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Master's Thesis
Integrated Product Design
Faculty of Industrial Design Engineering
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Appendix 1.1. Tour LUMC

Tour LUMC operating room and sterilisation

The tour started off in the cleaning and sterilisation facilities where we learnt the different steps the reusable equipment go through in the cleaning process. Everything is first pre-cleaned by hand. Scopes are then sanitized by putting them inside an acid bath for about an hour. These machines are called Medivators.

The cleaning of gastroenterology devices (for stomach, bowel and liver interventions) happens with the use of different machines that are placed in the department itself. The endocutter is part of this line of instruments. We can make another appointment to look more into this.

figure 1. *Medivators*

There is a difference between cleaning, disinfection and sterilizing. Cleaning is done with water and soap, disinfection means that most microbes are killed in the process. Sterilizing means that there is only a one in a million chance that there are still microbes alive after the process which can include exposing instruments to high temperatures, agressive chemicals and infrared light. In Dutch hospitals most instruments go through all these steps.

After the acid bath, scopes are machine dried.

figure 2. *Dryer*

There has been a lot of optimisation in the storage of new tools. There used to be bulk storage all over the building and in every single operating room, now everything is stored in one place and there are notification systems for when the hospital is almost out of a certain tool and there need to be new tools ordered. This way there is less unnessary bulk storage and space is used better.

figure 3. *Instrument storage*

Different operations require different tools. These tools are presorted in so called “nets” and also cleaned in this order. When the tools are properly sanitized they are hand sorted in this cleaning room and all the nets are checked for completion. You are still allowed to touch the instruments in this room since they have not gone through the sterilization process yet.

Since LUMC is a medical center and not a normal hospital they deal with a huge variety of instruments. Some instruments are not even owned by the hospital but borrowed from companies to place specific implants. All these instruments have their own cleaning manual and take expertise to deal with.

The cleaning process the instruments go through is quite agressive. there have been problems with differences in legislation between different countries or even single countries. Some countries expect you to sterilize an instrument for 18 minutes, while we in the Netherlands only require a sterilization of 4 minutes and our machines cannot handle much more. If a manufacturer then decides to put this requirement of 18 minute sterilization on the instrument it cannot be cleaned in this hospital. Sometimes there are also problems with manufacturers using certain plastics in their products that simply melt from the chemicals we are required to use in the cleaning process. LUMC has the most problems with American manufacturers because they usually design for the American market and regulations, without taking European law into account.

figure 5. *Net with borrowed instruments for implant from the company Nuvasive*

figure 4. *Cleaning room*

figure 6. *Disinfection conveyorbelt*

Nets are sanitized through these machines. They are placed in the glass box from the contaminated room in the back where they have been cleaned by hand, and taken out in the cleaning room on this side of the glass. Below you can see some of the cleaned nets.

figure 7. *Cleaned nets*

Needles and hollow instruments are disinfected by letting water and chemicals run through them on a special needle tray.

figure 8. *Needle tray*

CSA = Centrale Sterilisatie Afdeling (Central Sterilization Department) The CSA of LUMC has an overcapacity which means the scaling up of reusable instruments should be no problem.

figure 9. *Labeled nets*

Nets are labeled and can be tracked and traced this way. This way mistakes can be corrected easily. LUMC also uses a system of feedback forms to be more specific about what is wrong with a net and make the feedback loop accessible.

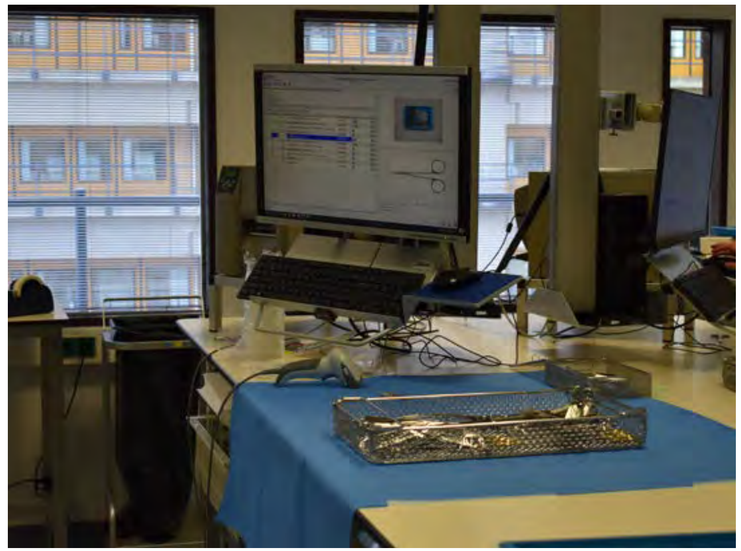

figure 10. *Sorting station*

Nets are checked and sorted by hand in these sorting stations inside the cleaning room. Sorters have lists of the instruments that should be in each net for each operation, they also have to be placed in a certain order. After sorting the net is packaged in polypropylene and labeled again. multiple nets are placed inside a cart, ready for sterilization.

figure 11. *Cart with packaged nets*

figure 12. *Autoclaaf or sterilization machine*

Metals and thermosets are sterilized through the use of a so-called autoclaaf, a machine that uses heat to kill germs. Because thermoplastics warp or melt when exposed to heat, they need to be sterilized in a separate machine. This machine uses hydrogen peroxide to sterilize instruments, but these cartridges make this cleaning process very expensive in comparison. Peripheral hospitals often don't have a hydrogen peroxide machine for this reason, but they also don't do the type of procedures that require thermoplastic instruments as often.

figure 13. *Hydrogen peroxide sterilization machine for thermoplastics*

On the other side of the sterilization machines there is a room that is entirely clean. this is also where pre-packaged single use surgery gear is stored, all sorted per procedure. This is all delivered completely sterile.

figure 14. *sorted single-use surgery products in the clean room.*

figure 15. *Sterilized nets*

From the clean room there is also a dedicated "clean" elevator that goes up to the operating rooms. The operating rooms are located right above the sterilization department. clean materials are sorted and prepped for surgery in a preparation room, as shown on the right. Up to four surgeries can be prepped in this room at the same time, as it's connected to four different operating rooms.

