SamarthClean

The design and development of a context-specific medical washer for laparoscopic instruments for rural Indian hospitals.

Biomedical Engineering | Integrated Product Design

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The design and development of a context-specific medical washer for laparoscopic instruments for rural Indian hospitals

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Abbreviations

POWI	Postoperative Wound Infection
MIS	Minimally Invasive Surgery
LMIC	Low and Middle Income Countries
HIC	High Income Countries
WD	Washer-Disinfector
SSI	Surgical Site Infections
OT	Operating Theatre
AMR	Anti-Microbial Resistance
WHO	World Health Organization
CSSD	Central Sterile Supply Department
CHC	Community Health Centre
PPE	Personal Protective Equipment
DALY	Disability-Adjusted Life Years

Preface

I am pleased to present this Master's thesis, in which I finalize my master's in Biomedical Engineering as well as Integrated Product Design. It could not have been accomplished without the support and assistance of numerous individuals. I would like to express my heartfelt gratitude to my supervisors from Biomedical Engineering and Integrated Product Design, Jenny Dankelman, Jan-Carel Diehl, Daniel Robertson, and Sonja Paus-Buzink for their invaluable contributions and assistance in completing this thesis. Their expertise in clarifying, structuring, and focusing on the core of this report was of great value.

In particular, I would like to thank my mentor Biomedical Engineering Daniel Robertson for his guidance during my thesis. He kept faith in the successful outcome of this thesis and was constantly positive and supportive. Daniel opened my eyes to the world of reprocessing in India and the magnitude of the problems there. We have been through a lot together, especially in the period before and during the concept evaluation in India.

I would also like to express my appreciation to Sonja Paus-Buzink, my industrial design mentor, for her inspiring conversations, clear insights, and constructive feedback, which were essential in shaping the final outcome of this report.

During the graduation period, I had the privilege of working with Dr. Gnanaraj from India, who provided valuable insights into the context of hospitals in rural India. I would like to extend my sincere thanks to him for his hospitality and guidance, which enabled us to conduct our research in the hospitals in India.

I would also like to thank Jan Huijs for his interest and advice during the concept development. He put me on the right track with his explanation and experience in reprocessing in low-resource settings.

I would also like to acknowledge the contributions of Daniel, Marijn, Siebe, and Charlotte, who provided invaluable help during stressful times, particularly in shaping and finishing the prototype before our trip to India.

Finally, I would like to express my gratitude to Bart van Straten for his advice and donation of medical baskets to build the prototype.

This project has been a transformative experience for me, and I hope that the knowledge and skills I have gained will help me make a meaningful contribution to the quality of medical care in the bottom of the pyramid as a biomedical engineer and industrial designer.

I hope you enjoy reading.

Executive summary

Rural India faces many challenges in providing adequate health care for all. Health awareness among the Indian population is low due to poor functional literacy and low emphasis on education within the health sector.

Minimally Invasive Surgery (MIS), such as laparoscopy, offers many advantages, including smaller incisions, less tissue damage and faster recovery for patients compared to traditional open surgery. The use of laparoscopy in low- and middle-income countries (LMICs) is particularly advantageous because it can minimise the morbidity associated with laparotomies and provide benefits such as fewer postoperative infections and faster return to work. The laparoscopic instruments must be carefully cleaned and sterilised after each use to prevent infection. In any surgery, there is a risk of infection. Postoperative wound infections (POWIs) occur after surgery on the part of the body being operated on. Globally, the rate of POWIs varies between 0.5 and 15 per cent, while in India, rates between 23 and 38 per cent are consistently measured (Arora et al., 2018). These complications lead to revision surgery, delayed wound healing, increased use of antibiotics and longer hospital stay, all of which have a significant impact on patients and healthcare costs. The increased use of antibiotics causes antimicrobial resistance which is one of the greatest threats to human health we face worldwide. (World Health Organisation, 2012a, 2012b).

Therefore, this project focuses on making laparoscopy safely applicable in low- and middle-income countries through a medical washer. It aims to find a research-based solution to improve the reprocessing of laparoscopic instruments, to reduce POWIs and the need for antibiotics. The current method of reprocessing in hospitals in rural India does not result in sterile laparoscopic instruments and is harmful to patient, nurse and all other staff present in the OT. Instruments are also damaged during the cleaning process. These problems mainly stem from lack of training of nurses, time pressure and due to lack of cleaning equipment.

The project approach was implemented using the Double Diamond Design Model. First literature research into the Indian healthcare system, laparoscopy, reprocessing and cleaning was performed. This was supplemented with interviews with a rural Indian surgeon, an expert in reprocessing in LMICs and a visit to a CSSD.

All the information acquired was used to frame the problem and sub-problems which arise during the reprocessing of laparoscopic instruments. Seven key challenges were determined: a lack of a proper CSSD, a lack of training in reprocessing, a lack of safety, insufficient flushing in washer-disinfectors, a lack of time for reprocessing, complex geometries which are hard to clean and a frugality concerning resources. These challenges all result in insufficiently cleaned laparoscopic instruments. These challenges can be solved by a medical washer which fits the context of the rural Indian hospitals. Therefore, the design goal was defined as:

The design of a concept of a medical washer that supports and protects the nurses in hospitals in rural India during their tasks in between surgeries by cleaning one set of laparoscopic instruments while using little resources.

To achieve this goal the focus of the project was on the loading system which requires the most physical interaction with the nurses and the cleaning system as an effective cleaning system can lower the amount of water and power needed and can ensure clean laparoscopic instruments every cycle.

Through different generative methods concepts were developed for the loading system and the cleaning system. For the loading system, firstly, different loading mechanisms were developed which were compact as well as safe and easy in use. Secondly different mechanisms were designed to achieve alternated flushing in the lumens.

For the design of the cleaning system the development focused on the different geometries to be cleaned, which were: the complex geometries (hinges, ridges and serrations), the regular geometries and the lumens.

To clean the different geometries effectively while minimizing resource-usage different cleaning strategies for the different geometries were selected. Regular geometries are most effectively cleaned by rinsing, complex geometries by ultrasonic cleaning and the lumens by two-phase flow.

The different concepts were integrated into one design. Of this integrated design the loading system was selected to be tested in context. This was done because the health workers in rural India lack training and experience with medical equipment, however, improper loading results in insufficiently cleaned instruments. Therefore, it is of large importance the medical washer can be loaded by health workers without the need of extensive training.

The study in India consisted of usability test and an evaluation interview. A number of use errors occurred during the usability test. Insufficient guidance caused the health workers to place the instruments at incorrect locations which could lead to insufficiently cleaned instruments. Increased guidance was required for the nurses to correctly load the system. The concept evaluation showed the nurses experienced their current reprocessing cycle as dangerous and stressful. The nurses were aware that the current reprocessing cycle resulted in insufficiently cleaned instruments. Therefore, the medical washer was perceived as desirable as it could relieve the stress experienced currently, while guaranteeing clean instruments.

Using the insights gained from the usability test and concept evaluation a final design was made. The medical washer 'SamarthClean' effectively cleans the laparoscopic instruments while using minimal resources and supports the nurses by a loading system which can be loaded fast and safely by health workers with limited training. A cleaning cycle was designed using geometry-specific cleaning strategies. During the pre-rinse the outer geometries of the laparoscopic instruments are rinsed by spray jets while the lumens are flushed using two-phase flow created by the addition of a venturi to remove all gross soil. Secondly, the complex geometries located at the bottom of the baskets are ultrasonically cleaned with a detergent to remove soil in the hard to clean areas. Thirdly, all geometries are washed by the spray jets with a detergent while the lumens are flushed to remove soil from all geometries. Lastly, all geometries are rinsed and flushed to remove any remaining detergent.
In addition, instructions were added to the loading system in the form of illustrations of the loaded baskets on top of the medical washer to show the health workers where to place the instruments. Symbols have also been added to the lumen basket to indicate where which lumens should be loaded.

To fit the context of LMICs SamarthClean was designed to be durable and require minimal maintenance. This was done by minimizing the amount of moving parts inside of the wash chamber which are prone to damage. Only two consumables are used within the design which can be easily acquired online. SamarthClean combines the functionalities of an ultrasonic cleaner and a medical washer while using less resources and increasing the lifetime of the laparoscopic instruments in rural Indian hospitals.

This report concludes with an evaluation of the design of the medical washer and recommendations for further research and development. A design was made of the medical washer which integrated a loading system, cleaning system and housing. The loading system was tested in context, however further testing with the added instructions is necessary to verify whether the loading system can be loaded correctly every time. A design of the cleaning system was made, however not yet tested. To determine whether the instruments can be cleaned so no visual soil is present, a prototype of the cleaning system must be developed and tested. Lastly, a cost estimation must be done to determine if the medical washer is viable for patients and hospital management in the long run. Overall, SamarthClean has the potential to increase the safety of laparoscopy in rural India and to reduce the risk of AMR globally.


Samarthclean, 2023, Samarth meaning efficiently in Hindi

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1 Introduction

1.1 Assignment

My final thesis project is a part of Daniel Robertson's research project. *Smart Surgery: Towards clean laparoscopy in India. The project focuses on making Minimally Invasive Surgery such as laparoscopy safely applicable in low and middle-income countries (LMIC).*
Minimally Invasive Surgery (MIS), such as laparoscopy, has gained widespread acceptance in hospitals worldwide in recent decades due to its numerous benefits, including smaller incisions, less tissue damage, and faster recovery for patients compared to traditional open surgery. The use of laparoscopy in low and middle-income countries (LMICs) is particularly impactful as it can minimize the morbidity associated with laparotomies and provide benefits such as fewer postoperative infections and quicker return to work, which is important in LMICs where lost work time can affect a family's ability to support themselves (Alfa-Wali, M., & Osaghae, 2017b). However, the instruments used in MIS, which are referred to as "hollow instruments" and characterized by their long, thin design with internal hollow spaces or channels, pose a challenge in terms of sterilization. These reusable instruments are more difficult to clean than conventional instruments, particularly the internal channels which can harbour tissue, residues, and bacteria. Cleaning these instruments thoroughly, both externally and internally, is crucial for the Central Sterile Services Department (CSSD). However, the sterile reprocessing departments in hospitals in LMICs often have limited access to the appropriate equipment and do not have sufficient well-trained staff (figure 1).
If hospitals in LMICs wish to use laparoscopy, an update of the standard procedure for sterile processing is required. Prior to this project, extensive research was conducted on the reprocessing of laparoscopic instruments in rural India. The purpose of The study by Robertson et al. (2021) was to identify laparoscopic sterile reprocessing procedures in rural India and to test the effectiveness of sterilization equipment.
The study found that standard operating procedures have not been updated since the introduction of laparoscopy and the same reprocessing methods are used for regular surgical instruments. In addition, staff have not received additional training and are unaware of the dangerous effects of their current reprocessing cycle. The study concludes that since laparoscopy is increasingly used in LMICs, it is necessary to include minimally invasive instrument reprocessing in training programs for physicians and staff. In addition, it is essential to develop instruments and reprocessing equipment that is more suitable for rural surgical environments with limited resources.
This thesis focuses on the design of a medical washer for laparoscopic instruments for LMICs. This is to make minimally invasive surgery applicable and safe for resource-limited settings in rural India. The medical washer aims to reduce the workload for nurses and provide reliable cleaning.

Figure 1: Current reprocessing practices in rural India.

1.2 Approach

The project approach was implemented using the Double Diamond Design Model, which consists of four phases: Discover, Define, Develop, and Deliver. These phases provide structure, but the model is not linear. In order to understand and solve the problem, it is important to move back and forth between the phases. A visual of the approach can be seen in figure 2.

During the discover phase a review of the literature on laparoscopic instruments, as well as the cleaning, disinfection, and sterilization of such instruments in both low and middle-income countries (LMICs) and high-income countries (HICs), was conducted in the initial phase of the project. In addition, the challenges and issues facing the healthcare system in rural India and the medical devices used in LMICs were examined. To supplement this theoretical knowledge, a visit to a CSSD was made to gather empirical observations. Through interviews with users, including nurses and a doctor from India, the needs, preferences, and behaviours of these individuals were able to be focused on. The goal of this phase was to comprehensively understand the real problems associated with cleaning laparoscopic instruments and to have a detailed understanding of the process developed for both HICs and LMICs.

The Define phase was used to filter and process all of the information and define the design task. The relevant problems were collected, the problem statement was formulated, and the design goal was determined. The list of requirements made it clear what needed to be taken into account when designing the medical washer.

During the develop phase, solutions for the design task of the medical washer were sought as extensively as possible. As the Define phase revealed, minimal resource use and safe, efficient loading of the machine were required, and therefore efficiency, safety, and resource conservation were the fundamental design objectives. Concepts and prototypes were developed and expert reviews were completed to develop the final concept.

In the deliver phase, a prototype was built of the loading system of the medical washer. To determine whether the loading system could be used without prior explanation and to determine the perception of the nurses on the added value of the medical washer to their current working routine, the prototype was evaluated in the context of rural India. The evaluation led to a series of design suggestions. These suggestions were integrated into the final design of the medical washer.

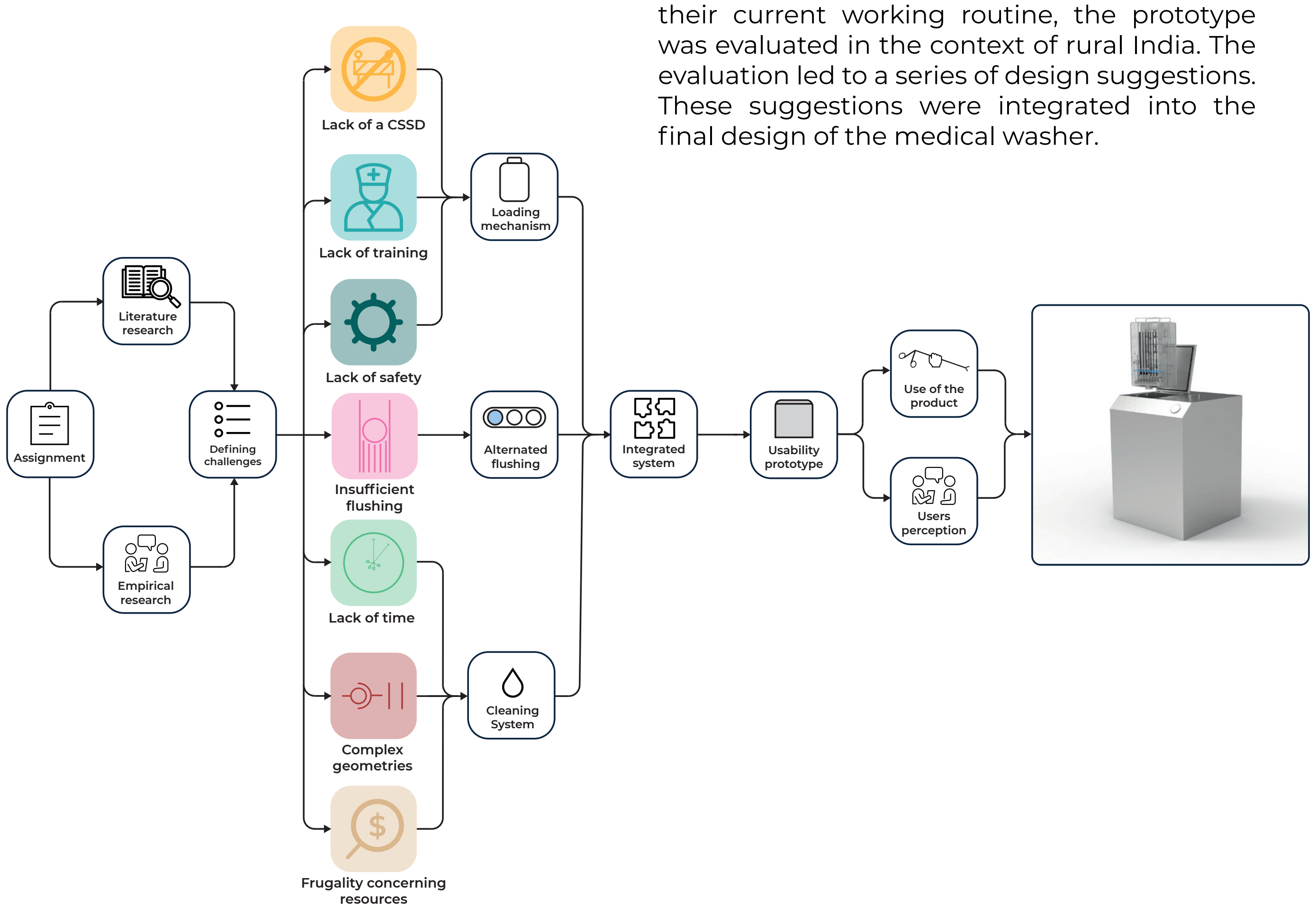


Figure 2: The approach of the project.

2 Healthcare In India

In this chapter the population, economics, and healthcare system of India are discussed. Secondly, the chapter is focused on surgical site infections and why these infections are especially harmful for the Indian population.

2.1 General healthcare system

The Indian healthcare system is very diverse. At one end of the spectrum, there are the hospitals of large steel and glass constructions that can provide high-tech medical care to the well-to-do and mostly urban Indian people. At the other end of the spectrum are the ramshackle outposts in remote and rural India (figure 3). Rural India faces many challenges in providing adequate healthcare to all. In addition, health awareness among the Indian population is low, due to poor functional literacy, a low emphasis on education within the health sector, and a low priority for health among the population. The access or lack of access for the urban poor and the rural population is mainly due to certain access barriers in different areas such as financial, organizational, social, and cultural. These can limit the use of services even in places where they are available. Many of the primary health centres lack basic infrastructure facilities, such as beds, toilets, drinking water facilities, clean work areas for delivery, and regular electricity (Kasthuri, 2018).

Socio-cultural situation

After China, India has the largest population in the world and is expected to pass China by 2027 (United Nations, 2019). Of the 1.4 billion people in India, most of the population (70%) lives in rural areas while hospitals are usually concentrated in urban areas.
Many different languages are spoken locally in India. The most prominent language is Hindi which, like ancient Sanskrit, is written in the Devanagari script. 29 languages are spoken by more than a million people. The literacy rate in India is 74 percent. Language, religion and the caste system form an important basis for determining one's position in society. Indian culture is a mixture of several waves of immigrations that have mainly influenced the north of the country.

Economic situation

There are many differences in the Indian economy. India is among the ten most industrialized countries in the world, with a high technological level in the areas of space travel, nuclear energy and satellite communications. On the other hand, India still has a large part of the population that is dependent on often small-scale agriculture. When focusing on healthcare this becomes very prevalent. In India, only 30 percent of total health expenditure is financed by the government, 28 percent less than the global average (World Bank, 2021c). Healthcare expenditure mostly consists of out-of-pocket expenditure, which is about 62%. This is much more than the global average of 18%. Expenditure on medical devices was about 3 dollars per capita in 2015. The Indian population consists of 22.5% living below the poverty line. This amounts to at least 307 million who cannot afford healthcare and therefore often go without it (World Bank, 2021c). Due to the high percentage of out-of-pocket expenditure and a large amount of poverty, cost dominates the decision-making in seeking healthcare. Not only consumers but also medical equipment and device buyers are more focused on economic aspects (Jaiswal & Angeli, 2022).

Figure 3: Comparison of OTs in different Indian hospitals (purevertech.com, n.d.).

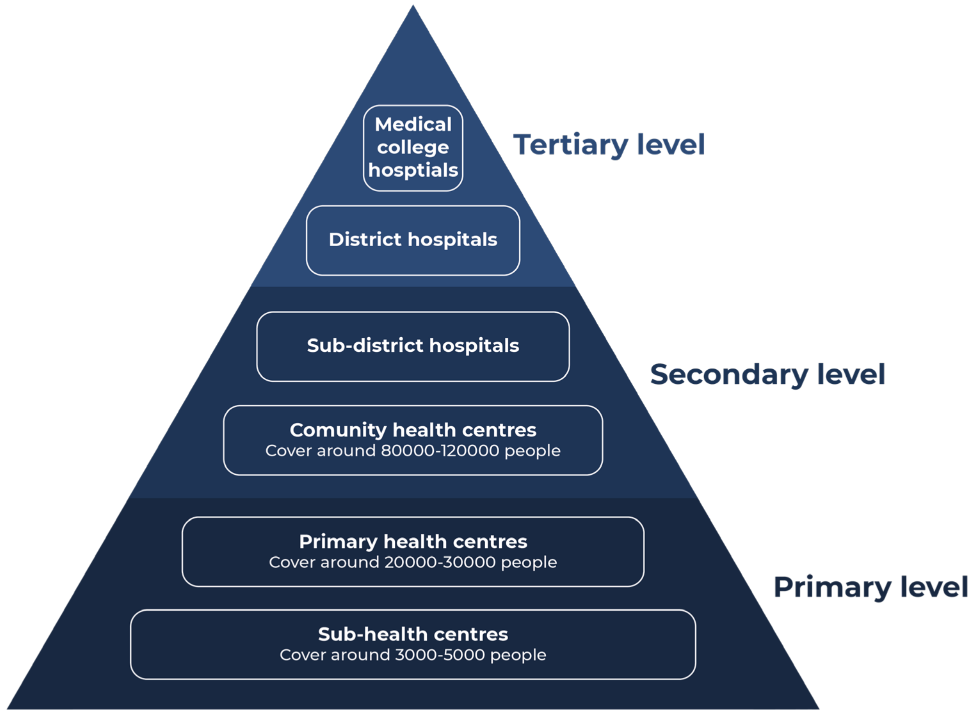


Figure 4: Public health sector of India

Structure of the public health sector
The public health sector in India is organized in three levels (figure 4). The medical college and hospital in the district form the top of the system. Next is sub-district hospital and the community health centre. The community health centre is a 30-bed hospital that covers a population of around 100.000. It serves as the first point of referral. The next level consists of a network of primary health centre which each cover a population of 30000. At the bottom a large network of sub-centres which are the first access point to receive care (Humphries et al., 2020).

2.2 Surgical site infections in India

With every surgery, there is a (slight) risk of infection. Surgical site infections (SSI) occur after surgery on the part of the body that is being operated on. Despite the fact that efforts are made to work as sterile as possible with every surgery. Because the wound is open during surgery, there is a high risk of bacteria entering the wound. These infections can be limited to the skin, or can be more serious, affecting the subcutaneous tissue. Many wound infections occur within 30 days after surgery. Surgical site infection is the most common healthcare-related infection. Globally the surgical site infection rate varies between 0.5 to 15 percent. While in India consistently rates between 23 and 38 percent are measured (Arora et al., 2018). Apart from causing significant morbidity and mortality, SSIs also cause severe financial consequences for individual patients. SSIs extend the patient's hospital stay, which increases their healthcare costs, keeps the patient away from work longer, and hinders the patient's overall career (Arora et al., 2018). The increased healthcare cost is a large financial burden as most healthcare costs are paid directly out of pocket by the patient (World Bank, 2021c).

Causes of SSIs
There are a wide range of patient-related (endogenous) and process-related (exogenous) variables which can cause surgical site infections. Exogenous variables which can increase the risk of SSI are skin preparation, surgical duration, unsterile surgical instruments, and, unsterile OTs (Harrop et al., 2012).

Impact of SSIs on rural India
Surgical site infections have a large effect on the Indian population. SSIs can cause complications after surgery. These complications lead to revision surgery, delayed wound healing, increased use of antibiotics, and increased length of hospital stay, all of which have a significant impact on patients and the cost of health care. Antimicrobial resistance (AMR) is one of the greatest threats to human health we are globally facing (World Health Organization, 2012a, 2012b). Antibiotic-resistant bacteria can cause grave amounts of harm. For instance, the mortality caused by methicillin-resistant Staphylococcus aureus (MRSA) is higher than the mortality caused by emphysema, HIV/AIDS, Parkinson's disease, and homicide combined in the US. Currently, little innovative antibiotic development is underway to combat this problem. The WHO predicts a future where a 100 years of healthcare development is nullified due to increased mortality caused by AMR (World Health Organization, 2012a, 2012b). India is one of the nations which suffers the most from infectious diseases, with crude mortality of 417 persons per 100,000 caused by them (WHO, 2017). In 2010, India had the highest consumption of antibiotics for human health with 12.9 x 109 units of antibiotic (~10.7 units per person). These numbers show that AMR is of major concern in India (Laxminarayan & Chaudhury, 2016).

2.3 Key insights

Insights

- **In India, the average income is low and most patients pay for medical procedures out-of-pocket. This causes patients to go without care due to financial reasons. Cost is the highest priority in decision making for patients as well as hospital management.**
- **Surgical site infections occur more often in India compared to HICs. SSIs can increase healthcare costs.**
- **AMR is a global threat we are currently facing. It is accelerated by misuse and overuse of antibiotics, as well as poor infection prevention and control. In 2010, India had the highest antibiotic consumption for human health increasing the risk of AMR.**

3 Laparoscopy

In this chapter, the specific advantages for laparoscopy for the context of rural India are described. A description is given on how a laparoscopic procedure is done, the instrumentation necessary to perform laparoscopy is considered and finally the challenge for laparoscopy in rural India is discussed.

3.1 Advantages for rural India

Laparoscopic surgery is a form of minimally invasive surgery. During laparoscopic surgery, small incisions are made through which long thin instruments are positioned and used to operate inside the abdominal cavity of the patient. Laparoscopic surgery has multiple advantages compared to conventional surgery. Due to the smaller incisions made, the patient has a smaller risk of contracting a surgical site infection, a faster recovery time, and a shorter hospital stay (Agha & Muir, 2003). Due to these advantages, laparoscopic surgery is done more and more in low-resource settings like rural India.

For instance, SSI rates for appendectomies (surgical removal of the appendix) have dropped by 9 percent in LMICs when the procedure is done laparoscopically (Foster et al., 2018b). Diagnostic laparoscopy is a laparoscopic procedure which is especially beneficial for LMICs. Diagnostic laparoscopy is done to directly view the contents of the abdomen in order to make a diagnosis. Diagnostic laparoscopy allows doctors in LMICs to view the inside of the patient without expensive diagnostic medical devices such as MRIs and CT scanners (Alfa-Wali & Osaghae, 2017).

Laparoscopic procedure

- The surgeon makes one or more incisions on the abdomen.
- The abdominal wall is lifted to avoid puncturing major vessels.
- A trocar or Veress needle is used to enter the intra-abdominal cavity (figure 5).
- The laparoscope is inserted through the trocar and connected to a camera.
- Insufflation is started to create a pneumoperitoneum, an increased space in the abdomen
- The inside of the abdomen is examined systematically before exiting.
- In a laparoscopic surgery, surgical instruments are also inserted through the trocar (Udwadia, 2004).

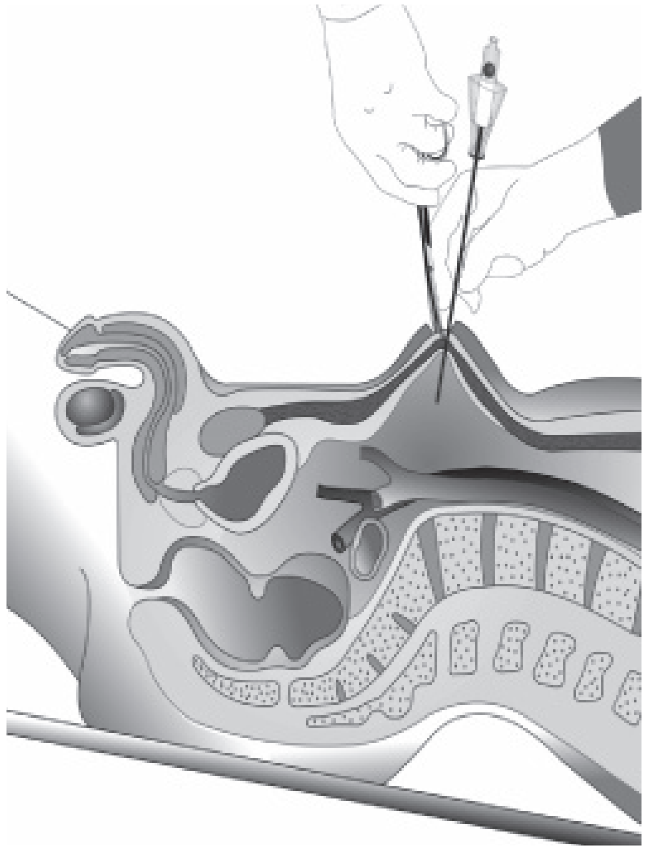


Figure 5: Insertion into the peritoneal cavity (Azevedo, 2006).

3.2 Instruments & equipment

Imaging devices

The laparoscope (figure 6) is used to visualize the inside of the patient. Traditionally, it is a rigid endoscope which consists of a rod of lenses which is surrounded by an outer ring of optical fibres which transmit light into the peritoneal cavity. The laparoscope is attached to a laparoscopic camera, which creates an image that can be seen on a monitor. The laparoscopes are easy to clean. However, the instruments cannot be cleaned in an ultrasonic cleaner as the cavitation can damage the lenses. Some laparoscopes can be sterilized, and some cannot (Ferreira, 2015).

Figure 6: Laparoscope (Olympus Medical Systems, n.d.).

Insufflation

The insufflator is used for insufflation of the peritoneal cavity during laparoscopic surgery. CO_2 gas is insufflated into the peritoneal cavity. This raises the intra-abdominal pressure and thus enlarges the peritoneal cavity (Perrin, 2004). CO_2 gas is used because it is colourless, non-combustible, and lastly it is highly soluble in blood and readily expired by the lungs (Lacy, 1998) (Ferreira, 2015).

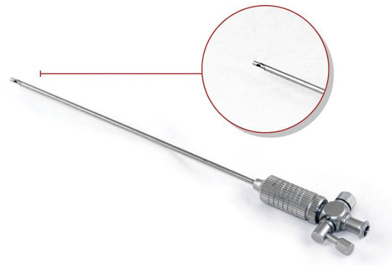


Figure 7: Veress needle (3-Dmed, n.d.).

Ports of entrance instruments

The Veress Needle (figure 7) is a spring-loaded needle that is used to penetrate the peritoneal cavity. The Veress Needle consists of two parts. An outer shell that has a sharp end and an inner spring-loaded blunt obturator. When the fascia of the patient is punctured, the blunt obturator is moved beyond the sharp end of the outer shell due to the spring force thus preventing vascular damage (Ferreira, 2015). The trocar (figure 8) is used as a portal for other laparoscopic instruments Some trocars can also be used to penetrate the peritoneal cavity combining the functions of the Veress needle and the conventional trocar. (La Chappelle, 2015). Standard sizes for trocars are: 3.5, 5.5, 11, 12, 15 and 22 mm and 50 to 200 mm in length. (Ferreira, 2015).

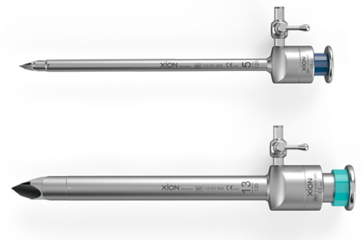


Figure 8: Two trocars of different diameters (Xion Medical, n.d.).

Operative instruments

Operative instruments (figure 9) are used to perform the procedure. The instruments are used for grasping, cutting, sealing, suturing, coagulating, and removing tissue. There are three generations of operative instruments. The first generation is designed as a single-piece instrument and cannot be disassembled. The second-generation operative instrument is still a single piece instrument, however, the second-generation instruments have an added flushing port. The third-generation instruments can be disassembled into several parts to ensure proper cleaning and inspection

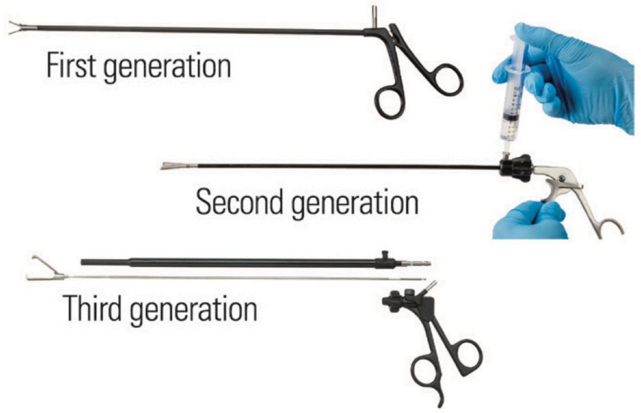


Figure 9: The three generations of laparoscopic instruments.

of the instrument (Ferreira, 2015). The most common diameter of operative instruments is 5 mm, but the diameter can range from 2-12 mm. The standard length for such instruments is between 340 and 370 mm. The flushing port is added to increase the cleanability of the instrument.

Suction/irrigation
Suction is necessary to drain fluids during laparoscopy. Irrigation is done to clean wound surfaces so they can be inspected more clearly. Suction and irrigation is performed through a cannulated instrument which is attached to a central vacuum system and/or a water supply (Ferreira, 2015).

Instrument sets used in rural India
When viewing the observations done by Mr. Robertson, the instrument sets used in rural India are somewhat similar to the general sets used in HICs. Looking at figure 10 the different instruments used in laparoscopic surgery in rural India can be seen. The figure shows four trocars, four operative instruments, three suctions/irrigation lumens, and a collection of different conventional surgical instruments. A general laparoscopic instrument consists of around six operative instruments, three or four trocars, one or two suction/irrigation lumens, one or more laparoscopes, and some accessories (AA medical store, n.d.). The dimensions of the trocars, operative instruments and suction-irrigation lumens can be seen in figure 11. In Appendix 2 the instruments can be found, which are used in the laparoscopic surgeries most commonly performed in India.

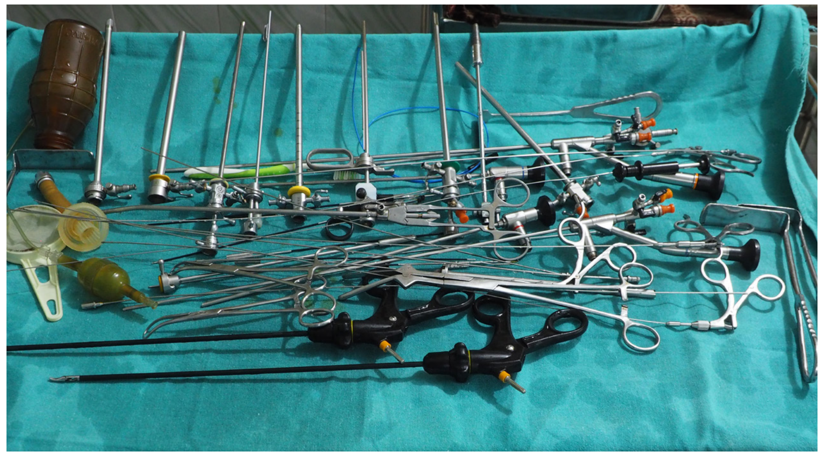


Figure 10: Collected instruments after laparoscopic surgery in rural India.

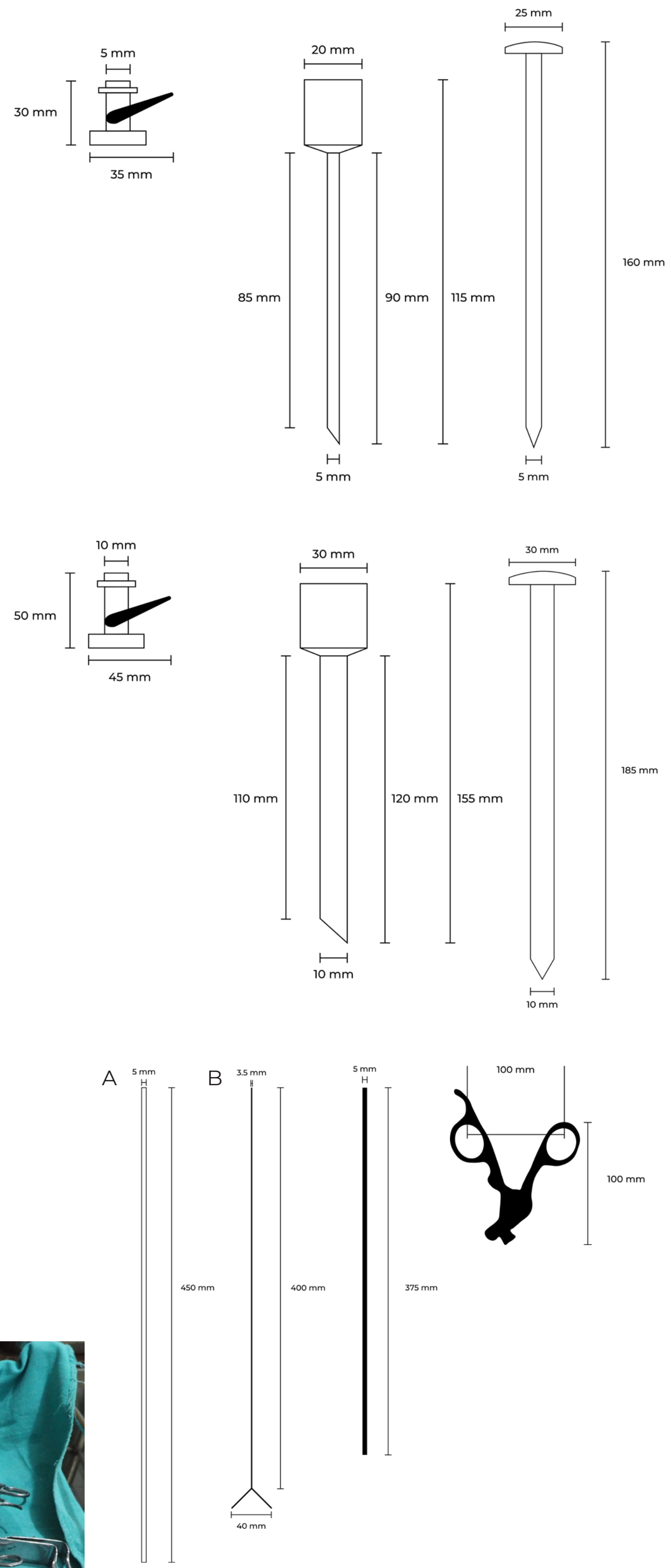


Figure 11: A: Dimensions of a suction-irrigation lumen. B: Dimensions of an operative instrument.

3.3 Challenge for laparoscopy in India

Even though laparoscopic surgery decreases the risk of surgical site infections, the surgical site infection rate during laparoscopic surgeries in LMICs is still much higher than in HICs. For laparoscopic appendectomies, the SSI rate in LMICs is 8.8 percent while the SSI rate found in studies in HICs varies between 0.8 and 2.9 percent (Foster et al., 2018b). Improper reprocessing has led to various outbreaks of SSIs after laparoscopic surgery in India (Raina et al., 2018)(Chaudhuri et al., 2010)(Vijayaraghavan et al., 2006). The field research done by Daniel Robertson showed a wide variety of factors which play a role in the lack of properly sterilized laparoscopic instruments which will be further discussed in chapter 4. An important factor is the complex geometry of the instruments. Literature shows the soil is hardest to remove in the complex geometry (hinges, ridges, blades, claws etc) and inside of the lumen (Fengler et al., 2003)(Marlow & Petruschke, 1995b). This was also observed during mr. Robertsons field research and verified in an interview with an Indian laparoscopic surgeon. In figure 12 the insufficiently reprocessed instruments that were encountered during the field research can be seen.

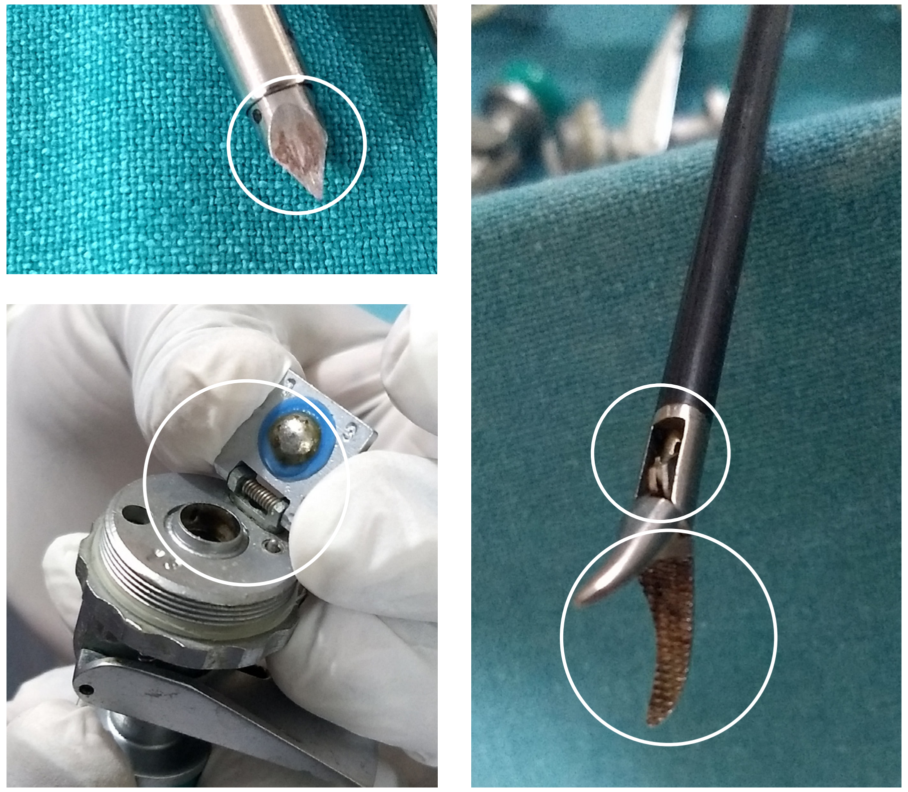


Figure 12: Different instruments with residual soil present after reprocessing were encountered during the observations in rural India.

3.4 Key insights

Insights

- **Laparoscopy can be highly beneficial for the rural Indian hospitals.**
- **In LMICs the SSI rate for laparoscopy is higher than in HICs. This is due to a number of reasons, one of them being the unsterile laparoscopic instruments used.**
- **Laparoscopic surgery is performed using different instruments. Usually, three or four trocars, five or six operative instruments and one or two irrigation lumens are used.**
- **The hardest to clean geometries are the lumens of the laparoscopic instruments and the complex geometries.**

4 Reprocessing

In this chapter, a more in-depth look is taken into which hospitals perform laparoscopy, how surgical instruments should be properly reprocessed, how the rural hospitals reprocess their laparoscopic instruments, how HIC hospitals reprocess their laparoscopic instruments, and lastly which differences exist between the two reprocessing cycles. The information found in this chapter was gathered through literature research, observations and interviews done by Mr. Robertson in rural India and an interview with an Indian laparoscopic surgeon.

4.1 The recommended reprocessing cycle

To ensure surgical instruments are properly sterilized and cannot cause SSIs the instruments are cleaned, decontaminated packaged, and sterilized. This whole process is called reprocessing and the WHO-recommended reprocessing cycle can be seen in figure 13. The reprocessing is done in Central Sterile Service Departments (CSSDs). CSSDs usually consist of a dirty room where the contaminated instruments arrive, a clean room where the cleaned instruments are inspected and packaged and a sterile room where the instruments are stored.

4.2 Healthcare facilities

CHCs
The lowest level healthcare center that performs laparoscopies in the hierarchy of hospitals that are permitted to perform these surgeries is the Community Health Centre (CHC) (figure 14) (Department of Medical Health and Family Welfare Government of Uttarakhand, 2022). The focus of the project is primarily on the context of CHCs, and this is where the research will focus. The Indian Public Health Standards (IPHS) has guidelines that a CHC must meet, including the availability of facilities such as electricity, road communication under all weather conditions, sufficient water supply, and telephone communication, as well as a minimum water supply of 10,000 liters of water. There must be daily access to drinking water to meet all requirements (IPHS, 2012). However, not all community health centers meet these requirements (Gambhir et al., 2016). The laparoscopic surgeries performed in the intended hospitals require continuous electricity to function because a monitor is essential for viewing the inside of the patient. Almost all public health centers and general hospitals have 24-hour piped water access (Chauhan et al., 2016) (Gambhir et al., 2016). However, the water quality in India is often poor. The water is hard due to high levels of calcium and magnesium. The water can also have high levels of microbial contamination (Singh et al., 2015). The hospitals that perform laparoscopies in rural India generally only have one set of laparoscopic instruments that must be used for every laparoscopic surgery due to a lack of funds. A variety of tasks related to the surgery are carried out by nurses. In addition to the surgeon and anesthesiologist, there is no specialized personnel present.

Reprocessing area
The laparoscopic instruments are cleaned in the OT itself or in a room adjacent to the OT. Often these rooms are small and packed with different supplies and machinery as can be seen in figures 15, 16 and 17. The water is supplied through a faucet. Often there is no proper water connection for coupling with an automatic reprocessing system. In the rural hospitals the water from the faucet is drained by a pipe which ends in a perforated drain (figure 18).

Personnel responsible for reprocessing
In rural India the nurses are responsible for reprocessing the laparoscopic instruments. Nursery is taught at a General Nursing School (GNA). The nurses are taught a wide range of subjects. More specialised subjects such as laparoscopic instrument reprocessing are not taught. Reprocessing is taught by other more senior nurses at the hospital.

Nurses perform many different tasks in the rural hospitals: scrubbing the instruments, circulating the patients, preparing the OT and assisting the surgeon during surgery. Five or six nurses usually have to perform all these tasks in the 40 minutes in between surgeries. This time is often too short to properly perform these tasks causing stress to the nurses. Because the nurses live in the countryside, there is little access to training on how to handle the laparoscopic instruments. Due to this lack of training there is no standard procedure and the protocol depends on each hospital. The lack of training can cause possibly dangerous situations to nurse and patient as improper handling of instruments can cause injury and subsequent infection.

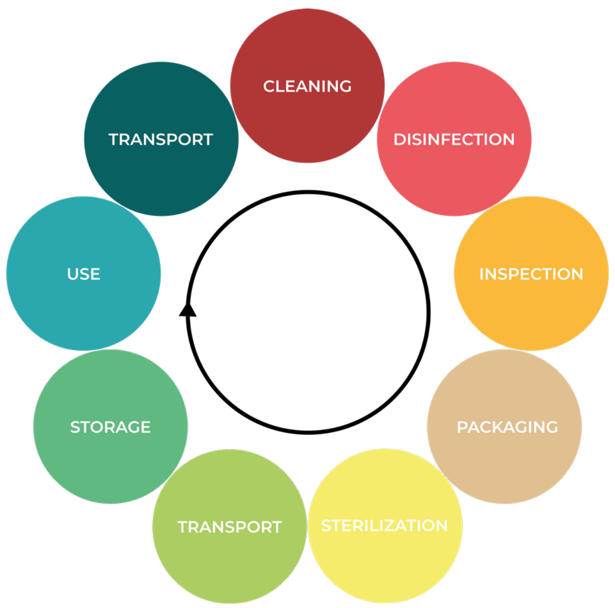


Figure 13: The WHO recommended reprocessing cycle (WHO, 2016).

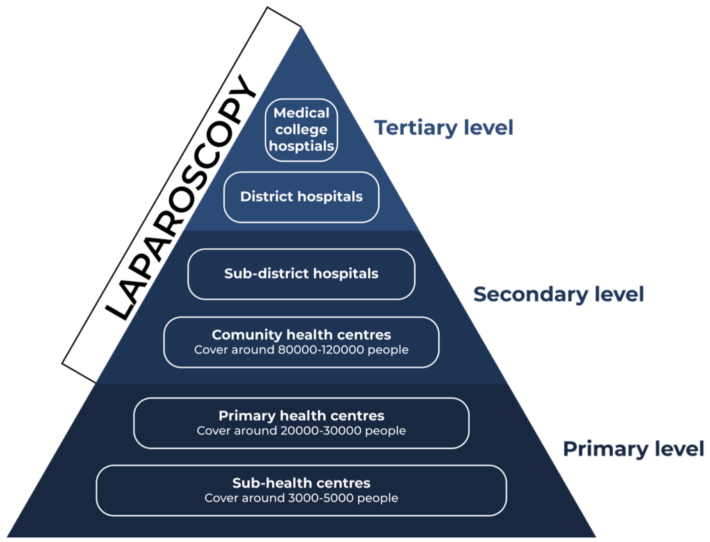


Figure 14: Healthcare centres where laparoscopy is performed.

Figure 15: Reprocessing room in hospital 4 view 1.

Figure 17: Reprocessing in the OT in hospital 3.

Figure 16: Reprocessing room in hospital 4 view 2.

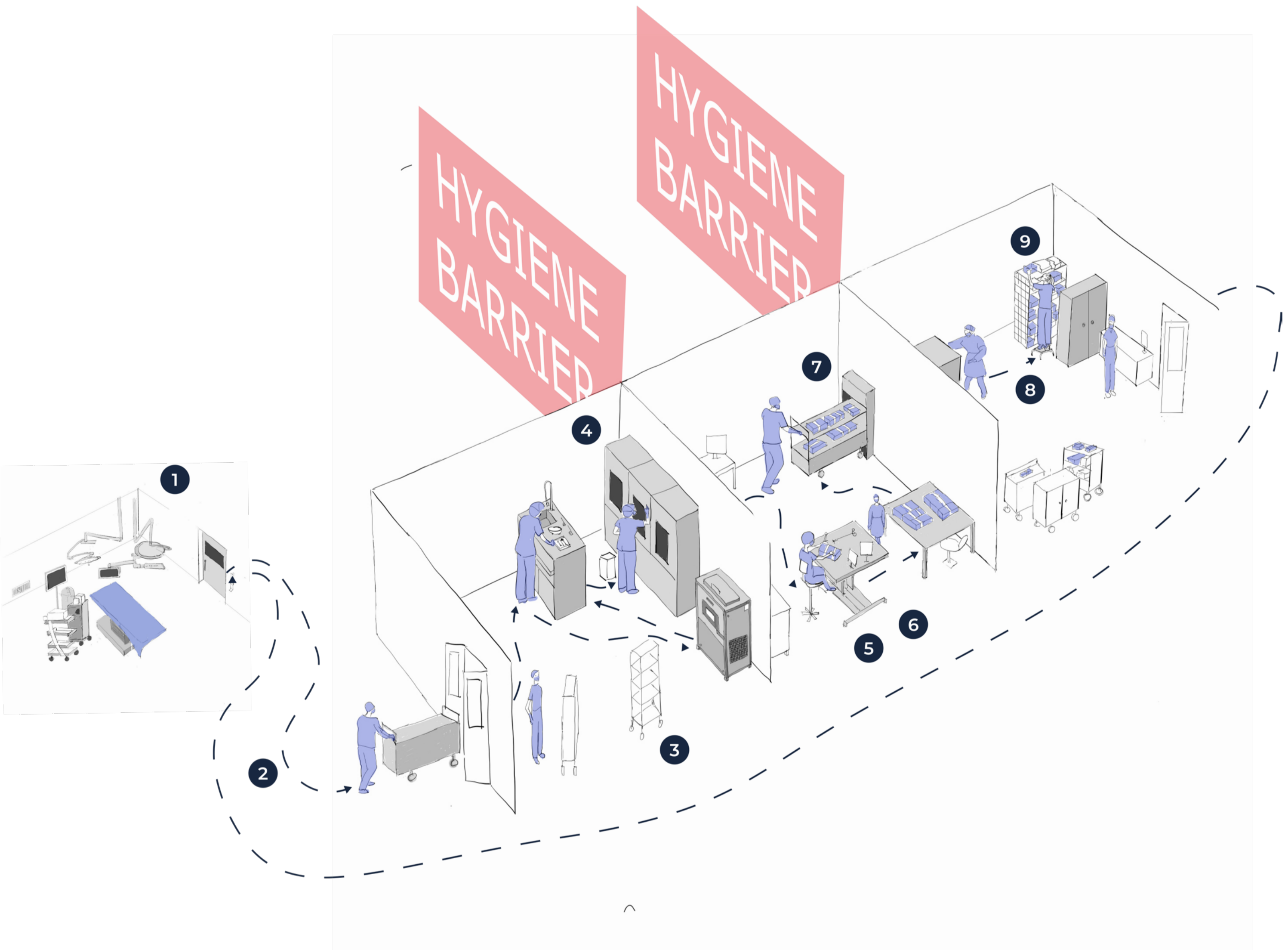
Figure 18: The drain in hospital 2.

4.3 Reprocessing in HICs

To determine how reprocessing in HIC hospitals is done an instrument journey was made. The information used to describe the journey was collected through a literature review (Rüther, 2014).

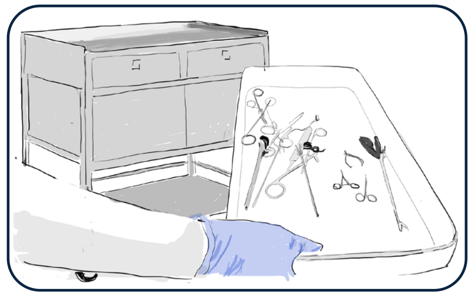
4 hours

1. Use
2. Transport
3. Cleaning
    - Manual-cleaning
    - Ultrasonic cleaning
    - Washer-disinfector
4. Disinfection
    - Washer-disinfector
5. Inspection
6. Packaging
7. Sterilization
8. Transport
9. Storage



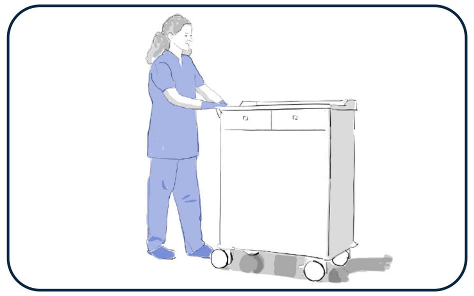
1 Use

The laparoscopic instruments are used by the surgeon to treat the patient. During use the instruments become contaminated. A nurse or OT technician collects the instruments and puts them into the instrument container. The instruments can now be transported to the CSSD.



2 Transport

The instruments are transported to the unclean area of the CSSD in sealed containers. The OT technician is responsible for loading and sealing the containers correctly preventing possible harm caused by sharp instruments when the containers are opened.

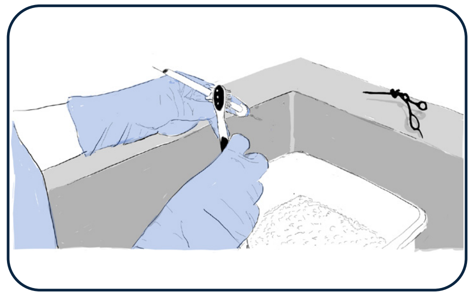


3 Pre-cleaning

In the unclean area of the CSSD the containers are opened, and the baskets are moved to the workspace. The instruments are disassembled and rinsed.

3 Pre-cleaning

The instruments are scrubbed.

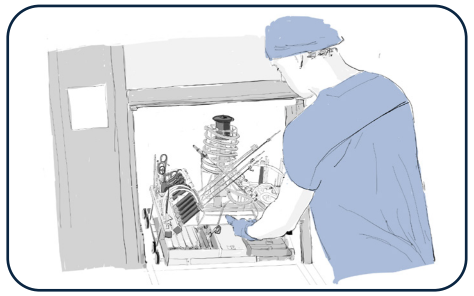


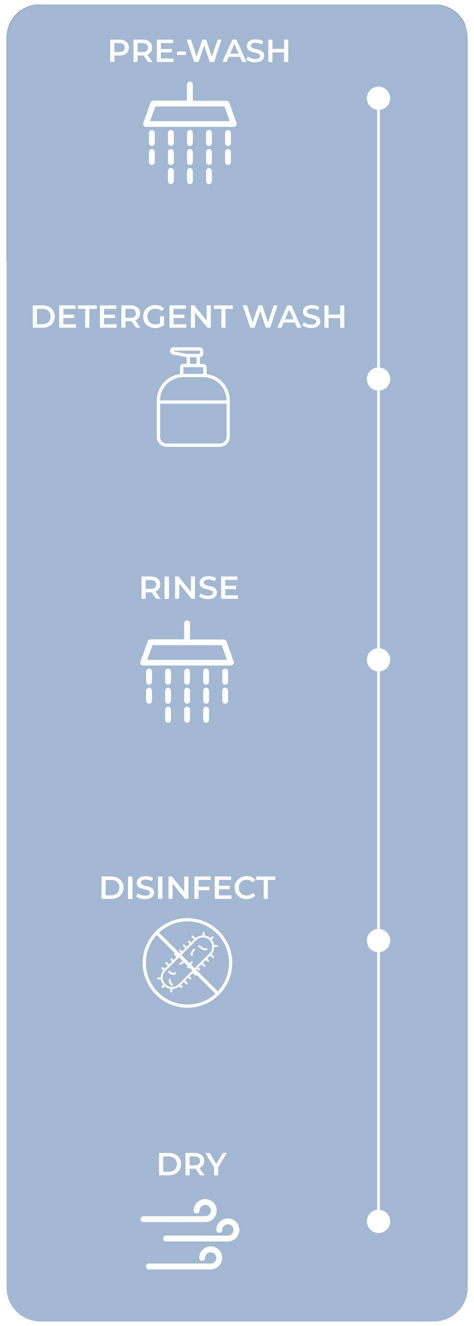
3 Pre-cleaning

After the instruments are scrubbed they are put in the ultrasonic cleaner in which the instruments are cleaned through acoustic cavitation.

