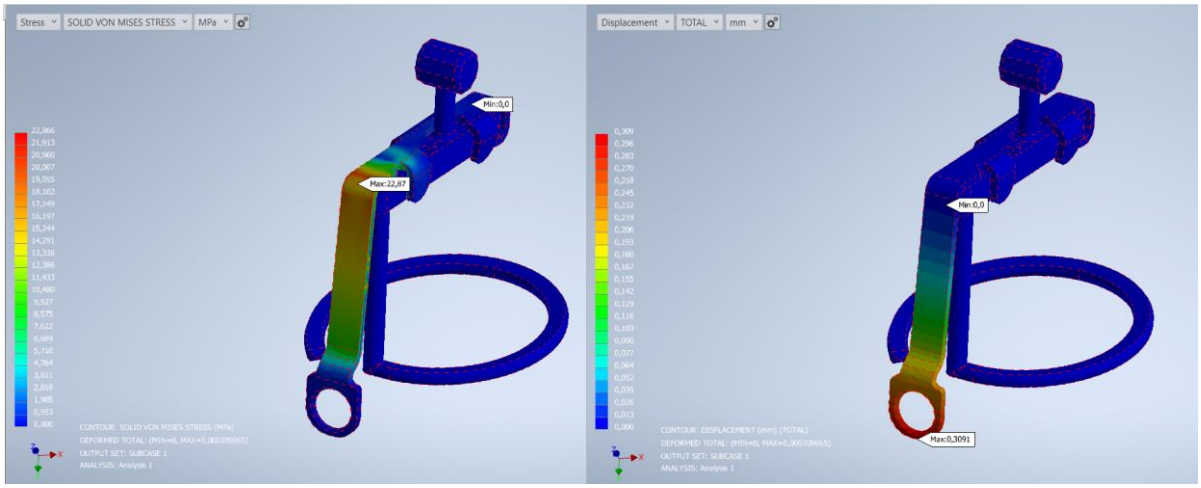


Figure 35 FEM analysis of the final design, distribution of the Von Misses stress (left) and displacement (right).

A maximum stress of 22.87 MPa is found which is well below the minimum 167MPa of fatigue strength model at 1e7 cycles, see Figure 36. Secondly, the FEM analysis indicates that a maximum displacement of 0.03mm has no impact on the functionality of the holder. This is within the acceptable limit, as requirement C3.2 allows for a maximum displacement of 3.0 mm.

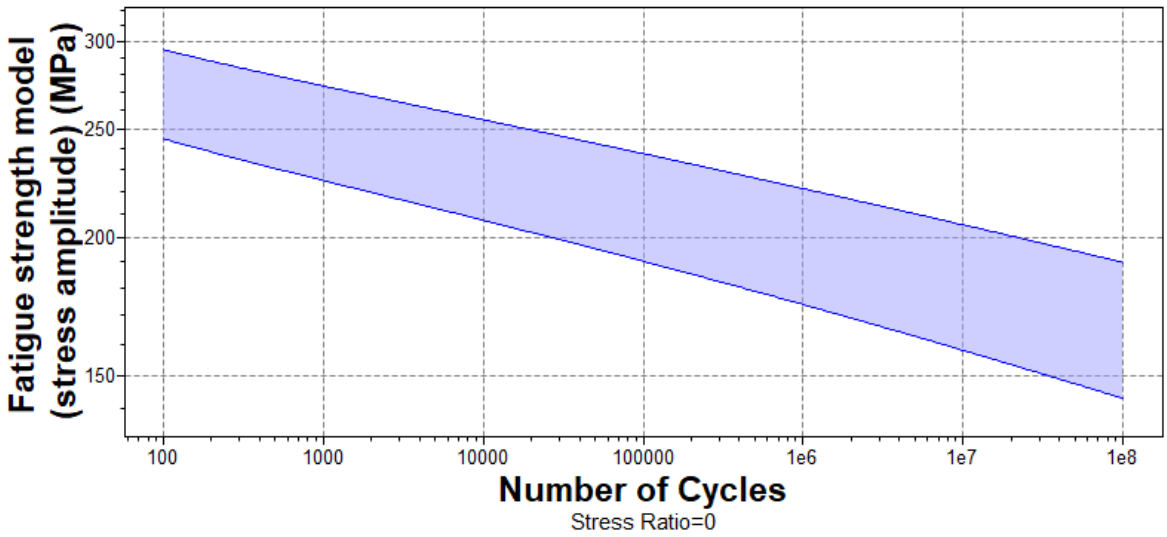


Figure 36 Fatigue strength model of AISI 316L vs the number of cycles

Phase 5: Phantom model validation

The last validation step is this design process is to validate the final product with the end users. The initiator of this project planned a visit to The Netherlands in November 2023. This opportunity was used for a final evaluation moment. The following tests were conducted:

1. Establish size hole that is comparable with the same field of view of a gas insufflation-less laparoscopic cholecystectomy
2. Discussion about the integration method with stakeholder and maximum purchase price
3. Force component test
4. Phantom A/B test
5. Holder attachment
6. Ergonomic test
7. Evaluation of laparoscopic holder statements
8. Validation phantom test

Establish size hole that is comparable with the same field of view of a gas insufflation-less laparoscopic cholecystectomy without holder

From the second field research it is know that a hole size of 14mm in diameter was too small. Therefore, a metal plate was made with hole sizes varying from 14,5 till 25 mm, see Figure X. Also 2 holders were made with hole sizes 14,5, 16,5, 18,5mm. The participant concluded by using the laptop cystoscope 16,5mm big hole allows the same field of view in gas insufflation-less laparoscopic cholecystectomy. The Indian rural surgeon mentioned that laparoscopic equipment due to technological advancements slimmer and slimmer become. This means that in the future a slimmer laparoscopic camera and a smaller hole size the same field of view can be obtained.

Figure 37 Metal plate with different hole sizes, the 3 produced holders in 14.5 16.5 and 18.5 mm and set up

Force component test

Furthermore, the maximum vertical force component on the holder was measured, in the following set up. By asking the rural surgeon to exert with the laptop cystoscope the maximum vertical force on the holder, via a scale, the maximum horizontal force could be calculated by:

Formula: Fmaxhor= measured weight*gravitational constant

This result was used for input for the horizontal force component in the FEM analysis including a safety factor of X.

Formula Ffemhor = Fmaxhor * safety factor

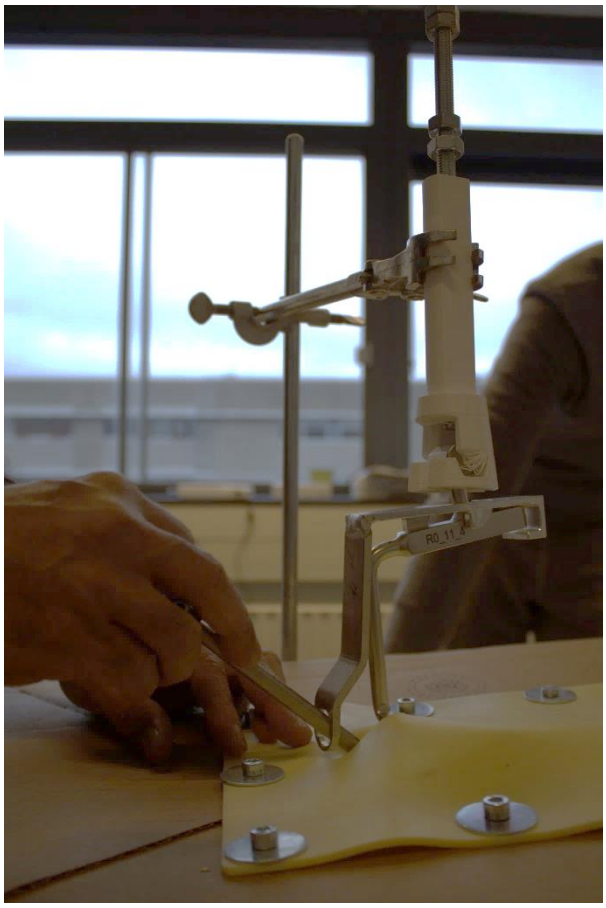
Fmaxhor = 0.262 [kg]*9,81 [m/s^2]

Ffemhor = 0.262 [kg]*9,81 [m/s^2] *10

Resulting in an Ffemhor, horizontal force used in the FEM analyses, *of 25.7022 N.*

Phantom A/B test

In a phantom model where an Indian rural surgeon had to simulate a gas insufflation-less laparoscopic surgery of the removal of the gallbladder, cholecystectomy. The choice of procedure was based on the outcome of the field researches were cholecystectomy was listed as most common procedure.




Holder attachment

To test if attaching the holder is a one person's job and how easy it is too attach the holder to the ring, the participant was asked without instructions to attach the holder to the ring. The average time it took to attach the holder to the abdominal ring was *4,29 seconds*. With the maximum amount of required time of 6,49 second in the first try. This gives an indication that the holder can be attach by one person and does not require too much time. The participant noted that in the current set up the holder is easier to attach than in the real life situation, because in the current set up it is easy to view the back of the abdominal ring as well. However, during an operation this might not be the case.

Evaluation of laparoscopic holder statements

After, the phantom cholecystectomy, the laparoscopic holder was evaluated by expressing the participant's opinion to the following statements:

"The Laparoscopic holder is suitable for X in low-income settings."

X	answer
OVERALL USE	Agree
Training	Neutral
Transportation	Agree
Repair	Agree*
Maintenance	Agree*
Clean and sterile	Agree
Perform surgery	Agree
Compatibility with OT	Agree

	Strongly agree
	Agree
	Neutral
	Disagree
	Strongly disagree

* The rural surgeon mentioned that he does not think repair or maintenance is necessary. If repair and maintenance are necessary it will not be available in low resource settings. He claims surgical graded steel is not available also as bending and welding techniques.

Validation phantom test

Table 8 Surgical phantom and training environment validation questionnaire.

Title	Endpoint low/high (0-5)	Description
Experiment's applicability	1	How appropriate is the experiment to teach MIS during the modelled surgery?
Movement similarity	1	How similar are the movements to those required during surgery?
Anatomical similarity	1	How realistic is the anatomical phantom designed to model the surgical area?

Although, the valiation of the phantom test scored low, it was not the goal to make a laparoscopic simulator. The test revealed that the surgeon was able to make all the movement needed for the operation. During the test, the laparoscopic model showed no sign of obstructing the surgeons movement.

After a discussion a new phantom model is drawn up that from experience of the rural surgeon solving these problems, see Phase 5: Phantom model validation.

DISCUSSION

This report presents the design of a laparoscopic camera holder suitable for Gas Insufflation-Less Laparoscopic Surgery (GILLS) in low resource settings. Co-creating (designing with stakeholders) was part of the frugality approach and instrumental for the output, which greatly resulted from of the insights of the two field studies. Furthermore, the field studies expanded the established collaborative network of local stakeholders, including academics, WHO representatives, a diverse group of (rural) surgeons within the Indian healthcare system and anesthetists. Marking the initial steps towards the production of 20 laparoscopic holders in India.

Unfortunately, no over-arching framework exist for the development of medical devices for low resource settings, in stark contrast to the multitude which targets devices for high resources settings (Marešová et al., 2020). The structure of this project was strongly based on the framework and interpretation of the roadmap for safe surgery (Oosting, 2019; Webb et al., 2022) combined with literature which aligned with principles from Co-creation and frugality. In particular, Phase 3.3, where stakeholders in the field could give input in the design direction and suggest alterations to the existing prototypes. Albeit this method is not commonly used, also because the main focus of designing medical instruments is for a different market, it provided the desired results. It would, however, be desirable if norms like ISO could also focus on frameworks for low resource settings.

In the first field research in India, it was found that a laparoscope holder would be an ideal solution to improve the ergonomics for the healthcare assistants. More surgeons agreed that it is indeed the ideal location for a holder. This shows that a same test on different surgeons in a different country would result in the same result, the location of the holder.

Based on the hole location and the requirement to improve ergonomics for the assistant, a design could be made. A concept is developed and tested by a surgeon during the phantom test. By reducing the force needed for the assistants it would be a logical conclusion to assume the ergonomics are improved. Fortunately, this is also what is concluded by the surgeon during an interview. However, the assistants need to work with the holder. They are the final stakeholder who need to test the holder under realistic conditions. Unfortunately, it was not possible to conduct such a test within the set timeframe. It is expected that the ergonomics are improved, but by how much remains unknown after this study. On the other hand, surgeons are more experienced and familiar with the surgery, therefore it is not a must to test with laparoscopic assistants.

Initially it was desired that the holder would be able to keep the laparoscope at a changeable, but easily fixable position after the surgeon moved it as disered. This wish was not considered anymore when the first and second field study showed that there is no lack of laparoscopic assistants, but of surgeons and antitheists. However, such a holder would improve ergonomics for the assistants more. Because requirements changed over the project, this requirement was set aside. A future design can be made that provides this option, but this also complicates the holder. A more complex holder means a more expensive design with higher operational costs, meaning it is less applicable for low resource settings. This is why complexity needs to be reduced as much as possible.

The same holds for the validation of the holder. Performance can be tested directly by a phantom test and design requirements can be tested by a FEM analysis. More complex components would increase the complexity of a FEM analysis as well.

The FEM analysis of the holder is performed under certain conditions. For example, the two components cannot go through each other, the abdominal ring is ideally constrained and the force of the laporoscope is an ideal distributed load. In this case the FEM analyses shows desirable results stating well below the 167 MPa fatigue requirement. It must be taken into account that a FEM analysis is an idealisation of the real world meaning there will be a difference between reality and the FEM analysis. This report shows that the stress is well below the yield stress and the fatigue stress, however test with the design must show how the holder behaves after autoclave cleaning, rubbing alcohol, high concentration of acid, usage during operation and outside the operation. An example is that surgeons and personnel tend to 'throw' tools in a bucket on the ground to set off for cleaning, this scenario is unfortunately not possible to test during a FEM analysis.

The requirements stated in the final P-diagram including the validation and if they have been met in the project can be found in, Figure 38. Most of the requirements have been met. However, in order to establish a significance result out of the tests mentioned in Phase 5, it is imperative to engage a larger participant group for validation. Nevertheless, initial results show that the camera holder can support a laparoscopic camera during operation, making enough room for the instruments to move while the field of view stays the same as in conventional laparoscopy. Additional, improvement in ergonomics, and stability have been found, followed by a frugal and robust design, backed up with a finite element analysis and possible for manufacture in low resource settings. Further detailing of the manufacture method and implementation strategy are needed to optimize for cost-efficiency and accessibility to gain insight on the most effective distribution method and options for repair if needed.

The results of this research highlight the potential for designing products tailored to low- and middle-income countries (LMICs) and the feasibility of co-creating solutions with local stakeholders, benefitting both the community and collaborators. This underscores the viability of creating solutions that address the specific needs of these regions and significance of partnerships in addressing healthcare challenges.

While this research demonstrates promising prospects for laparoscopic holders, a more comprehensive examination is required for their broader implementation. Although the RAIS device has been introduced in four countries spread over two continents, a detailed assessment of suitability of the laparoscopic holder in other low resource setting is necessary.

Reflecting back on this project, the project team has listed recommendations for individual that are working on surgical device innovation for low resource settings:

- After establishing the need for equipment, make a clear overview of the underlying problems to validate the origin of the problem between stakeholders.
- Let participants use the (low fidelity) prototype in the most realistic environment as possible. Even participants are biased with their own ideas and to let them test their own proposed solution it can shift the design input that was first given.
- Invest in an early stage of the project time to find a local manufacturer to avoid unnecessary iterations
- Invest time in updating the stakeholders on the project, so they are aware of the projects process and it is easier to ask for input in a later stage of the project

IDEAL FUNCTIONS							
	Category		**Unit**	**Validation**	**Date (dd-mm-'yy)**	**Stakholder**	**Met**
ESSENTIAL	A1.1	Weight of the laparoscopic camera needs to be supported for at least 90 percent by the laparoscopic holder	[-]	Ergonomic A/B test: hold laparoscope with and without laparoscopic holder	01-11-'23	Project team	Yes
	A1.3	The field of view of the operative field the same as the gas insufflation/RAIS system of 70 degrees workspace	[degree]	Phantom test: decision size hole and literature	10-06-'23	Leeds	Yes
	A1.4	Enables surgeon to access surgical area of interest with laparoscopic tools, causing minimal physical obstruction	[-]	Phantom test: ability to reach surgical area and more laparoscopic tool without obstruction from the holder	10-06-'23	Leeds	Yes
	B2.1	Set up of the laparoscopic camera holder is <10 minutes by one person	[s]	Phantom test: record 5 times attachment of laparoscopic holder [s]	24-06-'23	Project team	Yes
	C3.1	Lifetime of >10 years	[years]	Design follows the infinity life design cycles approach/ Maximum occuring stress during operation is below 10 percent of the materials yield stress.	24-06-'23	Project team	Yes
	C3.2	The maximum movement of the laparoscopic holder in x,y and z direction attached to the abdominal ring is less than 3mm	[mm]	FEM analysis, maximum displacement is 0.03mm	1-12-'23	Project team	Yes
	C3.3	Product must be able to sustain 25N vertical/down force	[N]	FEM analysis; maximum Von Misses stress is below fatique stress model at 1e7 cycles	10-06-'23	Project team	Yes
	D4.1	Product must be compatible with the all the sizes of abdominal rings of the LEEDS and field research version of the RAIS device	[-]	Holder fits all abdominal rings	24-06-'23	Gnanaraj	Yes
	D4.2	Product must adapt to an abdominal wall thickness corresponing to a person with a BMI up to 25.	[-]	Test holder with different abdominal wall thicknesses	14-10-'23	Gnanaraj	Yes
	D4.3	Product must be compatible with 0 and 30 degree laparoscopic camera during surgery	[-]	Phantom test perfomed with largest workspace needed by persoming the test with a 0 degree laparoscope	14-10-'23	Gnanaraj	Yes
	E5.1	Laparoscopic holder is autoclavable in a rural hospital	[-]	CES EDUPACK, AISI 316L is excellent autoblavable	24-06-'23	Gnanaraj	Yes
	E5.3	Material is alcohol resistance so laparoscopic holder is able to be able to be cleaned by alcohol rub in a rural hospital	[-]	Good resistance against rubbing alcohol(Alcohol, Isopropy) 112	27-11-'23	Leeds	Yes
	F6.1	Easy to maintain and spare parts readily available / repair possible in rural setting	[-]	Phantom test: statement check. No medical grade material or bending/welding is possible in rural settings	24-06-'23	Project team	No
	F6.2	Local maintaince and production of spare parts is possible	[-]	Phantom test: requirment check	24-06-'23	Project team	Yes
	F6.3	Material has to be medical grade, suitable for medical application	[-]	Medical graded materials in CES EDUPACK	27-11-'23	Norms	Yes
	G7.1	The laparoscopic camera holder uses no single products in usage	[-]	No single used producst are needed during usage	24-06-'23	Project team	Yes
	G7.2	Product must cost less than 5 euros	[Euro]	cost analysis	21-11-'23	Gnanaraj	Yes
	G7.3	A minimum of 80% product weight must be recyclable	[-]	CES EDUPACK, AISI 316L is recyclable	24-06-'23	Project team	Yes
	I8.1	Placing and using camera holder can't damage tissue (no sharp edges and max applied forze per is below recommended)	[N/m^2]	All edges are rounded and holder does not come in contact with tissue during operation	10-06-'23	Leeds	Yes
DESIREABLE	W1.3	Laparoscope holder enhances the percieved stability of the laparoscopic camera	[-]	Phantom test	24-06-'23	Project team	
	W2.1	The product must be usable by personnel with as little training time as possible	[-]		24-06-'23	Project team	
	W2.2	The holder should be as light and compact as possible (for transporation and storage)	[-]		24-06-'23	Project team	
	W7.1	The laparoscopic camera should be as cheap as possible	[Euro]		24-06-'23	Project team	
	W7.2	Minimizing the amount and moving parts	[-]	Holder exist out of 1 part	24-06-'23	Project team	
	W7.3	Can be maintained and repaired using as much as possible local resources	[-]		24-06-'23	Project team	
	W7.4	Uses as little as possible resources during usage(electricity, water, etc.)	[-]	Holder does not require additional resources during usage	21-07-'23	Project team	
	W7.5	As much of the product can be recycled	[-]	CES EDUPACK, AISI 316L is recyclable	24-06-'23	Project team	

Figure 38 Validation of requirements set in final P-diagram

CONCLUSION

The initiator, a rural surgeon, requested assistance of Delft University of Technology to 'design a laparoscopic camera holder that enables solo surgery. Part of this problem was the lack of healthcare personnel to hold the laparoscopic holder. After the second field research it got concluded that sufficient healthcare personnel was present. Therefore, the design goal got refined into:

'Design a product to improve the ergonomics for healthcare personnel that holds a laparoscope during surgery in low resource settings'.

This goal addresses the problem that especially during single incision laparoscopic surgery the laparoscopic camera physically abrupt the movements of the laparoscopic instruments. The reasons is that it is easier for the laparoscopic camera assistant to let the laparoscope rest on the bottom part of the incision, making the weight the assistant needs to hold in the air less. However, this does not only physically abrupt the instruments but lead also to an unwanted view. This is because a 30 degree laparoscope need to be placed above the instruments in order to view the tips of them. This struggle leads to unwanted camera and instrument movement and unstable camera view.

Using the framework and interpretation of the Roadmap for safe surgery combined with a frugal approach was crucial in this project. The continued collaboration with stakeholders enabled a time-effective development of the laparoscopic camera holder. Especially rapid development and understanding of the local context and design iteration resulted out of the two field studies, as well as large spectrum of stakeholder. This projects marks the steps from identifying surgical equipment till the initial steps for manufacturing.

Field testing in India at a WHO conference and at rural hospitals concluded that the ergonomics for healthcare assistants, during laparoscopic surgery, need to be improved with a product that is specifically designed for low resource settings.

In phase two of the roadmap described in the report, a location was chosen for this holder. It needs to be located below the RAIS abdominal ring (top of the incision) and above the laparoscopic instruments(placed at the bottom of the incision) and connected to the RAIS device. Requirements for the holder are based on experience gained during field testing in India, requirements set by the initiator and ISO norms. It was concluded that the product needs to be autoclavable and designed according to ISO 7153-1 to make sure the holder remains hygienic. A maximum retail price of 5 euro and a batch size of twenty resulted in clear demands for production method. With these requirements, a suitable design is made.

A formfitting frugal laparoscopic camera holder is designed that can be connected to the abdominal ring of the RAIS device. Due to the form fitting it can be can be easily removed and attached during surgery in only one way, so it constraints all other degrees of freedom. It is placed on the horizontal part of the abdominal ring and leaves a round opening with to insert the laparoscope. The laparoscope's weight of the laparoscope is supported by the holder, improving the ergonomics for the laparoscopic camera assistants.

The design is made with medical grated AISI 316L stainless steel, a material that is widely used and available for a low price compared to its capabilities to withstand harsh environments. It will be produced by cold forming, meaning bending at room temperature. This is a cost effective method widely used all over the world. An Indian company stated once the design is final the design can be easily sold below 500

rupees till 200 Indian rupees per holder. This is about 5,5 and 2,2 Euros respectively. Ease of production, of this one part product, is considered by designing the product in a way that large tolerances are suitable without decreasing the performance of the product.

With a phantom test in phase 5 of the roadmap it was possible to find out what the performance is of the holder during a phantom surgery. The phantom test concluded that the product is suitable for low resource settings, improves the ergonomic and can be attached by one person under one minute.

To conclude, a holder that is compatible with the RAIS device that supports the laparoscope does improve the ergonomics for healthcare assistants. The weight of the laparoscope is carried by the holder and therefore it is easier for the healthcare assistants to stay hold and manoeuvre the laparoscope without obstructing the laparoscopic instrument and ensuring and optimal view for the surgeon, improving the quality of operations and therefore the chance of success.

