Appendix

A . India Hospital Observations

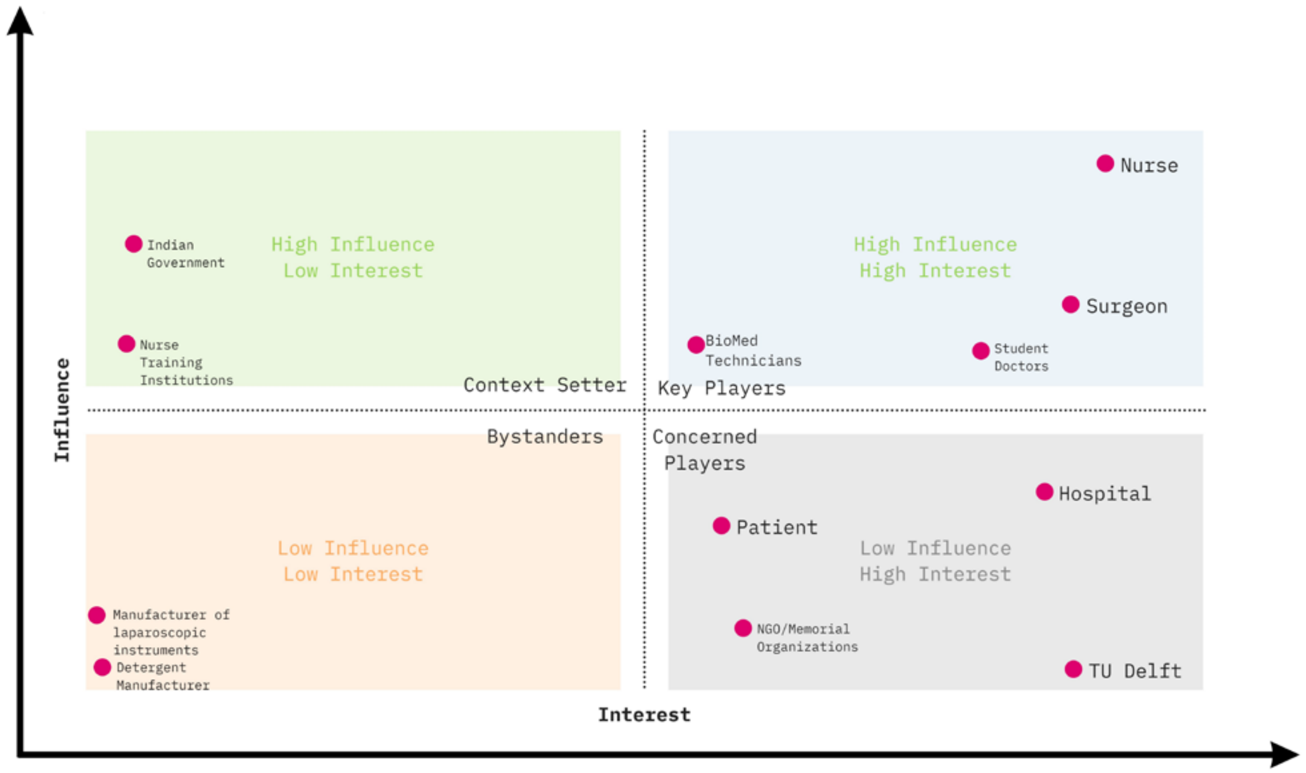
General	Hospital A		Hospital B		Hospital C		Hospital D	
Action	**Y/N**	**Comment**	**Y/N**	**Comment**	**Y/N**	**Comment**	**Y/N**	**Comment**
Basic general hospital statistics								
Hospital type		Tertiary rural mission hospital		Tribal Mission Hospital		Tribal secondary healthcare mission		Secondary rural
Total number of beds		100		35		50		25
Number of operating theatres		4		2 1 big with 2 beds, 1 small with 1 bed		2		1
Number of surgeries per year		300 depending on present surgeones		2 days p/w. 800 surgeries incl. minor		600, 40 laparoscopic		360, 50 Laparoscopic
CSSD general information								
Number of CSSD staff				none		0		0
Number of OT nurses		5 or 6 during surgery		28, 5-6 on surgery teams		6		3-4
Number of Biomedical technicians		0		0		0		0
Who reprocesses the laparoscopic instruments		OT Nurses		OT nurses		OT nurses		OT nurses
Compliance with standards is verified against				none		NABH entry level		
There is record keeping of sterile reprocessing				paper based		Autoclave tape results are recorded		
There is periodic review of reprocessing performance								
Product descriptions/documentation are available for all products to be sterilized								
There is a procedure for new materials/instruments								
Disposables are being reprocessed and reused								
What types?		Ports, ESU knives, Vessel sealers, lap instruments		Ports, ESU knives, Vessel sealers, lap instruments		Ports and handles		Vessel sealers
Number of reuses is documented								
How often		not tracked		not tracked		Not known		Not known
For instruments that can be disassembled, (manufacturer) instructions are available for disassembly								
There is a written protocol for manual cleaning								
There is a protocol for repair of instruments								
CLEANING FACILITIES IN AND AROUND THE OT								
How often are the OT and cleaning areas cleaned?		Daily		daily		2 times per week		After surgery
Sinks are cleaned at the end of the day						2 times per week		After surgery
Personal protection								
Gloves of different materials						One type of glove		one type of glove
Watertight aprons with long sleeves								
Safety goggles								
Splash screen								
Equipment in the OT								
Compressed air gun								
Water gun								
Hand Shower								
Ultrasonic cleaner								
Flash autoclave								
Compressed Air								
Sink where instruments are rinsed								
other equipment				2 autoclaves				
The disinfectant trays (for Cidex) are kept near the OT		In the OT		in the OT		in the OT		in the OT
What sort of disinfectant tray is used?		Stainless container		plastic CIDEX container		Stainless steel container		Plastic Cidex container
How often are the disinfectant trays cleaned?								Once per month
How often are the rinsing trays cleaned?		No rinsing tray						Once per month
DESCRIPTION OF THE CSSD								
There is a CSSD						area is near but separate		
All surgical instruments are fully processed in the CSSD		All instruments are cleaned near the OT						
The CSSD is cleaned daily						bi-weekly		
Sinks are cleaned at the end of the day						bi-weekly		
There are separate rooms for dirty, clean and sterile goods						yes but not used		
Transport of sterile and contaminated goods is strictly separate		It can be but not used						
The instruments are only passed through machine hatches						2 door autoclave is present but not used		
There is a storage area with racks				yes but open		But not used		
Personal protection								
Gloves of different materials								
Watertight aprons with long sleeves								
Safety goggles								
Splash screen								
Dirty area equipment available in CSSD								
Water gun								
Hand Shower								
Sufficient materials for manual cleaning are available (brushes for external and internal cleaning)						Only dish brushes		
Washer-disinfector		Not used						
Ultrasonic cleaner								
Drying machine		Broken						
Compressed air gun								
How often is the ultrasonic cleaning fluid replaced?								
The used cleaning agents are suitable for the washer-disinfectors								
Inspection and assembly area								
Insulation tester								
Microscope								
Composition reference (paper or computer)								
There are composition basket sets of instruments								
Instrument set compositions are documented								
Of each set a photograph is available								
The documentation of set compositions is								
Paper based								
Based on electronic documents (database)								
There are multiple laparoscopic instrument sets for consecutive surgeries								
Packaging materials available								
Cotton sheets		For surgical equipment						
Crepe paper								
Non-woven sheets								
Sterilization paper bags								
Sterilization pouches		For ETO machine						
Schimmelbush drums		For linen sheets and drapes						
Filter drums		not seen in use						
Sterilization containers								
Heat sealer is available for sealing pouches								

Sterilizing area								
Information is available on the chemical and physical behaviour of the items to be sterilized								
Sterilisers available								
Steam steriliser (size in liters)						240L		
ETO steriliser								
Sterrad steriliser								
Formaldehyde steriliser								
other								
The steam steriliser is:				manual		manual		pressure cooker
The steam steriliser has a readout		Only the ETO machine						
The steam steriliser has a vacuum cycle						Yes but not used properly		
Sterilisers with toxic gasses are given time to vent								
Routine sterilizer performance testing								
How often is a Bowie Dick test carried out?				never		Never		
The result of the Bowie-Dick test is documented								never
Routine sterilization performance testing is done by...								
Standard Bowie and Dick test pack (textile)								
Disposable Bowie and Dick test pack								
Chemical indicator strips								
Process challenge device such as GKE with chemical indicator								
Helix with chemical indicator								
Electronic process challenge device such as ETS (3M), EBI 16 (Ebro) or DPCD (Interster)								
Process challenge device with Biological Indicator								
If in use: ….. x per week per sterilizer								
How often is maintentance performed on the autoclaves?		Once per year and when the autoclave is broken				Yearly		
Is there record keeping of the maintenance?				when autoclave is broken				
Disinfection in Cidex trays is done in the CSSD								
Reprocessing procedure laparoscopic equipment								
Before start of first surgery								
Lap equipment is HLD'd		in CIDEX		in CIDEX				soaked in CIDEX
Lap equipment is sterilised		in the formalin chamber						
In Surgery & Pre-cleaning								
Gloves of OT nurses are changed for surgery after cleaning		Only when assisting in surgery						Between cases, not during surgery
After surgery, used lap instruments are stored in a soaking solution								Between cases, not during surgery
What solution is this?		tap water				water		water
The transport containers are leak proof, can be cleaned well		stainless bowl		stainless steel bowls		stainless steel bowls		no container
Transport to cleaning								
Laparoscopic equipment is transported to CSSD								
Regular surgical equipment is transported to CSSD						But first stored outside OT		Regular instruments are also placed in form. chamb
Where is the lap equipment moved?		The sink outside the OT		sink is outside the OT				Sink next to OT
Equipment is kept moist		Cleaned directly after use		cleaned directly after use		In water		
Cleaning of laparoscopic equipment								
Disinfecting								
Lap equipment is disinfected before cleaning								
What disinfectant is used?						bleach		
Lap equipment is rinsed after disinfecting								
Removing gross soil								
Whenever possible, lap instruments are disassembled.								
Hollow instruments are flushed with water using a spray gun				sometimes with a syringe		Flushed with the tap		
Gross soil is removed by rinsing		Under running tap water		under running tap water				
Gross soil is removed using tools								
What tools are used?		Toothbrush		needle for the ligasure blade gap, toothbrush		Toothbrush		toothbrush
Automatic methods								
Equipment is ultrasonically cleaned								
Lap equipment is cleaned in washer/disinfector								
Lumens are connected for mechanical flow								
Instruments are loaded in open position								
Manual Cleaning								
What cleaning solution is used?		soap powder		soap powder		soap powder		soap powder
Manufacturer instructions for the agent are followed								
Instruments are fully disassembled		ligasures and disposables are soaked						
Cleaning solution is deep enough to submerge instruments		Under running water and soap powder		Under running water and soap powder				
Appropriate quantity of detergent is used								
Sufficient brushes for manual cleaning are present for external and internal cleaning)		only toothbrush		toothbrush and needle		toothbrush		toothbrush
The lumens are brushed (submerged)								
The instrument tips are brushed								
Rinsing								
Instruments are rinsed								
In what basin		In sink under running tap water		In sink under running tap water		in sinkk		in the sink
What water is used?				tap water		tap		tap
		tap water						
Drying								
Instruments are dried								
Lumens are dried		Lumens are dried with a hairdrier						
Brushes are cleaned at the end of the day								
Cleaning tools are disinfected								
INSPECTION								
Instruments are inspected for cleanliness				But revealed to be dirty		While cleaning		
Dirty instruments are reprocessed				But not always				

Instruments are lubricated. Which lubricant?				With refined coconut oil, only before storage		Silicone oil		
Insulation in inspected				Instruments with broken insulation are not used for ESU		Visually		not seen
Instruments are assembled								
Instruments are being opened and spread out for functionality checks								
Instrument set compositions are consulted during set assembly						No compositions available		no compositions available
Damaged instruments are removed from a set and replaced by an adequate replacement		Only when broken		Only when broken				not seen
Chemical Disinfection								
Instruments are chemically high-level disinfected								
Gloves are changed when handling instruments in Disinfectant								
What disinfectant is used?		CIDEX + SPIRIT		CIDEX + spirit		Cidex and Formalin		CIDEX and Formalin
Soaking times are tracked		when next patient is ready				20 min		
How is time tracked?		clock on wall		Roughly with clock on the wall		on cell phone		clock on the wall
Number of soaks is tracked				Not needed because no lap surg every day				Few cases, new bottle is opened each time
When is liquid discarded?		14 days		after 14 days		After every day of surgery, no multiple surgery days		After every day of surgery, no multiple surgery days
Date of the liquid activation is noted								
When was the liquid last discarded?				New bottle opened		new bottle		new bottle
Chemical indicators are present								
Chemical indicators are used periodically								
The lumens are filled with disinfectant								
There is flow present in the disinfectant								
Disinfectant is deep enough to submerge instruments		some instruments stick out						
How are the disinfectant trays cleaned?						Washed and autoclaved		
Gloves are changed before rinsing instruments								
Instruments are rinsed								
What type of water is used?				saline from bottles		sterile saline		sterile saline
Are the lumens flushed? How?		saline from bottle						soaked in container
How many times is the instrument rinsed		once		once		once		left to soak
Water is discarded after each use						end of the day		kept for next day
Drying								
How are the instruments dried?		Not dried before surgery.		not		Not seen		Not seen
How are the lumens dried?		Not dried before surgery.		not		Not seen		Not seen
What air source is used?								
Formalin								
Formalin chambers are used						On reusable trocars		On all instruments, regular and laparoscopic
How many tablets are used		9 per chamber		10 per chamber		3 per tray		Multiple tablets in various containers
Date of tablet placement is noted								No, kept for 1 week to 1 month
How long are the instruments in the chamber?		Between surgery		not seen		For storage		Overnight for storage
Time in chamber is tracked		Between surgery						
Chambers are opened between surgeries						Not seen		
Instruments are stored in Formalin chambers until the next day								
TRANSPORT & STORAGE								
In what state are the instruments stored at the end of the day?		cleansed						Cleaned and soaking in Cidex
Sterilised instruments are kept in storage								Stored in formalin chamber

These observations and observation sheet was made by ir. Daniel Robertson on his field trip to the four hospitals in February-March 2020.

B . Stakeholder Map



The stakeholder map is created to map all the possible parties who are interested in this project and problem. This map has been divided into four quadrants based on their influence vs interest. The stakeholder map clearly states that the rural Indian nurses are of the highest influence and have the highest interest in cleaning surgical instruments, hence are the primary users of the frugal mechanical washer that is designed in this project.

C . Questionnaire

Laparoscopic Instrument Reprocessing

Questions to be asked to the cleaning staff. It is important that the translator is a local who asks the questions in a very friendly and informal way, preferably a local dialect.

1) Hospital Location: To be filled by interviewer

> --

2) What is your name?

> --

3) What is your age?

> --

4) What is your educational qualification?

> --

5) How long have you worked in this job?

>-------- x years ---------------------------------

6) What was your job before this?

> --

7) Have you had training for this job? If yes, please explain.

> --

8) In the process of cleaning surgical tools, what are your specific duties?

> --

9) Please take us through the entire process of cleaning of these (laparoscopic) instruments. (can be a video interview)

> --

----

10) What has changed in your process of cleaning surgical instruments since your training?

> --

11) And why did this part of your process change?

> --

12) What would you like to do differently in your job of cleaning the laparoscopic tools?

> --

13) How much time does each step take?

> --

14) How man sets of laparoscopic tools do you clean each day?

- ◯ 1 - 5
- ◯ 5 - 10
- ◯ 10 - 15
- ◯ 15+

15) Do you clean the laparoscopic tools any differently from the regular tools?

> --

16) Are you aware of existing guidelines? (guidelines: disha nirdeshon)

◯ Yes ◯ No

17) In your personal opinion, what are the stress points when cleaning of the laparoscopic tools?