In this room the packaging is removed from the nets and separated into a PP bin. Since this material is removed before surgery it's treated as industrial waste instead of surgical waste.

Everywhere in the hospital there is a goal of more logistical efficiency. They are for example going to remodel the operating room and sterlization department, but also look at the layout of individual nets and net carts. This way less material is needed and less instruments need to be cleaned. Everything that enters the operating room is considered as contaminated and either needs to be sterilized or discarded, even when it hasn't been used and is still stored in its sterile packaging.

figure 16. *Preparation room*

figure 17. *Operating room*

There is a dilemma between the specialization of operating rooms, which would mean you would not need certain materials in every single room, and standardisation of operating rooms. Right now the rooms are mostly standardized with a few small exceptions to certain layouts.

After surgery the contaminated nets are placed back in carts and covered with a green plastic slip-over. together with the trash from the operation the cart is driven into the appointed contaminated elevator which goes up to the contaminated room. In this room everything is treated with extra care and workers here are well protected.

figure 18. *Contaminated carts with green plastic slip-overs*

Appendix 1.2. Tour Erasmus MC

There is lots of decontamination options in the hospital

In Europe the legislation is, in the hospital the first question is is it infectious

There are two possibilities, discard or decontaminate. After decontamination more is possible

UMC Utrecht has a machine that shreds confectious waste, shred it, microwave it and then it is normal waste. 50.000 euros +- its really hard to recycle because they are tiny pieces. If bigger pieces can be decontaminated it would be way easier.

Everything you put in the pharmafilter you don't need a bin for.

Shredded waste from pharmafilter is not really useful for recycling. Its still incinerated.

Theoretically all plastics can be recycled. Here they do soft plastics, hard plastics and polystyreend. Hard plastics are separated.

Q: what level of disinfection is necessary for waste? Sterilisation?

Most valuable for them is like PP boxes. It actually generates money. The problem is that there is no space for extra waste streams. Then prezero has to separate again and that costs money.

Biomaterials: try to compost but mostly its through fermentation. Gases are collected for electricity. What you have left is compost. There is companies that do that. They have a max time for waste (6 weeks) but most biodegradables take longer to decompose. So the materials will not be entirely gone after the plant is done. In the Netherlands there are no factories that can process for that long.

There is a difference between what is possible and what is done.

Is recycling viable; Erasmus really wants to recycle more so its not all about cost. Contaminated waste is about 5 times more expensive compared to general waste, but you also need to buy the boxes and these are expensive too.

Sharps as well as bodily fluids are always infectious, after that we ask the hospital whether or not something is infectious. The one who makes the waste needs to decide if something is infectious.

LAP3 sector 20 is all about hospital waste

Its theoretically not allowed to transport infectious waste across borders. If you were to ask special permission because you plan to close loops with it, you have a big chance for permission.

Appendix 1.3. Tour UMC Utrecht

- Most hospitals do not have a microwave treatment for waste. It takes time and effort. You need to also separate it from the other waste because you don't want to microwave everything, that's a waste of energy. Also of course you need the machine.

The endocutter:

- The metal part cannot be shredded, it would damage the machine. So if you were to put an endocutter inside the sterilwave you would need to first take off the shaft etc.
- The handle can be shredded but you shouldn't because its electronic waste.
- Focco; shredding is for infectious waste, which I assume the handle is. But is it really? How can I find out? There is a lot of normal waste coming from the OR that is not treated as infectious waste. Most of the ORs also have bins for normal waste.
- If you would keep the device as one, with the metal plastic and electronics, focco really doesn't know how to treat it because of the small numbers.
- When you separate the two waste streams you can recycle it. However we need to know if the entire shaft is metal.

- Getting rid of a battery as infectious waste is ridiculous. You're not even allowed to incinerate batteries at zavin. But what they don't see they don't know.

- Contact dave – focco's contact for waste so would know when something is infectious.

- End of life service – you would still need to separate infectious waste from all the devices.

- The companies now that sterilise waste don't have a permit to take in waste.

- Separation methods work, but not on the "dust" from the sterilwave machine

Maybe I can find out a comparison in cost between the reusable and single use over time?

- The separation between reusable and single use devices externally could be possible but currently there is not one company that can do that because of legislation.

Interview vragen:

- How sterilwave works; it shreds the waste. The shredding process raises the temperature up to 70 degrees. Then the microwave turns on for 15/20 mins. After that it can be treated as normal waste.
- For now only infectious waste from the labs can be processed in it. No human materials or big steel things and no cytostatics (because sterilisation doesn't work on that).
- The waste is not collected in the gray bins but in specialised cardboard boxes for infectious waste.
- The machine has to be filled and emptied by hand and they also have to clean it. So it needs someone responsible for it.
- If you wanted to put in OR waste there would need to be another waste separation.