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Conflicts of Interest

The author declares no conflict of interest

Ethics approval

The research is approved by the Human Research Ethics (HREC) of the TU Delft

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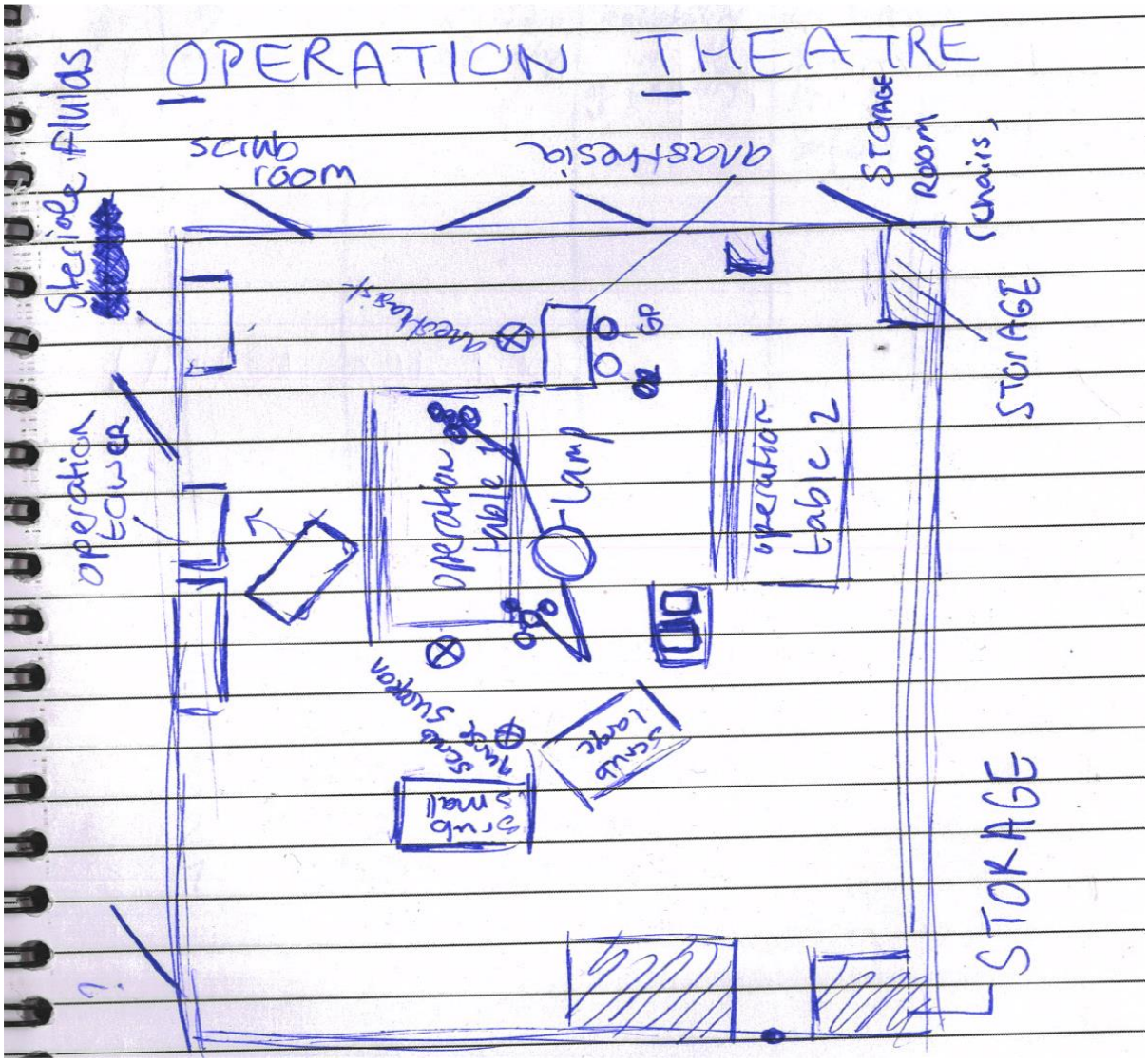
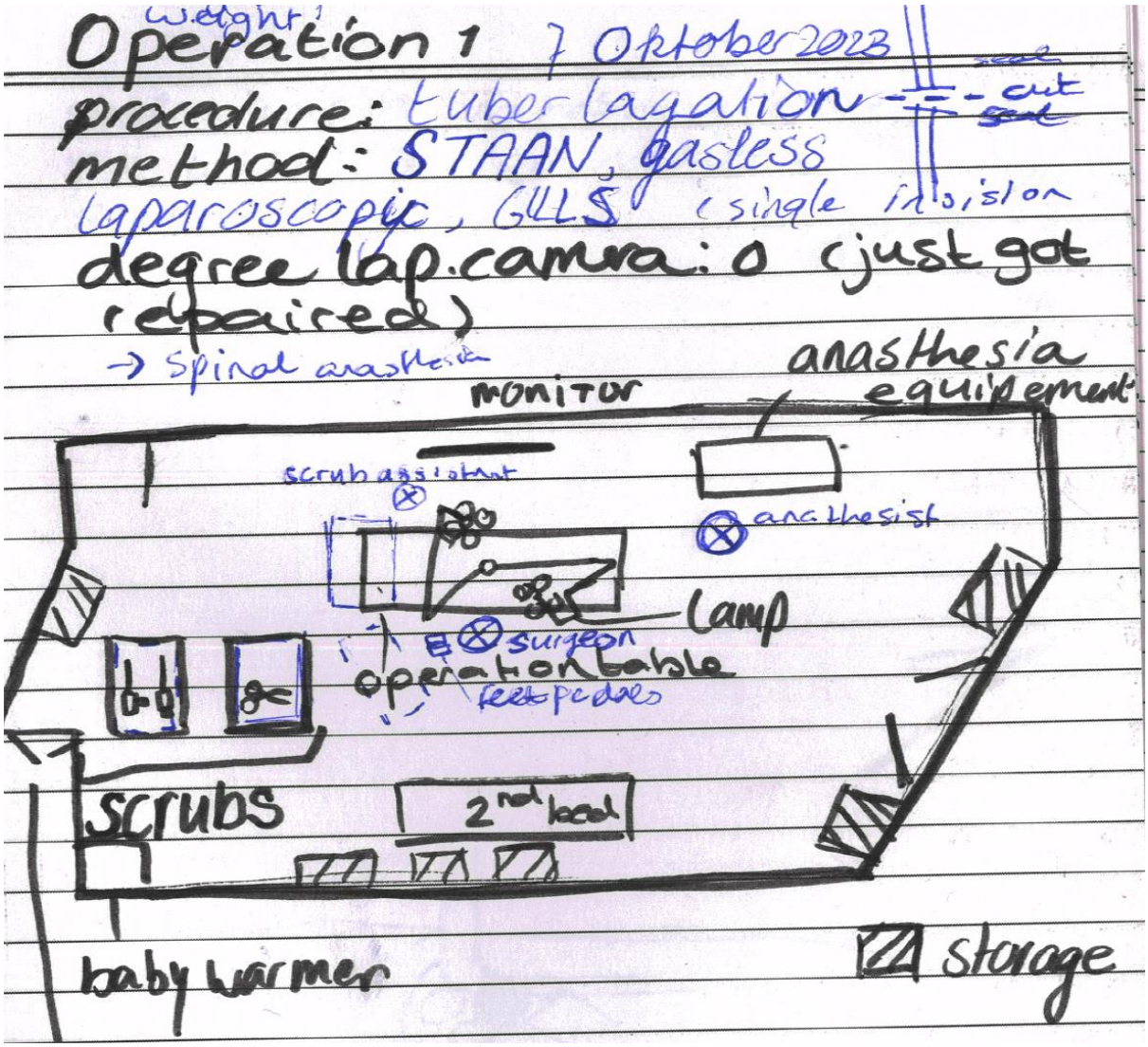
APPENDICES

APPENDIX A: Lay out OT of rural hospitals

Layout of the operation theatre H1



Layout of the operation theatre H2



APPENDIX B Linked requirement to literature

		Requirements ranked according to importance to design in low resource settings	Projects requirements linked to literature
most important	**6.**	**Cost**	
	6.1	Maintenance costs	
	6.2	Running costs	
	6.3	Initial cost	Price: as cheap as possible ()
	7.	**Lifetime**	
	7.1	Lifetime of MD parts/components	
	7.2	MD lifetime	Robustness: An as long as possible lifetime
	2.	**HTM**	
	2.1	Need for consumables	
	2.2	Need for spare parts	
	2.3	Installation requirements	
	2.4	Maintenance complexity	Simplicty: Minimazing the moving and amount of parts
	2.5	Maintenance frequency	"
	2.6	Compatible consumables/spare parts	
	3.	**Design**	
	3.1	Portability, compactness, robustness	Robustness: An as long as possible lifetime, Transport: As light and compact as possible
	3.2	Limiting the number of components/spare parts	Simplicty: Minimazing the moving and amount of parts
	3.3	Reusability	
	1.	**User type**	

	1.1	End users' background	
	1.2	Easiness of use	
	1.3	Training needs	Training time: The product must be usable by personell with as little training time as possible
	1.4	User's understanding of the technical and clinical impact	
	5.	**Material**	
	5.1	Durability of the material	
	5.2	Robustness of the material	
	4.	**Reliance on external factors**	**Resources: Uses as little as possible resources during usage (electricity, water, etc.)**
	4.1	Reliance on power sources	
	4.2	Reliance on water distribution	
	4.3	Reliance on medical location air	
	4.4	Need for sample preparation	
least impor tant	4.5	Understanding/stating the dependence of the MD from the medical location characteristics	
	4.6	Resilience to dusty environments†	
	4.7	Resilience to high-temperature environments†	
	4.8	Resilience to high-humidity environments†	
			Recyclable: As much of the products can be reccycled

Appendix C Interview guide

In this Appendix the interviewguide can be found which was used in the second field study. Additionally, the wish cards and booklet for concept feedback and ideation can be found.

Reminder: consent form

Full name	
Profession	
Location	
Do you have experience working in rural hospitals/clinics?	YES / NO, thank you for your time
Is performance of laparoscopic practices in this location possible?	YES / NO, go to 4b - 6
Do you have experience in performing laparoscopic surgery?	YES / NO

	Interviewee has experience in laparoscopic practises (WHO and first hospital)	Interviewee has **no** experience in laparoscopic practices (second hospital)
1	Amount of years experience with laparoscopic system: _____years	Would implementing laparoscopy benefit your hospital/clinic? Yes / no, _____
2	What kind of Laparoscopic system is used (gas or gasless)?: STAAN/RAIS/_____	Which burdens needed to be overcome before laparoscopy can be introduced?
3	How often is it used: _____ amount of patients per week/month/year/_____	
4	What is the primary type of surgery performed with this system?:	
4a	Do you have access to enough trained laparoscopic personnel? Yes/No ☐ Surgeon ☐ First assistant ☐ Second assistant ☐ Anaesthetist	
4a No	What do you consider to be the bottlenecks in rural laparoscopic practices?	

4b Yes	What kind of impact does that make on daily practice?	
5	What needks to be changed to solve this problem?	
	Evaluation	
6	Considering the conditions of rural laparoscopy. Could you rank the following list of requirements from most important to least important: A. Price B. Simplicity C. Robustness D. Local maintenance + repairs E. Training time F. Resources G. Recyclable H. Transport I. (blank if participants want to add a requirement that I missed)	MOST IMPORTANT (provide cards) 1. 2. 3. 4. 5. 6. 7. 8. LEAST IMPORANT
7	I brought 3 concepts with and I would like to assess some of the most important functional requirements: FUNCTIONS a) Holder enable surgeon to access/view all surgical areas of interest b) Holder leaves enough space to insert and move laparoscopic equipment during the surgery c) Internal component can be inserted through a 20mm incision d) [black] Present concept 1 and fill in the table below:	

CONCEPT 1

Function	Full filled?	Why?	How should the concept be altered?

			→ Worksheet
	Yes / No		
	Yes / No		
	Yes / No		
	Yes / No		

Concept 1: Suitable to be implemented as laparoscopic camera holder in rural settings (in India)? YES / NO

CONCEPT 2

Function	Yes / No	Why?	How should the concept be altered? → Worksheet
	Yes / No		
	Yes / No		
	Yes / No		
	Yes / No		

Concept 2 Suitable to be implemented as laparoscopic holder in rural settings (in India)? YES / NO

CONCEPT 3

Function	Yes / No	Why?	How should the

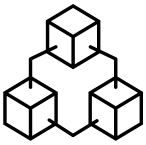
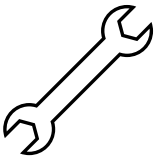
			concept be altered? → Worksheet
	Yes / No		
	Yes / No		
	Yes / No		
	Yes / No		

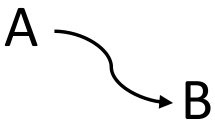
Concept 3 Suitable to be implemented as laparoscopic holder in rural settings (in India)? YES / NO

After

1. Would concept 1/2/3 solve the burdens mentioned in 4a/b?
2. Explore possible solution space (provide paper and pens) Do you have an suggestions for a 4th prototype? How would it work/look like?

Wish cards

Price 	As cheap as possible
Simplicity 	Minimizing the moving and amount of parts
Robustness 	An as long as possible lifetime
Local maintenance & repairs 	Can be maintained and repaired using as much as possible local resources
Training time 	The product must be usable by personnel with as little training time as possible

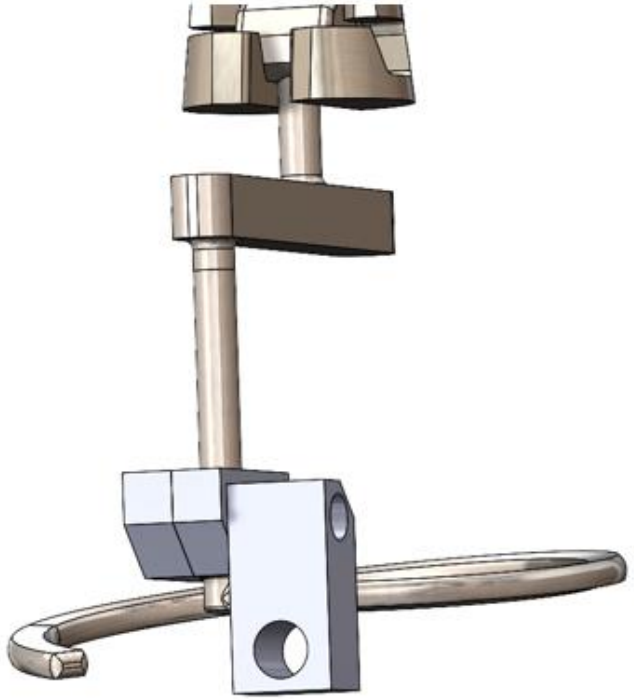
Resources 	Uses as little as possible resources during usage(electricity, water, etc.)
Recyclable 	As much of the product can be recycled
Transport 	As light and company as possible
_____	_____ _____

Booklet

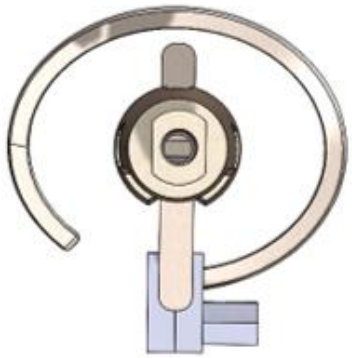
On the next pages the handout is presented given to the participants to give design suggestions.

Concept 1

IN PERSPECTIVE



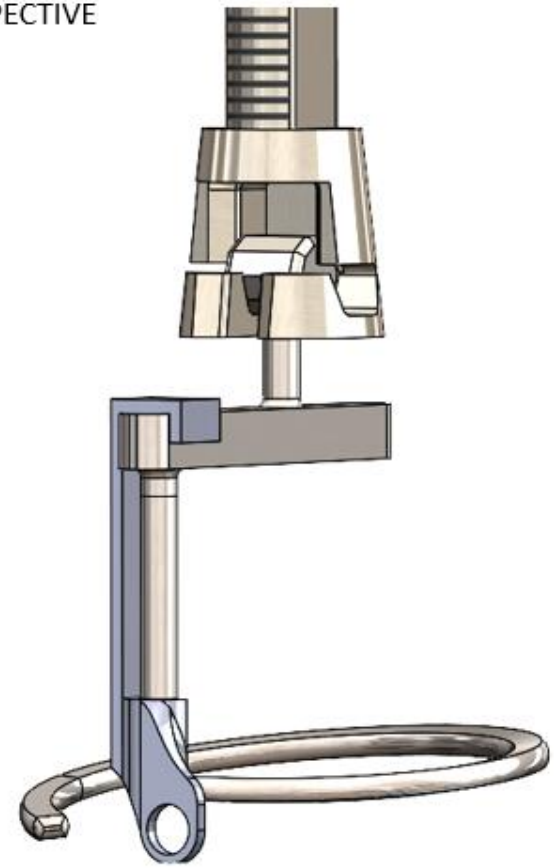
TOP



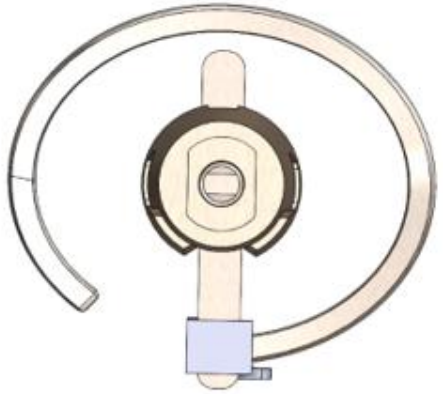
SIDE

Concept 2

IN PERSPECTIVE



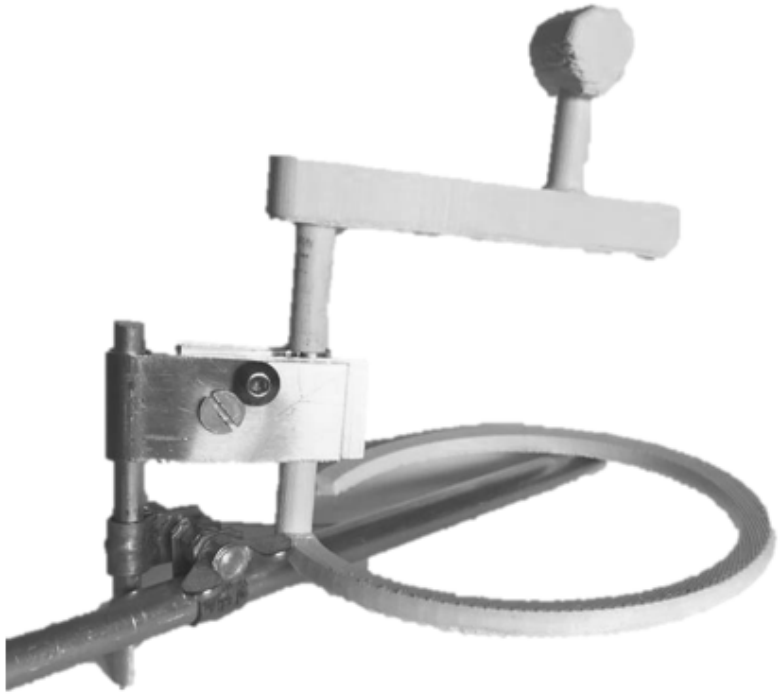
TOP



SIDE

Concept 3

IN PERSPECTIVE



TOP

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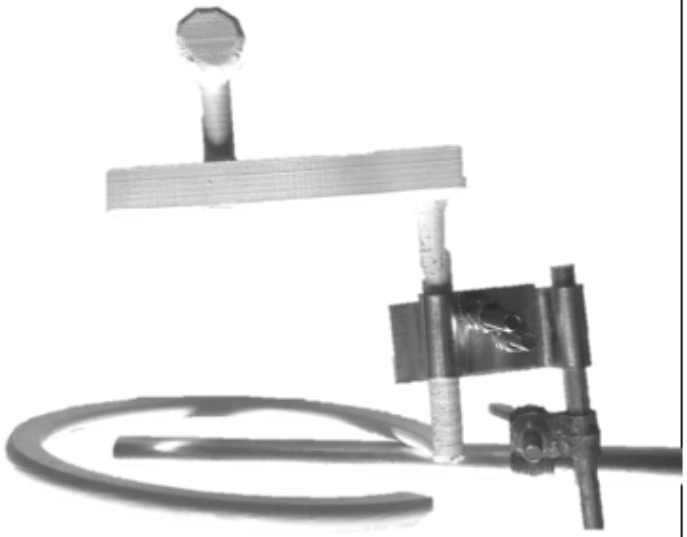
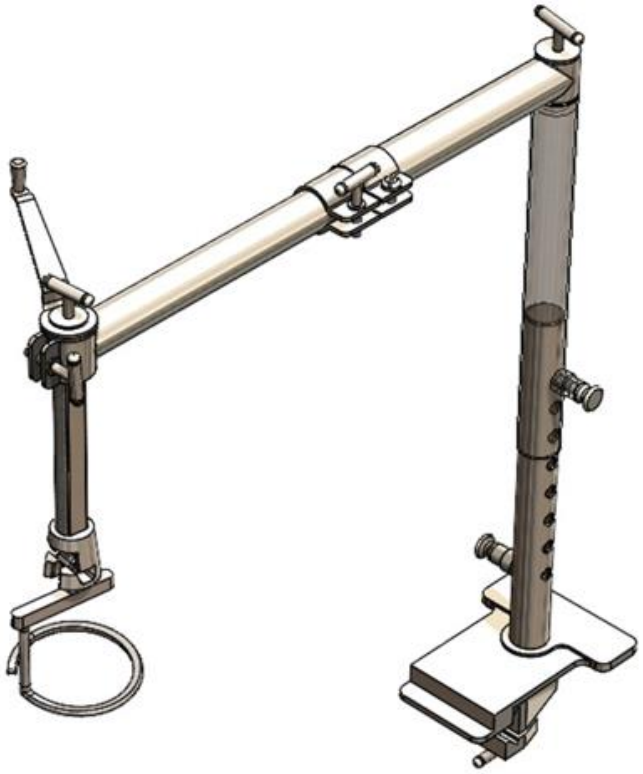