> --

D . Interview Notes

Date: March 2020
Meeting Objective: Discuss the sterile processing practices in rural India.
Attendees: Nurse in Guwahati

Discussion

1. Training: no specific programme. Only undergo orientation with the staff
2. Information is very hospital specific. If Hospital A as a good laparoscopic facility, they will be better at treating those instruments compared to hospital B that only does general surgery.
3. Knowledge is limited based on facilities.
4. Time: cleaning the instruments is relative less compared to HIC hospitals because they don't have standard operating procedures.
5. Proper cleaning before surgery is minimal.
6. There can be clean instruments that are not sterilized, but instruments cannot be sterilized without cleaning.
7. Cleaning is done better at the end of the day and most time is spent because the nurse duties are less.
8. The effort put by nurses in cleaning instruments in rural hospitals is more than HICs but outcome is not up to the mark.
9. Steps: between surgeries, the hospital does not have enough time to clean the instruments. Surgeries need to be done in quick succession because of availability of anaesthesiologist.
   Instruments are cleaned in detergent soap powder by scrubbing the tips and then disinfected in CIDEX for 20minutes.
10. Instruments are properly dismantled cleaned, dried and stored at the end of the day.
11. Some hospitals don't dismantle but only scrub and dry for the next day.
12. Instruments are not autoclaved because hospital staff believe that the autoclave ay damage the laparoscopic instruments.
13. 2 methods for sterilization are followed. Immersion in CIDEX or placing instrument in Formalin chamber.
14. There is no guarantee that the instruments are completely sterile.
15. Indicators are not used in rural hospitals.
16. Formalin tablets are most commonly used sterilizers.
17. Instruments are exposed to formalin for the entire night. OT is also fumigated with formalin.
18. Formalin chambers are clear plastic boxes. White formalin tablets are placed in the box. Formaldehyde is released by these tablets that kills pathogens.
19. Formalin is gentle on the instruments, but it is very unhealthy for the staff.
20. The knowledge of the ill effects of formalin is low. It's like smoking. The effects may be felt later.
21. Choke points in the surgical instrument journey: minimal availability of instruments. Usually one or 2 sets.
22. The frequency of surgery may be 30min – 60 min. The same sets must be cleaned asap.
23. Low cost items like solutions are not available.
24. Rubber and electronic parts of the instruments cannot be autoclaved.
25. Steam sterilization is available but rarely
26. Only steel-based items are autoclaved.
27. Laparoscopic instruments are not autoclaved, but they can be.
28. A study to prove that disposables can be autoclaved is needed.
29. Solutions to sterilize rubber and electronics is needed.
30. Guidelines: there are no uniform guidelines followed by rural hospitals. Hospitals make their own rules depending upon availability of resource.
31. To minimize the biofilm accumulation on trays, trays are cleaned every 2 weeks as it is the lifecycle of CIDEX.
32. Ease for cleaning and sterilization is necessary in LMI hospitals.
33. Procedures are very subjective. They are based on hospital to hospital.
34. There is poor accountability for the nurses. There is a lack of monitoring. Nurses have to jump between departments and cannot focus on cleaning only.

Conclusions

1. Nurses are not trained under a fixed training programme.
2. Procedures for sterile processing vary from hospital to hospital. Guidelines are virtually non-existent.
3. Proper cleaning of instruments before consecutive surgeries is minimum.
4. Tools are more properly cleaned at the end of the day.
5. CIDEX and Formalin is commonly used.
6. Instruments are not properly dismantled.
7. Instruments are cleaned using toothbrush and detergent powders.
8. Poor accountability among nurses is common. Nurses are overworked and cannot focus on sterile processing.
9. There is no guarantee that the instruments are completely sterile because sterile indicators are not available.
10. Ease for cleaning and sterilization is necessary in LMI hospitals.
11. Formalin is safe for instruments but dangerous for staff who are exposed to it for long durations.

E . List of Requirements

- Requirement met (green)
- Requirement met partially (blue)
- Unknown for now (needs testing) (orange)

The research and analysis of laparoscopic reprocessing practices and facilities in rural India has led to addressing the need for mechanical washing systems for laparoscopic instruments. Many of the insights from the previous chapters have been converted to requirements. The development of a low cost frugal mechanical washing system should satisfy a list of requirements that states the necessary characteristics it must have for it to become a successful device. Requirements have been listed into clusters following a checklist mentioned in the appendix X .

Performance

The washer should be a standalone device with minimal dependence on hospital infrastructure.	Demand	Requirement met
The washer should not take up more than 1.5m X 1.5m floor space.	Demand	Requirement met
The washer should be able to flush, wash and rinse the laparoscopic instruments.	Wish	Requirement met
The washer should regulate water and detergents used according to instrument loads	Demand	Unknown for now (needs testing)
The washer should wash laparoscopic instrument sets that consist of 10 graspers, 5 trocars, 1 set of basic surgical instruments and pipes.	Demand	Requirement met
The washer should have a separate provision for non lumened instruments and smaller attachments.	Demand	Requirement met
The washer should be able to rid the laparoscopic instruments of all gross bioburden.	Demand	Requirement met
The washer should be able to neutralize and eliminate pathogens on the laparoscopic instruments.	Wish	Requirement met partially
The washer should use a fixed amount of water for every batch.	Demand	Unknown for now (needs testing)
The washer should dry the instruments after washing	Demand	Requirement met
The washer should clean and disinfect laparoscopic instruments without damaging and melting the laparoscopic instruments.	Demand	Requirement met
The washer should be able to regulate water temperature.	Wish	Unknown for now (needs testing)

The washer should run a minimum of 3 instrument batches per day.	Demand	Unknown for now (needs testing)

Time

The washer cart should be loaded within 5 minutes.	Demand	Unknown for now (needs testing)
The washer should clean the laparoscopic instruments batch within 30minutes.	Wish	Requirement met

Context

The washer should be able to withstand heat, humidity and dust.	Demand	Requirement met
The washer should be able to withstand power fluctuations		
The washer should be able to function the same even with lower water pressure from the source.	Demand	Unknown for now (needs testing)

Safety

The washer should be fully sealed to prevent splashing and aerosolization of soiled water.	Demand	Requirement met
The washer should have emergency shut down features.	Demand	Requirement met
The washer components should not have sharp edges.	Demand	Requirement met
The washer should have luer locks for every lumened instrument.	Demand	Requirement met

Durability

The washer should be able to withstand rough use.	Wish	Unknown for now (needs testing)
The washer should be able to withstand strong detergents, water pressure and corrosion.	Demand	Requirement met

Repairability

The washer should be easy to dismantle.	Demand	Requirement met
Spare parts of the washer should be locally available.	Demand	Requirement met
Spare parts of the washer should be easily replaceable.	Demand	Requirement met
The washer should be repairable by locally available servicemen.	Demand	

Manufacturing

The washer should be locally manufactured.	Wish	Unknown for now (needs testing)
The washer manufacturing should employ local		

workers and skill.	Wish

Ergonomics

• The washer should be ergonomically feasible, taking into account average height of Indian females.	Demand
• The loading of the instruments on the instrument cassette should be simple, straightforward and quick.	Demand
• The loading of the cassette into the washer chamber should be smooth, easy and minimal.	Demand
• The loaded instrument cassette should not weigh more than 5kg.	Demand
• The instrument loading should be smooth and guided by railings	Demand
• The emergency system should be easily accessible and visible.	Demand

Resource Demand

• The washer should use <200L of water per batch.	Demand
• The washer should be compliant with a wide variety of detergents.	Wish
• The washer should use a fixed amount of water per batch.	Demand
• The washer should be able to function with a generator.	Wish

User Interaction

• The washer should be operated with minimum interaction and vigilance from the hospital staff	Demand
• The staff should only physically interact with the washer during loading and unloading the instrument rack.	Demand
• The interaction interface of the washer should be familiar, minimal and non intimidating.	Demand
• The washer interface should be adaptable to local languages.	Demand
• The washer should be easy to operate by illiterate/ semi literate users.	Demand

F . Analysis of Automated Washer Disinfector

For reprocessing laparoscopic instruments in rural India, the implementation of mechanical/automatic cleaning systems is now seen as a requirement. In order to achieve this, it is necessary to study how automatic cleaning machines like automated washer disinfector works. Studying these high-end machines will give an insight into the steps and requirements for making a frugal version of the same. This section breaks down the existing automated washer-disinfectors already used by all the high-income hospitals.

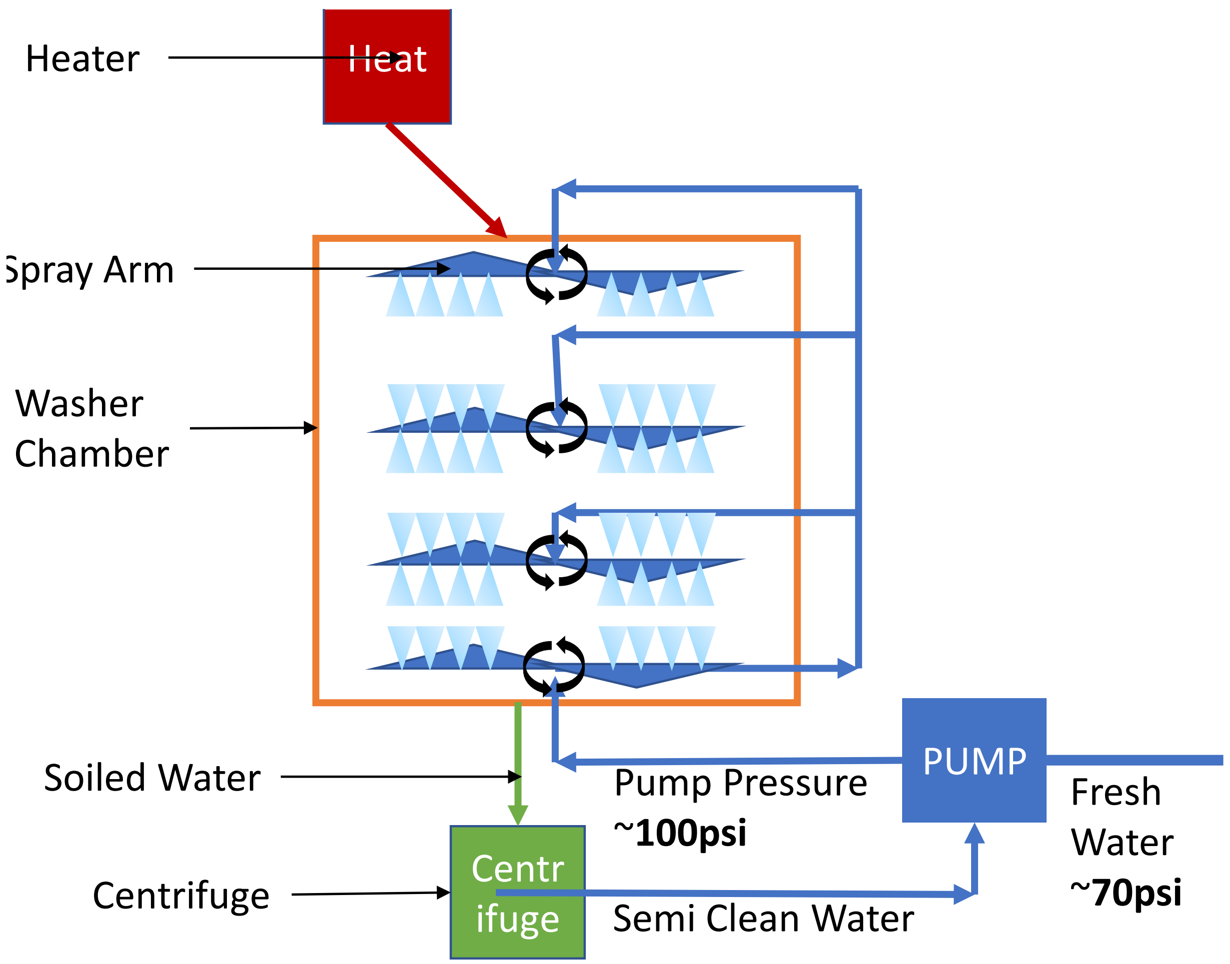
The primary role of an automated washer-disinfector is to wash a load of surgical instruments with water, impregnated with enzymatic detergents, and uses the principle of impingement to flush away contaminants from the surgical instrument surface. Automatic washers are similar to household dishwashers. Fluid-induced shear stress is induced through high-pressure pumps and nozzles which is the contributing factor to effectively cause impingement (Hariharan et al. 2018). A thorough cleaning can only be guaranteed when all the instrument surfaces are exposed to the water jets, exposing the soiled surfaces to the water.

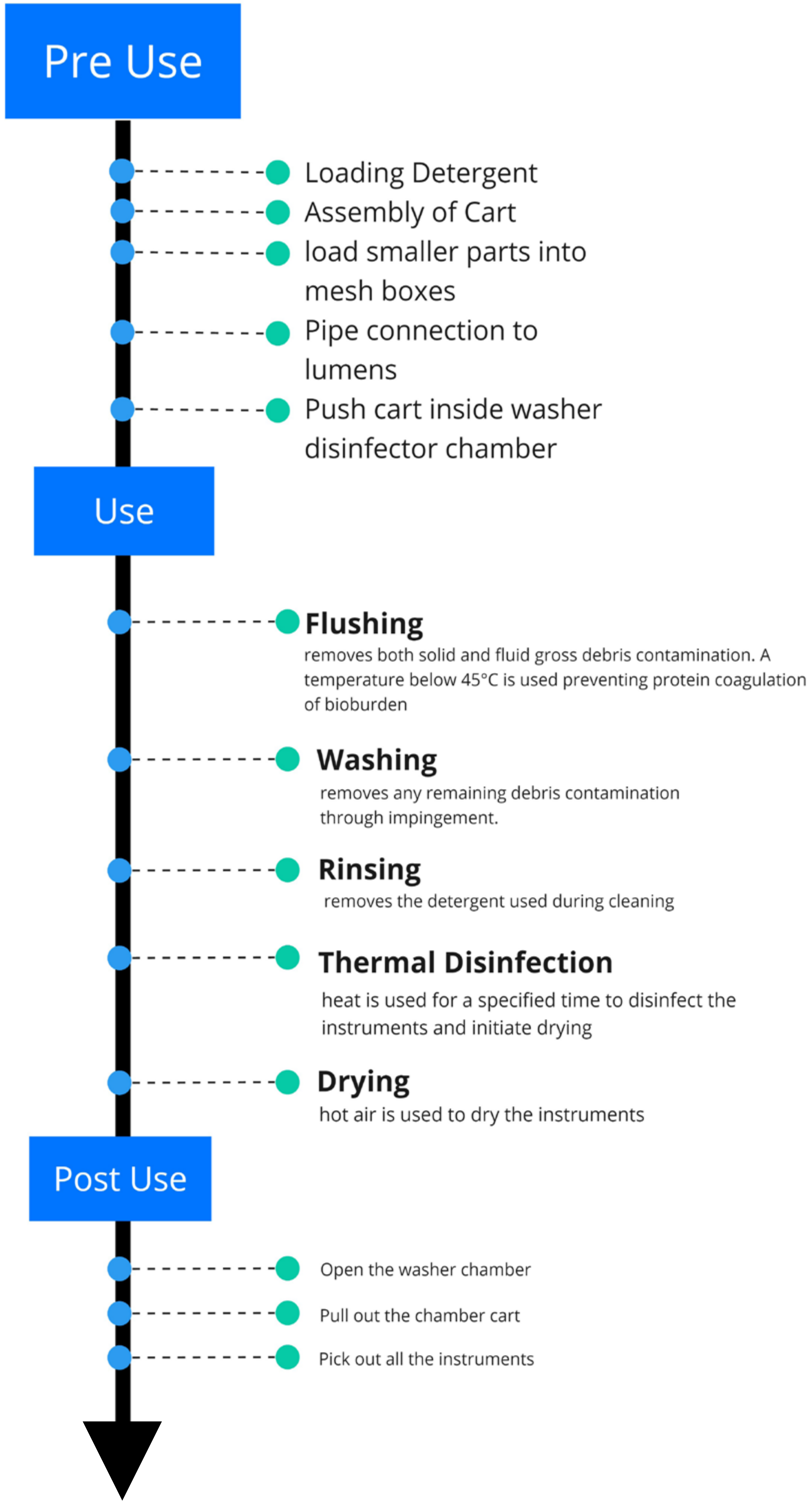
Functional analysis of a standard single-chamber automated washer-disinfectors is done to understand the working of the machine. Single chamber washer-disinfectors are expensive devices costing several thousands of euros.

The figure below divides the working of the washer-disinfector into 3 stages of use per batch.

The device where user interaction is most prominent is the washer rack. The washer rack is the device that houses numerous valves, Luer locks, irrigation sheaths, and holders for mounting a variety of dismantled surgical instruments. Sterile processing technicians extensively use this rack to mount soiled surgical instruments before pushing it inside the washer chamber.

Mentioned below is the general working principle and steps of a conventional medical automated washer-disinfector.