- What happens to the liquids put inside? There is no sewage output so any liquid put in stays in. you have to mind that. The end result is still quite dry, also because the cardboard boxes can absorb some liquid. Some liquid evaporates too.
- There are no unforeseen problems with implementation yet, it was implemented three months ago. A process like this takes years from a pilot to getting all the permits. Now they have a permit.
- The cleaned waste cannot be recycled right now because its shredded to dust. Because the dust can still absorb fluids, it can be used as an alternative to wooddust in the cement industry. If the pieces were a bit bigger it could be recycled.
- The machine can process around 20 percent of infectious waste. They have the medium machine.

Appendix 2. VIP report

A redesign of the single-use endocutter for circularity -
An analysis of the current challenges for the implementation of the circular economy on surgical devices

TU Delft

ETHICON
a Johnson & Johnson company

Faculty Industrial Design Engineering, Delft University of Technology,
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1. Introduction

The first part of this graduation project was mainly focused on researching the current state of the medical device industry, the possible circular recovery flows for laparoscopic devices and their benefits and drawbacks. From this point there is a need to take a step back and look at the bigger picture before moving forward to the design stage.

Designing is a subjective practice at its core. The Vision in Design (VIP) method is a way designers can structure this subjectiveness and explain and understand their own views and considerations in the process. This is why, unlike the research phase of this project, this appendix is a lot more fluffy and personal. It is not centred around facts and figures but more focused on personal observations, views and ideas. There are no right or wrong answers. These subjective thoughts will always be used to guide a design process, but analysing them and bringing them to light in an early phase will make the whole process more guided, deliberate and structured.

In this appendix the whole VIP process for this graduation process is explained and documented. The document will be used as a boundary object for discussions about future design steps and directions with the client to align views and expectations.

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2. The method

Design according to the Vision in Design (VIP) method, means reasoning from context to product. The VIP design approach is a "reverse deconstruction". If you can see that products are always reflections of a certain set of views and considerations, you also see that you first need to design this set of views and considerations to come up with a new product.

Instead of trying to formulate a product idea that matches a certain goal, the VIP method asks the designer to come up with a vision of the relationship between the user and the product. From there the designer can use that vision as the foundation for a new design. Basically you first need to take a step back and look at the bigger picture, before being able to move forward.

The VIP design approach is grounded in three basic principles:

1. Future oriented – The goal is to look for possibilities in the future instead of solving everyday problems.

2. Interaction centered - products are a means to accomplish or develop appropriate interactions and relationships, and are a means to an end.

3. Context driven - the appropriateness of any designed interaction is determined by the context for which it has been designed.

I will follow the method as described in the book Vision in Design – a Guidebook for Innovators (Hekkert & van Dijk, 2011).

Designing is the act of defining a vision of what you want to create, instead of simply creating something in response to a demand. This is why the process of designing needs to start with analysing why a design should exist. VIP is a process that can be altered in any way necessary to fit the design assignment, context, or personal preferences of the designer. It is a subjective process at its core.

The model shown in figure 1 represents the three layers you will go through when using the VIP method; the context level, the interaction level and the product level. A design is always a reflection of the interaction people have with it, which is in turn a reflection of the context in and for which the product was designed. The left side of the model represents the past, and the right represents the designed or envisioned future.

The process of deconstruction allows you to look at a current design or solution in these different levels. Understanding the current situation is crucial for later design steps. From an understanding of the past context you need to look forward into the future, and envision a new context. From this point you can ask yourself what kind of interaction would fit, and what kind of product characteristics would make this interaction possible.

An important note is that in this case I am not necessarily designing a product, even though a product is the starting point of the VIP process. The end result could be a service too. I am looking for specific qualities of a new, not yet defined, situation.

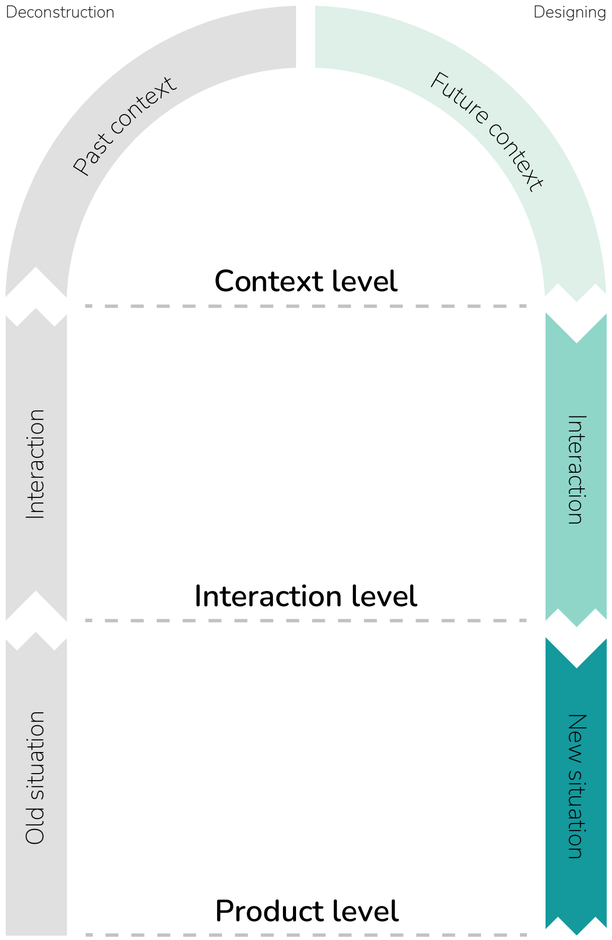


figure 1. *The VIP process*

3. Deconstruction

First, I need to deconstruct the endocutter and its features to understand the possibilities for a redesign of the product or the structures and logistics around the product. Since the main goal for this VIP process is to define characteristics of a new situation instead of a new product, an in-depth product analysis of the endocutter is not part of the destructuring process (figure 2).