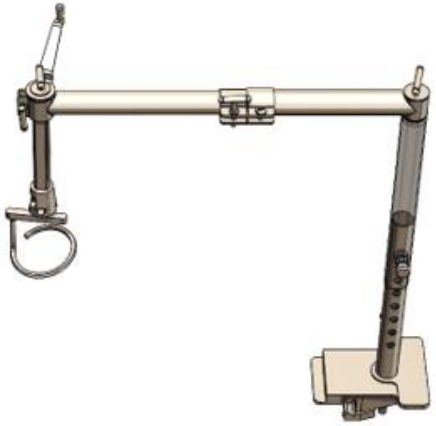
RAIS SYSTEM

IN PERSPECTIVE



TOP

SIDE



Appendix D Phantom Instructions

Instructions for performing the phantom test

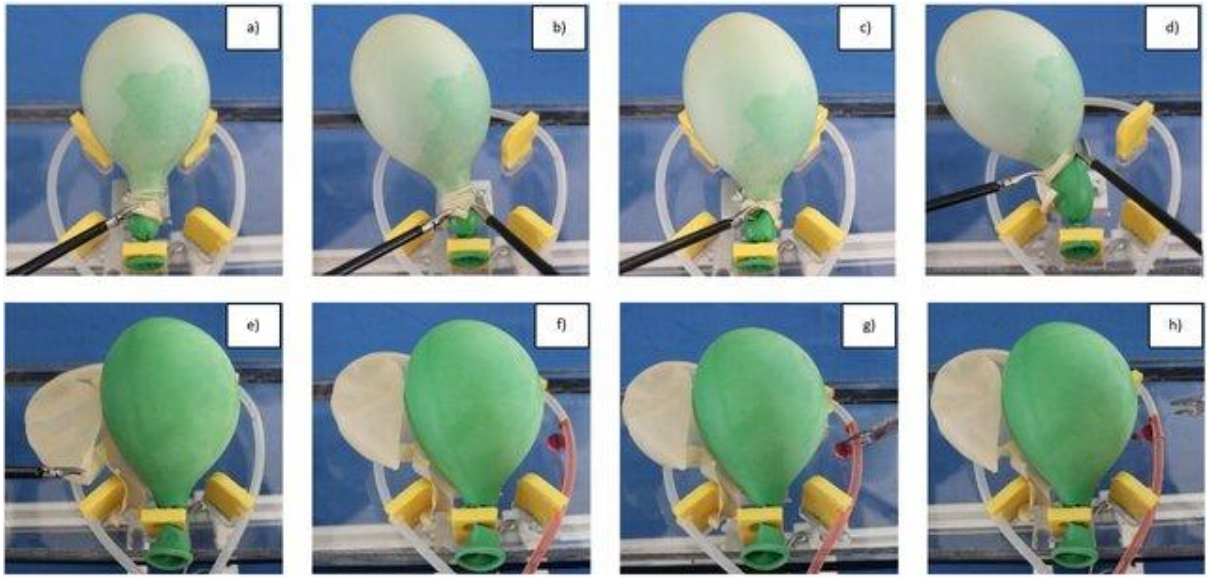
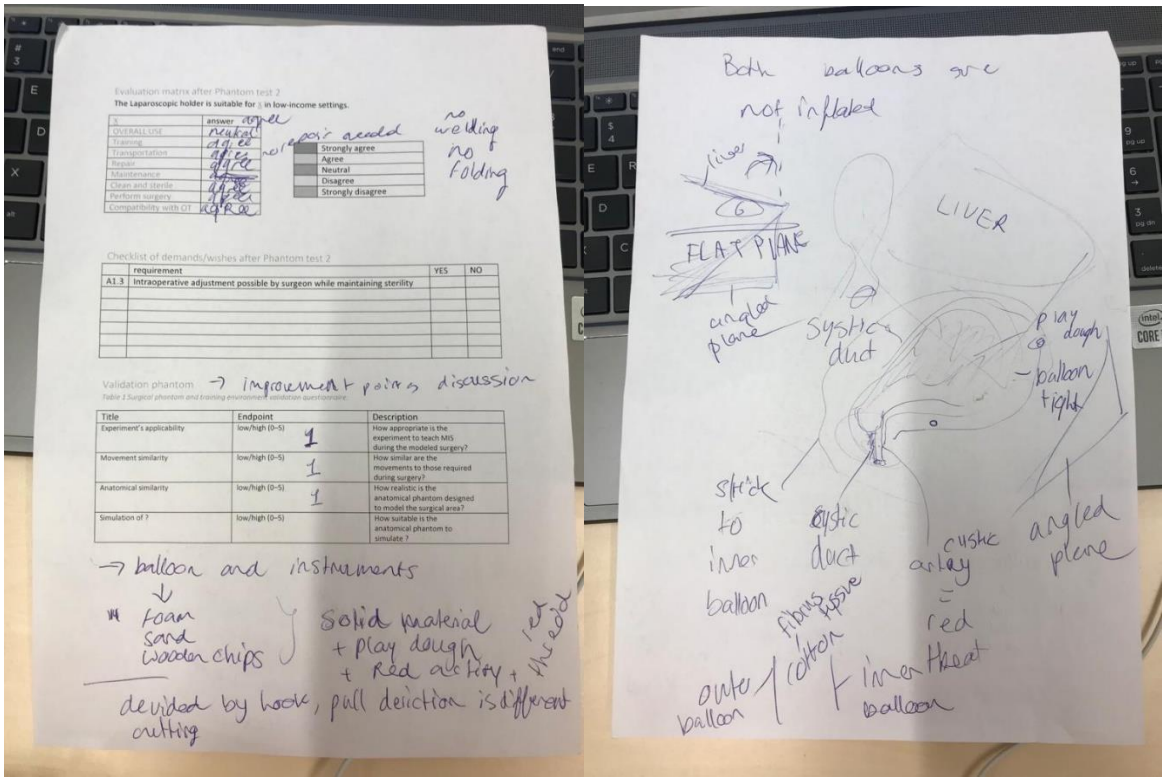


Figure 39 Proposed workflow of the MIS experiment; (a) Grasping the outer layer (representing the parietal peritoneum) with a dissector; (b) Cutting the outer layer with a pair of scissors; (c) Blunt dissection; (d) Cutting; (e) Removing the covering layer; (f) Abrupt bleeding; (g) Localize the bleeding source, change the tool(s) to the clipper; (h) Clipping the blood vessel considering the direction of the blood flow (Nagyné Elek & Haidegger, 2022).

Suggested new phantom model by surgeon



Appendix E Requirements

The complete list of requirements can be found in the table below and is categorized in 8 categories(A-H):

A. Functions
B. User friendliness
C. Robustness
D. Compatibility
E. Cleaning
F. Manufacturing & Maintenance,
G. Frugality & Sustainability, definition frugality criteria regarding environmental impact, cost, recyclability and end-of-life plan
H. Safety & Regulations, patient safety and product environment

Each category is divided into demands, starting with the letter of the category, and wishes, starting with W.

A. Functions		Unit	Validation	Date (dd-mm-'yy)	Stakeholder	Met
A1.1	Lowers the perceived exertion of the laparoscopic assistant with at least 3 points on the Borgs RPS scale during an laparoscopic operation.	[-]	Ergonomic A/B test: hold laparoscope with and without laparoscopic holder	01-11-'23	Project team	No
A1.2	Intraoperative adjustment of STAAN/RAIS device possible by surgeon while maintaining sterility	[-]	Phantom test requirements check	24-06-'23	Project team	Yes
A1.3	The field of view of the operative field the same as the gas insufflation/RAIS system of 70 degrees workspace	[degree]	Phantom test: decision size hole and literature	10-06-'23	Leeds	Yes
A1.4	Enables surgeon to access surgical area of interest with laparoscopic tools, causing minimal physical obstruction	[-]	Phantom test: ability to reach surgical area and more laparoscopic tool without obstruction from the holder	10-06-'23	Leeds	Yes

A1.5	Horizontal pressure on laparoscopic holder does not exceed recommended maximum	[N/m^2]	FEM analysis	10-06-'23	Leeds	Yes
A1.6	Enables insertion of imaging equipment to view abdominal cavity pre- and post- lift, and rotations of view sufficient to image entire cavity	[-]	Phantom test	10-06-'23	Leeds	Yes
W1.1	The surgeon can control (horizontal, vertical and zoom) the laparoscopic camera without compromising his operating task	[-]	Phantom test: A/B test with and without laparoscopic holder	24-06-'23	Project team	No
W1.2	The camera holder is able to let the laparoscope follow the whole path of new instrument(from the insertion point to the point of operation)	[-]	Phantom test	16-07-'23	Gnanaraj	Yes
W1.3	Laparoscope holder enhances the perceived stability of the laparoscopic camera	[-]	Phantom test	24-06-'23	Project team	Yes
B. User friendliness		Unit	Validation	Date	Stakeholder	Met
B2.1	Set up of the laparoscopic camera holder is <10 minutes by one person	[s]	Phantom test: record 5 times attachment of laparoscopic holder [s]	24-06-'23	Project team	Yes
B2.2	Easy transportable between operating rooms/through the room itself	[-]	Phantom test: requirement test	24-06-'23	Project team	Yes
B2.3	Laparoscopic assistant must be able to use the holder in an operation within two hours of training in a low resource setting	[hours]	Phantom test: make IKEA instruction sheet --> record "training time"	24-06-'23	Project team	No

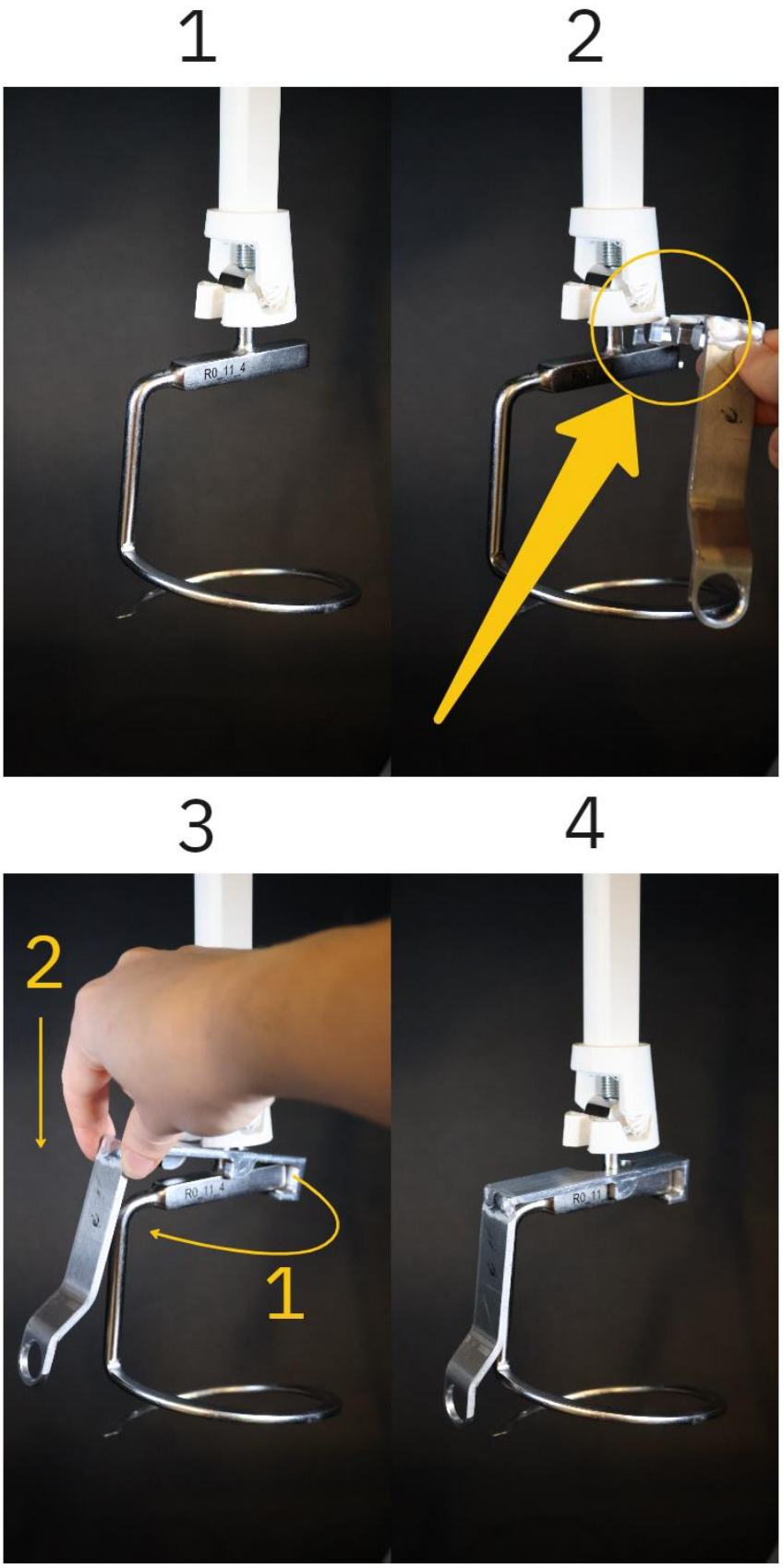
W2.1	The product must be usable by personnel with as little training time as possible	[-]		24-06-'23	Project team	
W2.2	The holder should be as light and compact as possible (for transporation and storage)	[-]		24-06-'23	Project team	
W2.3	Product must have a clear and intuitive interface	[-]	Phantom test: make IKEA instruction sheet--> participant understood?	24-06-'23	Project team	
C. Robustenness		Unit	Validation	Date	Stakeholder	
C3.1	Lifetime of >10 years	[years]	Design follows the infinity life design cycles approach/ Maximum occuring stress during operation is below 10 percent of the materials yield stress.	24-06-'23	Project team	Yes
C3.2	The maximum movement of the laparoscopic holder in x,y and z direction attached to the abdominal ring is less than 3mm	[mm]	FEM analysis, maximum displacement is 0.03mm	1-12-'23	Project team	Yes
C3.3	Product must be able to sustain 25N vertical/down force	[N]	FEM analysis; maximum Von Misses stress is below fatique stress model at 1e7 cycles	10-06-'23	Project team	Yes
C3.4	Product must be able to sustain 25N distributed horizontal force	[N]	Phantom test: maxverforce=testforce*safetyfactor	10-06-'23	Project team	
C3.5	Product must be able to survice a 2 meter vertical drop	[-]	Drop test/FEM	10-06-'23	Project team	
W3.1	An as long as lifetime as possible	[-]		24-06-'23	Project team	
D. Compatability		Unit	Validation	Date	Stakeholder	

D4.1	Product must be compatible with the all the sizes of abdominal rings of the LEEDS and field research version of the RAIS device	[-]	Holder fits all abdominal rings	24-06-'23	Gnanaraj	Yes
D4.2	Product must adapt to an abdominal wall thickness corresponing to a person with a BMI up to 25.	[-]	Test holder with different abdominal wall thicknesses	14-10-'23	Gnanaraj	Yes
D4.3	Product must be compatible with 0 and 30 degree laparoscopic camera during surgery	[-]	Phantom test perfomed with largest workspace needed by persoming the test with a 0 degree laparoscope	14-10-'23	Gnanaraj	Yes
E. Cleaning		Unit	Validation	Date	Stakholder	
E5.1	Laparoscopic holder is autoclavable in a rural hospital	[-]	CES EDUPACK, AISI 316L is excellent autoblavable	24-06-'23	Gnanaraj	Yes
E5.2	laparoscopic holder is able to be able to be cleaned and sterilized with CIDEX in a rural hospital	[-]	Good resistance against rubbing alcohol(Alcohol, Isopropy) 112	10-06-'23	Leeds	Yes
E5.3	Material is alcohol resistance so laparoscopic holder is able to be able to be cleaned by alcohol rub in a rural hospital	[-]	Good resistance against rubbing alcohol(Alcohol, Isopropy) 112	27-11-'23	Leeds	Yes
E5.4	Surface roughness, according to ISO 1672:2020 the surface roughness is maximum 0.8 um		Defined in manufacture process	27-11-'23	Norms	Yes
W5.1	The laparoscopic camera holder includes an (automatic) lens cleaner	[-]		14-10-'23	Gnanaraj	No
W5.2	Material has a strong acids resistance	[-]	CES EDUPACK, AISI 316L has a excellent resistant to acids	27-11-'23	Gnanaraj	Yes

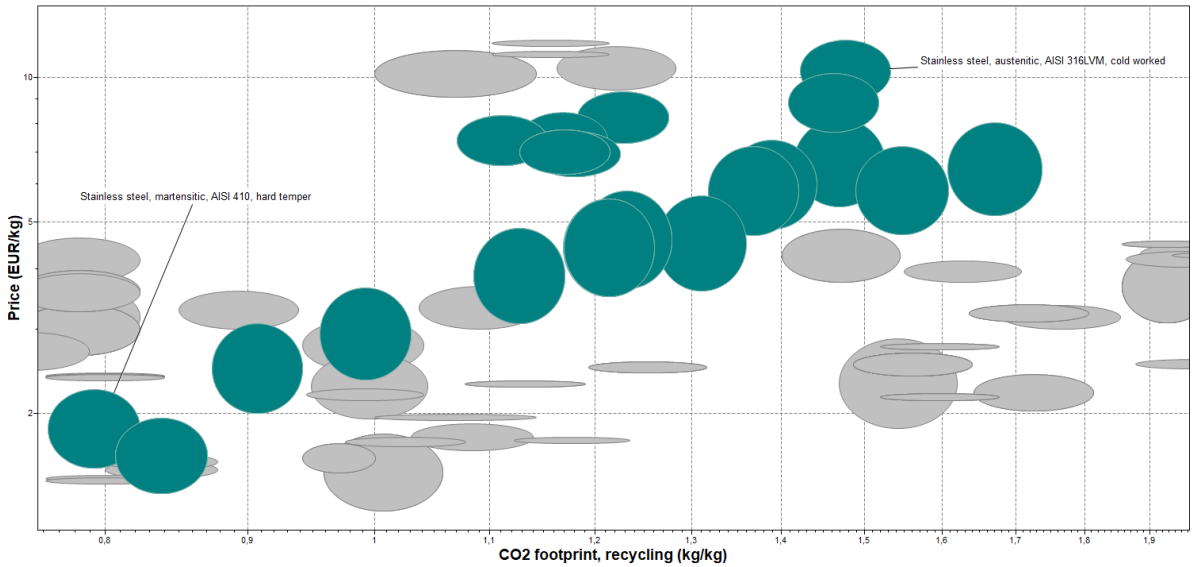
W5.3	Good stress corrosion handling	[-]	CES EDUPACK, AISI 316L had a slightly susceptible behaviour	27-11-'23	Gnanaraj	Yes
F. Manufancturing & maintenance		Unit	Validation	Date	Stakeholder	
F6.1	Easy to maintain and spare parts readily available / repair possible in rural setting	[-]	Phantom test: statement check. No medical grade material or bending/welding is possible in rural settings	24-06-'23	Project team	No
F6.2	Local maintaince and production of spare parts is possible	[-]	Phantom test: requirment check	24-06-'23	Project team	Yes
F6.3	Material has to be medical grade, suitable for medical application	[-]	Medical graded materials in CES EDUPACK	27-11-'23	Norms	Yes
F6.4	Optimize production technique for a batch size of 20 pieces	[-]	Defined manufacture process considering specific batch size	27-11-'24	Gnanaraj	Yes
W6.1	Material should be weldable in case repairs are needed	[-]	CES EDUPACK, AISI is weldable and no post and pre heating is required	27-11-'23	Norms	Yes
G. Frugality & Sustainability		Unit	Validation	Date	Stakeholder	
G7.1	The laparoscopic camera holder uses no single products in usage	[-]	No single used producst are needed during usage	24-06-'23	Project team	Yes
G7.2	Product must cost less than 5 euros	[Euro]	Discussion with Indian manufacturer	21-11-'23	Gnanaraj	Yes
G7.3	A minimum of 80% product weight must be recyclable	[-]	CES EDUPACK, AISI 316L is recyclable	24-06-'23	Project team	Yes
G7.4	Product must have a planned end-of-life	[-]	Make a planned end-of-life plan		Project team	
W7.1	The laparoscopic camera should be as cheap as possible	[Euro]		24-06-'23	Project team	
W7.2	Minimizing the amount and moving parts	[-]	Holder exist out of 1 part	24-06-'23	Project team	Yes
W7.3	Can be maintained and repaired using as much as possible local resources	[-]		24-06-'23	Project team	

W7.4	Uses as little as possible resources during usage(electricity, water, etc.)	[-]	Holder does not require additional resources during usage	21-07-'23	Project team	Yes
W7.5	As much of the product can be recycled	[-]	CES EDUPACK, AISI 316L is recyclable	24-06-'23	Project team	Yes
I. Safety & Regulations		Unit	Validation	Date	Stakeholder	
I8.1	Placing and using camera holder can't damage tissue(no sharp edges and max applied forze per m^2 is __N)	[N/m^2]	All edges are rounded and holder does not come in contact with tissue during operation	10-06-'23	Leeds	
I8.2	Product must work between [-5 and 60 degrees Celcius] during usage	[]		06-08-'23	Piaggio	
I8.3	Product must be waterproof at IP level 9K	[]		06-08-'23	Piaggio	
I8.4	Product must be completely dust-tight at IP level 6	[]		06-08-'23	Piaggio	

Appendix F Universal instructions



Appendix G CES EDUCPACK material selection



According to ISO 10993-1 it is necessary to perform a biological evaluation of medical devices as part of a risk management process.

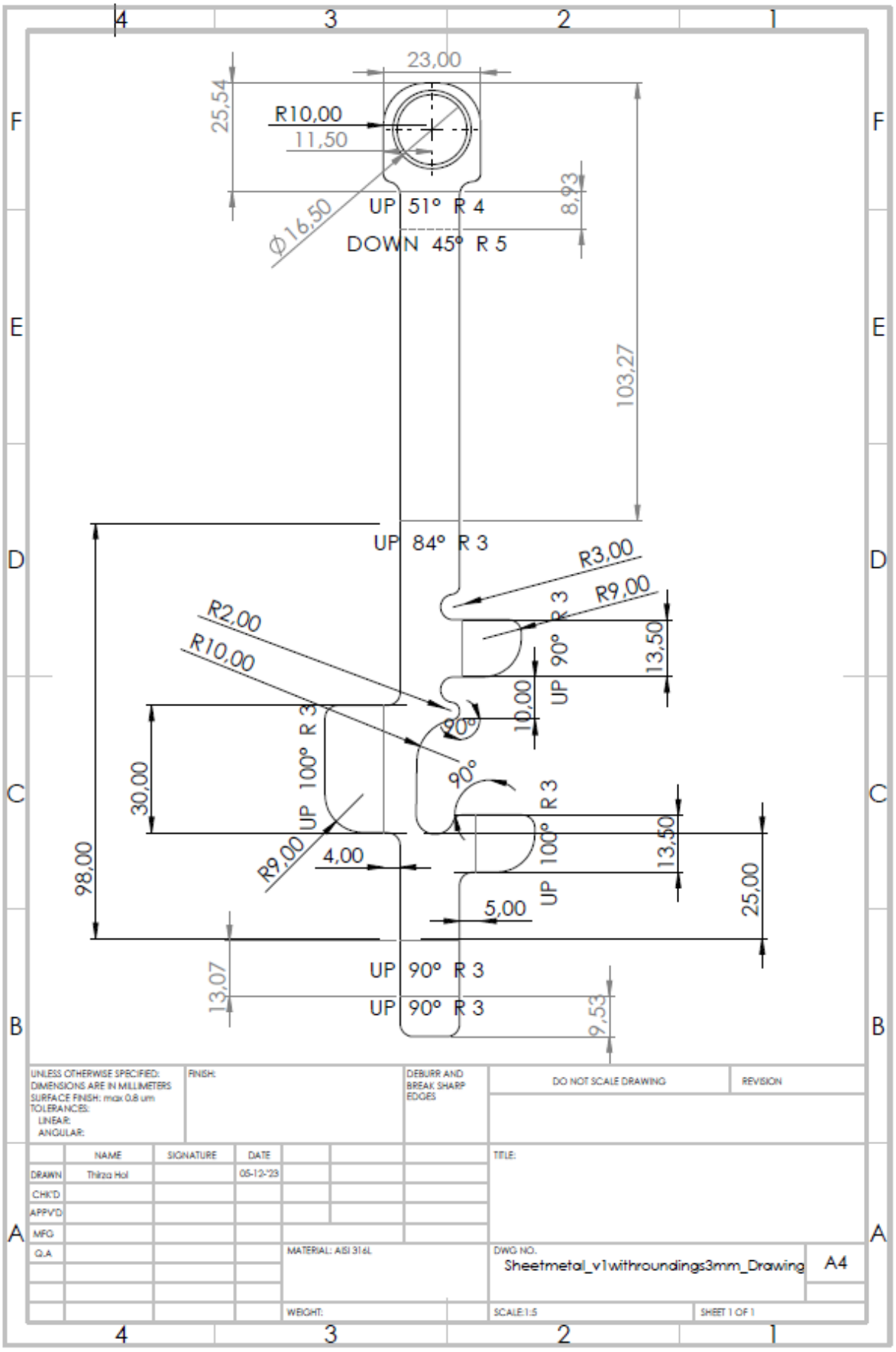
used in medical device

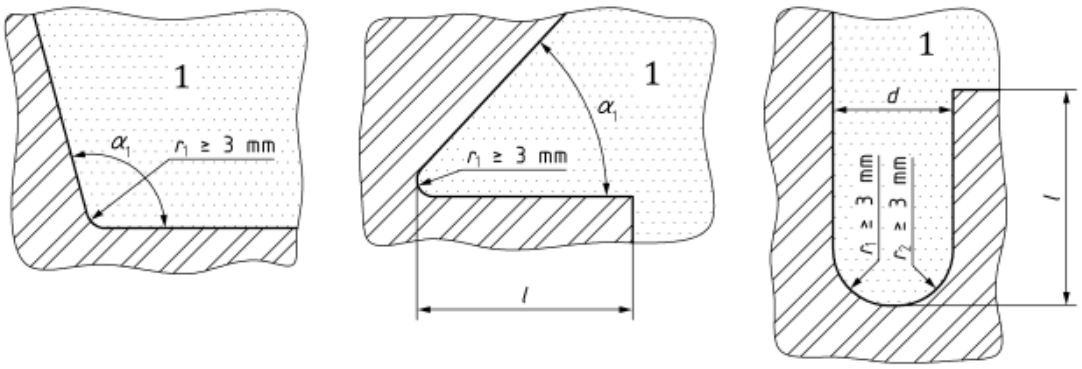
According to ISO 10993-18 of a medical device that will come into direct contact with the human body a chemical characterization of the material is needed . Due to time constraints, only materials certified for medial application are included in the material selection.