3 Pre-cleaning

After ultrasonic cleaning the instruments are rinsed again and moved to the Washer-Disinfector cabinets.





3 4 Cleaning & Disinfection

After sorting and pre-cleaning the racks of the washer-disinfector are loaded. The lumens of the instruments are connected to injectors and the other parts are loaded on trays. Small parts are collected in a small fine mesh tray. The trays are moved to the WDs on carts and loaded into the WD. The work flow in the CSSD is designed to ensure minimal contact between the CSSD staff and the contaminated instruments. The washer-disinfector has a two-door system. This is to create a hygiene barrier. The trays are loaded from the unclean area and are collected at the clean area of the CSSD.

WD cycle
Pre-rinse
First gross soil is removed from the instruments by rinsing. This is done with water below 45 Celsius preventing protein coagulation and fixing of soil on the instrument surface.

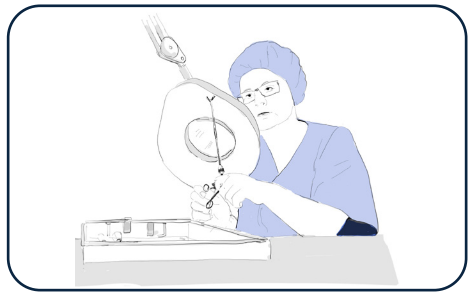
Detergent wash
Water at 65 Celsius and detergent is used to remove the residual soil still present on the instruments

Post-rinse
The instruments are rinsed to remove any detergent still present on the instruments with water at 65 Celsius.

Thermal disinfection
Water at 85 Celsius is used for a specified time to disinfect the instruments.

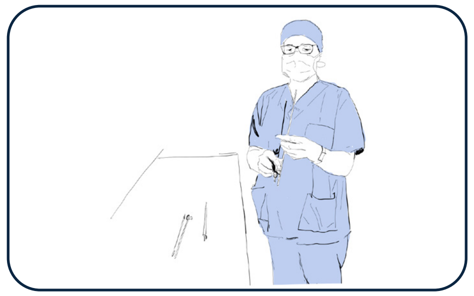
Drying
Hot air is used to dry the instruments.

5 Inspection



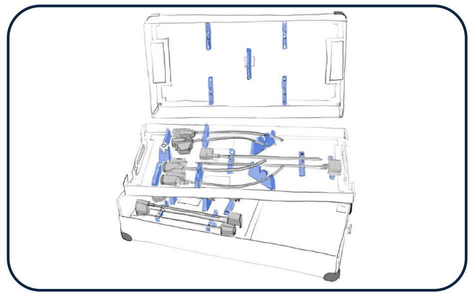
When the trays are removed from the WD in the clean area they are moved to the packaging station. Here, the CSSD staff member visually inspects the instruments to check whether all the soil has been removed during WD cycle. Instruments with residual soil present are returned to the unclean area. Clean instruments are reassembled, maintained, and tested. The inspection step is done to ensure the instruments are cleaned and working properly.

5 Inspection



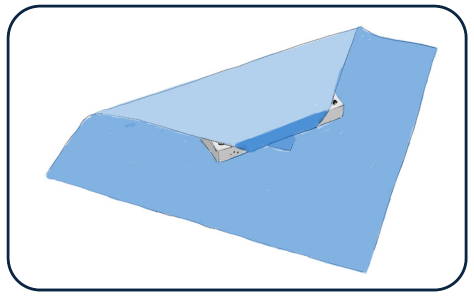
After the sets are inspected for soil and possible damage and the instruments are lubricated.

5 Inspection



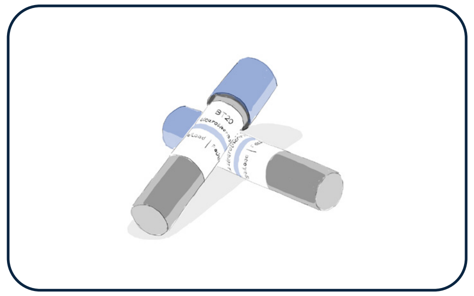
After lubrication all the instruments are assembled into complete instrument sets.

6 Packaging

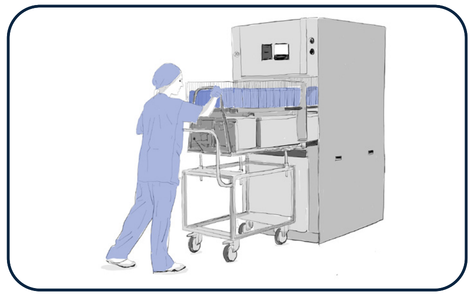


The instruments are packaged before sterilization to maintain their sterility until the next point of use. After the set is complete the baskets are put into the sterilization container. The container is then sealed.

6 Packaging



Before the instruments go into the sterilizer a biological indicator is added to verify whether the instruments have been sterilized properly.



7 Sterilization

Autoclaves achieve sterilization by exposing the packages to steam by during a time of at least 15 minutes at a temperature of 121 C at a pressure of 100 kPa, or 3 minutes at a temperature 134 C at 100 kPa. The autoclave has a two-door system like WD which forms another hygiene barrier.

8 9 Transport & storage

In the sterile area the CSSD staff member checks whether the instruments have been sterilized successfully. If this is the case the set is either stored or brought directly to the OT. The reprocessing cycle is now completed, and the instruments are ready to be used again. The expiration date for sterilized instruments is half a year after sterilization.

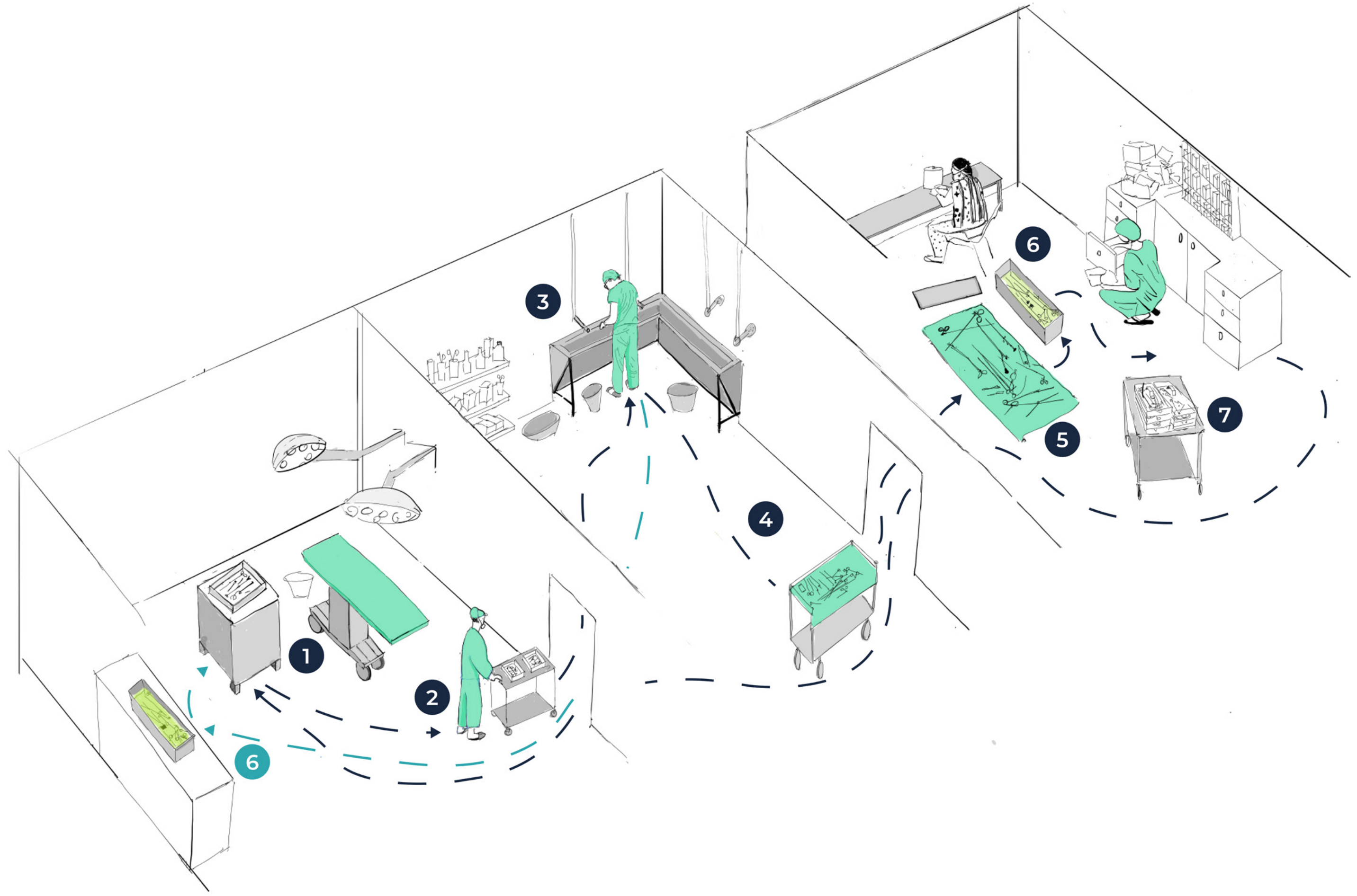
Conclusion
In HIC hospitals very strict protocols are followed. Due to the two door systems in the washer-disinfector and the sterilizer hygiene barriers are created to prevent cross-contamination. The reprocessing steps are performed by trained sterile reprocessing technicians. If a step has created insufficient results the sterile reprocessing technicians are immediately aware through thorough inspection and biological indicators. All these factors minimize the risk of surgical site infections.

4.4 Reprocessing in rural India

To determine what factors play a role in the challenge of insufficiently reprocessed laparoscopic instruments an instrument journey was made for the reprocessing cycle in hospitals in rural India. An attempt was made to create universal instrument journey for hospitals by determining which steps were taken in multiple hospitals. The journey was created by using the observations and interviews done by Mr. Robertson and the interview that was conducted with the Indian laparoscopic surgeon. On the left page the different steps of the reprocessing cycle can be seen while on the right page the problems that arise during these steps are shown.

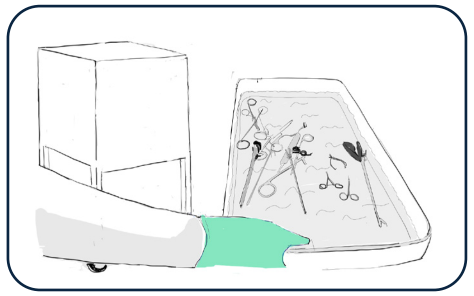
40 min

1. Use
2. Transport
3. Cleaning (5 min)
   - Manual cleaning
4. Transport
5. Drying (5 min)
6. High-level disinfection (20 min)
7. Storage



1 Use

The surgical instruments (regular and laparoscopic) are collected in uncovered stainless-steel basins. The instruments are soaked with tap water in these basins.



2 Transport

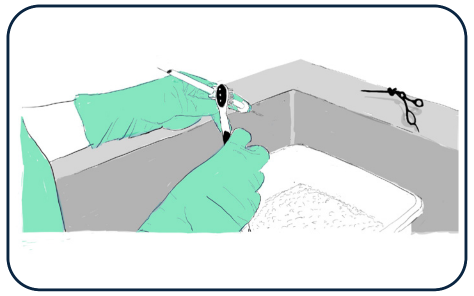
The instruments are then moved to a room adjacent to the OT for further reprocessing.

3 Manual cleaning

The instruments are first rinsed with tap water.

3 Manual cleaning

The instruments are cleaned manually using soap powder and gauze pieces, toothbrushes, and sharp objects like needles. The lumens are held under running water. No specific brush is used to clean the inside of the lumen. The soap is not used to soak the instruments and is only used when necessary to remove contamination.



3 Manual cleaning

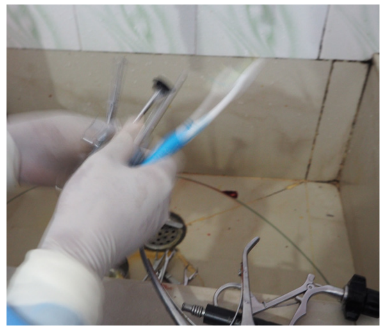
After the manual scrubbing, the instruments are rinsed again to remove any remaining detergent. If the patient was infected with hepatitis or HIV the instruments are soaked in bleach for 1 day.

Problems

- Aerosolized pathogens can be released from the uncovered steel basins possibly infecting the medical staff.
- The instruments are transported unsealed risking cross-contamination.

Problems

- Proper tools are lacking to clean the laparoscopic instruments. No lumen specific brushes were used in any of the hospitals.



- Using sharp objects like needles to clean the medical instruments can damage them.

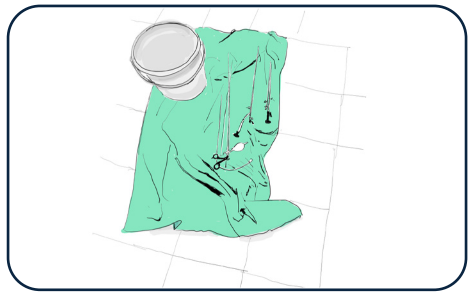
- Exposure to bleach causes pitting corrosion on the instruments.

4 Transport

After the instruments have been cleaned, they are transported to a different room. This can be the OT itself or a different room within the hospital.

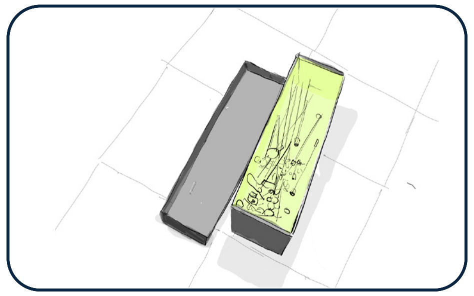
5 Drying

The regular and laparoscopic instruments are separated before sterilization or disinfection. If there is enough time the instruments are air dried on the ground. If not, the instruments are directly high-level disinfected.



6 Disinfection

Laparoscopic instruments are high-level disinfected by being soaked in trays filled with disinfectant. The disinfectant used for this is glutaraldehyde (cidex). The laparoscopic instruments need to soak in the disinfectant for 20 minutes.



6 Disinfection

After the instruments have soaked in the cidex they are rinsed with a saline solution.

- The detergent is not used to soak the instruments

Problems

- Aerosolized pathogens can be released from the uncovered steel basins possibly infecting the medical staff.
- The instruments are transported unsealed risking cross-contamination

Problems

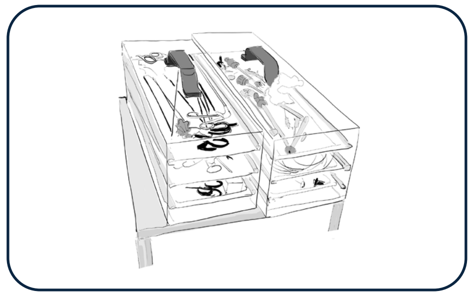
- The instruments are not fully dried. Wet instruments can affect the effectiveness disinfection step because the solution can become diluted.
- The instruments are air-dried on the ground risking new contamination sticking to the instruments.

Problems

- Proper Personal Protective Equipment is not worn. The cidex can cause occupational asthma and contact dermatitis (WHO, 2016).
- The concentration of glutaraldehyde in the environment is not monitored (WHO, 2016).
- The instruments are at times disinfected in the OT risking respiratory problems for the patient (WHO, 2016).
- When the instruments are not properly cleaned the glutaraldehyde can fix the contamination to the instruments.
- Laparoscopic instruments can also be sterilized using an autoclave, however the autoclave is not used. Using an autoclave increases the amount of organisms removed in comparison to high-level disinfection and is less harmful to the nurses.

7 Storage

The laparoscopic instruments stored in formalin chambers at the end of the day. The formaldehyde gas released by the formalin tablets in the chambers disinfects the instruments.



Conclusion

In the rural Indian hospitals no official protocols are followed. No hygiene barriers are present causing possible cross-contamination. The reprocessing steps are performed by nurses which lack training. The current reprocessing cycle causes damage to the instruments, harm to the nurses and finally results in visual soil still present on the instruments after reprocessing.

A comparison of the journeys

A comparison of the journeys of reprocessing laparoscopic instruments in HIC hospitals and rural hospitals reveals striking differences in the methods used. Specifically, in HIC hospitals, a significant number of steps in the reprocessing process are carried out by machines, whereas in rural hospitals, all steps are done manually (figure 19). Moreover, in rural hospitals, the process of drying is often skipped when time pressures are high. In addition, proper visual inspection of the instruments is often not carried out. Furthermore, the recommended 20-minute soaking time in cidex for the instruments is not consistently adhered to in rural hospitals. In addition, proper visual inspection of the instruments is often not carried out. Furthermore, the recommended 20-minute soaking time in cidex for the instruments is not consistently adhered to in rural hospitals.

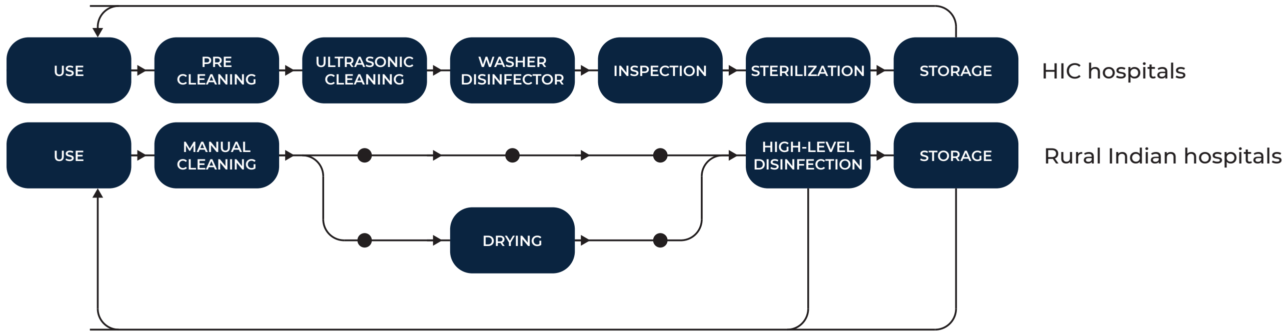
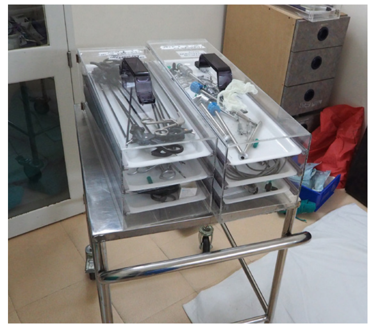


Figure 19: A comparison between the different reprocessing steps in a HIC and rural Indian hospital.

Problems

- Formaldehyde is possibly carcinogenic (WHO, 2016).
- The use of formaldehyde requires proper PPE which is not worn at the moment (WHO, 2016).



4.5 Key insights

Insights

- **There is a lack of trained & specialized personnel due to this no official protocol is followed. Maintenance is rarely done on the equipment, finally causing damaged instruments and equipment.**
- **There is a lack of safety for the staff. The different reprocessing steps require PPE to be worn, causing possible morbidity to the staff.**
- **There is a lack of time for reprocessing due to lack of instrument sets causing the instruments to be insufficiently dried disinfected and inspected.**
- **There is a frugality concerning resources and equipment causing disposables to be re-used and washer-disinfectors to remain unused for laparoscopic instruments. No proper brushes or other disposables are present for reprocessing.**
- **There is a lack of an official CSSD There are no hygiene barriers, which cause cross-contamination.**
- **At the end of the reprocessing cycle visual soil is still present on the instruments.**

5 Cleaning

The cleaning step is the most important step in the reprocessing cycle. Sterilization or high-level disinfection is impossible without proper cleaning. Any residual gross contamination can cause the sterilization step to fail, leading to unsterile laparoscopic instruments (Alfa, 2019). Therefore, cleaning is explored in this chapter. Firstly, the basics of cleaning are explored, secondly, the cleaning phases of the systems currently used In HIC hospitals are discussed and finally the method which the laparoscopic instruments are cleaned in these systems is analysed.

5.1 The Sinner circle

The effectiveness of cleaning depends on a wide range of factors. These include the cleaning detergent used, the properties of the specific soil to be cleaned and hydrodynamics. The European research project studying food production, PathogenCombat PathogenCombat. (2011) suggest that there are four factors influencing the effectiveness of cleaning (PathogenCombat, 2011). These factors are the cleaning time, the cleaning temperature, the chemical reaction between the detergent and the soil and lastly the mechanical action caused by the cleaning fluid. These factors form the Sinner circle. The most efficient use of these factors varies among situations and a lack of one factor can be compensated by enhancing another. The Sinner circle can be seen in figure 20.

Figure 20: The Sinner circle, which contains the four elements that influence the effectiveness of cleaning: the mechanical action of the cleaning fluid, the cleaning time, the temperature and the chemical reaction.

5.2 Analysis of automatic cleaning systems for laparoscopic instruments

In high income countries laparoscopic instruments are cleaned in washer-disinfectors. As mentioned in chapter 4.3, this is done in five distinct phases. In this section an analysis is done on how washer-disinfectors remove the gross soil. This is done in the first three phases (figure 21).

Washer-disinfector cleaning phases

Pre-rinse

Firstly, the instruments are pre-rinsed to remove all gross soil. The rinsing phase is started by filling the sump **(1)**. The fill valve connected to the cold water is opened and the sump is filled. The recirculation pump creates a flow from the sump to the different spray-arms in the wash chamber rinsing the instruments **(2)**. At the end of the rinsing phase the pump stops and the drain valve is opened **(3)**. The drain valve is located at the bottom of the system causing the water to be removed naturally.

Detergent wash

Secondly, the remaining soil is removed in the detergent wash. The valves of the hot and cold water are opened. The sump is filled again **(4)**. A temperature sensor measures the temperature of the water in the sump and a heating coil is used to maintain temperature at 65 degrees Celsius. A peristaltic detergent pump is used to pump the detergent fromm the container into the sump. A sensor is used to measure the correct amount of detergent **(5)**.

Post-rinse

Thirdly, the post-rinse removes any remaining detergent from the instruments. The post-rinse follows the same steps as the pre-rinse.

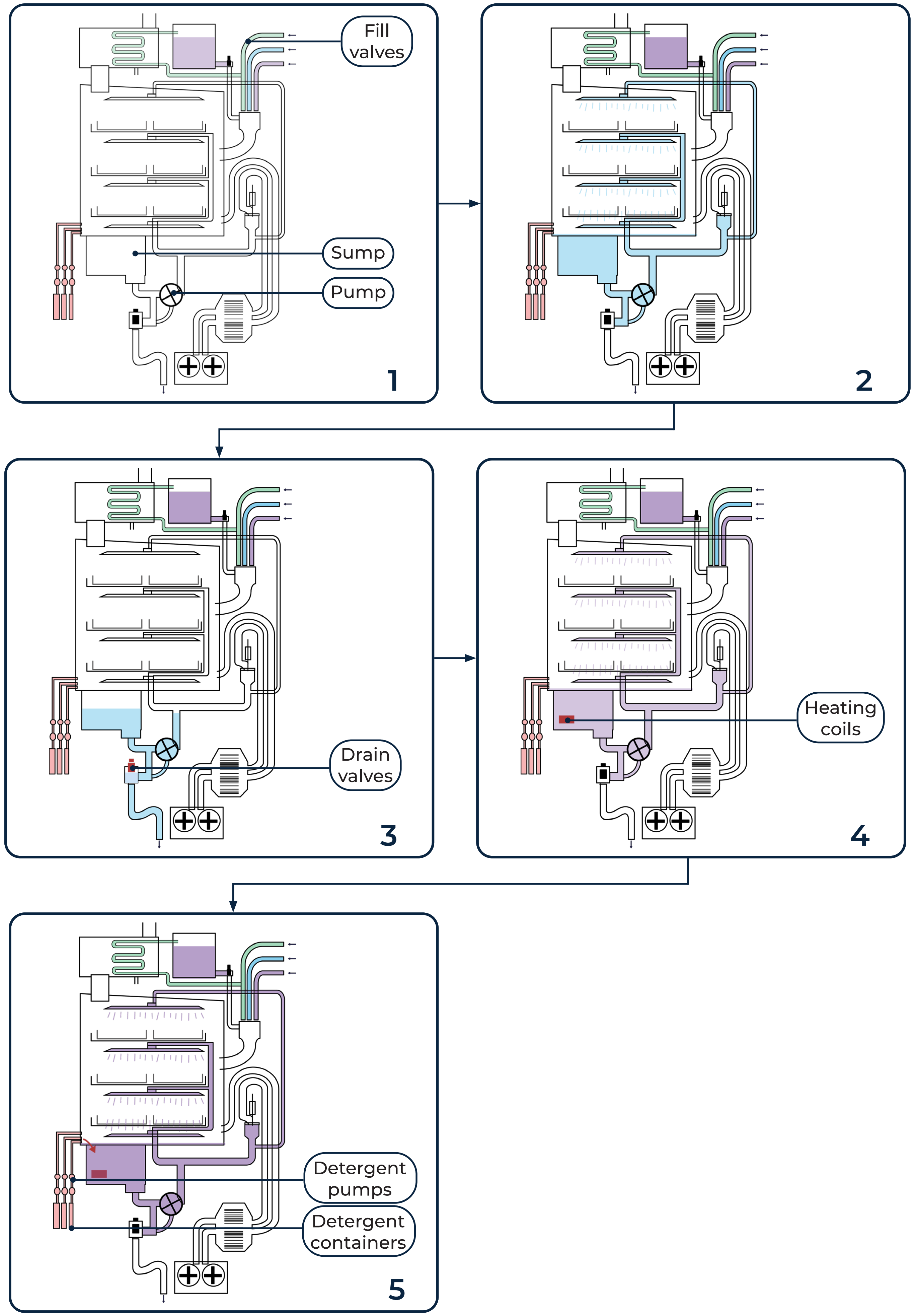
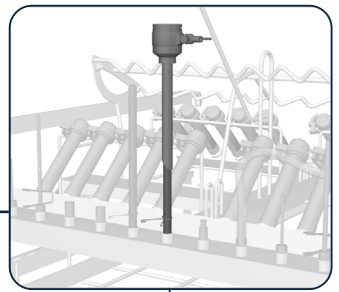
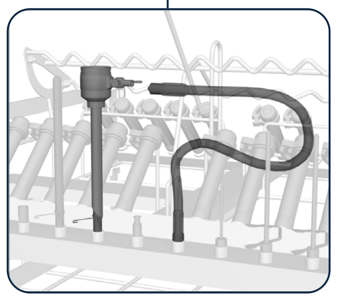


Figure 21: Cleaning phases of a washer disinfector.

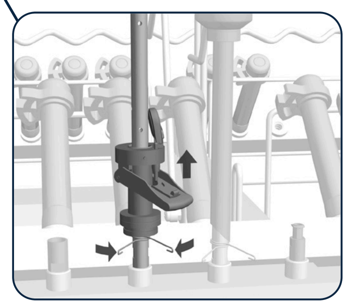
Cleaning modules for laparoscopic instruments
The lumens of the laparoscopic instruments are cleaned in washer-disinfectors in specially designed modules in which they are flushed. Figure 22 shows how the different lumens are connected. The other components of the laparoscopic instruments are cleaned in baskets as can be seen in figure 23.



The trocar sleeves with a diameter of 10 mm and up are placed around jets which rinse the inside of the lumen.



The sleeves are connected to connector hoses to rinse all parts of the complex geometry.



The trocar valves are placed around jets which rinse the inside of the lumen.

Other smaller diameter lumens like the insulated sheaths and trocars with a diameter of 5-10 mm are placed in the injector sleeves.

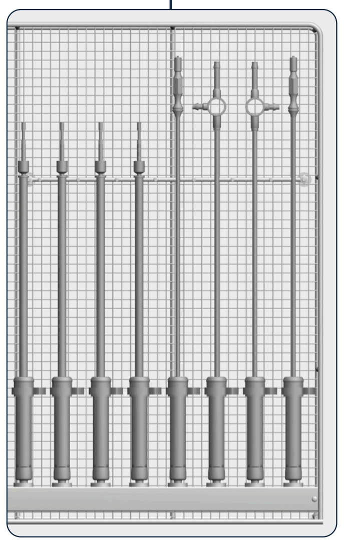


Figure 22: Attaching the different instruments lumens on the module.

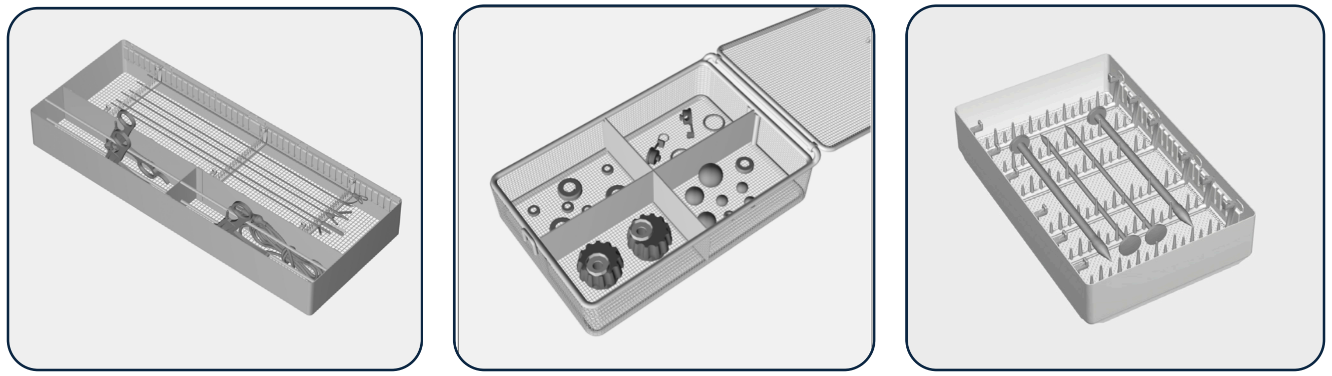


Figure 23: The three baskets containing laparoscopic instruments. The first holds the handles and inserts, the second the small components and the third the obturators.

The pain point of current automatic cleaning of laparoscopic instruments
The large amount of branching in the mobile unit can cause some lumens to be insufficiently flushed if the lumen is clogged (figure 24). In conventional washer-disinfectors this issue is solved by making use of a circulation pump which creates a large flow rate. In the Belimed WD200 washer-disinfector a pump flushes the lumens with a flow rate of 625 L/min (Belimed, n.d.).

Figure 24: Washer-disinfector rack for cleaning lumens with arrows showing how water flows through.

5.3 Key insights

Insights

- The instruments are cleaned by all the elements of the Sinner circle: the cleaning time, the cleaning temperature, the chemical reaction between the detergent and the soil and lastly the mechanical action caused by the cleaning fluid.
- During the cleaning phases of a washer-disinfector pumps are used to pump the water and detergent through the system, valves are used to control the water supply and heating elements are used to heat up the water.
- The lumens of the instrument are loaded in modules and the other components in baskets.
- The large amount of branching in the mobile unit can cause some lumens to be insufficiently flushed if the lumen is clogged.

6 Problem definition, design goal and requirements

6.1 What is the problem?

The surgical site infection rate in India is much higher than the world average. Surgical site infections create a large burden on the Indian population as surgical site infections cause increased morbidity and mortality. Surgical site infections increase the use of antibiotics for medical use which increases the risk for antimicrobial resistance which is considered one of the biggest threats to global health we are currently facing by the WHO. Lastly, surgical site infections cause increased hospital stays which creates a financial burden for the patient. Laparoscopy can be a powerful tool for LMICs due to its ability to reduce the risk of SSI. However, the benefits of laparoscopy are undermined by the risk of SSI due to inadequate reprocessing of laparoscopic instruments.

6.2 Why does it occur?

There are a number of reasons that contribute to the problem of insufficiently reprocessed instruments. In figure 25 the different factors can be seen that influence the current reprocessing cycle of laparoscopic instruments. The outer layers show the more specific problems created due to these factors.

Complex geometry of the instruments
The laparoscopic instruments consist of geometry that is hard to clean and inspect. Especially, the geometry directly in contact with tissue and the lumens are hard to clean. As the diameter of the lumen of the laparoscopic instruments is small, it is especially hard to inspect for contamination.

Lack of time for reprocessing due to lack of instrument inventory
Due to the lack of laparoscopic instrument inventory, the laparoscopic instruments must be cleaned between each laparoscopy which causes a high level of time pressure causing steps of the reprocessing cycle to be carried out incompletely.

Branching in washer-disinfectors
When lumens are cleaned in washer-disinfectors, the large amount of branching causes clogged lumens to be insufficiently flushed.

Lack of a proper CSSD
Due to the lack of a proper CSSD there are no hygiene barriers which protect the instruments from cross-contamination.

Frugality concerning resources and equipment
Firstly, washer-disinfectors are not used to clean the laparoscopic equipment as the water and power usage would be too high for one set of instruments. Secondly, disposables are re-used.

Lack of trained & specialized personnel
Due to the lack of trained and specialized personnel maintenance is hardly done causing equipment to stop working earlier than necessary. The nurses have not been trained in reprocessing of laparoscopic instruments. Due to this lack of training methods of cleaning are applied which are harmful to the instruments. The use of bleach causes pitting corrosion, the use of needles to clean small geometry can cause damage and glutaraldehyde can fixate contamination to the instruments if the instruments still have contamination present on them.

Lack of safety for the staff
The lack of PPE causes the nurses to be exposed to a multitude of harmful fumes and contaminants. Furthermore, the extensive physical contact with the contaminated instruments during reprocessing can increase the risk of the nurses becoming injured.

6.3 Who is affected?

The problem directly affects the patient. The increased risk of SSI caused by insufficiently reprocessed instruments causes a financial and physical burden on the patient. The increased risk of SSI causes more morbidity and mortality. The increased hospital stay causes the cost of the care received by the patient to rise and elongates the time the patient is incapable of working. The family of the patient is therefore indirectly affected by the problem as they might depend on the salary earned by the patient.
The staff working in the hospitals and the patient are also affected indirectly as well. The current reprocessing practices cause possible harm to patient and hospital staff due to the fumes caused by incorrect usage of disinfectants. Lastly, the risk of Anti-Microbial Resistance AMR is a worldwide threat which can affect the entire global population.

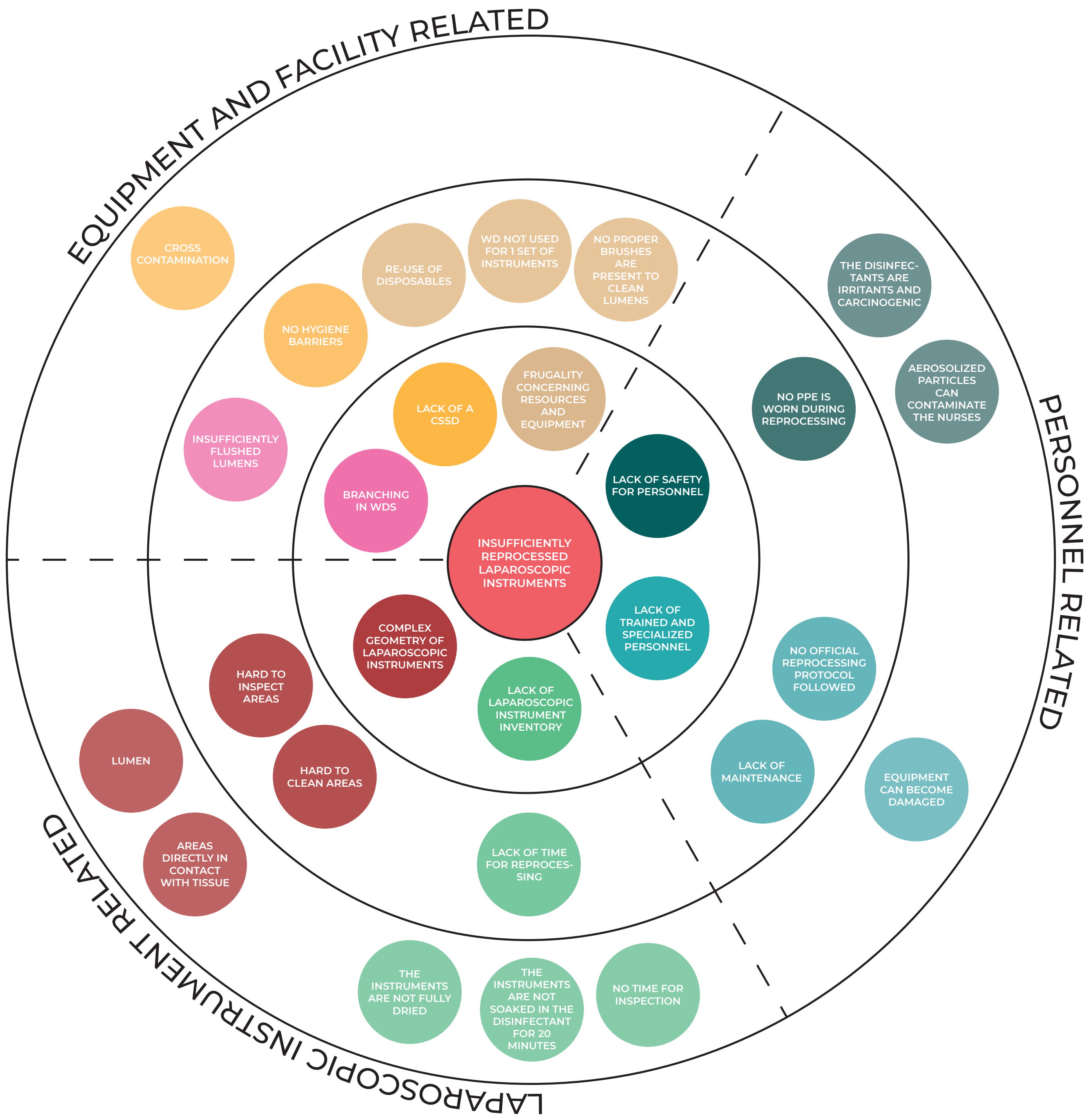


Figure 25: The different factors affecting the reprocessing of laparoscopic instruments.

Problem statement

Currently, laparoscopic instruments are reprocessed insufficiently in rural India which causes an increase in surgical site infections resulting in a financial and physical burden on the rural Indian population.

6.4 Solution space

Automated cleaning of laparoscopic instruments can be of value to the rural Indian hospitals. The hospitals currently face a wide range of problems during reprocessing of laparoscopic instruments. The seven key challenges defined in itself are very hard to solve as they all stem from a lack of funds.

The key challenges can however be solved by implementing a product in the reprocessing cycle of the rural Indian hospitals thus mitigating the effect of the seven key challenges. In figure 26 the potential for automatic cleaning and its advantage for every of key challenge defined can be seen.

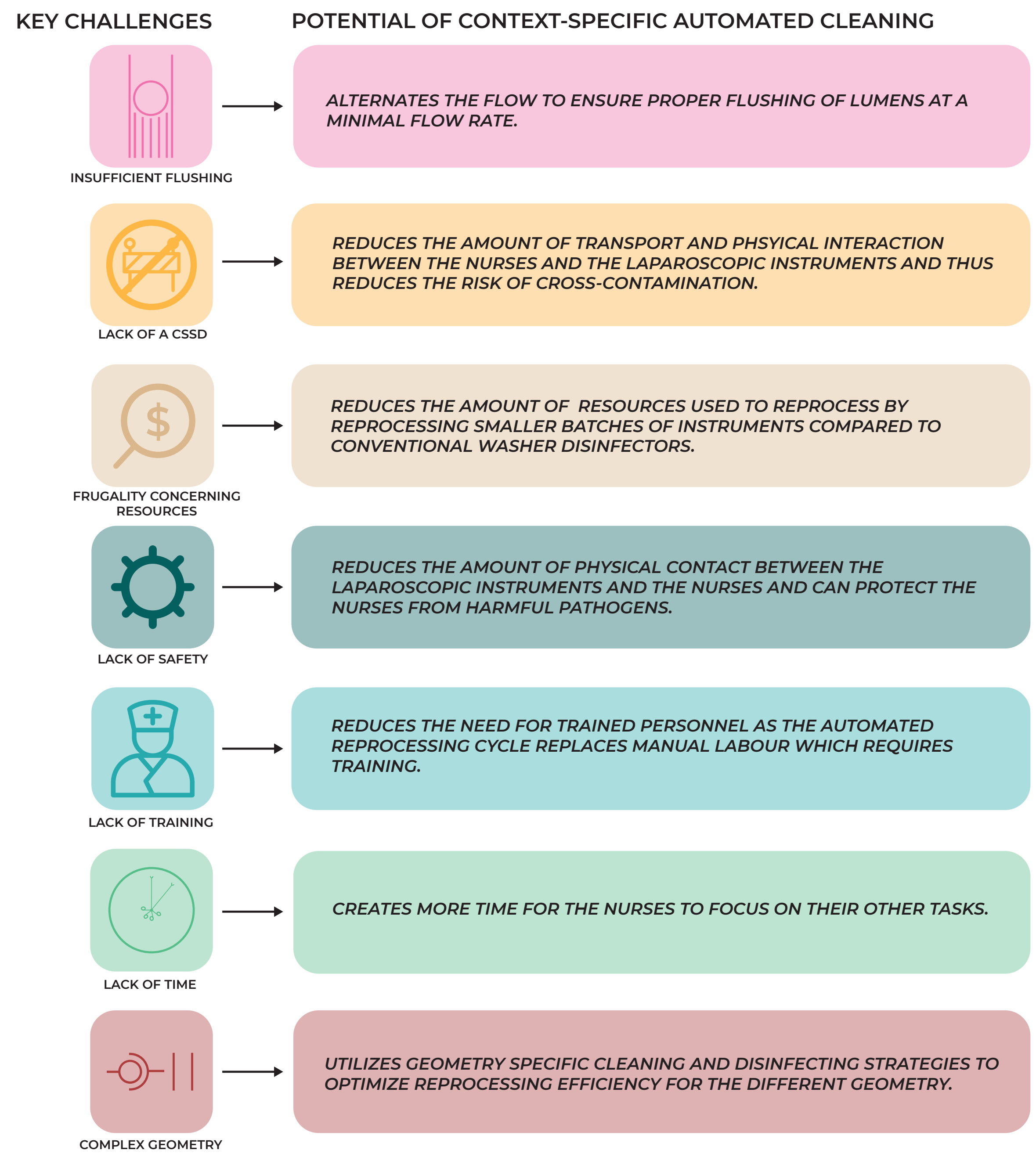


Figure 26: Potential for automated cleaning for rural India.

6.5 Design goal

Based on the problem definition and the key challenges defined the following design goal was defined:

The **design** of a **concept of a medical washer** that **supports and protects the nurses in hospitals** in **rural India** during their tasks in between surgeries by **cleaning one set of laparoscopic instruments** while using **little resources**.

6.6 Sub-goals

Cleaning
Instruments should be clean when fully visually inspected. There should be no gross soil present on the instruments after the cleaning stage. This would ensure the instruments can be properly sterilized or high-level disinfected without residual soil fixating on the instruments.

Supporting
The medical washer supports the nurses by alleviating them from one of the tasks they have to perform in between surgeries. The medical washer should reduce the amount of time spent on cleaning by the nurses.

Protecting
The medical washer protects the nurses by shielding them from harmful pathogens which could cause possible morbidity.

Little resources
The medical washer uses little resources so the washer can be used without creating a financial burden on the hospital and patient.

6.7 Scope

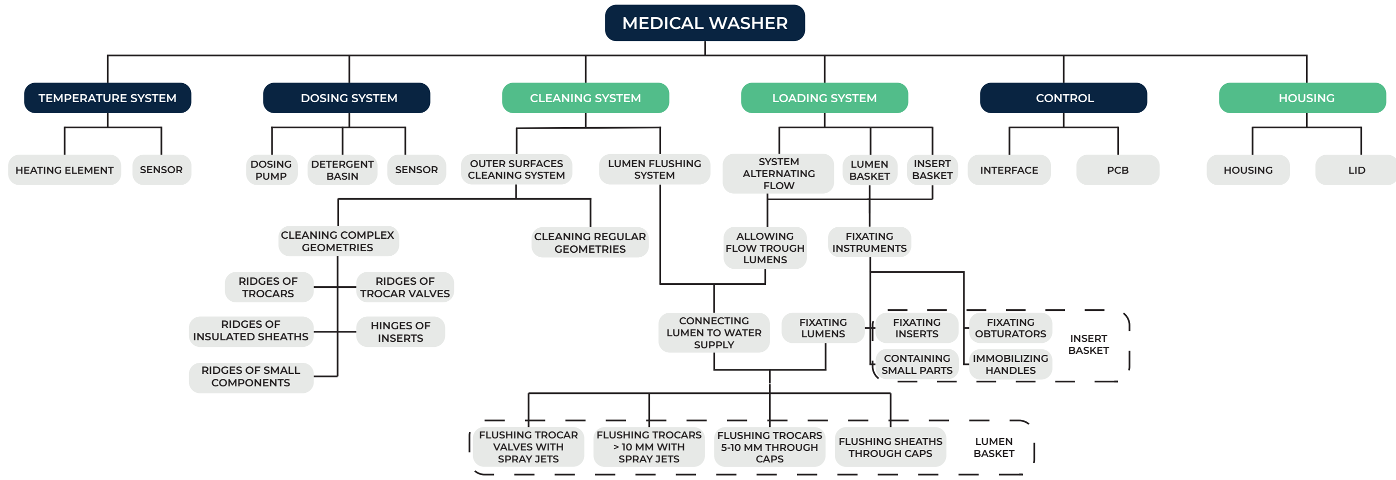


Figure 27: The medical washer and its sub-systems.

A medical washer consists of different sub-systems. A function analysis was done to determine these sub-systems and to discover which functions these sub-systems must perform. The function analysis and the design goals were used to determine which sub-systems first require focus for the success of the medical washer. In figure 27 the function-analysis and the selected sub-systems can be seen.

Temperature system & the dosing system
The dosing system as well as the temperature system consist of parts which can be bought of the shelf and differ little in between medical washers.

Loading system
The loading system is the system of the medical washer which requires the most physical interaction with the nurse. To ensure the medical washer can be used fast and safely without extensive training, requires a specially designed loading system.

Cleaning system
How the cleaning system performs determines how much water is needed to clean the laparoscopic instruments and how much time is needed to clean the instruments. Therefore, the cleaning system will be one of the sub-systems of focus.

Control
The control of the medical washer is of importance as the nurse must interact with the interface correctly. However, first the other systems must be developed before the interface can be designed. So, the control system is not a focus point of this project.

Housing
As the housing is both connected to the loading system and the cleaning system it is within the scope of the project.

The function analysis was used to determine the Technology Readiness Levels (TRLs) of the sub-systems. The TRL diagram can be seen in figure 28.

The final goal of the project is to design a concept of a medical washer in which a cleaning system is used which guarantees clean instruments every washing cycle while using little resources and a loading system which can be loaded safe, in a short time frame, by a nurse who has received no training in the use of the medical washer.

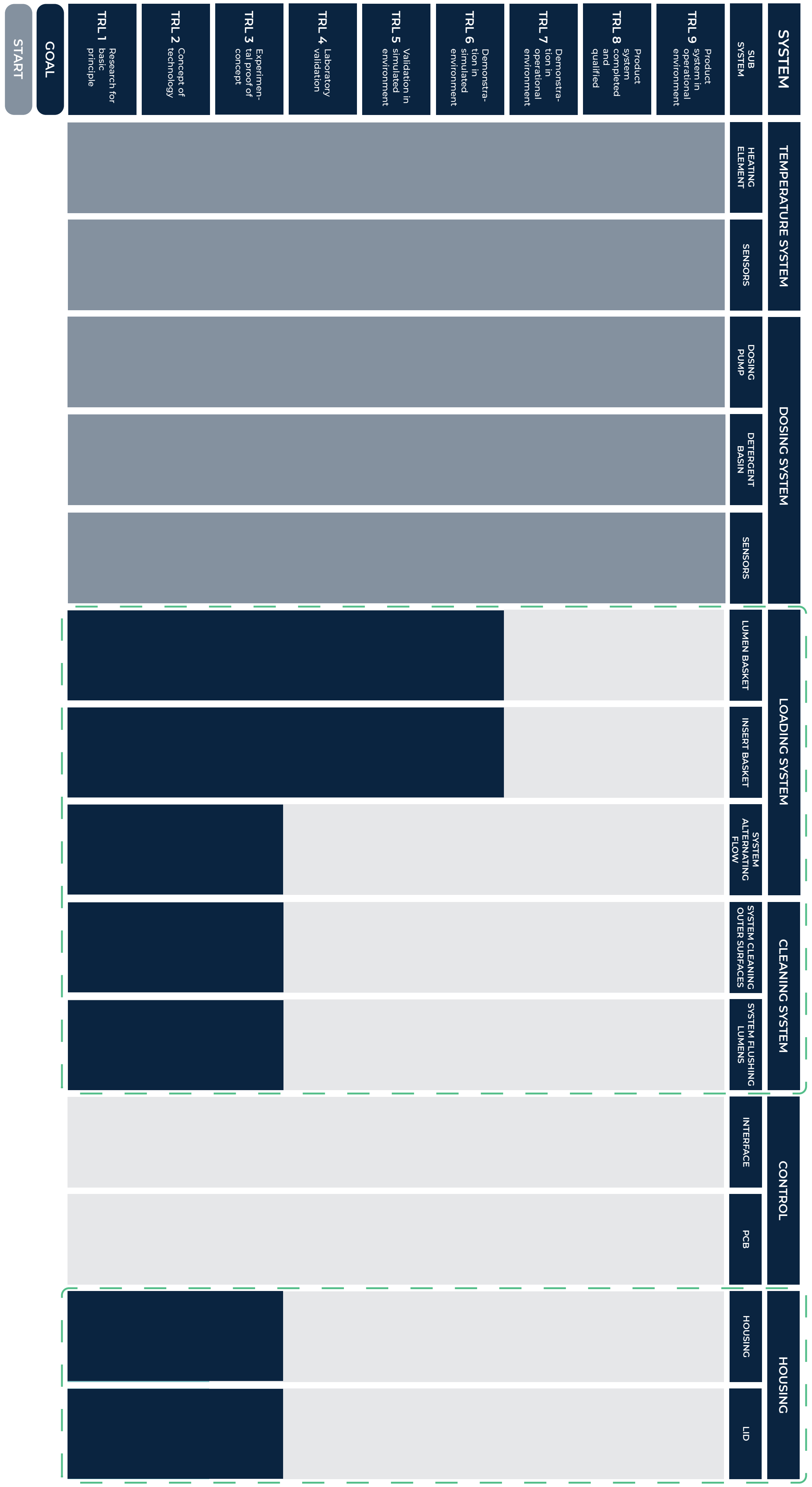


Figure 28: TRLs of the medical washer at the start and end of the project.

6.8 List of requirements

Out of all the insights gained in the discover phase a list of requirements was defined. The list is divided in three parts: device specific requirements, sub-system specific requirements and LMIC specific requirements. The full list of requirements can be found in Appendix 3.

Device specific requirements

Cleaning
After the medical washer is done cleaning the instruments must be clean when visually inspected to ensure no gross contamination fixates on the instruments during disinfection and cause failure of the high-level disinfection.

Batch size
The medical washer must clean one set of laparoscopic instruments. The set of instruments is defined as 16 lumens, 8 handles, 8 obturators, 8 inserts and a compartment for small components (Appendix 2).

Process time
The medical washer must clean the instruments in 15 minutes (Appendix 4).

Ground area
As the space in the reprocessing area is limited, the ground area of the medical washer must not take up more than 1 m x 1 m.

Water supply
Some hospitals do not possess a proper water inlet for automated cleaning. Therefore, the nurses must be able to manually add water to the system as well as an automatic system.

Sub-system specific requirements

Loading system
- Loading time

As the nurses currently spend 5 minutes on the cleaning step of the reprocessing cycle the medical washer must be loaded in less than 5 minutes to alleviate the time pressure experienced by the nurses.

- Safety

To protect the nurses from the sharp components of the instruments, The instruments containing sharp edges must be fixated.

- Usability

As the nurses lack training in handling medical devices, especially devices focusing on reprocessing. The loading system must be able to be correctly loaded by nurses who have no experience loading medical washers.

- Alternating flow

As lumens in current washer-disinfectors are insufficiently flushed at times due to branching of the flow through the modules and to limit the flow rate needed of the pump, the system must alternate the flow between lumens to ensure proper flushing.

Cleaning system
- Lumen flushing

The lumen is very hard to clean and inspect. Therefore, the washer must flush the lumens of the laparoscopic instruments.

- Complex geometries

The complex geometries of the laparoscopic instruments must be accurately cleaned.

- Water use

As the regular washer-disinfectors are not used due to their consumption of water. The medical washer must use less water than a regular washer-disinfector which is 180 L of water per cycle (Steris, n.d.).

- Water quality

As the water is of low quality in rural India the water must be filtered before it is used in the medical washer (Appendix 4).

Housing
- Sealing

To protect the nurses, doctors, and patients from aerosolized pathogens the medical washer must be sealed.

- Height of the washer

The medical washer must take into account the height of the average Indian female.

LMIC specific requirements

Spare parts
- Consumables

The transport of parts to rural areas can be very hard due to the poor infrastructure, therefore the amount of consumables used in the medical washer must be minimized and the consumables used must be easily obtainable online.

- Repairability

The automatic washer must be easily repairable with locally available and affordable parts.

Affordability
As the target hospitals constantly experience a lack of funds the price is the most important factor to consider and must be as low as possible. The price of the medical washer must be less than 50000 rupees (580 Euro) (Appendix 4).

Maintenance
As no biomedical technician is present in the hospitals the medical washer must not depend on frequent maintenance.

Cleanability
The medical washer must be easily cleanable.

6.9 Overview of key requirements

N0	Requirements
	Functional requirements
F1	After the medical washer is done cleaning, the instruments must be clean when visually inspected.
F2	The medical washer must clean 16 lumens, 8 handles, 8 obturators, 8 inserts and small components
F3	The medical washer must flush the lumens of the laparoscopic instruments.
F4	The flow must be alternated between lumens to guarantee flow through every lumen.
F5	The instruments containing sharp edges must be fixated.
F6	the medical washer must be sealed.
F7	The medical washer must clean the instruments in 15 minutes.
F8	The medical washer must use less water than 180 L of water per cycle.
F9	Water must be filtered before it is used in the medical washer.
F10	The complex geometries of the laparoscopic instruments must be accurately cleaned.
	Usability requirements
U1	The medical washer must be loaded in less than 5 minutes.
U2	The loading system must be able to be correctly loaded by nurses who have no experience loading medical washers.
U3	The medical washer must be adaptable to local languages.
U4	The ground area of the medical washer must not take up more than 1 m x 1 m.
U5	The medical washer must be able to be filled with water automatically as well as manually.
U6	The medical washer must take into account the height of the average Indian female.
	Context requirements
C1	The design of the medical washer must minimize the use of consumables. The consumables used must be easily replaceable.
C2	The automatic washer must be easily repairable with locally available and affordable parts.
C3	The medical washer must not depend on frequent maintenance.
C4	The automatic washer must operate in many different climates.
C5	The price of the medical washer must be less than 50000 rupees (580 euro).
C6	The medical washer must be easily cleanable.