Product level

The description of a product at product level is quite literal. It's about its physical features like materials, colours and parts, but also certain personality characteristics a product may express.

Interaction level

When looking at the interaction between the user and the product, it is important to not only consider obvious interaction features like use cues. What the product expresses or communicates determines how people experience or interact with the product, and should be considered in this phase too.

Context level

To describe a product on a context level, you want to step inside the shoes of the designer and try to retrieve the factors that determined their design choices. At this level there are ideas, views, values, opinions and considerations to take into account. It is a subjective step with a lot of guessing to why things are the way they are, but very useful at the same time because you will have an easier understanding of what has changed since and what will change in the future.

figure 2. *The deconstruction of the endocutter*

4. The domain

The first step of the VIP design process is deciding on the domain. The domain is the focus area the designer is dealing with, and determines the factors that should or should not be taken into account in the context of the design. Since the aim of defining my vision is not necessarily a redesign of the endocutter itself, but its entire lifetime instead, I decided to work in the following domain:

The domain:

The life of a laparoscopic device

5. Context factors

Context factors are building blocks that make up the domain. Factors can be facts or figures, but also subjective opinions, thoughts or beliefs. They can point to a possible solution or can be a very distantly related to the problem. The choice of factors is highly impacted by the designer's values and insights. Factors can be found anywhere, but they must be relevant to the domain you are working on.

Factors can be structured in different ways. One strategy is to device them into four types:

Developments = factors representing a phenomenon which is currently changing, or which is expected to change in the near future.

Trends = developments concerning tendencies in behaviour, values, or preferences of (groups of) people.

States = surrounding world conditions that will probably not change in the near future, but which are not necessarily fixed.

Principles = factors that are by their unvarying nature constant over longer periods of time.

Factors can also be found in many different fields, and they can be on a micro level (directly related to the domain) or a macro level (abstract and further removed from the domain). A large variety between these types, fields and levels of factors can create the most complete overview of the context.

Most of the factors I have collected are already explained and described in my midterm report, some are insights from interviews and some are my own opinions or observations.

The next step in the VIP process is to cluster and map the context factors to show patterns and directions in the context. I made two iterations of the context map based on different clusters, and decided to include them both in this appendix.

Economical

1. Extra surgery time is costly *State*
2. Business models of OEMs depend on economies of scale *Development*
3. Labelling a device as reusable takes more time and money compared to labelling it as single use *State*
4. Hazardous waste is the most expensive waste stream from hospitals *State*
5. Disposables are more expensive compared to reusables in the long run *State*

Psychological

6. The operation of an endocutter requires a long education and a lot of experience *Principle*
7. There is an enormous pressure inside the OR on surgeons and OR personnel to cure the patient and keep them safe. *Principle*
8. Hospitals base their choice on in-house vs external reprocessing partly on previous experiences with third parties *Principle*
9. People are afraid of making wrong decisions, especially when there are lives on the line *Principle*
10. People need to feel safe and at ease as much as possible when going into surgery *Principle*
11. SUDs are perceived to have a lower risk of cross-contamination compared to reusable devices *state*

Political/Regulatory

12. The reprocessing of SUDs is not allowed in the Netherlands *State*
13. For circular end-of-life strategies, exceptions can be made to international waste transportation restrictions *State*
14. Regulation in the medical device industry occurs via a complex network of organisations in which the devision of responsibilities and roles is somewhat unclear. *State*
15. The Dutch green deal for healthcare drives healthcare facilities to become more sustainable *State*

Cultural

16. There is a safety first culture in healthcare *Principle*
17. The medical device industry is highly competitive *State*
18. People find it increasingly important to live sustainably *Trend*
19. There is very little to no collaboration between third party remanufacturers and OEMs *State*
20. Organisational practices become have become more transparent because of social media *Trend*

Organisational/Logistical

21. Everything used in the OR is treated as a contamination hazard for patient and employee safety — *State*

22. Complex products with electronics are harder to reuse — *Principle*

23. Lower purchase costs, perceived infection risks and potential for human errors in reprocessing have led to a surge in the use of disposable products. — *Development*

24. End-of-life opportunities within hospitals depend on available facilities — *Principle*

25. Healthcare facilities aim to cut costs as safely as possible — *Trend*

26. Remanufacturing is already widespread in the medical industry, but mostly happens with high value, low criticality products like MRI machines. — *Development*

27. Healthcare facilities are increasing in size — *Development*

28. Hospitals are looking to reduce their stock of medical devices — *Development*

29. There is no room for extra waste streams in the OR — *State*

30. External reprocessing requires more time before the device can be reused because of transportation — *Principle*

31. External reprocessers have to take full responsibility for the reprocessed devices — *Principle*

32. The users of endocutters are not the ones in charge of choosing and purchasing the devices — *Principle*

33. Hospitals can focus more on their core business when they outsource reprocessing — *Principle*

Sociological

34. Big pharmaceutical companies have been experiencing reputational issues — *Development*

35. People become increasingly aware of their environmental impact — *Trend*

36. People are gaining a better understanding of the concept of “greenwashing” — *Trend*

Technological

37. Medical devices are becoming increasingly complex — *Development*

38. Function comes first in designing medical devices — *State*

39. Laparoscopic surgery is more precise and safe compared to open wound surgery — *State*

40. Many laparoscopic instruments are too complex for cleaning and maintenance — *State*

41. Recycling is becoming more efficient — *Development*

42. The same sterilisation techniques are available in in-house SDs of bigger hospitals as in external SDs. — *State*

Environmental

43. The sterilisation of a device can be so impactful that it makes the entire environmental impact of a device larger than that of a single-use device. However, usually single-use devices have a higher environmental impact. — *Principle*