Figure 40 General chemical characterization process, P.9
https://connect.nen.nl/standard/openpdf/?artfile=3632163&RNR=3632163&token=e7455251-75e2-4e3e-abcc-cfbf5eade00f&type=pdf#pagemode=bookmarks

ISO 7153-1 provides a list of medical grades of stainless steels commonly used to manufacture various types of surgical instruments. (used 316, but not specifically 316L)

Appendix H Part drawing metal sheet





$30° < \alpha_1 < 135°$

3a)

l shall be specified so as not to impair cleanability

$0° < \alpha_1 \leq 30°$

3b)

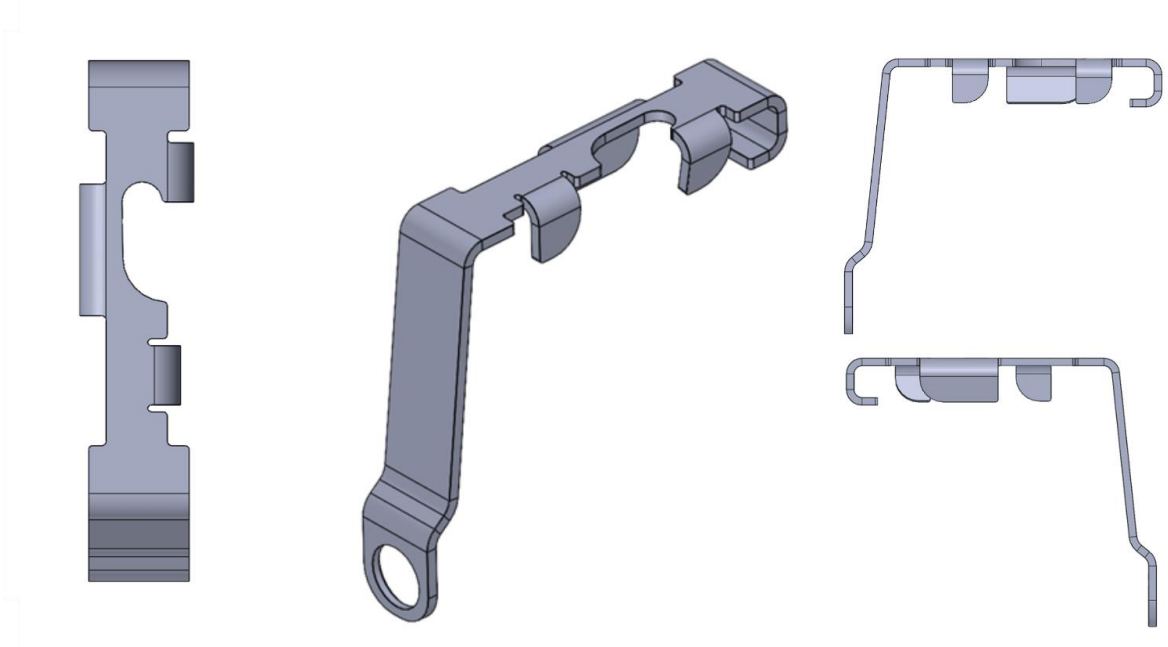
$d \geq 6$ mm so as not to impair cleanability

If $d \leq 50$ mm, l shall be $\leq d$

3c)

Figuur 1. **https://connect.nen.nl/standard/openpdf/?artfile=3641192&RNR=3641192&token=a30e93cb-ad29-4cf9-9880-a8f8732a39a2&type=pdf#pagemode=bookmarks** **(ISO 1672:2020)**

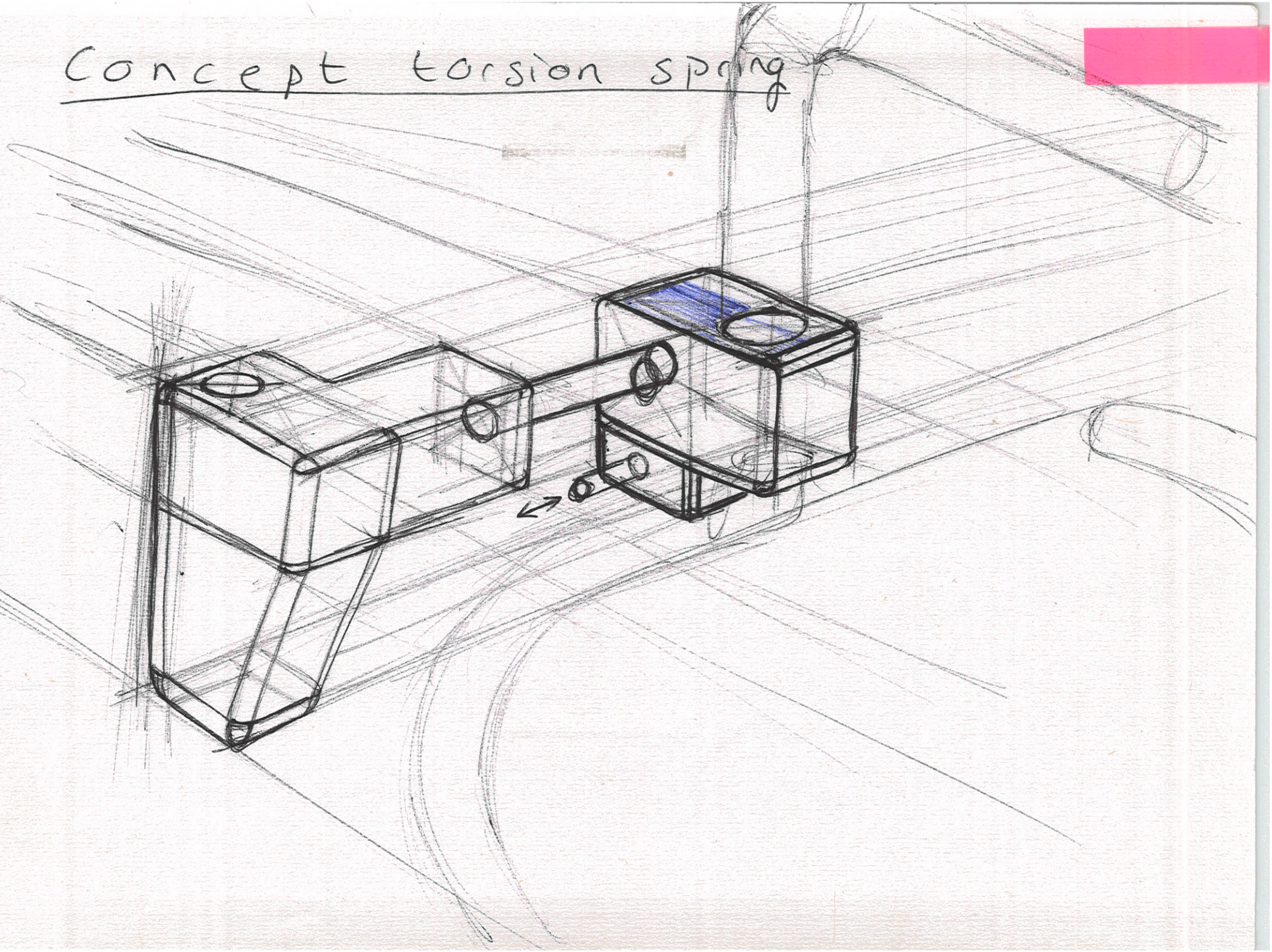
The model before the ISO standard for cleanability, 1672:2020, is met:



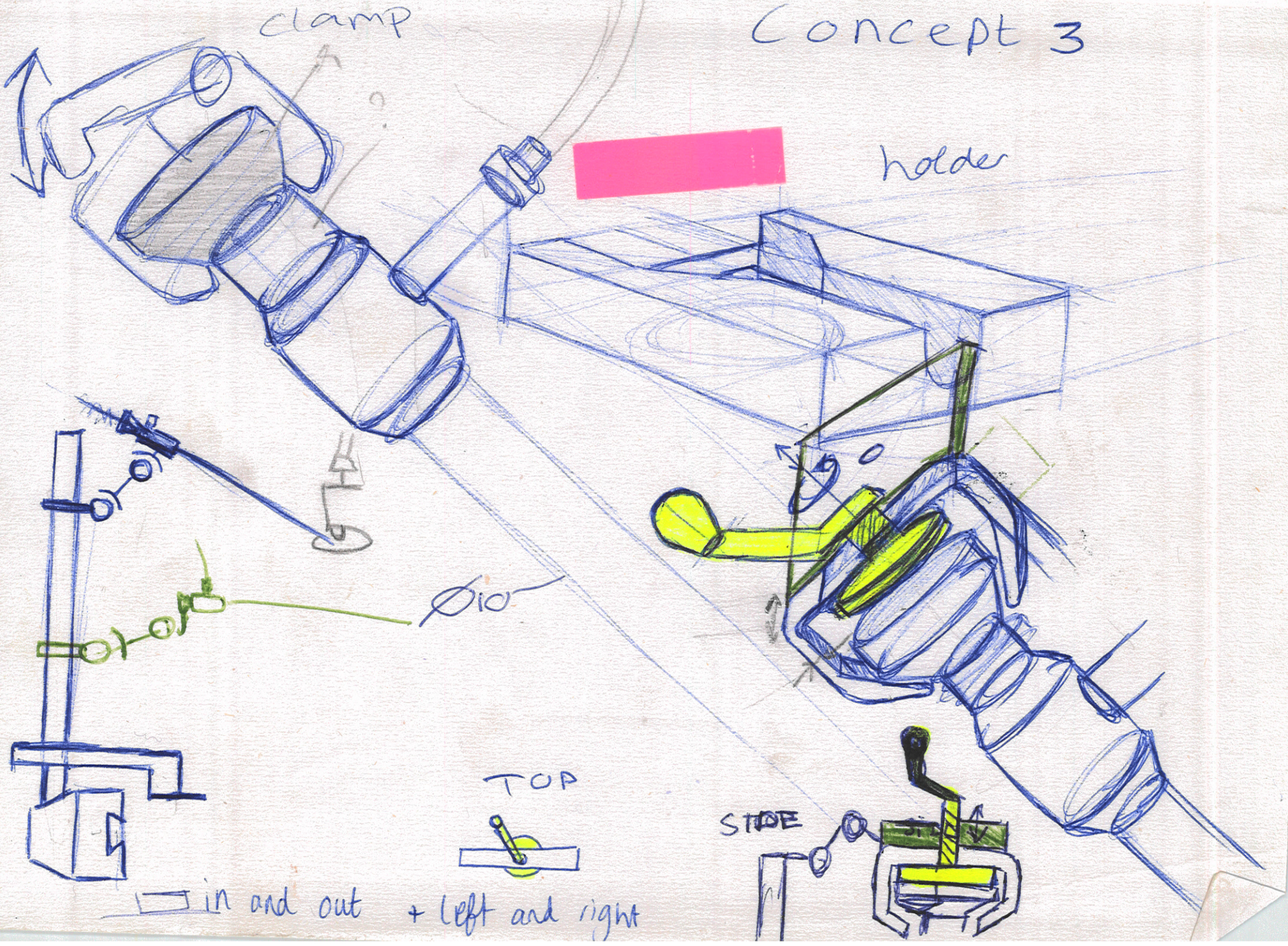
The part drawing metal sheet of the final design including meeting the ISO standard for cleanability, 1672:2020

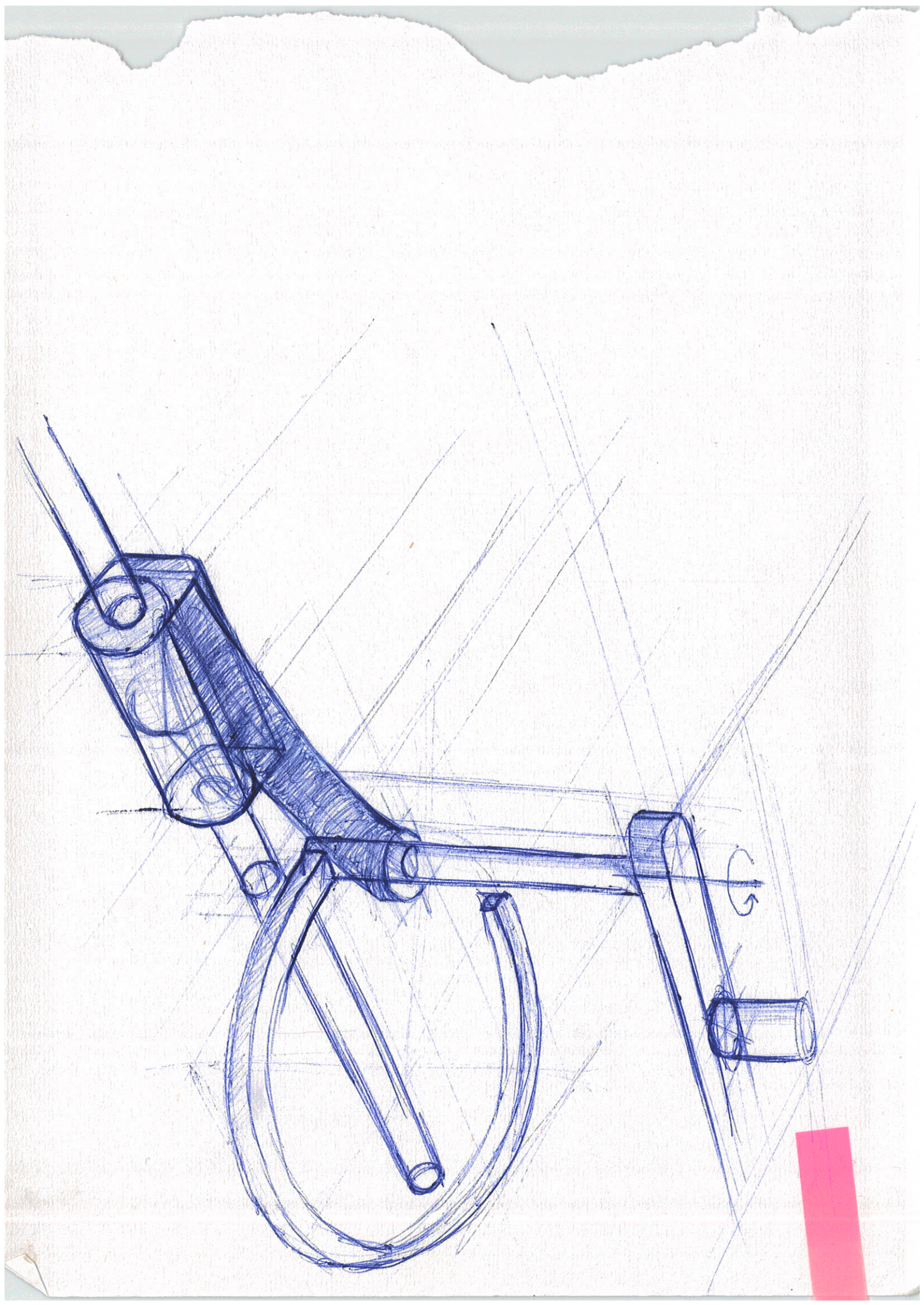
Appendix I Concept generation and future improvements