7 Developing the concept of the cleaning system

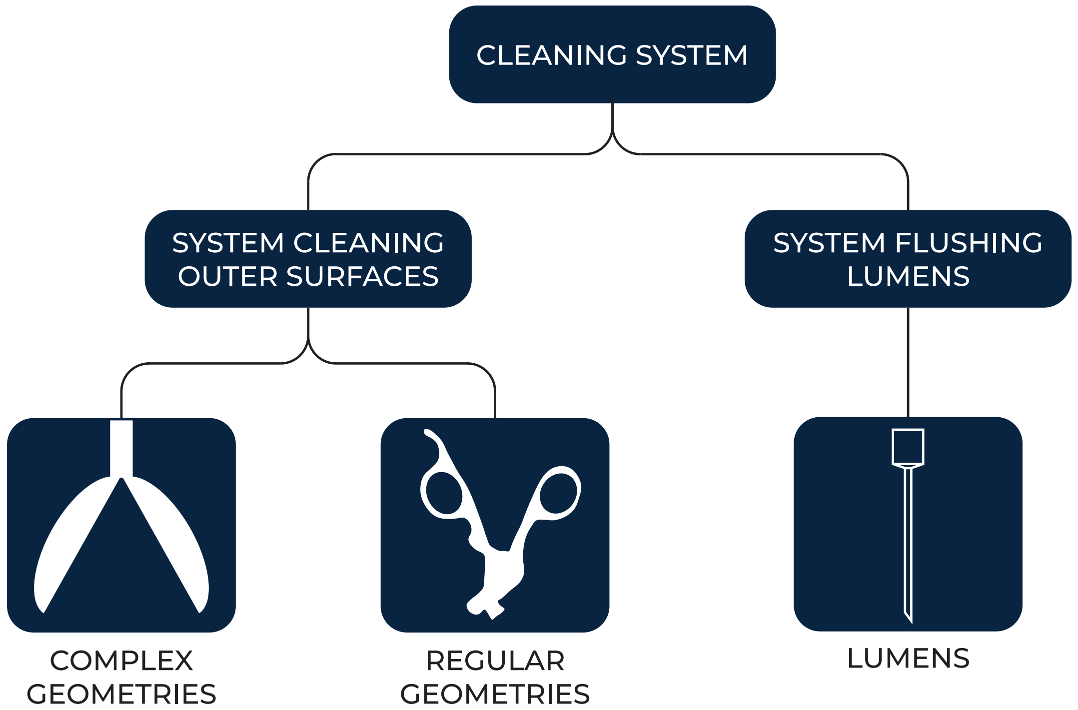


Figure 29: The cleaning system and its sub-systems.

The cleaning system is a crucial part of a medical washer. Proper shear force created by the water is necessary to remove the contamination of the instruments. As the medical washer must use as little resources as possible while cleaning the instruments it is important that the design of the cleaning system uses geometry specific cleaning strategies to clean the instruments as effectively as possible. In figure 29 the sub-systems of the cleaning system can be seen and which geometries the system must clean. In this chapter a concept of the cleaning system is developed in which specific cleaning strategies are selected for the different geometries.

7.1 The system cleaning the outer geometries

To create the mechanical action necessary to remove the soil from the outer surfaces of the laparoscopic instruments there are two basic strategies which are in turn divided into different sub-strategies. The first strategy is spray wash systems in which one or more high-pressure jets spray the cleaning liquid on the surfaces of the geometry to be cleaned. Spray wash systems rely on impingement to create the mechanical action for soil removal. The second strategy is immersion cleaning, in which the geometry is fully immersed in the cleaning solution (Kanegsberg & Kanegsberg, 2020).

Spray wash systems

Spray wash systems exist in all different sizes and shapes. In the reprocessing cycle in HICs spray washing is performed by the washer-disinfector. Surgical instruments are loaded on the wash rack which is then put inside the washer-disinfector. In the washer-disinfector the instruments are cleaned by the impingement of water jets coming from multiple sprays and nozzles As can be seen in figure 30. Spray wash systems are most effective in cleaning simple geometry.(Kanegsberg & Kanegsberg, 2020).

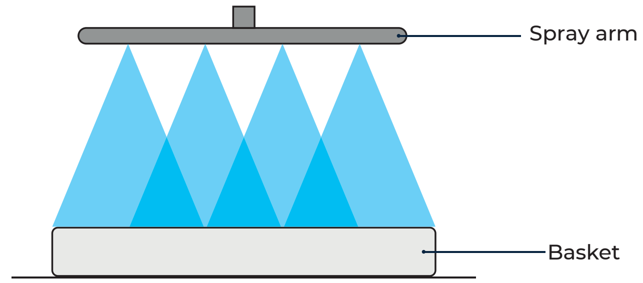


Figure 30: The spray wash system of a washer-disinfector.

Immersion cleaning

Immersion cleaning is the most suitable option for cleaning complex geometries which require precision cleaning. Immersion cleaning is done by loading the parts to be cleaned in a basket which is submerged into a heated bath which is filled with a cleaning solution. The most effective method of immersion cleaning is ultrasonic cleaning (Kanegsberg & Kanegsberg, 2020). Ultrasonic cleaning uses acoustic cavitation to remove soil from the surfaces of geometry. Acoustic cavitation creates bubbles that implode on a surface. These implosions cause high shear forces and results in the removal of soil. The working principle of acoustic cavitation is based on the pressure variation in the fluid caused by acoustic waves. The ultrasound waves cause the pressure to periodically lower in the liquid. When the pressure in the liquid decreases below the vapour pressure or cavitation threshold, bubbles are generated in the liquid (Vyas et al., 2019). When the generated bubbles near a solid surface implode, a liquid jet is formed that impacts the surface. This impact causes high shear forces which remove soil (Verhaagen & Rivas, 2016). The ultrasound waves are created by ultrasonic transducers. These transducers are connected to the bottom of the cleaning basin. The ultrasonic transducers receive their power from an ultrasonic generator. For effective cleaning 70-100 Watts per gallon of ultrasonic power is necessary. Different ultrasonic frequencies serve different cleaning purposes. For cleaning parts like laparoscopic instruments 40 kHz is a proper frequency. In figure 31 a schematic of an ultrasonic cleaning bath can be seen.

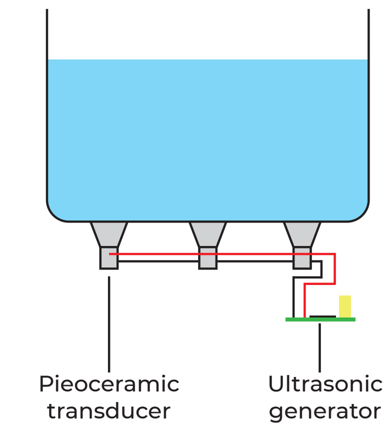


Figure 31: A schematic of an ultrasonic cleaning bath.

Choice of cleaning strategy for outer surfaces

To effectively clean the laparoscopic instruments, it is important that the correct cleaning strategy is selected for the different cleaning phases: Pre-rinse, detergent wash and post-rinse. The selection of the different cleaning strategies for the outer geometries can be seen in figure 32.

	COMPLEX GEOMETRIES	REGULAR GEOMETRIES
PRE-RINSE	To remove the gross soil spray washing is the most effective.	To remove the gross soil spray washing is the most effective.
DETERGENT WASH	To remove the smaller soil from hard to clean areas ultrasonic cleaning is most effective.	To remove the smaller soil from simple geometries spray washing is most effective.
POST-RINSE	To remove the remaining detergent spray washing is the most effective.	To remove the remaining detergent spray washing is the most effective.

Ultrasonic cleaning

Spray washing

Figure 32: The selection of the different cleaning strategies for the regular and complex geometries during the different cleaning phases.

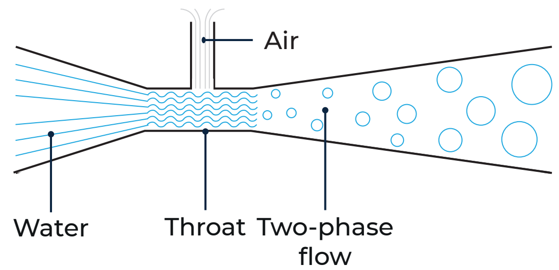
7.2 The system flushing the lumens

Prior to the thesis, a comprehensive literature review was conducted. From the various options available for flushing strategies, three distinct concepts were selected for further investigation.

Concept 1: Two-phase flow using a venturi
A two phase flow can increase the turbulence in a flow thus increasing the cleaning effect of the flow (Wibisono et al, 2014). In Cleaning-In-Place systems two-phase flow can increase wall shear stress 10 to 20 times compared to continuous fluid flow (D.J. Reineman, 1996). A two -phase flow can be created using a venturi (figure 33). A venturi is a device that combines a converging and a diverging pipe. A pressurized flow is flown through the device. At the throat of the device the pressure decreases. This causes air to move in through the suction port which creates the two-phase flow. The increased cleaning effect can improve current cleaning strategies for laparoscopic instruments.

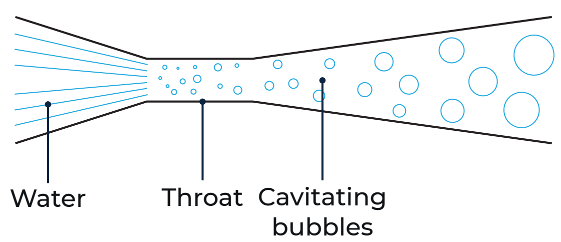
Concept 2: Cavitating venturi
A venturi can also be used to create cavitation (figure 34). In contrast to acoustic cavitation, the pressure variations in hydrodynamic cavitation are caused by a constriction channel. At the constriction the flow increases in kinetic energy and the pressure of the liquid decreases. In a cavitating venturi the pressure is reduced to the vapour pressure of the liquid and bubbles are generated. As the constriction expands the pressure of the liquid increases which eventually makes the bubbles implode. A large inlet pressure is necessary for cavitation to be developed (Carpenter et al., 2017).

Concept 3: Pulsing flow by an air compressor
By including an air compressor in the cleaning system, the flow can be pulsed at high velocities while creating a flow that is partly a two-phase flow (figure 35). Different studies have tested pulsing flows through pipes to improve cleaning efficiency. Accelerating the flow periodically causes a directional change in the velocity of the flow. This directional change generates an increase in the mass transfer of the cleaning fluid to the surface which creates a steeper velocity gradient near the surface, resulting in an increased wall shear stress and an increased cleaning effect (Goode et al., 2013)(Blel et al., 2009).



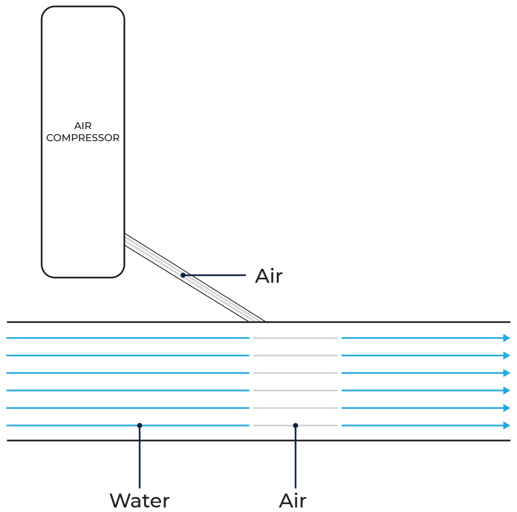
Components
- Venturi
- Air supply tube

Figure 33: Concept 1: the two-phase flow venturi.



Components
- Venturi

Figure 34: Concept 2: the cavitating venturi.



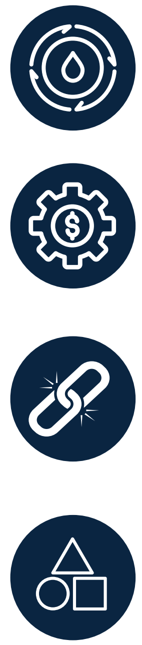
Components
- Air compressor

Figure 35: Concept 3 pulsing flow using an air compressor.

7.3 Concept choice

The determine which concept of the flushing strategiess is best suited for the medical washer a Harris profile was used. Four criteria were used to compare the different concepts:

- **Resources:** To minimize the cost of the use of the medical washer, the mechanism must use as little resources as possible.
- **Cost:** To ensure the rural hospitals can afford the medical washer, the cost must be minimized.
- **Durability:** To limit the amount of maintenance necessary and to extend the lifetime of the medical washer, the system must be as durable as possible.
- **Complexity of mechanism:** To increase repairability and to reduce the amount of maintenance of the medical washer, the mechanism must consist of as little parts as possible.



Based on these factors a Harris profile was used to determine the most suitable strategy (see figure 36).

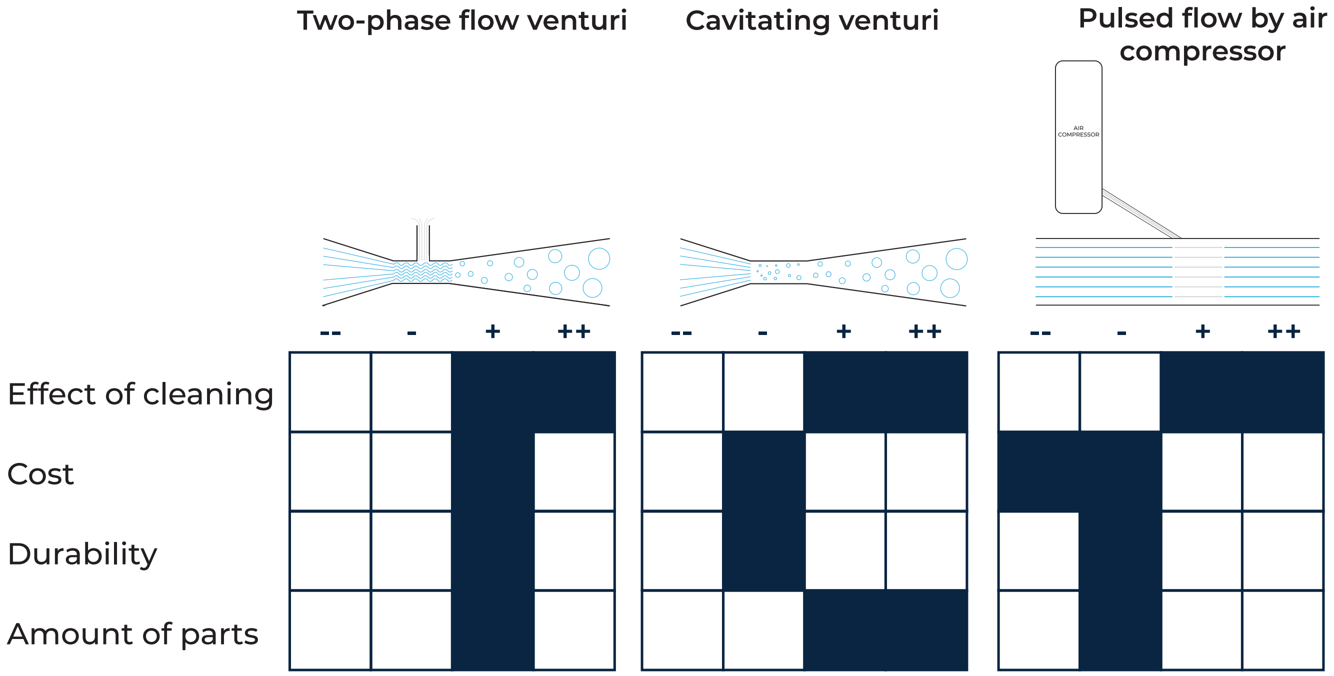


Figure 36: Harris profile for concept choice flushing mechanisms.

Resources
All three concepts significantly enhance effectiveness of cleaning compared to using continuous flow.

Cost
The two-phase flow venturi would not add large costs to the medical washer as the only added part is the venturi and a tube for the air supply. To create the hydrodynamic cavitation in the venturi a high upstream pressure is necessary (Ghassemi & Fasih, 2011). A circulation pump able to create such pressure will increase the cost of the medical washer. Pulsed flow requires the addition of an air compressor which will also add cost.

Durability
Increasing the pressure in the system will increase its wear. The cavitating venturi increases the pressure on the system (Ghassemi & Fasih, 2011). The bursts of compressed air used to create the pulsed flow intermittently increase the pressure. Comparatively, the two-phase flow venturi increases the pressure in the piping by a smaller amount than the other two concepts.

Amount of parts
The two-phase flow venturi requires the addition of a venturi and tube to supply air from outside the medical washer, the cavitating venturi requires a venturi and the pulsed flow requires the addition of an air compressor. Which consists of a large amount of parts.

Chosen concept
The most suitable concept for the medical washer is the two-phase flow venturi. The concept effectively cleans the lumens without increasing the cost, decreasing durability and adding a large amount parts.

7.4 Conclusion

For the design of an effective cleaning system the most suitable cleaning strategies for the different cleaning phases and geometries were selected. For outer surfaces the pre-rinse and post-rinse will consist of a spray wash while the detergent wash is done using ultrasonic cleaning and spray washing. The lumens will be flushed by two-phase flow.

8 Developing the concept of the loading system

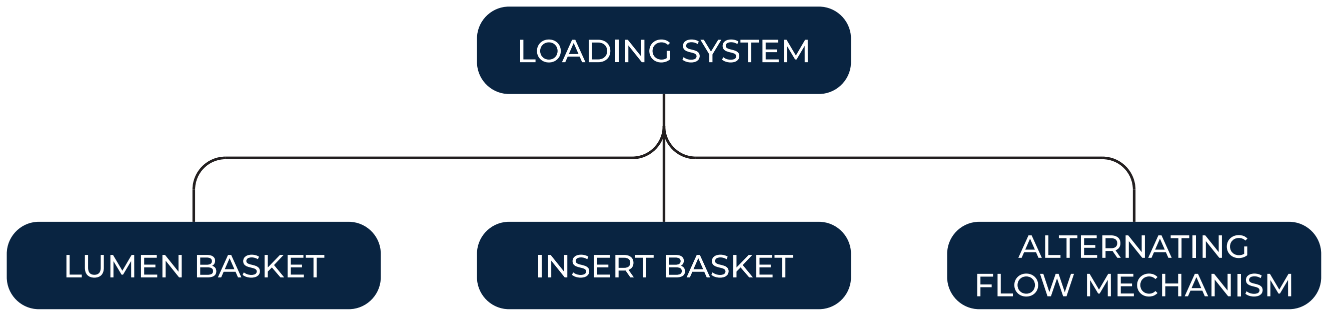
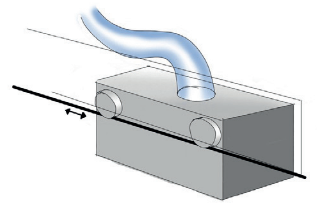


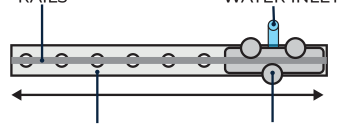
Figure 37: The loading system and its sub-systems.

The design of the loading system is a crucial factor in the effectiveness of the medical washer. For the system to be successful, it must be user-friendly, especially for rural nurses who have limited experience with medical equipment, particularly those designed for reprocessing. To address the time constraints faced by nurses, the loading system must also be able to be loaded within a five-minute time frame, while also ensuring that nurses are protected from injury from laparoscopic instruments. In order to ensure that all instruments are thoroughly cleaned, the loading system should expose all surfaces to water jets and contain a mechanism for alternating the flow to guarantee proper flushing of lumens while minimizing pump size. Lastly, the baskets must be loaded from the top as ultrasonic cleaning is integrated in the system. In figure 37 the sub-systems of the loading system can be seen. The development of the concepts for the loading system was initiated through the use of a variety of design methods. The process began with a function analysis of the loading system (Appendix 1). This analysis served as the foundation for generating ideas using the 'how-to' method. The ideas that were generated were then combined through the use of a morphological chart. Multiple prototypes were constructed and subjected to expert reviews in order to identify the positive aspects of each concept. The final concepts were chosen through the use of a Harris profile.

8.1 Table-top loader

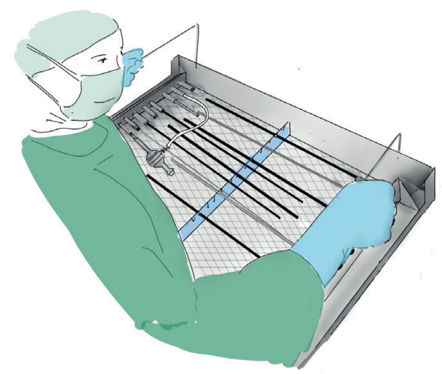
WATER JET



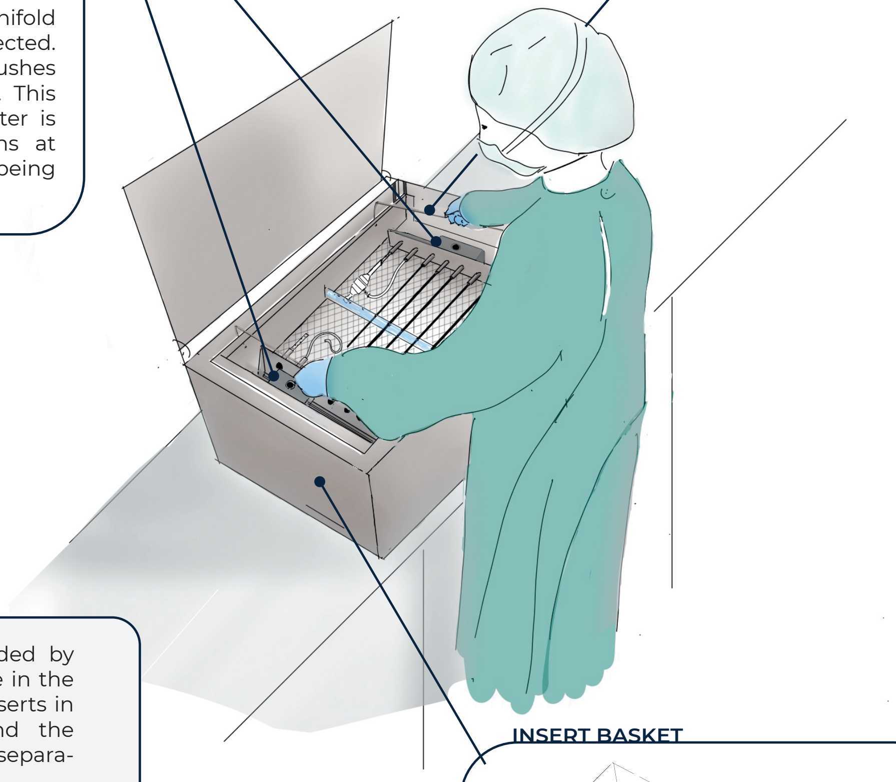


To ensure that every lumen is flushed, the lumens are alternately flushed through. This is done by a water jet that moves back and forth along the rail through the manifold where the lumens are connected. This water jet alternately flushes three holes of the manifold. This way, a larger amount of water is sprayed through the lumens at once, resulting in the lumens being cleaned more thoroughly.

LUMEN BASKET



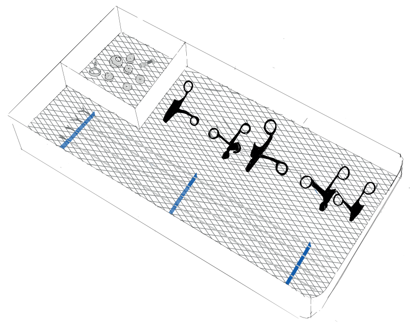
The baskets are loaded horizontally using two handles. The lumens are connected horizontally and are fixated on a silicone holder.



LOADING

1. The insert basket is loaded by placing the handles loose in the basket, obturators and inserts in the silicone holders and the small components in the separate compartment.
2. The lumen basket is loaded by fixating the lumens in the silicone holder. The smaller lumens are pushed in the holes in the manifold and the larger lumens are placed on spray jets. Eight lumens are loaded on each side of the manifold.
3. The baskets are loaded into the medical washer. First the insert basket and then the lumen basket.
4. The lumen flushing system is connected to the sides of the manifolds.

INSERT BASKET

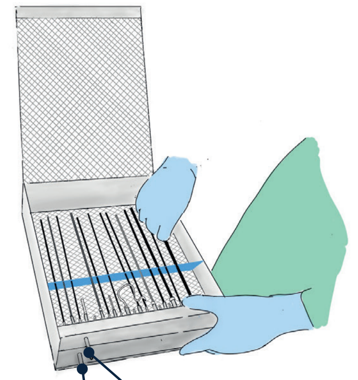


The second basket contains the inserts, handles, obturators, and smaller parts. The inserts and obturators are fixated and the small parts and handles are placed in the basket.

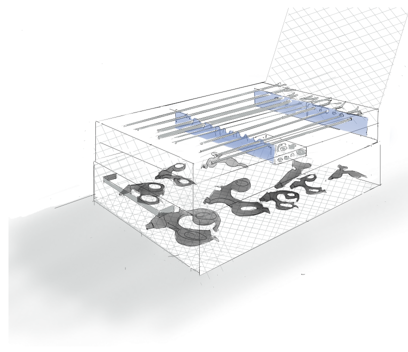
8.2 Cabinet loader

LUMEN BASKET

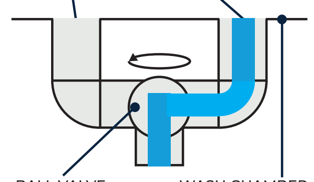
The lumen basket has two manifolds with 8 holes each, stacked on top of each other, and both manifolds have their own water inlet. The basket has a lid to contain the instruments while loading the basket vertically.



INSERT BASKET



The basket containing the inserts, obturators, small components and handles is loaded vertically. Therefore, the container for the inserts and obturators is stacked on top of the handles and small components in order to fixate them.



Alternated flushing is achieved through the use of a branch in the water line that includes a ball valve, which alternately provides water to the two connections of the two manifolds. As a result, each of the two manifolds receives the full water flow from the pump in turn.

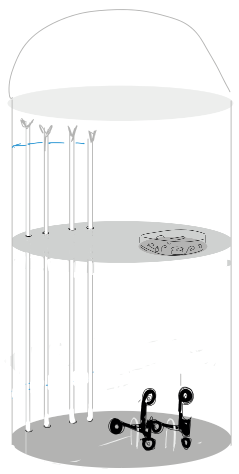
BALL VALVE

LOADING

1. The insert basket is loaded by opening the lid of the basket and placing the handles loose in the basket. Small components are put in the separate compartment. The obturators and inserts are put in the silicone holders in the second level and the second level is put on top of the handles.
2. The lumen basket is loaded by opening the lid and fixating the lumens in the silicone holder. The smaller lumens in the holes in the manifold and the larger lumens are placed on spray jets.
3. The baskets are loaded into the medical washer and the water inlets connect to the water supply from the ball valve.

8.3 Bucket loader

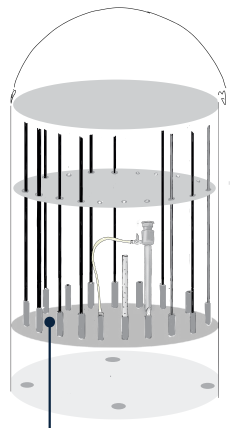
INSERT BASKET



The basket containing the inserts, obturators, small components and handles is cylindrical. The basket consists of circular holders which hold the obturators and inserts a two platforms on which the box containing the small components, and the handles can be placed.

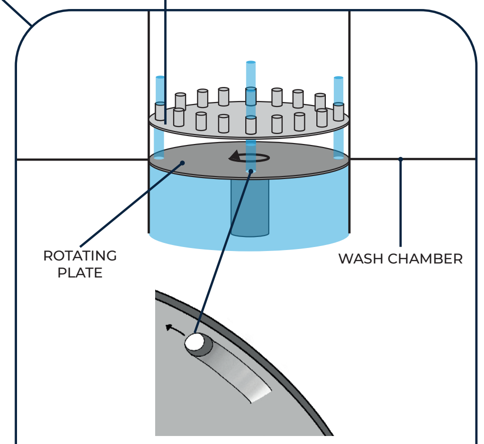
LUMEN BASKET

The lumen basket is round and can be opened from the side, from where the different lumens can be loaded.



LOADING

1. The insert basket is loaded by opening the door of the basket. The insert and obturators are placed in the silicone holder. The handles are placed on the platforms and the small components are placed in a small box on platforms.
2. The lumen basket is loaded by opening the door of the basket. The lumens are fixated in a silicone holder. The smaller lumens are placed in the holes in the manifold and the larger lumens are placed on spray jets.
3. The baskets are loaded into the medical washer. First, the lumen basket, placing it on top of the rotating plate. Second, the insert basket.



In concept 3, the alternating flushing is created by a rotating plate with four holes in it. Water is supplied from underneath the plate. The flow creates a rotating motion in the plate due to the grooves next to the four holes. Due to the rotating motion, the lumens are alternately flushed with a greater amount of water.

ROTATING PLATE

8.4 Concept choice

After the concepts were developed three prototypes were made and experts were interviewed to determine the strong and weak aspects of the different concepts (Appendix 6). To determine which concept would fit the context the best, a Harris profile was used (figure 38). In the Harris profile the different concepts are weighed according to a set of the most important criteria. The loading mechanism and the mechanism alternating the flow were weighed in two separate Harris profiles to determine which sub-systems fit the context best.

Loading baskets in the medical washer

- **Cleanability:** The instruments must be cleaned using as little water as possible. Therefore, all the surfaces of the instruments must be exposed to the cleaning fluid and the lumens must be flushed using as little water as possible.
- **Ease of use:** The medical washer must be easy to load. Understanding how the system is loaded should be clear to nurses with little experience with automatic reprocessing equipment.
- **Time:** The medical washer must be loaded in a time frame which is as small as possible as nurses have little time for reprocessing.
- **Surface area:** The surface area on the ground must be as small as possible to fit the small reprocessing areas (The approximate dimensions can be found in Appendix 5).

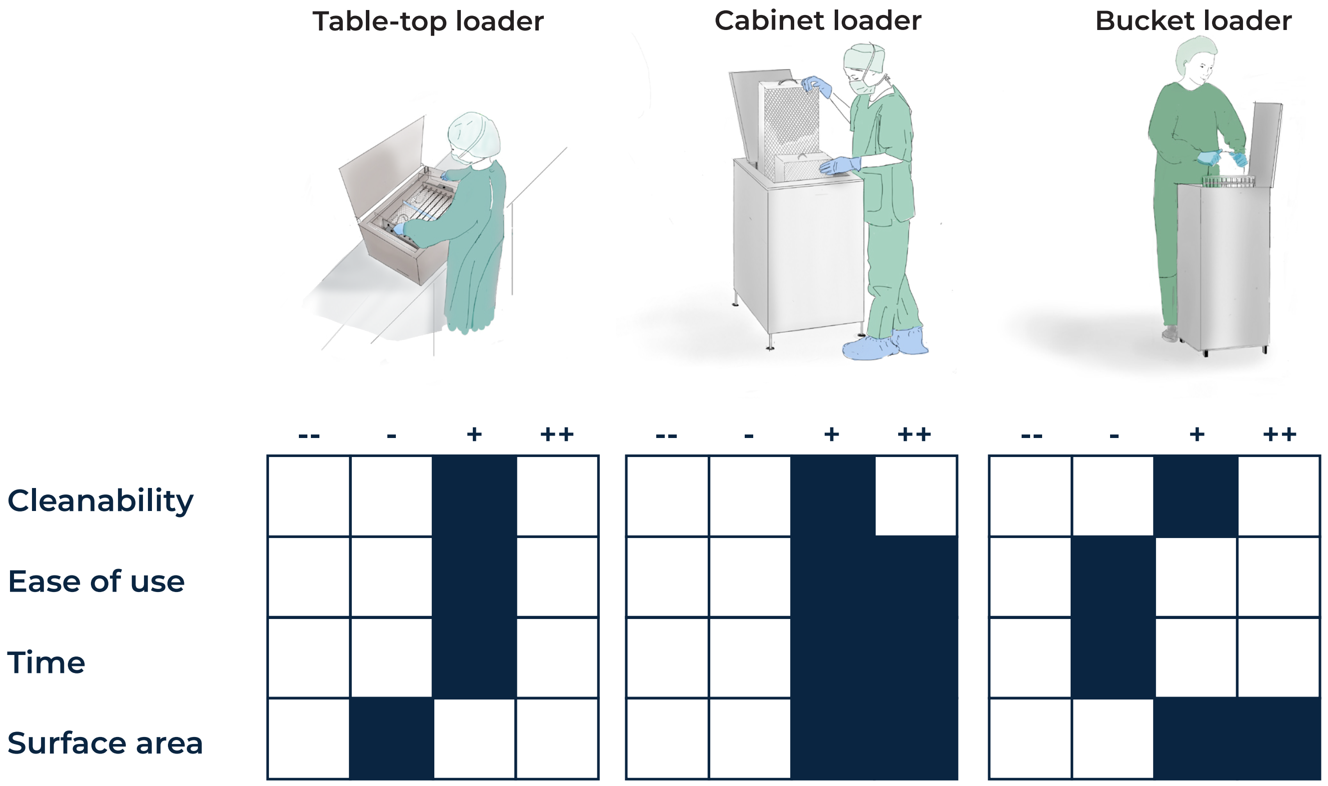


Figure 38: Harris profile of the different loading mechanisms.

Analysis of Harris profile

Cleanability
In the table-top loader, the instruments are fully exposed to the water as the top of the baskets is fully exposed. The cabinet loader contains a lid on both the baskets possibly inhibiting the exposure of the water to the surfaces of the instruments. The bucket loader contains baskets which consist of platforms which could inhibit contact between the water and the instruments. However, the horizontal positioning, does not allow for natural draining of the soil in the lumens. To fully clean the lumens additional water is necessary compared to the cabinet loader and bucket loader in which the lumens are placed vertically.

Ease of use
Compared to the cabinet loader and the bucket loader, the loading process requires an additional step, connecting the mechanism alternating the flow. The circular shape of the baskets of the bucket loader complicates the loading process compared to the table-top loader and the cabinet loader as placing the instruments at the far end from the door of the basket requires more effort.

Time
As mentioned before, due to the additional required step in table-top loader and due to the loading mechanism being more cumbersome in the bucket loader. The loading mechanism in the cabinet loader would require the least amount of time.

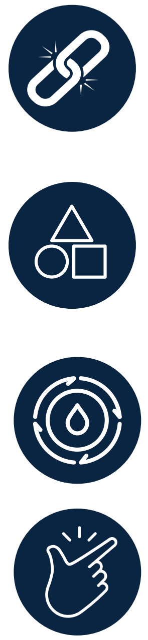
Surface area
Using the prototypes of the baskets (Appendix 6) an approximation was made of the dimensions of the different medical washers. The ground area of the table-top loader is 400 x 600 mm, the ground area of the cabinet loader 300 x 400 mm and the ground area of the bucket loader is 350 x 350 mm.

Chosen concept
The cabinet loader is chosen for further development as it fits the criteria the best. However, the expert review showed that immobilizing the handles using different levels could inhibit cleanability as not all surfaces are exposed to the water. This aspect of the concept must be adapted.

A separate Harris profile was used to select the best alternating flow mechanism. This was done to determine whether the most promising loading mechanism for the baskets would match the most advantageous alternating flow mechanism or if the concept must be adjusted to integrate the two sub-systems (figure 39). Again the different concepts are weighed against the most important criteria determining the success of the system.

Alternated flushing of the lumens

- **Durability:** To limit the amount of maintenance necessary and to extend the lifetime of the medical washer. The system must be as durable as possible.
- **Complexity of mechanism:** To increase repairability and to reduce the amount of maintenance of the medical washer the mechanism must consist of as little parts as possible.
- **Resources:** To minimize the cost of the use of the medical washer the mechanism must use as little resources as possible.
- **Ease of use:** The medical washer must be easy to load and understanding how the system should be loaded should be clear to nurses with little experience with automatic reprocessing equipment.



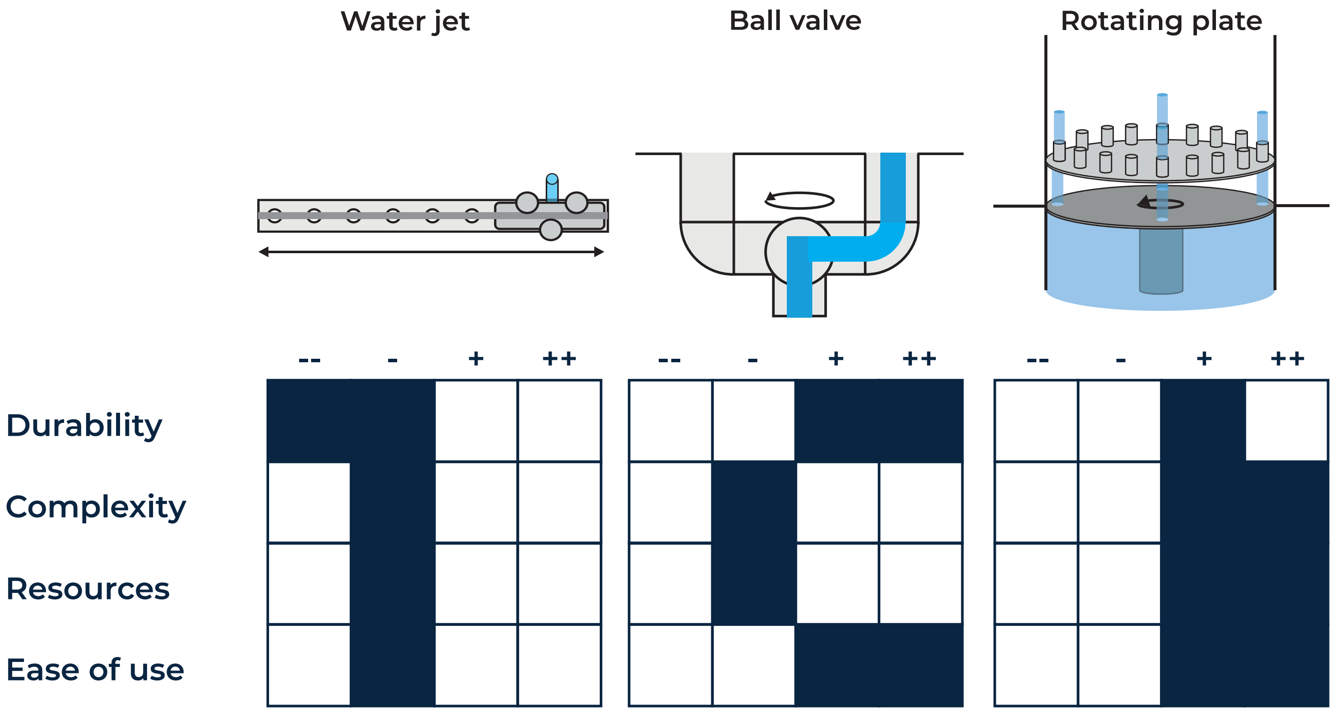


Figure 39: Harris profile of the different mechanisms alternating flow.

Analysis of Harris profile

Durability
Moving parts especially in the wash chamber itself can increase the wear of the system (Appendix 6). Therefore, the system should consist of as little moving parts as possible. The water jet consists of a moving jet driven by wheels that are connected to a rail. The system consists of multiple moving elements within the wash chamber. The ball valve consists of only one moving element (the ball of the ball valve), which is not located inside the wash chamber. The rotating plate also only consists of one moving element (the rotating plate), however this component is located in the wash chamber.

Complexity of system
The water jet consists of multiple parts and for the movement of the spray jet a motor is needed to drive the wheel. The ball valve requires a motor to rotate the valve. The rotating plate only consists of one part which spins on an axle. The mechanism is driven by the flow of the water.

Resources
The system should require minimal resources. Both the water jet and the ball valve require power while the rotating plate is driven by the flow of the water.

Ease of use
The ball valve and the rotating plate are connected to the basket by loading it, while the spray jet needs to be installed before the instruments are cleaned.

Chosen concept
The rotating plate is chosen for further development as it fits the criteria the best.

8.5 Conclusion

In this chapter different concepts were developed for the loading system of the medical washer. A Harris profile was used to determine the best performing loading mechanism for the baskets and the best alternating flow mechanism. The cabinet loader came out as most advantageous, while the rotating plate came out as the most favourable. These systems should therefore be integrated.

9 Integration of sub-systems

In this chapter the chosen concepts are integrated in one system. The integrated design required integrating the cleaning system, which consists of the ultrasonic cleaning system, the spray wash system and the two-phase flow venturi, and the loading system which consists of the loading mechanism and the rotating plate.

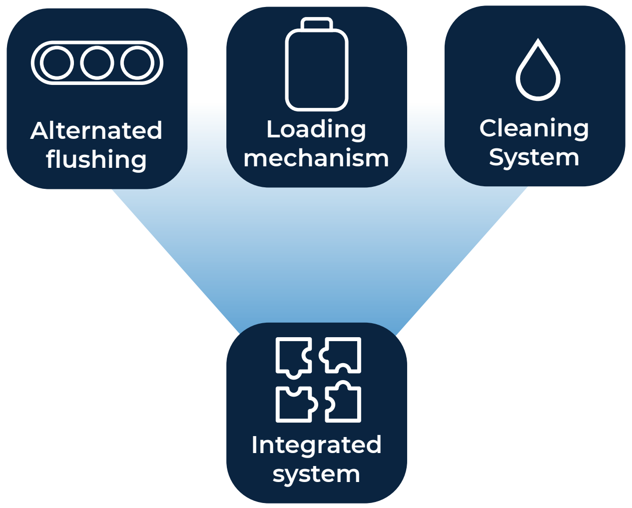
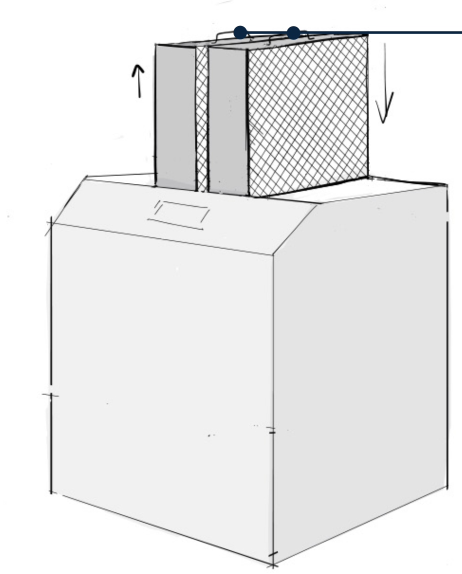


Figure 40: The different systems that must be integrated.

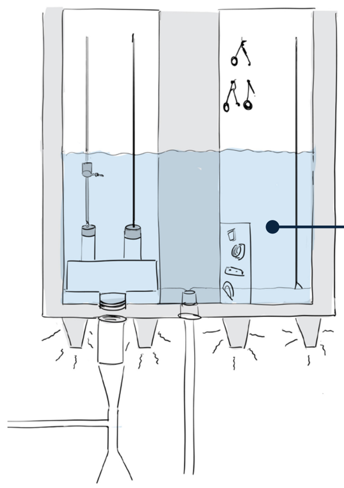
9.1 Integration

To integration of the sub-systems required the focus on the areas where the different systems interact (figure 40). Firstly, to minimize the water needed for ultrasonic cleaning, the complex geometries must be located at the bottom of the baskets. Secondly, the spray jets must be able to rinse all the areas of the instruments in the basket. Thirdly, the manifold containing the lumens must be connected to the rotating plate and the rotating plate must be connected to the venturi to supply the lumens with two-phase flow. Below and on the next page the integration of the systems can be seen. The different design choices are highlighted in the text boxes.

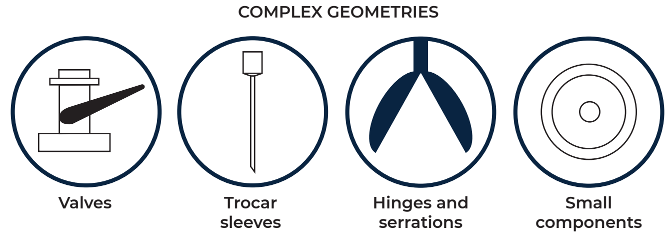


LOADING

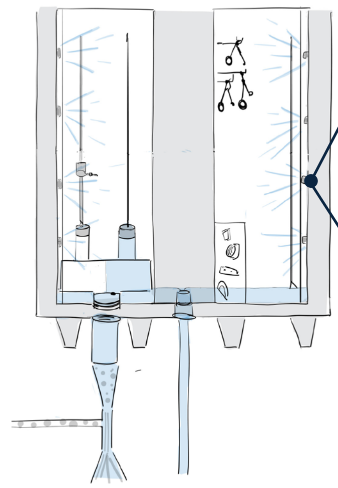
The baskets can be loaded and unloaded using the handle on the top. The handles are turned 90 degrees towards the user so the baskets can be loaded and unloaded simultaneously.



ULTRASONIC CLEANING



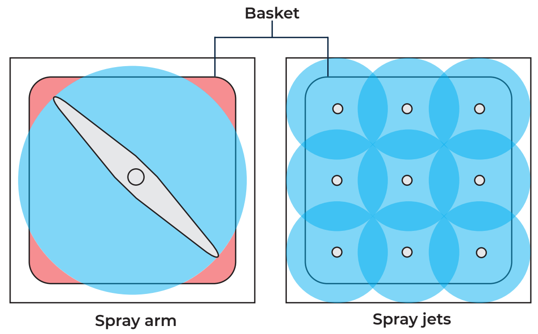
To minimize the use of water only the complex geometries should be cleaned. Therefore, the complex geometries should be located at the bottom of the baskets.



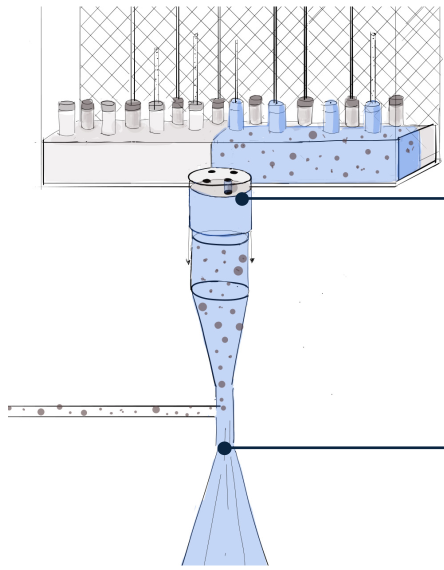
RINSING

The baskets are rinsed from the sides by spray jets located in the wall of the wash chamber. While the outer surfaces are rinsed, the lumens are flushed.

SPRAY JETS



The spray jet in spray wash systems can consist of static spray jets or spray-arms. Static spray jets are installed in the walls of the wash chamber while the spray-arm is connected to a water inlet in the top of the wash chamber. Static spray jets can provide a more evenly distributed cleaning area compared to spray arms. As the spray jets do not move there is decreased wear compared to a spray-arm which will prolong the need for maintenance.



ROTATING PLATE

The flow is alternated by a rotating plate. The manifold consists of four compartments which are alternately flushed. Each compartment has a hole on the bottom which lines up with hole in the rotating plate, flushing the 4 lumens connected to the compartment.

TWO-PHASE FLOW

The venturi creating the two-phase flow is connected to the mechanism alternating flow. The venturi is connected to a tube which supplies the venturi with air.

9.2 Prototype

To evaluate the usability of the concept of the loading system and to evaluate the concept of the medical washer itself a concept evaluation was performed. For the purpose of this evaluation a prototype was built using the chosen concept of the loading mechanism and the insights gained by the expert reviews. In figure 41 the prototype can be seen.

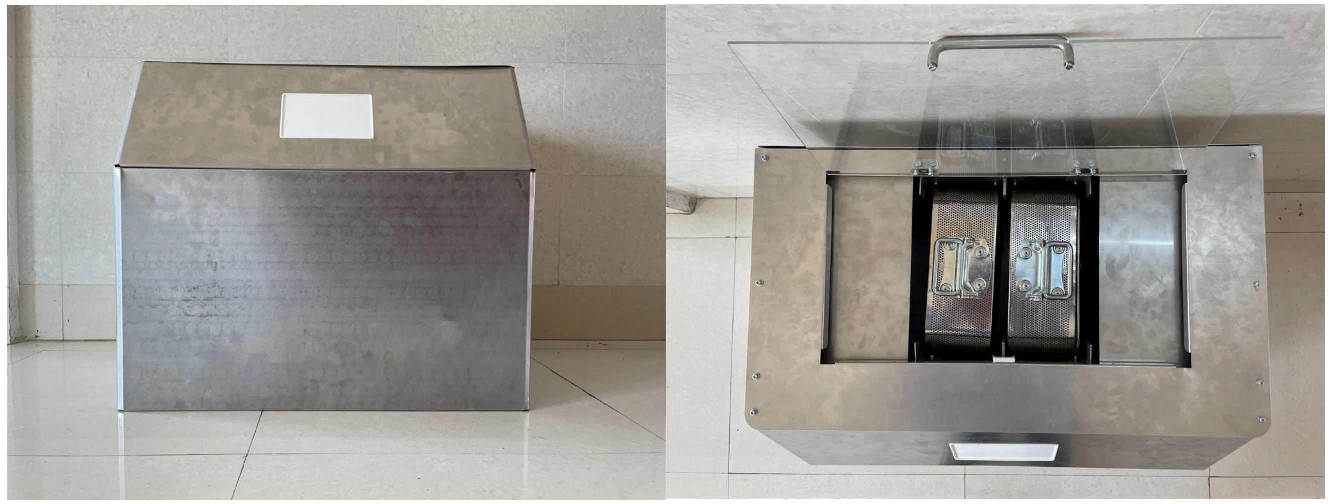


Figure 41: Front view and top view of the prototype of the medical washer.

Loading the prototype
The loading process for the prototype of the medical washer is performed in a vertical manner by using the handles located on the top of the baskets (as illustrated in Figure 41.

Basket 1
Basket 1 stores the following components: obturators, handles, inserts, and small rubber parts. The basket itself is composed of two distinct parts: the basket and the lid. Basket 1 can be seen in figure 42. The basket component is designed to hold obturators securely in place using a silicone holder. Handles can be easily fixed onto the basket using hooks provided for this purpose. Small rubber parts can be conveniently stored in a small box located within the basket. The lid component is attached to the basket using a turning mechanism. This lid component features a silicone holder on which various inserts can be fixated. In this way, the lid serves as an additional means of organizing and storing the different components of the surgical instruments.

Basket 2
Basket 2 stores the lumens of the insulated sheaths and the trocars and the valves of the trocars (figure 43). All the lumens are flushed by water which move through the manifold. The water arrives at the manifold from the pipe at the bottom of the basket which attaches to the water supply from the medical washer when the basket is loaded. For the prototype the alternating flushing mechanism was not incorporated as the focus of the prototype was on the usability of the loading system.

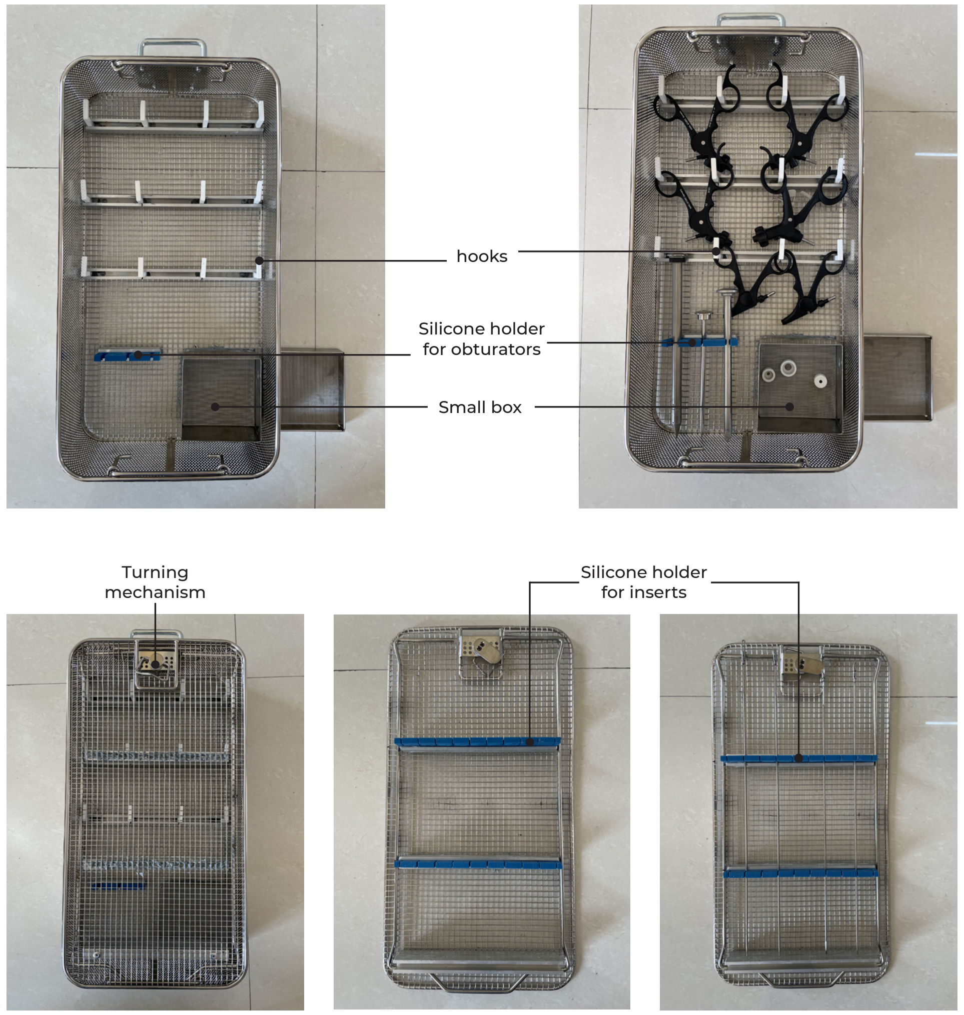


Figure 42: Basket 1

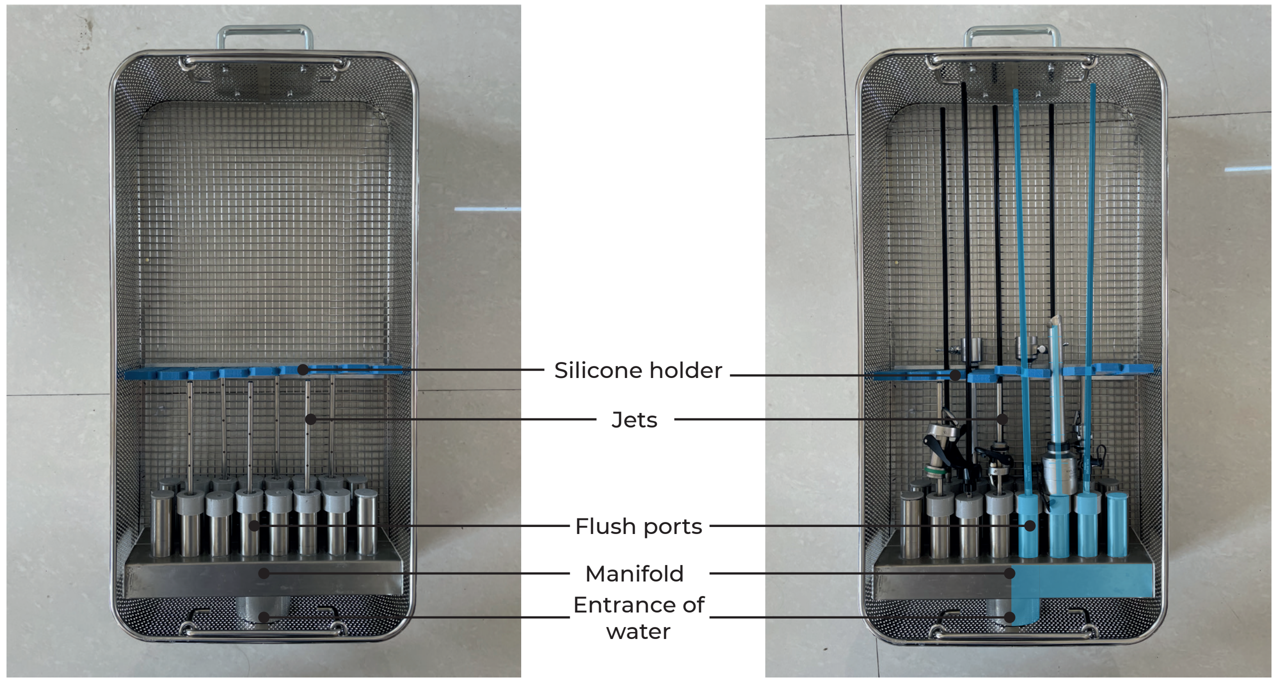


Figure 43: Basket 2, on the left side when the basket is empty, on the right side when the lumens are flushed.

10 Concept evaluation in India

10.1 Purpose

As mentioned in chapter 4.2 nurses in rural Indian hospitals often lack training and experience in the field of medical devices, especially devices focussing on reprocessing. However, improper loading of the medical washer can have grave consequences like surgical site infections. Therefore, it is of importance that the medical washer is able to be loaded by a nurse without the need of training.

Hence purpose of this research, to examine the loading system of the medical washer for laparoscopic instruments in the context of hospitals in rural India and to understand how it is used by nurses and health workers without any prior explanation and how the concept of the medical washer is perceived by the end-user. Specifically, the research will address the following sub-questions:

- Which instances of correct use, perception error, cognition error, and action error occur during the use of the loading system?
- Which root causes give rise to these use errors?
- What is the perception of the nurses and health workers on the improvement of the medical washer on their current working routine?

Understanding the factors that contribute to errors in the use of the loading system and the perceptions of nurses and health workers on the medical washer will provide valuable insights into how the safety and effectiveness of laparoscopic surgery in rural India can be improved.