44. Preserving a higher level of product integrity can be assumed to be a more environmentally friendly solution — *Principle*

45. The waste from a device could be reduced by up to 70% by just switching to a reusable alternative — *Principle*

46. The healthcare sector is responsible for 7.3% of the entire environmental impact of the Netherlands — *Development*

47. 20-30% of the total hospital waste volume originates in the OR — *State*

48. The healthcare industry lacks behind other industries when it comes to sustainable development — *State*

6. Context construction iteration 1

Clustering context factors

The separate factors do not tell the whole story. They need to be structured in a way that explains how they are connected and in which direction they point. There are two types of possible clusters:

A common-quality cluster: a combination of factors that all point into the same direction

An emergent-quality cluster: a combination of factors together represent a new direction that is not represented by the factors separately.

The first iteration of clusters I produced from my 48 context factors are visualised on the next page in figure 4.

Economical

1 2 3 4 5

Psychological

6 7 8 9 10 11

Political/Regulatory

12 13 14 15

Cultural

16 17 18 19 20

Organisational/Logistical

21 22 23 24 25 26 27 28 29 30 31 32 33

Sociological

34 35 36

Technological

37 38 39 40 41 42

Environmental

43 44 45 46 47 48

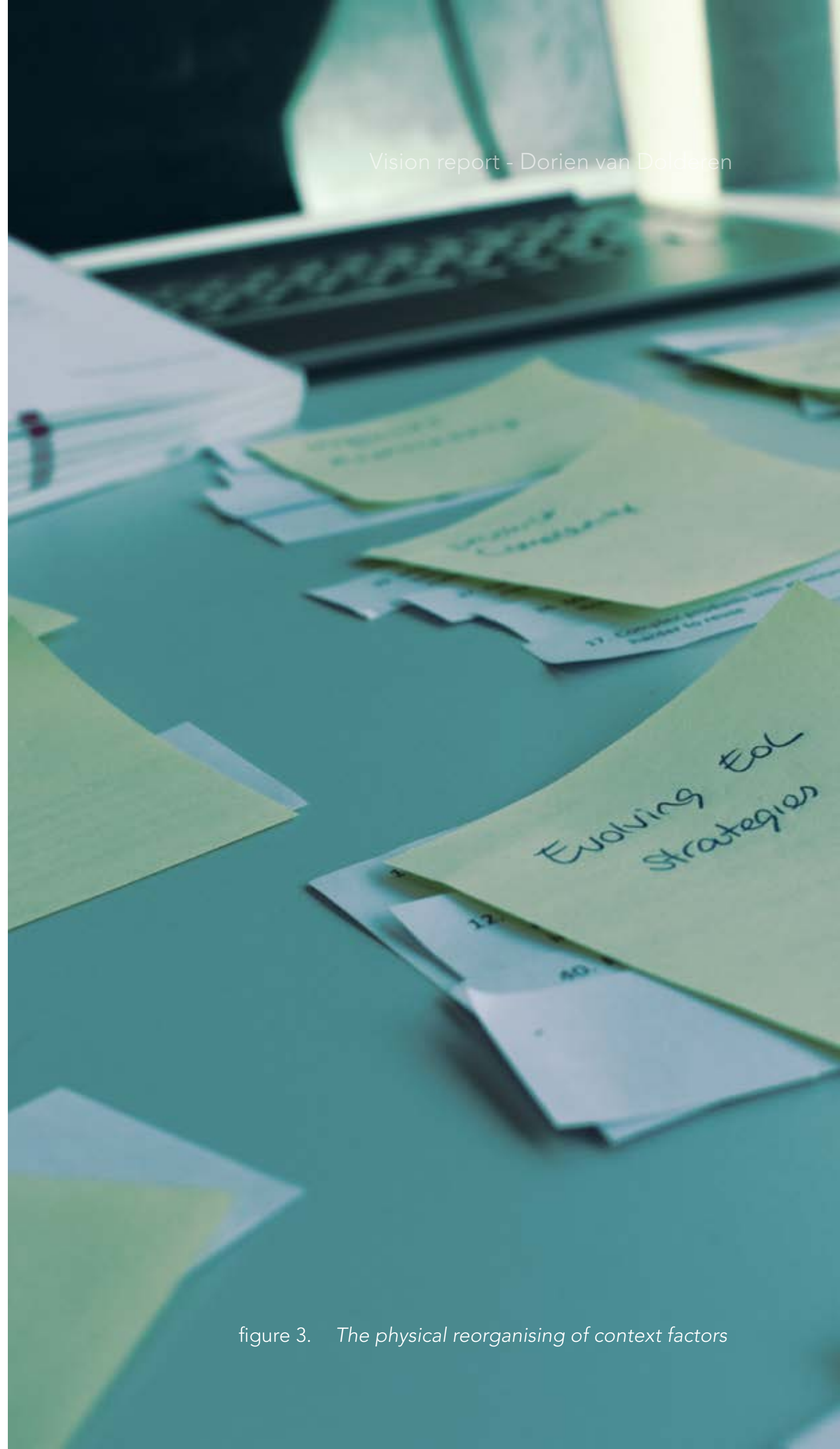


figure 3. *The physical reorganising of context factors*

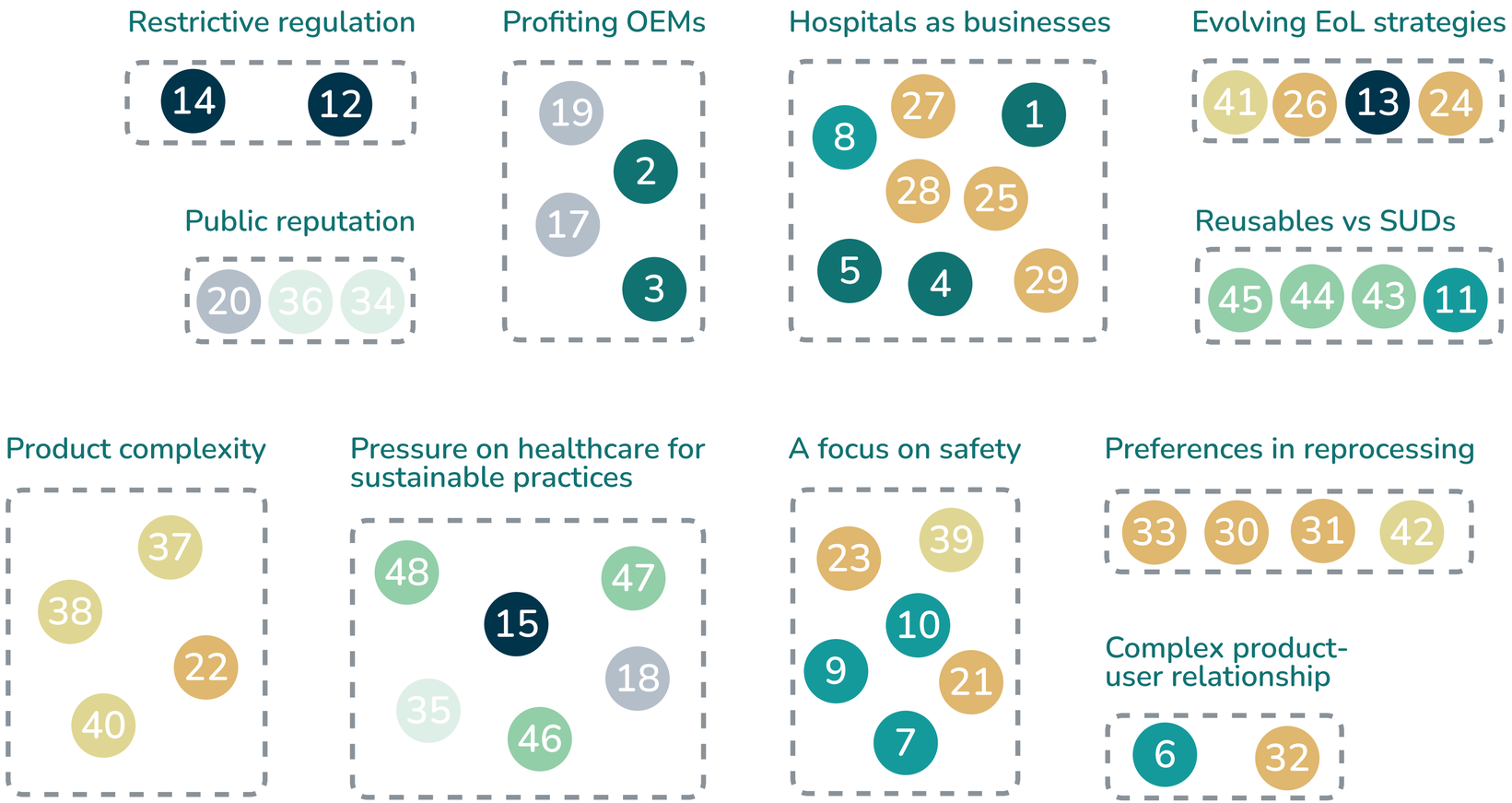


figure 4. *The clusters of context factors*

Context mapping (iteration 1)

The next step is to look for relationships between the de different constructed clusters. They can point in the same direction or be at conflict with each other. They could form a pattern, or highlight different dimensions

A 3-dimensional context

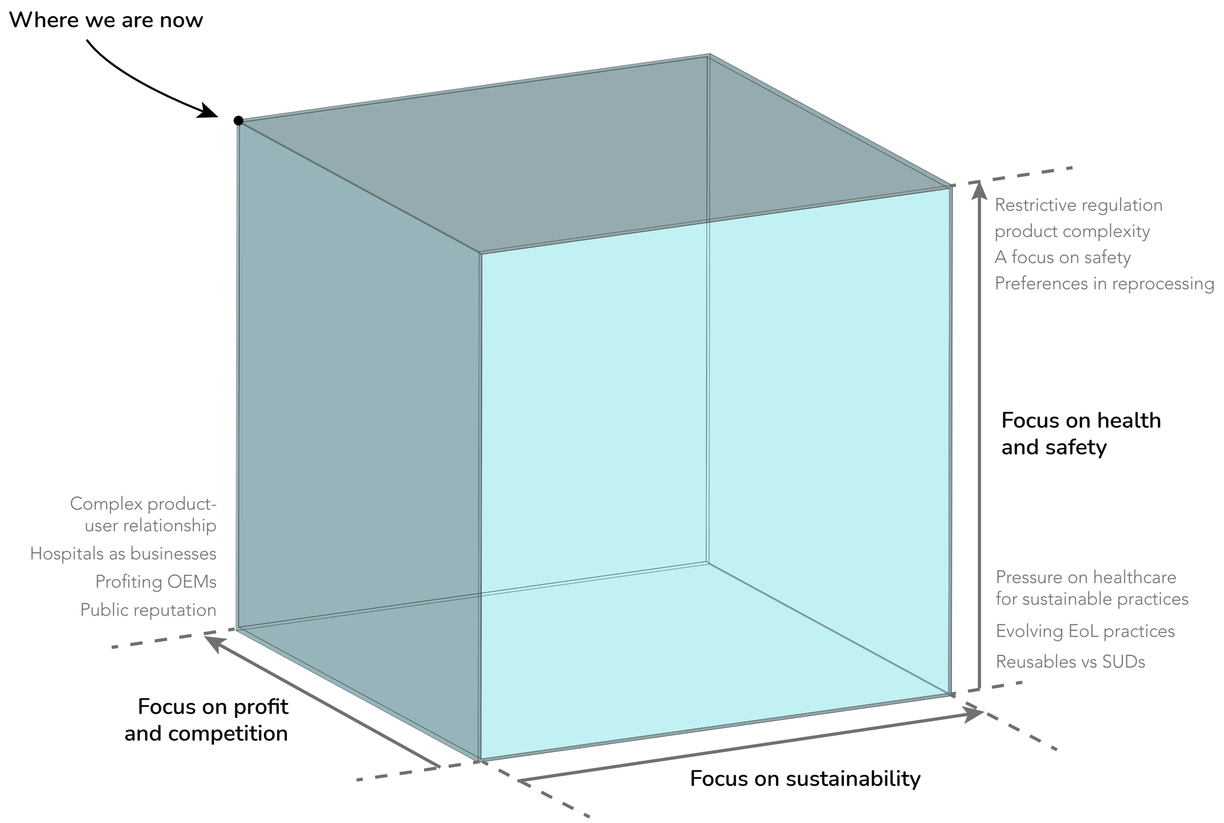
In this case, I see the clusters pointing into three separate directions.