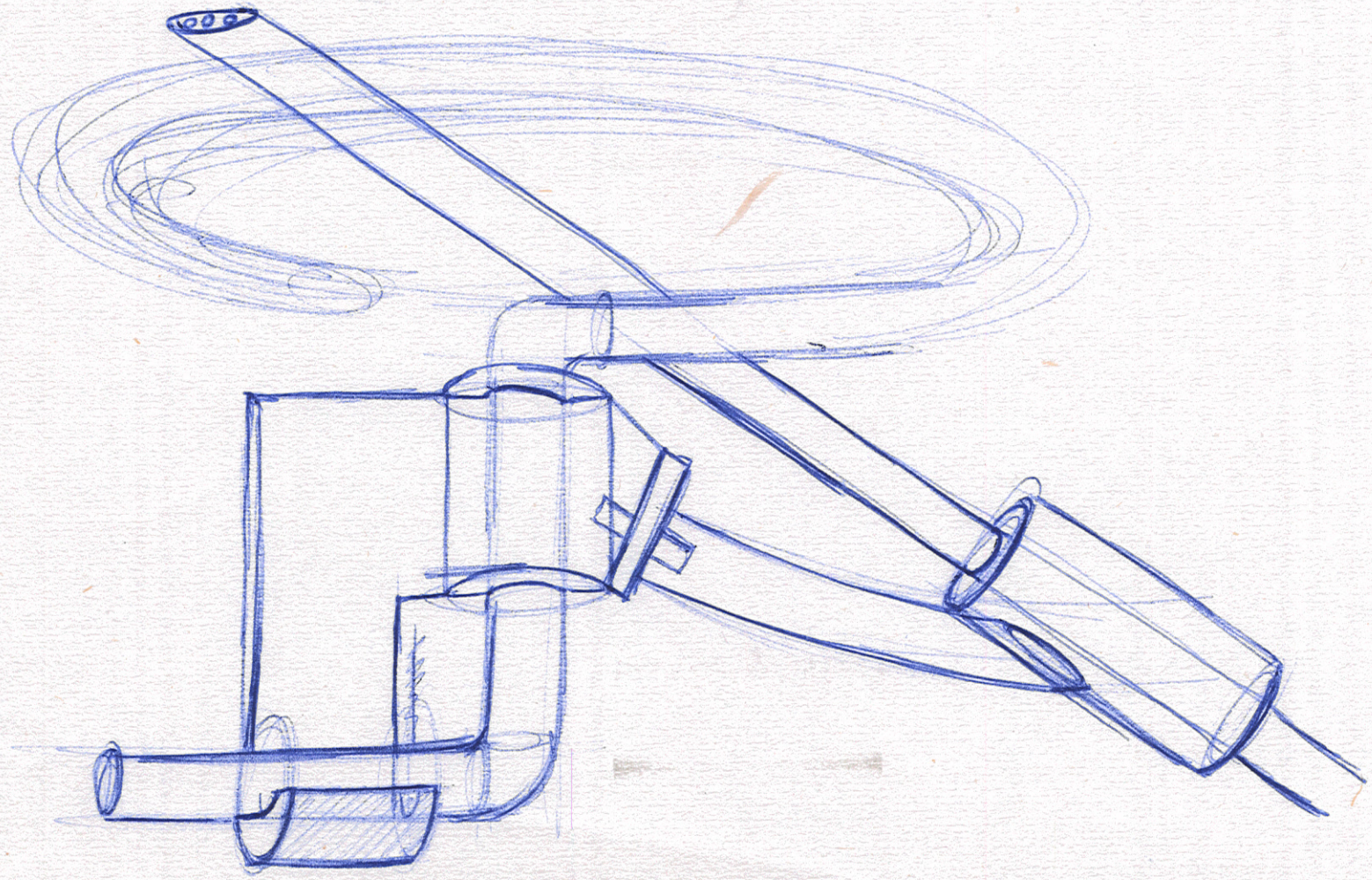
Concept torsion spring

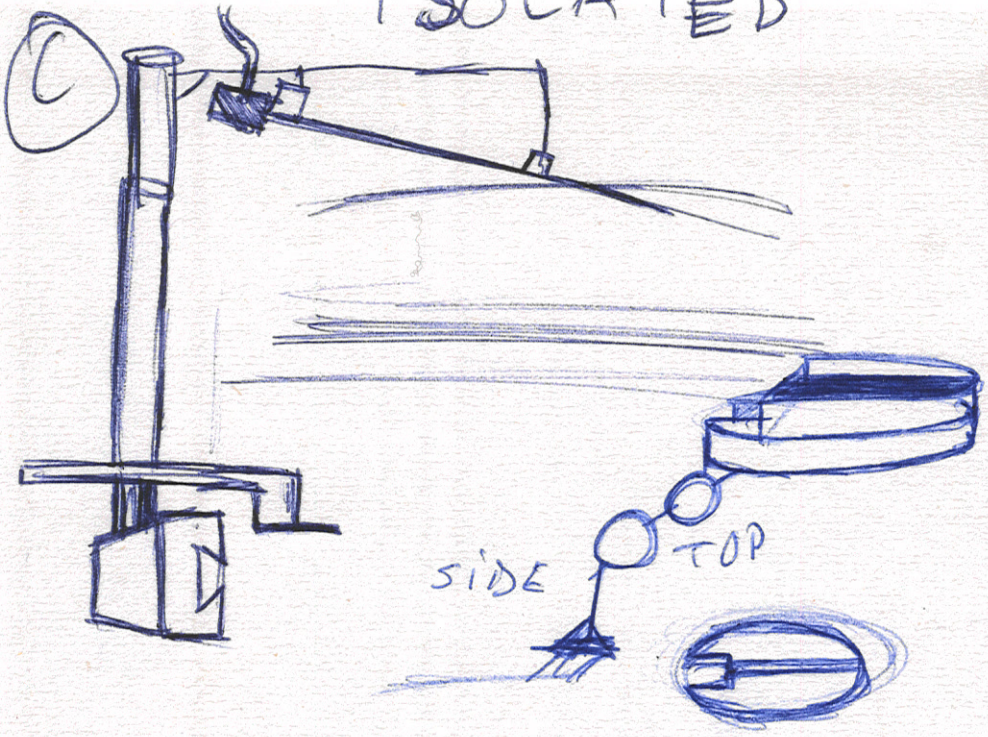


Concept 3

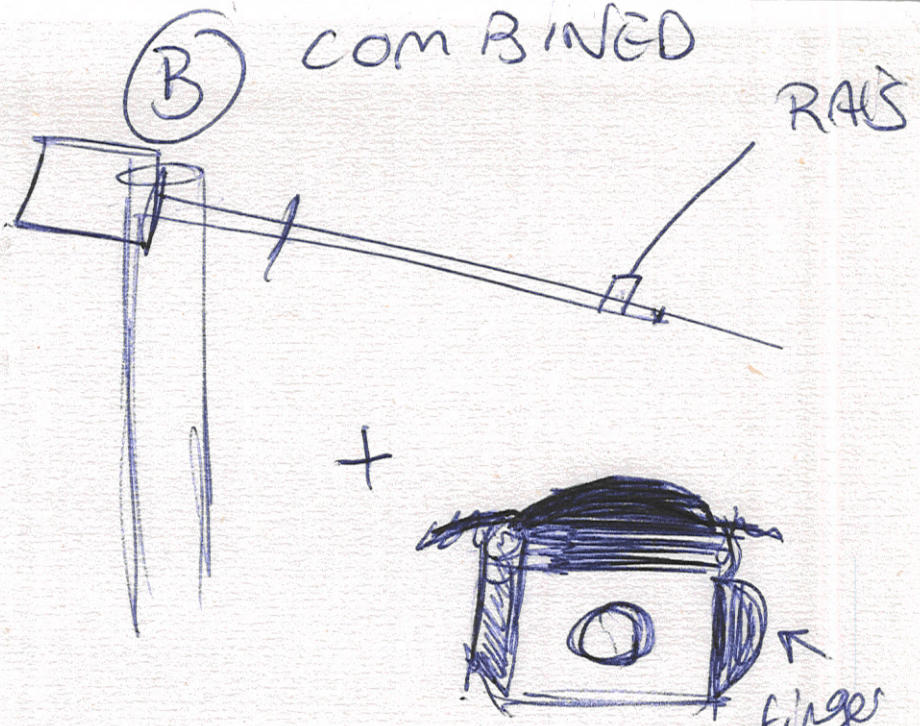





TOP

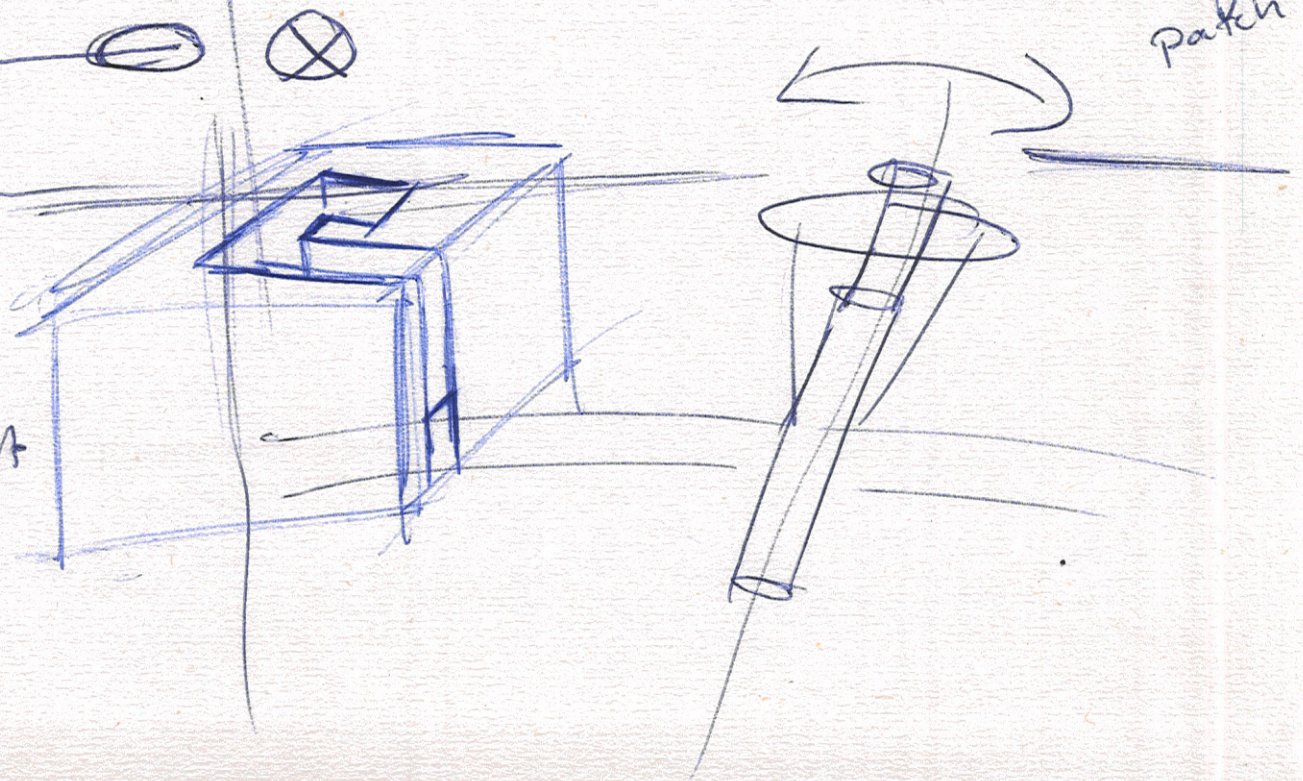


OR



→ left right X

→ up and down

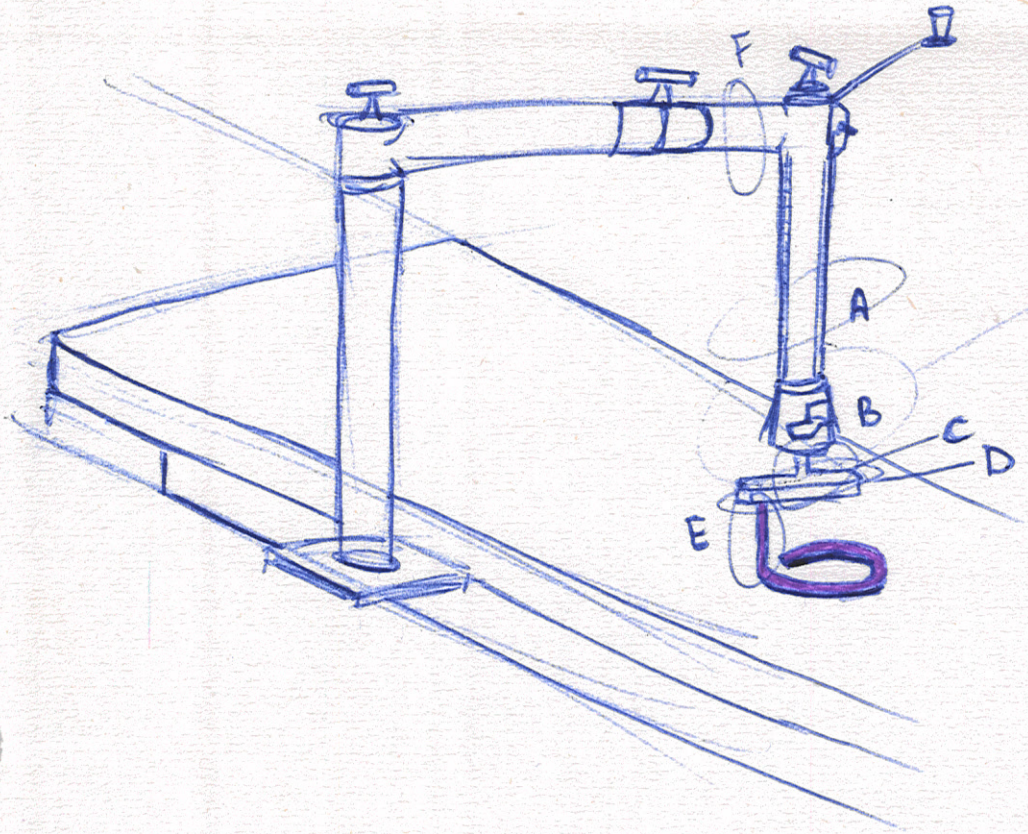


(A) ONLY RAS

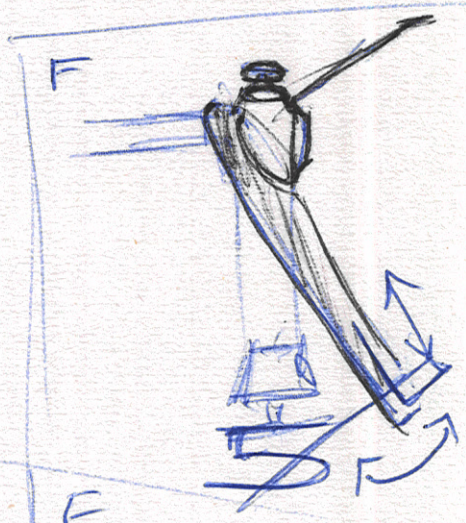
→ Minimum amount equipment

only hook

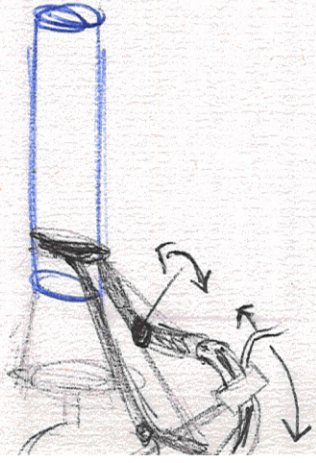
$980 (£802)
1/3 of old retractors



A	B	C	D	E	F



A



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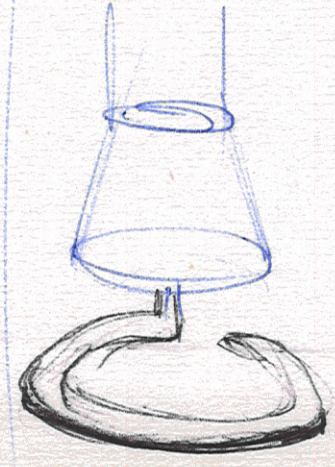

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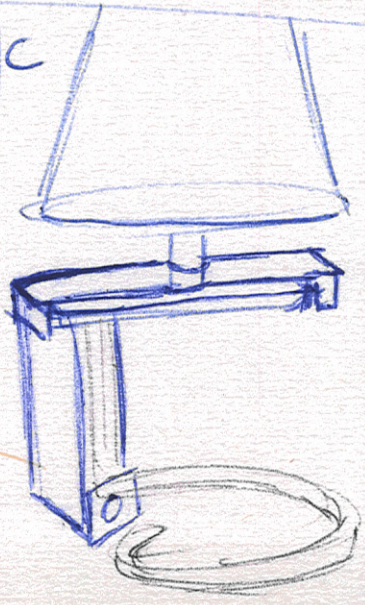

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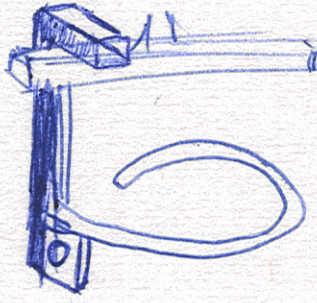
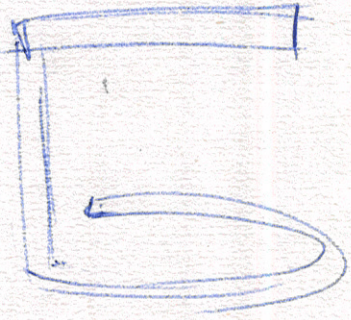


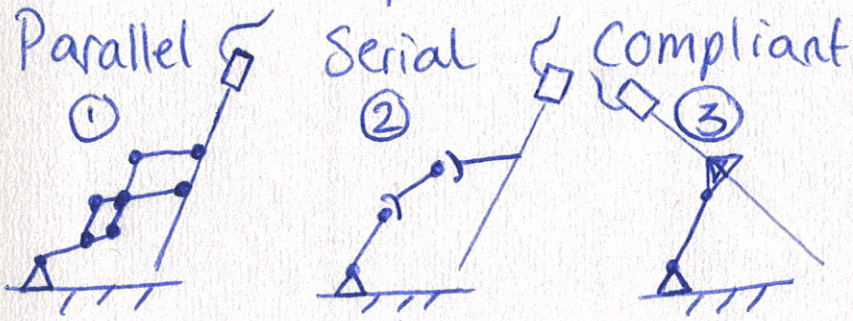
E



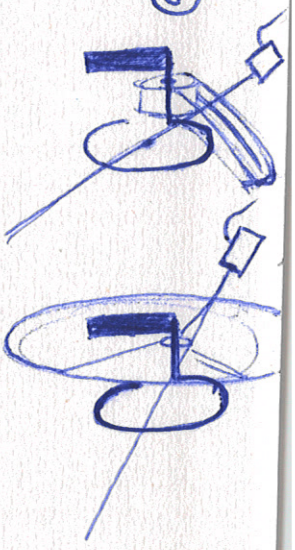
OPTIONS

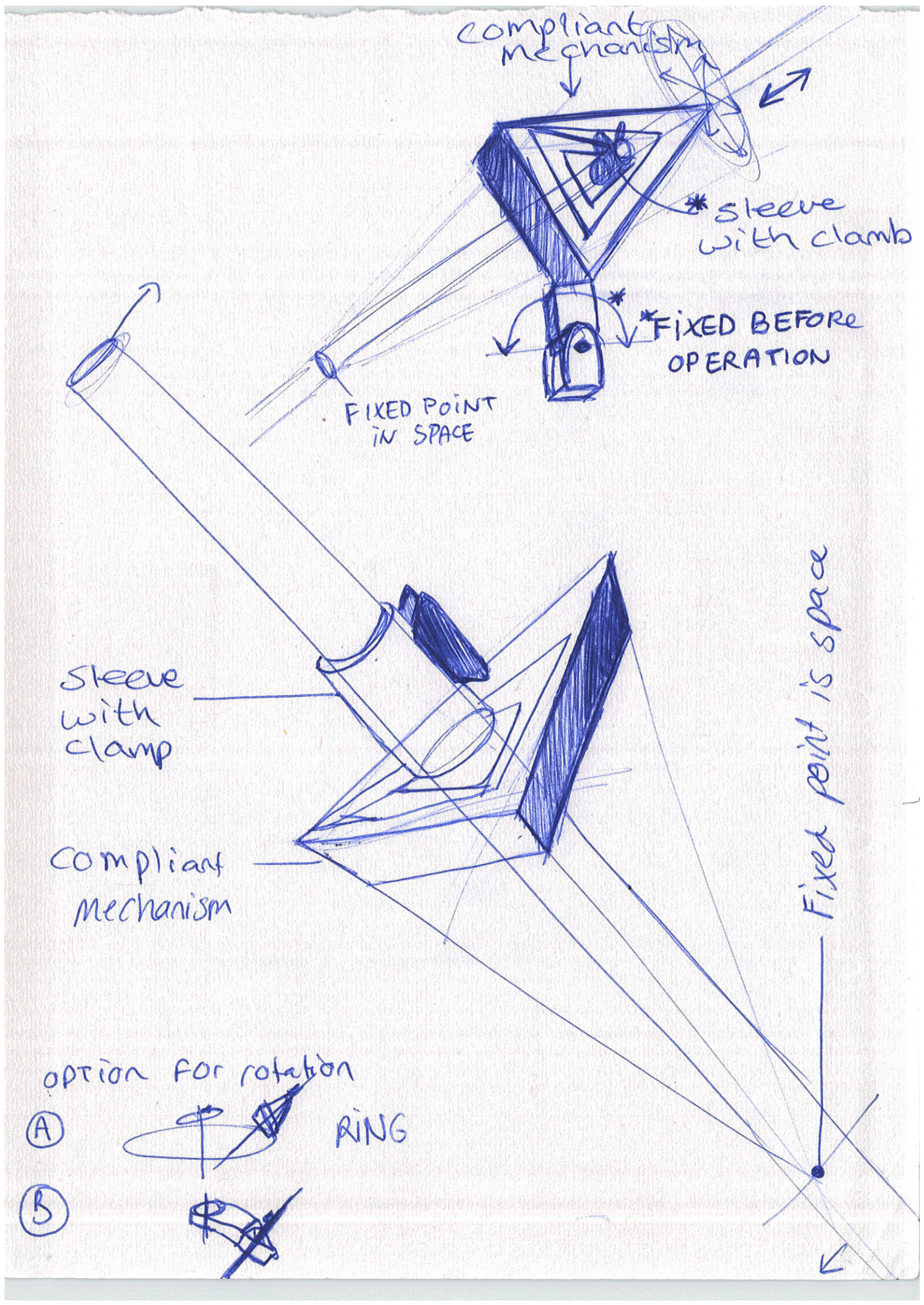
Compatible with RAIS device

- No, stand alone device
  - Parallel ①
  - Serial ②
  - Compliant ③
- Yes, add on
  - change RAIS system
    - change HOOK ④
    - change more ⑤
  - No change in RAIS
    - design around ⑥



axis in the centre




compliant mechanism
sleeve with clamb
FIXED BEFORE OPERATION
FIXED POINT IN SPACE
sleeve with clamp
compliant mechanism
Fixed point is space
option for rotation
A
RING
B