10.2 Method

Task analysis & risk analysis
The prototype development process included both a task analysis and a risk analysis to identify potential risks during the performance of tasks and to determine measures for mitigating these risks. The task analysis is presented in table 1 and demonstrates that tasks are divided into one or more subtasks. The risk analysis, presented in Appendix 7, identifies potential risks associated with the use of the product, assesses the severity of these risks, and outlines strategies for mitigating them. This includes an assessment of the potential harm that may be caused by these risks.

Protocol design
The study was divided into two parts. The first part consisted of two tests in which the participant was asked to load a set of laparoscopic instruments in the medical washer, the test set-up including the set of laparoscopic instruments can be seen in figure 44.

Figure 44: Test set-up of the study.

Prior to the tests, a short introduction was given and the participant was provided with a poster explaining the concept and functions of the medical washer (Appendix 9). In the first test, the participant was asked to perform three tasks: unload the baskets from the washer, load the instruments in the baskets, and load the baskets back in the medical washer. Following the first test, a short interview was conducted to assess the performance of the sub-tasks and determine the root causes of the participant's actions. Before the second test, the participant was informed of which instruments belong in which basket. The participant was then asked to repeat the tasks from the first test. An additional interview was conducted to determine the root causes of the participant's

Loading the medical washer			
U. Unloading baskets from washer	A. Loading instruments in basket 1.	B. Loading instruments in basket 2.	L. Loading baskets in washer
U1. Unload baskets from washer	A1. Remove lid from basket	B1. Load black sheaths in the ports of manifold.	L1. Load baskets in washer
	A2. Load the obturators in the silicone holders	B2. Load lumens of trocars on the spray jets on the manifold.	
	A3. Load handles on the hooks	B3. Load valves of trocars on the spray jets on the manifold.	
	A4. Load the inserts in the silicone holders		
	A5. Load small parts in the small box		
	A6. Attach lid on basket		

Table 1: Task analysis of the use of the loading system of the medical washer.

actions in the second test. Finally, an interview was conducted with the participant to evaluate their overall perception of the medical washer. In figure 45 the procedure can be seen.

Data collection & analysis
A root cause analysis was done by observing the occurrence of different instances of use. These instances of use were evaluated in order to determine the type of use error according to IEC 62366-1:2015 (International Electrotechnical Commission, 2015). Participant comments and observations were used to determine which type of use error occurred. The use errors were divided into three categories: Firstly, *Perception errors*, which occur when individuals encounter difficulties in perceiving information provided by a device, such as difficulty reading text on a display or failing to hear audio information. These errors may be caused by impairments in visual, auditory, or tactile perception. Secondly, *Cognition errors* refer to a range of mistakes made in the process of thinking, including forgetting important information, misinterpretation of data, miscalculations, over-generalization, incorrect inference, and poor decision making. These errors may arise due to various factors, including lack of attention, inadequate understanding of the material, or cognitive biases. Thirdly, *action errors* involve problems with physically interacting with a device, including difficulties or failures in activities such as lifting, pinching, twisting, turning, or pushing it (Reeves et al., 2019). Participant comments were also taken into account and linked to the instances of use in order to identify the root causes of the errors. In addition to this, the results of the

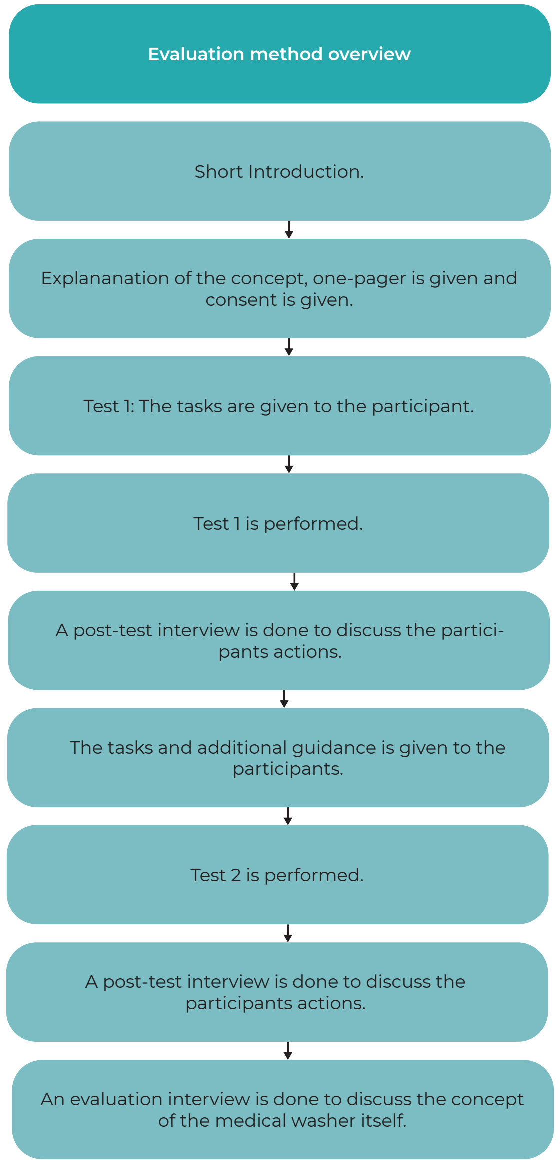


Figure 45: The procedure of the study.

evaluation interviews were analysed through the use of coding in ATLAS.TI (8.4.24.0, ATLAS.ti Scientific Software Development GmbH, Berlin, Germany). This allowed for the determination of the frequency with which the code was mentioned and the number of participants who mentioned it.

10.3 Results

The results of this study are presented in two sections. The first section presents the root cause analysis, while the second section presents the results of the evaluation interviews.

Participants

In this study, four hospitals were selected as the research sites. The participant groups included in the study are outlined in table 2. It should be noted that all participants in this study had no previous experience with automatic cleaners.

	Participant group	Number of participants	Experience
Participant groups performing 1 test.	Nurses (N1-9)	9	Between 3 and 27 years
	Nursing students (S1-3)	3	Second year students
Participant groups performing 2 tests.	Nurses (N2-9)	8	Between 3 and 27 years
Participant groups performing evaluation interview.	Nurses (N1-9)	9	Between 3 and 27 years
	OT helpers (OT1)	1	12 years

Table 2: Participant groups included in the study.

Root cause analysis

In the following section the results of the root cause analysis can be seen. In Appendix 10 a table is added for every sub-task to show the occurrence of the different instances of correct use and use error, the comments by the participants and finally, the root causes that give rise to these instances of use.

U1. Unload baskets from washer

In 18 out of 20 tests, the participants successfully removed the baskets from the medical washer. However, in two tests, the participants only removed one basket. This outcome may be due to the device not providing sufficient information to the participants about the requirement to remove both baskets, or it may be due to a lack of understanding about the task instructions.

A1. Removing the lid from the basket

Of the 20 tests, in 18 the participant was able to remove the lid from the basket. However, in two tests the participant unable to do so. The tests showed that the turning mechanism was not clear to these participants. As a result, they requested further instructions. This suggests that the clarity of the turning mechanism may have played a role in the participants' ability to successfully remove the lid from the basket

A2. Load the obturators in the silicone holders

In six out of 20 tests, the participants placed the obturators at the correct location in the basket. Two types of use errors occurred during this subtask. In eight tests, the participants placed the obturators loose in basket 1. In an additional six tests, the participants placed the obturators in the flush ports. These use errors may have been caused by the silicone holders providing insufficient information about the correct placement of the obturators. As a result, the participants placed the obturators loose in the basket or fixed them in the ports, which have comparable diameters.

A3. Load handles on the hooks

During the loading of the handles, two types of correct use were observed. In five tests, the handles were placed over the hooks using two ears, as described in the task analysis. In four tests, the handles were placed over the hooks using one ear. This latter method was not anticipated beforehand. The most common instance of use involved placing the handles loose in basket 1 (10 tests). One nurse clamped the handles between the hooks. These use errors may be attributed to the hooks not providing sufficient information about the correct placement of the handles.

A4. Load the inserts in the silicone holders

In five tests, the participants placed the inserts in the silicone holders due to the comparable diameter of the inserts and the holders, as well as the proper fixation at this location. In eight tests, the participants placed the inserts in the silicone holder for the obturators, and in six tests, the participants placed the inserts in the silicone holder for the lumens. These latter two locations were chosen by the participants because the silicone holders provide fixation. In one test, a participant placed the inserts loose in basket 1. These use errors may have occurred because the participant did not notice the silicone holder on the lid of basket 1, which was inconspicuous and therefore easily overlooked.

A5. Load small parts in the small box

In 16 out of 20 tests, the participants placed the small rubber parts in the small box in basket 1, with the intention of containing the rubber parts in a closed-off area (figure 46). As noted by Nurse 8, 'I put them there so the small parts stay in one place.' However, in two tests, the rubber parts were placed loose in basket 2, and in one test, they were placed loose in basket 1. This suggests that the small box may not have provided enough information to guide the participants in correctly placing the rubber parts. One participant also assembled the instruments, which may be due to a lack of information provided by the device or insufficient instructions before performing the tasks.

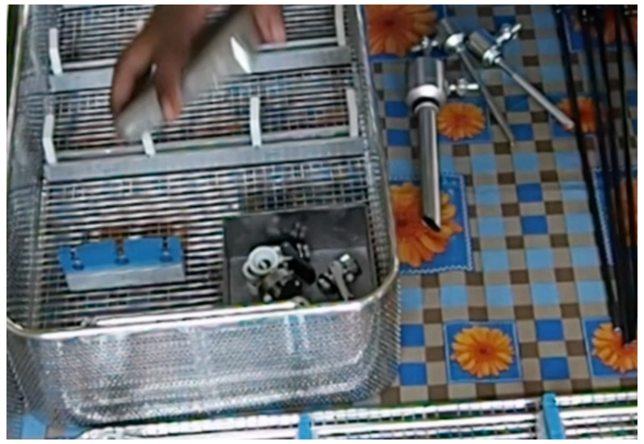


Figure 46: Nursing student 3 putting the small rubber parts in the small box in test 1.

B1. Load black sheaths in the ports of manifold

In seven tests, the participants placed the black sheaths in the flush ports. According to the participants, immobilization of the sheaths was a primary factor in this decision. For example, Nurse 3 stated, 'I put all the insulation in the holes so you can take it without it falling.' In nine additional tests, the participants placed the black sheaths in the silicone holders, but not in the flush ports. Nurse 5 explained, 'I put the black sheaths there because the rubber stand is designed for black sheaths. The flush port has a very small hole to install it.' This suggests that the diameter of the flush ports may have been too small, preventing the participants from placing the black sheaths in them. In four tests, the participants placed the black sheaths in the silicone holder for the obturators (figure 47). Nurse 2 noted, 'Actually, the trocar is just there, with a sharp edge. Yeah, well, mixing with the instruments, the sheath, the black one. It can get damaged.' During the process of loading the trocars and black sheaths, it is observed that the edge of the trocar and the black sheaths make contact.

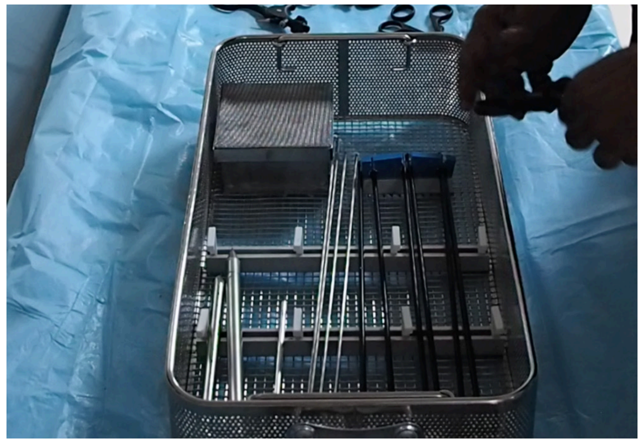


Figure 47: Nurse 3 putting the black sheaths in the silicone holder for the obturators in basket 1 in test 1.

B2. Load lumens of trocars on the jets on the manifold

In seven tests, the participants placed the trocars over the jets on the manifold (figure 48). Nurse 2 cited the amount of space at this location as the reason for this decision, while Nurse 8 and 9 noted the fixation provided by the spray jets and the silicone holder for the trocars. However, a variety of use errors occurred during the tests, all resulting from the device failing to guide the participants in placing the trocars at the correct location. These errors included placing the trocars loose in basket 1 or 2, or attempting to fixate the trocars by placing them in the flush ports, under the hooks, or below the spray jets. One participant also assembled the instruments. This may be due to insufficient information provided by the device or unclear instructions.

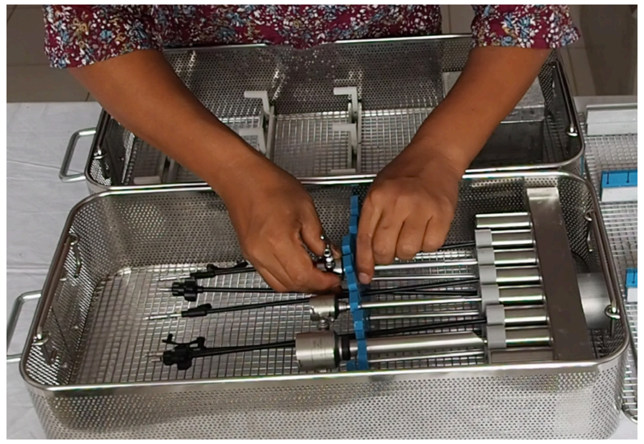


Figure 48: Nurse 9 putting trocars on the spray jets in test 2.

B2. Load lumens of trocars on the jets on the manifold
In seven tests, the participants placed the trocars over the jets on the manifold. Nurse 2 cited the amount of space at this location as the reason for this decision, while Nurse 8 and 9 noted the fixation provided by the spray jets and silicone holder for the trocars. However, a variety of use errors occurred during the tests, all resulting from the device failing to guide the participants in placing the trocars at the correct location. These errors included placing the trocars loose in basket 1 or 2, or attempting to fixate the trocars by placing them in the flush ports, under the hooks, or below the spray jets. One participant also assembled the instruments. This may be due to insufficient information provided by the device or unclear instructions.

B3. Load valves of trocars on the jets on the manifold
During the subtask of loading the valves on the trocars on the spray jets on the manifold, no instances of correct use were observed. The most common use error (occurring in 12 tests) was placing the valves in the small box. The participants cited the same reason as in subtask A5: containing the small parts in a closed-off area. In four tests, the participants placed the valves loose in basket 2, and in two tests, the valves were placed loose in basket 1. These errors may be attributed to the device failing to provide sufficient information about the correct placement of the valves. Two participants also mistakenly assembled the instruments, which may be due to a lack of clear information from the device or inadequate instructions before the tests.

L1. Load baskets in washer
In 17 tests, the participant loaded the baskets back into the washer successfully. In two tests baskets were loaded upside down, due to the device failing to provide clear information on how the baskets should be loaded. One participant was excluded as the participant did not load the baskets back in the washer.

Comparison between test 1 and 2
In table 3 and 4 the most occurring instances of correct and use error can be seen. Only participants who performed both tests have been incorporated in this table. When comparing test 1 and test 2, it was found that the occurrence of correct use increased in all instances. However, while the majority of use errors were reduced in occurrence due to the additional information provided, some use errors actually increased in occurrence. For example, no participants placed the valves loose in basket 2 in test 1, but in test 2, four made this use error, while three participants still placed the valves in the small box in basket 1. Additionally, in Test 2, four participants placed the black sheaths in the silicone holders without placing the sheaths in the flush ports, an increase from the three instances in Test 1. Similarly, the number of participants who placed the inserts in the silicone holder for the obturators increased from two instances in test 1 to four instances in Test 2.

Observation	Classification	Test 1	Test 2
Participant removes lid from basket 1.	Correct use	7	8
Participant removes both baskets.	Correct use	6	8
Participant loads baskets.	Correct use	6	8
Participant puts small rubber parts in the small box in basket 1.	Correct use	5	6
Participant puts trocar over rinsing rod.	Correct use	1	5
Participant puts obturator in silicone holders.	Correct use	2	4
Participant puts black sheaths in flushing ports.	Correct use	2	3
Participant puts handles over the hooks by one ear.	Correct use	0	3
Participant puts handles over the hooks by two ears.	Correct use	1	3
Participant puts inserts in silicone holder on lid of basket 1.	Correct use	2	3

Table 3: Comparison of occurrence of correct use in test 1 and 2.

Observation	Classification	Test 1	Test 2
Participant puts valves of trocars in the small box in basket 1.	Use error	5	3
Participant puts handles loose in basket 1.	Use error	4	2
Participant puts obturators in the flushing holes.	Use error	4	2
Participant puts black sheaths in silicone holder for lumens without putting it in the port.	Use error	3	4
Participant puts valves of trocars loose in basket 2.	Use error	0	4
Participant puts obturators loose in basket 1.	Use error	3	3
Participant puts inserts in silicon holder for lumens in basket 2.	Use error	3	1
Participant puts inserts in silicon holder for the obturators.	Use error	2	4

Table 4: Comparison of occurrence of use error in test 1 and 2.

Evaluation interviews
Evaluation interviews were done with nine nurses and one OT helper. The interviews were coded and these codes were divided into different sub-categories. These can be seen in table 5.

Safety of the nurses
Three nurses mentioned working with the medical washer would increase the safety of the nurses during the cleaning process by decreasing the amount of physical contact with the contaminated instruments compared to manual cleaning.

'Especially in this area HIV, hepatitis is very high. So it will be very safe for the staff who are involved with this surgery and we do not deal with all this blood.' [Participant 9]

Minimal water usage
Two participants mentioned the minimal water usage of the medical washer as an important advantage. Currently, the instruments are manually cleaned under continually running tap water. The current cleaning practice is perceived as wasteful by the nurses.

Reliability of the cleaning process
Four nurses and one OT helper considered the medical washer as a more reliable system for cleaning the laparoscopic instruments compared to the current system of manual cleaning. The participants explained that due to the time pressure while manually cleaning the laparoscopic instruments, at times, not all soil is removed when the instruments are disinfected.

	Codes	Frequency mentioned	Mentioned by participants
Comparison of current cleaning method and the medical washer	Cleaning with the medical washer is perceived as safer for the nurses compared to manual cleaning.	4	3/10
	Minimal water usage of medical washer	5	2/10
	The medical washer is perceived as a more reliable form of cleaning compared to manual cleaning.	6	5/10
	The medical washer is seen as less damaging to the laparoscopic instruments as manual cleaning.	5	3/10
Cleaning time	Explanation of current cleaning time	5	4/10
	The medical washer saves the time of the nurses.	9	8/10
Design of the medical washer	Comfort of the loading system	6	6/10
	Suggested improvements for the medical washer	9	4/10

Table 5: Evaluation interview codes.

'While manually washing 50 percent of the time we will make a mistake. We have 15 minutes or a half an hour. So in that time we have to wash the instruments and we do very quickly. So while washing the instrument very quickly we always lose something, which you can't see by your eyes. But there might be some spot or blood or something else. Yeah, but we have to wash thoroughly and bring back. But while using the machine. It will be very safe for us and for it will be very good for the patient. There will be no infections. It will be very good for us.' [Nurse 3]

Damage to the instruments
Damage was a subject mentioned by multiple participants. The laparoscopic instruments are perceived as costly, and nurses want to extend the instruments' lifetime as long as possible. Three participants mentioned the decrease in damage to the instruments while cleaning as an advantage of the medical washer.*'The machine does the things in a proper way. The damage of the instrument is quite less so. While man handling, there is a chance of damaging instruments.' [Nurse 2]*

Cleaning time
Currently, there is time pressure on the nurses and OT helpers while reprocessing the laparoscopic instruments due to a lack of instrument inventory and staff shortages. Four participants described the time frame of the current reprocessing cycle. Cleaning of the laparoscopic instruments takes between 15 and 30 minutes and the full reprocessing cycle takes about one hour. 9 participants mentioned that the medical washer could save time during the reprocessing cycle and decrease the pressure currently put on the nurses. The participants mentioned that this time can be used to work on their other tasks and take a rest in between cases.

'We have lots of work. We can see other patients. We need to put aside. We need to arrange the next patient. So, all these things. Sometimes we also have no time to rest.' [Nurse 9]

Loading system
Five participants described loading the baskets as comfortable. No discomfort was experienced during the loading and unloading of the baskets. One participant described the baskets as a little heavy mentioning that she had to get habituated to the mechanism.

Suggested improvements
Multiple suggestions were made for improvements on the medical washer.

- More space is needed in between the instruments.
- The medical washer should be able to load multiple instrument sets at a time.
- Instructions should be available outside of the medical washer.
- The medical washer should be able to house larger instruments like retractors and clip appliers.
- The medical washer should also sterilize the laparoscopic instruments.
- The medical washer should drain automatically so no buckets are required.

10.4 Discussion

Root cause analysis
During the study, all critical tasks were successfully completed by a number of participants, except for placing the valves of the trocars on the spray jets in basket 2. The tasks that were most often performed correctly were attaching the lid on basket 1, unloading and loading the baskets, and placing the rubber parts in the small box. During these tasks the device conveyed a clear message to the users. In seven tests, the black sheaths were placed in the flush ports, and in six tests, the trocars were placed around the spray jets. The reasoning behind these actions was similar in both cases, with the participants citing proper fixation as the primary factor. Flushing of the lumens was not mentioned as a reason by any of the participants. The information provided about the lumen flushing function of the medical washer did not seem to impact the participants' decisions about lumen placement. Instead, proper fixation and the similar diameters of the instruments and the silicone holders appeared to guide the participants in properly placing the instruments. The information given on the poster was not sufficient for the participants to recognize the flush ports and place the black sheaths in them to be flushed.

Three perception errors were identified during the tests. These errors involved the lid of basket 1 and the silicone holder, which seemed too inconspicuous to be noticed by the participants. As a result, the participants placed the inserts at different locations. To increase the instances of correct use, it is recommended that the silicone holder for the inserts be made more noticeable. A variety of cognition errors were observed during the tests. Firstly, the device appeared to provide information that could be misinterpreted by the user. For instance, 12 participants placed the valves of the trocars in the small box in basket 1, citing the same reasoning as for placing the small rubber parts in the small box. Six participants also placed the obturators in the flush ports, and three participants placed the trocars in the flush ports, citing proper fixation and similar diameters as their motivations. Secondly, the device seemed to fail at providing any information on proper placement, leading some participants to place the instruments loose in the basket.

These perception and cognition errors demonstrate the need for additional guidance to help participants accurately perform the tasks. One way to achieve this would be to add labels to the different compartments in the baskets or provide instructions on the medical washer itself.

Two action errors occurred during the tests. Eight participants placed the black sheaths in the silicone holders without inserting them into the flush ports, which was likely due to the small diameter of the flush ports creating resistance. To prevent this error from occurring, it is suggested to increase the diameter of the flush ports. Three participants placed the black sheaths in the silicone holder for the obturators, with one participant citing the potential contact between the trocars and the sheaths as the reason for this placement. Another participant demonstrated this issue during the test. To address this problem, increasing the space between the flush ports and creating larger serrations in the silicone holder is recommended.

In comparing the results of the two tests, it was observed that the provision of additional information resulted in an increase in the number of instances of correct use. However, for the task of placing the valves of the trocars, the guidance led to a different use error instead of an increase in the instances of correct use. In the second test, four participants placed the valves loose in basket 2, an error that did not occur in the first test. The placement of the valves was unclear to all participants. Therefore, it is important to focus on the placement of the valves when creating some form of guidance or instructions. The provided information in test 2 led the participants to place the instruments in the correct basket, but it also led to an increase in the occurrence of use errors within the correct basket. For example, an increase in the use errors of "placing the black sheaths in the silicone holders without inserting them into the flush ports" and "placing the inserts in the silicone holder for the obturators" may be attributed to the provided information.

Evaluation interviews
During the evaluation interviews, several advantages of the medical washer were identified by the participants. One key advantage is that it can increase the safety of nurses by reducing the amount of physical contact they have with potentially sharp instruments.

This is important because handling these instruments manually can pose a risk of injury or infection, such as HIV and hepatitis. India has a high burden of HIV and hepatitis infections, with an estimated 2.4 million people living with HIV and over 40 million people living with hepatitis B and C (UNAIDS, 2019)(Premkumar & Chawla, 2021). The use of a medical washer can mitigate these risks by effectively cleaning and sterilizing the instruments, thus limiting the need for direct contact.

Rural hospitals often face resource constraints that can impact the delivery of care. During the evaluation interviews, the participants identified cost as a major factor in the current method of cleaning under running water. They described minimizing water usage as a desirable goal. This is particularly relevant in the context of rural hospitals, where access to water may be limited.

During the evaluation interviews, five participants indicated that they believed the medical washer would clean instruments more effectively than their current cleaning methods. They also described the medical washer as more reliable than their current practices. These findings suggest that the use of a medical washer may improve the overall quality and effectiveness of instrument cleaning in the healthcare setting.

Resource constraints in rural hospitals can lead staff to try to extend the lifespan of laparoscopic instruments for as long as possible. During the evaluation interviews, three participants described the medical washer as being less damaging than their current cleaning methods, which they saw as a valuable advantage. This suggests that the use of a medical washer may help to improve the longevity of laparoscopic instruments in these settings. This is important because the replacement of laparoscopic instruments can be costly, especially in the context of resource-constrained rural hospitals. The use of a medical washer that is less damaging to the instruments may help to reduce the frequency of replacement, thus improving the overall cost-effectiveness of instrument cleaning.

Time pressure is a major factor that impacts the quality of the current reprocessing cycle in many healthcare settings. Nurses are often required to clean laparoscopic instruments within a short time frame, such as 15 to 30 minutes, which can lead to a lack of thorough cleaning. This is a concern because inadequate cleaning can compromise the sterilization of the instruments and increase the risk of infection transmission. During the evaluation interviews, one participant reported that soil was present on the instruments approximately 50% of the time after cleaning, highlighting the challenges with the current cleaning process.

Nine participants mentioned that the medical washer could help them save time, which could be used for other tasks or for rest between surgeries. This implies that the use of a medical washer may help to improve the efficiency of the reprocessing cycle, which could in turn enhance the overall quality of instrument cleaning.

Five participants described the loading system as comfortable, while one participant mentioned that she had to get habituated to it and found it a little heavy. This indicates that the loading system of the medical washer may be well-received by some users, but may not be universally comfortable for all users.

During the evaluation of the medical washer, multiple suggestions were made for improvements to the device. These suggestions included the need for more space between the instruments, the ability to load multiple instrument sets at a time, the availability of instructions outside of the medical washer, the ability to house larger instruments such as retractors and clip appliers, and the inclusion of sterilization capabilities. Additionally, it was suggested that the medical washer should have an automatic draining feature to eliminate the need for buckets. These suggestions highlight the areas where the participants felt that the medical washer could be improved, and could serve as a starting point for further development of the device. Further research and testing may be needed to determine the feasibility and potential benefits of implementing these suggestions.

Limitations
There are several limitations to consider when interpreting the findings of this study. First, there is a limited amount of previous research in the field on the usability of medical washers in rural India. This may limit the ability to compare the results of this study to other work in the field.

Second, there was a language barrier that may have affected the results of the study. One participant mistook the medical washer for an autoclave, which could have influenced her perception of the device.

Third, three of the hospitals where the study was conducted did not own their own set of laparoscopic instruments, which may have limited the experience of the nurses at those hospitals with handling such instruments. This could have affected their ability to accurately assess the usability of the medical washer.

Recommendations
A concept evaluation of a medical washer specifically designed for use in rural India was conducted in this study. The findings indicate that the nurse perceive the medical washer as a positive addition to their current reprocessing method. But there are several areas for improvement in terms of usability and user satisfaction. Different design suggestions for a new iteration of the medical washer can be seen in table 6.

System	Redesign suggestions
Loading system	The silicone holder for the inserts should be more noticeable.
	More guidance should be given to the user when loading the baskets.
	The placement of the valves should be a point of focus when creating added guidance.
	The diameter of the flush ports should be increased.
	The space should be increased in between the flush ports.
	The serrations in the silicone holder for the lumens should be increased in size.
	The medical washer should be able to house larger instruments like retractors and clip appliers.
Cleaning system	The medical washer should also sterilize the laparoscopic instruments.
	The medical washer should drain automatically so no buckets are required.

Table 6: Redesign suggestions for the next iteration of the medical washer.

In addition to the various redesign suggestions presented, there are several topics that warrant further research. For example, further testing should be conducted to determine the amount of weight that is comfortable for nurses to load into the washer. Additionally, more research is needed on the sets and quantity of laparoscopic instruments available in rural Indian hospitals. These areas of study would provide valuable insights that could inform the design of future versions of the medical washer.

10.5 Conclusion

In conclusion, the root cause analysis and evaluation interviews conducted in this study provide valuable insights into the correct and incorrect use of the medical washer in rural India. The findings reveal that the medical washer is generally perceived positively by rural nurses, with many reporting that it helps to improve safety, consumption of water, hygiene, instrument lifetime and cleaning time. However, the study also identified several areas for improvement, including the need for clearer instructions and more user-friendly design features.

11 Final design

In this chapter the final design of SamarthClean, a medical washer for laparoscopic instruments for rural Indian hospitals is discussed. The chapter will go into the use, the components and the performance requirements of the medical washer. In the final design the concepts for the loading mechanism, the mechanism alternating flow and the cleaning system were integrated as well as the insights gained in the concept evaluation. The text boxes show the relevant requirements for the design of the various components of the medical washer.

SamarthClean

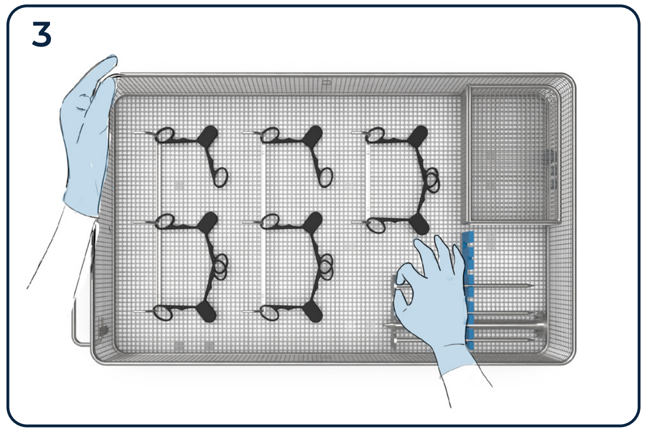
The medical washer for laparoscopic instruments was designed with the aim to ensure safe laparoscopy in rural Indian hospitals for patients and health workers, while relieving the time pressure experienced by the nurses and using little resources in the process. To ensure clean instruments while using little resources different geometry specific cleaning strategies and to ensure fast and easy use symbols are used to allow the nurses to load the instrument without the need for training.

11.1 Use

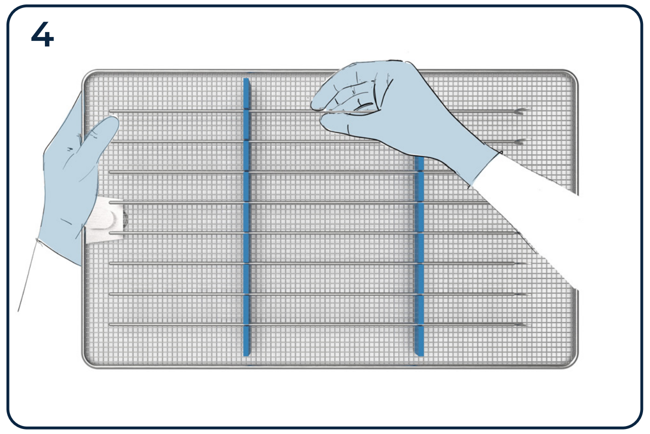
The medical washer is designed to be used in rural Indian hospitals. It should fit the context of the hospitals and be adapted to the facilities of the hospitals. In figure 49 the use of the medical washer can be seen.

The hot and cold water basins are filled.

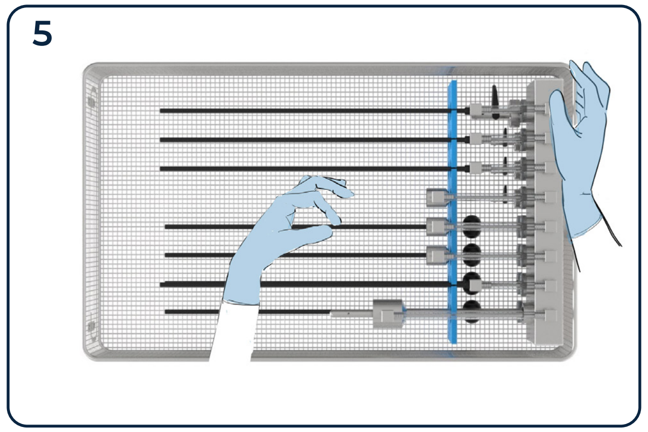
The baskets are unloaded.



The handles, obturators and small components are loaded in basket 1.



The inserts are loaded in the lid of basket 1.



The different lumens are loaded in basket 2.

The baskets are loaded into the medical washer.

Figure 49: The use of the medical washer.

11.2 Cleaning cycle

The cleaning cycle consists of four phases, first a pre-rinse is done to remove all the gross soil. After the pre-rinse, the detergent wash starts. In the first part of the detergent wash the complex geometries are ultrasonically cleaned. In the second part the all the geometries are washed through the impingement of the spray jets. Movement of the water can inhibit the effect of ultrasonic cleaning, therefore, lumen flushing is stopped when the instruments are ultrasonically cleaned (Kanegsberg & Kanegsberg, 2020). A visual of the cleaning cycle can be seen in figure 50. In figure 51 the rinsing process of the spray jets and the process of ultrasonic cleaning can be seen.

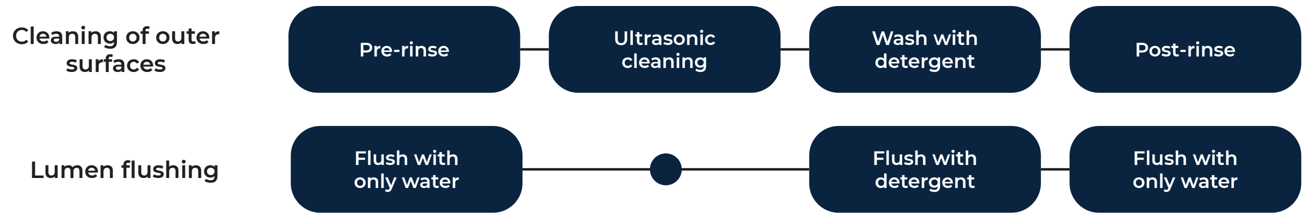


Figure 50: The different phases of the cleaning cycle for both the system cleaning outer surfaces and the system flushing the lumens.

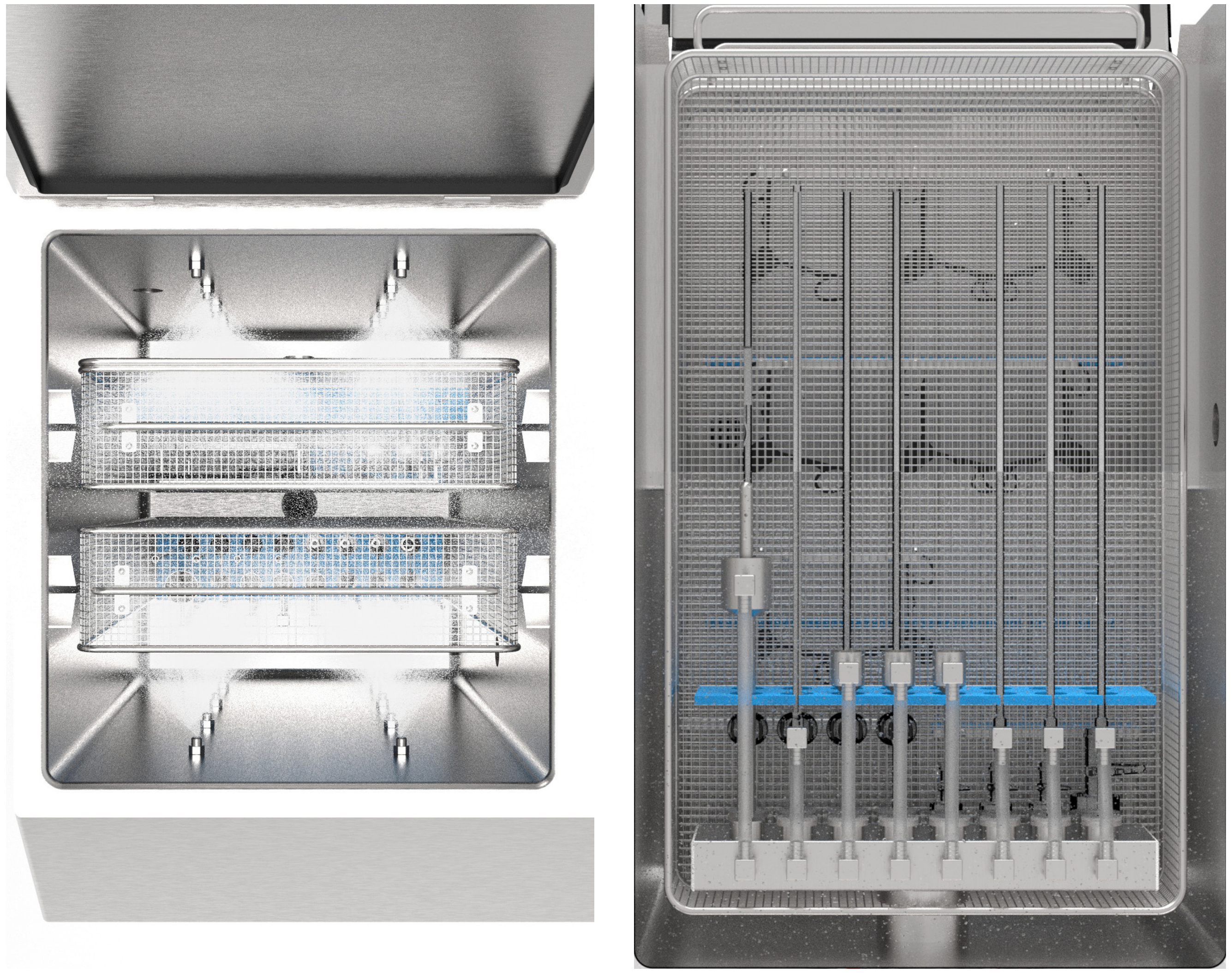
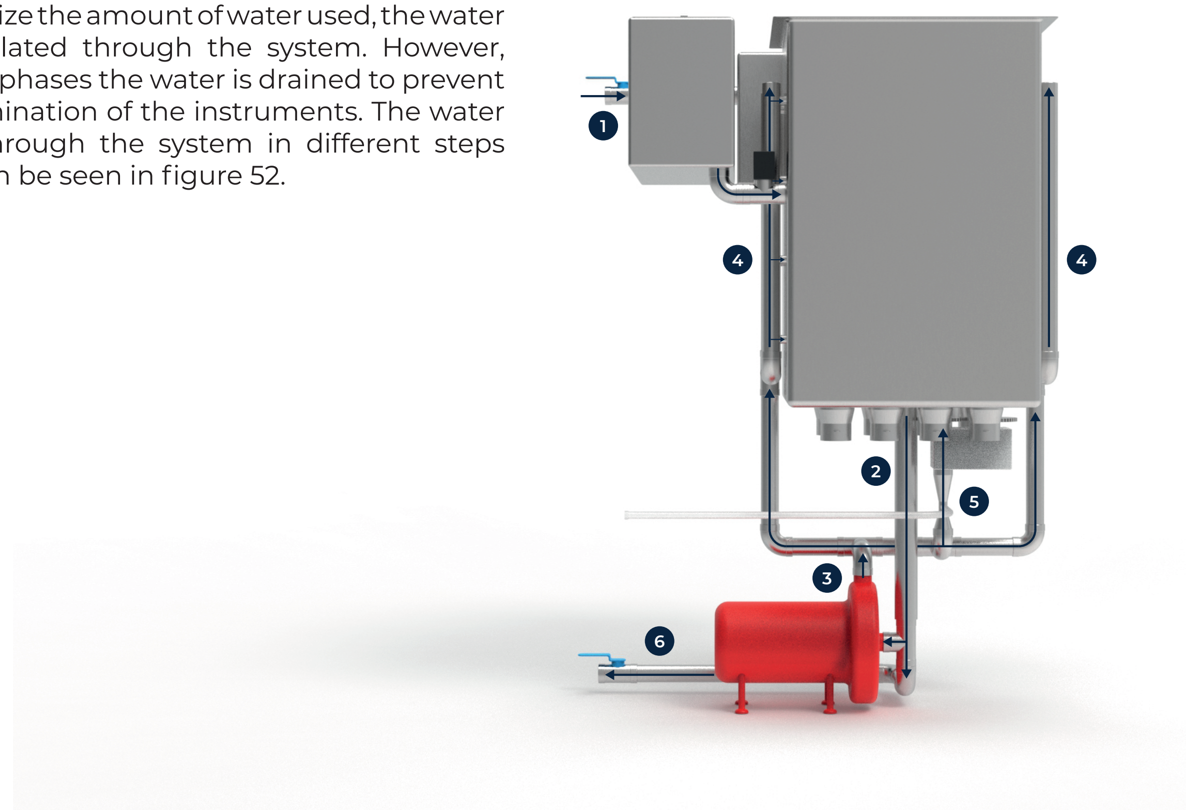


Figure 51: Rinsing and ultrasonic cleaning of the baskets.

11.3 The circulation of water

To minimize the amount of water used, the water is recirculated through the system. However, between phases the water is drained to prevent recontamination of the instruments. The water moves through the system in different steps which can be seen in figure 52.



1. The hot and cold basin are filled with water either automatically or manually.
2. The valves in the basins are opened and water flows through the drain in the wash chamber.
3. The circulation pump pumps the water through the system.
4. The water flows through the manifold to the spray jets.
5. The water flows through the venturi and the system alternating the flow.
6. After the cleaning phase is done the pump stops and the water is removed through the drain valve.

Figure 52: The steps of the circulation of water.

Relevant requirements

- The water must be recirculated to minimize the water use.

11.4 The size and housing of the washer

The medical washer contains two basins (figure 53). The basins can be filled both automatically and manually depending on the water connection of the hospital. The front view, side view and back view of the medical washer can be seen in figure 53 as well. The medical washer is designed to be used comfortably by the nurses in the hospitals in India. The dimensions of the washer are adjusted to fit these nurses (Appendix 11). The dimensions can be seen in figure 54.

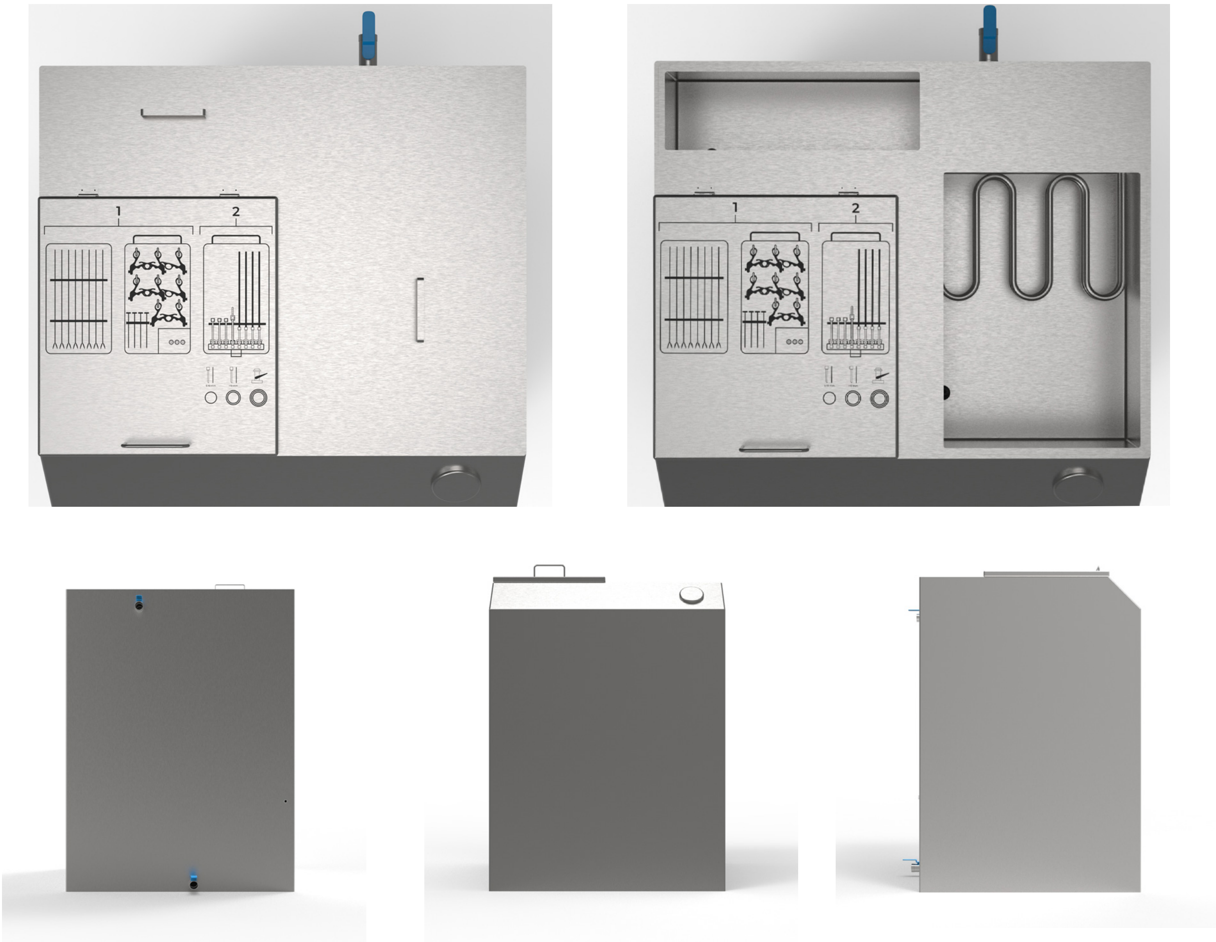


Figure 53: Different sides of the medical washer.

Figure 54: The dimensions of the medical washer.

Relevant requirements

- The ground area of the medical washer must be less than 1 m x 1 m.
- The medical washer must be able to be filled with water manually as well as automatically.
- The medical washer must take into account the height of the average Indian female.
- The medical washer must be sealed to prevent earolization.

11.5 The components of the system

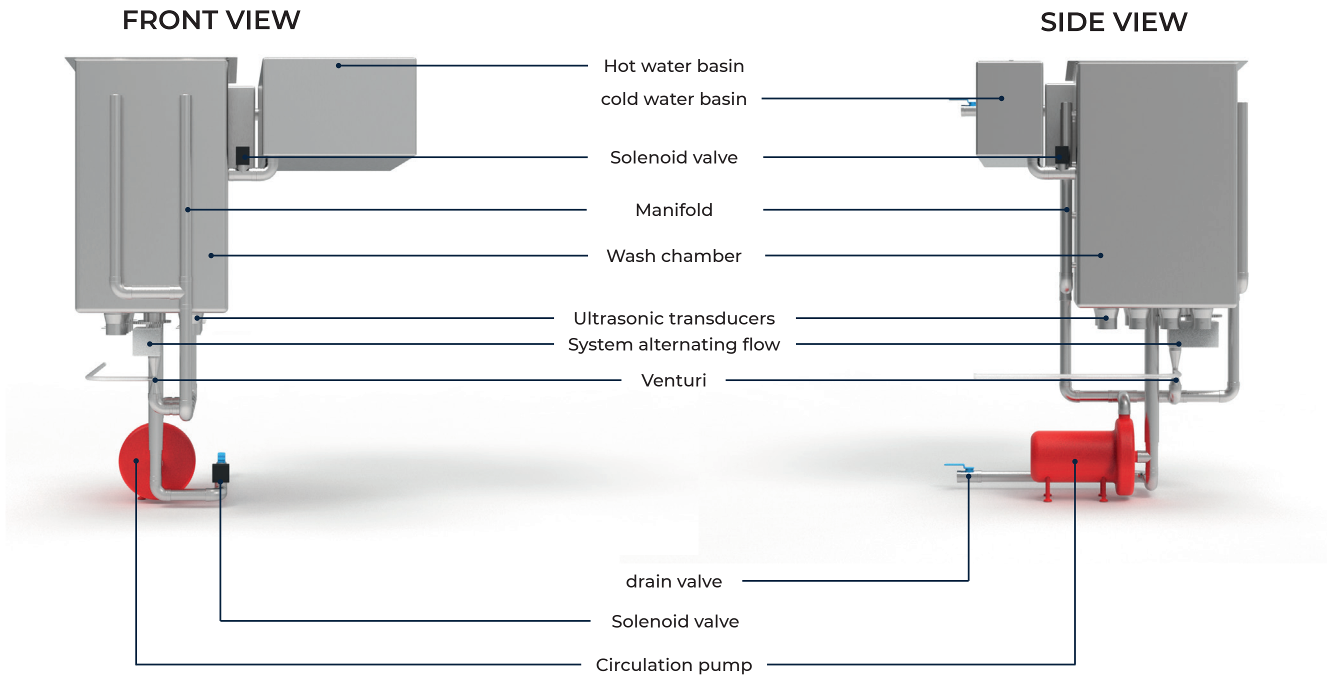


Figure 55: The dimensions of the medical washer.

In figure 55 an overview of the different components of the medical washer can be seen.

Water basins
The medical washer consists of a cold water basin for the pre- and post-rinse and a hot water basin to provide water at a temperature of 65 degrees Celsius during the detergent wash.

Solenoid valves
The solenoid valves can open and close electronically when necessary. The medical washer includes five solenoid valves. Two valves which regulate the water to the cold and hot water basin, two which regulate the amount of water from the basins to the wash chamber and one which opens and closes the drain.

Manifolds
The four manifolds connect to the spray jets in the wash chamber. Each manifold is connected to four spray jets.

Wash chamber
The wash chamber is connected to two water inlets from the water basins, to the manifolds to the system alternating flow, to the drain, and to the ultrasonic transducers.

Ultrasonic transducers
Eight 100 Watt ultrasonic transducers are connected to the wash chamber. As mentioned before 26 Watts of ultrasonic power per litre is required to effectively clean the complex geometries. The volume which requires ultrasonic cleaning is 32 litres which would require 800 Watt of ultrasonic power.

The system alternating flow
The system which alternates the flow is connected to the wash chamber. Only one moving object is present in the wash chamber. The other components are located outside the wash chamber.

Venturi
The system which alternates the flow to the lumens is connected to a venturi with a tube which supplies it with air.

Circulation pump
The circulation pump pumps the water through the entire system.

Relevant requirements

- The pipes supplying water to the basins, from the basins and to the drain the must contain solenoid valves to automatically control the flow of water.
- The basins must be placed higher than the entrance of the water in the wash chamber so water moves naturally in the chamber.
- The pipe supplying the water to the mechanism alternating flow must contain a venturi providing two-phase flow.

11.6 Wash chamber

The baskets are loaded in the wash chamber. The instruments are cleaned by the impingement of 16 120 degree spray jets located 55 mm from the baskets (Appendix 11). The wash chamber contains rails to ease the loading process. At the sides of the chamber the two water inlets can be seen. Looking at the bottom of the chamber the drain is located in the centre. The drain contains a filter so the recirculated water does not recontaminate the instruments (figure 56). The system alternating the flow connects to the lumen basket when it is loaded (figure 57). The numbers guide the nurses to place the baskets at the correct location (figure 58). The edges of the chamber are curved to ensure the wash chamber can be properly cleaned. The dimensions of the wash chamber can be seen in figure 59. The spray jets are connected to the manifolds through the holes in the wash chamber (figure 58 and 60). All the components of the wash chamber can be seen in figure 61.

Figure 58: The numbers in the wash chamber.

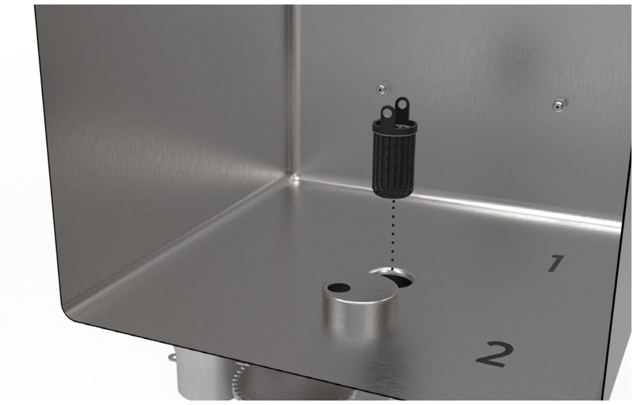


Figure 56: The filter in the drain of the wash chamber.

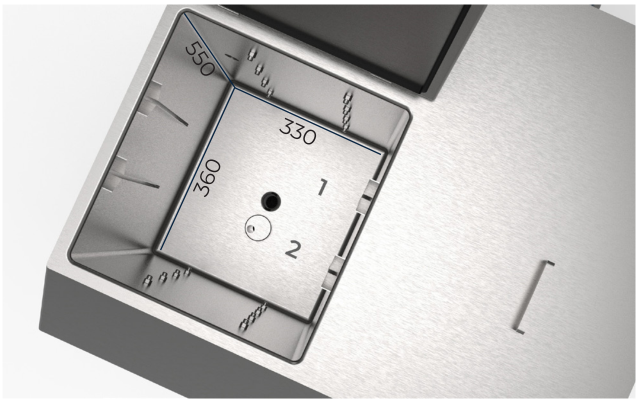


Figure 59: Dimensions of the wash chamber.

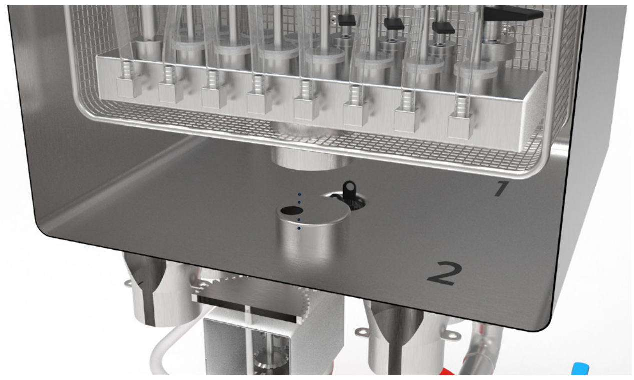


Figure 57: Connecting the lumen basket to the mechanism alternating the flow.

Figure 60: The manifold and spray jet.

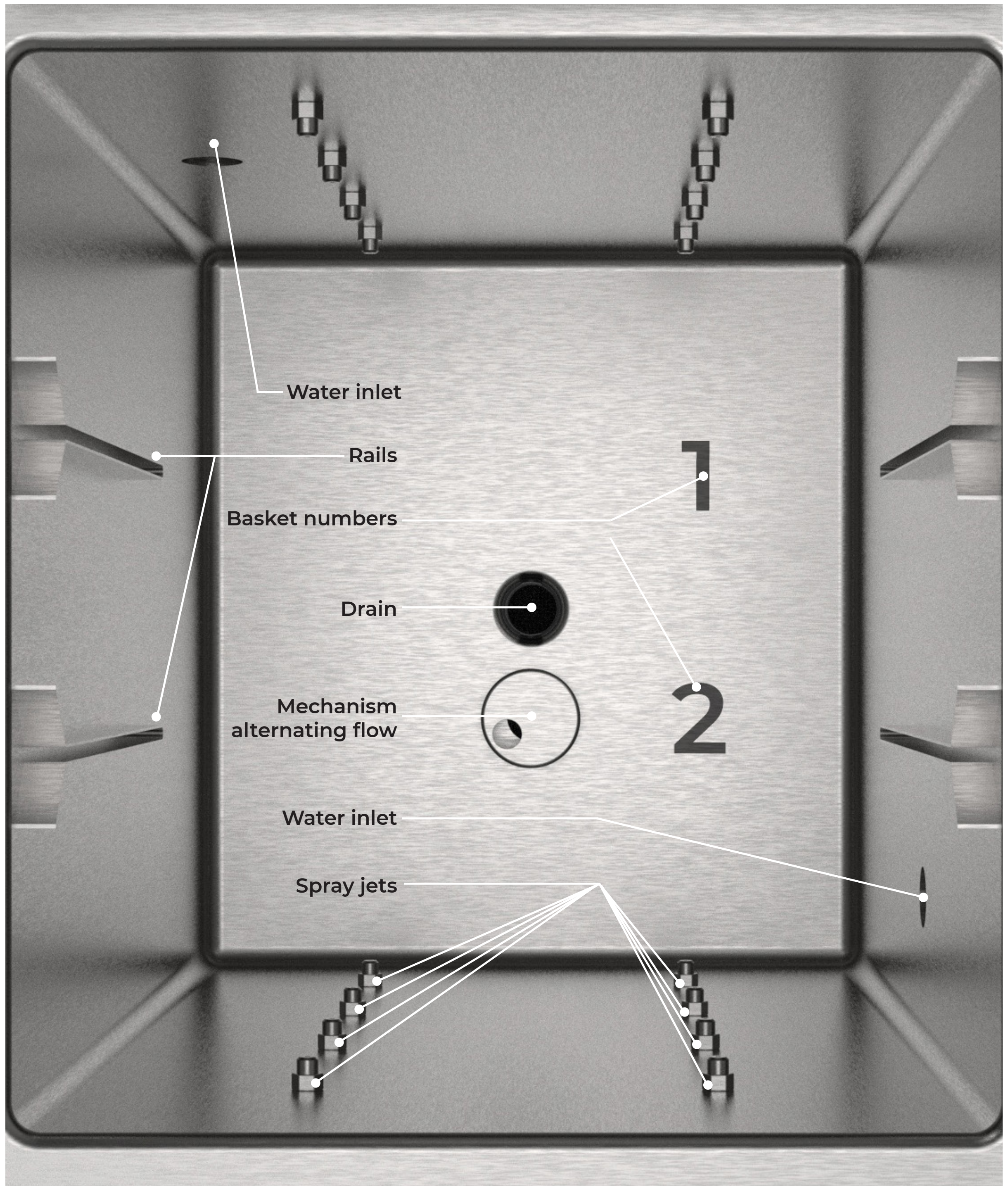


Figure 61: The various components of the wash chamber.