1. The focus on profit and competition between OEMs, affected by the factor clusters *complex product-user relationship, hospitals as businesses, profiting OEMs* and *public reputation*.

2. The focus on health and safety, affected by the factor clusters *restrictive regulation, product complexity, a focus on safety* and *preferences in reprocessing*.

3. The focus on sustainability, affected by the factor clusters *pressure on healthcare for sustainable practices, evolving EoL practices* and *reusables VS SUDs*.

Together they can be visualized in three dimensions, with the current state of the medical device industry on this context cube positioned with a focus on profit and competition and health and safety, while not being focused on sustainability at all (figure 5).



the 3D context of the laparoscopic device industry

figure 5. *A three dimensional visualisation of the context of the laparoscopic device industry*

The triple constraint in the medical device industry

However, the three described dimensions that make up the cube seem to influence and impact each other. This reminds me of a project management model called the triple constraint. This model contends that the quality of work is constrained by the project's allocated budget, time and scope. As a project's manager you can trade between these three constraints, but changes in one constraint means you need to compensate with the others, otherwise the quality of work will suffer. According to the triple constraint: "You can't have it good, fast and cheap, pick two" (Microsoft support, n.d.).

As an example, you can complete a project faster if you allocate more money, or decrease the scope. Cutting budget from a project without adjusting the schedule or scope will result in a lower quality result. Since several clusters suggest there is often a trade-off between the different dimensions of the laparoscopic device industry, maybe it is better to visualise the three dimensions of the laparascopic device industry as three constraints (figure 6).

If this were the case, there are three possible future directions, each focuses on two dimensions and compromises on the third:

1. A laparoscopic device industry with a focus on profit, competition, health and safety. This is the current state of affairs. There is obviously a compromise on sustainability.

2. A laparoscopic device industry with a focus on sustainability and profit and competition. This would mean there needs to be compromised on health and safety, which is not something that I can consider an option from an ethics standpoint.

3. A laparoscopic device industry with a focus on sustainability and health and safety. This would mean there needs to be a compromise on profit and competition. Is this an option? How would that work? From the three scenario's, I consider this the most desirable future.