~~FVS~~

OPTIONS

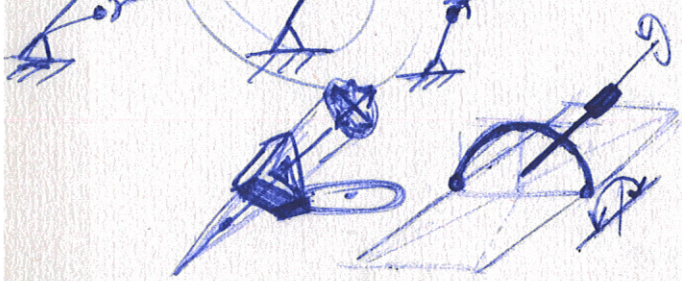
compatible with RAIS system

no, standalone device

① Parallel

② Compliant

③ serial



yes, addon

change in current system

④ change more

add second support system

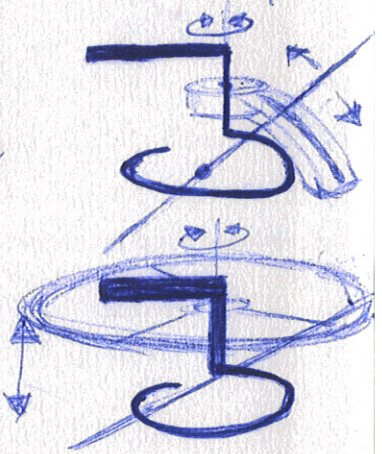
+hook attachment

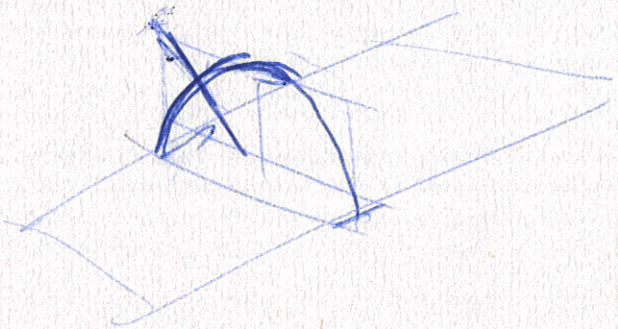
⑤ change hook

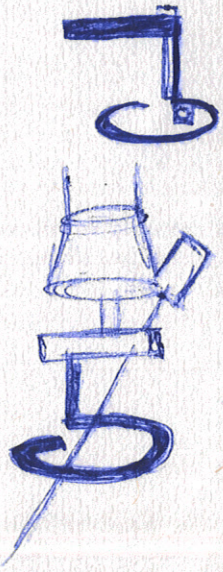
axis in the middle

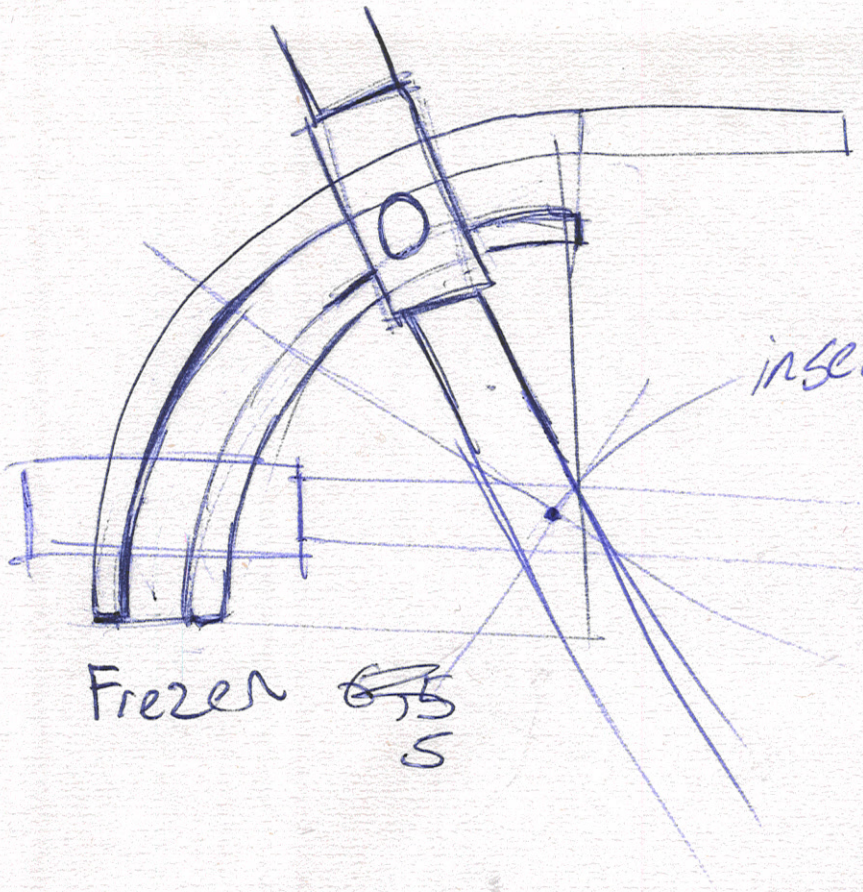
change, NO

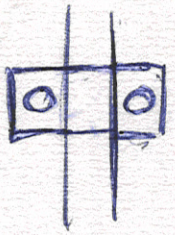
⑥ design around hook/system

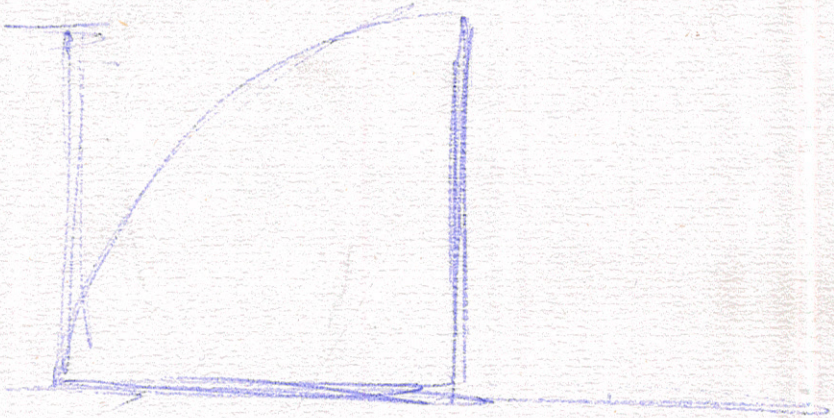


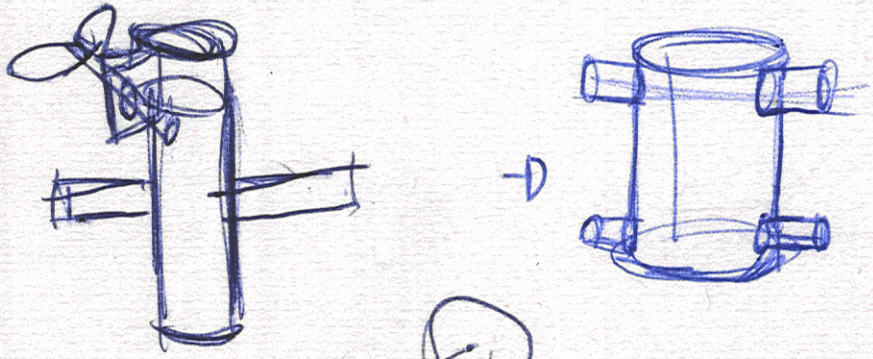





insection point
Frezer
5



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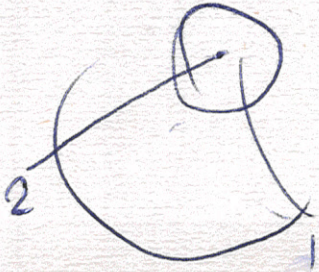
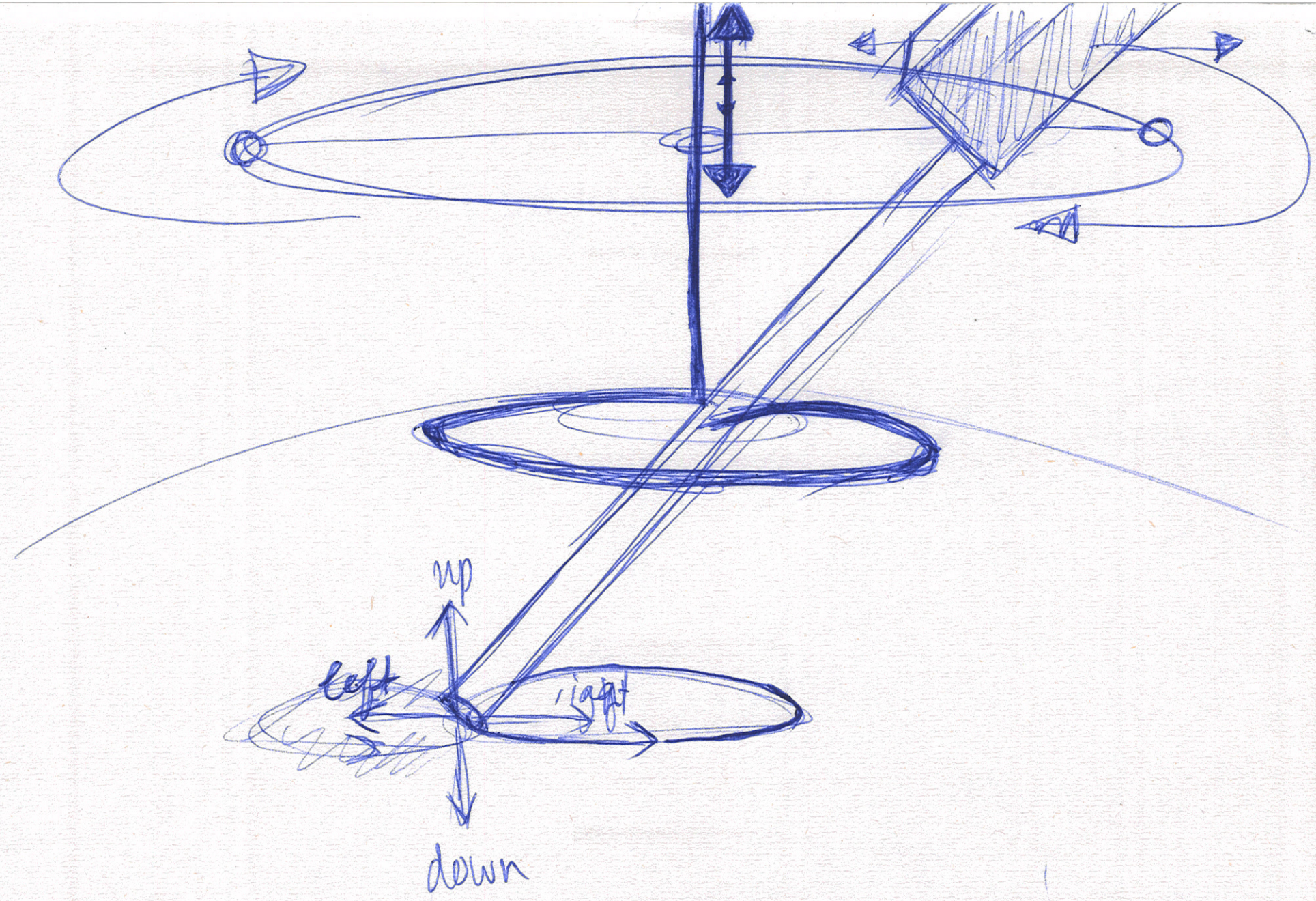
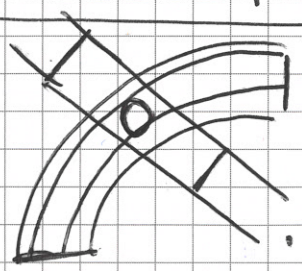
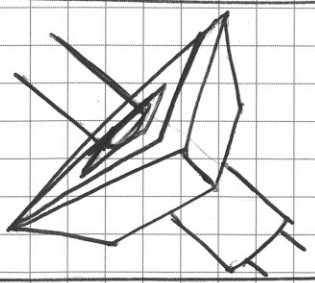
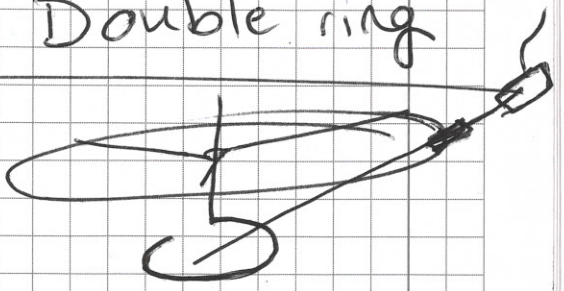
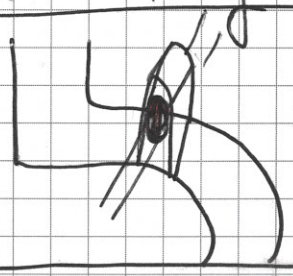
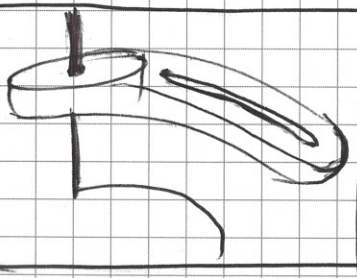
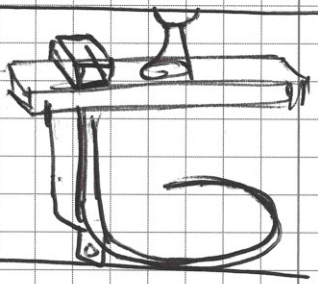
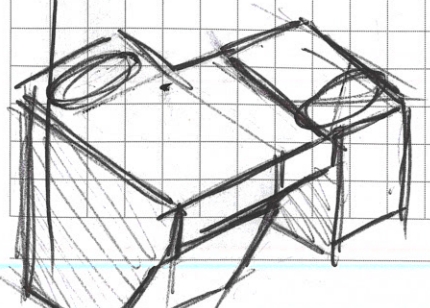
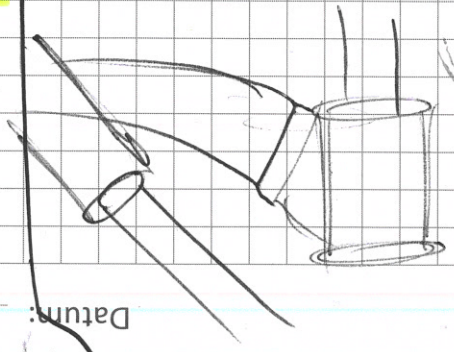

2
1



No space for instruments
Needs additional holes

Quater Moon

name	concept	complaint	Double ring
			
)W		Yes	Yes
3.D		Yes	
FBG			Yes
FBG			No
ring			
	Extra ring	Thirza-ol.	
			
)W	No	Yes	No
, D	No		Yes
BC	-	Yes	-
BG	No	X	
ring			
	Mini	Nils	Concept eongarm
			

Yes Yes Yes Yes Yes

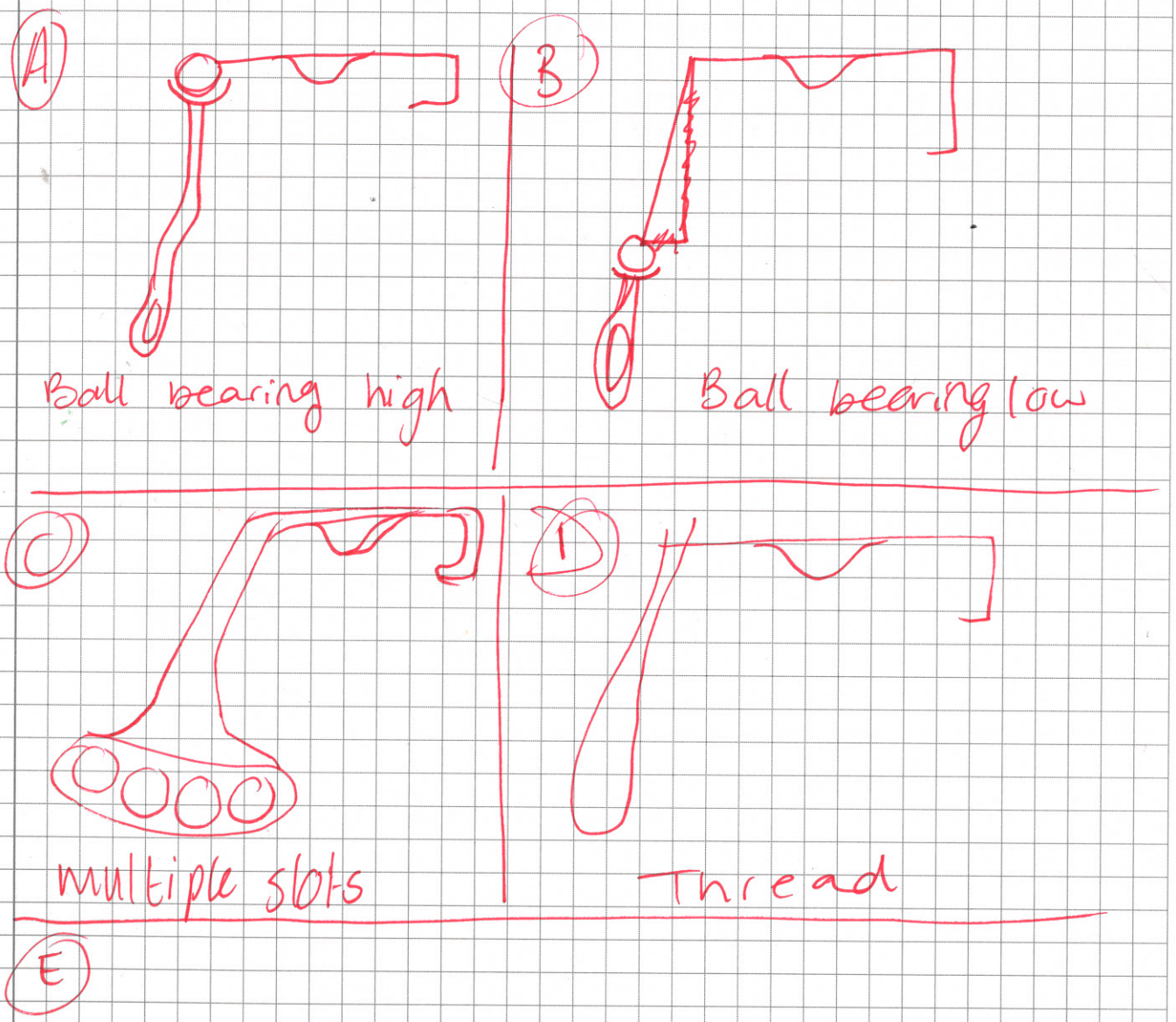
Datum:

Onderwerp:

Onderwerp: _____

Datum: _____

SUGGESTION NEXT GENERATION



Appendix FEM analysis

Autodesk Nastran Analysis Report

Date: 12/05/23
Author: Autodesk Customer
Subject: Analysis Report
Prepared For: Autodesk Customer
Software Used: Autodesk Nastran Version 18.0.0.17

Tables of Contents

1. Summary

The report documents design and analysis using Autodesk Nastran engineering simulation software. A linear static analysis was performed using the finite element model shown in the figure below. The model is divided into 1 property group(s). The units system is m-N-s. The model consists of a total of 59506 nodes and 33641 elements.

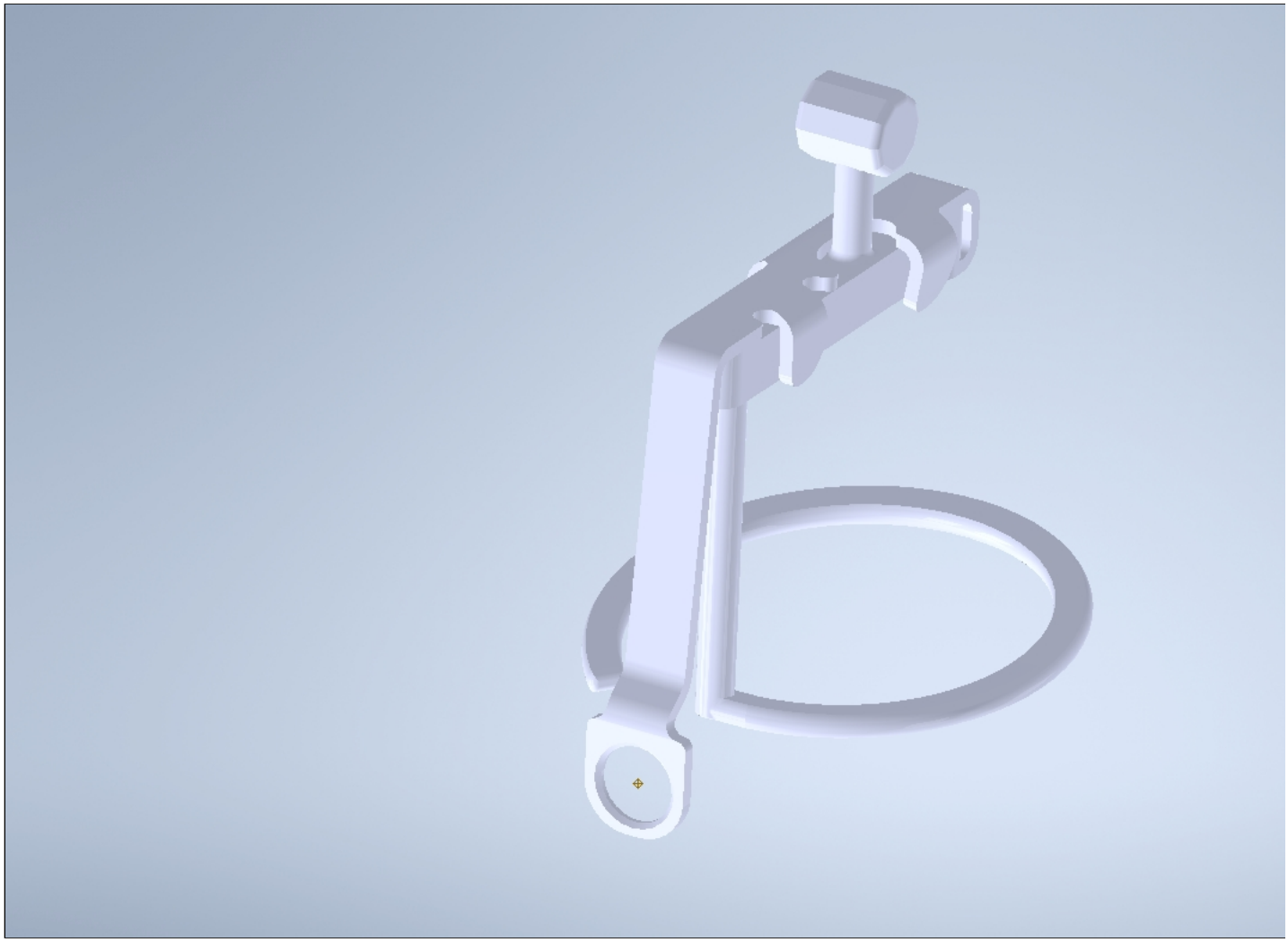


Figure 1 - Finite Element Model

2. Assumptions

1. Displacements are small.
2. Follower forces are ignored.

3. Model Definition

3.1 Group Definition

The model is divided into 1 property group(s). Details for each group are given in Table 3.1.1.
1. The bounding box for all positioned bodies in the model measures 0,115 by 0,1369 by 0,1146m along the basic coordinate system x, y and z axes, respectively.
2. The total mass of the model is 0,3429 kg.
3. The model center of mass is located at (-3,066E-02, -9,533E-02, -1,987E-02) m.

Table 3.1.1 Group Definition

Property Group	Material	Bounding Box (m)	Mass (kg)	Volume (m^3)	Nodes	Elements
SOLID 1	MAT 2	0,115, 0,1369, 0,1146	0,3429	4,292E-05	56252	33641

Table 3.1.2 Part Mass Properties

Property Group	Material	Mass (kg)	Center of Mass (m)	Moments of Inertia (m)
SOLID 1	MAT 2	0,3429	-3,066E-02, -9,533E-02, -1,987E-02	7,23E-04, 4,747E-04, 7,121E-04

3.2 Contact Definition

The model contains 1 contact region(s).
- Adaptive stiffness scaling is enabled.

Table 3.2.1 Contact Definition

Name	Type	Contact Surface	Normal Stiffness	Penetration
Contact Region 6	General Contact	Surface 8, Surface 7	Stiffness Controlled	Symmetric

3.3 Material Properties

3.3.1 Isotropic Material Definition

Material ID	E	G	NU	RHO	ALPHA	T-REF
2	1,93E+11	7,72E+10	0,25	7990,0	1,6E-05	0,0

3.3.2 Anisotropic Shell Element Material Definition

No Data

3.3.3 Anisotropic Solid Element Material Definition

No Data

3.3.4 Orthotropic Shell Element Material Definition

No Data

3.3.5 Orthotropic Solid Element Material Definition

No Data

3.3.6 Hyperelastic Element Material Definition

No Data

3.4 Mesh

The finite element mesh is shown in the figure below. The model consists of a total of 59506 nodes and 33641 elements.

Table 3.4.1 Element Initial Distortion Summary

Property Group	Property Type	Aspect Ratio	Recommended Limit	Taper Ratio	Recommended Limit	Skew Angle	Recommended Limit	Warping Angle	Recommended Limit
SOLID 1	TET	6,141	100,0	0,0	0,0	159,9	80,0	0,0	0,0

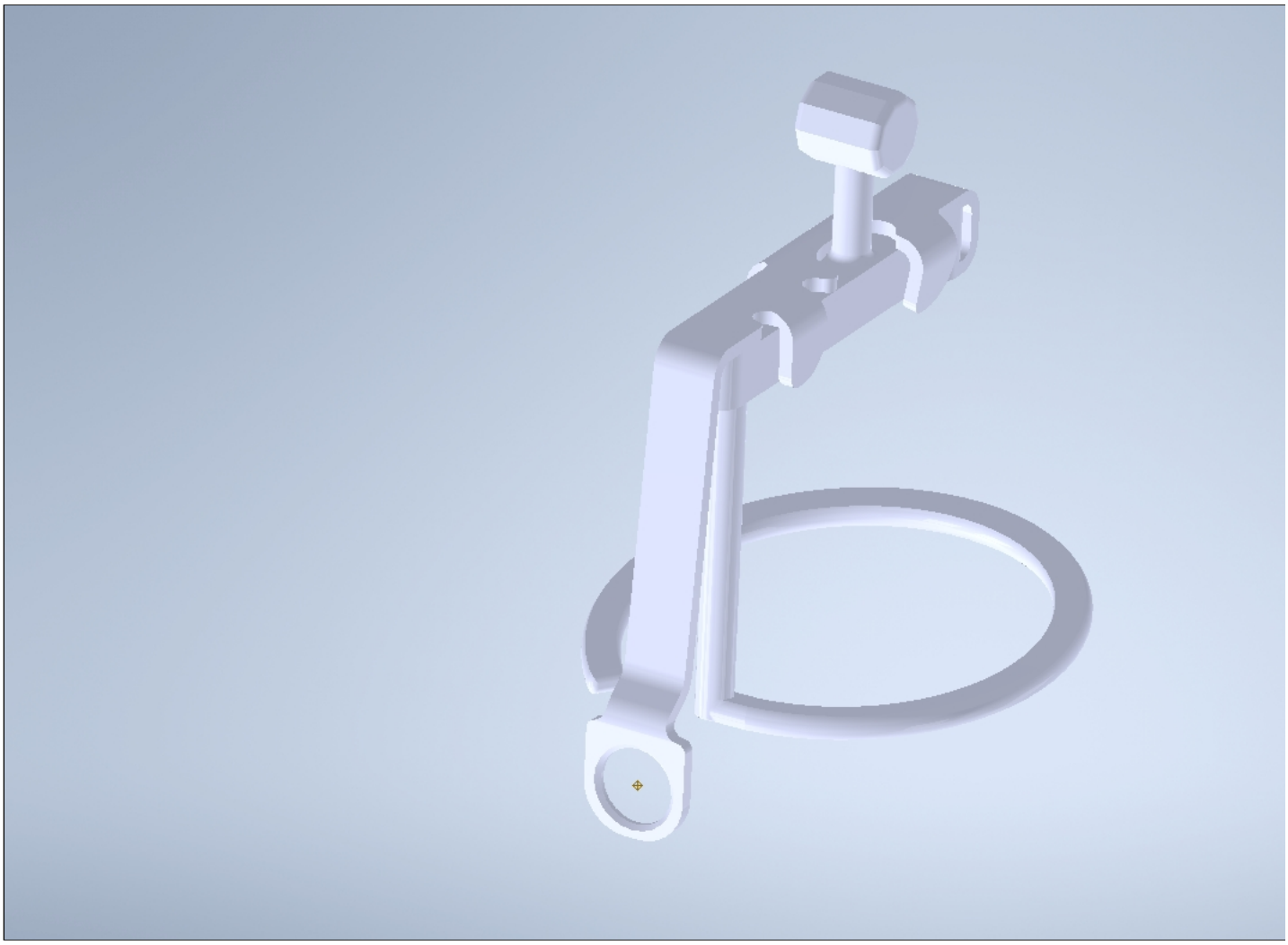


Figure 2 - Finite Element Mesh

4. Environment

4.1 Structural Loading

The finite element environments are shown in the figures below. Applied structural loading is summarized in Table 4.1.1. Applied load vector resultants are defined in the basic coordinate system. Moments are summed about location (0.0,0.0,0.0).

Table 4.1.1 Applied Load Vector Resultant

	Resultant Force(N)			Resultant Moment(N m)		
Subcase	**XT**	**YT**	**ZT**	**XR**	**YR**	**ZR**
SUBCASE 1	0,0	25,7	0,0	1,658	0,0	-1,96

4.2 Structural Support

Reaction loads are summarized in Table 4.2.1. Reaction load vector resultants are defined in the basic coordinate system. Moments are summed about location (0.0,0.0,0.0).