Relevant requirements

- The wash chamber must contain spray jets to rinse the laparoscopic instruments.
- The wash chamber must contain an entrance for warm and cold water.
- The wash chamber must contain a drain with a filter.
- The wash chamber must contain a water-tight entrance for the mechanism alternating the flow.
- The wash chamber must contain rails to ease the loading process and fixate the baskets.
- The was chamber must contain the numbers of the baskets to show where which basket must be loaded.
- The edges of the wash chamber must be curved to ensure cleanability of the wash chamber.

11.7 Mechanism alternating flow

In figure 62 the limitation of the rotating plate can be seen. To ensure proper flow through the lumens, a mechanism was integrated which flushes the lumens in increments. The lumens are flushed in alternate increments. This is done by a Geneva mechanism (figure 63). The mechanism in figure 64 moves as follows:
Water flows through the bottom.

- The flow drives the wheel which is connected to a gear.
- The gear turns, which causes the second gear to turn.
- The gear is connected to the first part of the Geneva mechanism.
- Every rotation of the gear the second part of the Geneva mechanism is turned 90 degrees.
- The second part is static until the gear finishes its rotation and rotates the second part of the Geneva mechanism again.
- This movement is translated back to the flow by the top gears.
- Finally, the outlet of water rotates 90 degrees in increments flushing four lumens for a specified amount of time.

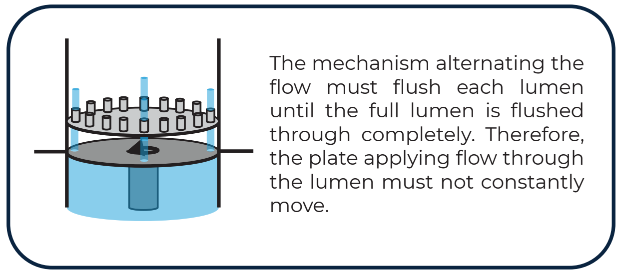


Figure 62: The limitation of concept 3 of the mechanism alternating flow.

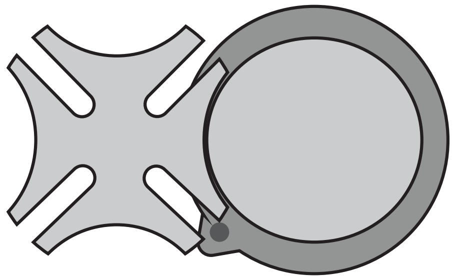


Figure 63: A Geneva mechanism.

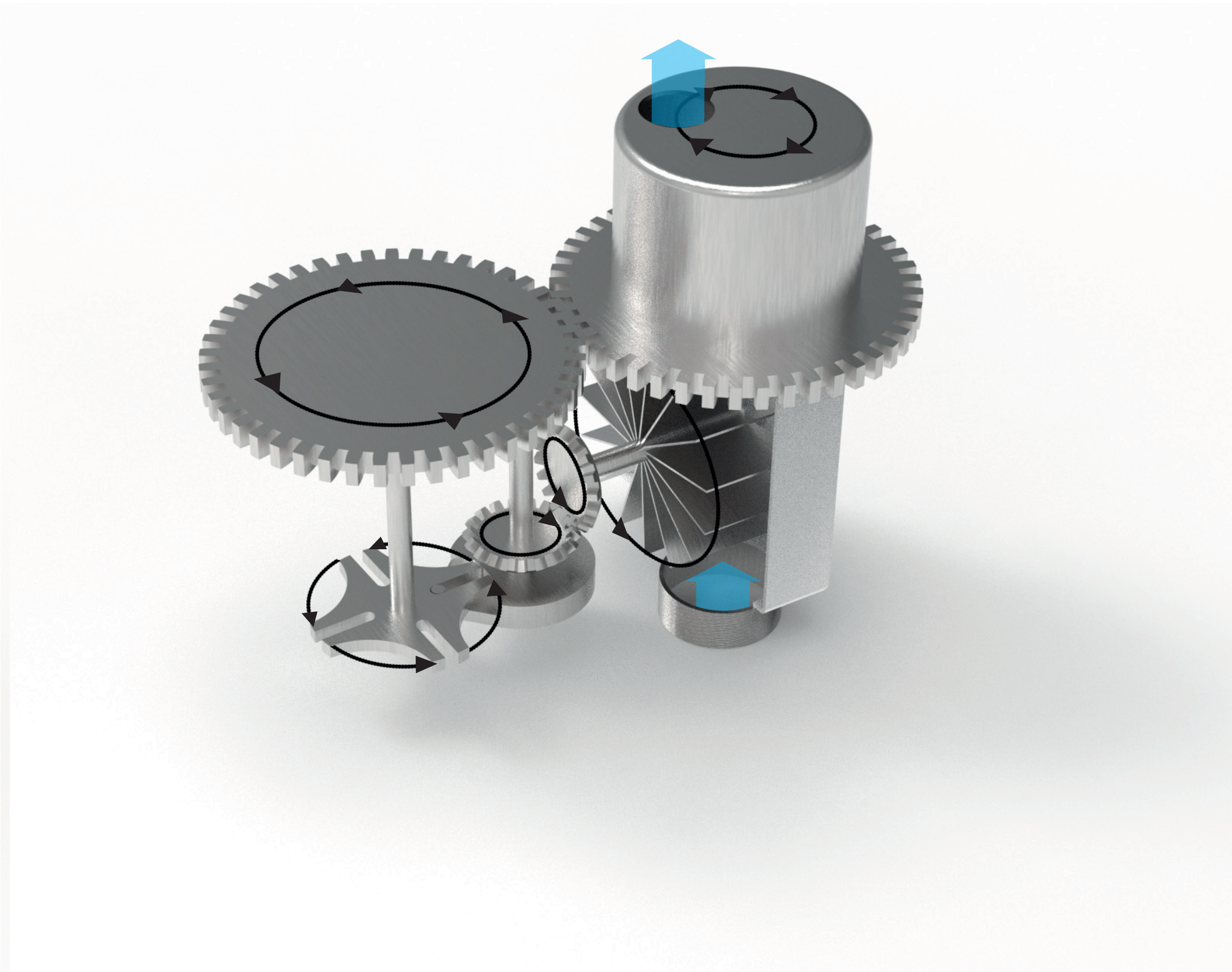


Figure 64: The movement of the gears in the mechanism alternating flow.

Figure 65: Connecting the lumen basket to the mechanism alternating the flow.

The hole of the alternating flow mechanism (figure 65) lines up with one of the holes at the bottom of the manifold (figure 67). The manifold consists of four compartments each containing four flush ports (figure 66). Each of the four compartments is flushed at different moments.

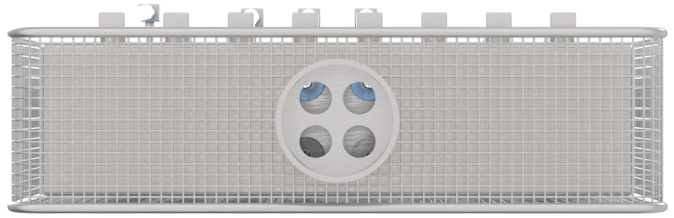


Figure 67: The bottom of the lumen basket.

Figure 66: A cross section of the manifold of the lumen basket.

Relevant requirements

- The flow through the lumens must be alternated in increments to ensure each lumen is fully flushed.
- The mechanism alternating flow must be seperated from the wash chamber.

11.8 Ultrasonic cleaning

To effectively clean the complex geometries while using little resources only the part of the wash chamber is filled with water which contains the complex geometries thus limiting the amount of water used and ultrasonic power needed for ultrasonic cleaning. The basket needs to be filled to the height of the largest trocars which are 200 mm in length. Taking into account the distance from the bottom of the chamber the height of the water must be 275 mm (figure 68). The volume of the water used is 32 liters.

Ultrasonic transducers are used to create the ultrasonic power to clean the complex geometries of the laparoscopic instruments figure 69. Eight transducers are installed at the bottom of the tank and spaced equally throughout the bottom surface to spread the ultrasonic power equally and to avoid spots in the wash chamber with insufficient ultrasonic power. The transducers are installed by welding screws at the bottom of the tank. The screws can be seen in figure 70. Then, the transducers can be mated using the screws. Lastly, epoxy glue is used to connect the surface of the wash chamber and the surface of the ultrasonic transducers.

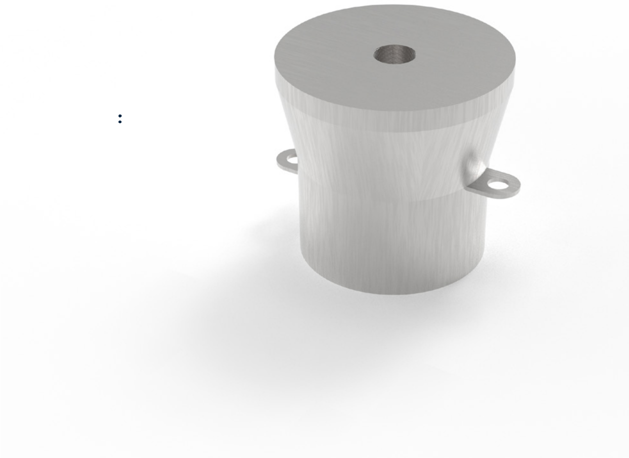


Figure 69: An ultrasonic transducer with a threaded hole at the top.

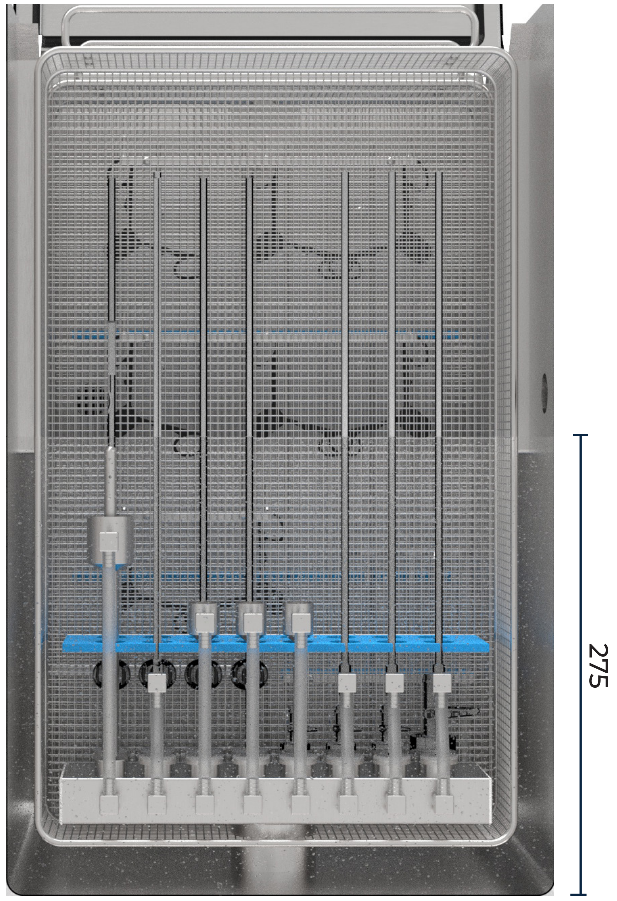


Figure 68: Ultrasonic cleaning of the complex geometries.

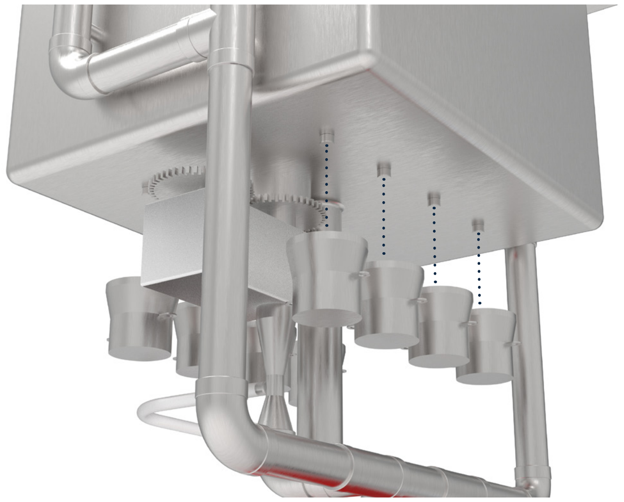


Figure 70: The screws located at the bottom of the was chamber.

Relevant requirements

- The complex geometries must be ultrasonically cleaned.
- The ultrasonic cleaning system must contain a 100 Watts of ultrasonic power per gallon of water.
- The ultrasonic transducers must be fixated by screws attached to the wash chamber.

11.9 Flow rate of the circulation pump

Spray jets
The spray jets used require 1.9 L/min of water (Alibaba.com, n.d.). The system uses 16 spray jets, therefore, a flow rate of 30.4 L/min is needed for the spray jets to function.

Lumen flushing
To determine the flow rate needed to remove the soil from the inside of the lumens the minimal flow rate needed was determined. The shear stress necessary to clean stainless steel surfaces was determined by Hariharan et al. (2018), who found that 5 minutes of flow causing a shear stress of 0.3 Pa combined with an enzymatic detergent after soaking for 10 minutes removed 99 percent of the soil. Using the shear stress and a derivation of the Hagen-Poiseuille equation it was found that a flow rate of 39 L/min is required to remove the soil from the surfaces of an instrument set of 8 insulated sheaths three 5 mm trocars and one 10 mm trocar. The calculation can be seen in figure 71.

In the modules of conventional washer-disinfectors a flow rate of 0.9 L/min is used to flush the lumens (J.M.A. Zuijdweg, 2014). For 16 lumens this would total 14.4 L/min.

To ensure all lumens are properly flushed the flow rate calculated was used. The total flow rate needed to clean instruments is 70 L/min.

Pump size
To ensure the durability of the pump, a pump is chosen with a flow rate larger than 70. A pump with a max flow rate of 100 L/min can increase the longevity of the medical washer (ingco.com, n.d.).

Water use
The detergent wash requires 32 liters. It is assumed that the pre- and post-rinse will require a similar amount of water. Therefore, the water use of the medical washer totals 96 liters.

$$Q_{spray\ jets} = 30{,}4\,\frac{L}{min}$$

$$R_{insulated\ sheaths} = 0.00175\ M$$

$$R_{5mm\ trocar} = 0.005\ M$$

$$R_{10mm\ trocar} = 0.010\ M$$

$$Shear\ stress\ (\tau) = 0.3\ Pa$$

$$Dynamic\ viscosity\ of\ the\ water\ (\mu) = 0.001\ \text{Pas}$$

$$Q_{16\ lumens} = 8 * (\pi * (R_{insulated\ sheaths})^{\wedge}3 * \tau) / (4 * \mu) + 6 * (\pi * (R_{5mm\ trocar})^{\wedge}3 * \tau) / (4 * \mu) + 2 * (\pi * (R_{10mm\ trocar})^{\wedge}3 * \tau) / (4 * \mu)$$

$$Q_{16\ lumens} = 6.581 \times 10^{(-4)}\ \frac{M^3}{s} = 39\,\frac{L}{min}$$

$$Q_{total} = 30.4 + 39 = 69.4\,\frac{L}{min}$$

Figure 71: Calculation of the flow rate required for flushing 16 lumens.

Relevant requirements

- The medical washer must have a lower flow rate than 625 L/min.
- The medical washer must use less than 180 liters of water per cycle.

11.10 Lumen basket

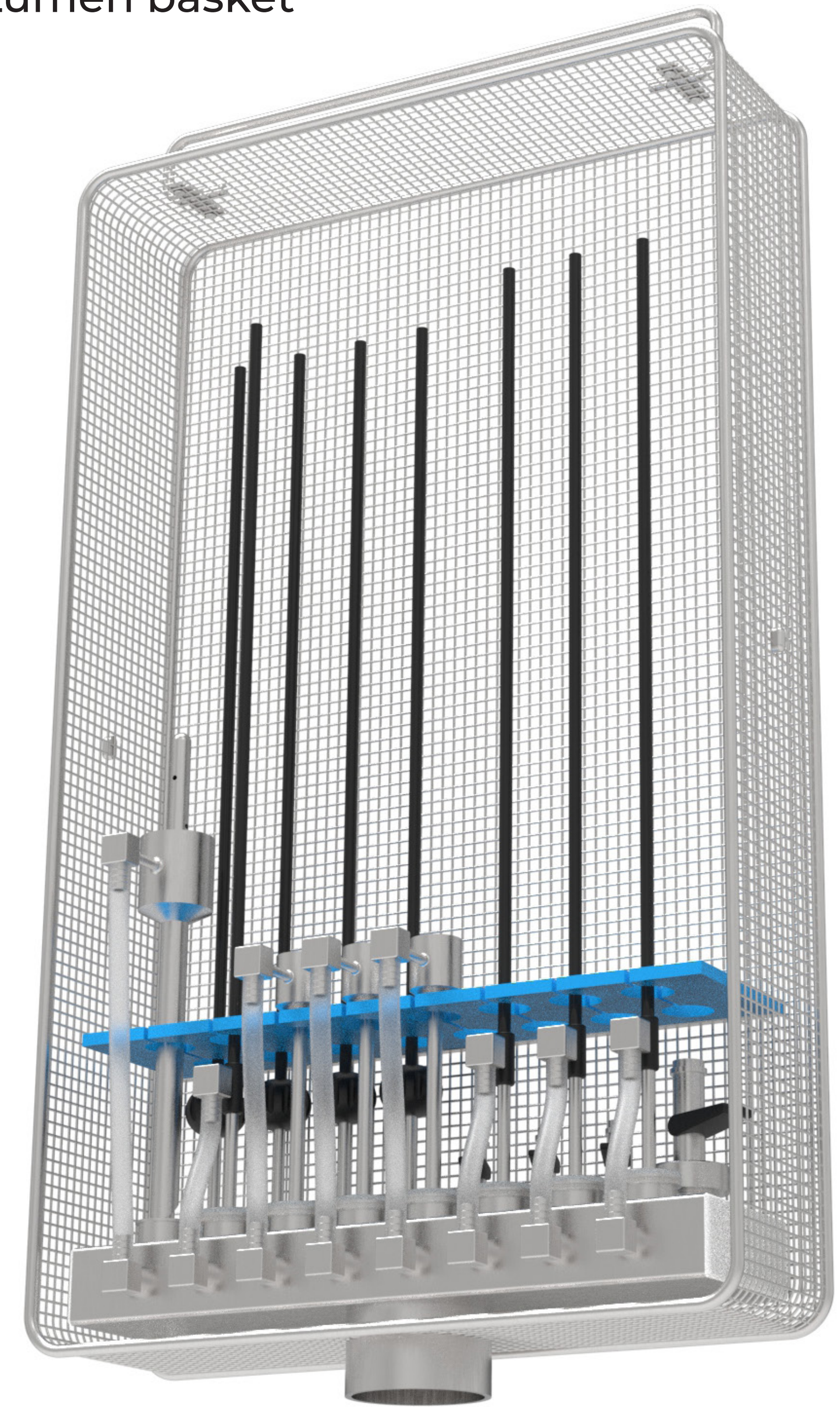


Figure 72: The lumen basket containing valves, trocar sleeves and insulated sheaths.

The lumen basket contains 16 flush ports in which different configurations of laparoscopic instrument sets can be cleaned (figure 72). On the back side of the manifold the lumens can be loaded which do not contain flush ports. On the front side of the manifold the lumens containing flushports can be loaded and connected to connector hoses.

Each flush port contains thread on the inside to ensure the spray jets can be installed. The ridge on the edge of the flush port fixates the caps. The design of the flush port allows for different instrument sets to be cleaned as caps or spray jets can be connected to each flush port. Loading the lumen basket is done as follows and can also be seen in figure 73: Firstly, the caps and spray jets are installed. Secondly, the different instruments are installed. Insulated sheaths and trocars with an inner diameter of 5-10 mm diameter are installed in the caps. The trocars with a diameter larger than 10 mm are installed on spray jets and the valves of the trocars are connected to small spray jets. Thirdly, the connector hoses are connected to flush ports of the instruments. To ensure the manifold can be cleaned. The sides of the manifold can be removed to remove soil from the compartments. The lumen basket can be carried by two hands which are placed around the handle, so all health workers can carry the baskets comfortably. All the different components of the lumen basket can be seen in figure 74.

Relevant requirements

- The manifold must contain 16 flush ports.
- The manifold must be compartmentalized to facilitate the alternated flow through the lumens.
- The manifold must contain ports for connector hoses.
- The flush ports must be threaded so the amount of spray jets and caps can be changed depending on the set of instruments that needs to be cleaned.
- Four of each spray jet must be available so any configuration of instruments can be cleaned.
- The lumen basket must contain a silicone holder to fixate the lumens.
- The sides of the manifold must be removable so the manifold can be properly cleaned and maintained.
- The lumen basket must contain a handle for loading.

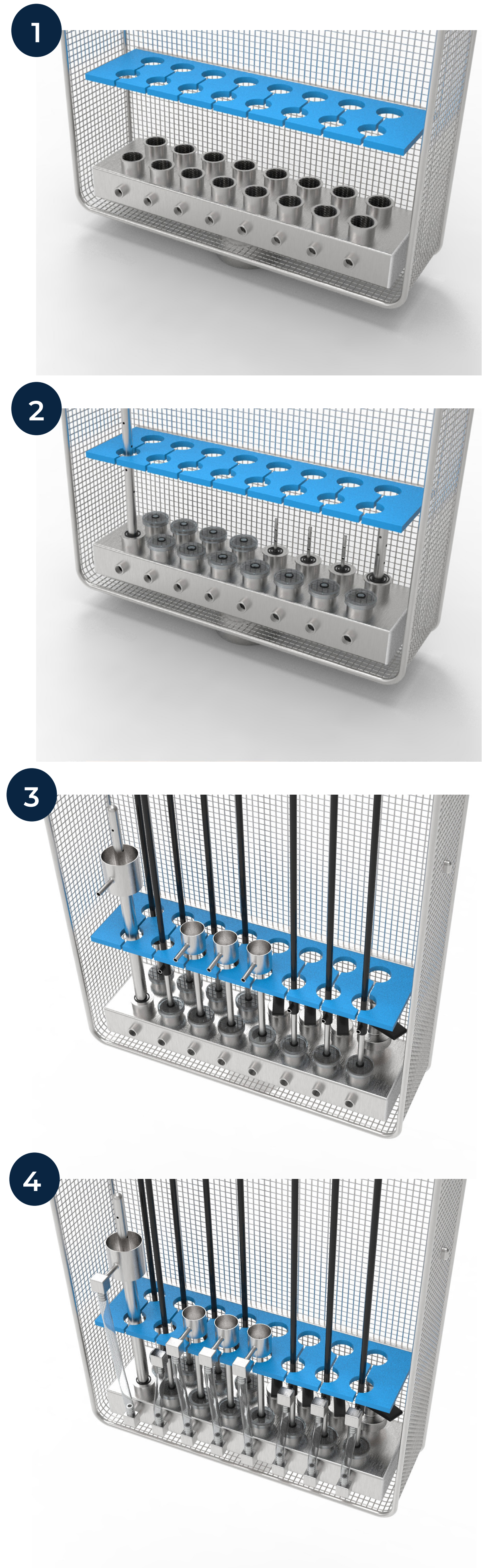


Figure 73: Loading of the lumen basket.

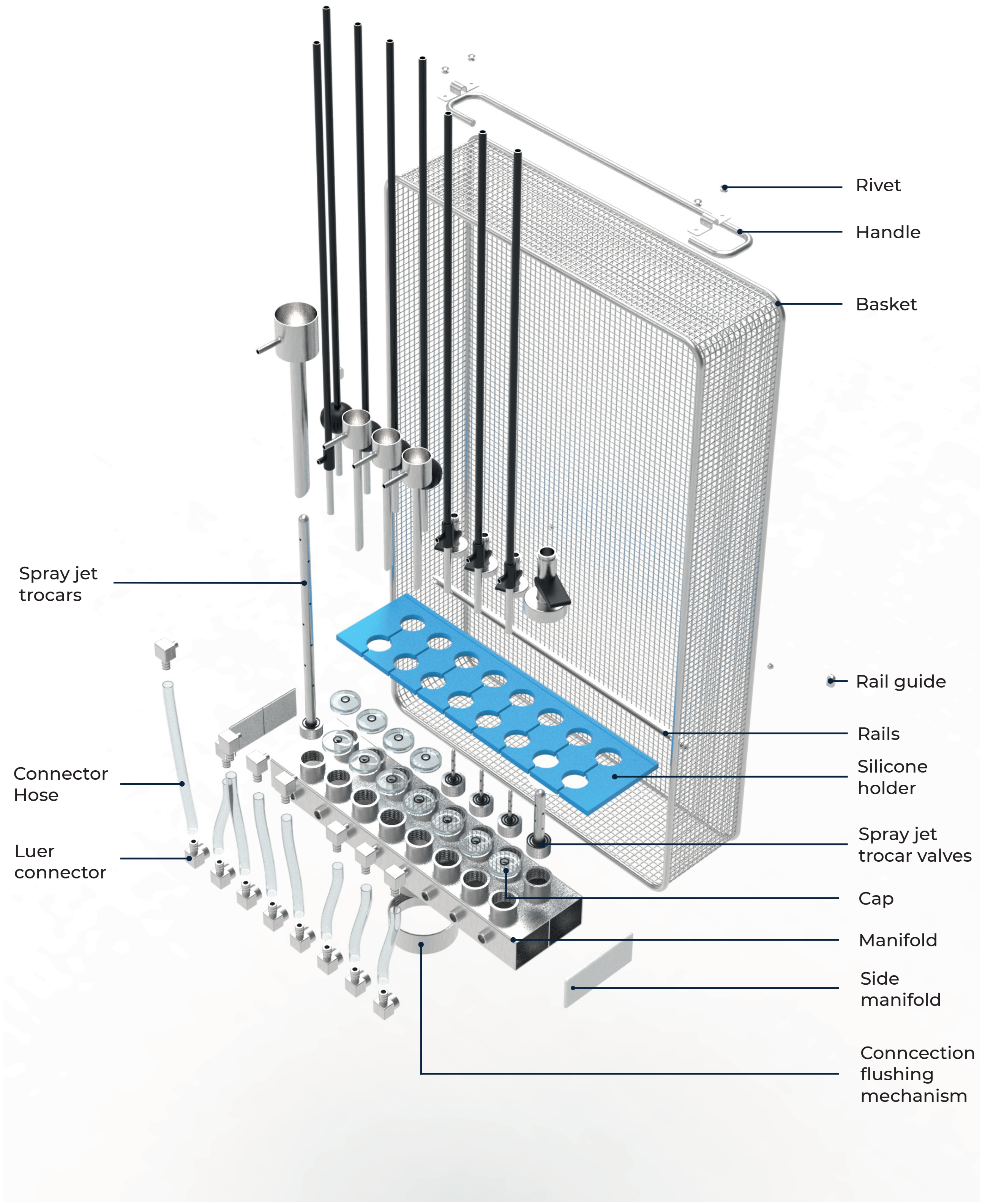


Figure 74: Exploded view of the lumen basket.

11.11 Insert basket

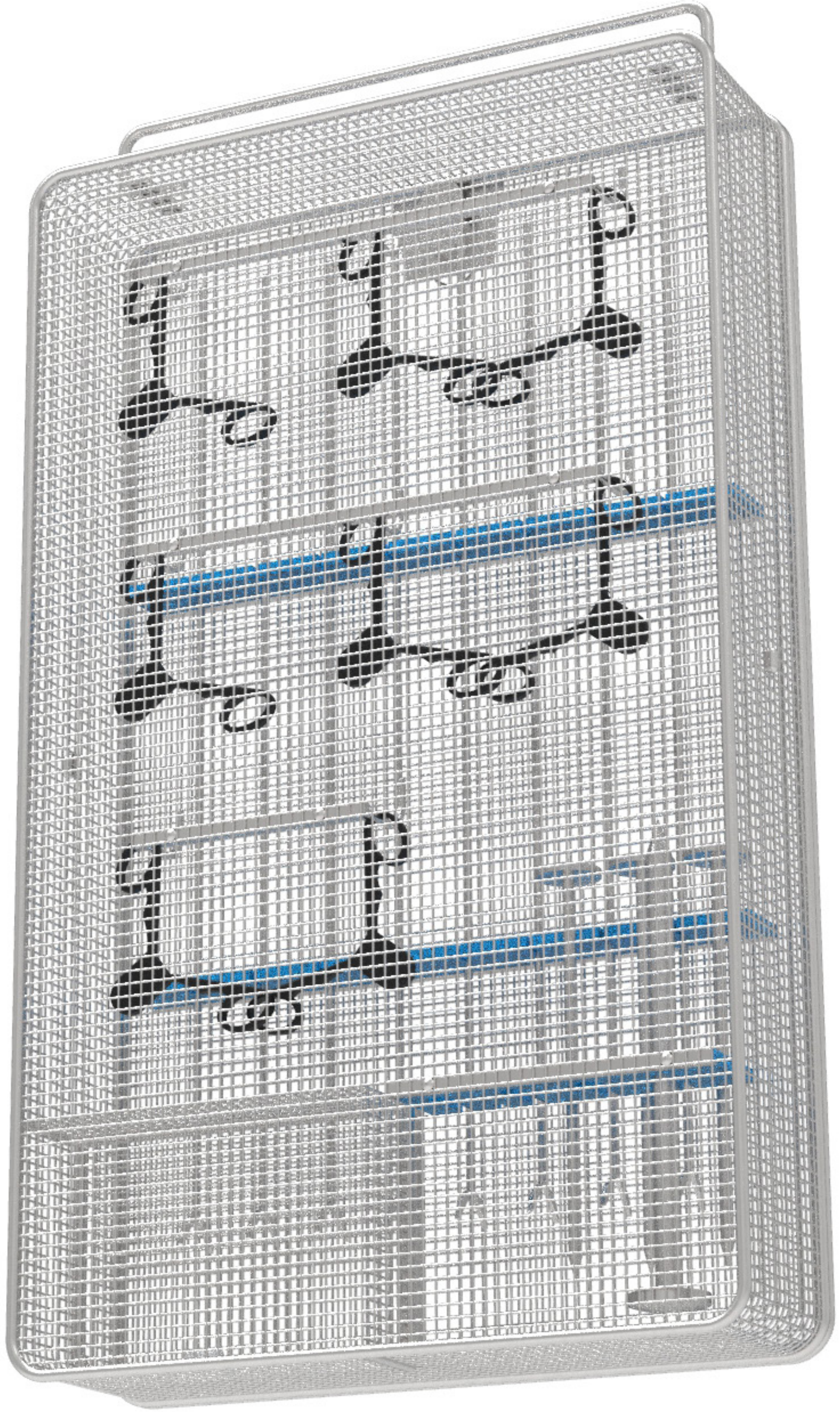


Figure 75: The insert basket containing the handles, inserts, obturators and small components.

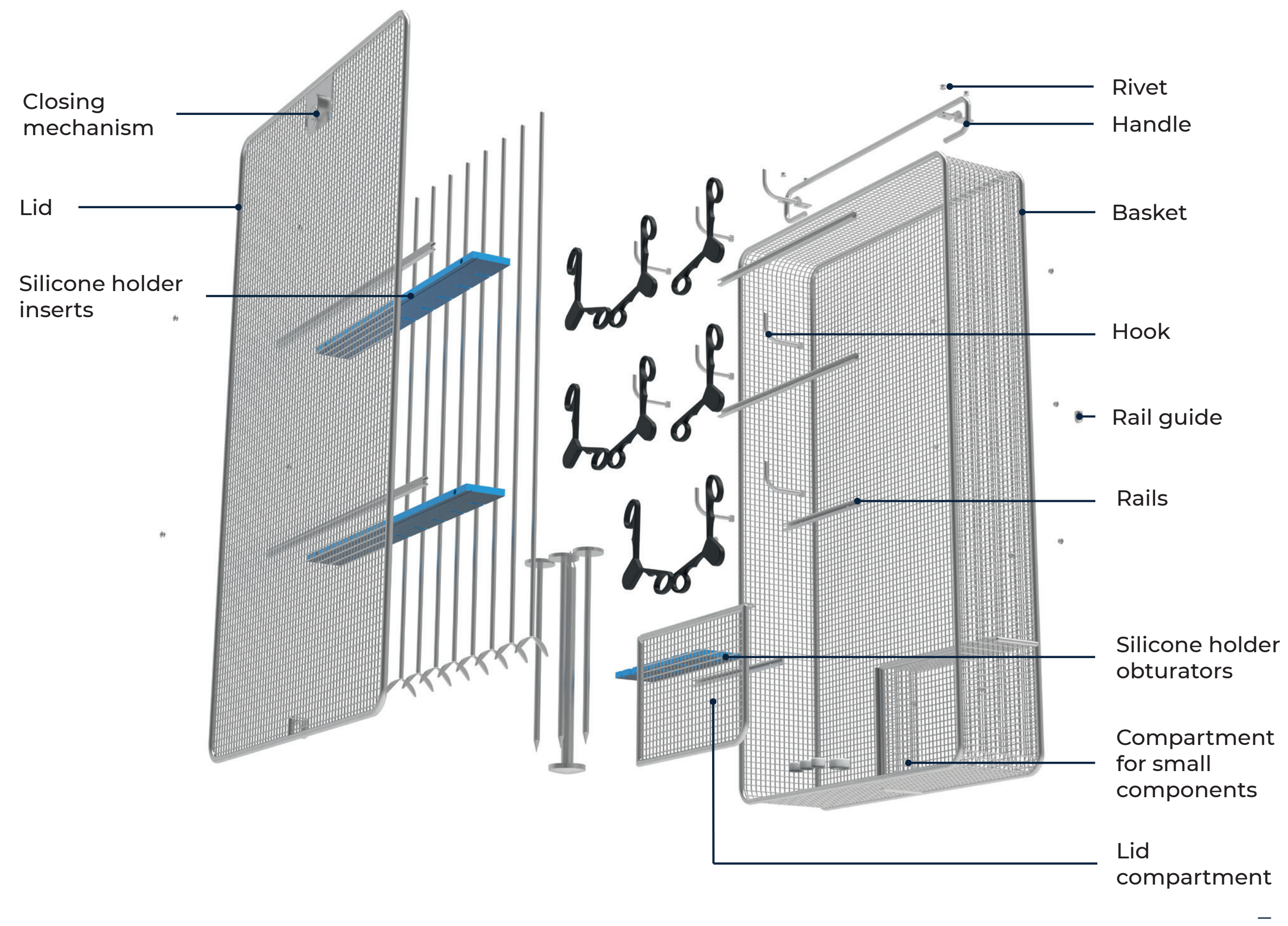


Figure 76: Exploded view of the insert basket.

The insert basket contains a basket and a lid (figure 75 and 76). In the basket eight handles can be immobilized on hooks. In the silicone holder for the obturators four 5 mm obturators and four 10 mm obturators can be fixated. The basket contains a small compartment for the small components of the laparoscopic instruments. On the lid eight inserts can be fixated in the silicone holders. The lid can be attached to the basket by a turning mechanism in the lid. Both the lumen basket and insert basket have a height of 500 mm, width of 300 mm and a depth of 80 mm.

Relevant requirements

- The insert basket must contain a volume that can be closed off to keep the small parts in one place.
- The insert basket contain a silicone holder to fixate four 10 mm obturators and four 5 mm obturators.
- The insert basket must immobilize eight handles of the laparoscopic instruments.
- The insert basket must fixate eight inserts.
- The insert basket must contain a handle for loading.

11.12 Instructions

A number of cognition errors were observed during the concept evaluation. Additional guidance was needed for the nurses to correctly load the instruments. Therefore, instructions were added to the lid of the medical washer (figure 77). The symbol shows an outline of where what instruments should be placed. Below the outline of the second basket a symbol can be seen which shows which instruments should be placed in the caps and the different spray jets. The lumens with a diameter of 5-10 mm are placed in the caps which feature one black circle.

The lumens with a diameter of larger than 10 mm are placed on the spray jets which feature two circles and the valves of the trocars are placed around the shorter spray jets which feature three circles.

In the wash chamber the two numbers can be seen. The numbers show the nurses where which baskets should be loaded. The symbols can be laser marked on the stainless steel surfaces using laser annealing. Laser annealing marks the surfaces while maintaining its corrosion resistance (N. Lemieux, 2019).

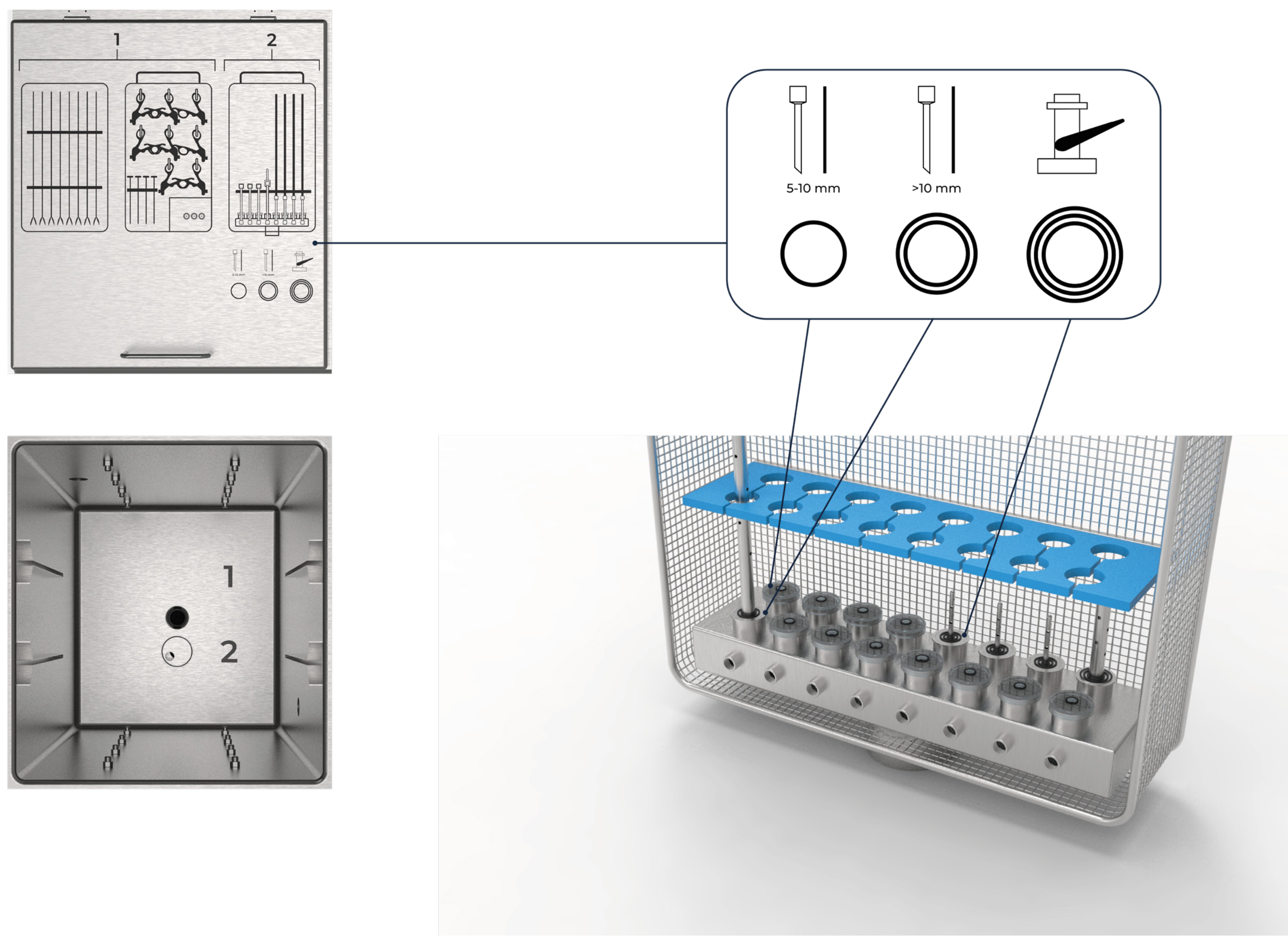


Figure 77: The symbols on and in the medical washer and what they refer to.

Relevant requirements

- The loading system must be able to be correctly loaded by nurses who have no experience loading medical washers.

11.13 Consumables

The design features two consumables: the caps attached to the flush ports and the connector hoses which connect the Luer connectors attached the flush ports of the laparoscopic instruments and the Luer connectors connected to the manifold. The amount of consumables used was minimized as consumables are often hard to acquire in rural areas. These consumables were identified as necessary.

In the first place, the lumens between 5 and 10 mm need to be connected to the manifold flushing the lumens. A flushing system which is contactless inhibits the flow through the lumens (J.M.A. Zuijdweg, 2014). Using a connection made from a less flexible, more durable material could damage the instruments at the point of connection. Especially the insulated sheaths are prone to damage and damage to the insulated sheaths can cause the insides of the patient to be burned during surgery. To ensure the caps are easy to access, different measurements can be taken. A large amount of caps should be added when a hospitals purchases the medical washer. Furthermore, the caps should be easily obtainable. The silicone rubber caps can be ordered form many different suppliers and cost 0.30$ per piece (alibaba.com, n.d.). Lastly, a replacement for the caps could be made by using materials present in the reprocessing area (figure 78).

In the second place, the flush ports of the instruments need to be flushed. This is done by Luer connectors which attach to the manifold and the flush ports of the instruments. The connector hose forms the connection between the Luer connectors. The hose needs to be flexible to allow the connection of instruments of different sizes. Again, a large amount of hoses should be delivered when the medical washer is purchased, the hoses are also widely available by suppliers. Lastly, the hoses could be replaced by devising hoses which are locally available.

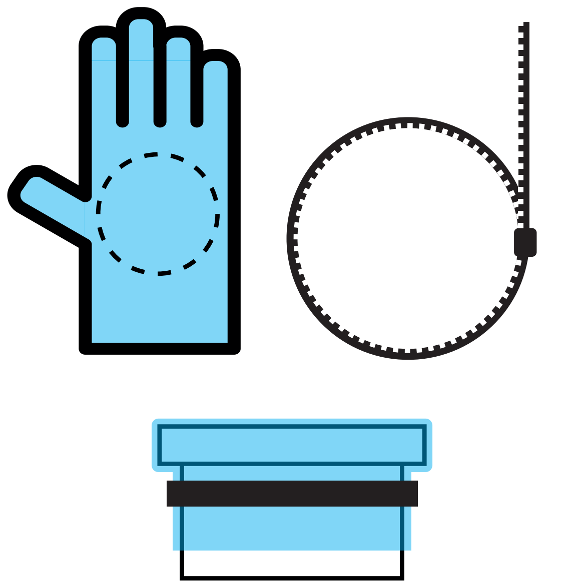


Figure 78: A visual of how the caps could be replaced using surgical gloves and tie wraps.

Relevant requirements

- **The amount of consumables used in the medical washer must be minimized and the consumables used must be easily obtainable online.**

12 Discussion

The design and development of a medical washer for laparoscopic instruments, with a focus on rural India, has been deemed crucial for maintaining the safety and effectiveness of laparoscopy in areas where access to proper cleaning equipment may be limited. In this discussion section the design goals that have guided the development of the medical washer will be explored, with specific emphasis on its suitability for use in rural healthcare settings. Furthermore, the requirements set will be reflected on. The achieved TRLs will be compared to the envisioned TRLs. Moreover, the added value of the medical washer will be discussed. Finally, recommendations for future improvements and considerations for further development of the medical washer will be provided.

12.1 Design goal

In this section the design goal defined, is evaluated. The design goal of this project was defined as:

The **design** of a **concept of a medical washer** that **supports and protects the nurses in hospitals** in **rural India** during their tasks in between surgeries by **cleaning one set of laparoscopic instruments** while using **little resources**.

In figure 79 an overview is given of how the design goal is achieved through the design of the medical washer.

Cleaning

Instruments should be clean when fully visually inspected. There should be no gross soil present on the instruments after the cleaning stage. This would ensure the instruments can be properly sterilized or high-level disinfected without residual soil fixating on the instruments.

The design of the cleaning process for instruments includes several distinct phases and uses different strategies to clean the different geometries.

The outer surfaces of the instruments are first pre-rinsed to remove any loose debris. Next, the complex geometries of the instruments are subjected to ultrasonic cleaning to further remove any remaining dirt or contaminants. Following, all outer geometries are spray washed. Finally, the outer surfaces of the instruments are rinsed a second time to remove any detergent remaining on the surfaces (figure 80).

In addition to cleaning the outer surfaces of the instruments, the lumens of the instruments are flushed using a two-phase flow created by a venturi. To ensure all lumens are properly flushed, the flow through the lumens is alternated.

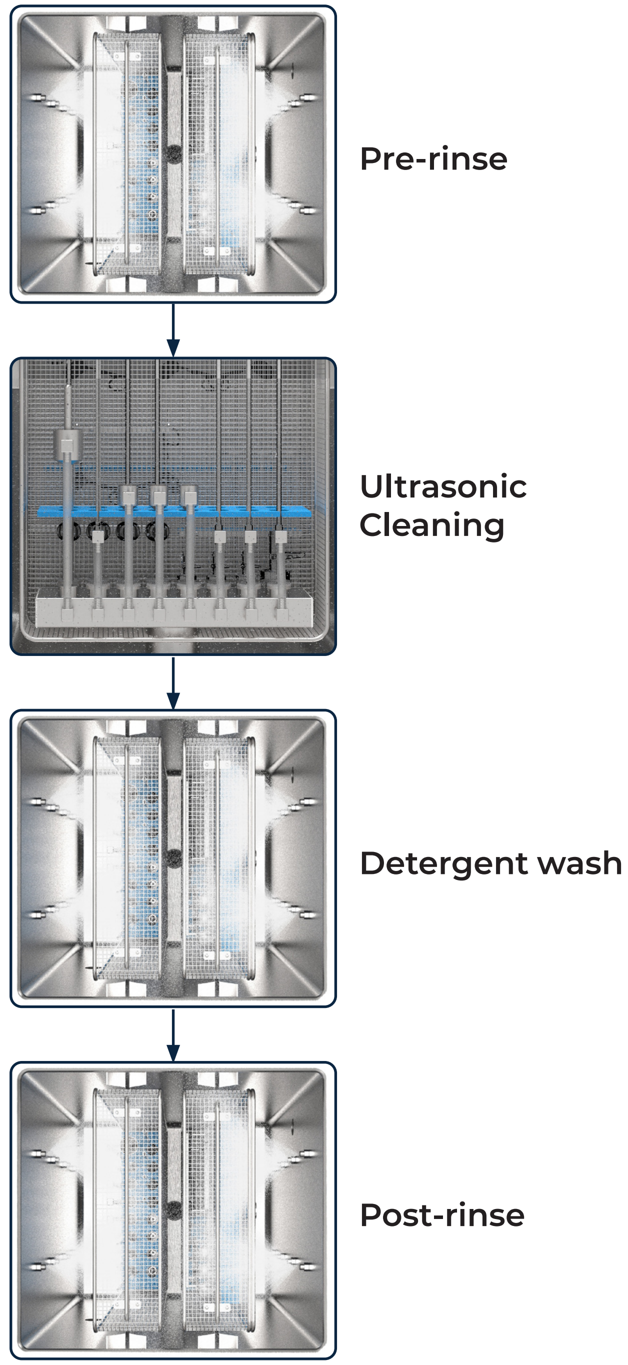


Figure 80: The different cleaning phases of the medical washer.

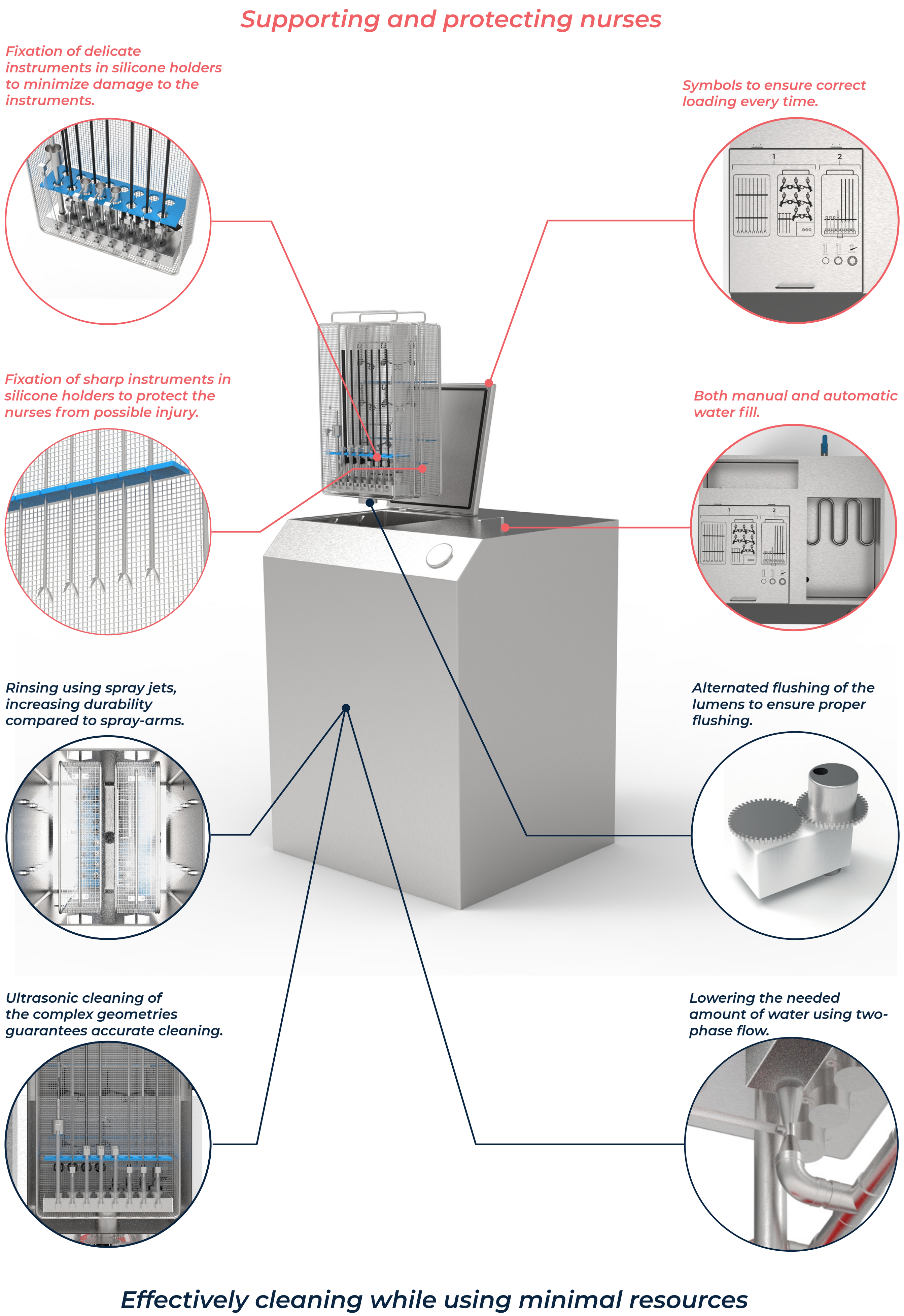


Figure 79: An overview of how the medical washer has achieved the design goal.

Supporting

The medical washer supports the nurses by alleviating them from one of the tasks they have to perform in between surgeries. The medical washer should reduce the amount of time spent on cleaning by the nurses.

Firstly, the medical washer supports the nurses through a loading system which can be loaded by nurses with limited training through instructions on the medical washer. Secondly, to ensure comfortable loading and unloading the baskets can be carried with two hands and the height of the medical washer is adjusted to the height of the Indian nurses. Thirdly, to alleviate the time-pressure experienced by the nurses the loading system can be loaded and unloaded within five minutes.

Protecting

The medical washer protects the nurses by shielding them from harmful pathogens which could cause possible morbidity.

The medical washer protects the nurses in multiple ways. Firstly, the medical washer reduces the amount of physical contact between the contaminated instruments and the nurses, compared to manual cleaning, thus decreasing the risk of possible morbidity due to the instruments. Secondly, the sharp components of the instruments are fixated to prevent the nurses from injury during loading and unloading (figure 81). Thirdly, the medical washer is sealed and the drain of the medical washer is automated to protect the nurses from aerosolized pathogens.

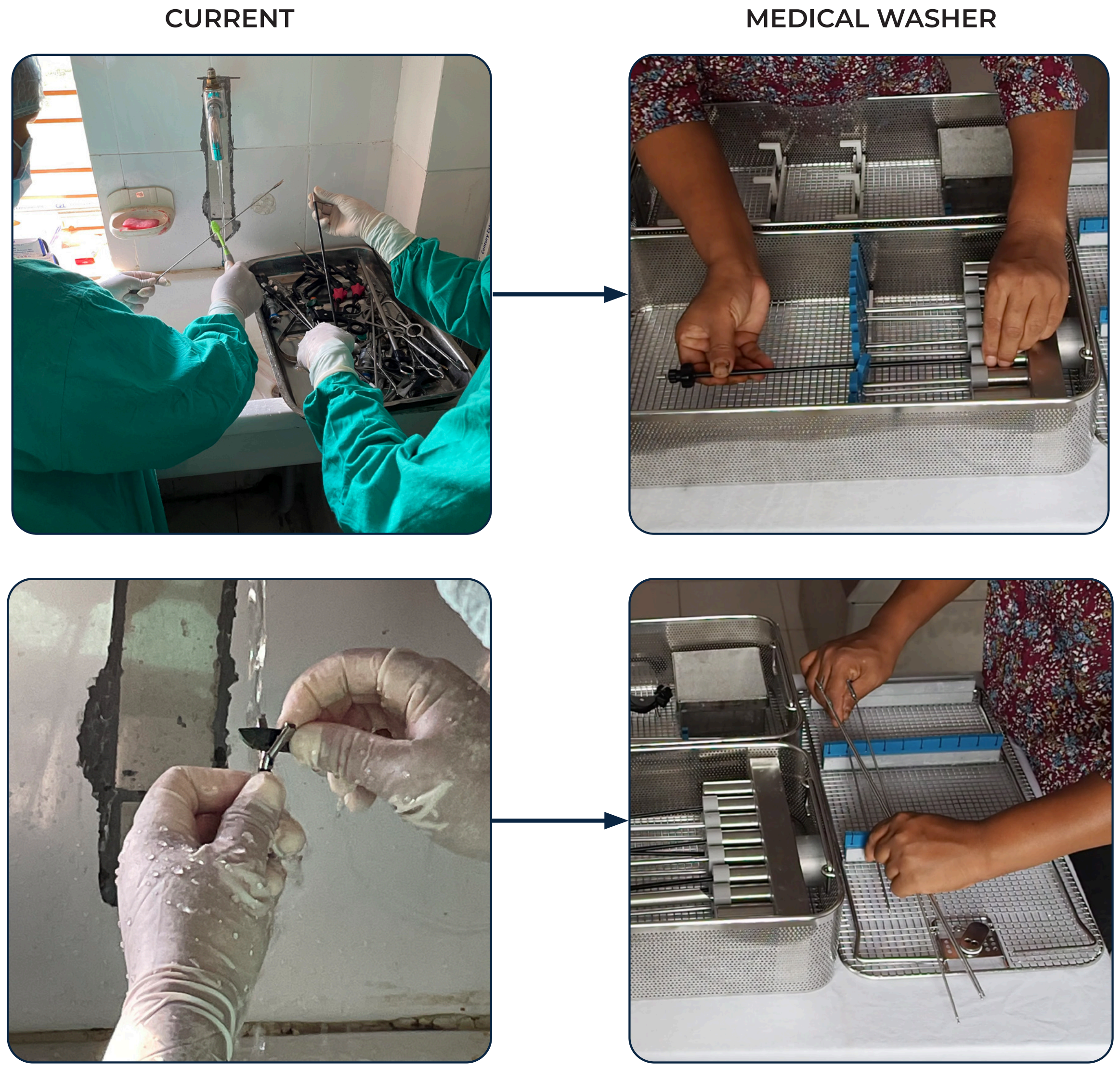


Figure 81: Comparison of the current physical interaction with the laparoscopic instruments compared to the physical interaction using the medical washer.