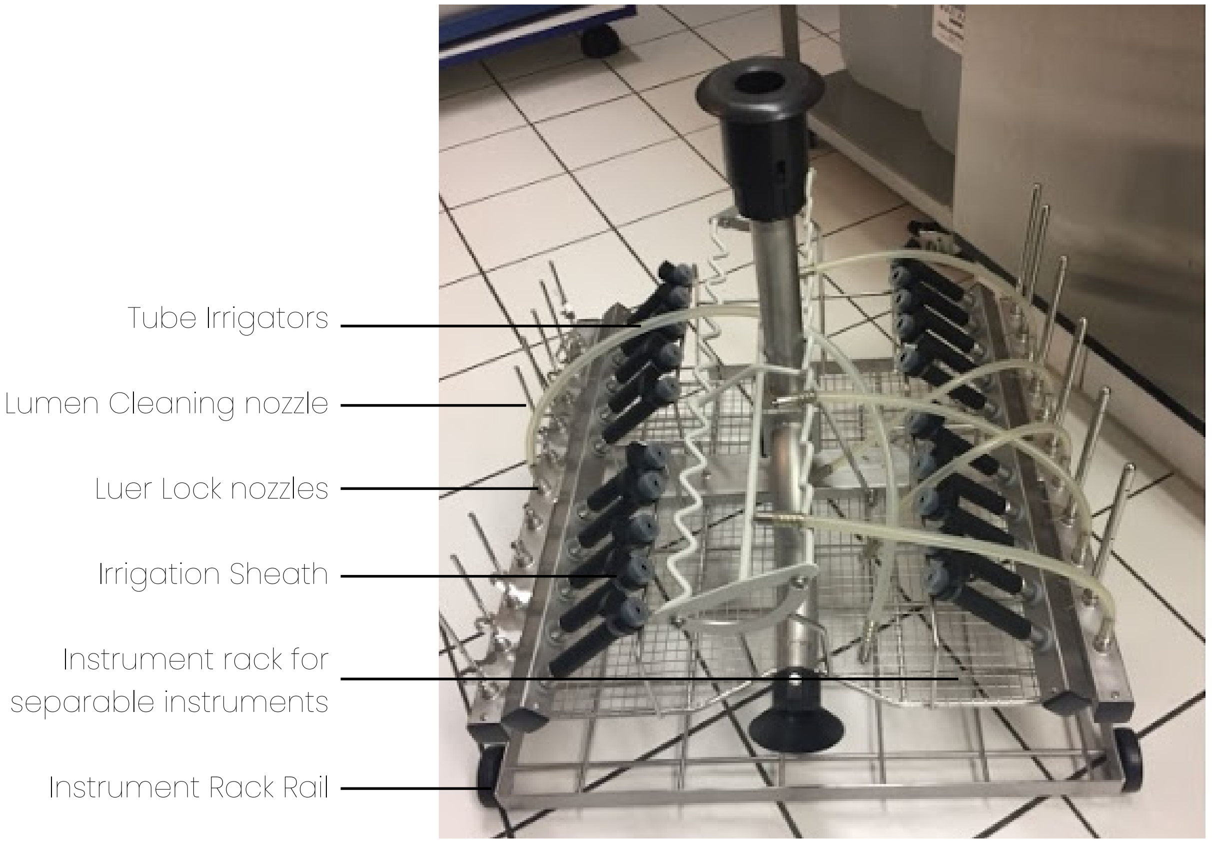
Appendix

1) Pre Use

Dismantled instruments that are non-lumened are placed inside in an instrument basket. This basket is specially provided for small separable components like valves and rings and larger components like grasper handles. This basket is placed at the bottom of the existing movable rack, over the bottom rotating spray arm.

All tubular lumened instruments like trocars and graspers are dismantled and placed either on the irrigation sheaths or Luer lock adapters mounted on the washer rack. Trocars are connected to a hose and placed on the irrigation nozzles with side perforations.

The long and hollow tubular instruments shafts are arranged in a diagonal arrangement inside the washer cabinet. An additional basket is used for cleaning grasper inserts to facilitate adequate cleaning by maintaining open grasper jaws.



Meile E450 Instrument Rack for Laparoscopic Instruments

Optic cables, gas, and irrigation tubing are accommodated in a spiral rack, connected to a Luer lock connector for flushing from the insides. The washer rack is now pushed into the washer chamber and closed.

2) Flushing

Once the washer rack is in position and switched on, the first step of the cycle is flushing. Flushing removes both solid and liquid gross debris from the instrument surfaces. The temperature of the water is ~45°C to prevent protein coagulation.

3) Washing

The washing cycle is where enzymatic detergents are mixed with the water. The enzymatic detergents act as surfactants and emulsify and sequester protein, fats, carbohydrates and other enzymes and remove more bioburden. The water temperature is ~93°C to facilitate the removal of bioburden.

4) Rinsing

Rinsing is similar to flushing. Instruments that are subjected to hot and detergent impregnated water are washed with water at room temperature. This washing takes away all loose bioburden and dirt to the drain.

5) Thermal Disinfection

Heat is used for a specific time period to disinfect the instruments with heat and facilitates the drying step.

6) Drying

Hot air is blown into the washer chamber through HEPA filters to dry the surgical instruments.

7) Post Use

Now that the instruments are washed and dried, the washer rack is pulled out manually from the washer chamber and unloaded.

Key Takeaways

- The washer disinfectors are easy to use.
- The washer disinfectors are expensive.
- The time taken for each batch is 45minutes, including loading and unloading.
- The average water use is ~200L
- The average usable volume of single chamber washer disinfectors in this range is 600mm x 600mm x 800mm.
- The user interaction is maximum in the pre and post use where the dismantled laparoscopic instruments are loaded and unloaded.

G . Testing and Validating the Brainstorm Ideas

Interesting ideas were presented by the group during the brainstorm. The participants were oriented with the problem, provided with the instruments for exploration, dismantling, and finding pain points. Some instruments were also stained with artificial test soil before asking the participants to clean the instruments manually by the kitchen sink. It was observed that the participants would naturally reach out for the dishwashing sponge or use their own fingers or nails to scrape the contaminants off the instrument surface. Clearly proving that friction is indeed a powerful method of cleaning.

The scope of the project was already defined. The group conducted a desktop research and analysis of an existing washer disinfector used in HIC hospitals to divide its functionality and mechanisms. The analysis of existing washer disinfectors mentioned in Appendix F gave rise to three clusters for ideation: loading, flushing, and washing the instruments. Post-its with ideas and illustrations were grouped in the above clusters and explored for feasibility through physical prototyping and testing.

During the testing phase to choose the best concept, participants were asked to think aloud to gauge their experiences.

Instrument Rack Loading

- **Instrument Cassettes**

Various orientations of the cassettes were tested Various orientations of the cassettes were tested through a crude setup using a box and a tray with weights to simulate a loaded instrument cassette. Gauging the ergonomic feasibility of loading the cassette into the washer chamber is the primary aim of the test. Participants were asked to narrate their experience of inserting this cassette (tray) inside the washer chamber (box) with different grips.

Participants were most comfortable with lifting the

Fig G.1.1 (top), G.1.2 (right) Comfort testing of the Instrument Cassette idea. .

cassette from the sides, however, they were afraid that this position may cause their fingers to get stuck between the mesh and the outer chamber of the washer while sliding it in. Shifting hands would be tedious. Installing handles on the top of the cassette would allow for easier insertion.

During insertion, the participant prefers holding the tray at an angle, rest it on the chamber then straighten the cassette to slide inside the chamber (fig G.1.1, G.1.2).

- **Inverted Rack System**

Dismantled laparoscopic instruments are attached in an inverted position to the envisioned instrument rack (fig G.2.1). Instruments are either screwed into the Luer lock connections or held by irrigation adapters. The rack allows equal distribution of water from the central pipe to the smaller capillary tubes for water distribution. The flow of water incorporated due to the instrument orientation is top to down to avoid the need for high-pressure pumps. Water flows from a

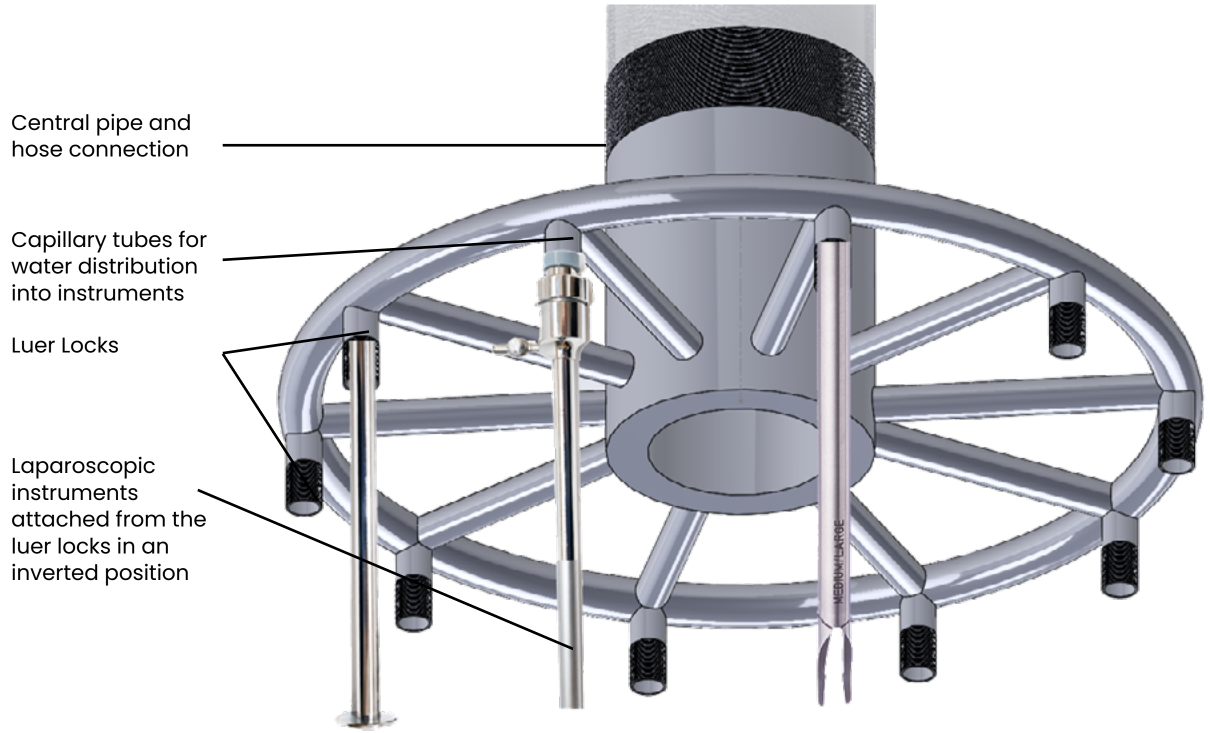


Fig G.2.1 Concept design of the inverted instrument attachment hub .

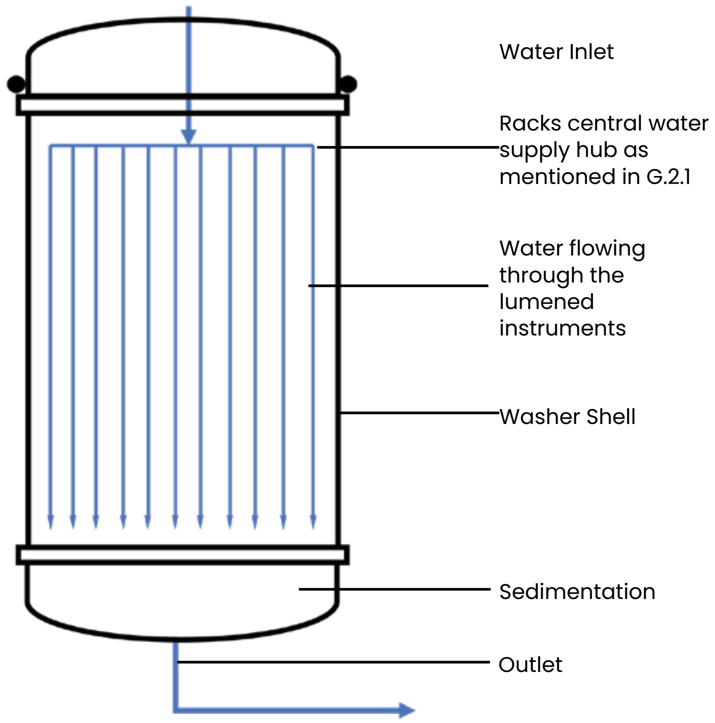


Fig G.2.2 Functional Sketch of the Inverted Rack Concept top to down manner (fig G.2.2). The participant was asked to screw a 10mm diameter clip applicator to a mock setup of the Luer lock assembly in the inverted instrument attachment hub (fig G.2.3, fig G.2.4). The act of attaching this instrument to the Luer lock mockup was deemed cumbersome and difficult which demanded the use of both hands. The instrument slipped out of the participant's hand while attempting to attach the instrument, which in the event of a real scenario would be a cause of injury to the nurse and damage to the instrument.

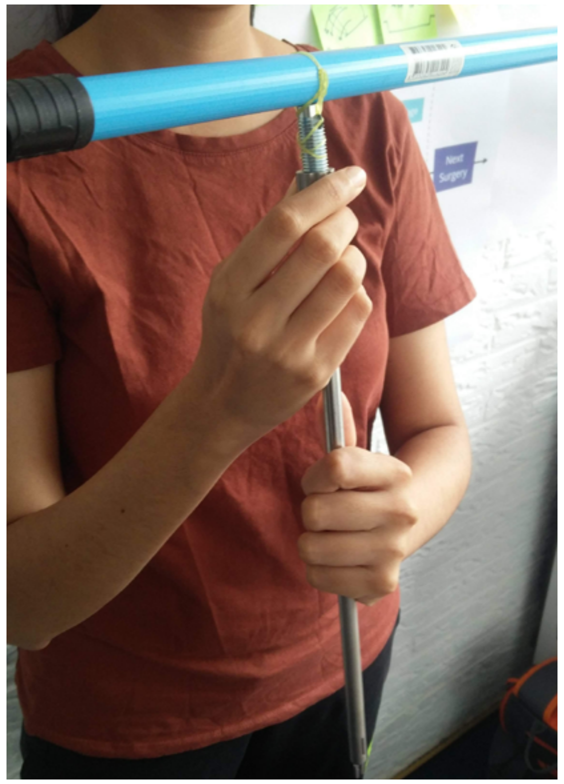


Fig G.2.3 Attaching the laparoscopic instrument to a make-shift luer lock nozzle. Participant uses both hands to support the instrument.

Fig G.2.4 Turning the treading of the laparoscopic instrument to the make-shift luer lock nozzle. Participant had trouble aligning the threading to the nozzle.

Flushing

The idea of implementing water jets to spray water with high pressure through an atomized nozzle was not tested due to the lack of time and availability of the apparatus. It can however be assumed that this process would demand substantial volumes of water to cause instrument wetting.

- **Blender Action**

Kitchen blenders are powerful machines run by motors with high torque and speeds. The fluid currents observed by these machines are significant. This fluid speed could be used to agitate the water in the compartment and be harnessed to induce fluid shear stresses on the soiled surgical instruments without the need for a constant supply of running water.

To test this idea, a conventional kitchen blender was fitted with a lid for holding dismantled and contaminated laparoscopic grasper inserts and graspers. The same test protocol i.e contaminate> dry for 2 hours> soak for 10 minutes> insert the graspers in the apparatus for 3 minutes> remove and observe was implemented (fig G.3.1).

Fig G.3.1 Mounting laparoscopic instruments in a conventional blender.

The limitations of this experiment are that a more powerful industrial blender was not available. Industrial blenders rotate with a higher rpm, thus agitating the water more than conventional household blenders. It was observed that the instruments attached near the blender walls were susceptible to stronger forces compared to the instrument placed near the center.

After removing and drying, visual inspection with the naked eye exposed several pockets of contaminants on the instrument surfaces displaying the lack inefficacy of this setup (fig G.3.2).

Fig G.3.2 Residual contaminants visible to the naked eye after testing in this setup.

- **Irrigation through the cassette rack.**

Combining the loading systems with flushing systems is a tried and tested idea. All existing automated washer disinfectors implement irrigation systems into the instrument racks. The cassettes mentioned in the Loading section can be designed with hollow steel sections to allow the flow of water on and inside the surgical instruments.

Brushing

To reduce the dependence on large quantities of water for impingement, friction through brushing is preferred. After the brainstorm, the most feasible ideas pertaining to the brushing methods were tested. A detailed description of the double and triple rotary brushing methods are in appendix H. This section pertains to the testing of the first "Single Rotary Drill Brushing" concept.

To test multiple instruments being brushed simultaneously, a model of sun and planetary gear setup with a provision for 10 brushes was 3D printed (fig G.4.1). The inner and outer rings spin in opposite directions to ensure the brushes stay stationary in relation to the graspers.