Table 4.2.1 Reaction Load Vector Resultant

	Resultant Force (N)			Resultant Moment(N m)		
Subcase	**XT**	**YT**	**ZT**	**XR**	**YR**	**ZR**
SUBCASE 1	-1,18E-06	-25,7	-1,378E-06	-1,658	1,112E-07	1,959

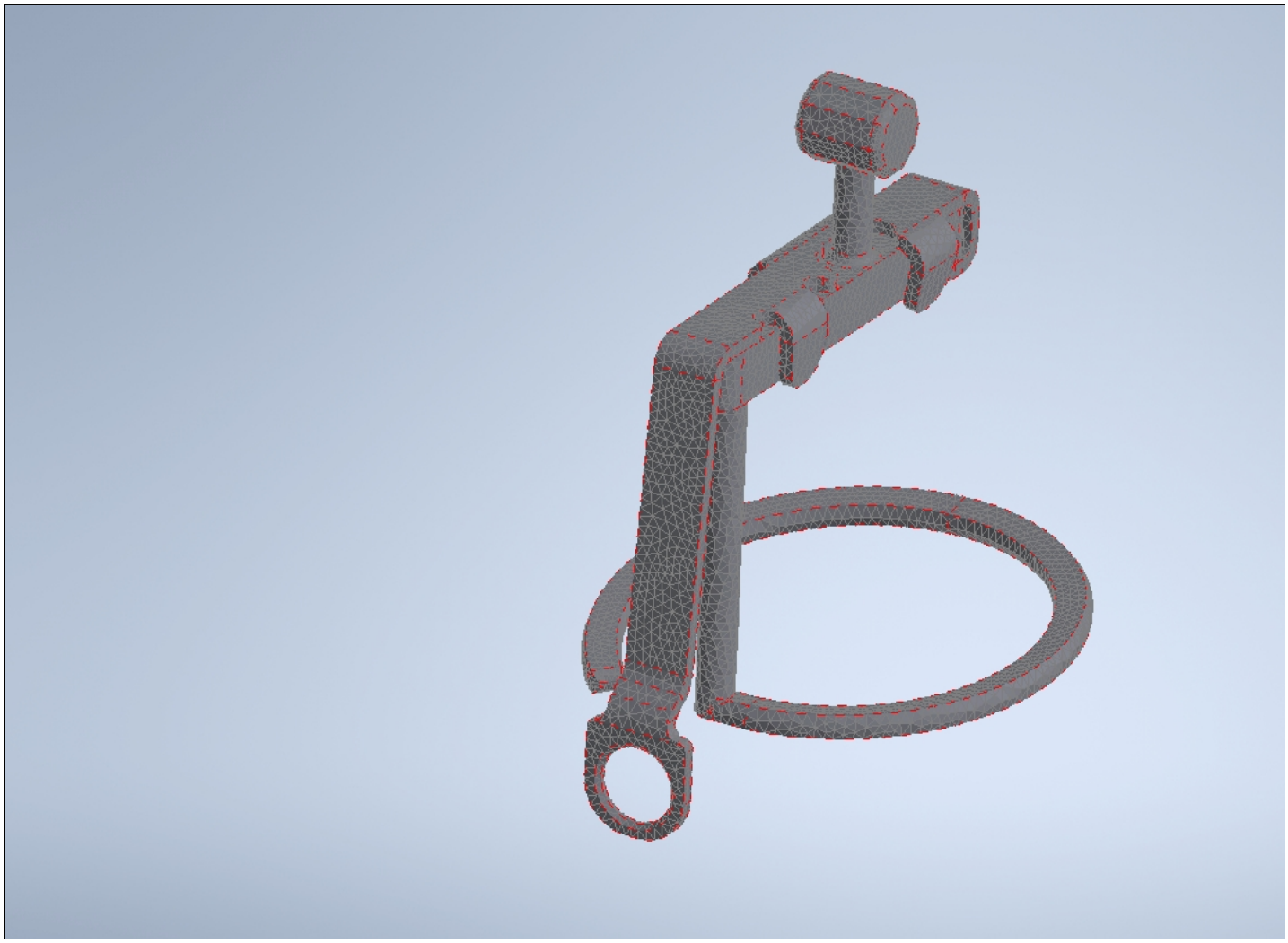


Figure 3 - Applied Load

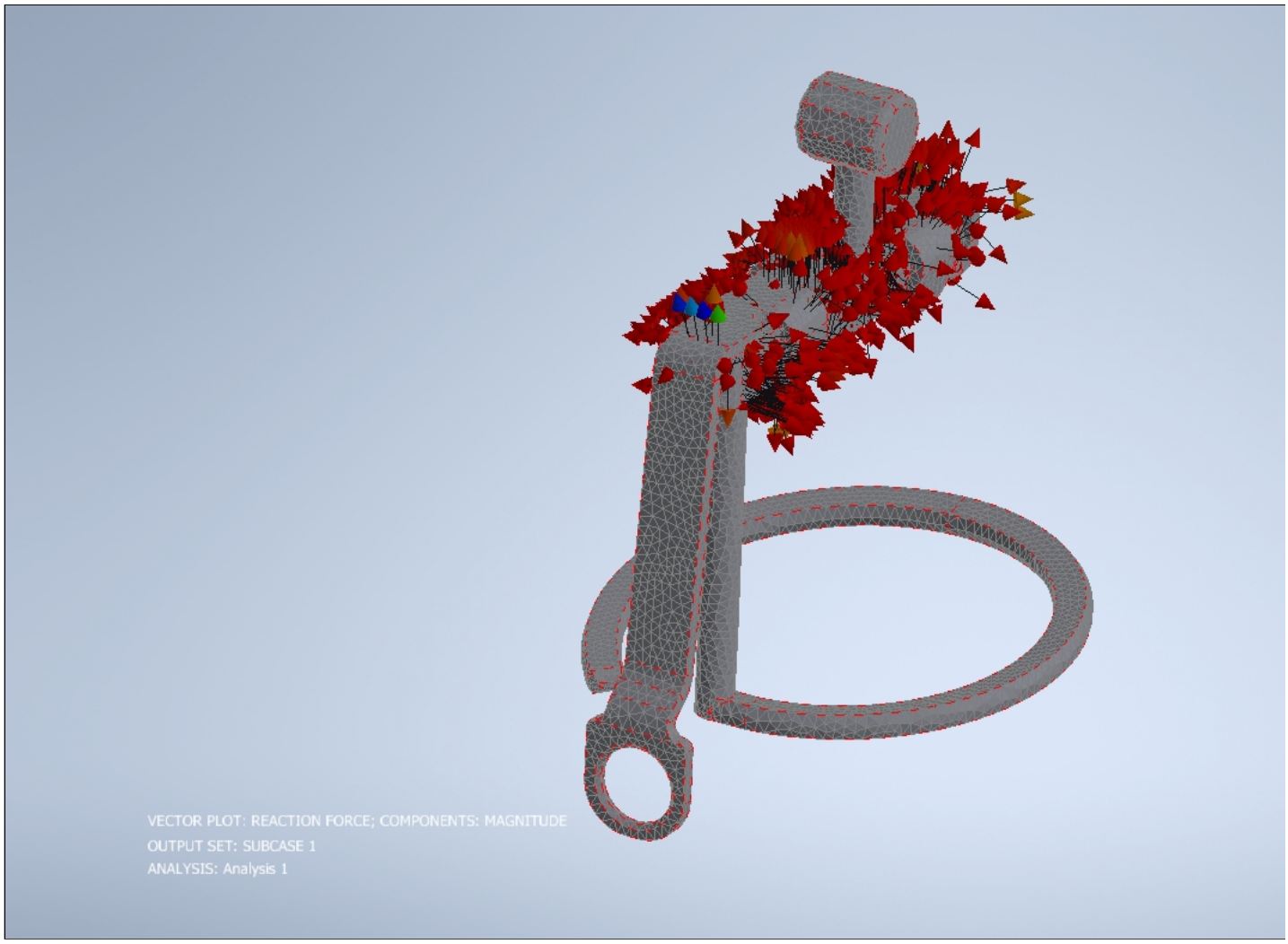


Figure 4 - Reaction Load

5. Solution

The solution to the Environment defined in Section 4 applied to the Model defined in Section 3 is given below. The program selected the PCGLSS linear solver. Total solution time was 56.83 seconds.The largest solution error measure was 3,335E-08 for SUBCASE 1.The largest solid element relative stress error was 4,345E-02 for SUBCASE 1.The results are summarized in the table(s) and figure(s) below.

Table 5.1.1 Displacement Summary

Subcase	Minimum Displacement (m)	Property Group	Maxmium Displacement (m)	Property Group
Subcase 1	3,249E-09	Sheetmetal_v1withroundings3mm2mm:1	3,091E-04	Sheetmetal_v1withroundings3mm2mm:1
Subcase 1	0,0	R0_11_2 Abdominal Ring (Version A MED):1	1,389E-08	R0_11_2 Abdominal Ring (Version A MED):1
Subcase 1	0,0		3,091E-04	

Table 5.1.2 Peak Displacement Component Summary

	Displacement Components (m)			Rotation Components (m)		
Subcase	XT	YT	ZT	XR	YR	ZR
SUBCASE 1	2,123E-04	5,838E-05	2,171E-04	2,911E-03	9,929E-06	2,853E-03

Table 5.1.3 Stress Results Summary

Subcase	Minimum Principal Stress (Pa)	Property Group	Maximum Principal Stress (Pa)	Property Group	Maximum Von Mises Stress (Pa)	Property Group
Subcase 1	-2,758E+07	Sheetmetal_v1withroundings3mm2mm:1	2,228E+07	Sheetmetal_v1withroundings3mm2mm:1	2,287E+07	Sheetmetal_v1withroundings3mm2mm:1
Subcase 1	-1,795E+06	R0_11_2 Abdominal Ring (Version A MED):1	1,114E+06	R0_11_2 Abdominal Ring (Version A MED):1	1,971E+06	R0_11_2 Abdominal Ring (Version A MED):1
Subcase 1	-2,758E+07		2,228E+07		2,287E+07	

Table 5.1.4 Solution Error Measure and the Relative Stress Error Summary

Subcase	Solution Error Measure	Shell Element Relative Stress Error	Solid Element Relative Stress Error
SUBCASE 1	3,335E-08	n/a	4,345E-02

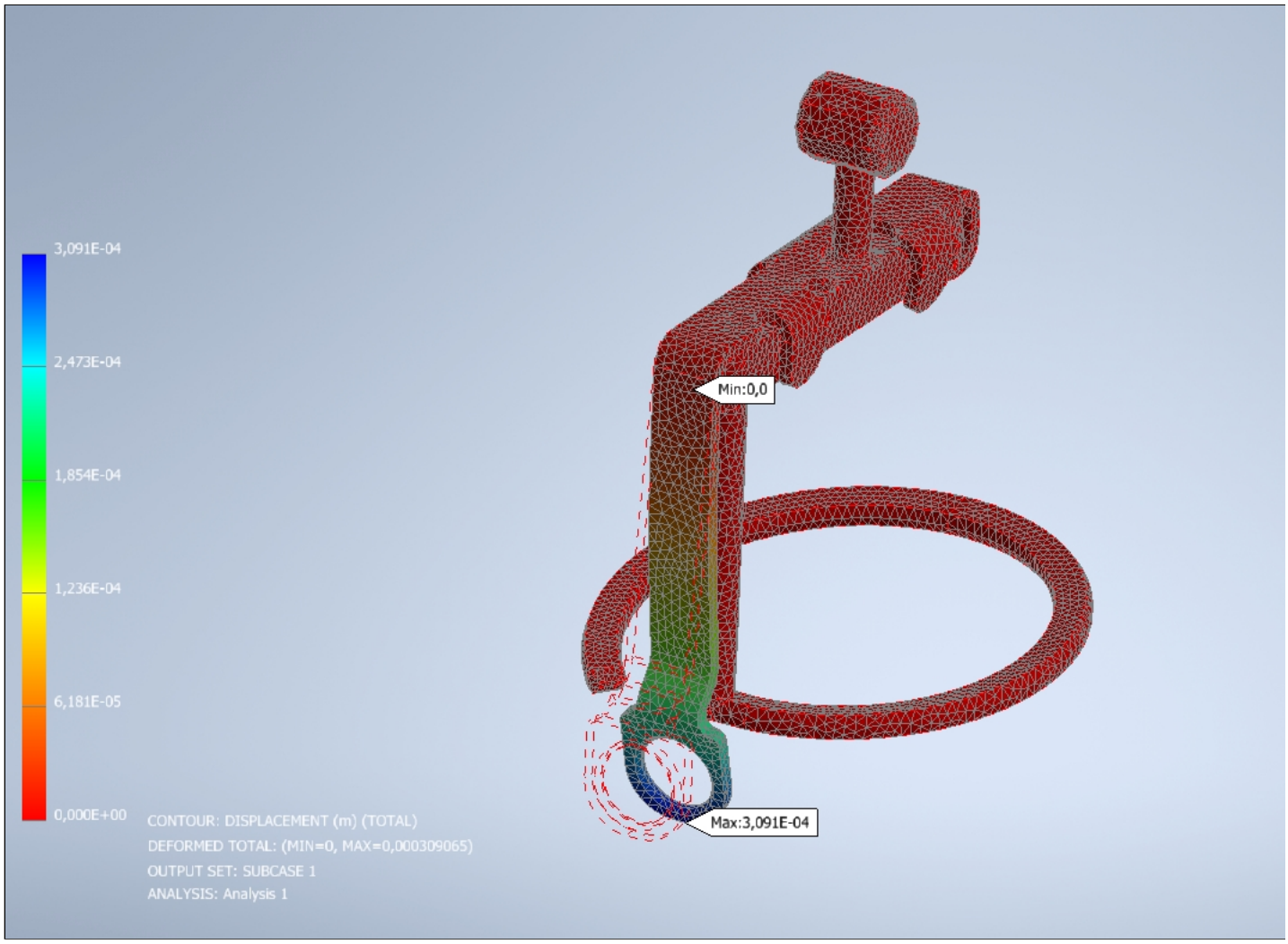


Figure 5 - OUTPUT SET: SUBCASE 1 -- DEFORMED TOTAL: (MIN=0, MAX=0,000309065) -- CONTOUR: DISPLACEMENT (m) (TOTAL)

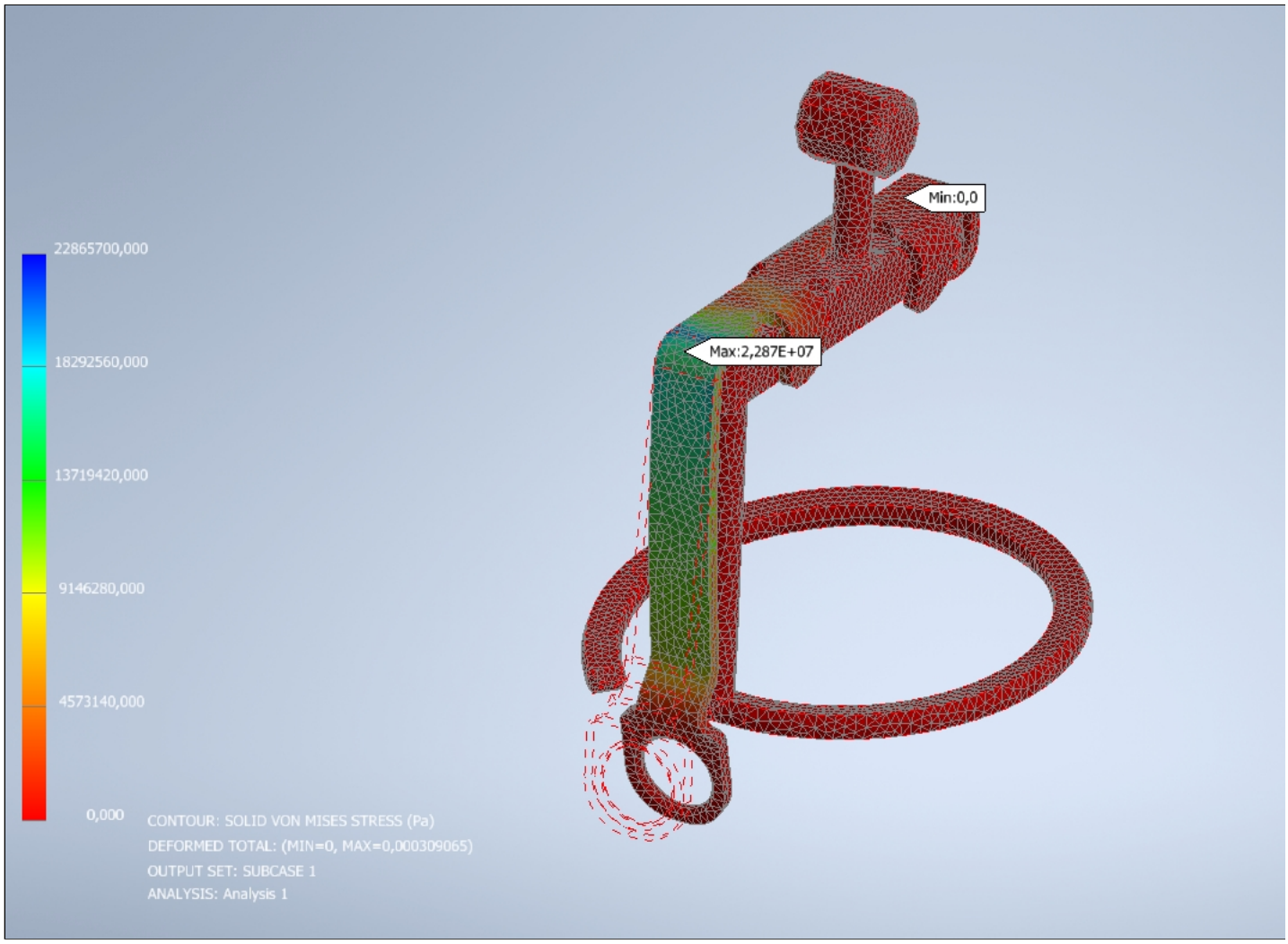


Figure 6 - OUTPUT SET: SUBCASE 1 -- DEFORMED TOTAL: (MIN=0, MAX=0,000309065) -- CONTOUR: SOLID VON MISES STRESS (Pa)

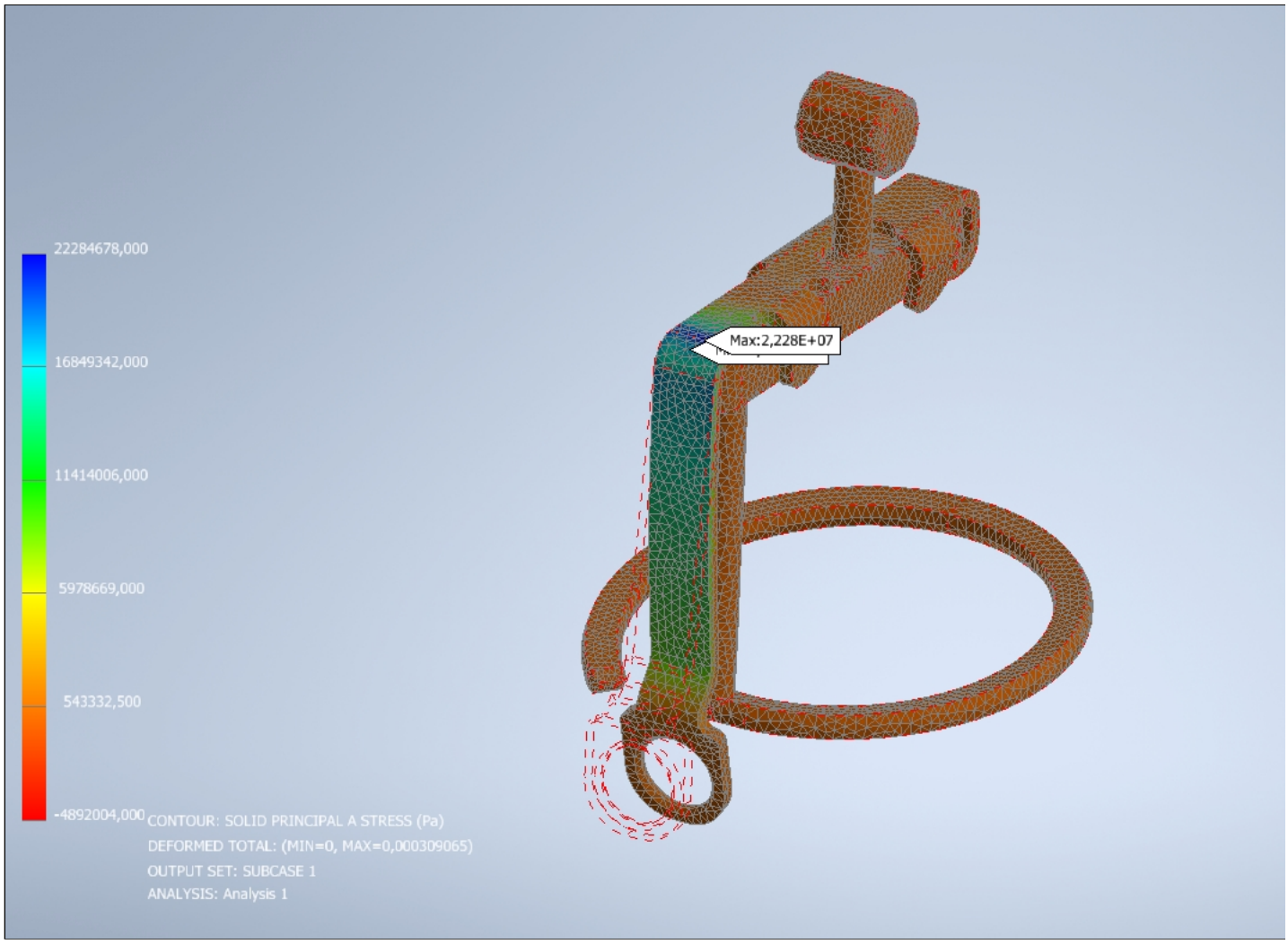


Figure 7 - OUTPUT SET: SUBCASE 1 -- DEFORMED TOTAL: (MIN=0, MAX=0,000309065) -- CONTOUR: SOLID PRINCIPAL A STRESS (Pa)

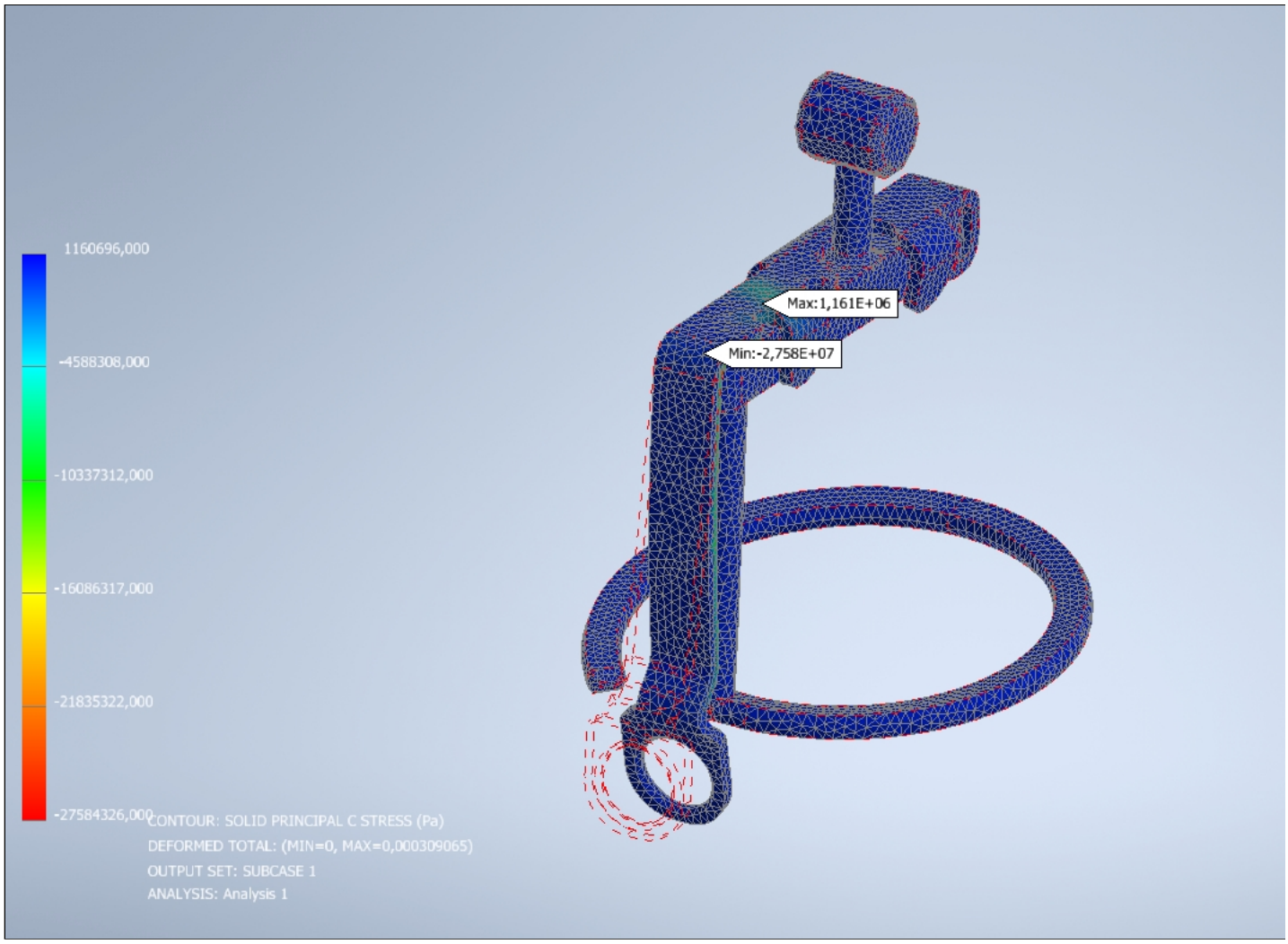


Figure 8 - OUTPUT SET: SUBCASE 1 -- DEFORMED TOTAL: (MIN=0, MAX=0,000309065) -- CONTOUR: SOLID PRINCIPAL C STRESS (Pa)

6. Conclusion:

A linear static analysis was performed using the Autodesk Nastran Version 18.0.0.17 finite element solver on the 1q4uvl2aa structure. The finite element model contained mainly R0_11_2 Abdominal Ring (Version A MED):1 elements and consisted of 192255 degrees of freedom.1 loading condition was analyzed.The maximum displacement was 3,091E-04 m (load case Subcase 1)The maximum von Mises stress was 2,287E+07 (load case Subcase 1).