Little resources

The medical washer uses little resources so the washer can be used without creating a financial burden on the hospital and patient.

To limit the financial burden on the hospitals and patients effective cleaning strategies were chosen to clean the laparoscopic instruments while limiting water and power usage and the complexity of the system was minimized while ensuring the durability of the system.

To limit the amount of water and power used, firstly, ultrasonic cleaning is used to clean the complex geometries, while the regular geometries are cleaned using spray jets.
Secondly, the water used is recirculated through the system by the pump.
Thirdly, two-phase flow can flush lumens more effectively compared to continuous flow, decreasing the amount of water necessary to clean the lumens. The pulsed flow created by the mechanism alternating the flow further decreases the amount of water necessary to clean the lumens.
In table 7 different specifications can be seen for the different reprocessing journeys. As can be seen SamarthClean uses half of the water used in HICs and 5 times less power to clean the laparoscopic instruments.

To minimize the complexity of the system while ensuring the durability of the system, the lumens are placed vertically to allow natural draining and drying.
Moreover, the flow in the lumens is alternated to allow proper flushing of the lumens while lowering the needed flow rate by the pump. Furthermore, the moving elements in the wash chamber were minimized by replacing the conventional spray-arm by spray jets and by minimizing the moving elements of the mechanism alternating flow to one.
In addition, the water from the basins to the wash chamber and from the wash chamber to the drain can flow naturally without the need of a pump.
Also, the amount of consumables is minimized.
Lastly, the medical washer can increase the lifetime of the costly laparoscopic instruments as the current reprocessing method causes damage to the instruments (figure 81).

	Rural Indian hospitals[1]	HIC hospitals[2]	SamarthClean
			
Water use (L)	45	210	96
Flow rate (L/min)	NA	625	100
Pump power (W)	NA	4000	550
Ultrasonic power (W)	NA	1200	800

Table 7: A comparison of the specifications of the different cleaning methods. 1: The water use was estimated by opening the faucet at a comparative flow rate and calculating the water use for 30 minutes of cleaning. 2: the water use was determined by combining the water use of an ultrasonic cleaner and washer-disinfector (Belimed, n.d.) (Pommee Machines & Equipment B.V., n.d.).

12.2 Requirements

Below a short overview of the requirements and whether they have been met. In Appendix 3 an evaluation of the full list of requirements can be seen.

N0	Requirements	
	Functional requirements	
F1	After the medical washer is done cleaning, the instruments must be clean when visually inspected.	?
F2	The medical washer must clean 16 lumens, 8 handles, 8 obturators, 8 inserts and small components	✓
F3	The medical washer must flush the lumens of the laparoscopic instruments.	✓
F4	The flow must be alternated between lumens to guarantee flow through every lumen.	✓
F5	The instruments containing sharp edges must be fixated.	✓
F6	the medical washer must be sealed.	✓
F7	The medical washer must clean the instruments in 15 minutes.	?
F8	The medical washer must use less water than 180 L of water per cycle.	✓
F9	Water must be filtered before it is used in the medical washer.	N/A
F10	The complex geometries of the laparoscopic instruments must be accurately cleaned.	✓
	Usability requirements	
U1	The medical washer must be loaded in less than 5 minutes.	✓
U2	The loading system must be able to be correctly loaded by nurses who have no experience loading medical washers.	?
U3	The medical washer must be adaptable to local languages.	N/A
U4	The ground area of the medical washer must not take up more than 1 m x 1 m.	✓
U5	The medical washer must be able to be filled with water automatically as well as manually.	✓
U6	The medical washer must take into account the height of the average Indian female.	✓
	Context requirements	
C1	The design of the medical washer must minimize the use of consumables. The consumables used must be easily replaceable.	✓
C2	The automatic washer must be easily repairable with locally available and affordable parts.	?
C3	The medical washer must not depend on frequent maintenance.	✓
C4	The automatic washer must operate in many different climates.	?
C5	The price of the medical washer must be less than 50000 rupees (580 euro).	?
C6	The medical washer must be easily cleanable.	✓

✓ Requirement met
? Needs testing
N/A Requirement not met

Functional requirements
The functional requirements F1, F7 and F9 have not been met. A cleaning system was designed, however, it has not been experimentally validated. Therefore, it was not possible to assess whether the instruments are clean when visually inspected within a time frame of 15 minutes.
Furthermore, a system filtering the water before it is used in the medical washer has not been integrated in the current design of the medical washer.

Usability requirements
Usability requirement U2 has not been met. The usability test In India showed the nurses performed a number of use errors. Therefore, instructions for loading were added to the medical washer. However, further testing is required to determine whether requirement U2 is met due to the added instructions.
Usability requirement U3 was not met as the interface of the medical washer was outside of the scope of the project.

Context requirements
To determine whether the medical washer is locally repairable (requirement C2), further development and testing is necessary. Key components like the ultrasonic transducers, the spray jets and the recirculation pump of the medical washer are widely available online. However, the tools locally available for repair and the experience level of the technicians has not been assessed yet.

The housing is designed to protect the components for different climates (requirement C4). However, further testing is required to assess whether the medical washer can operate in different climates.
During the development no cost estimation has been performed due to time constraints (requirement C5). To assess whether it is feasible that the medical washer can be manufactured for less than 580 Euro the other sub-systems must be designed and a cost estimation must be done.

12.3 Added value

During the concept evaluation of the medical washer, its desirability was examined through interviews with medical personnel. The results of these interviews revealed that all participants perceived the medical washer as having advantages in terms of improving the cleaning process, increasing safety for both patients and personnel, and reducing damage to laparoscopic instruments. The most frequently cited advantage was the decrease in time required for instrument cleaning, which would allow nurses to allocate more time to other tasks or take rest periods between surgeries. In figure 82 the reprocessing journey in HIC hospitals, the current reprocessing journey in the rural Indian hospitals and the new reprocessing journey including the medical washer can be seen. SamarthClean can integrate the missing ultrasonic cleaning and washing step in the rural Indian hospital's reprocessing cycle.

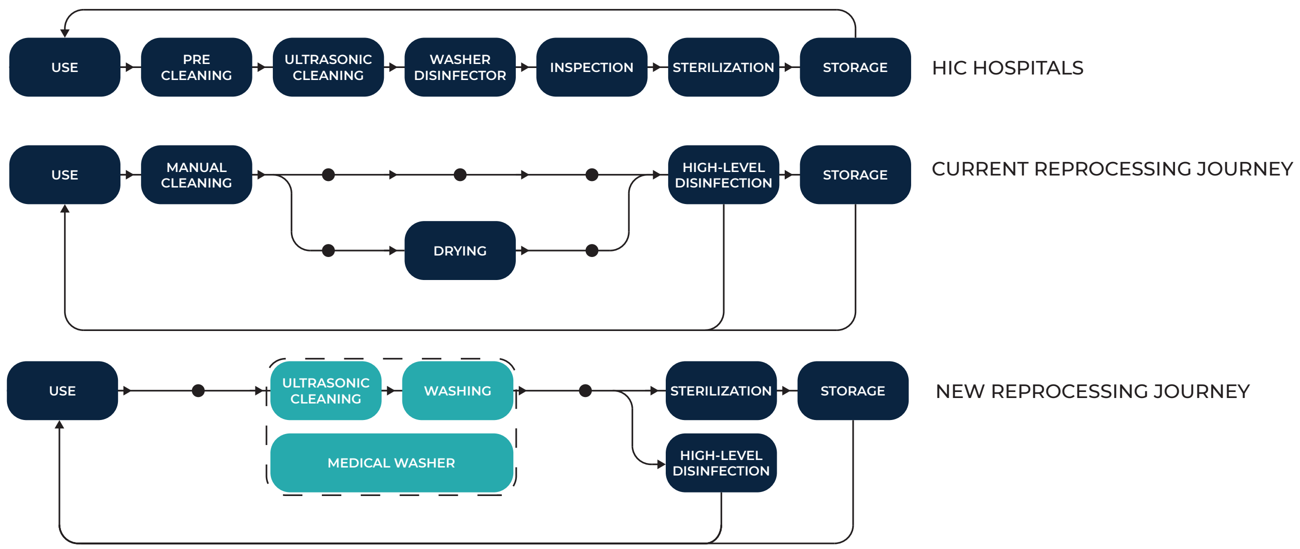


Figure 82: A comparison of the different reprocessing journeys.

12.4 TRLs

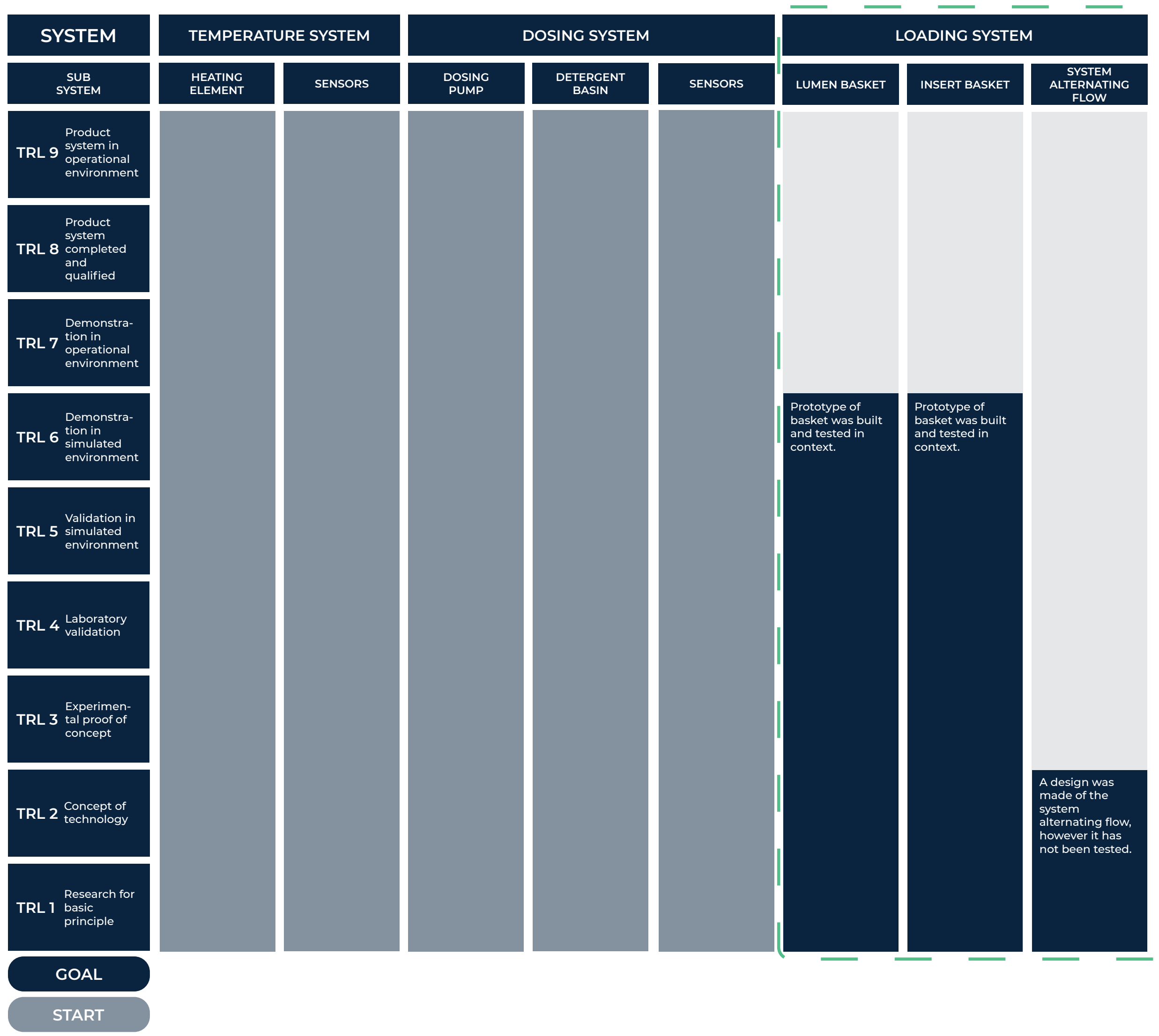


Figure 83: The TRLs that have been achieved during the project.

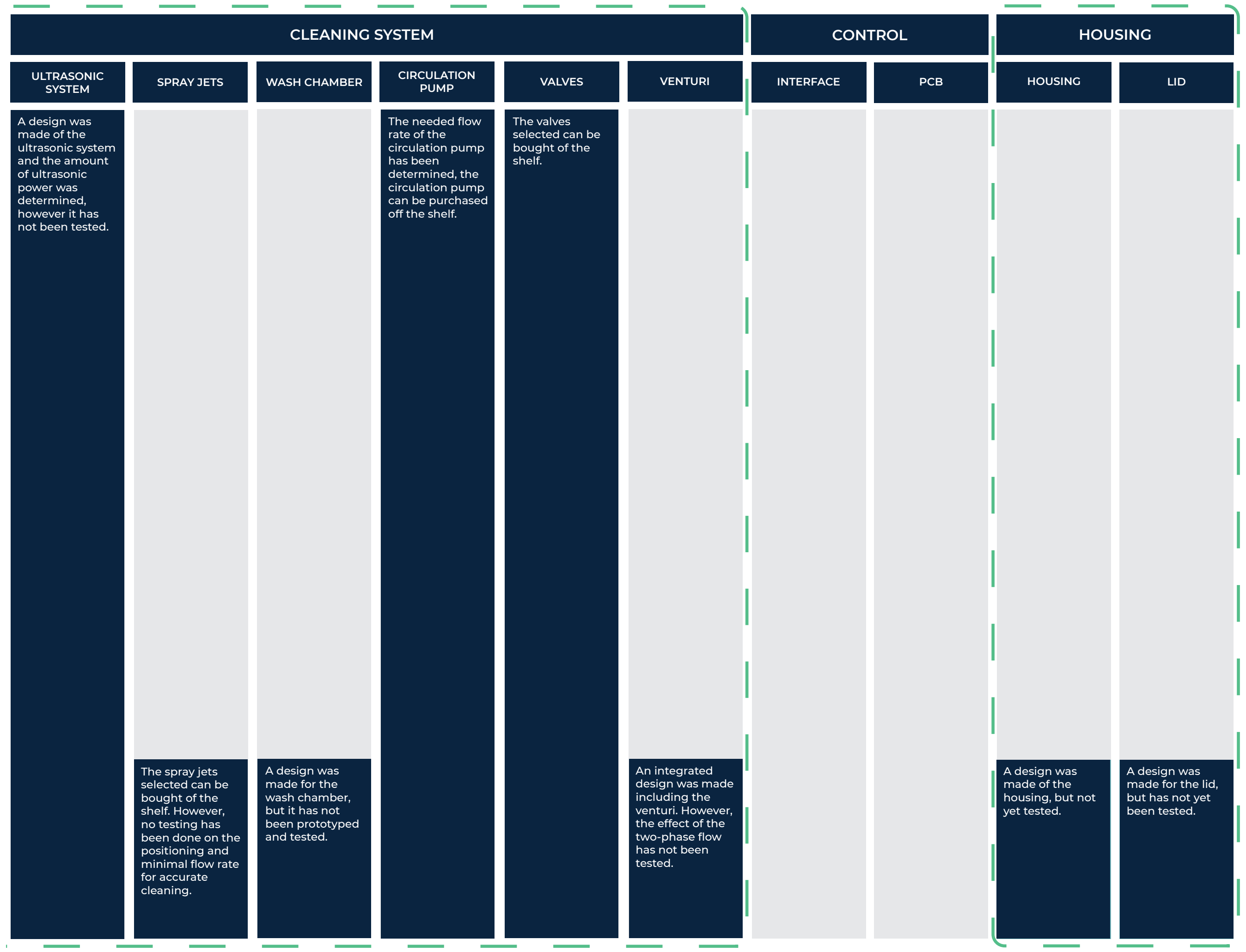
In figure 83 the TRLs that have been achieved at the end of the project can be seen.

Loading system
The loading mechanism consisting of the two baskets has been tested in context with the nurses. During the tests some nurses were able to load the instruments and some were not. Therefore, further testing must be done with the increased guidance to ensure all nurses can load the system correctly every time. A design was made for the system alternating the flow, however, it has not been tested to validate whether the clogged lumens are flushed properly due to the system.

Cleaning system
A design of the cleaning system was made. The ultrasonic transducers and ultrasonic generator as well as the circulation pump, spray jets and valves can be purchased off the shelf. The other components of the cleaning system must be prototyped.

Housing
A design was made for the housing, however it has not been tested.

Evaluation of the development of the sub-systems
Comparing the development of the sub-systems with the intended development the goal of the project was to develop the baskets of the loading system to TRL 6 which was achieved. The intended development for the mechanism, alternating flow, the cleaning system, and the housing was TRL 3. A design for these systems was made, however, it was not prototyped and tested so the final TRL for these systems is TRL 2.



12.5 Recommendations

Cleaning system

A concept of the cleaning system has been developed, but has yet to be experimentally validated. In order to further develop and test the concept, several steps should be taken. Firstly, the various cleaning phases should be subject to examination in order to determine the degree to which instruments are rendered visually clean following a cleaning cycle. Such experiments should validate the needed:

- Ultrasonic power
- Flow rate, pressure and power of the circulation pump
- Water

Moreover, an experimental comparison should be made between the water usage of the proposed cleaning system and that of the current manual cleaning method.

Furthermore, feasibility studies should be conducted to establish whether a cleaning time of 15 minutes is realistically achievable.

Lastly, a water filtering systems must be integrated into the design of th cleaning system to protect the medical washer from the high ion levels in the water.

Loading system

To ensure the loading system can be used without extensive training, additional testing should be done with the new instructions integrated into the loading system.

The mechanism alternating flow should be prototyped and tested. Alternating flow is of large importance as it can flush the lumens without requiring large amounts of water.

During the concept evaluation participants mentioned that the medical should also load larger instruments like clip appliers and retractors. Therefore, a new iteration of the medical washer should integrate the possibility of loading larger MIS instruments.

Housing

The housing should protect the nurses from harmful pathogens. Therefore, the sealing on the housing must be evaluated to ensure no pathogens escape while the instruments are cleaned.

In addition, the housing must tested to ensure the components inside are protected from the different climates in India.

The medical washer

Cost is a major determinant of healthcare provision and accessibility in both hospitals and for patients in India. Given this, it is essential to conduct research on the cost of the medical washer and assess its feasibility for rural hospitals in India. A method to determine its value to the Indian hospitals would be to assess the initial cost of the medical washer as well as how many disability-adjusted life years (DALYs) can be averted by implementing the medical washer (Dawkins et al., 2022). Such a study could indicate whether the medical washer would be more cost-effective for the patient in the long run. Such research is of paramount importance in order to evaluate the potential impact of this technology on healthcare facilities and to identify potential barriers to its widespread adoption.

The medical washer contains complex technology that comprises various systems that require further research and development. The control system, the temperature system and the dosing system must be further developed.

To protect the nurses from the fumes of the glutaraldehyde and to further decrease the amount of contact between the nurses and the contaminated laparoscopic instruments, the medical washer should also high-level disinfect the instruments after a cleaning cycle.

To ensure the medical washer can be locally repaired and maintained an indication must be made of the local availability of the components. Furthermore, close collaboration with local repairmen which are familiar with similar machinery is advised, to assess their experience and their ability to repair the machine. If the process requires specialized knowledge eventual redesigns must be made.

Rural hospitals in India

The most essential of these recommendations is to increase the amount of training and awareness for rural Indian healthcare workers on the topic of reprocessing. As can be seen in figure 68 some steps of the reprocessing cycles can be automated. However, steps like the inspection of the cleanliness of the instrument can not. Therefore, it is important that training programs should be developed that are specifically tailored to the context of rural hospitals and are easily accessible to nurses and other healthcare personnel. These training programs should provide instruction on effective and safe cleaning and disinfection practices, as well as the proper use and maintenance of the medical washer and other reprocessing equipment.

Application for HIC hospitals

In the CSSDs in HIC hospitals large quantities of laparoscopic instruments are cleaned simultaneously. The focus of SamarthClean is to clean one set of laparoscopic instruments as the inventory in rural Indian hospitals is much smaller. Therefore, the medical washer itself does not fit the context of the HIC hospitals. However, multiple components of SamarthClean are relevant for improving HIC washer-disinfectors as lowering water usage, power usage and reprocessing time is desirable in any context. Improper flushing is a problem which also occurs in the current washer-disinfectors. A mechanism alternating flow can improve the effectiveness of cleaning of these machines. Furthermore, using two-phase flow can lower the water usage while flushing the lumens. Lastly, combining the functions of an ultrasonic cleaner and a washer-disinfector can further decrease the amount of physical contact between the CSSD personnel and the contaminated instruments and lower the time needed for the reprocessing cycle.

13 Conclusion

In conclusion, SamarthClean, the medical washer for laparoscopic instruments for the context of rural India has the potential to significantly improve current reprocessing practices. By automating the cleaning process, the medical washer reduces the risk of human error and ensures that instruments are thoroughly cleaned. The inclusion of a loading system which can be used without extensive training ensures the system can be used safely and properly by all health workers. The cleaning system in the medical washer further adds value by increasing cleaning efficiency and reducing resource usage. Additionally, the reduction in cleaning time would allow nurses to allocate more time to other tasks or take rest periods between surgeries. Overall, the adoption of the medical washer in rural Indian hospitals can help to improve the quality of reprocessing and increase patient safety while reducing the risk of antimicrobial resistance worldwide.

References

AA Medical Store. (n.d.). General Laparoscopic Complete Instrument Set. https://aamedicalstore.com/products/general-laparoscopic-complete-instrument-set

Agha, R., & Muir, G. (2003). Does laparoscopic surgery spell the end of the open surgeon? JRSM, 96(11), 544–546. https://doi.org/10.1258/jrsm.96.11.544

Alfa-Wali, M., & Osaghae, S. (2017b). Practice, training and safety of laparoscopic surgery in low and middle-income countries. World Journal of Gastrointestinal Surgery, 9(1), 13. https://doi.org/10.4240/wjgs.v9.i1.13

Alfa, M. J. (2019). Medical instrument reprocessing: current issues with cleaning and cleaning monitoring. American Journal of Infection Control, 47, A10–A16. https://doi.org/10.1016/j.ajic.2019.02.029

Alibaba.com. (n.d.). 'Factory Custom Silicone Rubber Parts Medical Rubber Stopper For Medical Use - Buy Oem Medical Silicone Sealing Products,Custom Silicone Parts Without Burr And Burr,Medical Silicone Products Product on Alibaba.com.' https://www.alibaba.com/product-detail/Factory-Custom-Silicone-Rubber-Parts-Medical_1600579283718.html?spm=a2700.galleryofferlist.normal_offer.d_title.1e0149f6vL1Ak0&s=p

Alibaba.com. (n.d.). 'Hot Selling 1/4 304SS Solid Cone Spray Nozzle, Full Cone Nozzle, Full Jet Spray Nozzle' https://www.alibaba.com/product-detail/Hot-Selling-1-4-304SS-Solid_62095303748.html?spm=a2700.galleryofferlist.normal_offer.d_title.1521751a08zFHm

AMSCO 7052HP Washer Disinfector | STERIS. (n.d.). Steris. https://www.steris.com/healthcare/products/washing-and-decontamination-systems/washer-disinfectors/amsco-7052-hp-washer-disinfector

Belimed Infection Control. (n.d.) Product Specification_WD 200 Washer Disinfector

Blake, J. R., & Gibson, D. C. (1987). Cavitation bubbles near boundaries. Annual review of fluid mechanics, 19(1), 99-123.

Blel, W., Legentilhomme, P., Le Gentil- Lelièvre, C., Faille, C., Legrand, J., & Bénézech, T. (2010). Cleanability study of complex geometries: Interaction between B. cereus spores and the different flow eddies scales. Biochemical Engineering Journal, 49(1), 40–51. https://doi.org/10.1016/j.bej.2009.11.009

Cai, S., Phinney, D. M., Heldman, D. R., & Snyder, A. B. (2020). All Treatment Parameters Affect Environmental Surface Sanitation Efficacy, but Their Relative Importance Depends on the Microbial Target. Applied and Environmental Microbiology, 87(1), 1–17. https://doi.org/10.1128/AEM.01748-20

Carpenter, J., Badve, M., Rajoriya, S., George, S., Saharan, V. K., & Pandit, A. B. (2017). Hydrodynamic cavitation: an emerging technology for the intensification of various chemical and physical processes in a chemical process industry. Reviews in Chemical Engineering, 33(5). https://doi.org/10.1515/revce-2016-0032

Dawkins, B., Aruparayil, N., Ensor, T., Gnanaraj, J., Brown, J., Jayne, D., & Shinkins, B. (2022). Cost-effectiveness of gasless laparoscopy as a means to increase provision of minimally invasive surgery for abdominal conditions in rural North-East India. PLOS ONE, 17(8), e0271559. https://doi.org/10.1371/journal.pone.0271559

Fryer, P. J., & Asteriadou, K. (2009). A prototype cleaning map: A classification of industrial cleaning processes. TRENDS IN FOOD SCIENCE & TECHNOLOGY, 20(6–7), 255–262. https://doi.org/10.1016/j.tifs.2009.03.005

Gillham, C., Fryer, P., Hasting, A., & Wilson, D. (2000). Enhanced cleaning of whey protein soils using pulsed flows. Journal of Food Engineering, 46(3), 199–209. https://doi.org/10.1016/s0260-8774(00)00083-2

Goode, K. R., Asteriadou, K., Robbins, P. T., & Fryer, P. J. (2013). Fouling and Cleaning Studies in the Food and Beverage Industry Classified by Cleaning Type. Comprehensive Reviews in Food Science and Food Safety, 12(2), 121–143. https://doi.org/10.1111/1541-4337.12000

Ghassemi, H., & Fasih, H. F. (2011). Application of small size cavitating venturi as flow controller and flow meter. Flow Measurement and Instrumentation, 22(5), 406–412. https://doi.org/10.1016/j.flowmeasinst.2011.05.001

Humphries, C., Jaganathan, S., Panniyammakal, J., Singh, S., Dorairaj, P., Price, M., Gill, P., Greenfield, S., Lilford, R., & Manaseki-Holland, S. (2020). Investigating discharge communication for chronic disease patients in three hospitals in India. PLOS ONE, 15(4), e0230438. https://doi.org/10.1371/journal.pone.0230438

INGCO Water Pumps Water pump CPM5508. (n.d.). https://www.ingco.com/eg/product/water-pump/CPM5508

International Electrotechnical Commission. (2015). IEC 62366-1: 2015, Medical devices—Part 1: Application of usability

Jaiswal, A. K., & Angeli, F. (2022). Medical Device Innovation at the Base of the Pyramid: General Electrics' India Strategy to Make Healthcare Affordable 1. In Organizing for Sustainable Development (pp. 236-260). Routledge.

Joppa, M., Köhler, H., Kricke, S., Majschak, J. P., Fröhlich, J., & Rüdiger, F. (2019). Simulation of jet cleaning: Diffusion model for swellable soils. Food and Bioproducts Processing, 113, 168– 176.

Kanegsberg, B., & Kanegsberg, E. (Eds.). (2020). Handbook for Critical Cleaning, -2 Volume Set. CRC Press.

Karan, A., Negandhi, H., Hussain, S., Zapata, T., Mairembam, D., de Graeve, H., Buchan, J., & Zodpey, S. (2021). Size, composition and distribution of health workforce in India: why, and where to invest? Human Resources for Health, 19(1). https://doi.org/10.1186/s12960-021-00575-2

Kasthuri, A. (2018). Challenges to healthcare in India-The five A's. Indian journal of community medicine: official publication of Indian Association of Preventive & Social Medicine, 43(3), 141.

Kathare, S. S., Shinde, D. N. D., Ahmed, F., & Ahmed, A. (2019). Comparative study of open versus laparoscopic appendicectomy. Int J Surg Sci, 3(3), 131-6.

Lamminen, M. O., Walker, H. W., & Weavers, L. K. (2004). Mechanisms and factors influencing the ultrasonic cleaning of particle-fouled ceramic membranes. Journal of membrane science, 237(1-2), 213-223.

Laparoscopes - General Surgery - Olympus Medical Systems. (n.d.). Olympus. https://www.olympus-europa.com/medical/en/Products-and-Solutions/Products/General-Surgery/Laparoscopes.html

Lei-Aloha, D. (2022, July 9). Laparoscopic Cholecystectomy. CSTSetup. https://cstsetup.com/laparoscopic-cholecystectomy/

Lei-Aloha, D. (2022b, December 9). Laparoscopic Appendectomy. CSTSetup. https://cstsetup.com/laparoscopic-appendectomy/

Lemieux, N. (2019). “How does laser annealing work?”. https://www.laserax.com/blog/how-does-laser-annealing-work

Nowak, T., Cairós, C., Batyrshin, E., & Mettin, R. (2015, October). Acoustic streaming and bubble translation at a cavitating ultrasonic horn. In AIP Conference Proceedings (Vol. 1685, No. 1, p. 020002). AIP Publishing LLC.

Ohl, C. D., Arora, M., Ikink, R., de Jong, N., Versluis, M., Delius, M., & Lohse, D. (2006). Sonoporation from Jetting Cavitation Bubbles. Biophysical Journal, 91(11), 4285–4295. https://doi.org/10.1529/biophysj.105.075366

Palabiyik, I., Olunloyo, B., Fryer, P. J., & Robbins, P. T. (2014). Flow regimes in the emptying of pipes filled with a Herschel–Bulkley fluid. Chemical Engineering Research and Design, 92(11), 2201–2212. https://doi.org/10.1016/j.cherd.2014.01.001

PathogenCombat. (2011). Factors affecting fouling and cleanability of closed food contact surface. EU Integrated Project PathogenCombat; p, http://www.pathogencombat.com/Publications/~/media/Adtomic/Unique% 20Achievements/Leaflets/Factors%20affecting%20fouling%20and%20cleanability%20of%20closed%20food%20contact%20surface.ashx.

Plesset, M. S., & Prosperetti, A. (1977). Bubble dynamics and cavitation. Annual review of fluid mechanics, 9(1), 145-185.

Pommee Machines & Equipment B.V. (n.d.). TIERRA TECH® ultrasonic cleaner MOT-30 - 30 LITRES. MOT-30. https://www.pommee.nl/webshop/contents/en-uk/p3002_Product_3542.html

Ray, G. G., Chatterjee, L., & Varghese, M. A. (1990). Body dimensions of Indian housewives. Journal of human ergology, 19(1), 31-40.

Reinemann, D. J. (1996). Technical design and assessment of tube equipment using two-phase flow for cleaning and disinfection. Zentralblatt Fur Hygiene Und Umweltmedizin = International Journal of Hygiene and Environmental Medicine, 199(2–4), 355–365. https://pubmed.ncbi.nlm.nih.gov/9353551/

Robertson, D., Gnanaraj, J., Wauben, L., Huijs, J., Samuel, V. M., Dankelman, J., & Horeman-Franse, T. (2021). Assessment of laparoscopic instrument reprocessing in rural India: a mixed methods study. Antimicrobial Resistance & Infection Control, 10(1). https://doi.org/10.1186/s13756-021-00976-x

Rüther, S. (2014). Assistive systems for quality assurance by context-aware user interfaces in health care and production(Doctoral dissertation, Universitätsbibliothek Bielefeld).

Trocar system for laparoscopy. (n.d.). Xion Medical. https://www.xion-medical.com/en/products/instruments/trocar-system-for-laparoscopy

Vasan, A., & Friend, J. (2020). Medical Devices for Low- and Middle-Income Countries: A Review and Directions for Development. Journal of Medical Devices, 14(1). https://doi.org/10.1115/1.4045910

Veress Needle 2mm x 120mm, 5mm. 3-Dmed. https://www.3-dmed.com/product/veress-needle-2mm-x-120mm-5mm/

Verhaagen, B., & Fernández Rivas, D. (2016). Measuring cavitation and its cleaning effect. Ultrasonics Sonochemistry, 29, 619–628. https://doi.org/10.1016/j.ultsonch.2015.03.009

Vyas, N., Manmi, K., Wang, Q., Jadhav, A. J., Barigou, M., Sammons, R. L., Kuehne, S. A., & Walmsley, A. D. (2019). Which Parameters Affect Biofilm Removal with Acoustic Cavitation? A Review. Ultrasound in Medicine & Biology, 45(5), 1044–1055. https://doi.org/10.1016/j.ultrasmedbio.2019.01.002

Wibisono, Y., Cornelissen, E. R., Kemperman, A. J. B., van der Meer, W. G. J., & Nijmeijer, K. (2014). Two-phase flow in membrane processes: A technology with a future. Journal of Membrane Science,

World Health Organization. (2016). Decontamination and reprocessing of medical devices for health-care facilities.

APPENDIX

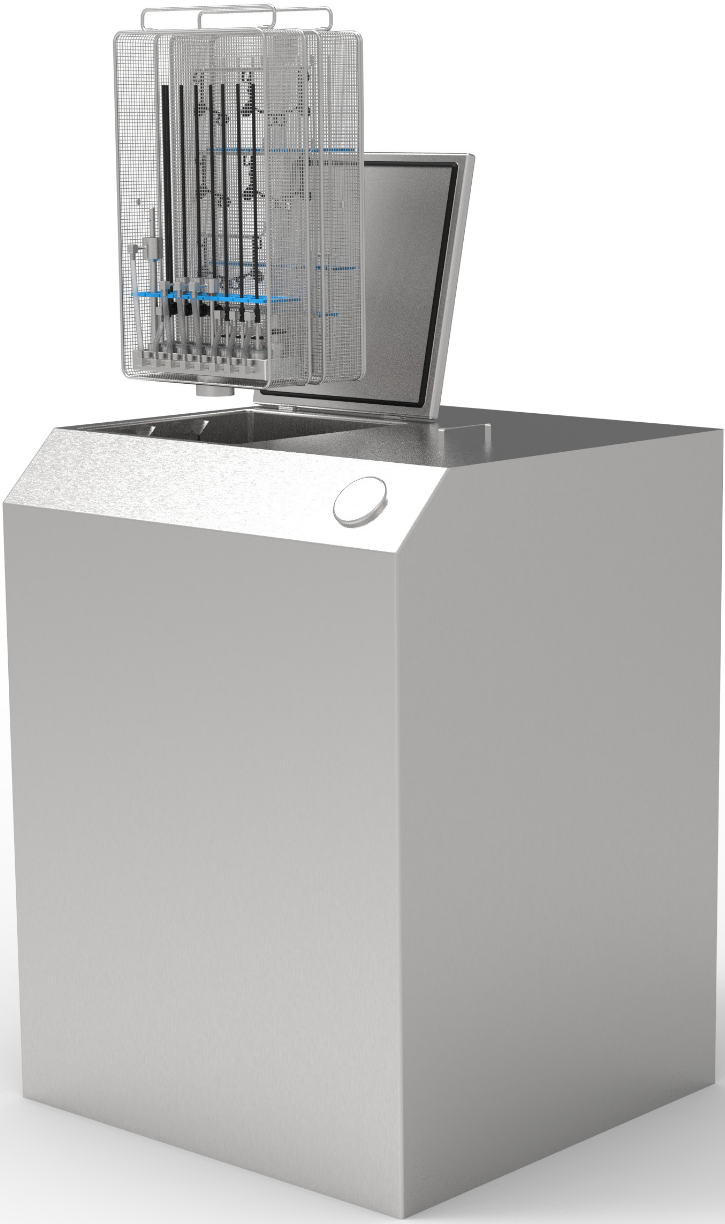


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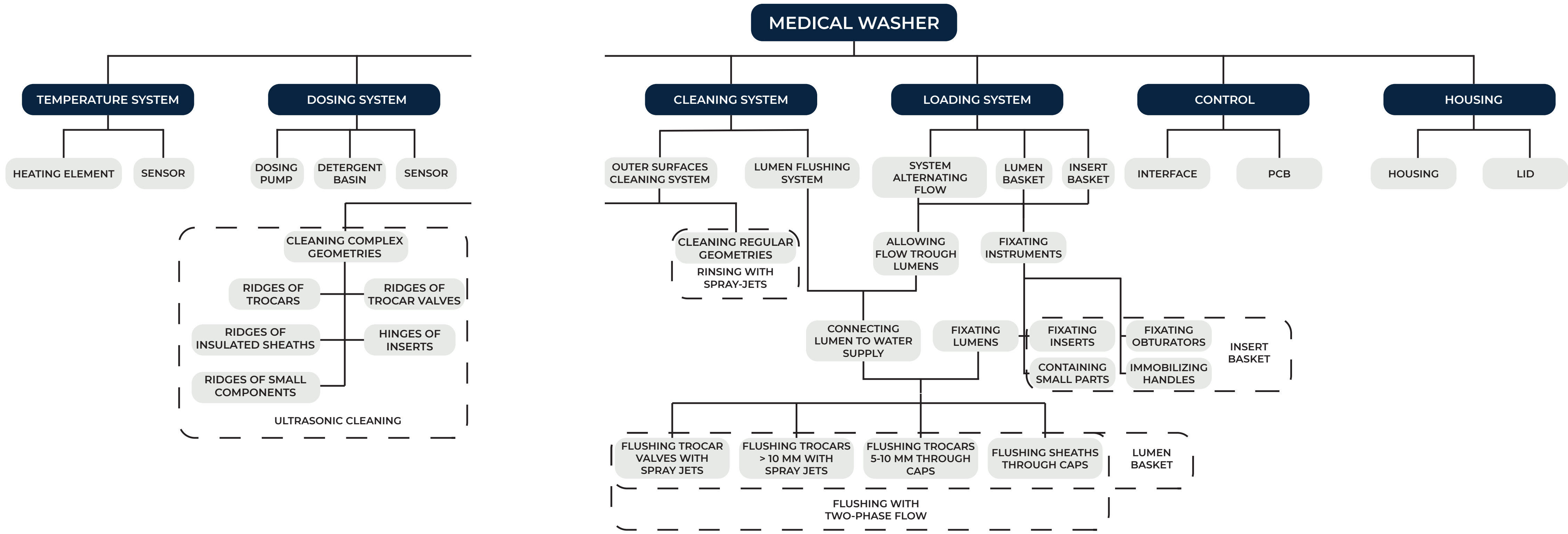
Table of contents

Appendix 1: Function analysis of the medical washer



Appendix 2: Instruments to be cleaned

To determine which instruments need to be cleaned, the disassemblible instruments used in the most commonly performed laparoscopic surgeries in india were identified (figure 4). The most performed laparoscopic surgeries were the laparoscopic cholecystectomy and the laparoscopic appendectomy. In table 1 the lumens used in the surgeries can be seen (D. Lei-Aloha, 2022) (D. Lei-Aloha, 2022b). In table 2 the other components can be seen. In table 3 the total amount of lumens and other components that can be loaded in the medical washer can be seen.

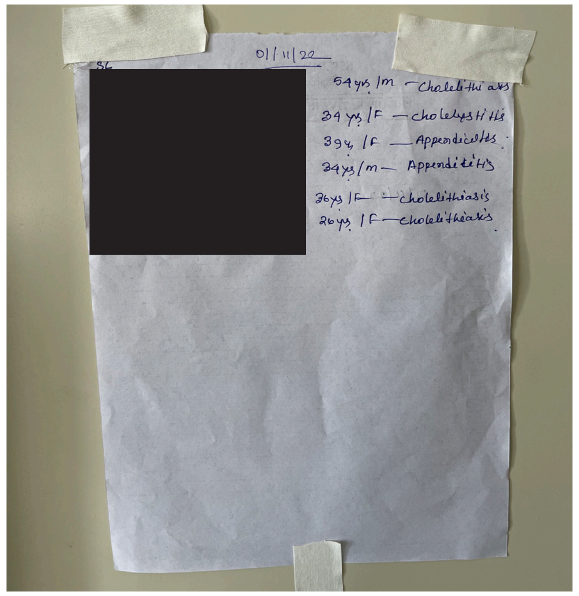


Figure 1: List of surgeries in a hospital in India.

Components	Cholecystectomy	Appendectomy
Trocar sleeve	4	3
Trocar valve	4	3
Insulated lumen	5	6
Suction-irrigation lumen	1	1
Suction-irrigation valve	1	1
Total:	15	14

Table 1: Lumens used during different laparscopic surgeries (D. Lei-Aloha, 2022) (D. Lei-Aloha, 2022b).

Components	Cholecystectomy	Appendectomy
Rubber valve trocar	4	3
Trocar valve	4	3
Insert	5	6
Handle	5	6

Table 2: Other components used during different laparoscopic surgeries (D. Lei-Aloha, 2022) (D. Lei-Aloha, 2022b).

Components	Loading system
Lumen	16
Rubber valve trocar	N/A
Obturator	8
Insert	8
Handle	8

Table 3: Amount of instruments that can be loaded in the medical washer.

Appendix 3: Full list of requirements

Through literature and imperical research the full list of requirements was defined.

Requirement met

Needs testing

Requirement not met

Context specific requirements

- The medical washer must be able to be filled with water manually as well as automatically.
- The ground area of the medical washer must be less than 1 m x 1 m.
- The medical washer must be able to be loaded without extensive training.
- The medical washer must be adaptable to local languages.
- The most frequently replaced parts must be easy to access.
- The medical washer must be able to be locally maintained.
- The medical washer must consist of minimal complexity in its number of parts.
- The medical washer must be loaded within 5 minutes.
- The instruments must not get damaged during the use of the medical washer.
- The medical washer must clean the instruments within 15 minutes.
- The medical washer must use less than 180 liters of water.
- The medical washer must take into account the height of the average Indian female.

Performance requirements

- The lumens must be placed vertically to ensure natural drying.
- All elements of the sinner circle specified cleaning time, temperature, chemical reaction, and mechanical action of the water must be incorporated in the design of the medical washer.
- The flow through the lumens must be alternated to ensure proper flow through every lumen.
- The baskets must fit the sizes of the instruments.
- The pre- and post-rinse must consist of multiple small rinses.
- The complex geometries must be cleaned using ultrasonic cleaning.
- The lumens must be flushed using two-phase flow.
- The flushing mechanism must be separated from the washing chamber.
- After the medical washer is done cleaning, the instruments must be clean when visually inspected.
- The medical washer must flush the lumens of the laparoscopic instruments.
- The medical washer must be sealed to prevent earolization.
- Water must be filtered before it is used in the medical washer.
- The water must be recirculated to minimize the water use.

Component specific requirements:

Basket 1:

- Basket 1 must contain a volume that can be closed off to keep the small parts in one place.
- Basket 1 must contain a silicone holder to fixate four 10 mm obturators and four 5 mm obturators.
- Basket 1 must fixate eight handles of the laparoscopic instruments.
- Basket 1 must contain a silicone holder to fixate eight inserts.
- Basket 1 must contain a handle for loading.

Basket 2:

- The manifold must contain 16 flush ports.
- The manifold must be compartmentalized to facilitate alternating the flow through the lumens.
- The manifold must contain ports for connector hoses.
- The flush ports must be threaded so the amount of spray jets and caps can be changed depending on the set of instruments that is cleaned.
- Four of each spray jet must be available so any configuration of instruments can be cleaned.
- Basket 2 must contain a silicone holder to fixate the lumens.
- The sides of the manifold must be removable so the manifold can be properly cleaned and maintained.
- Basket 2 must contain a handle for loading.

Wash chamber:

- The wash chamber must contain spray nozzles to rinse the laparoscopic instruments.
- The wash chamber must contain an entrance for warm and cold water.
- The wash chamber must contain a drain with a filter.
- The wash chamber must contain a water-tight entrance for the mechanism alternating the flow.
- The wash chamber must contain rails to ease the loading process and fixate the baskets.

Warm water basin:

- The basin must be placed higher than the entrance of the water in the wash chamber so water moves naturally in the chamber.
- The basin containing warm water must contain a heating element.
- The basin containing warm water must contain enough water to submerge all trocars in the wash chamber.
- The wash chamber must contain the numbers of the baskets to show where which basket must be loaded.

Cold water basin:

- The basin must be placed higher than the entrance of the water in the wash chamber so water moves naturally in the chamber.
- The basin containing cold water must contain enough water to remove all gross soil in the pre-rinse phase and detergent in the post-rinse phase.

Ultrasonic cleaning system:

- The ultrasonic cleaning system must contain 100 Watts of ultrasonic power per gallon of water.
- The ultrasonic transducer must be fixated by screws attached to the wash chamber.
- The ultrasonic cleaning system must contain an ultrasonic generator supplying power to the transducers.

Pump:

- The pump must be able to produce a flow rate sufficient to rinse the instruments and flush the lumens simultaneously.
- The medical washer must have a flow rate lower than 625 L/min.

Piping:

- The pipe supplying the water to the alternating flow mechanism must contain a venturi providing two-phase flow.
- A tube must be connected to the venturi to supply air.
- The pipes supplying water to the basins must contain solenoid valves to automatically start and stop the flow of water.
- The drain and water inlet must contain a manual valve.

Drain:

- The drain must be located at the bottom of the system.
- The drain must contain a solenoid valve.

Appendix 4: Interview results

Between the define and discover phase different experts in the field of reprocessing were interviewed to gain insight on reprocessing in LMICs.

Expert in training related to sterilization of medical supplies in LMICs:

Training

- For the success of the implementation of a device in LMICs training and spreading awareness on the risks of SSIs is of large importance.
- Management of hospitals in LMICs often find it unnecessary to spend money on training for reprocessing.

Device

- For the success of a medical device in LMICs, the entire ecosystem must be present, as additional products are usually difficult to obtain.
- Power fluctuations can damage the electronics of the device which is a problem many hospitals deal with. It is therefore important to add surge protection for the electronics.
- The water quality of the water in LMICs can be of a lower quality causing calcification of pipes. It is therefore important to use filtered water when cleaning.
- There is often a lack of funds for maintenance in LMICs, therefore a device should require minimal maintenance to work.

Rural surgeon in India

Requirements for a medical washer

- The instruments should be cleaned within 15 minutes, so surgeries are not delayed.
- A medical washer must be 50000 rupees or less to be affordable for rural hospitals in India.

Ideas for the design of the medical washer

- Ultrasonic cleaning - Cleaning of the laparosocp is very easy so this can still be done manually.
- It would be very advantageous if the washer can disinfect the instruments using cidex.

Description of the rural hospitals

- Laparoscopic instruments are currently cleaned within 10 minutes.
- Very often soaking in cidex is done for less than 20 minutes.
- All the hospitals the surgeon visits depend on a generator which often fails. There always is a back-up generator. The voltage can vary between 140-300 V.
- The water in the hospitals has a high ion count.

Expert in Sterile Medical Devices and Expert in Cleaning and Disinfection of laparoscopic instruments:

Insights on washer-disinfector systems for laparoscopic instruments:

- All the water to the different manifolds arrives from one point.
- There is a large pressure drop between the access point at the coupler and inside the lumen.
- Due to the large amount of branching from the coupler. The flow through different lumens can differ and lumens can be insufficiently flushed.
- At times the right diameter inserts are missing so two lumens are placed in one insert to create a snug fit.
- All unused holes should be closed off, but this is not always done.
- Removable candles are used to fixate the black sheaths.
- Rinsing rods are used to rinse the insides of the trocars.
- The handles and the inserts are cleaned in baskets.

Conclusion

Experts on different topics were interviewed to gain insight on what factors are of large importance when designing a medical washer for the context of hospitals of rural India. Important factors for the success of the medical washer are surge protection, the use of filtered water, minimal need for maintenance, fast cleaning time and lastly, a system which alternates the flow through the manifold to ensure proper through all the lumens.

Appendix 5: Prototypes of the different concepts of the loading system.

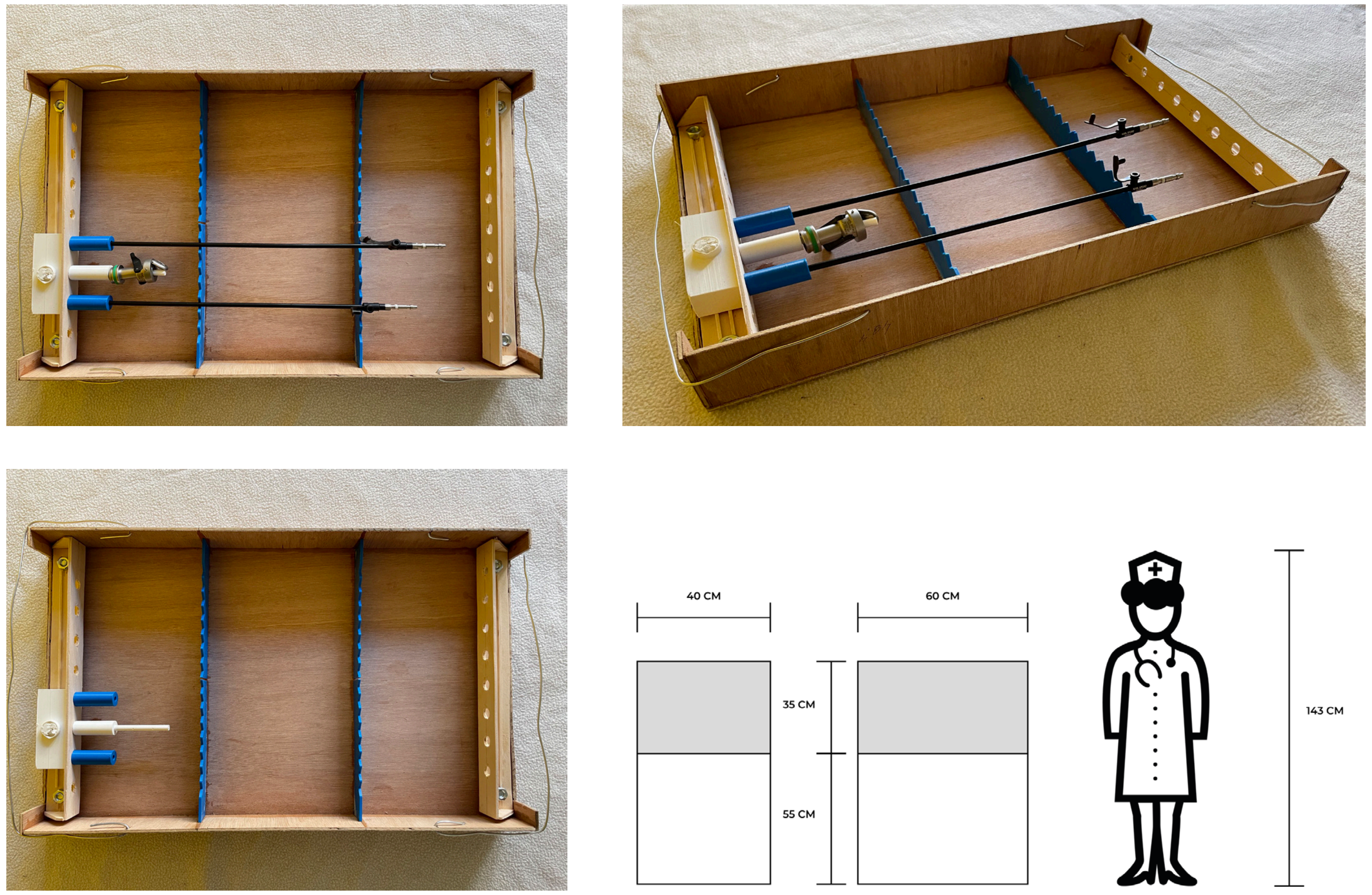


Figure 2: Prototype lumen basket concept 1

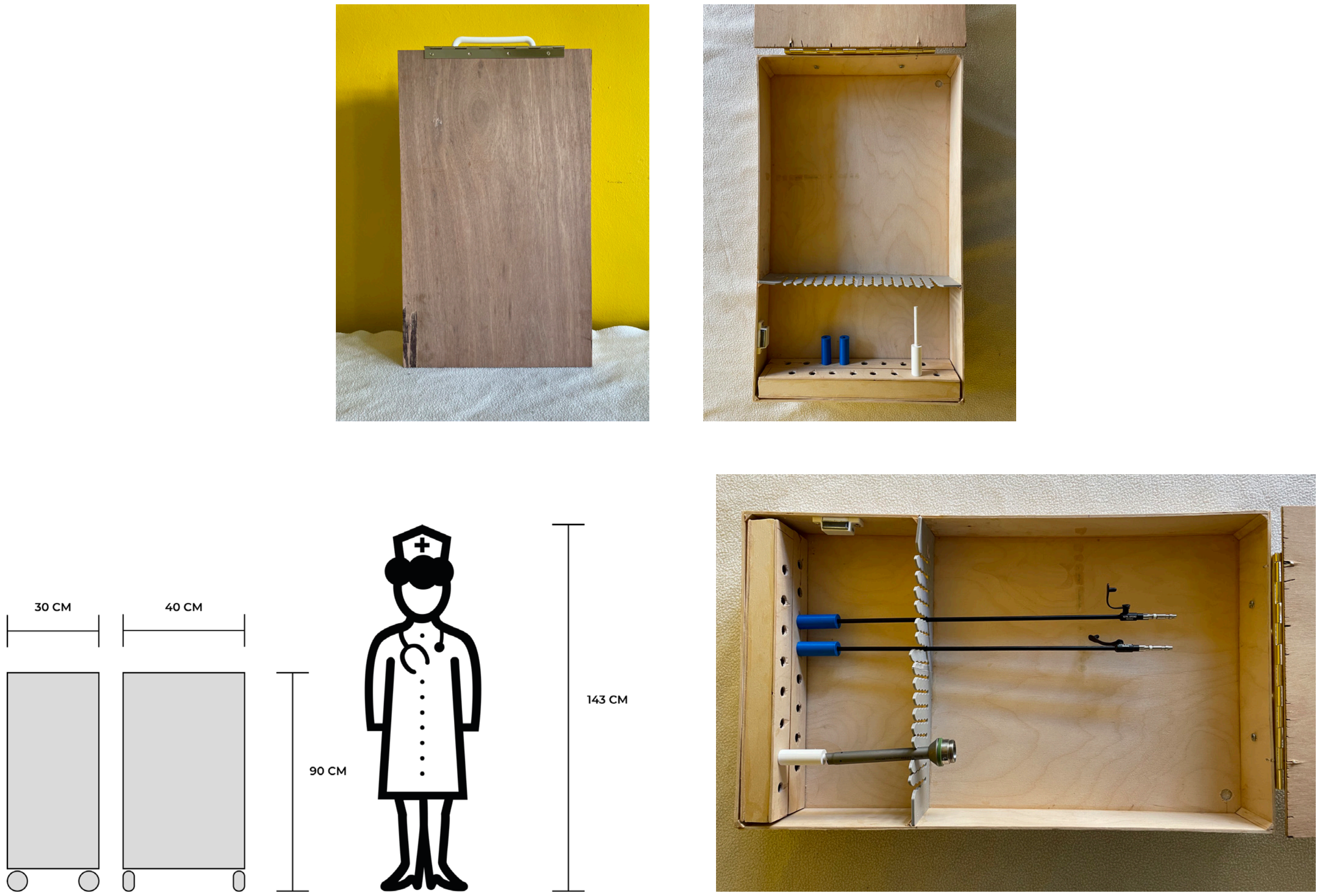


Figure 3: Prototype lumen basket concept 2.