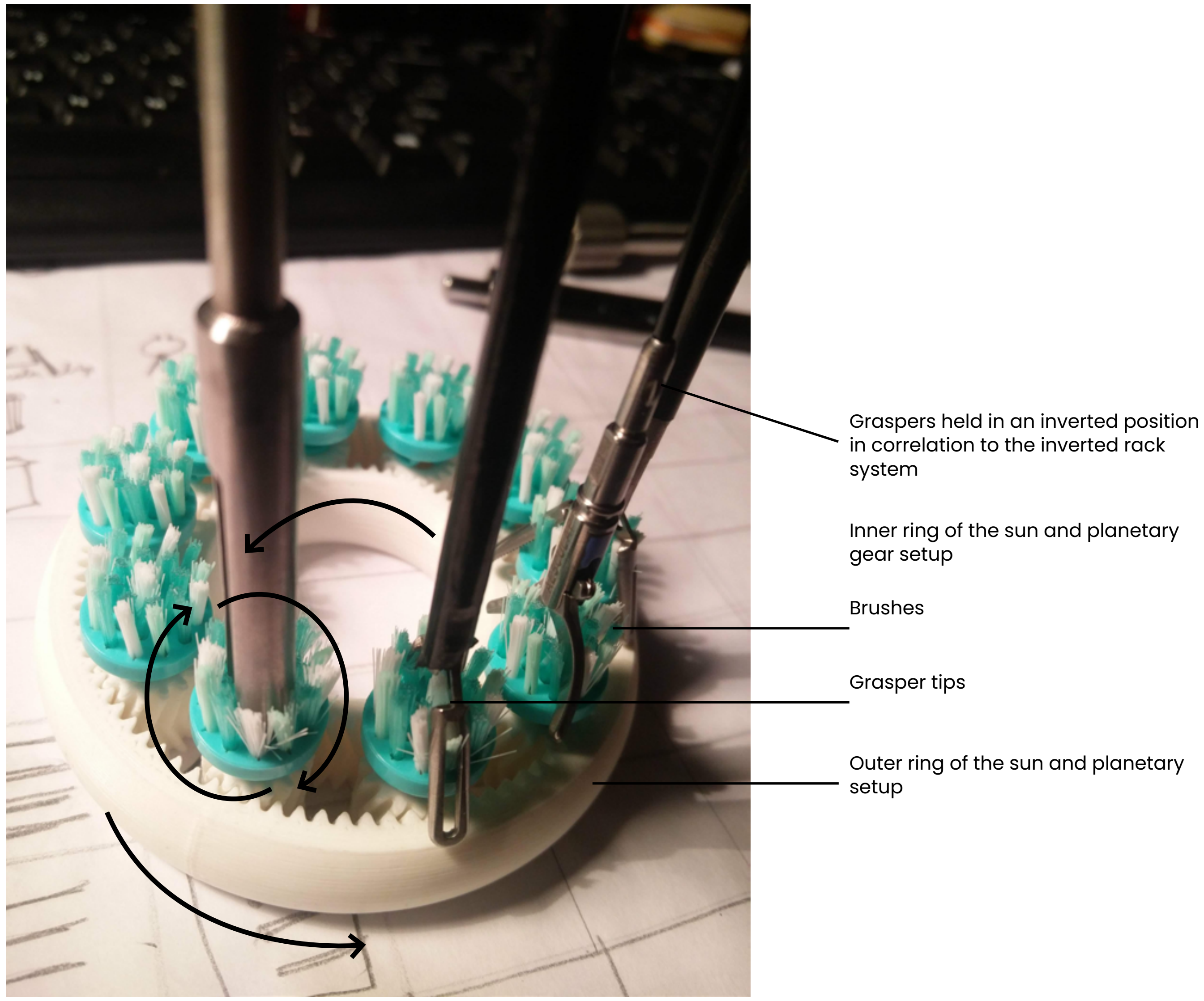


Fig G.4.1 Sun and Planetary gear pattern mock-up to show multiple graspers being brushed simultaneously.

A setup involving the first concept of using a single rotary drill brush was created with open graspers attached to vice and a rotary drill brush attached to a power drill. The instruments were initially contaminated with artificial test soil (appendix H) and dried for 2 hours. Post drying, the instruments were soaked in a detergent bath for 10 minutes. Rotary brushing action was attempted thereafter.

Within the initial 5 seconds, the graspers and inserts began spinning and twisting violently. It is difficult to align and maintain the alignment of the graspers with the center of the brush. The outcomes of this test were not favorable because the brushes focus on the insides of the laparoscopic grasper jaws thus neglecting the grasper hinges.

In conclusion, the single rotary brush concept was rejected because the pros outweighing the cons. The brushes were not properly cleaned and the setup was dangerous to implement further testing.

Fig G.4.2 Testing a single rotary drill brush with a a flexible non lumened grasper insert (left) and a 10mm diameter lumened clip applicator (right).

—the insert on the left began oscillating violently causing the grasper to twist. The clip applicator being stiff could withstand the spinning action.

In the previous tests, laparoscopic trocars were seldom mentioned. Similar to the graspers, cleaning the trocars is of equal importance. The long and slender build of trocars makes it difficult to clean the insides. Due to time constraints, only one concept of brushing trocars is explored.

This section details the methods used to clean conventional reusable laparoscopic trocars that have been contaminated with artificial test soil. Participants were given nylon brushes of 50mm bristle length and 10mm diameter. The trocars were dried for 2 hours after contamination, soaked for 10 minutes and provided to the participants. When participants were asked to clean the contaminated trocars with brushes, the most common motion was an up-down oscillatory motion. This method was highly effective as visible debris from the trocar tube was removed. To replicate this brushing motion, a test jig was made using a reciprocating saw and clamps to hold the trocar in place (fig G.5.2).

The reciprocating saw was actuated for 3 minutes with periodic wetting with water from a syringe. After the brushing action, the trocar was dried and visually inspected. The insides of the trocar tube were indeed observed to be clean and free from debris.

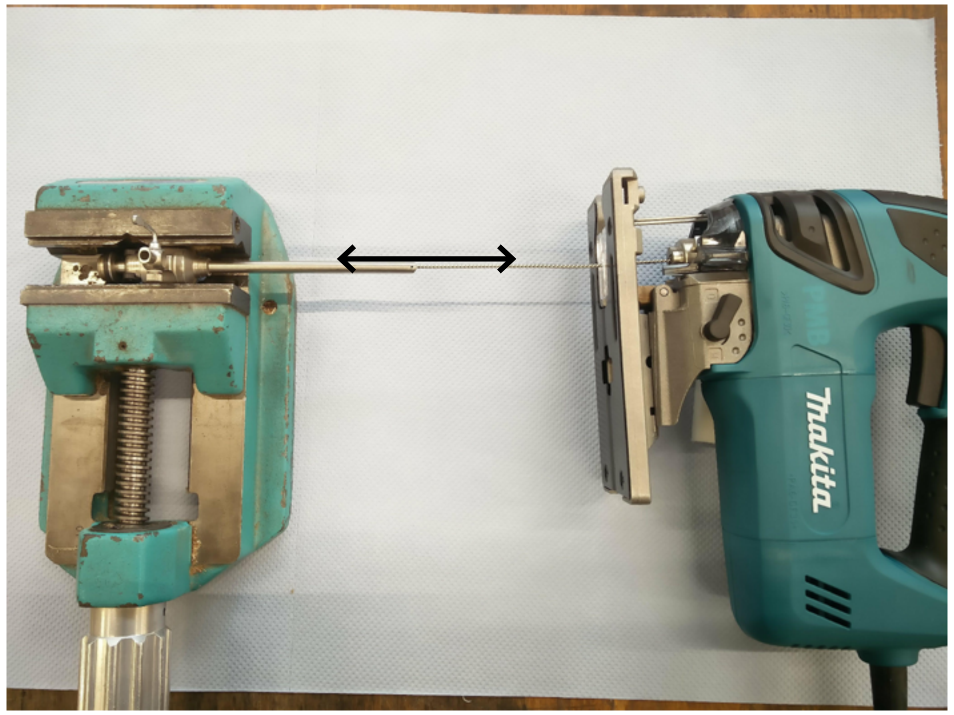


Fig G.5.2 Trocar cleaning Jig with trocar (left) and reciprocating saw (right) and 10mm diameter nylon brush.

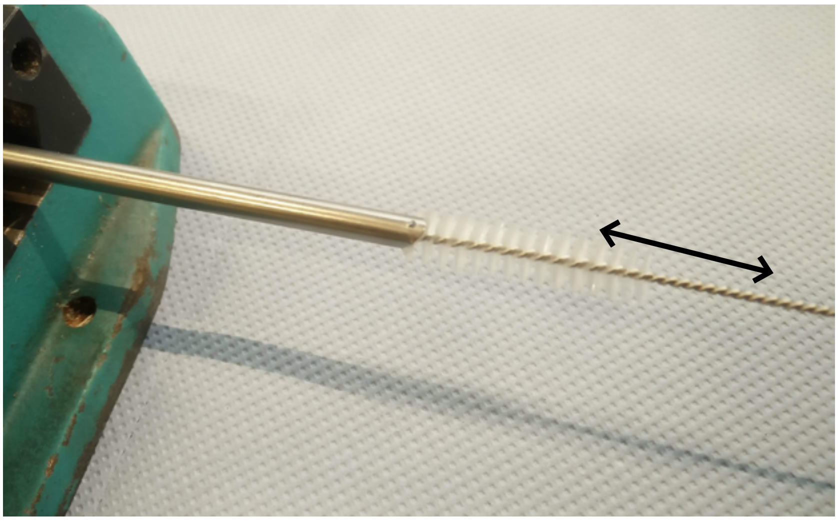


Fig G.5.3 10mm diameter nylon brush inside the trocar.

It was difficult to take pictures of the inner wall of the trocar. It is recommended to use cameras similar to endoscopes to visually inspect the trocars from inside.

To implement this oscillatory motion of brushes to multiple trocars, inspiration was taken from vehicle crankshafts where a custom-built crank could brush multiple trocars simultaneously (fig G.5.4).

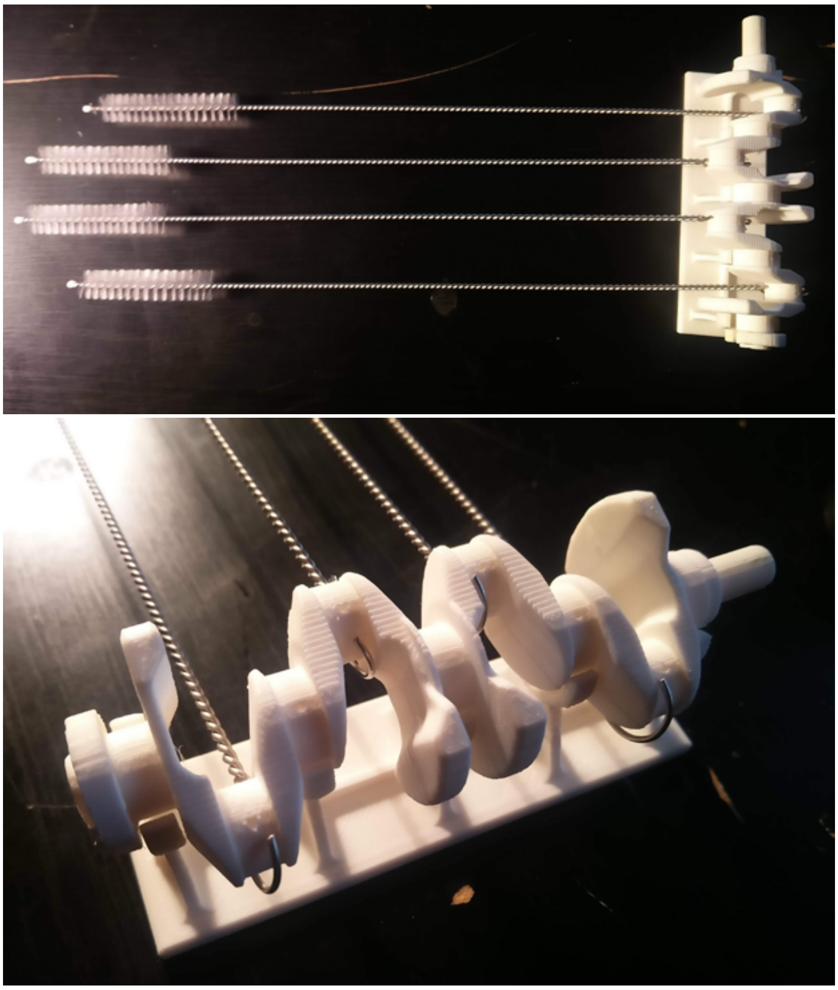


Fig G.5.4 Concept model of the trocar brushing actuators with a 3D printed crankshaft model.

H . Brush Testing

Testing the efficacy of mechanical brushing systems to clean laparoscopic instruments to substitute impingement methods in sterile processing of laparoscopic instruments.

Aim: The aim of this experiment is to determine the efficacy of cleaning reusable laparoscopic surgical instruments through surface friction induced by rotary mechanical brushing as compared to the use of ultrasonic cleaning.

Methods: Laparoscopic clip applicator, grasper inserts and graspers were initially cleaned, dried and weighed to determine the original "clean" weight of the individual instruments. Instruments were then contaminated with a viscous artificial test soil (ATS) made with arbitrary proportions of egg yolk and red food coloring to simulate blood being settled on instruments after a surgery. To mimic a worst case scenario, the instruments were allowed to dry for 2 hours then weighed again to account for rise in instrument weight due to contaminants. Pictures of the contaminated instruments after drying were made under ultraviolet light visual reference. The instruments were soaked in detergent solution at 25degrees celcius similar to the practices in rural Indian hospitals for 10 minutes and then subjected to individual tests that include
Ultrasonic cleaning only for 10 minutes
Double rotary brushing only for 3 minutes.
Triple rotary brushing only for 3 minutes.
It is necessary to note that the 3 tests mentioned were conducted in three cycles to ensure consistency in results and are conducted individually after soaking. The worst outcome of the 3 tests are shown in this document. The weights of the instruments after the individual tests were measured to determine the reduction of the contaminant after each test. Pictures of the cleaned and dried instruments after the individual cleaning protocols were taken under ultraviolet light and microscope. The efficacy of the instrument cleaning methods were measured objectively through weighing and confirmed through visual inspection under ultraviolet light and microscopic imaging. The goal of the tests is to obtain near to "clean"weight after the instruments are processed under the aforementioned 3 test protocols and determine which of the protocols achieves this goal. Special jigs were created to simulate the imagined brushing actions for test protocol 2 and 3.

Findings: Soaking in detergent solution is a necessary step to wet the ATSto loosen the debris from the instrument surface. Ultrasonic cleaning is an effective method of eliminating the contaminants from the instrument surface but was not very successful in cleaning the inaccessible parts of the instruments (grasper mechanism and grasper end) as seen by the microscopic images.
The use of 3 rotary brush jig managed to remove a significant amount of contaminants from the surgical instruments and a significant weight reduction has been observed. Ultraviolet and microscopic imaging supports the outcome accordingly.

Conclusion: The significant reduction in the artificial ATS from the instrument surface through the mechanical brushing jig is evident that friction is an effective method of cleaning laparoscopic surgical instruments and relieving the inaccessible regions of the instrument with the said contaminant. The triple rotary brushes can hence be an integral aspect of tackling the mechanical cleaning phase of the instrument reprocessing journey in rural Indian hospitals by reducing the dependence on shear forces induced by water pressure to impinge contaminants off the instrument surface.

Introduction

Unclean surgical instruments are a leading cause of surgical site infections in rural Indian hospitals. These hospitals lack the funds to employ trained sterile processing technicians and central sterile processing departments to effectively and safely reprocess reusable surgical instruments. To add to the plight of these understaffed and underfunded hospitals, the uncertainty in clean water and electricity supply plays a significant role in the practices adapted to reprocess instruments. The complex design of laparoscopic instruments in absence of mechanical methods of reprocessing pose a considerable challenge to overburdened and underprotected nurses in the rural Indian hospitals.

In the entire reprocessing journey of surgical instruments, cleaning is a primary stage and cannot be ignored. The cleaning stage consists of two individual sub-stages, manual cleaning and mechanical cleaning. This test focuses on mechanical cleaning where the efficacy of mechanical brushing compared to ultrasonic cleaning will be determined.

In current high income hospital practices, the mechanical cleaning phase involves the use of ultrasonic cleaning and automated washing. There seems to be a lack of data regarding the efficacy of mechanical brushing systems as compared to ultrasonic cleaning of surgical instruments. Many rural Indian hospitals cannot afford to purchase and use existing automated washer disinfectors because they are not suitable for the context, demand excessive amounts of water, specialized enzymatic detergents and trained hospital staff. Existing washer disinfectors wash surgical instruments through the use of impingement where water pressure applied to the instrument surface causes shear stresses that blasts contaminants off the instrument surfaces. This system demands ~150L of water per batch of surgical instruments. In rural India, due to the lack of instrument sets, these machines would be used multiple times a day, thus compounding to the demand of more ~1000L a day.

An alternative to the use of vast volumes of water is friction. In this design project, friction with the help of brushes is used to mimic the shear stresses of impingement to achieve similar outcomes with a fraction of the water use. Mechanical brushing is introduced to the existing practice of reprocessing laparoscopic instruments in rural India and reduces the nurse's exposure to unclean instruments and harmful reprocessing practices.

Method

For testing mechanical brushing, reusable surgical instruments like one 10mm diameter clip applicator, one grasper scissor insert, one curved atraumatic grasper insert were used. These instruments were cleaned, dried and weighed using a highly sensitive microgram scale (fig 1). This "clean" weight is the benchmark to the instrument cleanliness.