7. Glossary:

Aspect Ratio
Ratio of an element's longest side to its adjacent side.

Bi-Directional Slide
Prevents contacting regions from separating or closing but permits sliding (zero coefficient of friction

Bounding Box
A three-dimensional cube aligned to the global x,y and z axes that exactly contains a body or assembly.

Follower Forces
Loads that follow the motion of the structure as it deforms.

General Contact
Models standard nonlinear surface contact with friction if specified.

Relative Stress Error
A measure of mesh convergence (values greater than 0.01 may indicate that further mesh refinement is required in areas with large stress gradients over a few elements).

Rough Contact
Nonlinear contact that allows separation and closure but does not permit sliding (infinite friction).

Skew Angle
The angle between the lines that join opposite midsides of a quadrilateral face.

Solution Error Measure
A measure of solution quality (values less than 1.0E-07 are generally considered acceptable).

Taper Ratio
The ratio of the areas on the two sides of a diagonal of a quadrilateral face.

Warping Angle
The extent to which a quadrilateral face deviates from being planar.

Welded Contact
Prevents contacting regions from sliding, separating, or closing.

Appendix Project Brief

DESIGN FOR our future

TU Delft

IDE Master Graduation

Project team, Procedural checks and personal Project brief

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

- The student defines the team, what he/she is going to do/deliver and how that will come about.
- SSC E&SA (Shared Service Center, Education & Student Affairs) reports on the student's registration and study progress.
- IDE's Board of Examiners confirms if the student is allowed to start the Graduation Project.

USE ADOBE ACROBAT READER TO OPEN, EDIT AND SAVE THIS DOCUMENT

Download again and reopen in case you tried other software, such as Preview (Mac) or a webbrowser.

STUDENT DATA & MASTER PROGRAMME

Save this form according the format "IDE Master Graduation Project Brief_familyname_firstname_studentnumber_dd-mm-yyyy".
Complete all blue parts of the form and include the approved Project Brief in your Graduation Report as Appendix 1 !

family name
initials
student number
street & no.
zipcode & city
country
phone
email

Your master programme (only select the options that apply to you):

IDE master(s): ★ IPD ( ) DfI ( ) SPD

2nd non-IDE master: Biomechanical Design, Bio inspired Tech

individual programme: 21 - 10 - 2021 (give date of approval)

honours programme: ( ) Honours Programme Master

specialisation / annotation: ( ) Medisign

( ) Tech. in Sustainable Design

( ) Entrepeneurship

SUPERVISORY TEAM **

Fill in the required data for the supervisory team members. Please check the instructions on the right !

** chair: Prof.dr. J. Dankelman — dept. / section: BioMechanical Engineeri

** mentor: MSc. J.S. Broadhead — dept. / section: Sustainable Design Engi

2nd mentor: _____

organisation: _____

city: _____ country: _____

comments (optional)

Chair should request the IDE Board of Examiners for approval of a non-IDE mentor, including a motivation letter and c.v..

Second mentor only applies in case the assignment is hosted by an external organisation.

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

APPROVAL PROJECT BRIEF

To be filled in by the chair of the supervisory team.

chair Prof.dr. J. Dankelman date 07 - 03 - 2023 signature

CHECK STUDY PROGRESS

To be filled in by the SSC E&SA (Shared Service Center, Education & Student Affairs), after approval of the project brief by the Chair.
The study progress will be checked for a 2nd time just before the green light meeting.

Master electives no. of EC accumulated in total: 30 EC

Of which, taking the conditional requirements into account, can be part of the exam programme 30 EC

List of electives obtained before the third semester without approval of the BoE

-- Variant for Engineers

( ) YES all 1st year master courses passed

(X) NO missing 1st year master courses are:

ID4010 Design Theory and Methodology (3,0)
ID4070 IDE Academy (4,0)
ID4170 Advanced Concept Design (21,0)
ID4180 Managing Product Innovation (3,0)

name Robin den Braber date 03 - 04 - 2023 signature RdB

FORMAL APPROVAL GRADUATION PROJECT

To be filled in by the Board of Examiners of IDE TU Delft. Please check the supervisory team and study the parts of the brief marked **.
Next, please assess, (dis)approve and sign this Project Brief, by using the criteria below.

- Does the project fit within the (MSc)-programme of the student (taking into account, if described, the activities done next to the obligatory MSc specific courses)?
- Is the level of the project challenging enough for a MSc IDE graduating student?
- Is the project expected to be doable within 100 working days/20 weeks ?
- Does the composition of the supervisory team comply with the regulations and fit the assignment ?

Content: (V) APPROVED ( ) NOT APPROVED

Procedure: ( ) APPROVED (V) NOT APPROVED

- the 4 missing courses should be finished before the green light meeting

comments

name Monique von Morgen date 17/4/2023 - 2/5/2023 signature MvM

Initials & Name T.D.C. Hol Student number 4677447

Title of Project Laparoscopic solo-sugery for low resourch settings in India.

Laparoscopic solo-sugery for low resourch settings in India. project title

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

start date 21 - 02 - 2023 10 - 10 - 2023 end date

INTRODUCTION **

Please describe, the context of your project, and address the main stakeholders (interests) within this context in a concise yet complete manner. Who are involved, what do they value and how do they currently operate within the given context? What are the main opportunities and limitations you are currently aware of (cultural- and social norms, resources (time, money,...), technology, ...).

An Indian surgeon who trains and performs togheter with rural sugeons gasless laparoscopicy in low resource settings has asked the TU Delft for the development of a laparoscope holder to enable laparoscopic solo surgery. Laparoscopy is also known as keyhole surgery or minimally invasive surgery because it makes use of small incisions in the skin, see Figure 1. The advantages of this technique over traditional open surgery include the reduction of: hospital stay, recovery time, pain and bleeding after the operation, scarring [1].

In traditional laparoscopy, an assistant steers, rotates, and holds the laparoscopic in place during the surgical procedure in the abdomen (tummy) and pelvis. The laparoscope itself is a small tube with a light source and a camera that relays images of the inside of the abdomen or pelvis to a television monitor. Ideally, the surgeon should be able to manipulate all instruments, including the camera, to avoid communication problems and disturbing camera movements when the assistant has to stand still for a long time [2]. Camera holders return camera control to the surgeon and stabilize the laparoscopic image. Furthermore, an experienced surgeon moving the camera will only make desired movements. In addition, these camera movements will provide him with extra depth perception and navigational information, due to movement parallax, because the movements are performed by the observer, the surgeon, himself [2].

In low-resource settings, there is a higher rate of permanent laparoscopic assistants. Therefore, the assistant is less trained and familiar with the surgeons' preferences. Low resource settings can therefore benefit from solo surgery, since they remove the need for laparoscopic assistance. Although, laparoscopic holders with a locking mechanism can solve this, the surgeon has to stop this procedure and change the position of the holder himself before he can continue this procedure. Therefore, a holder with a locking mechanism that can be controlled without the hands of the surgeon would improve the procedure in terms of time and management.

In order to design a suitable solution for low-resource settings, the following main opportunities and limitations (cultural- and social norms, resources) are highlighted:
O1.The opportunity to broaden the knowledge about equipment use in rural health clinics and limitedly equipped hospitals in India.
O2. The opportunity to increase access to laparoscopy in low resource settings by taking into account the input of local end-users(surgeons) and context.

L1. The Indian surgeon trains local surgeons and performs laparoscopic surgeries as he travels through rural areas in India. Since, resources are limited such as materials and repair options, the design has to be transportable to travel along with the Indian surgeon, robust to minimize repair, low maintenance to minimize the amount of resources need, and repairable with local resources to aim for as many lifecycles.
L2. Low resource settings, in this case limited available materials are present in the rural areas and due to the unstable electricity network electricity is not guaranteed. In order for the solution to fit this context the roadmap "Design surgical equipment for worldwide use" [1] will be used as a framework. Here, research will be conducted on the financial, cultural, and structural barriers to investigate.
L3. The medical sector, safety and hygiene restrictions, and the broad spectrums of stakeholders. Therefore, an equipment journey will be made that explores the interplay of context, technology, and stakeholders to reveal safety concerns.

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introduction (continued): space for images

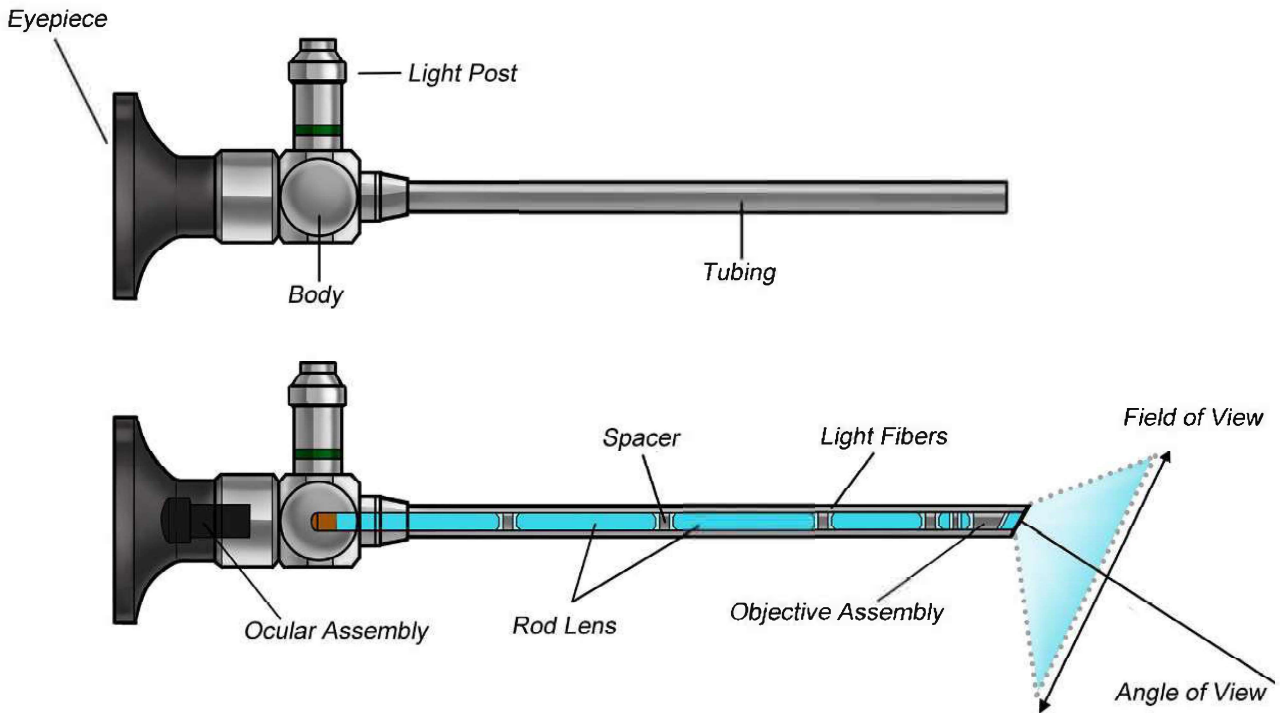


image / figure 1: overview of the different parts of a laparoscope an its functions [3]

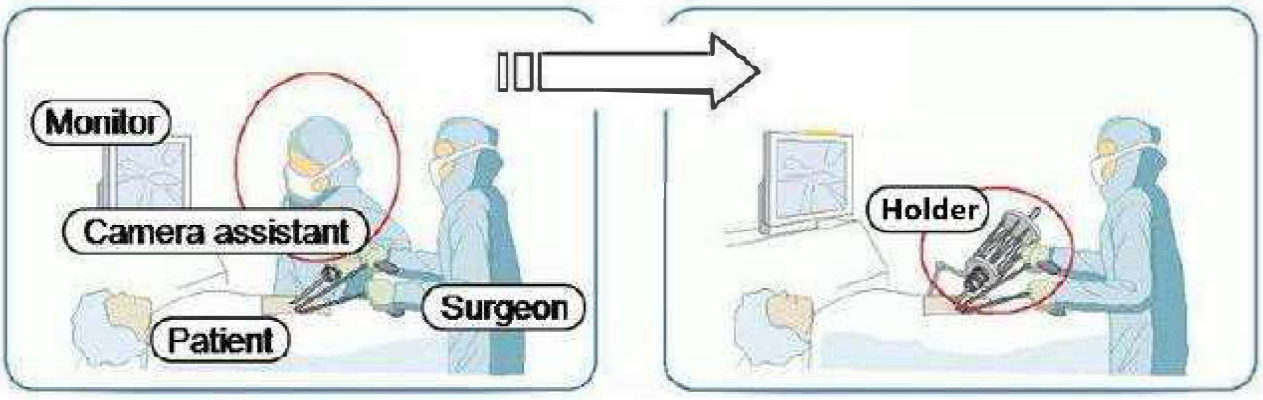


image / figure 2: A traditional setup with an assistant vs solo surgery. Figure based on [4]

Initials & Name T.D.C. Hol Student number 4677447

Title of Project Laparoscopic solo-sugery for low resourch settings in India.

PROBLEM DEFINITION **

Limit and define the scope and solution space of your project to one that is manageable within one Master Graduation Project of 30 EC (= 20 full time weeks or 100 working days) and clearly indicate what issue(s) should be addressed in this project.

The double degree changes this to the following statement:
Limit and define the scope and solution space of your project to one that is manageable within one Master Graduation Project of 45EC (= 30 full time weeks or 150 working days) and clearly indicate what issue(s) should be addressed in this project.

A laparoscopic holder needs to be designed that can be controlled without the need of a laparascopic assistant. Since, laparascopic assistents limit the performance of the surgeon.

During the literature research in the first 8 weeks the context of this problem needs to be investigated in order to understand the reason of the problem's existence and what requirements need to be set for this specific context. Furthermore, an overview of the state of the art laparoscopic holders will be presented that fit middle and low resource settings. After the literature research, a more in depth analysis of the context will be made by using the following methods:
1. In order for the solution to fit this context the roadmap "Design surgical equipment for worldwide use" [1] will be used as a framework. Here, research will be conducted on the financial, cultural, and structural barriers to investigate.
L3. An equipment journey will be made that explores the interplay of context, technology, and stakeholders to reveal safety concerns.

Followed by this, a prototype will be build, tested in a lab and when possible in the users context(rurual area in India). Here, I will gain insight that are used for the final prototype which will be my end delivery.

ASSIGNMENT **

State in 2 or 3 sentences what you are going to research, design, create and / or generate, that will solve (part of) the issue(s) pointed out in "problem definition". Then illustrate this assignment by indicating what kind of solution you expect and / or aim to deliver, for instance: a product, a product-service combination, a strategy illustrated through product or product-service combination ideas, ... In case of a Specialisation and/or Annotation, make sure the assignment reflects this/these.

First, a literature research(10ECTs) will be conducted that gives insights in the context with the main purpose to give an overview of the state of the art laparascopic holders that are suitable for low research settings. The expected outcome is a laparoscopich older which can be tested in the users context to gain insight which contribute the knowledge of developing laparoscopic holders in low resource settings, in particular India.

First, a literature research will be conducted to a) understand the problem, b) give an overview of the state of the art laparoscopic holders that are suitable for low research income countries and c) the alternative ways of controlling a laparoscope. Furthermore, an equipment journey will be made that explores the interplay of context, technology, and stakeholders to reveal safety concerns. This will show the different interactions of the product with all it's users. Based on this insight, requirements can be based to suit all users.

The concrete outcome is a prototype, which has been demonstrated in relevant environment lab and if possable in local context. My expected contribution is to practise, since I aim to solve a local problem by providing knowlegde and insights on the context.

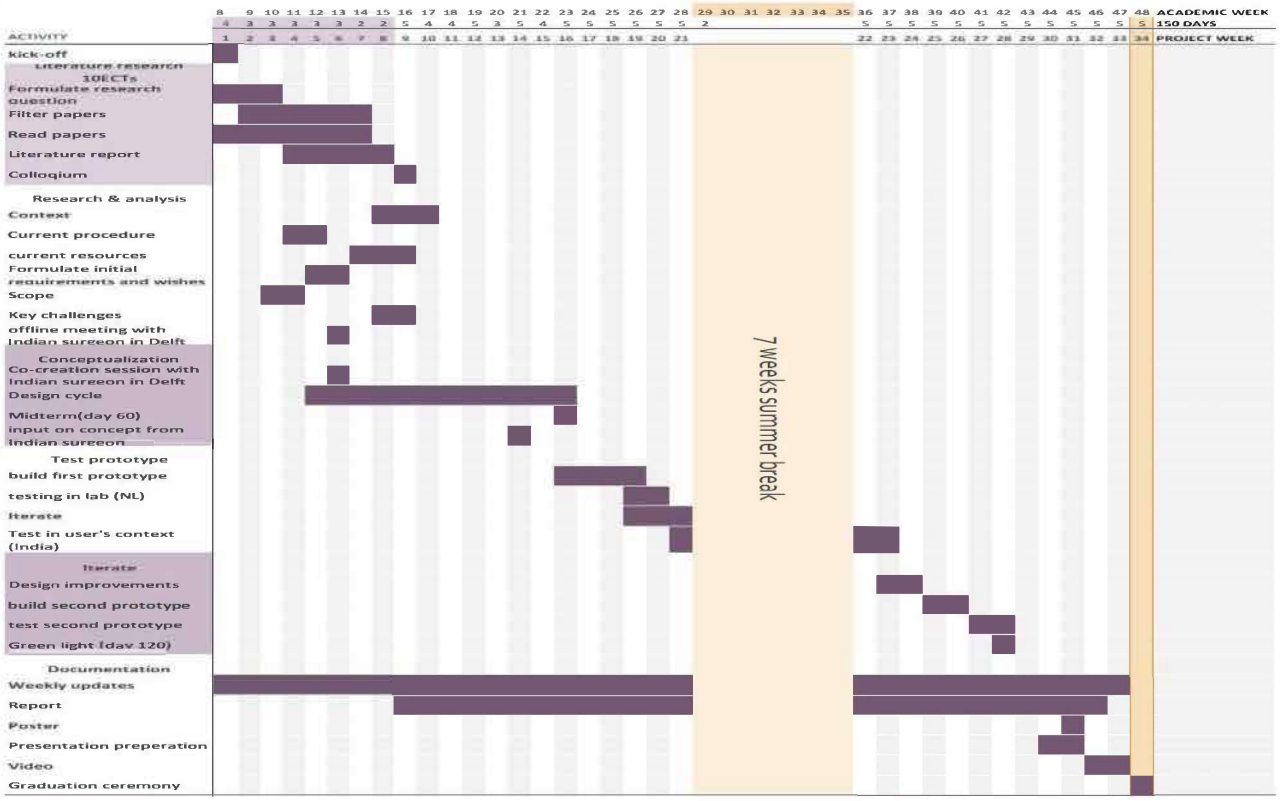
Initials & Name T.D.C. Hol Student number 4677447

Title of Project Laparoscopic solo-sugery for low resourch settings in India.

PLANNING AND APPROACH **

Include a Gantt Chart (replace the example below - more examples can be found in Manual 2) that shows the different phases of your project, deliverables you have in mind, meetings, and how you plan to spend your time. Please note that all activities should fit within the given net time of 30 EC = 20 full time weeks or 100 working days, and your planning should include a kick-off meeting, mid-term meeting, green light meeting and graduation ceremony. Illustrate your Gantt Chart by, for instance, explaining your approach, and 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 activities.

start date 21 - 2 - 2023 10 - 10 - 2023 end date



I will work part time during Quater 3, after Q4 I will work full time. The seven holidays in the TU Delft academic calender have been included as free days (Goede vrijdag, 2e Paasdag, Koningsdag, Bevrijdingsdag, Hemelvaart, dag na Hemelvaart, 2e Pinksterdag). Furthermore, the summer holiday break is in indicated as well.

Initials & Name T.D.C. Hol Student number 4677447

Title of Project Laparoscopic solo-sugery for low resourch settings in India.

MOTIVATION AND PERSONAL AMBITIONS

Explain why you set up this project, what competences you want to prove and learn. For example: acquired competences from your MSc programme, the elective semester, extra-curricular activities (etc.) and point out the competences you have yet developed. Optionally, describe which personal learning ambitions you explicitly want to address in this project, on top of the learning objectives of the Graduation Project, such as: in depth knowledge a on specific subject, broadening your competences or experimenting with a specific tool and/or methodology, ... Stick to no more than five ambitions.

Setup
The Double Degree demands a project that addresses both masters: Integrated Product Design and BioMechanical Design. Therefore, I choose a project that needed a physical product as outcome and where there is a need to study the context. There, I can put my cultural and social skills into practise to make this a worth while Industrial design project.

The following competences I want to prove and learn
1. Show that the masters complement each other by stressing the importance of studying the context and and taking the users input into account while designing. Furthermore, use my engineering skills to technically work out the product in detail and make material desicions based on stress simulations
2. I followed the following electives which I want to use into my graduation project
- Cultural sensative design, during this course we had 2 weeks to work on fictional project. However, now I have the opportunity and time to go in depth. Although, this cultural sensativity is quite new for me, I want to use it to open up blind spots which can contribute to a better understanding of the context.
- Sustainable design strategies, although my project will not be finshed for the market. I learned that you can from the start taking sustainability into account. Especially, in the medial sector their is room to improve on sustainability, since medical equipement often contains single use parts.

Personal learnings and ambitions I want to adress in this project
- I have always been interested in designing for the medical world. In the past I have designed a knee orthosis for hemiparetic patients in low and middle income countries. Since, the focus was on proof of concept of the technology, I still want to learn more about healthcare systems in low research countries.
- Design for low resource settings, during my minor in Kenya I saw for the first time what a low resource setting constitutes. Togheter with a Kenyan research team we interviewed start-ups and local practisioners that had developed a frugal innovation for their community. During these inspiring interviews I realized how . However, my minor was purely research based. Now I have the opportunity to work toghether with local surgeons and contribute to more accesable healthcare.

REFERENCES

[1] Oosting, R. M. (2019). Towards increased global availability of surgical equipment. https://doi.org/10.4233/uuid:330eec0a-7a67-4184-8716-9a6b456ddae9
[2] Jaspers, J. E. N., Breedveld, P., Herder, J. L., & Grimbergen, C. A. (2004). Camera and Instrument Holders and Their Clinical Value in Minimally Invasive Surgery.
[3]Rigid and Semi Rigid Endoscope Repairs Laparoscope Arthroscope. (n.d.). Retrieved March 7, 2023, from https://www.scopecare.com/rigid-and-semi-rigid-endoscopes/
[4] Nishikawa, A., & Sekimoto, M. (2010). Design and Control of a Compact Endoscope Manipulator: a Biologically Inspired Approach.

FINAL COMMENTS

In case your project brief needs final comments, please add any information you think is relevant.

References can be found at the end of the last section Motivation and Personal Ambitions

Initials & Name T.D.C. Hol Student number 4677447

Title of Project Laparoscopic solo-sugery for low resourch settings in India.