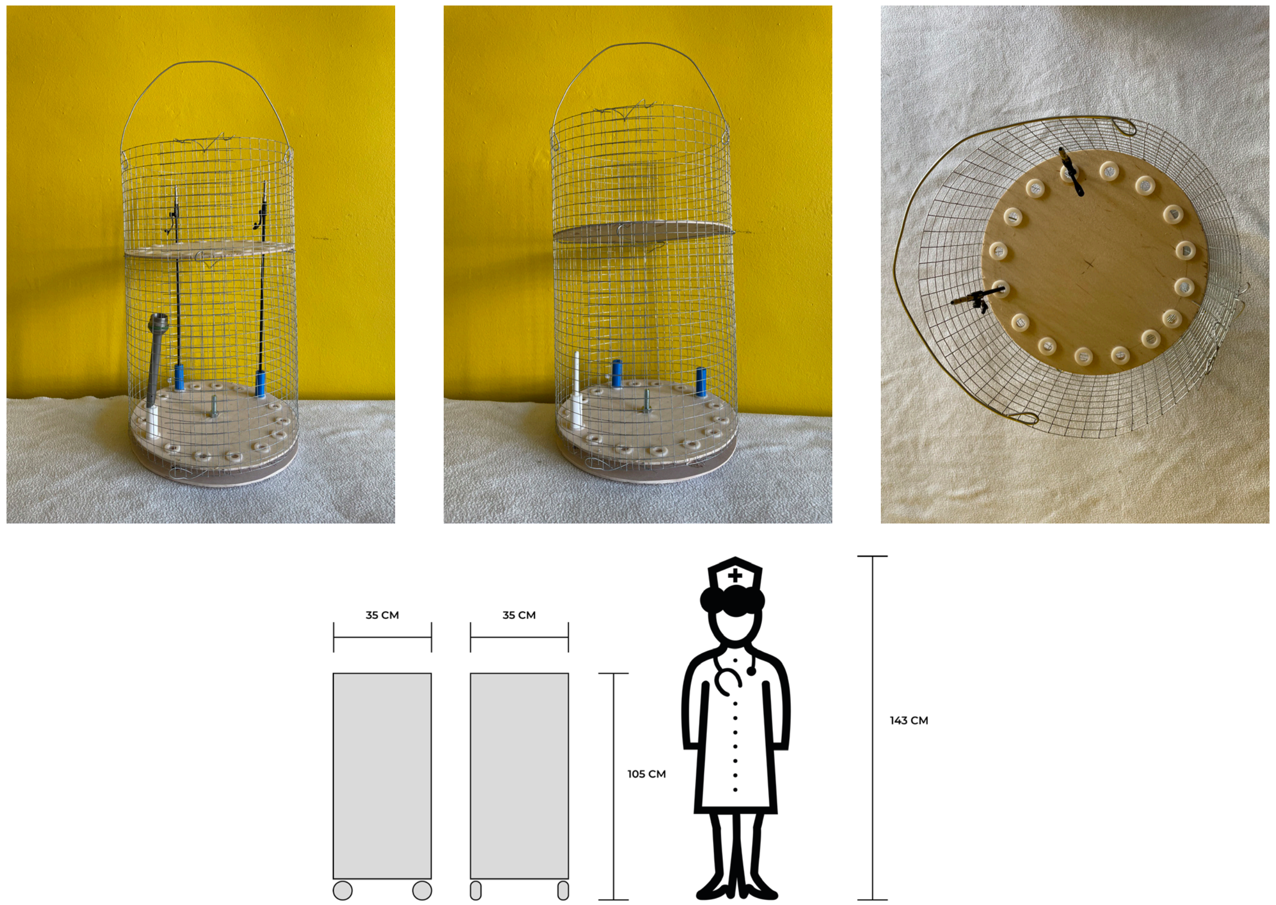


Figure 4: Prototype lumen basket concept 3.

Appendix 6: Expert reviews

Mulitple experts were asked to evaluate the concepts. Vertical loading of lumens was described as advantageous as it causes increased draining. Fixing the handles by stacking could cause the handles to be insufficiently cleaned. Moreover, Compartimentilizing of all the handles could inhibit the water jet from reaching all the surfaces. Therefore, a coat hanger system could improve the method of fixing the handles. To minimize wear of the alternating flushing system the system should be separated from the washing chamber and the system should consist of minimal moving elements

Appendix 7: Risk analysis of the use of the loading system

Tasks	Possible use errors	Possible hazards	Severity	Potential harm	Mitigation
U1. Unloading baskets					
A1. Remove lid from basket					
A2. Load the Obturators in the silicone holders	Trocars are loaded in the silicone holders for obturators.	Insufficiently cleaned instruments	4/5	H1. Possibly fatal infection can be caused in the patient.	The lumens can only be flushed in the manifold indicating their correct location.
A3. Load handles on hooks	Handles fall from hooks	Insufficiently cleaned instruments	4/5	H1. Possibly fatal infection can be caused in the patient.	The arms of the hook are high enough the instruments do not slip off while turning basket 1.
		Damage to instruments	4/5	H2. Damaged instrument can injure patient and nurse.	
		Damage to medical washer	4/5	H3. Damage to the medical washer can cause insufficiently cleaned instruments. These instruments can cause possibly fatal injuries in the patient.	
A4. Load the inserts in the silicone holders	Black sheaths of operative instruments are loaded in the holders	Insufficiently cleaned instruments	4/5	H1. Possibly fatal infection can be caused in the patient.	The lumens can only be flushed in the manifold indicating their correct location.
A5. Load small parts in the small box					
A6. Attach lid on basket					
B1. Load black sheaths in the ports of manifold	Trocar lumens loaded in the ports.	Insufficiently cleaned instruments	4/5	H1. Possibly fatal infection can be caused in the patient.	The rods rinsing lumens match the trocars diameter and fix them guiding the user to place them at that location.
		Damage to instruments	4/5	H2. Damaged instrument can injure patient and nurse	
		Damage to the medical washer	4/5	H3. Damage to the medical washer can cause insufficiently cleaned instruments. These instruments can cause possibly fatal injuries in the patient.	

Tasks	Possible use errors	Possible hazards	Severity	Potential harm	Mitigation
	Inserts are loaded in the ports	Insufficiently cleaned instruments	4/5	H1. Possibly fatal infection can be caused in the patient.	The diameter of the holes in the silicon sheet on the lid of basket 1 are the only holes which match the diameter of the inserts.
		Damage to instruments	4/5	H2. Damaged instrument can injure patient and nurse.	
		Damage to the medical washer	4/5	H3. Damage to the medical washer can cause insufficiently cleaned instruments. These instruments can cause possibly fatal injuries in the patient.	
		Harm to nurse	4	H4. The sharp edges of the inserts can harm the nurse if the inserts are improperly fixed.	
	Obturators are loaded in the ports.	Insufficiently cleaned instruments	4/5	H1. Possibly fatal infection can be caused in the patient.	The ports in the manifold flush the lumens. Therefore, the user is inhibited to place the obturators at that location.
		Damage to instruments	4/5	H2. Damaged instrument can injure patient and nurse.	
		Damage to the medical washer	4/5	H3. Damage to the medical washer can cause insufficiently cleaned instruments. These instruments can cause possibly fatal injuries in the patient.	
		Harm to nurse	4	H5. The sharp edges of the inserts can harm the nurse if the inserts are improperly fixed.	
B2. Load lumens of trocars and heads of trocars on the rods on the manifold					
B3. Load valves of trocars on the rods on the manifold.	Trocar valve not fully moved around rod		4/5	H1. Possibly fatal infection can be caused in the patient.	The silicon sheets connect to the end of the rod, so the user fully moves the heads of the trocars on the rods.
L1. Load baskets in washer					

Appendix 8: Interview script concept evaluation

Introduction (2 minutes)

Hello, (participant's name). My name is Abe, and this is Daniel, and I'm going to be walking you through this testing session today. We are both from the technical university of Delft, the Netherlands. We have been asked to conduct an evaluation with a new model for a medical washer for laparoscopic instruments. The purpose of the medical washer is to ensure the laparoscopic instruments are fully cleaned before sterilization. For the development of this medical washer, we need your feedback to make sure the developers are on the right track and to identify any problems that can occur during the use of the model. Our goal today is to test the model. We are not testing you. There are no wrong answers. We're looking for your honest feedback. First, we'll need you to sign this consent form. The evaluation is recorded with a video camera. Information gathered today will only be used for research purposes and will be kept secure. Published results of this study will be compiled with other participants and any specific references to participants will be done anonymously. Your privacy is our priority. Do you have any questions about the form or the activities we are going to perform?

What training have you received to clean the surgical instruments?

Have you received additional training for laparoscopic instruments?

Could you tell me what your height and age is?

How long have you worked as a nurse?

Are you responsible for cleaning the surgical instruments?

Have you used a washer disinfector before?

If no: Do you know of washer disinfectors or automatic instrument cleaners?

If yes: Have you used a washer-disinfector to clean laparoscopic instruments?

How many sets of laparoscopic instruments does your hospital own?

How many sets of laparoscopic instruments are used in one day?

Test (10 minutes)

Trial 1

Now we would like to start the test. I will give you a task and ask you to think aloud about what you are doing during the performance of the task. When you think you have completed the task you can tell me.

For the first task, you can remove the baskets from the tank.

For the second task, you can load these disassembled laparoscopic instruments in the baskets.

For the third task, you can load the baskets in the tank.

Post-task interview

I noticed you [did something]. Why?

Questions when asked for help during the test

What do you think you should do?

What do you think that would do?

What do you think that means?

Trial 2

I would now like you to repeat the steps

For the first task, you can remove the baskets from the tank.

For the second task, you can load these disassembled laparoscopic instruments in the baskets.

For the third task, you can load the baskets in the tank.

Post-task interview

I noticed you [did something]. Why?

Why did you do this differently from the first time performing the tasks?

Questions when asked for help during the test

What do you think you should do?
What do you think that would do?
What do you think that means?

Post-test questions (7 minutes)

How would you describe your overall experience with the loading system?

What did you like the most about using the loading system? Why?

What did you like the least? Why?

Did anything surprise you about the way of loading the instruments?

Did anything cause you frustration while loading the instruments?

What would you change about the loading system?

Now we have some questions about the cleaner in general.

Do you think the cleaner would help you in your daily work? Why?

Do you think this cleaner would clean the laparoscopic instruments better, the same or worse than by hand? Why?

Do you think this cleaner would save you time?

How long should the cleaning take?
If yes: What would you do with that time?

Wrap-up

That was the test. Thank you for all the feedback. Do you have any questions for us?

Appendix 9: One pager of the medical washer

TU Delft’s medical washer

For laparoscopic instruments

This medical washer is designed to clean laparoscopic instruments while minimizing water and power usage. The medical washer can provide standardized clean results at low cost. The medical washer can clean one set of laparosocopic instruments in a small amount of time to ensure the instruments can be sterilized in time for the next surgery.

Ultrasonic cleaning
Vibrations are used to clean even the most complex geometries of the laparoscopic instruments.

Minimal water usage
Through innovative cleaning strategies water usage is minimized to ensure a cost-effective sustainable cleaning cycle.

15 minute cleaning cycle
To ensure the laparoscopic instruments are clean in time for the next surgery the medical washer has a cleaning cycle of 15 minutes.

Lumen flush
The lumens of the laparoscopic instruments are flushed to ensure the entire inner geometry is clean.

Small loading volume
The medical washer can clean one set of laparoscopic instruments: 16 lumens, three puncturing elements and 9 handles. Such a volume is perfect for hospitals owning a small amount of laparoscopic instruments.

Vertical loading system
The vertical loading system fastens the natural drying process of the instruments.

TU Delft

Appendix 10: Full concept evaluation in India

11.1 Introduction

Laparoscopic surgery is a minimally invasive surgical technique that allows doctors to perform surgery through small incisions in the patient's body. One of the key instruments used in laparoscopic surgery is the laparoscope, a thin, lighted tube with a camera that allows the surgeon to see inside the patient's body. These instruments must be carefully cleaned and sterilized after each use to prevent infection. In hospitals, this task is typically carried out by medical washers, which are specialized machines designed to clean laparoscopic instruments.
However, in rural India, access to specialized medical equipment such as medical washers may be limited, and nurses and health workers may be required to use these machines without any prior explanation or training. This can lead to errors in the use of the loading system, which is the process of preparing the laparoscopic instruments for cleaning. These errors can have serious consequences for patient safety and the quality of care. The purpose of this research is to examine the loading system of the medical washer for laparoscopic instruments in the context of hospitals in rural India and to understand how it is used by nurses and health workers without any prior explanation and how the concept of the medical washer is pereived by the end-user. Specifically, the research will address the following subquestions:

- Which instances of correct use, perception error, cognition error, and action error occur during the use of the loading system?
- Which root causes give rise to these use errors?
- What is the perception of the nurses and health workers on the improvement of the medical washer on their current working routine?

Understanding the factors that contribute to errors in the use of the loading system and the perceptions of nurses and health workers on the medical washer will provide valuable insights into how to improve the safety and effectiveness of laparoscopic surgery in rural India.

11.2 Method

Task analysis & risk analysis
The prototype development process included both a task analysis and a risk analysis to identify potential risks during the performance of tasks and to determine measures for mitigating these risks. The task analysis is presented in table 4 and demonstrates that tasks are divided into one or more subtasks. The risk analysis, presented in appendix 7, identifies potential risks associated with the use of the product, assesses the severity of these risks, and outlines strategies for mitigating them. This includes an assessment of the potential harm that may be caused by these risks.

Prototype
The prototype consists of two parts:
- Non-functional prototype of the medical washer: The prototype consisted of a simulated washing chamber and non-functioning control panel, but did not have the capability to actually wash or disinfect medical instruments (figure 5).
- Two baskets: They were designed to hold medical instruments and were able to be loaded vertically into the prototype medical washer (figure 6).

Figure 5: Prototype of the medical washer.

Loading the medical washer			
U. Unloading baskets from washer	A. Loading instruments in basket 1.	B. Loading instruments in basket 2.	L. Loading baskets in washer
U1. Unload baskets from washer	A1. Remove lid from basket	B1. Load black sheaths in the ports of manifold.	L1. Load baskets in washer
	A2. Load the obturators in the silicone holders	B2. Load lumens of trocars on the rods on the manifold.	
	A3. Load handles on the hooks	B3. Load valves of trocars on the rods on the manifold.	
	A4. Load the inserts in the silicone holders		
	A5. Load small parts in the small box		
	A6. Attach lid on basket		

Table 4: Task analysis of the use of the loading system of the medical washer.

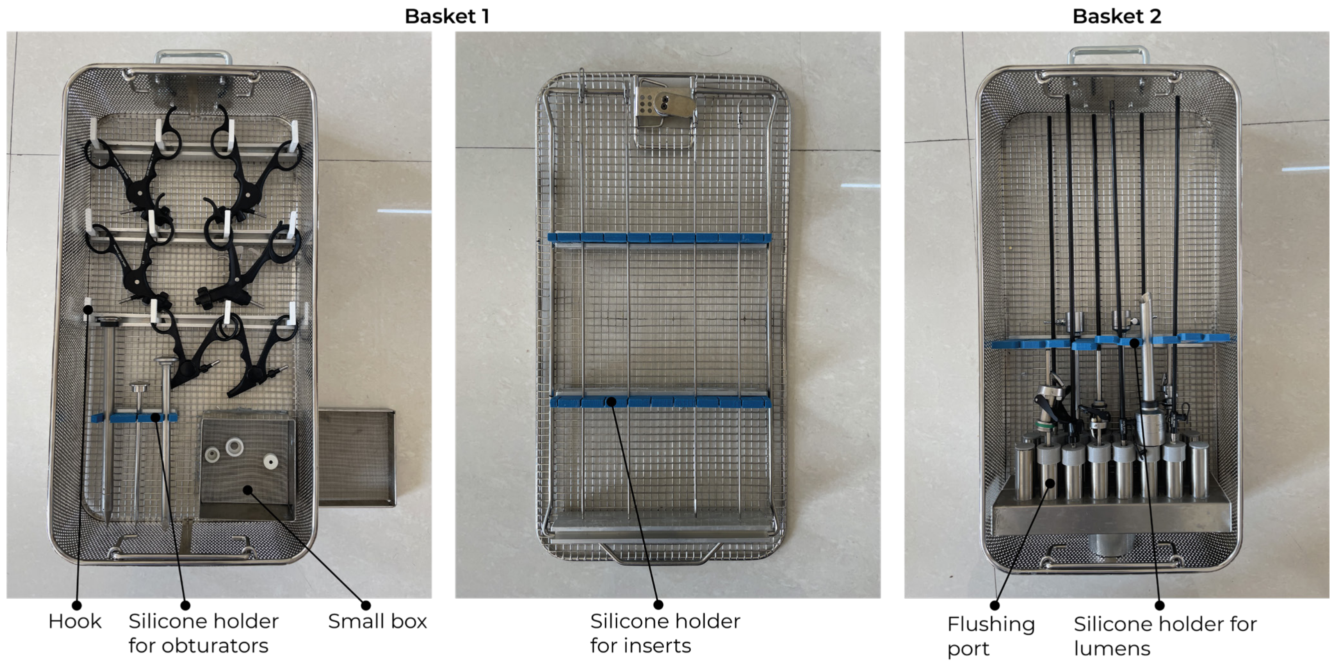


Figure 6: The two baskets with indication of the names of the parts.

Protocol design

The study was divided into two parts. The first part consisted of two tests in which the participant was asked to load a set of laparoscopic instruments in the medical washer, the test set-up including the set of laparoscopic instruments can be seen in figure 7. Prior to the tests, a short introduction was given and the participant was provided with a poster explaining the concept and functions of the medical washer (appendix fimxe). In the first test, the participant iwas asked to perform three tasks: unload the baskets from the washer, load the instruments in the baskets, and load the baskets back in the medical washer. Following the first test, a short interview was conducted to assess the performance of the sub-tasks and determine the root causes of the participant's actions. Before the second test, the participant was informed of which instruments belong in which basket. The participant was then asked to repeat the tasks from the first test. An additional interview was conducted to determine the root causes of the participant's actions in the second test. Finally, an interview was conducted with the participant to evaluate their overall perception of the medical washer. In figure 8 the procedure can be seen.

Figure 7: Test set-up of the study.

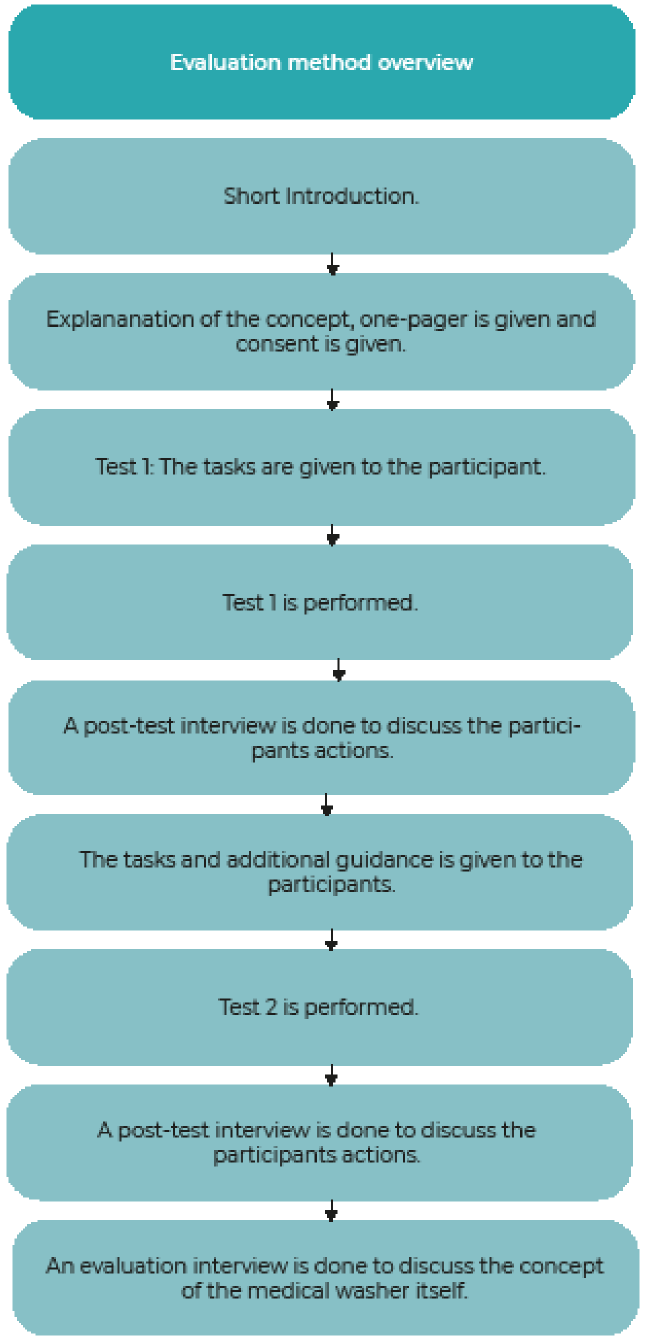


Figure 8: The procedure of the study.

Data collection & analysis

A root cause analysis was done by observing the occurrence of different instances of use. These instances of use were evaluated in order to determine the type of use error according to IEC 62366-1:2015 (International Electrotechnical Commission, 2015). Participant comments and observations were used to determine which type of use error occured. The use errors were divided into three categories: Firstly, *Perception errors*, which occur when individuals encounter difficulties in perceiving information provided by a device, such as difficulty reading text on a display or failing to hear audio information. These errors may be caused by impairments in visual, auditory, or tactile perception.

Secondly, *Cognition errors* refer to a range of mistakes made in the process of thinking, including forgetting important information, misinterpretation of data, miscalculations, overgeneralization, incorrect inference, and poor decision making. These errors may arise due to various factors, including lack of attention, inadequate understanding of the material, or cognitive biases. Thirdly, *action errors* involve problems with physically interacting with a device, including difficulties or failures in activities such as lifting, pinching, twisting, turning, or pushing it (Reeves et al., 2019). Participant comments were also taken into account and linked to the instances of use in order to identify the root causes of the errors. In addition to this, the results of the evaluation interviews were analyzed through the use of coding in ATLAS.TI (8.4.24.0, ATLAS.ti Scientific Software Development GmbH, Berlin, Germany). This allowed for the determination of the frequency with which the code was mentioned and the number of participants who mentioned it.

11.3 Results

The results of this study are presented in two sections. The first section presents the root cause analysis, while the second section presents the results of the evaluation interviews.

Participants

In this study, four hospitals were selected as the research sites. The participant groups included in the study are outlined in table 5. It should be noted that all participants in this study had no previous experience with automatic cleaners.

	Participant group	**Number of participants**	**Experience**
Participant groups performing 1 test.	Nurses (N1-9)	9	Between 3 and 27 years
	Nursing students (S1-3)	3	Second year students
Participant groups performing 2 tests.	Nurses (N2-9)	8	Between 3 and 27 years
Participant groups performing evaluation interview.	Nurses (N1-9)	9	Between 3 and 27 years
	OT helpers (OT1)	1	12 years

Table 5: Participant groups included in the study.

Root cause analysis

In the following section the results of the root cause analysis can be seen. For every sub-task a table is added to show the occurence of the different instances of correct use and use error, the comments by the participants and finally, the root causes that give rise to these instances of use.

U1. Unload baskets from washer

In 18 out of 20 tests, the participants successfully removed the baskets from the medical washer (table 6). However, in two tests, the participants only removed one basket. This outcome may be due to the device not providing sufficient information to the participants about the requirement to remove both baskets, or it may be due to a lack of understanding about the task instructions.

A1. Removing the lid from the basket

Of the 20 tests, in 18 the participant was able to remove the lid from the basket (table 7). However, in two tests the particpant unable to do so. The tests showed that the turning mechanism was not clear to these participants. As a result, they requested further instructions. This suggests that the clarity of the turning mechanism may have played a role in the participants' ability to successfully remove the lid from the basket.

Critical tasks	Observation	Use	Participant's comments	Root cause	Occurrence out of 20 tests
U1. Unload baskets from washer	Participant removes both baskets from the washer.	Correct use		The instructions and the device guide the user to remove both baskets.	18
	Participant only removes one basket.	Cognition error		The device fails to provide clear information that both baskets need to be removed or the instructions given were unclear.	2

Table 6: U1. Unload baskets from washer.

Critical tasks	Observation	Use	Participant's comments	Root cause	Occurrence out of 20 tests
A1. Remove lid from basket	Participant opens the turning mechanism of basket 1.	Correct use		The turning mechanism provides clear information on how the lid is opened.	18
	Participant is unable to open the turning mechanism of basket 1.	Cognition error		The device fails to provide clear information on how to open the turning mechanism.	2

Table 7: A1. Remove lid from basket.

Critical tasks	Observation	Use	Participant's comments	Root cause	Occurrence out of 20 tests
A2. Load the obturators in the silicone holders	Participant puts obturator in silicone holders.	Correct use	N6: It is designed it such a way. It clamps it.	The device provides proper fixation at that location.	6
	Participant puts obturators loose in basket 1.	Cognition error	N8: I thought the space was enough. N6: I am not sure where to put it.	The device fails to provide clear information on where the obturators should be placed.	8
	Participant puts obturators in the flushing ports.	Cognition error	N9: Because that is both are still in the same shape and so I feel maybe this is the design. N5: Making it stable	The device fails to provide clear information on where the obturators should be placed. The circular shape of the ports resembles the shape of the obturators. The participant therefore installs the obturators in the flushing ports.	6

Table 8: A2. Load the obturators in the silicone holders.

A2. Load the obturators in the silicone holders

In six out of 20 tests, the participants placed the obturators at the correct location in the basket, as depicted in Figure 9. Two types of use errors occurred during this subtask (table 8). In eight tests, the participants placed the obturators loose in basket 1 (Figure 10). In an additional six tests, the participants placed the obturators in the flush ports (Figure 11). These use errors may have been caused by the silicone holders providing insufficient information about the correct placement of the obturators. As a result, the participants placed the obturators loose in the basket or fixed them in the ports, which have comparable diameters.

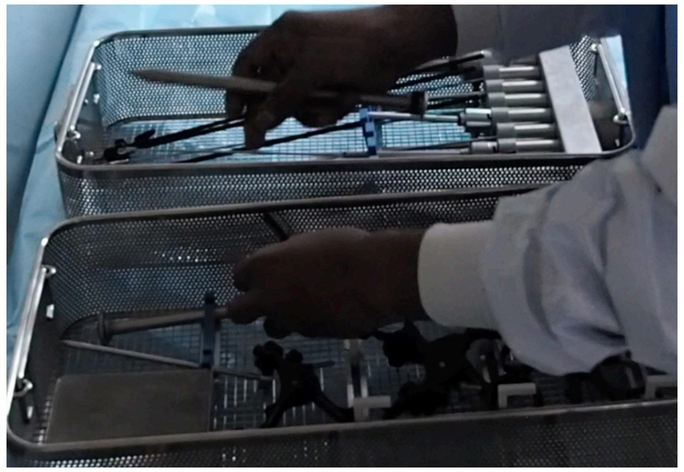


Figure 9: Nurse 2 putting the obturators in their silicone holder in test 2.

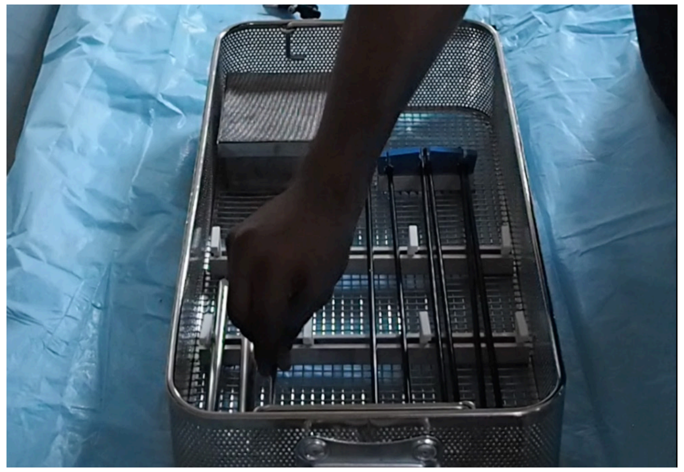


image 10: Nurse 3 putting the obturators loose in basket 1 in test 1.

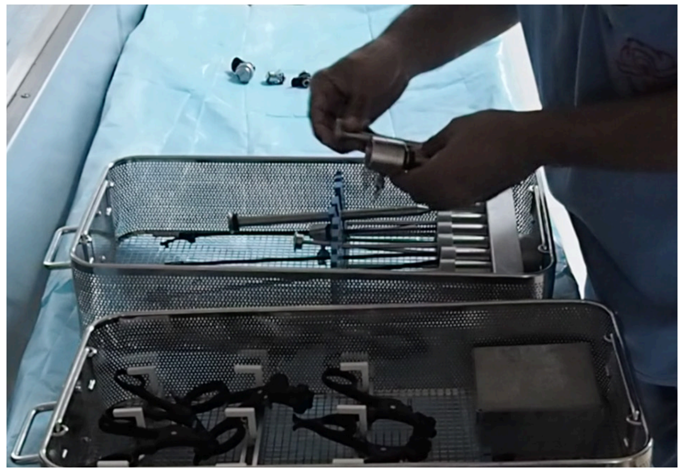


image 11: Nurse 5 putting the obturators in the flush ports in test 1.

Critical tasks	Observation	Use	Participant's comments	Root cause	Occurrence out of 20 tests
A3. Load handles on the hooks	Participant hooks handles over the hooks by two ears.	Correct use	N1: For the handles the rings are meant there. N9: if we did this, not if we did not put together it, it may close inside after. N5: We can hang, hang it properly and it will rinse and dust and other things will fall down.	The hooks provide information on how the handles are placed.	5
	Participant puts handles over the hooks by one ear.	Correct use	N6: I just wanted it to remain in the box, the handles not to fall.	The hooks provide information on how the handles are placed.	4
	Participant puts handles loose in basket 1.	Cognition error	N2: I separated the insulation from the handles to protect the insulation. N7: I am putting them there because it is easy. N3: I was feeling a difficulty of how to hang the handles. I was feeling the difficulty how to handle, handle the handle while keeping it and they were moving in the box.	The hooks in the basket fail to provide clear information on how the handles should be placed.	10
	Participant clamps handles in between the hooks of basket 1.	Cognition error		The hooks in the basket fail to provide clear information on how the handles should be placed.	1

Table 9: A3. Load handles on the hooks.

A3. Load handles on the hooks
During the loading of the handles, two types of correct use were observed (table 9). In five tests, the handles were placed over the hooks using two ears, as described in the task analysis (Figure 12). In four tests, the handles were placed over the hooks using one ear (Figure 13). This latter method was not anticipated beforehand. The most common instance of use involved placing the handles loose in basket 1 (10 tests) (Figure 14). In Figure 15, nurse five can be seen clamping the handles between the hooks. These use errors may be attributed to the hooks not providing sufficient information about the correct placement of the handles.

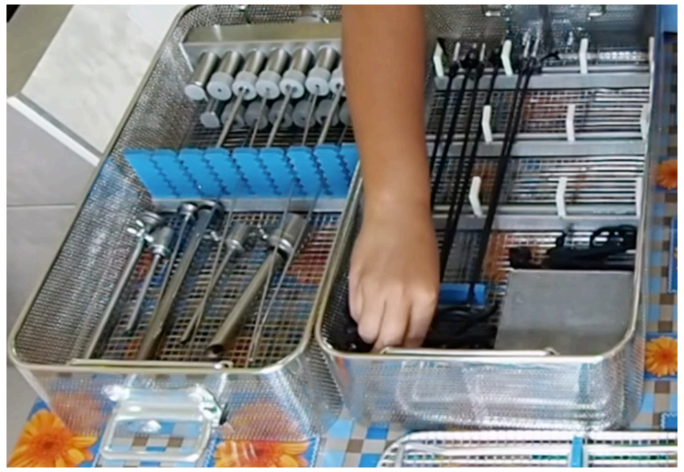


image 14: Nursing student 2 putting the handles loose in basket 1 in test 1.

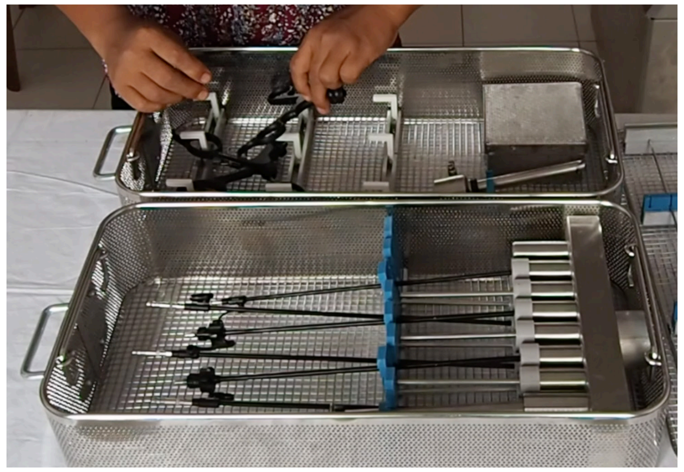


Image 12: Nurse 9 putting the handles on the hooks by two ears in test 1.

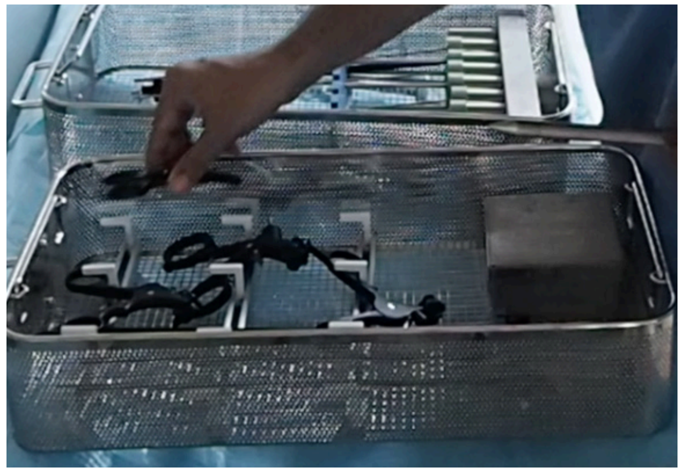


Image 15: Nurse 5 putting the handles loose in between the hooks in test 1.

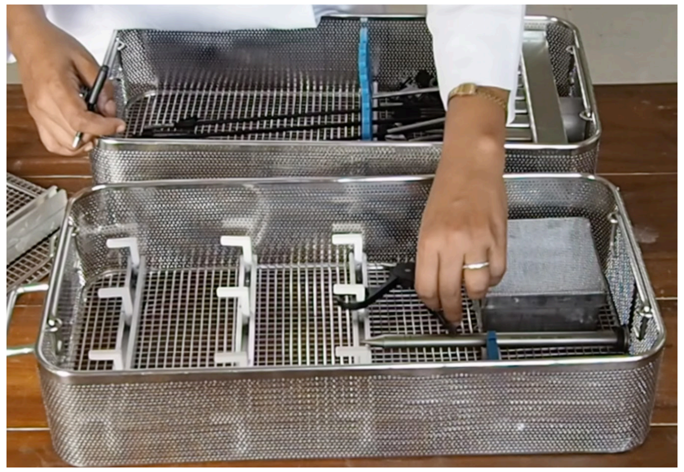


Image 13: Nurse 6 putting the handles on the hooks by one ear in test 2.

A4. Load the inserts in the silicone holders
In five tests, the participants placed the inserts in the silicone holders due to the comparable diameter of the inserts and the holders, as well as the proper fixation at this location (table 10)(Figure 16). In eight tests, the participants placed the inserts in the silicone holder for the obturators, and in six tests, the participants placed the inserts in the silicone holder for the lumens (figure 17)(figure 18). These latter two locations were chosen by the participants because the silicone holders provide fixation. In one test, a participant placed the inserts loose in basket 1 (figure 19). These use errors may have occurred because the participant did not notice the silicone holder on the lid of basket 1, which was inconspicuous and therefore easily overlooked.

Critical tasks	Observation	Use	Participant's comments	Root cause	Occurrence out of 20 tests
A4. Load the inserts in the silicone holders	Participant puts inserts in silicone holder on lid of basket 1.	Correct use	N9: It is the same length, and the hole is the same. N9: It will be fixed.	The diameter of the insert matches the diameter of the holder. The lengths are also comparable. The participant therefore places the inserts in the silicon holder on the lid.	5
	Participant puts inserts in silicone holder for the obturators.	Per-ception error	N2: I put the inserts and the black sheaths in a different box from the trocars. As the inserts and black sheaths get damaged more easily. N6: That would be not to fall down. So it remains in the box. It is the box that is closed off. N7: I put it there so it doesn't move.	The inserts seem to be incorrectly placed because the silicone holder on the lid is inconspicuous. The participant seems to want to separate the inserts and black sheaths from the obturators and the trocars because the inserts and black sheaths are seen as more fragile.	8
	Participant puts inserts in silicone holder for lumens in basket 2.	Per-ception error	N1: I think it is okay. The length is appropriate for this one. N7: It is fixed which means it will not be broken.	The inserts seem to be incorrectly placed because the silicone holder on the lid is inconspicuous. The device seems to provide proper fixation for the inserts at this location. The participant therefore fixes the inserts in the holder for the lumens.	6
	Participant puts inserts loose in basket 1.	Per-ception error		The inserts seem to be incorrectly placed because the silicone holder on the lid is inconspicuous.	1

Table 10: A4. Load the inserts in the silicone holders.


Image 16: Nurse 3 putting the inserts in the silicone holder on the lid in test 2.


Image 17: Nursing student 1 putting the inserts in the silicone holder for the obturators in test 1.

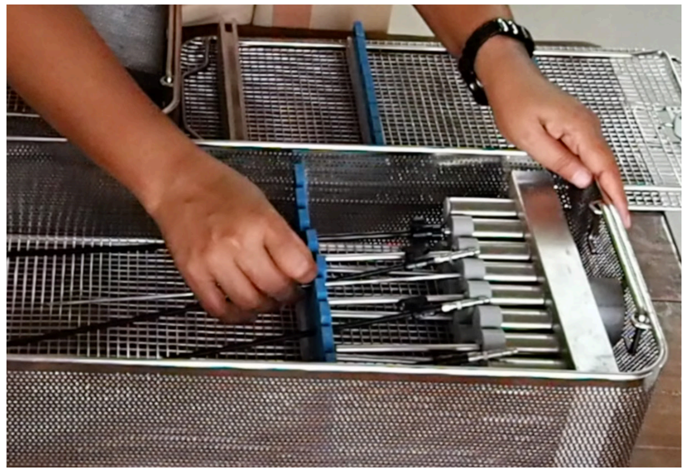


Image 18: Nurse 8 putting the inserts in the holder for the lumens in test 1.

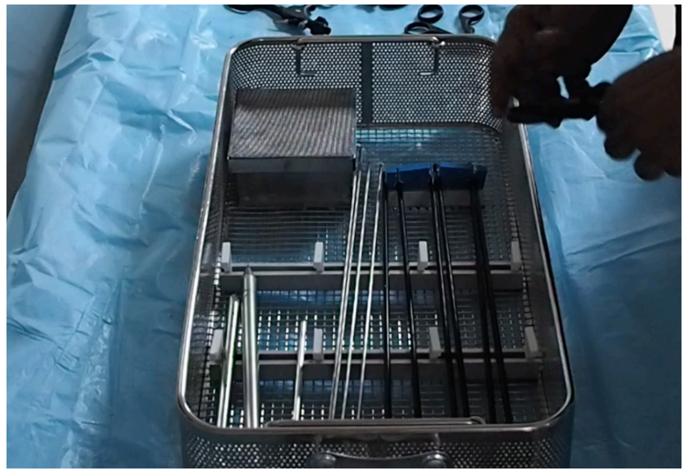


Image 19: Nurse 3 putting the inserts loose in basket 1 in test 1.

Critical tasks	Observation	Use	Participant's comments	Root cause	Occurrence out of 20 tests
A5. Load small parts in the small box	Participant puts small rubber parts in the small box in basket 1.	Correct use	N9: Because these are small. It can fall down. N8: I put them there the small parts stay in one place.	The device provides information where small parts can be stored. The participant wants to contain the small parts in the small box, so the instruments do not move around throughout the entire basket.	16
	Participant puts small rubber parts loose in basket 1.	Cognition error		The device fails to provide clear information on where the small rubber parts should be placed.	2
	Participant puts small rubber parts loose in basket 2.	Cognition error		The device fails to provide clear information on where the small rubber parts should be placed.	1
	Participant assembles instruments	Cognition error		The device fails to provide clear information the instruments should be loaded disassembled or the instructions given were insufficient.	1

Table 11: A5. Load small rubber parts in the small box.

A5. Load small parts in the small box
In 16 out of 20 tests, the participants placed the small rubber ports in the small box in basket 1, with the intention of containing the rubber parts in a closed-off area (table 11) (Figure 20). As noted by Nurse 8, 'I put them there so the small parts stay in one place.' However, in two tests, the rubber parts were placed loose in basket 2, and in one test, they were placed loose in basket 1 (figures 21 and 22). This suggests that the small box may not have provided enough information to guide the participants in correctly placing the rubber parts. One participant also assembled the instruments, which may be due to a lack of information provided by the device or insufficient instructions before performing the tasks (figure 23).

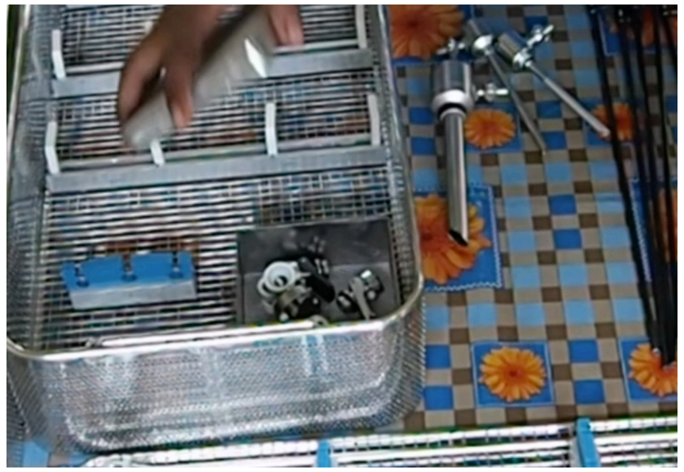


Image 20: Nursing student 3 putting the small rubber parts in the small box in test 1.

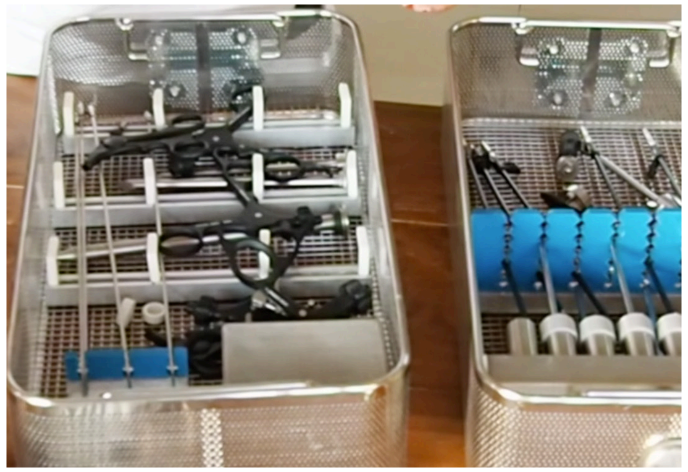


Image 21: Nurse 7 putting the small rubber parts loose in basket 2 in test 2.

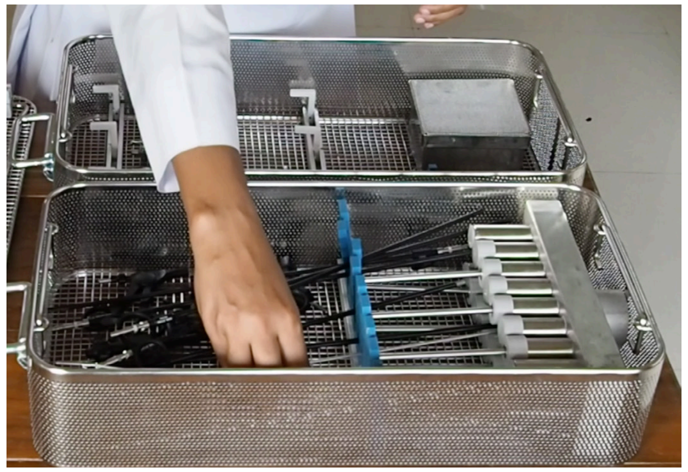


Image 22: Nurse 6 putting the small rubber parts loose in basket 2 in test 1.

Image 23: Nurse 4 assembles instruments in test 1.

A6. Attach lid on basket
All participants closed the lid on basket 1 (table 12). The turning mechanism guided the user successfully to close the basket.

Critical tasks	Observation	Use	Participant's comments	Root cause	Occurrence out of 20 tests
A6. Attach lid on basket	The participant closes the lid on the basket.	Correct use		The turning mechanism provides clear information on how the lid is closed.	20

Table 12: A6. Attach lid on basket.

Critical tasks	Observation	Use	Participant's comments	Root cause	Occurrence out of 20 tests
B1. Load black sheaths in the ports of manifold	Participant puts black sheaths in ports.	Correct use	N1: I put in between the rings otherwise the sheaths will fall during loading. N8: I put them there so they can be fixed in the hole. N9: There is no fixation except the holder. N3: I put all the insulation in the holes you can take it so that it could not fall.	The ports provide fixation for the sheaths preventing them from moving during loading and unloading. The participant therefore fixes the sheaths in the ports on the manifold.	7
	Participant puts black sheaths in silicone holder for lumens without putting them in the ports.	Action error	N5: I put the black sheaths there because rubber stand it. It is designed for black sheath. The flush port has a very small hole to install it.	The holes in the flushing ports are too small. Pushing the black sheaths too much force inhibiting the participant from performing the sub-task.	9
	Participant puts black sheaths in silicone holder for the obturators.	Action error	N2: Actually, trocar there is like just there is a sharp edge over there. Yeah, well, mixing with the instruments, the sheath, the black one. It can get damaged.	Mixing the trocars and black sheaths in one basket could cause the sheaths to be damaged. The participant therefore separates the part in different baskets.	4

Table 13: B1. Load black sheaths in the ports of manifold.

B1. Load black sheaths in the ports of manifold

In seven tests, the participants placed the black sheaths in the flush ports (table 13)(Figure 24). According to the participants, immobilization of the sheaths was a primary factor in this decision. For example, Nurse 3 stated, 'I put all the insulation in the holes so you can take it without it falling.' In nine additional tests, the participants placed the black sheaths in the silicone holders, but not in the flush ports (figure 25). Nurse 5 explained, 'I put the black sheaths there because the rubber stand is designed for black sheaths. The flush port has a very small hole to install it.' This suggests that the diameter of the flush ports may have been too small, preventing the participants from placing the black sheaths in them. In four tests, the participants placed the black sheaths in the silicone holder for the obturators as can be seen in figure 26, Nurse 2 noted, 'Actually, the trocar is just there, with a sharp edge. Yeah, well, mixing with the instruments, the sheath, the black one. It can get damaged.' During the process of loading the trocars and black sheaths, it is observed that the edge of the trocar and the black make contact, as depicted in Figure 27.

Figure 24: Nursing student 1 putting the black sheaths in the flush ports in test 1.

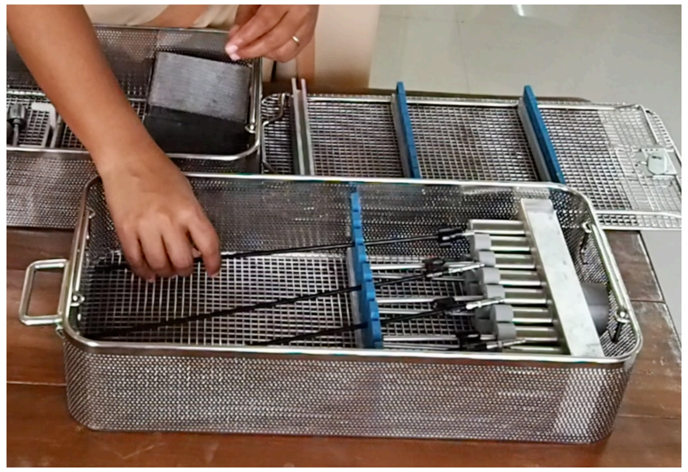


Figure 25: Nurse 8 putting the black sheaths in the silicone holders without putting them in the flush ports in test 1.

Figure 26: Nurse 5 putting the black sheaths in the silicone holders for the obturators in test 1.

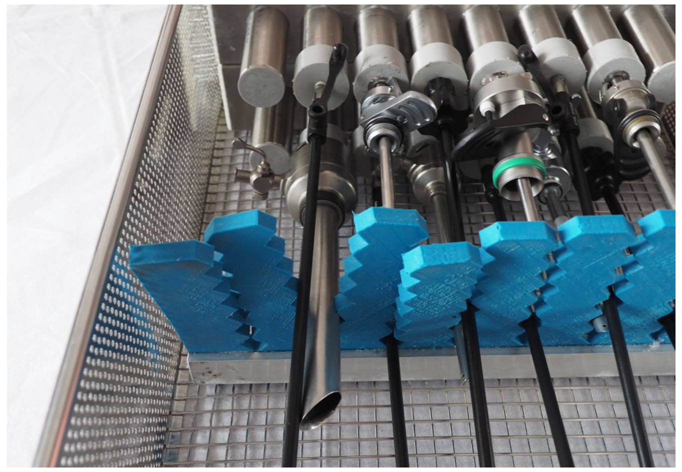


Figure 27: Contact between the trocar and the black sheath.

B2. Load lumens of trocars on the rods on the manifold

In seven tests, the participants placed the trocars over the rinsing rods on the manifold (table 14)(figure 28). Nurse 2 cited the amount of space at this location as the reason for this decision, while Nurse 8 and 9 noted the fixation provided by the rods and silicone holder for the trocars. However, a variety of use errors occurred during the tests, all resulting from the device failing to guide the participants in placing the trocars at the correct location. These errors included placing the trocars loose in basket 1 or 2 (Figures 29 and 30), or attempting to fixate the trocars by placing them in the flush ports, under the hooks, or below the rinsing rods (Figures 31, 32, and 33). One participant also assembled the instruments (Figure 34). This may be due to insufficient information provided by the device or unclear instructions.

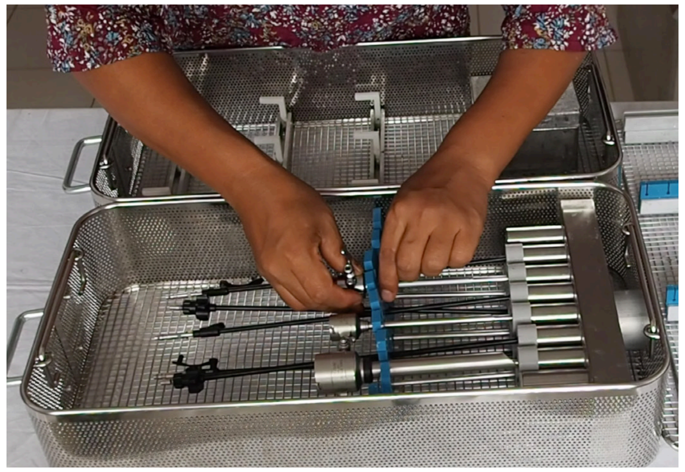


Figure 28: Nurse 9 putting trocars on the rinsing rods in test 2.

Critical tasks	Observation	Use	Participant's comments	Root cause	Occurrence out of 20 tests
B2. Load lumens of trocars on the rods on the manifold	Participant puts trocar over rinsing rod.	Correct use	N2: The trocar is more contaminated so in this location it has more space to be cleaned. N8: I thought it is for that because it fixes it. It holds it tightly. N9: The aluminum fixes the instrument and trocars are hollow, the inside will be autoclaved.	The trocar is often more contaminated. The instrument therefore needs to be cleaned more rigorously. Around the rod in basket 2 there is more space for the instrument to be cleaned. The rods also provide fixation.	7
	Participant puts trocars loose in basket 1.	Cognition error		The rods in the basket fail to provide clear information on how the trocars should be placed.	4
	Participant puts trocar in flushing port.	Cognition error	N9: I put it there because it is fixed there.	The device seems to provide proper fixation for the trocars at this location.	3
	participant puts trocars behind the hooks in basket 1.	Cognition error		The device fails to provide clear information on where the trocars should be placed. The hooks seem to provide fixation so the participant places the trocars behind them.	2
	Participant puts trocars loose in basket 2.	Cognition error		The device fails to provide clear information on where the trocars should be placed. The participant therefore places the trocars loose in the basket.	2
	Participant assembles trocars and does not load the instruments.	Cognition error		The device fails to provide clear information the instruments should be loaded disassembled or the instructions given were insufficient.	1
	Participant puts trocars below the rinsing rods in basket 2.	Cognition error	N6: I close it off with the rods.	The device fails to provide clear information on where the trocars should be placed. The rinsing rods seem to provide fixation so the participants place the trocars behind them.	1

Table 14: B2. Load lumens of trocars on the rods on the manifold.

Figure 29: Nursing student 1 putting trocars loose in basket 1 in test 1.

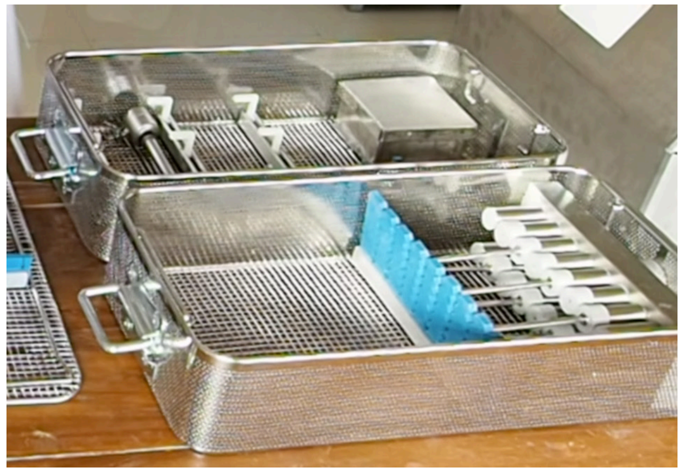


Figure 32: Nurse 6 putting trocars behind the hooks in basket 1 in test 1.

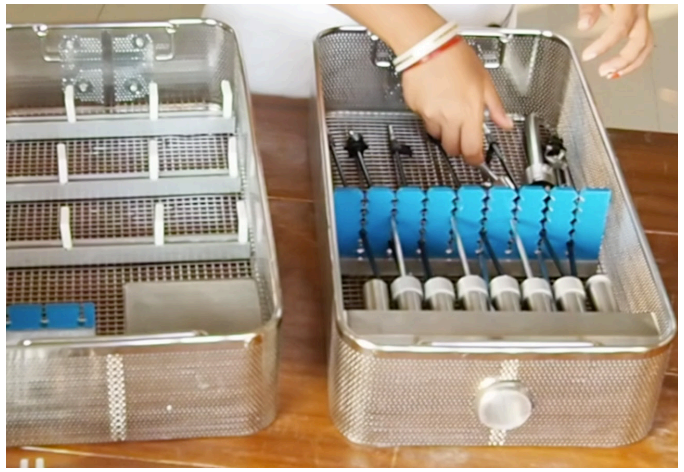


Figure 30: Nurse 7 putting trocars loose in basket 2 in test 2.

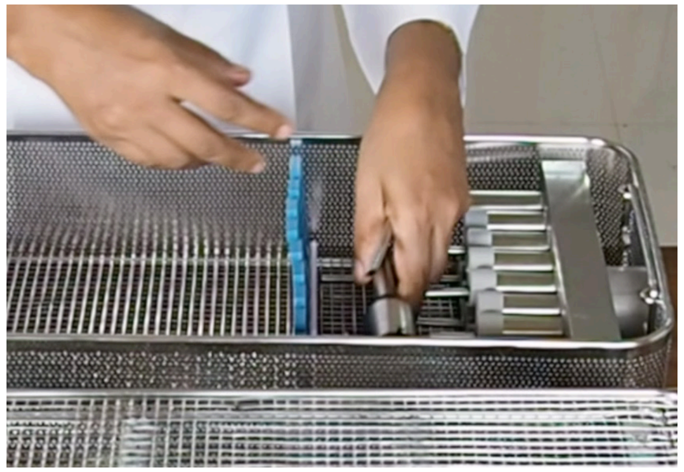


Figure 33: Nurse 6 Participant puts trocars below the rinsing rods in basket 2 in test 2.

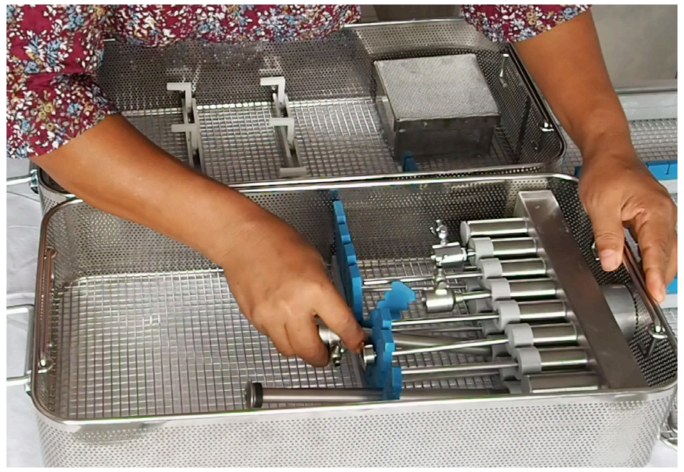


Figure 31: Nurse 9 putting trocars lin flush ports in test 1.