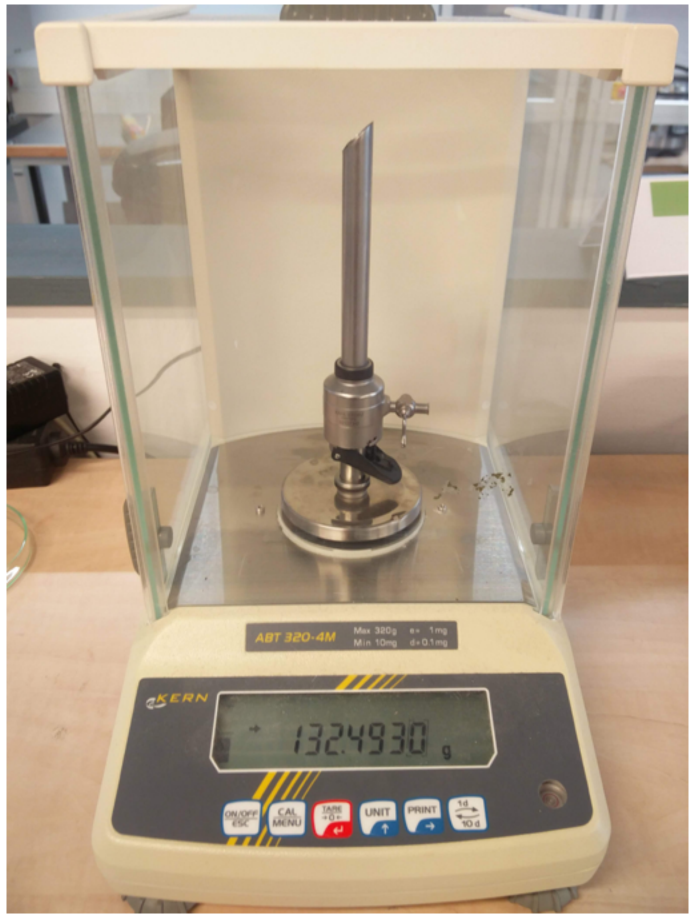


Fig 1. Microgram scale used to measure slight variations in the surgical instrument weight.

1) Instrument Contamination

The dry and clean instruments are immersed in a viscous ATS made of egg yolk and red food coloring of arbitrary proportions to simulate blood for 2 minutes. The contaminated instruments are suspended to dry for 2 hours in room temperature to simulate drying of blood and protein coagulation(fig 2). The contaminated instrument is weighed again to account for the dry artificial ATS attached to the instrument surface. Pictures of every instrument under UV light are taken. This is repeated for 3 test protocols.

The laparoscopic instruments that are dried and weighed are subjected to 3 test protocols

-Ultrasonic Cleaning

-Double rotor brushing

-Triple rotor brushing

Fig 2. Instrument contaminated with ATS left to dry in a suspended manner.

2) Instrument Cleaning Methods

After the instruments are dried, weighed and visually documented through UV imaging, the instruments are soaked in a detergent solution consisting of arbitrary proportions of clothes detergent and water at 25degrees celcius for 10 minutes to simulate the soaking practice of laparoscopic instruments in rural Indian hospitals. The soaking stage is repeated for every test protocol (fig3).

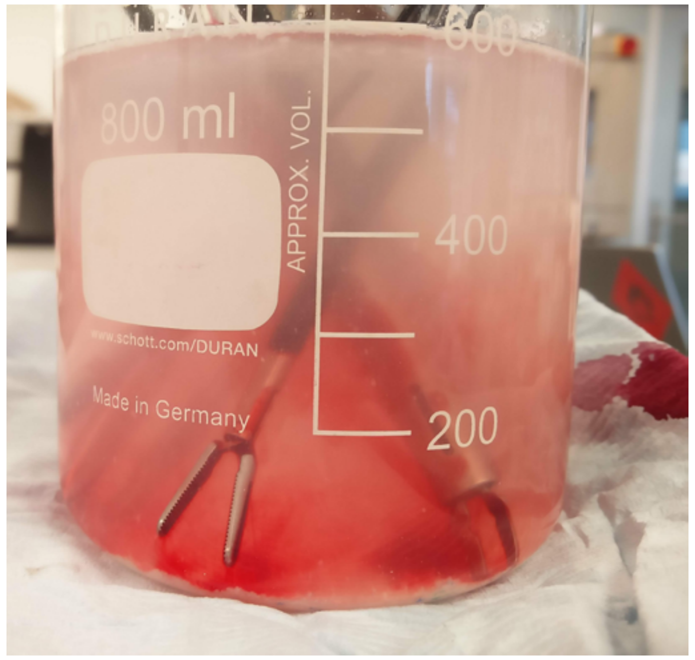


Fig 3. Contaminated instruments are soaked in detergent solution.

1) Ultrasonic Cleaning

For this test protocol, a 41kHz ultrasonic cleaner is used. After the instruments are soaked in a detergent solution for 10 minutes, the now wet instruments are directly placed in an ultrasonic bath at room temperature for 10 minutes (fig4) as suggested by WHO Surgical Instrument Reprocessing guidelines, 2006. Tap water is used in the ultrasonic cleaner. Fig 6 gives an overview of the ultrasonic cleaning test.

Following the ultrasonic cleaning for 10 minutes the instruments are removed from the bath and allowed to dry on a suspended wire mesh for 2 hours (fig 7). The dried instruments are weighed on the microgram scale to determine the amount of contaminants removed from the instrument surfaces.

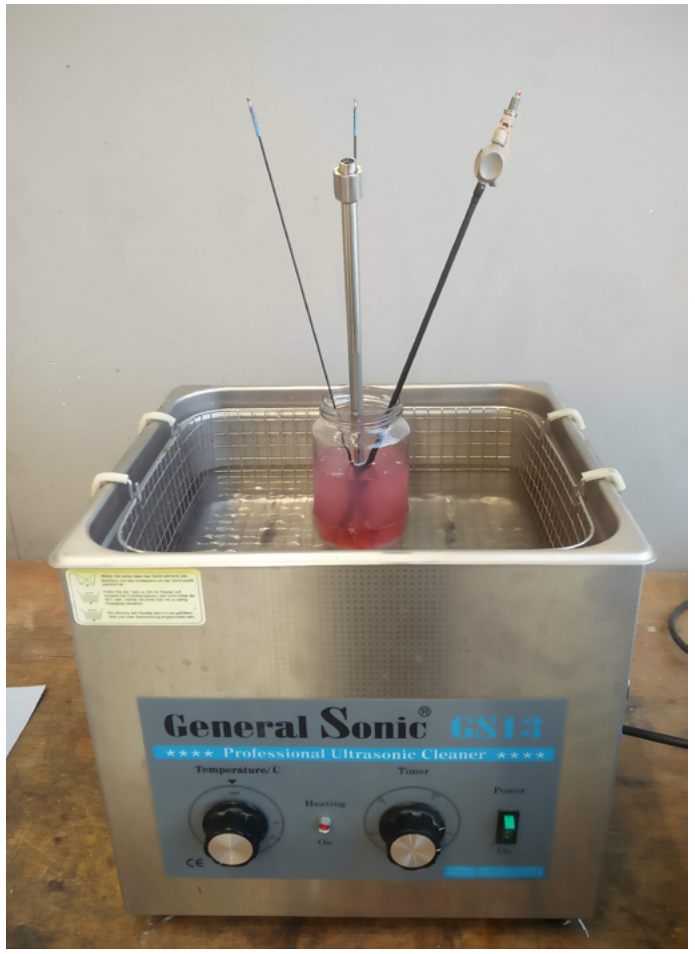


Fig 5. 41kHz ultrasonic cleaner.

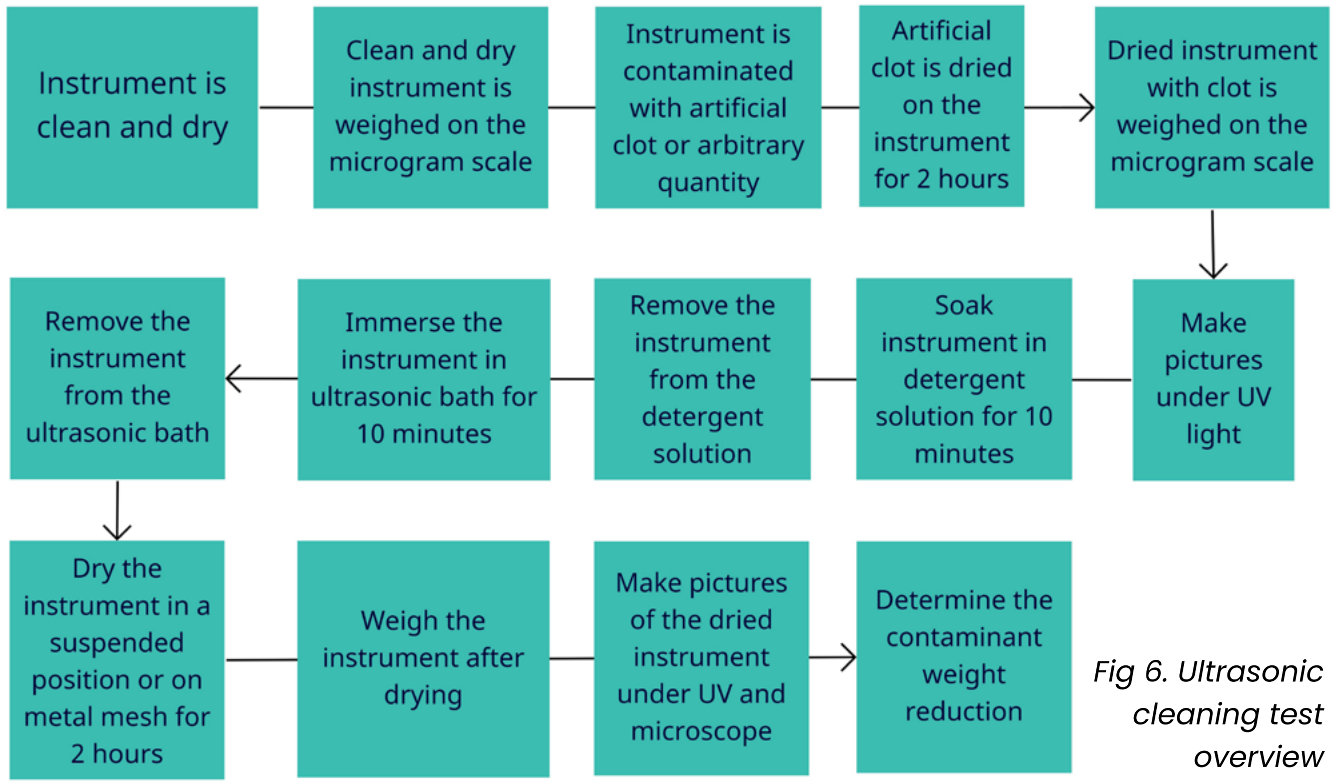


Fig 6. Ultrasonic cleaning test overview

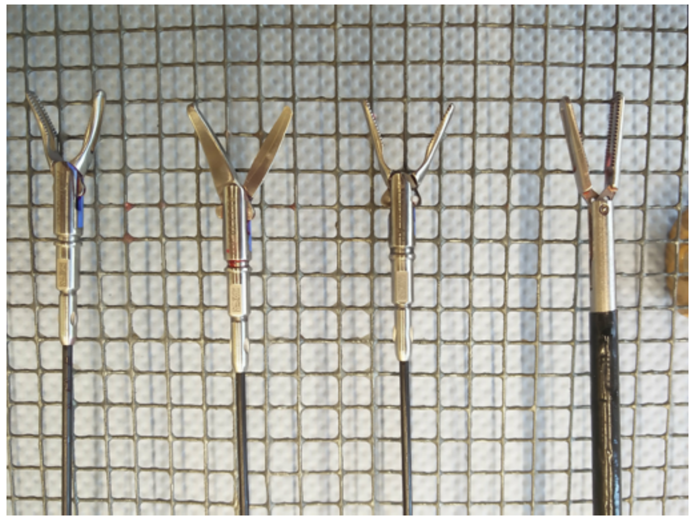


Fig 7. Drying the instruments.

2) Double rotor brushing.

Off the counter 80mm diameter bottle brushes are used to create a jig powered by a cordless drill (fig 8). Brushes are mounted 30mm apart to make the bristles interlock into each other (fig 9). Soaked graspers are removed from the detergent solution and directly mounted on the stand to hold multiple graspers simultaneously in open position. The open graspers are inserted in between the brushes and are in physical contact with the sides of the grasper tips. The brushes are made to spin using the cordless drill for 3 minutes (fig 10). The graspers are removed, dried and weighed to determine the weight of the ATS removed by this method. UV and microscopic imaging are conducted to find traces of debris on the instrument after drying. Fig 11 provides a brief overview of this test protocol and its methods.

Fig 8. Double Rotor Jig

Fig 9. Brushes interlocking in the jig.

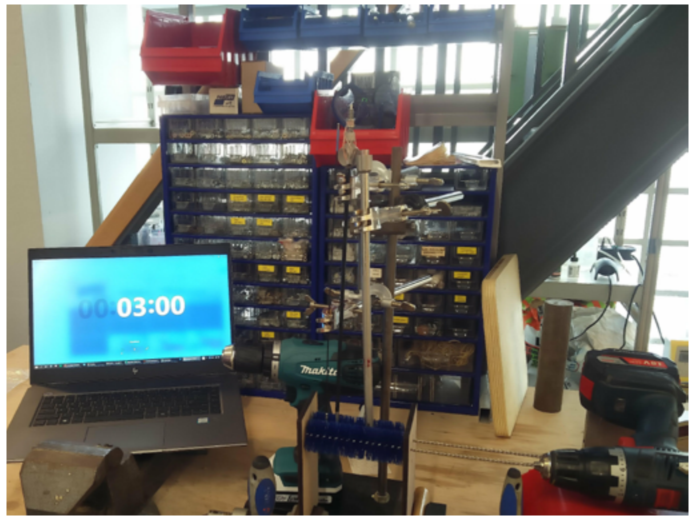


Fig 10. Graspers are inserted in the jig.

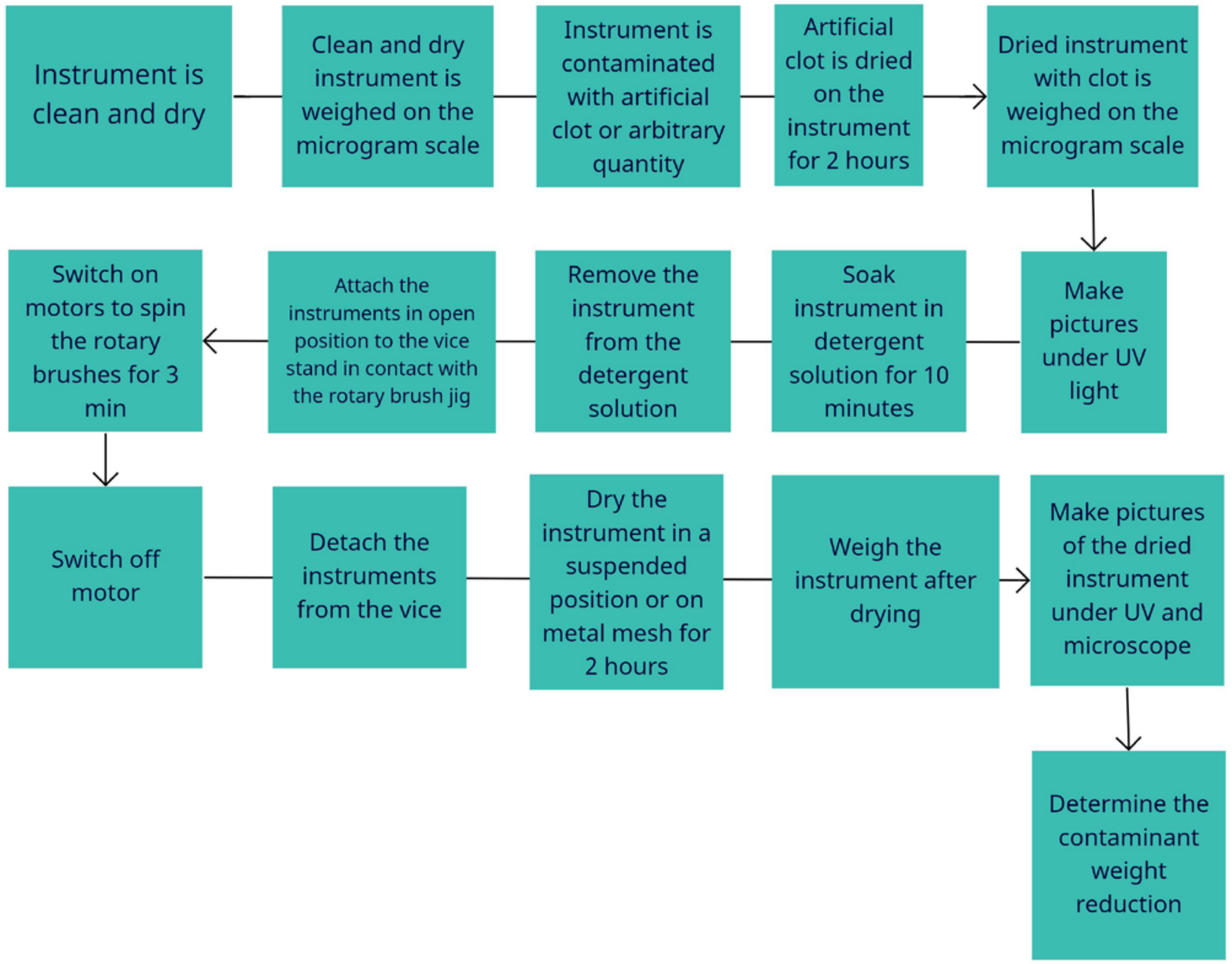


Fig 11. Double rotor brush test overview

3) Triple rotor brushing.

One extra rotor brush was installed to the existing double rotor brushing jig powered by a second drill to create a triangular setup (fig 12). The brush is installed to focus on the insides of the grasper jaws as regular and microscopic imaging revealed that double rotor rushing was not successful in eliminating ATS on these working ends of the instrument.

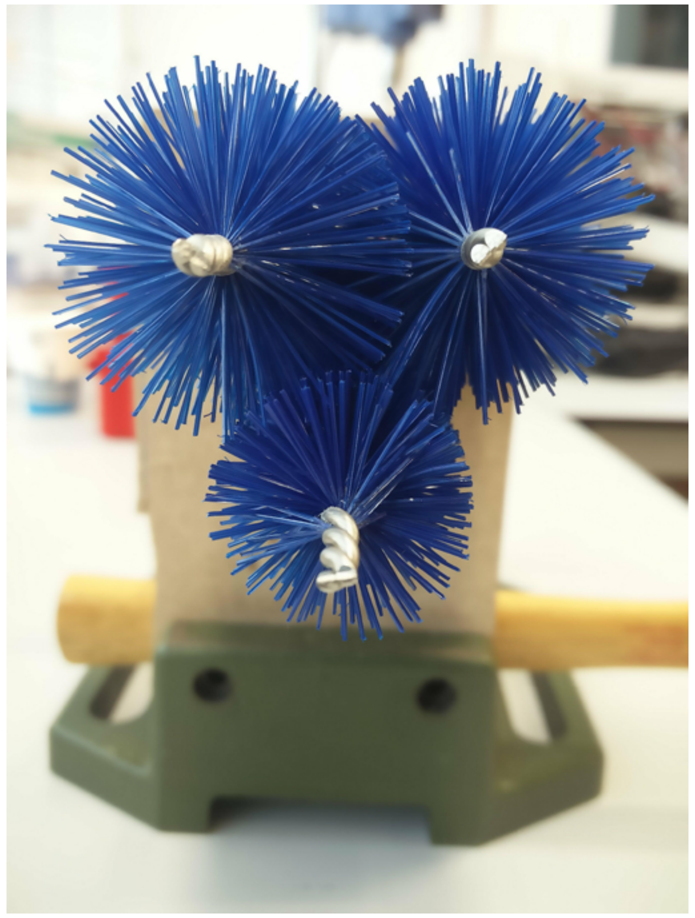


Fig 12. Triple rotor brushes interlocking in the jig.

Soaked graspers are removed from the detergent solution and directly mounted on the stand to hold multiple graspers simultaneously in open position. The open graspers are inserted in between the brushes. The insides of the open grasper tips are in physical contact with the third brush (fig 13). The brushes are made to spin using the cordless drills for 3 minutes. The graspers are removed, dried and weighed to determine the weight of the ATS removed by this method. UV and microscopic imaging are conducted to find traces of debris on the instrument after drying. Fig 14 provides a brief overview of this test protocol and its methods.

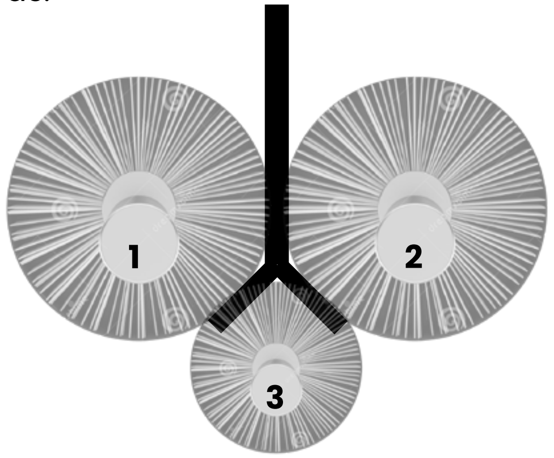


Fig 13.1 Grasper with brushes in contact.

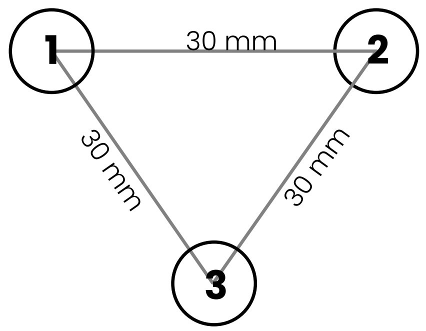


Fig 13.1.1 Brush center distance in the jig.

Fig 13.2 Triple brush rotor jig.

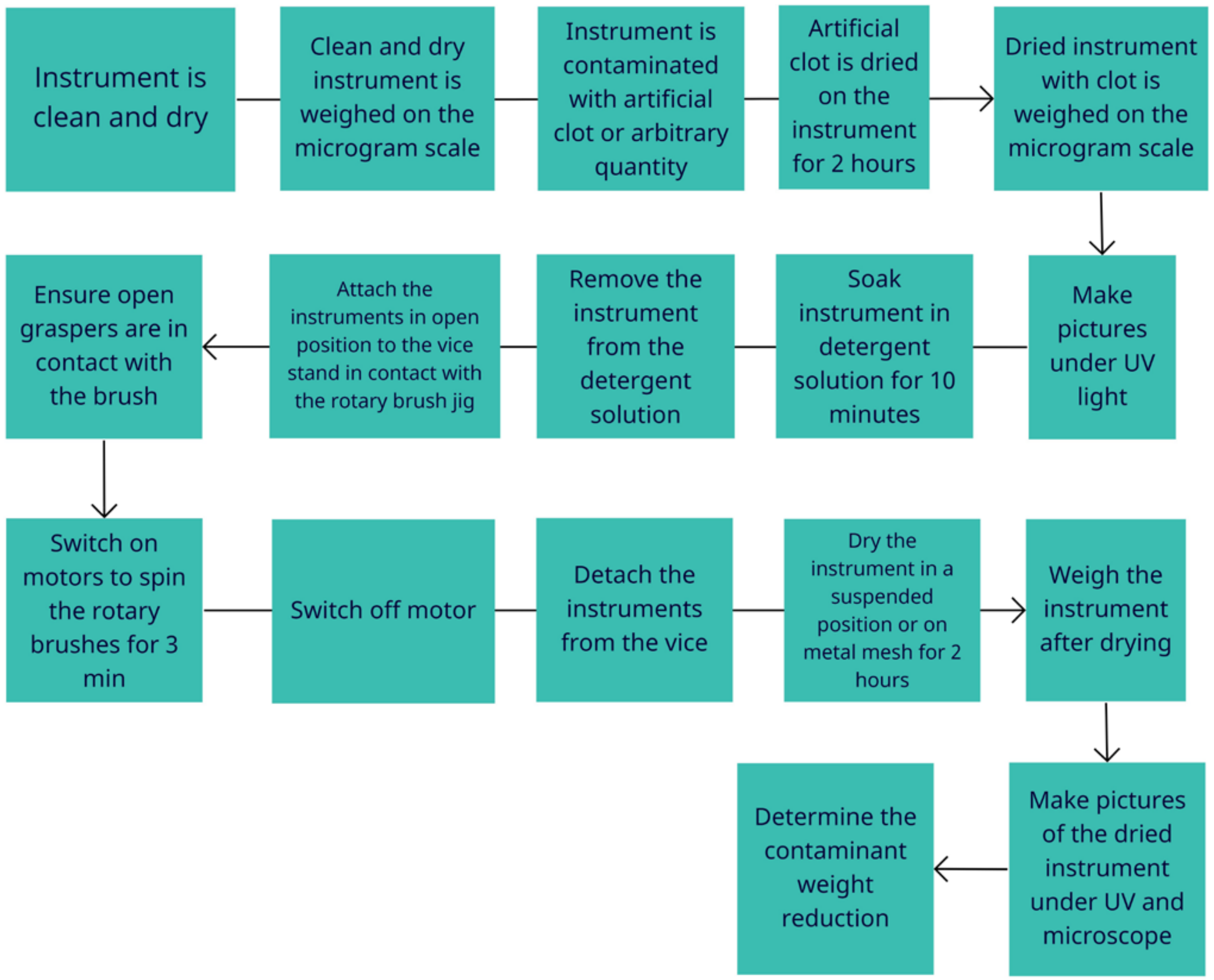
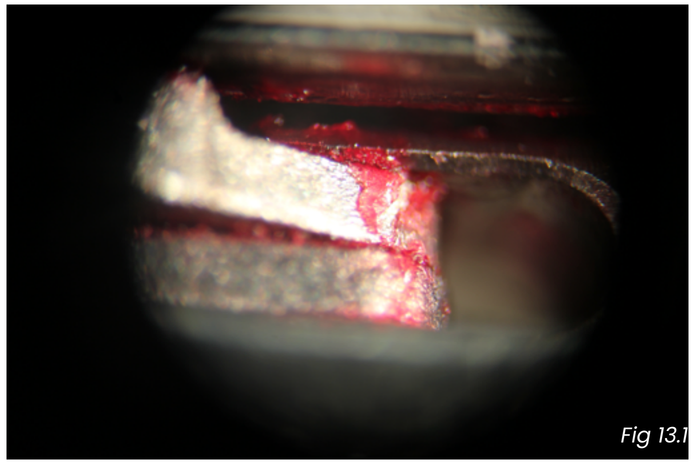


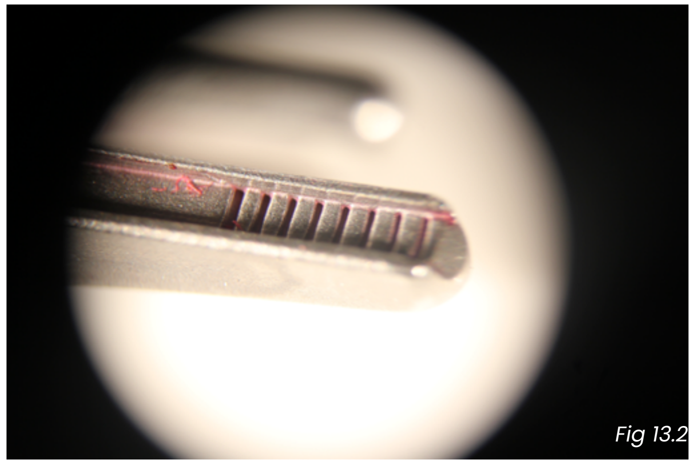
Fig 14. Triple rotor brush test overview

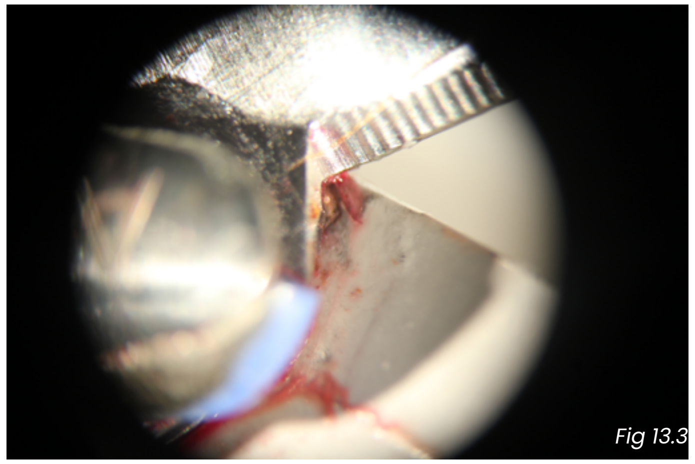
RESULTS

Detection of Residual Contamination through visual assessment.

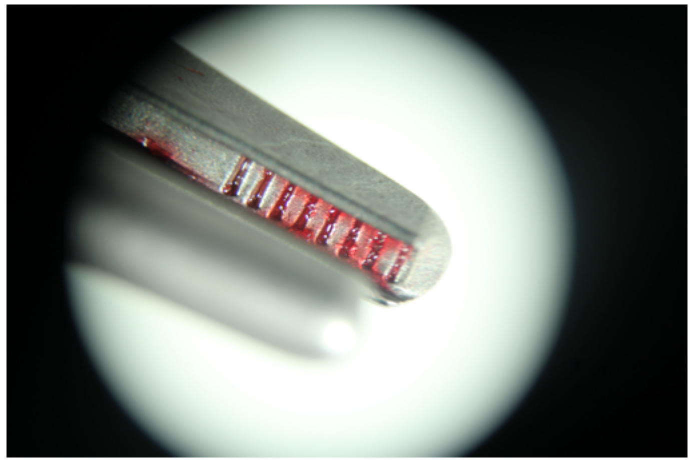
Through the naked eye and under the UV light, the ultrasonic cleaner has managed to remove a very significant amount of debris from the accessible and less complex parts of the instruments. Microscopic imaging of the surgical instruments into inaccessible crevices have shown that ultrasonic cleaning has not cleaned these regions and residual debris is still visible (fig 13.1, fig 13.2, 13.3).







As compared to ultrasonic cleaning, the use of the double rotor brush exhibited a significant reduction visual ATS debris from the instruments. Microscope imaging has revealed very slight traces of debris in the internal crevaces of the grasper hinges showing that the brushing has indeed managed to brush out the ATS. THis method has not been successful in removing th debris from the insides of the open grasper jaw and larger quantities of debris were observed to have collected here. Fig 14. 1, 14.2 shows traces of debris in the grasper jaw.



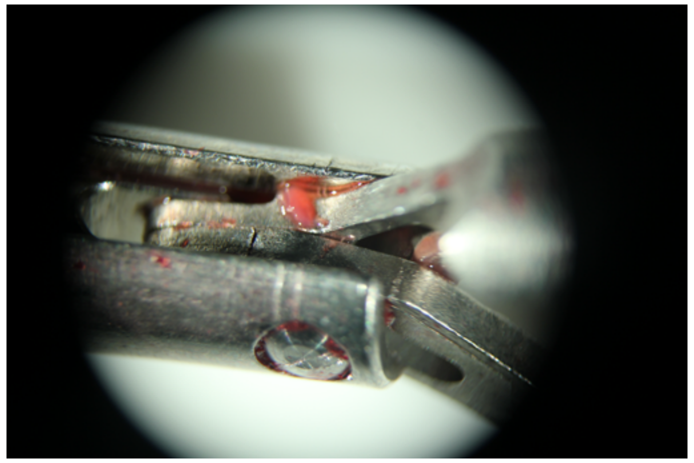


Fig 14.1 , 14.2 , 14.3 Laparoscopic graspers with visible ATS debris after ***ultrasonic cleaning*** *seen under the microscope.*

Fig 13.1 , 13.2 , 13.3 (left panel) Laparoscopic graspers with visible ATS debris after ***ultrasonic cleaning*** *seen under the microscope.*

Out of the three test protocols followed for this experiment, the triple rotor brush has exhibited the most reduction of ATS when operated under the same conditions as the previous test. Microscopic imaging ahs revealed little to no traces of debris after operating the triple brush jig for 3 minutes. The grasper sides and inside the grasper jaw were visibly much cleaner (fig15).