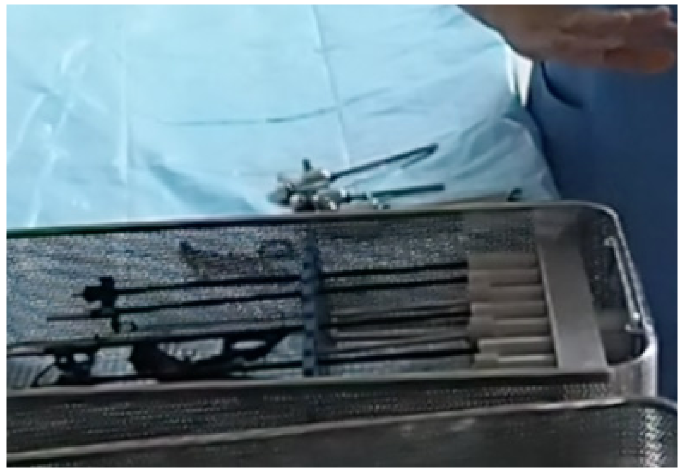


Figure 34: Nurse 4 not loading the trocars in the basket in test 1.

Critical tasks	Observation	Use	Participant's comments	Root cause	Occurrence out of 20 tests
B3. Load valves of trocars on the rods on the manifold	Participant puts valves of trocars in the small box in basket 1.	Cognition error	N8: So the small parts stay in one place. N9: Because these are small they can fall if I do not put them in the small box.	Users seem to want to contain the small parts in the small box, so the instruments do not move around throughout the entire basket.	12
	Participant puts valves of trocars loose in basket 2.	Cognition error		The device fails to provide clear information on where the trocars should be placed. The participant therefore places the valves loose in the basket.	4
	Participant puts valves of trocars loose in basket 1.	Cognition error		The device fails to provide clear information on where the trocars should be placed. The participant therefore places the valves loose in the basket.	2
	Participant assembles instruments.	Cognition error		The device fails to provide clear information the instruments should be loaded disassembled or the instructions given were insufficient.	2

Table 15: B3. Load valves of trocars on the rods on the manifold.

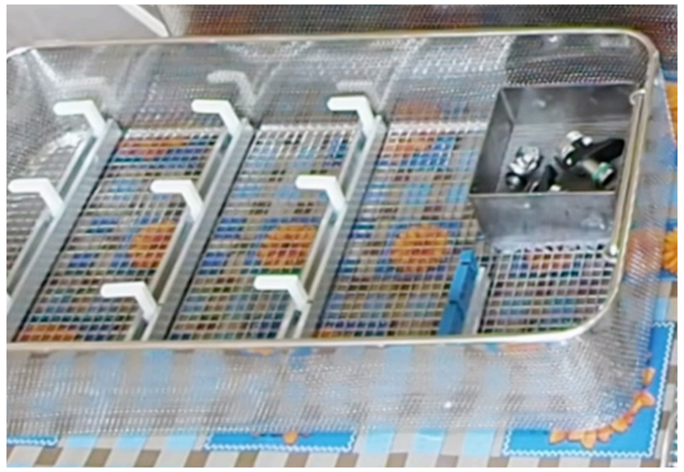


Figure 35: Nursing student 1 putting the valves of the trocars in the small box in test 1.

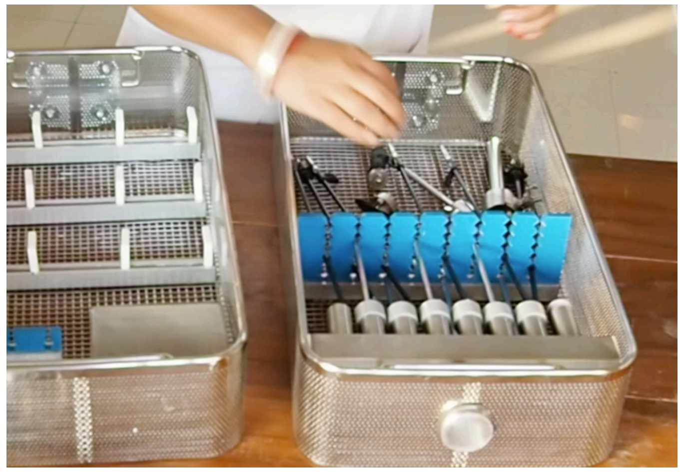


Figure 36: Nurse 7 putting the valves of the trocars loose in basket 2 in test 2.

B3. Load valves of trocars on the rods on the manifold

During the subtask of loading the valves on the trocars on the rods on the manifold, no instances of correct use were observed (table 15). The most common use error (occurring in 12 tests) was placing the valves in the small box, as depicted in Figure 35. The participants cited the same reason as in subtask A5: containing the small parts in a closed-off area. In four tests, the participants placed the valves loose in basket 2, and in two tests, the valves were placed loose in basket 1 (Figures 36 and 37). These errors may be attributed to the device failing to provide sufficient information about the correct placement of the valves. Two participants also mistakenly assembled the instruments (figure 38) which may be due to a lack of clear information from the device or inadequate instructions before the tests.

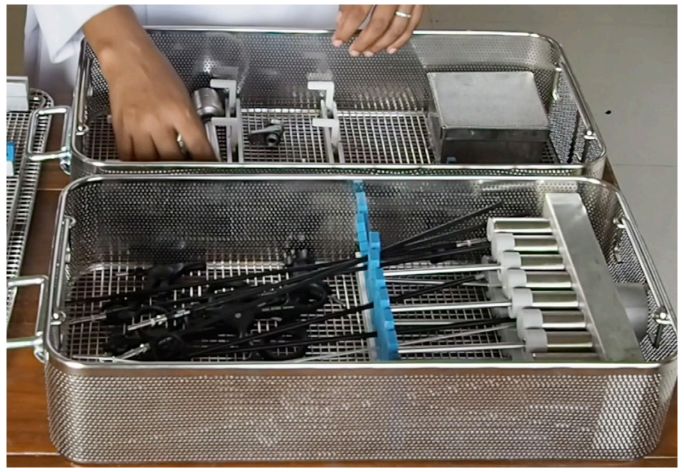


Figure 37: Nurse 6 putting the valves of the trocars loose in basket 1 in test 1.

Image 38: Nurse 4 assembles instruments in test 1.

L1. Load baskets in washer

In 17 tests, the participant loaded the baskets back into the washer successfully (table 16). in two tests baskets were loaded upside down, due to the device failing to provide clear information on how the baskets should be loaded. One participant was excluded as the participant did not load the baskets back in the washer.

Critical tasks	Observation	Use	Participant's comments	Root cause	Occurrence out of 20 tests
L1. Load baskets in washer	Participant loads baskets.	Correct use		The instructions and the device guide the user to load both baskets.	17
	Participant puts basket back upside down.	Cognition error		The device fails to provide clear information on how the baskets should be loaded.	2

Table 16: L1. Load baskets in washer.

Observation number	Observation	Classification	Test 1	Test 2
1	Partcipant removes lid from basket 1.	Correct use	7	8
2	Participant removes both baskets.	Correct use	6	8
3	Participant loads baskets.	Correct use	6	8
4	Participant puts small rubber parts in the small box in basket 1.	Correct use	5	6
5	Participant puts trocar over rinsing rod.	correct use	1	5
5	Participant puts obturator in silicone holders.	correct use	2	4
6	Participant puts black sheaths in flushing ports.	Correct use	2	3
7	Participant puts handles over the hooks by one ear.	correct use	0	3
8	Participant puts handles over the hooks by two ears.	correct use	1	3
9	Participant puts inserts in silicone holder on lid of basket 1.	Correct use	2	3

Table 17: Comparison of occurence of corrrect use in test 1 and 2.

Observation number	Observation	Classification	Test 1	Test 2
1	Participant puts valves of trocars in the small box in basket 1.	Use error	5	3
2	Participant puts handles loose in basket 1.	Use error	4	2
3	Participant puts obturators in the flushing holes.	Use error	4	2
4	Participant puts black sheaths in silicone holder for lumens without putting it in the port.	use error	3	4
5	Participant puts valves of trocars loose in basket 2.	Use error	0	4
6	Participant puts obturators loose in basket 1.	Use error	3	3
7	Participant puts inserts in silicon holder for lumens in basket 2.	Use error	3	1
8	Participant puts inserts in silicon holder for the obturators.	Use error	2	4

Table 18: Comparison of occurence of use error in test 1 and 2.

Comparison between test 1 and 2
In table 17 and 18 the most occurring instances of correct and use error can be seen. Only participants who performed both tests have been incorporated in this table. When comparing test 1 and test 2, it was found that the occurrence of correct use increased in all instances. However, while the majority of use errors were reduced in occurrence due to the additional information provided, some use errors actually increased in occurrence. in test 1 to four instances in Test 2.

For example, no participants placed the valves loose in basket 2 in test 1, but in test 2, four made this use error, while three participants still placed the valves in the small box in basket 1. Additionally, in Test 2, four participants placed the black sheaths in the silicone holders without placing the sheaths in the flush ports, an increase from the three instances in Test 1. Similarly, the number of participants who placed the inserts in the silicone holder for the obturators increased from two instances in test 1 to four instances in Test 2.

	Codes	Frequency mentioned	Mentioned by participants
Comparison of current cleaning method and the medical washer	Cleaning with the medical washer is perceived as safer for the nurses compared to manual cleaning.	4	3/10
	Minimal water usage of medical washer	5	2/10
	The medical washer is perceived as a more reliable form of cleaning compared to manual cleaning.	6	5/10
	The medical washer is seen as less damaging to the laparoscopic instruments as manual cleaning.	5	3/10
Cleaning time	Explanation of current cleaning time	5	4/10
	The medical washer saves the time of the nurses.	9	8/10
Design of the medical washer	Comfort of the loading system	6	6/10
	Suggested improvements for the medical washer	9	4/10

Table 19: Evaluation interview codes.

Evaluation interviews
Evaluation interviews were done with nine nurses and one OT helper. The interviews were coded and these codes were divided into different sub-categories. These can be seen in figure 19.

Safety of the nurses
Three nurses mentioned working with the medical washer would increase the safety of the nurses during the cleaning process by decreasing the amount of physical contact with the contaminated instruments compared to manual cleaning.

'Especially in this area HIV, hepatitis is very high. So it will be very safe for the staff who are involved with this surgery and we do not deal with all this blood.' [Participant 9]

Minimal water usage
Two participants mentioned the minimal water usage of the medical washer as an important advantage. Currently, the instruments are manually cleaned under continually running tap water. The current cleaning practice is perceived as wasteful by the nurses.

Reliability of the cleaning process
Four nurses and one OT helper considered the medical washer as a more reliable system for cleaning the laparoscopic instruments compared to the current system of manual cleaning. The participants explained that due to the time pressure while manually cleaning the laparoscopic instruments, at times, not all soil is removed when the instruments are disinfected.

'While manually washing 50 percent of the time we will make a mistake. we have 15 minutes or a half an hour. So in that time we have to wash the instruments and we do very quickly. So while washing the instrument very quickly. We always lose something, which you can't see by your eyes. But there might be some spot or blood or something else. Yeah, but we have to wash thoroughly and bring back. But while using the machine. It will be very safe for us and for it will be very good for the patient. There will be no infections. It will be very good for us.' [Nurse 3]

Damage to the instruments
Damage was a subject mentioned by multiple participants. The laparoscopic instruments are perceived as costly, and nurses want to extend the instruments' lifetime as long as possible. Three participants mentioned the decrease in damage to the instruments while cleaning as an advantage of the medical washer.

'The machine does the things in a proper way. The damage of the instrument is quite less so. While man handling, there is a chance of damaging instruments.' [Nurse 2]

Cleaning time

Currently, there is time pressure on the nurses and OT helpers while reprocessing the laparoscopic instruments due to a lack of instrument inventory and staff shortages. Four participants described the timeframe of the current reprocessing cycle. Cleaning of the laparoscopic instruments takes between 15 and 30 minutes and the full reprocessing cycle takes about one hour. 9 participants mentioned that the medical washer could save time during the reprocessing cycle and decrease the pressure currently put on the nurses. The participants mentioned that this time can be used to work on their other tasks and take a rest in between cases.

'We have lots of work. We can see other patients. We need to put aside. We need to arrange the next patient. So, all these things. Sometimes we also have no time to rest.' [Nurse 9]

Loading system

Five participants described loading the baskets as comfortable. No discomfort was experienced during the loading and unloading of the baskets. One participant described the as baskets a little heavy mentioning that she had to get habituated to the mechanism.

Suggested improvements

Multiple suggestions were made for improvements on the medical washer.

- More space is needed in between the instruments.
- The medical washer should be able to load multiple instrument sets at a time.
- Instructions should be available outside of the medical washer.
- The medical washer should be able to house larger instruments like retractors and clip appliers.
- The medical washer should also sterilize the laparoscopic instruments.
- The medical washer should drain automatically so no buckets are required.

11.4 Discussion

Root cause analysis

During the study, all critical tasks were successfully completed by a number of participants, except for placing the valves of the trocars on the rinsing rods in basket 2. The tasks that were most often performed correctly were attaching the lid on basket 1, unloading and loading the baskets, and placing the rubber parts in the small box. During these tasks the device conveyed a clear message to the users. In seven tests, the black sheaths were placed in the flush ports, and in six tests, the trocars were placed around the rinsing rods. The reasoning behind these actions was similar in both cases, with the participants citing proper fixation as the primary factor. Flushing of the lumens was not mentioned as a reason by any of the participants. The information provided about the lumen flushing function of the medical washer did not seem to impact the participants' decisions about lumen placement. Instead, proper fixation and the similar diameters of the instruments and the silicone holders appeared to guide the participants in properly placing the instruments. The information given on the poster was not sufficient for the participants to recognize the flush ports and place the black sheaths in them to be flushed.
Three perception errors were identified during the tests. These errors involved the lid of basket 1 and the silicone holder, which seemed too inconspicuous to be noticed by the participants. As a result, the participants placed the inserts at different locations. To increase the instances of correct use, it is recommended that the silicone holder for the inserts be made more noticeable.
A variety of cognition errors were observed during the tests. Firstly, the device appeared to provide information that could be misinterpreted by the user. For instance, 12 participants placed the valves of the trocars in the small box in basket 1, citing the same reasoning as for placing the small rubber parts in the small box. Six participants also placed the obturators in the flush ports, and three participants placed the trocars in the flush ports, citing proper fixation and similar diameters as their motivations. Secondly, the device seemed to fail at providing any information on proper placement, leading some participants to place the instruments loose in the basket.

These perception and cognition errors demonstrate the need for additional guidance to help participants accurately perform the tasks. One way to achieve this would be to add labels to the different compartments in the baskets or provide instructions on the medical washer itself.
Two action errors occurred during the tests. Eight participants placed the black sheaths in the silicone holders without inserting them into the flush ports, which was likely due to the small diameter of the flush ports creating resistance. To prevent this error from occurring, it is suggested to increase the diameter of the flush ports. Three participants placed the black sheaths in the silicone holder for the obturators, with one participant citing the potential contact between the trocars and the sheaths as the reason for this placement (figure 23). Another participant demonstrated this issue during the test. To address this problem, increasing the space between the flush ports and creating larger serrations in the silicone holder is recommended.
In comparing the results of the two tests, it was observed that the provision of additional information resulted in an increase in the number of instances of correct use. However, for the task of placing the valves of the trocars, the guidance led to a different use error instead of an increase in the instances of correct use. In the second test, four participants placed the valves loose in basket 2, an error that did not occur in the first test. The placement of the valves was unclear to all participants. Therefore, it is important to focus on the placement of the valves when creating some form of guidance or instructions. The provided information in test 2 led the participants to place the instruments in the correct basket, but it also led to an increase in the occurrence of use errors within the correct basket. For example, an increase in the use errors of "placing the black sheaths in the silicone holders without inserting them into the flush ports" and "placing the inserts in the silicone holder for the obturators" may be attributed to the provided information.

Evaluation interviews

During the evaluation interviews, several advantages of the medical washer were identified by the participants. One key advantage is that it can increase the safety of nurses by reducing the amount of physical contact they have with potentially sharp instruments.

This is important because handling these instruments manually can pose a risk of injury or infection, such as HIV and hepatitis. India has a high burden of HIV and hepatitis infections, with an estimated 2.4 million people living with HIV and over 40 million people living with hepatitis B and C (UNAIDS, 2019)(Premkumar & Chawla, 2021). The use of a medical washer can mitigate these risks by effectively cleaning and sterilizing the instruments, thus limiting the need for direct contact.
Rural hospitals often face resource constraints that can impact the delivery of care. During the evaluation interviews, the participants identified cost as a major factor in the current method of cleaning under running water. They described minimizing water usage as a desirable goal. This is particularly relevant in the context of rural hospitals, where access to water may be limited.
During the evaluation interviews, five participants indicated that they believed the medical washer would clean instruments more effectively than their current cleaning methods. They also described the medical washer as more reliable than their current practices. These findings suggest that the use of a medical washer may improve the overall quality and effectiveness of instrument cleaning in the healthcare setting.
Resource constraints in rural hospitals can lead staff to try to extend the lifespan of laparoscopic instruments for as long as possible. During the evaluation interviews, three participants described the medical washer as being less damaging than their current cleaning methods, which they saw as a valuable advantage. This suggests that the use of a medical washer may help to improve the longevity of laparoscopic instruments in these settings. This is important because the replacement of laparoscopic instruments can be costly, especially in the context of resource-constrained rural hospitals. The use of a medical washer that is less damaging to the instruments may help to reduce the frequency of replacement, thus improving the overall cost-effectiveness of instrument cleaning.
Time pressure is a major factor that impacts the quality of the current reprocessing cycle in many healthcare settings. Nurses are often required to clean laparoscopic instruments within a short timeframe, such as 15 to 30 minutes, which can lead to a lack of thorough cleaning.

This is a concern because inadequate cleaning can compromise the sterilization of the instruments and increase the risk of infection transmission. During the evaluation interviews, one participant reported that soil was present on the instruments approximately 50% of the time after cleaning, highlighting the challenges with the current cleaning process.

Nine participants mentioned that the medical washer could help them save time, which could be used for other tasks or for rest between surgeries. This implies that the use of a medical washer may help to improve the efficiency of the reprocessing cycle, which could in turn enhance the overall quality of instrument cleaning.

Five participants described the loading system as comfortable, while one participant mentioned that she had to get habituated to it and found it a little heavy. This that the loading system of the medical washer may be well-received by some users, but may not be universally comfortable for all users.

During the evaluation of the medical washer, multiple suggestions were made for improvements to the device. These suggestions included the need for more space between the instruments, the ability to load multiple instrument sets at a time, the availability of instructions outside of the medical washer, the ability to house larger instruments such as retractors and clip appliers, and the inclusion of sterilization capabilities. Additionally, it was suggested that the medical washer should have an automatic draining feature to eliminate the need for buckets. These suggestions highlight the areas where the participants felt that the medical washer could be improved, and could serve as a starting point for further development of the device. Further research and testing may be needed to determine the feasibility and potential benefits of implementing these suggestions.

Limitations

There are several limitations to consider when interpreting the findings of this study. First, there is a limited amount of previous research in the field on the usability of medical washers in rural India. This may limit the ability to compare the results of this study to other work in the field.

Second, there was a language barrier that may have affected the results of the study. One participant mistook the medical washer for an autoclave, which could have influenced her perception of the device.

Third, three of the hospitals where the study was conducted did not own their own set of laparoscopic instruments, which may have limited the experience of the nurses at those hospitals with handling such instruments. This could have affected their ability to accurately assess the usability of the medical washer.

Recommendations

A concept evaluation of a medical washer specifically designed for use in rural India was conducted in this study. The findings indicate that the nurse perceive the medical washer as a positive addition to their current reprocessing method. but there are several areas for improvement in terms of usability and user satisfaction. Different design suggestions for a new iteration of the medical washer can be seen in table 16.

System	Redesign suggestions
Loading system	The silicone holder for the inserts should be more noticeable.
	More guidance should be given to the user when loading the baskets.
	The placement of the valves should be a point of focus when creating added guidance.
	The diameter of the flush ports should be increased.
	The space should be increased in between the flush ports.
	The serrations in the silicone holder for the lumens should be increased in size.
	The medical washer should be able to house larger instruments like retractors and clip appliers.
Cleaning system	The medical washer should also sterilize the laparoscopic instruments.
	The medical washer should drain automatically so no buckets are required.

Table 20: Redesign suggestions for the next iteration of the medical washer.

In addition to the various redesign suggestions presented, there are several topics that warrant further research. For example, further testing should be conducted to determine the amount of weight that is comfortable for nurses to load into the washer. Additionally, more research is needed on the sets and quantity of laparoscopic instruments available in rural Indian hospitals. These areas of study would provide valuable insights that could inform the design of future versions of the medical washer.

11.5 Conclusion

In conclusion, the root cause analysis and evaluation interviews conducted in this study provide valuable insights into the correct and incorrect use of the medical washer in rural India. The findings reveal that the medical washer is generally perceived positively by rural nurses, with many reporting that it helps to improve safety, consumption of water, hygiene, instrument lifetime and cleaning time. However, the study also identified several areas for improvement, including the need for clearer instructions and more user-friendly design features.

Overall, the results of this study suggest that the medical washer has the potential to be an important tool for improving hygiene and preventing the spread of infection in rural healthcare settings. However, further design improvements and more robust training programs will be necessary to ensure that it is used correctly and effectively. Future research should focus on further identifying and addressing the comfort of the use of the medical washer and the amount of sets of laparoscopic instruments available in rural Indian hospitals.

Appendix 11: Reach envelopes

To ensure the baskets can be loaded comfortably anthropometric data was used. In India 80 percent of the workforce consists of females (Karan et al., 2021). The stature of a P50 female is 1540 mm (Dined, n.d.). Using the stature reach envelopes were used to determine the comfortable vertical reach distance. The fifth percentile was used of the test population of people between 20 and 30 years old smaller than 1700 mm. The measurements can be seen in figure 39.

The baskets are 500 mm in length and are loaded vertically. To avoid that the nurses have to lift the baskets above their head, the washer should be less than 1040 high. The minimal vertical distance for a comfortable reach is 1117 mm. Therefore, the height of 1025 mm of the washer is identified as optimal as the nurses do not have to lift the baskets above their head. However, the height is still in the vicinity of the minimal comfortable reach.

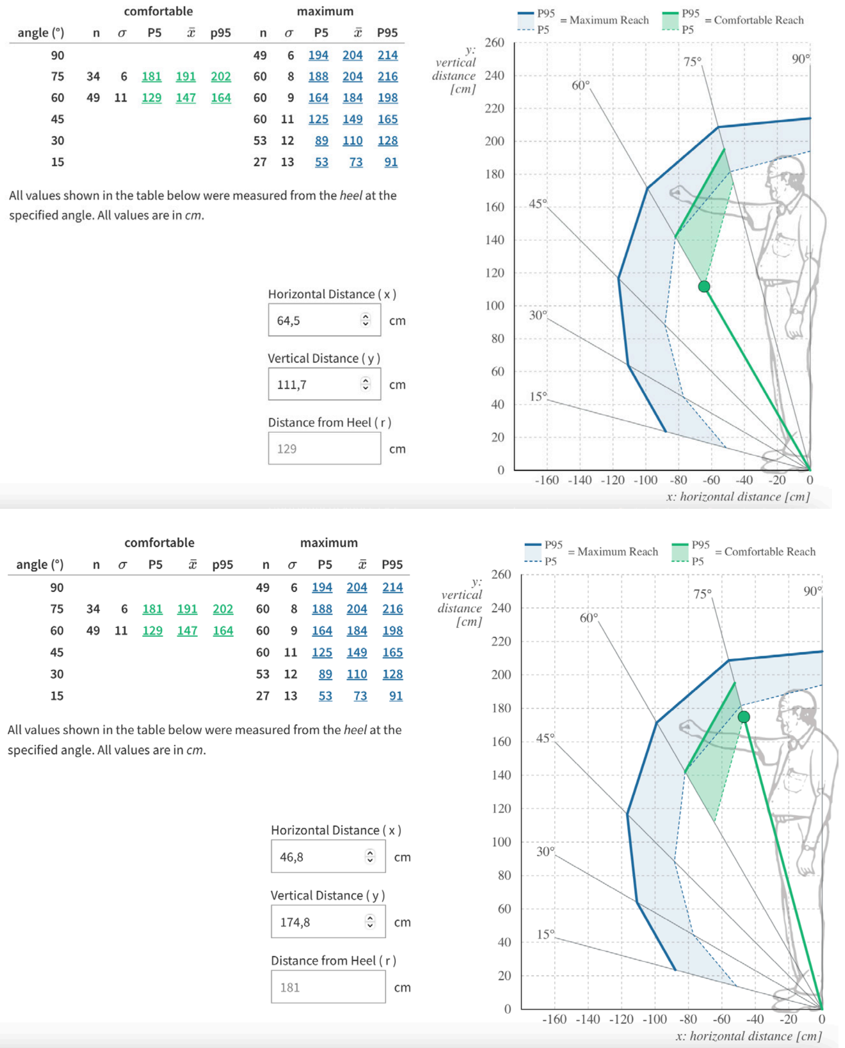
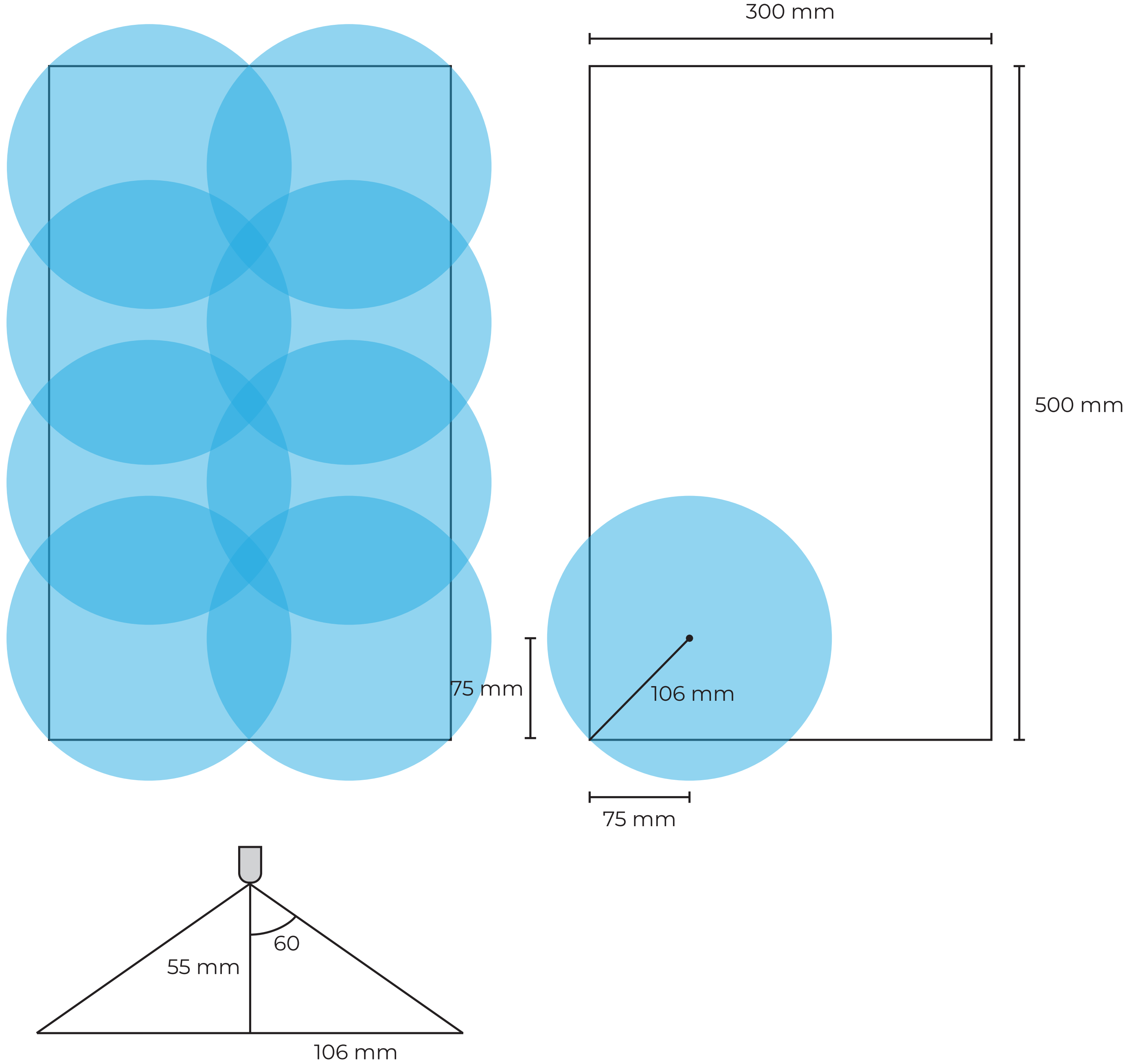
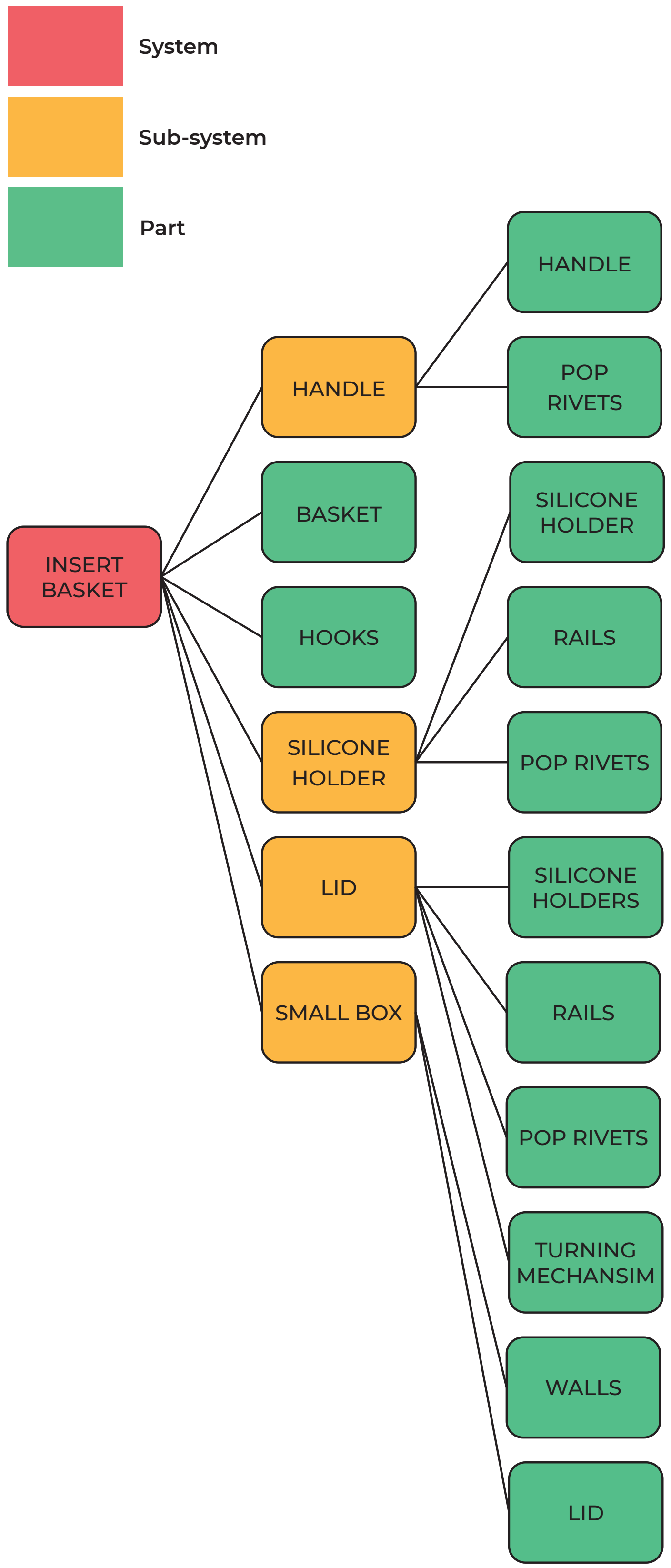


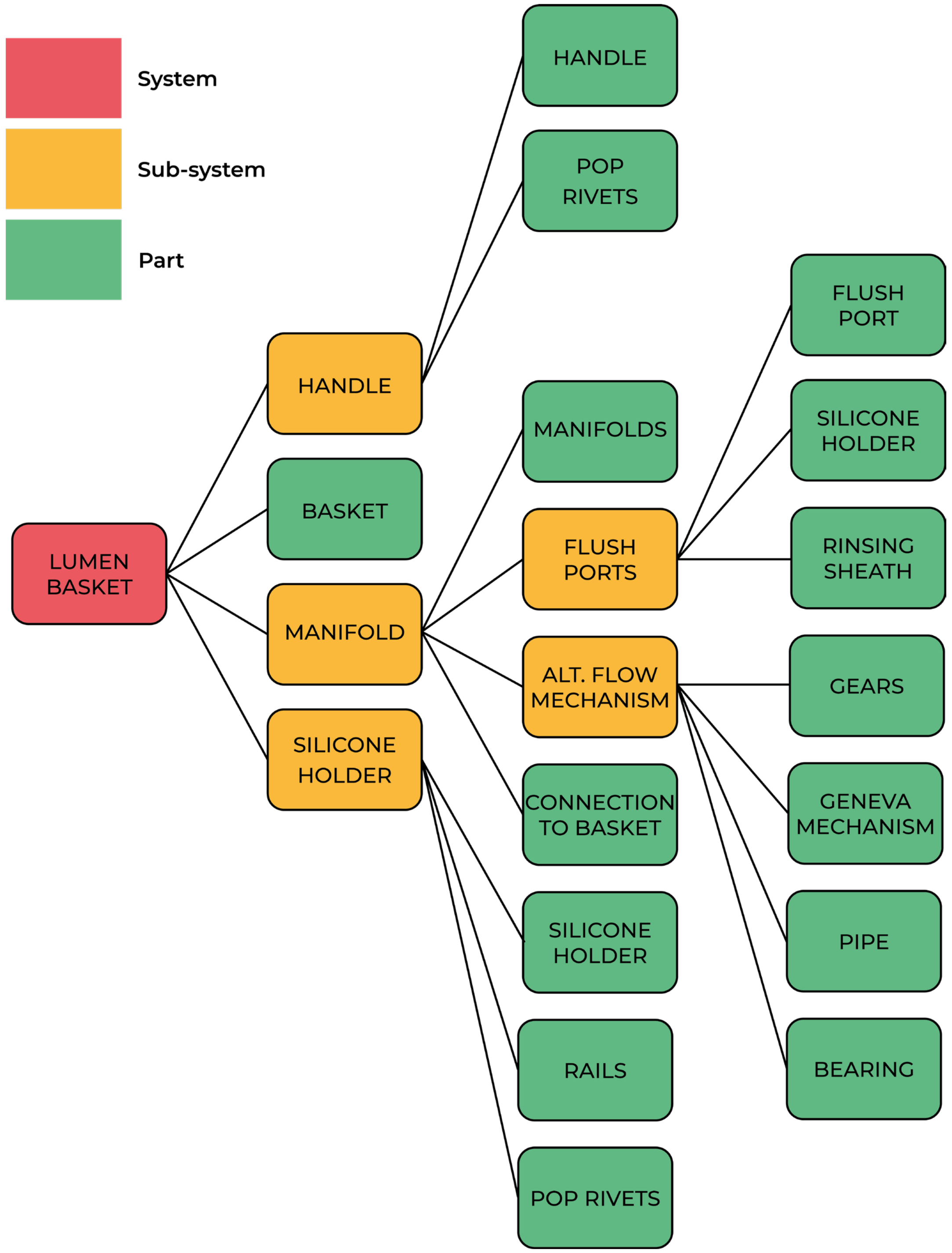
Figure 39: Reach envelopes of minimal and maximal comfortable reach for P5 of the population between the ages of 20 and 30 under 170 cm (Dined, n.d.).

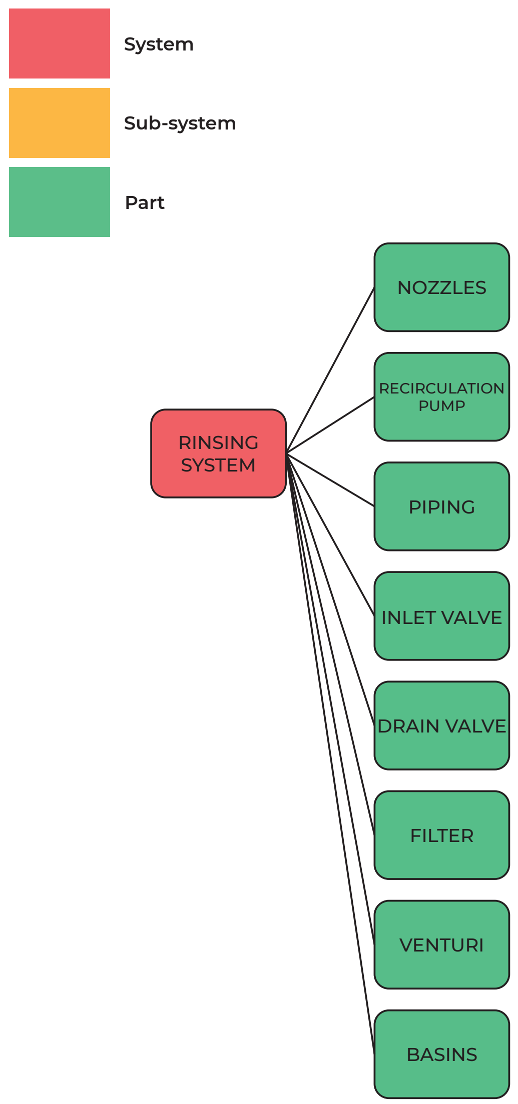
Appendix 12: Distance between spray jets and baskets.

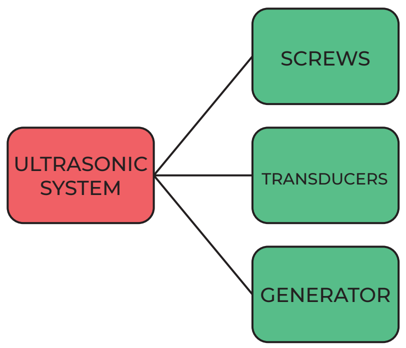


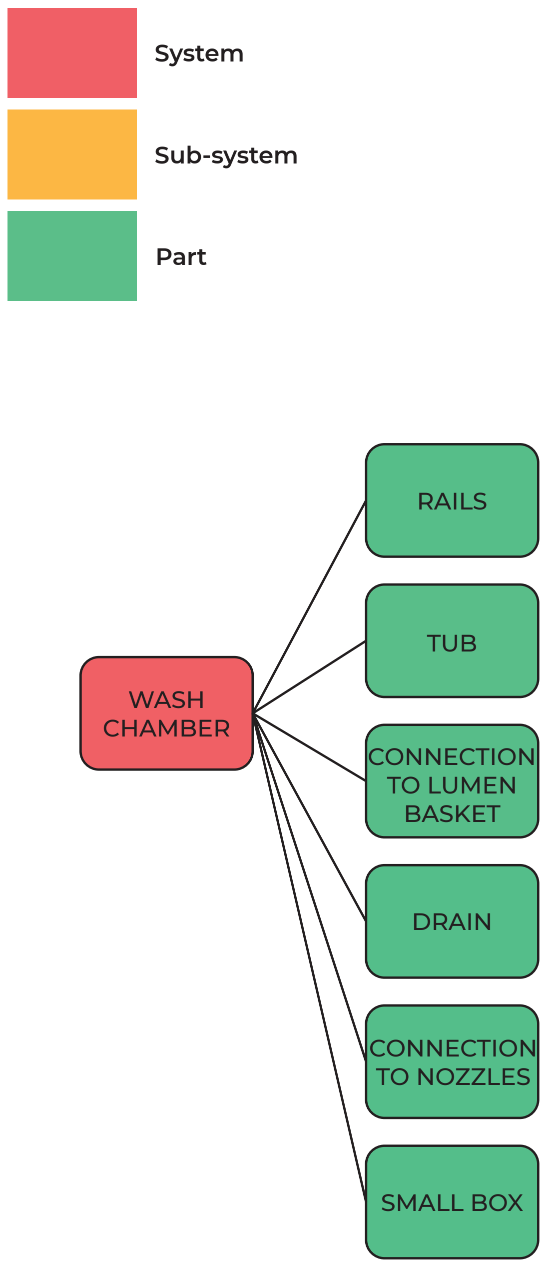
Appendix 13: Function analysis sub-systems






System
Sub-system
Part
RINSING SYSTEM
NOZZLES
RECIRCULATION PUMP
PIPING
INLET VALVE
DRAIN VALVE
FILTER
VENTURI
BASINS


ULTRASONIC SYSTEM
SCREWS
TRANSDUCERS
GENERATOR


System
Sub-system
Part
WASH CHAMBER
RAILS
TUB
CONNECTION TO LUMEN BASKET
DRAIN
CONNECTION TO NOZZLES
SMALL BOX

Appendix 14: Project brief

DESIGN FOR our future

5682

TUDelft

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: Kok
initials: A.G.W. given name: Abe
student number: 4375459
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: Biomedical Engineering - Track 2
individual programme: 22 - 02 - 2022 (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: Jan Carel Diehl — dept. / section: IDE/DfS
** mentor: Sonja Paus-Buzink — dept. / section: HCD
2nd mentor: Daniel Robertson
organisation: Biomedical Engineering
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 Jan Carel Diehl date 05 - 04 - 2022 signature jdiehl Digitally signed by jdiehl Date: 2022.04.05 21:37:12 +02'00'

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: 15 EC

Of which, taking the conditional requirements into account, can be part of the exam programme 15 EC

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

★ YES all 1st year master courses passed

NO missing 1st year master courses are:

name C. van der Bunt date 22 - 04 - 2022 signature C. van der Bunt Digitally signed by C. van der Bunt Date: 2022.04.22 12:32:36 +02'00'

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: V APPROVED NOT APPROVED

- also approved for Medisign

comments

name Monique von Morgen date 9/5/2022 - signature MvM

Design of a laparoscopic cleaning device for low to middle income countries

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 05 - 04 - 2022 | 15 - 11 - 2022 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, ...).

Laparoscopic surgery is a form of minimally invasive surgery. During laparoscopic surgery small incisions are made through which long thin instruments are positioned and used to operate inside the abdominal cavity of the patient. Laparoscopic surgery has multiple advantages compared to conventional surgery. Due to the smaller incisions made the patient has a smaller risk for contracting a surgical site infection, a faster recovery time and shorter hospital stay [1]. Due to these advantages laparoscopic surgery is done more and more in low resource settings like rural India. However, due to the complex geometry of the laparoscopic instruments and lack of time and training of the medical staff, the laparoscopic instruments are not reprocessed sufficiently, resulting in an increase in surgical site infections and mortality [2]. Cleaning of the laparoscopic instruments is currently done manually by the medical staff which results in variable amounts of contamination still present on the instruments. Untrained staff can also damage the instruments during the cleaning process [3]. When designing for rural hospitals in India there are several constraints to consider. There is a fluctuating amount of water of a variable quality available for cleaning per hospital, the hospitals are usually powered by generators which can shut off at times and the hospitals do not have a large budget for medical devices [4]. However, surgery is very cost-effective even in low-resource settings, especially when the risk for surgical site infections is minimized [5]. Much of the medical equipment that is currently sent to low-resource areas is unrepairable when broken as the staff lacks training and cannot afford or acquire the complex spare parts [6]. Due to the cost-effectiveness of surgery it is especially valuable as a treatment in low resource settings. Laparoscopic surgery specifically enhances this cost-effectiveness due to its specific advantages. However, for successful laparoscopic surgery the instruments need to be clean. To save the precious time of the medical staff and create a clean result an automatic laparoscopic instrument cleaner could be a valuable solution. The automatic laparoscopic instrument cleaner must be easily repairable and designed with attainable components which are low in cost and can withstand the fluctuating power supply. Creating a design which fits the context requires close contact with the stakeholders. The stakeholders and their interests can be seen in figure 1.

The idea to create a frugal laparoscopic instrument cleaner was developed by Daniel Robertson, who is a PhD student in the topic of medical instruments and Bio-Inspired Technology, while doing context research in rural India. Before me two graduation students have already worked on this project. Girish Malage, who has done initial context research for the laparoscopic instrument cleaner and Nabil el Hasnaoui, who did research into the effect of flow rate on contamination in hollow medical instruments. In my project I will continue the context research done by Girish and perform tests with the test setup by Nabil. I will use this to create requirements, while also researching other possible directions like ultrasonic cleaning. With these requirements I will develop concepts while working closely with the users. I will further develop the subsystems of my chosen concept and finally design and create the first full prototype of the laparosopic instrument cleaner.

[1] Agha, R., & Muir, G. (2003). Does laparoscopic surgery spell the end of the open surgeon? JRSM, 96 (11), 544–546. https://doi.org/10.1258/jrsm.96.11.544

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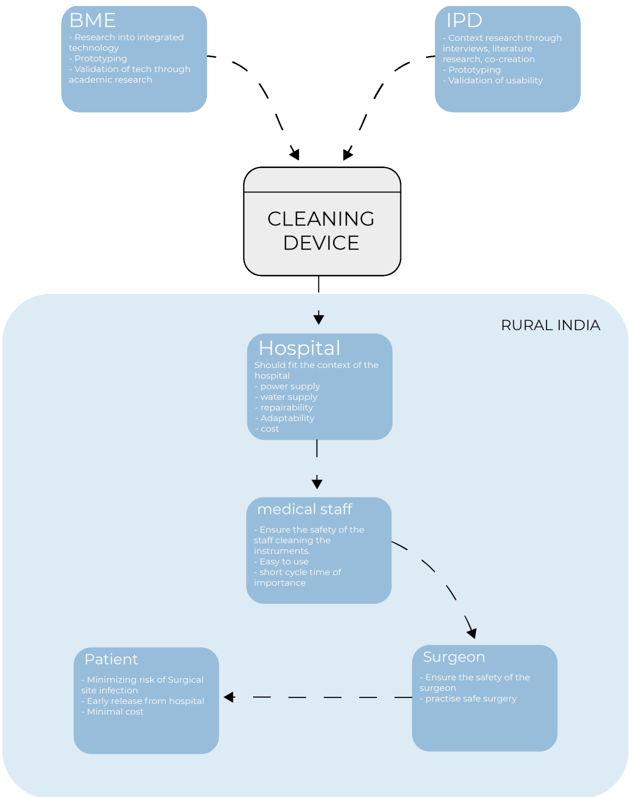


image / figure 1: Stakeholder map

TO PLACE YOUR IMAGE IN THIS AREA:

- **SAVE THIS DOCUMENT TO YOUR COMPUTER AND OPEN IT IN ADOBE READER**
- **CLICK AREA TO PLACE IMAGE / FIGURE**

PLEASE NOTE:

- **IMAGE WILL SCALE TO FIT AUTOMATICALLY**
- **NATIVE IMAGE RATIO IS 16:10**
- **IF YOU EXPERIENCE PROBLEMS IN UPLOADING, COVERT IMAGE TO PDF AND TRY AGAIN**

image / figure 2:

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.

Laparoscopic instruments are long slender instruments. Even when disassembled the instruments consist of complex geometries which are hard to clean and visually inspect. The instruments are currently cleaned manually between surgeries. This is done under high time pressure as the staff which cleans the instruments also has to clean the operating room itself and many procedures need to be done in a small time window. This results in residual contamination still present on the instruments and increased risk of infection of the staff. Residual contamination makes full disinfection or sterilization impossible which finally leads to increased surgical site infections [7][8]. An automatic laparoscopic instrument cleaner can create a better, more standardized result as there is no human error in the process and requirements can be set beforehand which result in a validated cleaning result.

Many medical devices which are sent to low resource areas end up at a dump, because the devices are hard to maintain, repair and spare parts are expensive or hard to acquire. For a design to fit this context it needs to be easily maintainable, repairable and designed with parts that can easily be obtained. The product and its spare parts must also be affordable for hospitals in rural |ndia.

The power and water supply in the hospitals in rural India can vary. The voltage generated by the generators can fluctuate between 150 and 300 volt and the water supply can be limited at certain hospitals. The design should therefore be able to withstand high voltage fluctuations and use a limited amount of water.

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.

The aim of the project is to design a laparoscopic instrument cleaner which can deliver a standardized result of cleanliness while alleviating the workload of the medical staff. This laparoscopic instrument cleaner should use little water and power and be affordable and easily repairable.

The result of this project will be a design which:

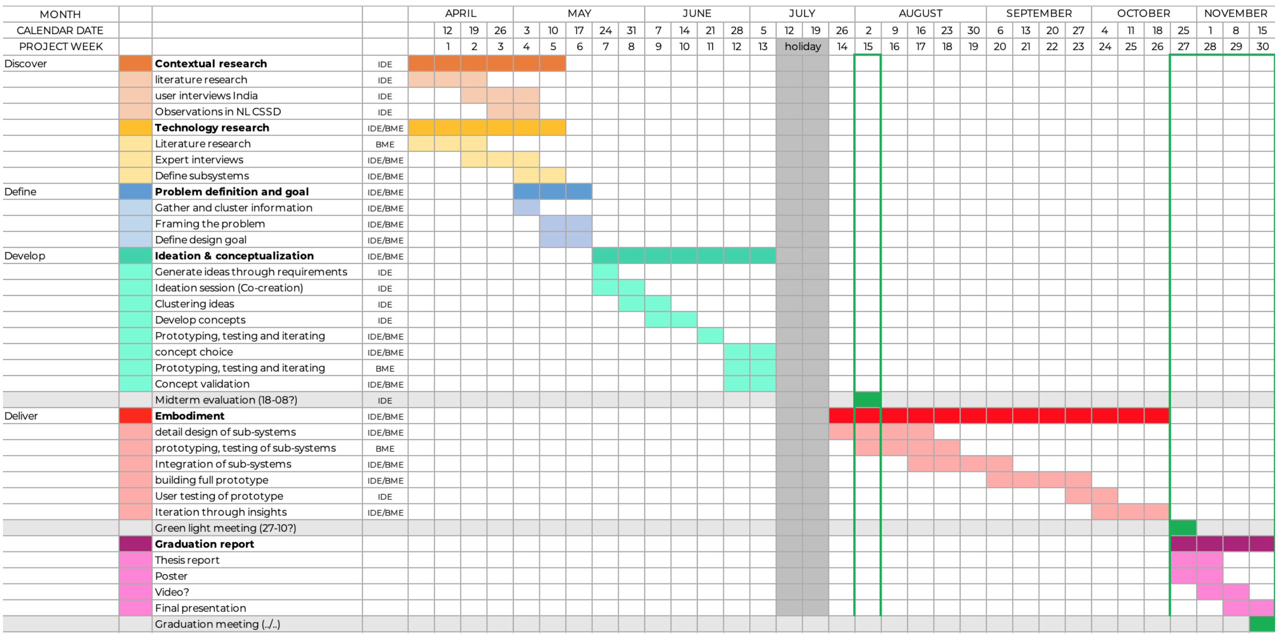
- Fits the context: This is done through surveys, expert interviews, observational research, and literature research. The design will decrease the workload of the staff. Which relieves some of the time pressure the staff is faced with and reduces the risk of infection the staff is subject to. This will be a frugal solution which focuses on repairability and minimizing the costs needed to create and distribute the product.
- Meets technical requirements: The prototype should meet FDA or similar requirements for the removal of bioburden on the laparoscopic instruments while using a limited amount of water and withstanding high voltage fluctuations. To achieve this, all elements of the sinner circle should be implemented in the design at certain levels. To identify at which levels each of the elements of the sinner circle create a result which matches the requirements of the FDA, literature research and experiments will be done.

As this graduation project combines both Integrated Product Design and Biomedical Engineering the assignment should reflect this. While the focus of Integrated Product Design is more on the design process of the device, the focus of Biomedical Engineering is more on academic research. I plan to integrate these directions by using academic research to generate requirements for the design of the device and to validate these requirements in the final prototype.

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 5 - 4 - 2022   15 - 11 - 2022 end date



The planning of the project is divided into 4 major stages: Discover, Define, Develop and Deliver (Design council, 2004).
DISCOVER: In the discover phase information is gathered on the context and technical aspects of the design. Context research is done into the health care system of India, the current reprocessing journey of the laparoscopic instruments and the stakeholders their values and interests. To understand the technical aspects research is done into the physics of cleaning, integrated technology needed and the governmental requirements of such a device.
DEFINE: In the define phase all the information gathered in the discover phase is framed and reframed to determine a design direction and define the challenges that need to be solved to create the laparoscopic instrument cleaner.
DEVELOP: In develop phase a large set of solutions are generated. These solutions are tested through rapid cycles of prototyping, improving and validating. The solutions are created in collaboration with the stakeholders.
DELIVER: In the deliver phase will focus on the embodiment and creating working prototype. Small iterations will be done to detail and refine the design.

The time frame of my graduation project is 150 days as I am following a individual double degree. In the planning can be seen which parts of the project are dedicated to which master program.

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.

During my bachelor at IDE I found that the projects that focused on healthcare were often the ones that created the most value. Therefore, I wanted to dive deeper into the subject of healthcare and started the master Biomedical Engineering. After my first year of Biomedical Engineering, I started Integrated Product Design with the specialization medisign. The design of medical devices is very interesting to me as it requires knowledge on the human anatomy, technical insight, and an empathic mindset. There is a large inequality in the quality of healthcare between high income and low-income countries. For that reason, I wanted to do a design project which focused on low-resource settings. I want to design something that helps in making higher quality healthcare accessible for all people.

My ambitions for this project are:

- To gain more experience in designing for a context which is foreign to me. I want to develop my interviewing skills further to understand the user and their culture.
- To create technical requirements which fulfill international norms by doing academic research through experiments and by analyzing these experiments.
- To gain knowledge on how to design a complex medical device which can be maintained and repaired locally.
- To further develop my project management skills by keeping all the stakeholders in the loop throughout the process.

[2] Raina, B., Malhotra, A.S., Gupta, S., & Mehta, K.S. (2018). The Study of Postoperative , Port-site Mycobacterium Tuberculosis Infection in Laparoscopic Surgeries in Jammu. [3] Robertson, D., Gnanaraj, J., Wauben, L., Huijs, J., Samuel, V. M., Dankelman, J., & Horeman-Franse, T. (2021b). Assessment of laparoscopic instrument reprocessing in rural India: a mixed methods study. Antimicrobial Resistance & Infection Control, 10(1). https://doi.org/10.1186/s13756-021-00976-x[4] Deodhar, J. (2002). Telemedicine by Email — Experience in Neonatal Care at a Primary Care Facility in Rural India. Journal of Telemedicine and Telecare, 8(2_suppl), 20–21. https://doi.org/10.1177/1357633x020080s209 [5] Chao, T. E., Sharma, K., Mandigo, M., Hagander, L., Resch, S. C., Weiser, T. G., & Meara, J. G. (2014). Cost-effectiveness of surgery and its policy implications for global health: a systematic review and analysis. The Lancet Global Health, 2(6), e334–e345. https://doi.org/10.1016/s2214-109x(14)70213-x [6] Marks, I. H., Thomas, H., Bakhet, M., & Fitzgerald, E. (2019). Medical equipment donation in low-resource settings: a review of the literature and guidelines for surgery and anaesthesia in low-income and middle-income countries. BMJ Global Health, 4(5), e001785. https://doi.org/10.1136/bmjgh-2019-001785 [7] Marlow, S. C., & Petruschke, H. K. (1995). Cleanability of Hybrid Laparoscopic Instruments. AORN Journal, 62(1), 32–36. https://doi.org/10.1016/s0001-2092(06)63681-8 [8] Fengler, T., Pahlke, H., Roth, K., & Michels, W. (2003). Again: What is Clean, What is Pure?. Zentral Sterilisation, 31. [9] PathogenCombat. Factors affecting fouling and cleanability of closed food contact surface. EU Integrated Project PathogenCombat; 2011. p, http://www. pathogencombat.com/Publications/~/media/Adtomic/Unique%20Achievements/Leaflets/Factors%20affecting%20fouling%20and%20cleanability%20of%20closed%20food%20contact%20surface.ashx.

FINAL COMMENTS

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