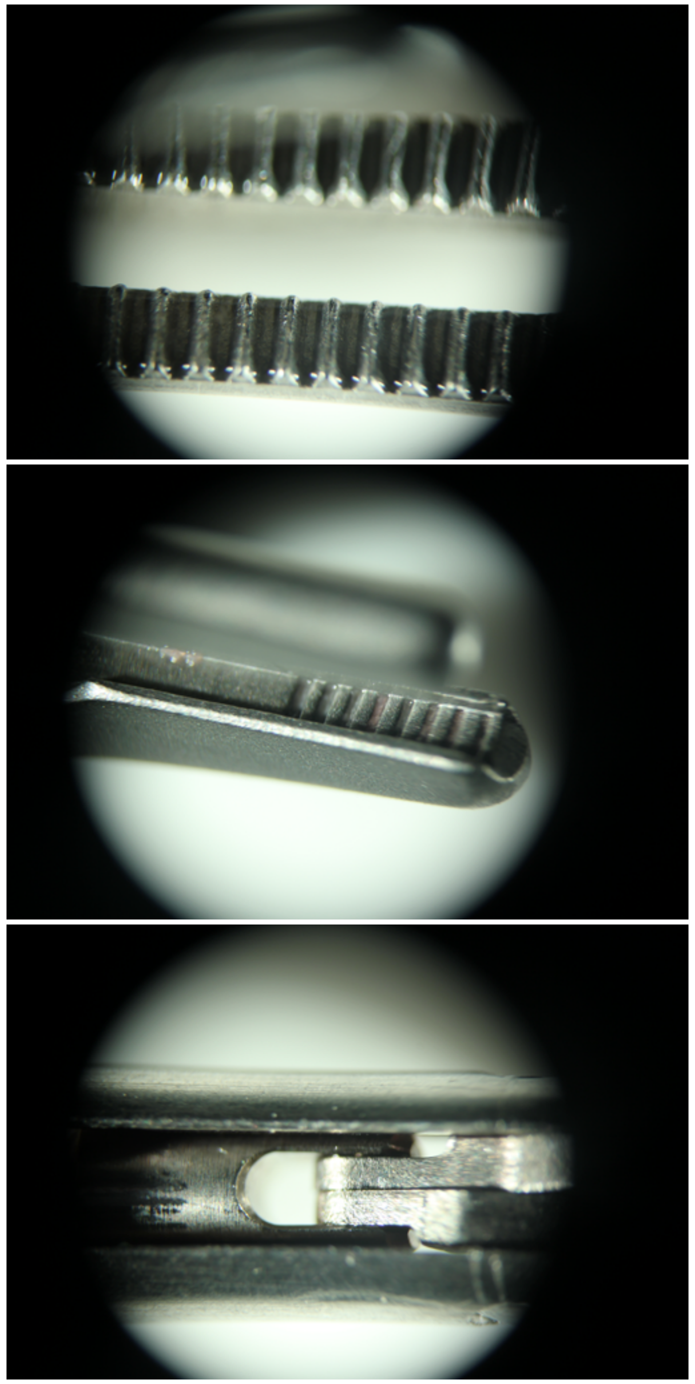


Fig 15.1 , 15.2 , 15.3 Laparoscopic graspers seen under the microscope after triple rotor brushing action.

Detection through Weight reduction

While visual detection is necessary to pinpoint traces of debris on the instrument surfaces and hard to reach spots, slight variations in the instrument weight after contamination and after cleaning methods provide a more definitive result.Detection through weight reduction is an objective method of measuring ATS on the instrument. .

As mentioned in the methods section, all instruments were cleaned thoroughly, dried and weighed before ATS contamination using a highly sensitive microgram scale. The instruments were than contaminated with ATS, allowed to dry and weighed again to measure the increase in instrument weight. Post soaking and cleaning using the three protocols, the instruments were dried and weighed again to measure the reduction in soil. Each instrument was tested thrice and the worst out of the three outcomes are noted. The reduction in ATS weight is calculated and displayed in percentage.
In all grasper inserts, the weight of ATS removed during the cleaning process was significantly high and the amount of debris left was significantly low when acted upon by the brushing mechanisms as compared to ultrasonic cleaning proving that even though ultrasonic cleaning is a very crucial step in the reprocessing journey of laparoscopic instruments, mechanical brushing has revealed very promising results. The graph plotted in fig 16 is a comprehensive overview of the efficacy of the various cleaning methods put in use for this study. It can be ovserved that the highest concentration of instruments fall under the 99.9% of the ATS removed axis of the triple rotor brush jig. This is a clear indication that this brushing system has been the most effective. Detailed data of the test is provided in Appendix.

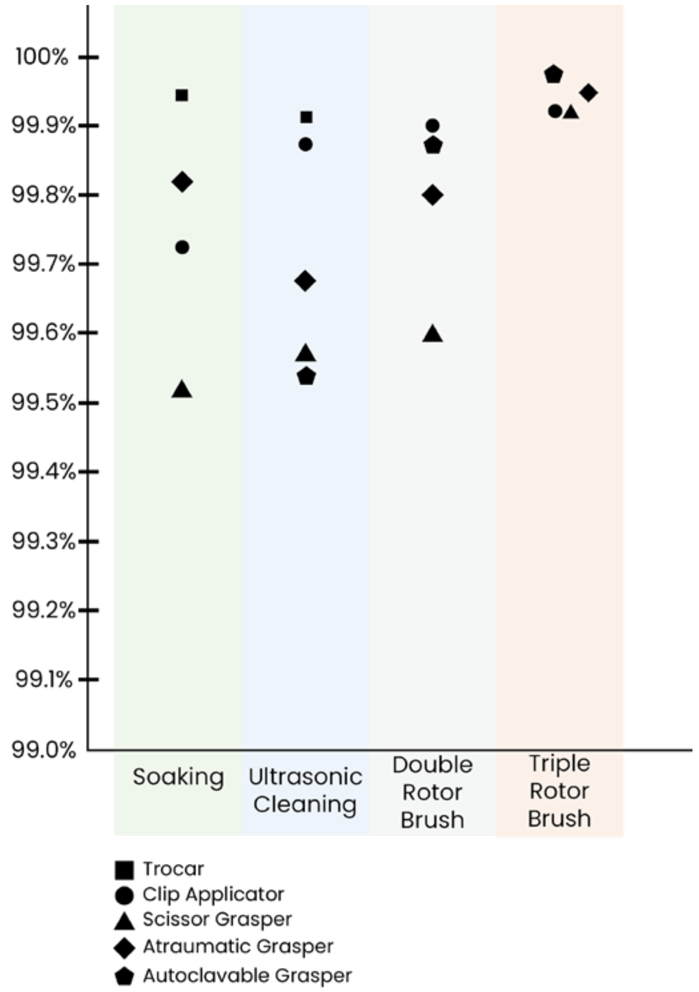


Fig 16 Amount of ATS removed by various cleaning protocols depicted in percentages.

DISCUSSION

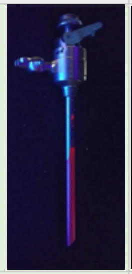
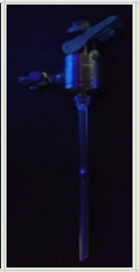
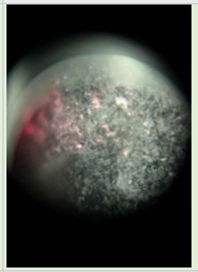
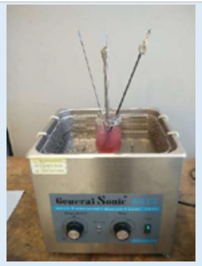
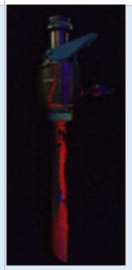
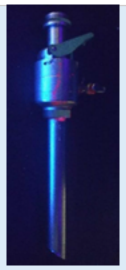
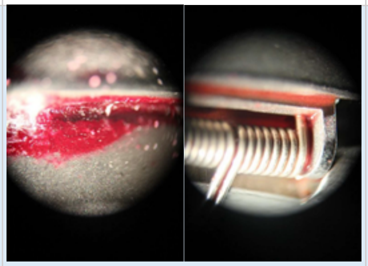
The demand for laparoscopic surgeries in rural India is increasing and would soon be the preferred method of surgery for issues pertaining to the abdomen. High demand coupled with a short inventory of laparoscopic instruments puts pressure on efficient and quick reprocessing.
Complex laparoscopic instruments are difficult to reprocess by the overworked and untrained rural Indian nurses employing the current practices or reprocessing. The lack of expensive and resource hungry devices like automated washer disinfectors puts added pressure on the hospital staff and resource management.
Ultrasonic cleaning is a highly cost effective, simple and efficient method of cleaning laparoscopic instruments. Unfortunately, none of the hospitals visited on the field trip used them. There is little to no information regarding why ultrasonic cleaning is not implemented in rural India. From the tests conducted with various laparoscopic instruments, it is clear that ultrasonic cleaning has managed to efficiently remove vast volumes of ATS, however, the microscopic images have clearly exposed clusters of debris in the hard to reach hinges and grasper jaws.
Inducing surface shear stress through mechanical brushing has clearly managed to clean the instruments better by allowing the bristles to penetrate into the aforementioned areas of the instruments.
In conclusion, further design considerations pertaining to the implementation of mechanical rotary brushing actions could prove to be a major addition to the surgical instrument reprocessing practices in rural India, thus alleviating the nurse's workload, guaranteeing standardized and consistent outcomes for resource constrained countries.

LIMITATIONS & RECOMMENDATIONS

Several limitations and considerations were overlooked while conducting this test due to lack of time and general lab rules.
Adding streams of water on the laparoscopic instruments during the brushing tests would have increased the amount of ATS displaced by the rotary brushes. It is recommended to install the jig in a chamber with water supply concentrated to the points of contact between instrument and brush.
It was not possible to confirm if the lumened laparoscopic instruments were properly dried. This could have hampered the overall weight of the instrument after applying the cleaning methods. It is recommended to ensure complete drying of the instrument by placing the cleaned instruments in desiccating agents or drying chambers. Trocars were not brushed as they demand a separate test protocol.

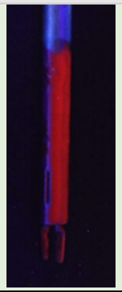
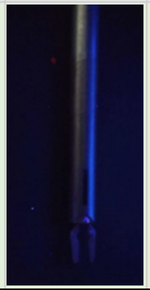
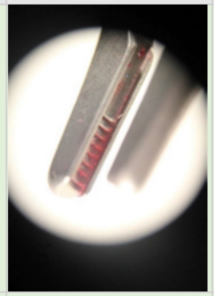
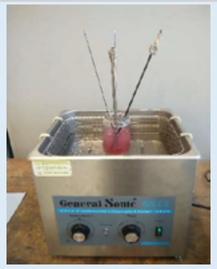
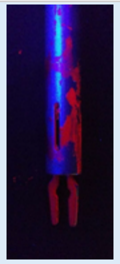
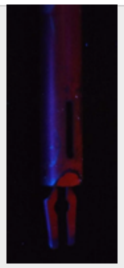
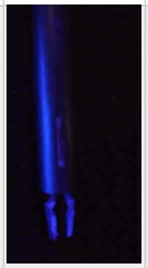
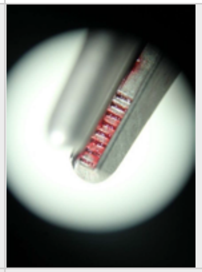
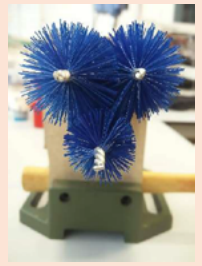
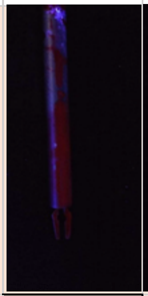
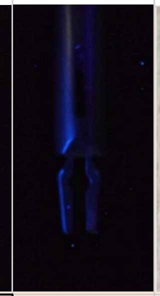
TROCAR

58,6183g

	ATS Contamination	Post Clean Method	ATS Weight Difference	ATS Removed	Microscope Image	Comment
 Soaking 10 min				99.94%		The trocar was soaked in detergent solution of arbitrary quantity for 10 minutes. Then dried and weighed. The reduction in ATS after soaking only is 0,2024g. Soaking only has removed 0.0039g of ATS Residual debris is still visible thourgh microscope.
	58,8546g	58,6522g	0,2024g reduction			
 Ultrasonic Cleaning 10 min				99,91%		After soak, the trocar is placed in the 41kHz ultrasonic bath for 10 minutes.The reduction in ATS after ultrasonic cleaning for 10 minutes is 0.1111g
	58,7831g	58,6720g	0,0537g reduction			

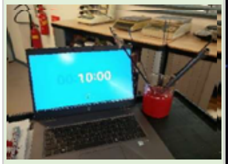
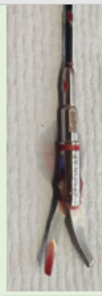
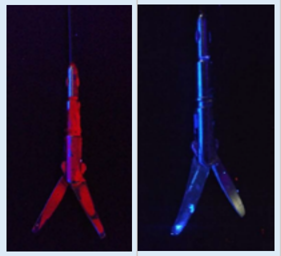
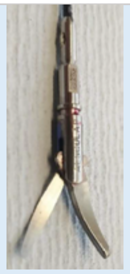
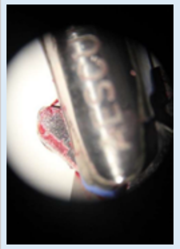
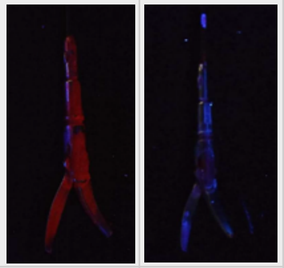
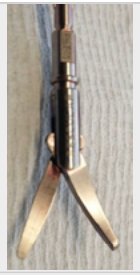
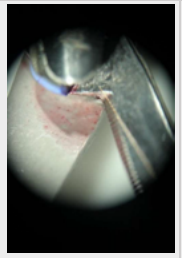
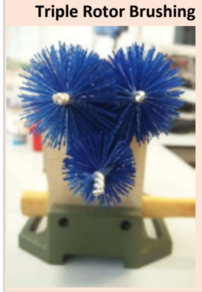
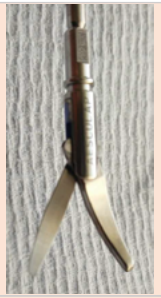
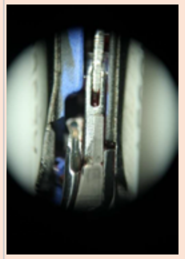
CLIP APPLICATOR

95,9438g

	ATS Contamination	Post Clean Method	ATS Weight Difference	ATS Removed	Microscope Image	Comment
 Soaking 10 min				99.73%		Soaking only removed 99,73% of ATS. Microsopic images show traces of debris lodged in the jaw of the clip applicator. To completely remove this debris, the jaw had to be brushed manually. There may be traces of moisture and debris on the inside of the lumen that is not visually accessable.
	96,2577g	95,982 g	0,2595g reduction			
 Ultrasonic Cleaning 10 min				99,88%		Ultrasonic cleaning for 10 minutes in a 41kHz ultrasonic cleaner removed 99,88% ATS. Traces of debris are significantly reduced on the clip applicator jaw compared to soaking. There may be traces of moisture and debris on the inside of the lumen that is not visually accessable.
	96,3464g	96,0623g	0,2841g reduction			
 Double Rotor Brushing 3 min				99,90%		Inserting the clip applicator tip in a double rotor brush for 3 minutes has eliminated 99,90% ATS. Microscopic image shows that the double rotor brush cannot reach the insides of the applicator jaw. There may be traces of moisture and debris on the inside of the lumen that is not visually accessable.
	96,1932g	96,0994g	0,0938g reduction			
 Triple Rotor Brushing 3 min				99,93%		Inserting the clip applicator tip in a triple rotor brush for 3 minutes has eliminated 99,93% ATS. Microscopic image shows that the triple rotor brush setup has managed to remove all debris from the applicator jaw. There may be traces of moisture and debris on the inside of the lumen that is not visually accessable.
	96,2571g	96,0994g	0,1577g reduction			

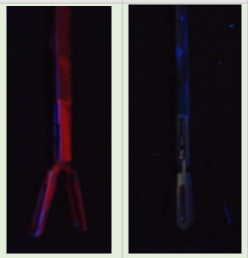
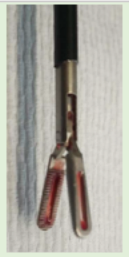
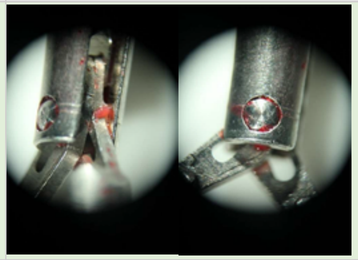
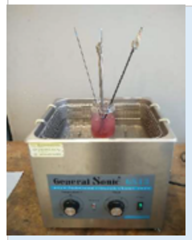
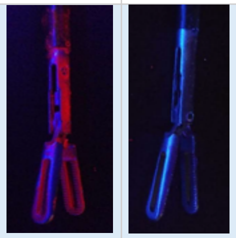
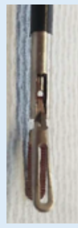
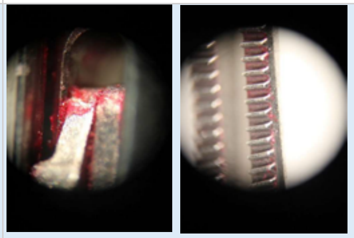
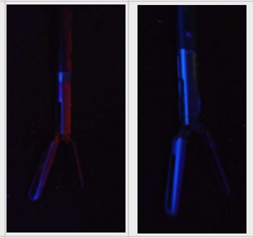
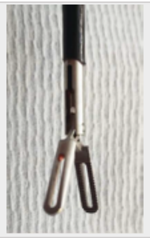
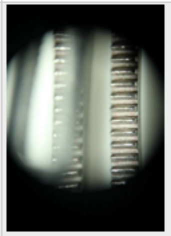
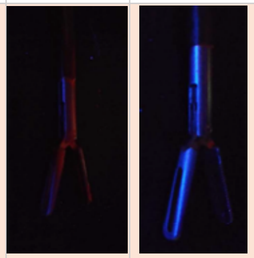
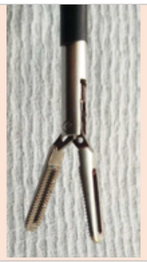
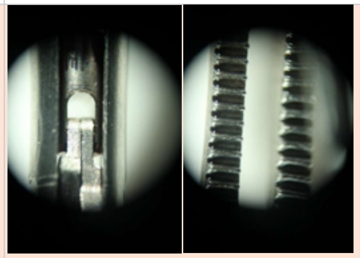
GRASPER SCISSOR INSERT

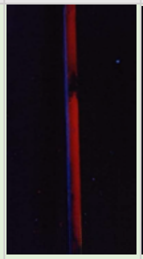
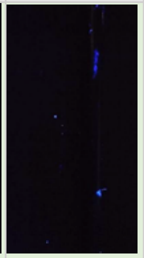
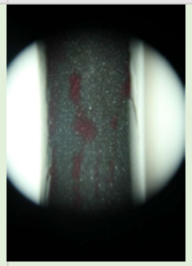
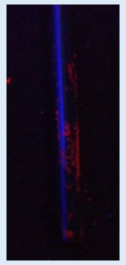
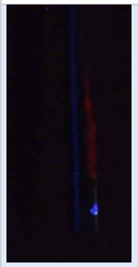
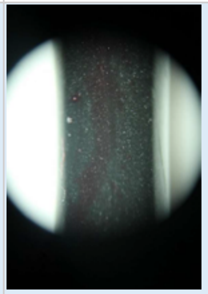
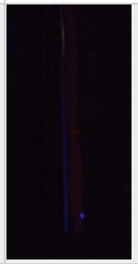
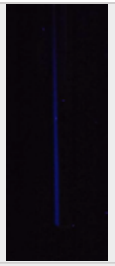
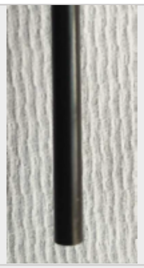
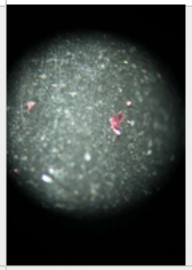
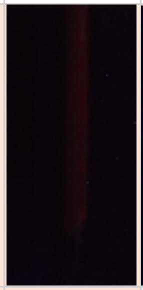
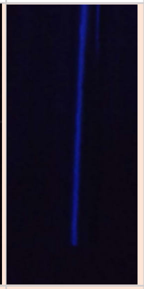
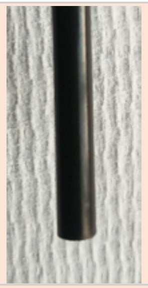
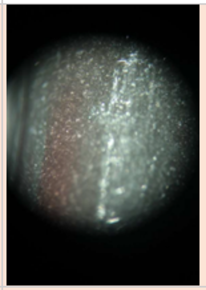
7,9400g

	ATS Contamination / Post Clean Method		ATS Weight Difference	ATS Removed	Microscope Image	Comment
 Soaking 10 min				99,53%		Soaking only has eliminated 99,53% of ATS from the grasper scissor insert. Images show that the the soaking has not managed to remove the clot from chamfers and the internal geometry of the grasper insert. Microscoic image shows significant collection of debris in the working hinges of the grasper insert.
	8,0350 g	7,9777g	0,0573g reduction			
 Ultrsonic Cleaning 10 min				99,58%		After immersing the scissor insert in an ultrasonic bath for 10 minutes, 99,58% ATS has been removed. The ultrasonic cleaner has not thoroughly cleaned the inaccessable hinge geometry. Microsopic images show traces of debris on the grasper hinge and blade.
	8,0014 g	7,9730 g	0,0284g reduction			
Double Rotor Brushing 				99,60%		Double rotor brushing for 3 minutes has removed 99,60% of ATS. Regular and microscopic imaging reveal traces of debris on the scissor blades.
	8,0038g	7,9717g	0,0319g reduction			
Triple Rotor Brushing 				99,90%		Triple rotor brushing for 3 minutes has removed 99,90% ATS from the grasper scissor insert. No traces of debris were found on the instrument tip and hinges.
	8,0225g	7,9554g	0,0671g reduction			

ATRAUMATIC GRASPER INSERT

53,3651g

	ATS Contamination / Post Clean Method		ATS Weight Difference	ATS Removed	Microscope Image	Comment
 Soaking 10 min				99,83%		Soaking for 10 minutes has removed 99,83% ATS from the instrument surface. Regular and microscopic imaging reveal large clusters of debris on the grasper hinge and teeth.
	53,6462g	53,4533g	0.0882g reduction			
 Ultrasonic Cleaning 10 min				99,68%		Immersing the grasper in an ultrasonic bath for 10minutes has cleaned the grasper by 99,68%. Microscopic images reveal significant collection of debris in the grasper teeth and hinge mechanism.
	53,3651g	53,5338g	0,0284g reduction			
Double Rotor Brushing 				99,79%		Inserting the grasper between double rotor brushes for 3 minutes has removed 99,79% of ATS. Regular and microscopic imaging shows traces of debris on the instrument tip and teeth.
	53,5074g	53,4771g	0.0303g reduction			
Triple Rotor Brushing 				99,95%		vInserting the grasper between triple rotor brushes for 3 minutes has removed 99,95% of ATS. Regular and microscopic imaging shows no traces of debris on the grasper hinge and teeth.
	53,5669g	53,3919g	0,1750g reduction			

	ATS Contamination	Post Clean Method	ATS Weight Difference	ATS Removed	Microscope Image	Comment
 80,0390g						
 Soaking 10 min				90,90%		Immersing the grasper tube in detergen solution for 10 minutes followed by drying and weighing has removed 90,90% ATS. Traces of trapped moisture and debris inside the long lumen of this instrument might have played a significant role in the weight outcome. Microsopic imaging reveals traces of debris adhered to the plastic instrument sheath.
	80,2246g	80,1197g	0,1049 reduction			
 Ultrasonic cleaning 10 min				99,55%		Immersing the grasper in an ultrasonic bath for 10 minutes followed by proper drying has removed 99,55% of ATS. Microscopic image shows a very slight trace of debris adhered to the instrument sheath.
	80,3985g	80,3972g	0,3582g reduction			
 Double Rotor Brushing				99,86%		Inserting the grasper between a double rotor brushing jig for 3 minutes has removed 99,86% ATS from the grasper tube.Microscopic image shows a debris particles adhered to the instrument sheath. Traces of trapped moisture and debris from the long grasper tube might influece weight calculation.
	80,2305g	80,1542g	0,0763g reduction			
 Triple Rotor Brushing				99,98%		Inserting the grasper between a double rotor brushing jig for 3 minutes has removed 99,98% ATS from the grasper tube.Microscopic image shows a very slight trace of debris on the sheath. Traces of trapped moisture and debris from the long grasper tube might influece weight calculation.
	80,2202g	80,0543g	0,165g reduction			

DESIGN FOR our future

TU Delft

IDE Master Graduation

Project team, Procedural checks and personal Project brief

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

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

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

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

STUDENT DATA & MASTER PROGRAMME

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

family name: Malage 4161
initials: G.A. given name: Girish
student number: 4781538
street & no.:
zipcode & city:
country:
phone:
email:

Your master programme (only select the options that apply to you):
IDE master(s): [x] IPD [ ] Dfl [ ] SPD
2nd non-IDE master:
individual programme: - - (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: Dr.ir. JC Diehl dept. / section: SDE/DfS
** mentor: Dr.ir.Sonja Paus-Buzink dept. / section: HCD/AED
2nd mentor: ir. Daniel Robertson
organisation: TU Delft MISIT
city: Delft country: Netherlands

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 Dr.ir. JC Diehl date 19 - 03 - 2020 signature jdiehl Digitally signed by jdiehl Date: 2020.03.19 22:06:35 +01'00'

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: 40 EC

Of which, taking the conditional requirements into account, can be part of the exam programme 23 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:

ID4185

name C. van der Bunt date 19 - 05 - 2020 signature

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: APPROVED (★) NOT APPROVED

Procedure: APPROVED NOT APPROVED (★)

- ID4185 is missing (Strategic and Sustainable Design) the student may start graduation, but the course should be finished before the green light meeting
- no abbreviations in title, please remove LIMC

comments

name Monique von Morgen date 26 - 05 - 2020 signature

Cleaning and Ensuring sterilization of Laparoscopic surgical tools in LMIC 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 23 - 03 - 2020 10 - 08 - 2020 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, ...).

Laparoscopy is a method for minimally invasive surgeries for the abdominal procedures, pertaining to gallbladder removal, hernia, hysterectomy etc. Laparoscopic surgery requires a specialized arsenal of tools such as graspers, a trocar, endoscopic cameras that are complex, long and slender making them expensive and difficult to clean. Due to proper healthcare systems already in place in high income countries (HICs), laparoscopic surgeries with disposable tools are affordable. Due to the vast number of patients below poverty line in low/middle income countries (LMICs), disposable laparoscopic tools are not viable as replacing tools after each surgery are too expensive (Udwadia 2001). Compared to open surgeries, laparoscopy is an advanced and logical method of surgery. Many hospitals in LMICs fail to comply with standards of practices due to severe lack of funds and resources. Surgical rooms in these hospitals are not guaranteed to be sterile and poses a great risk of infections for the already vulnerable patients. In open surgeries, the surgeon accesses the organs through larger incisions and has direct tactile access and demand a sterile operation room, which is difficult to maintain in LMICs (fig1). The risk of infections during and post surgery are high. In many instances, the cleaning and sterilization rooms are adjacent to the operation room, where staff this area to clean the surgical tools but also scrub before and after surgeries (fig2). This poses a serious health risk to the patients as contamination and contracting infections during surgery are high. Due to the expensive nature of laparoscopic tools, lack of autoclaves and underdeveloped sterilization systems, LMIC hospitals cannot afford to own multiple sets of reusable laparoscopic tools. Small incisions in laparoscopic operations heal faster, reduce infection, bleeding, post operative pain and scarring, thus reducing the dependence of pain medication which are costly and have side effects. The recovery speed allows patients to be discharged on the same day to within 2 days post surgery helping the patient to minimize costs, frees up hospital beds and allows him/her to recover to daily life quicker. Laparoscopy is also an inexpensive tool for diagnostics in LMICs as compared to MRI and CTs (Udwadia 2004) and is used to diagnose peritoneal tuberculosis and pelvic inflammation (Chao et al. 2016). For these aforementioned reasons, Laparoscopy is very beneficial in LMICs. In LMICs, the tools are dismantled, rinsed and either autoclaved in gas run autoclaves chemically or simply disinfected using CIDEX solution for 20 minutes after which they are rinsed again. Due to the chaotic nature of these surgery rooms, sterilization of the storage facility of these tools is not guaranteed. Cross contamination risk is high making this environment unsafe for staff and patients alike. Infection outbreaks due to unclean laparoscopic instruments have been reported due to biofilm formation at the bottom of disinfection trays (Vijayaraghavan et al. 2006), which was traced back to the cleaning departments of the hospital. Disposable laparoscopic tools can be reused to a certain extent, but material disintegration is a common. 68% of India's population lives in rural areas and 90% of this demographic are deprived from safe and timely surgery due to lack of resources. TU Delft MISIT lab (Minimally Invasive Surgery and Interventional Techniques) is working on surgery for all where ir. Daniel Robertson specializes in laparoscopy and has visited many LMI hospitals in India.
Due to the vast information and contacts gathered by Daniel and his team and the aforementioned statistics, LMI hospitals in India are the focus for further development of methods for the cleaning and ensuring sterilization of laparoscopic devices. The main stakeholders of the project are the patient being operated upon, hospital staff that include surgeons, nurses, cleaning staff and the TU Delft MISIT Lab.

space available for images / figures on next page

introduction (continued): space for images

image / figure 1: Example of surgery room in LMI hospital in Kolkata, India

image / figure 2: Example of scrub/cleaning area of surgical tools adjacent to operating room

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.

In summary, the problem I wish to address is that laparoscopic tools, in this case, reusable laparoscopic tools are complex and are still cleaned in traditional methods in LMI hospitals. No specialized methods are used to clean and sterilize them efficiently or faster. In order to tackle this, the problem focus is to address and resolve this complexity of cleaning and ensuring the sterilization of laparoscopic surgical tools in LMIC in the Indian context.

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.

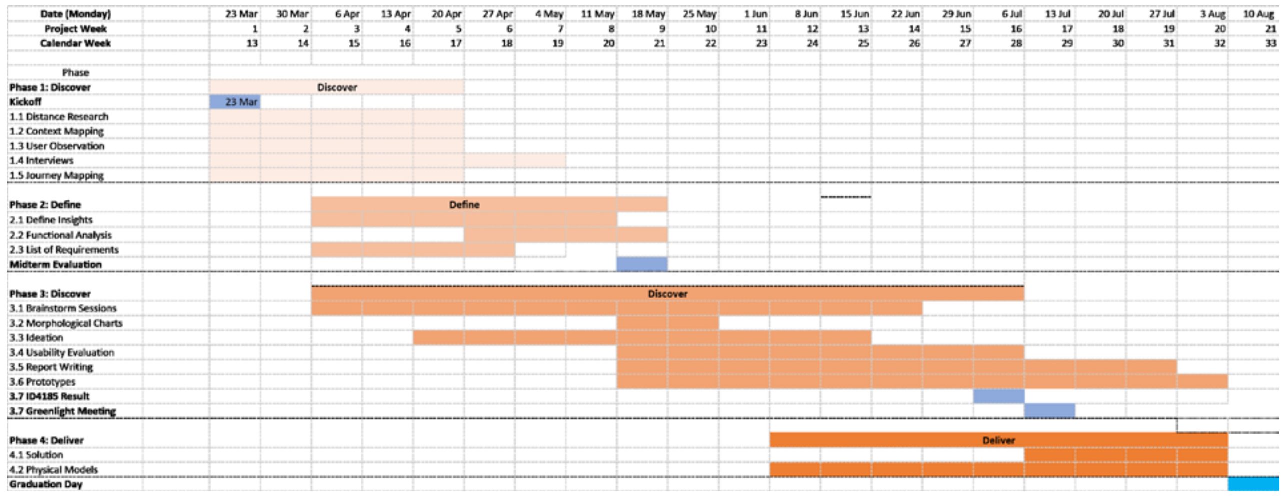
'Redesign the cleaning process of laparoscopic equipment and ensuring its sterilization between surgeries in LMIC settings, specifically India.

During this project, we are looking for a first solution to improve the instrument cleaning process and ensuring their cleanliness and sterilization in LMICs. Since the device is meant for hospitals in LMICs, a clear understanding of the local instrument cleaning process and the general handling of these tools is needed. This handling includes storage, transport from storage to operation and pre insertion. Therefore, we will start by identifying and visualising the critical steps in the journey between operations. Based on these insights, one or multiple concepts will be developed that might work in the local sterilization procedure. Due to the Coronavirus outbreak, a field research trip to India is not possible. Information will be gained through contacts in India through video conferencing and details collected by Daniel Robertson and his team from previous trips to LMI hospitals in India. Insights gained through this information will then be incorporated to make a 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 23 - 3 - 2020 | 10 - 8 - 2020 end date



An indepth research of existing practices of cleaning of laparoscopic devices in low and middle income hospitals in India will be conducted through online communication with nurses in India and through information collected by Daniel Robertson and members of the MISIT team. The research will include a thorough case study of existing techniques of instrument sterilization in the aforementioned hospitals.

Another case study to be done in LUMC Leiden which is a well funded hospital. Information gained in both will give insights into the stark differences between both contexts. Understanding the differences between cleaning processes in HICs and LMICs would give insight into the practices in both these contexts .

Through conducting this research, it will be clear so as to design the entire cleaning systems or simply focus on redesigning parts of the laparoscopic gripper. These deliverables will be submitted in the form context mapping and physical and computer simulated prototypes.

Every Wednesday, I work as a teaching assistant for IDE Academy with prof. Ianus Keller. This should take up not more than 4 hours each week. I have kept Mondays as the start day of the week for the sake of convenience. Calendar week 13 to week 33 is 100 days

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.

Topics pertaining to healthcare with an addition to LMIC contexts are inherently an interest of mine. Being an Indian citizen, I have had the opportunity of seeing suffering due to inadequate infrastructure and resources first hand and hence well aware of the context. A project that contributes to the efficiency of cleaning of laparoscopic devices would not only address the global low income populations but also pave the way for a HIC to amend their existing practices, thus addressing the global laparoscopic surgical practices. I was first affiliated with a project based on laparoscopy during the Design for Emerging Markets elective where I met Daniel and the MISIT team. Joining the laparoscopy in LMIC team in the aforementioned elective was the foundation to this graduation project. In the short 3 months, the solutions spaces were filled up with basic concepts pertaining to the cleaning of laparoscopic tools and an in depth understanding of laparoscopic surgery in India with the help of Daniel's research and interviews with Indian surgeons. Competencies yet to develop are getting an even deeper understanding of surgical practices in LMICs, designing, prototyping and validating material, design concepts through national and international healthcare and surgical guidelines.

FINAL COMMENTS

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