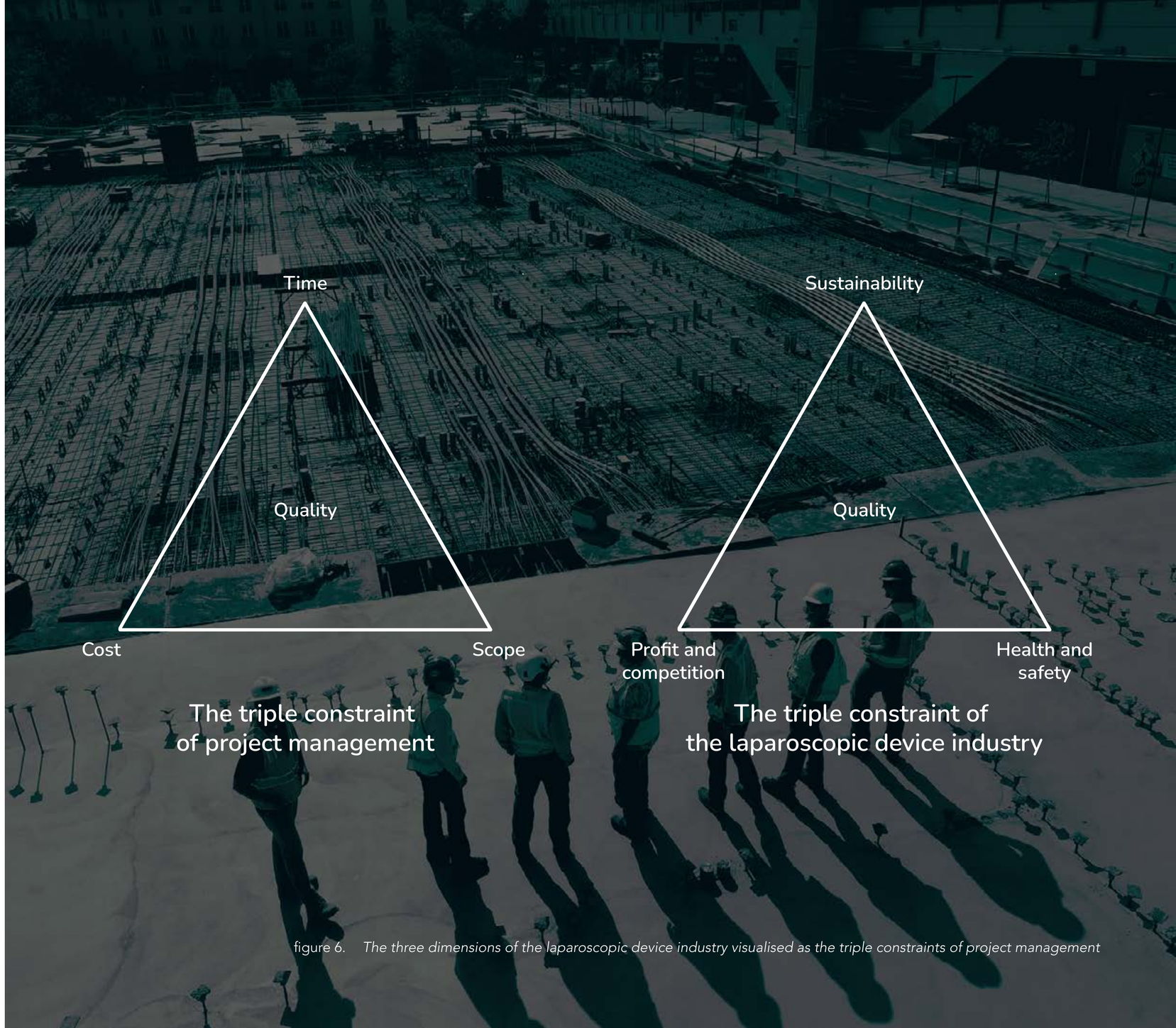
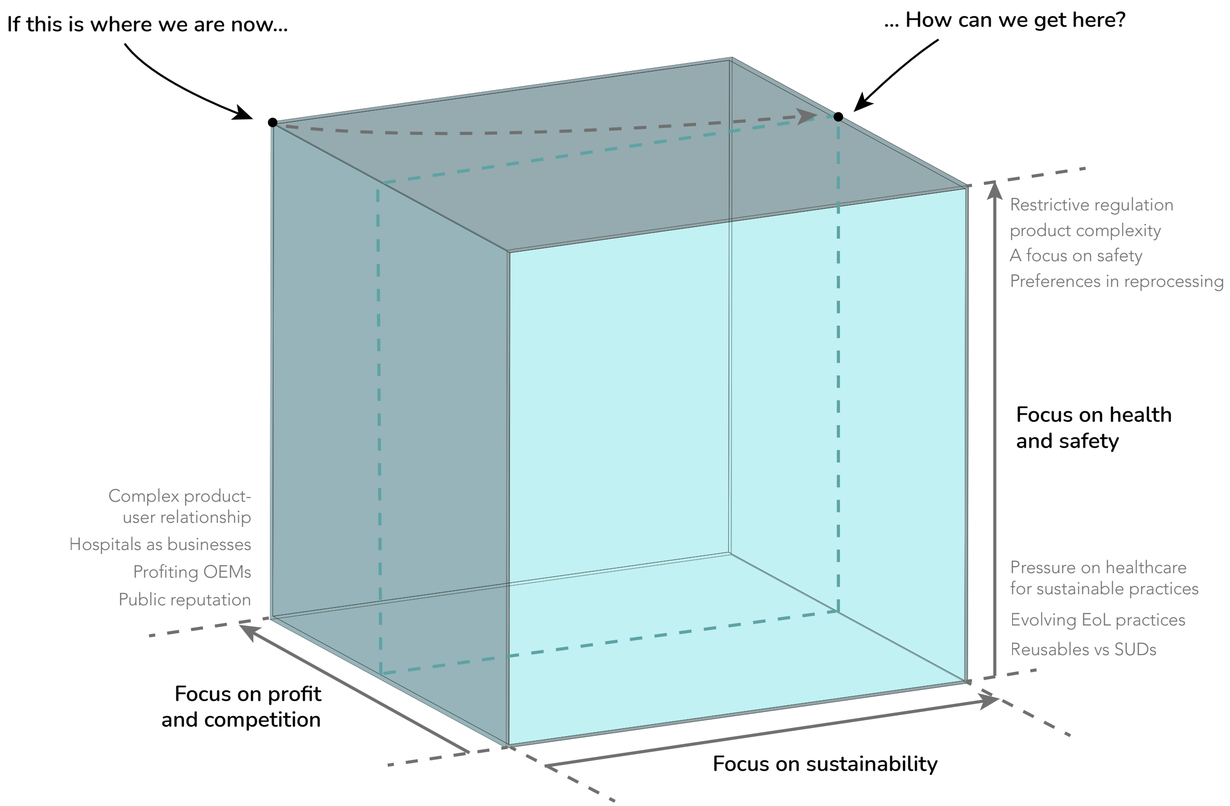


figure 6. *The three dimensions of the laparoscopic device industry visualised as the triple constraints of project management*

Discussion context iteration 1

Even though it is very useful to view the medical device industry in these three dimensions or constraints, I felt that the result of this iteration of context mapping was too close to the surface and too solution oriented. On top of that, the focus on health and safety is a fixed requirement while the focus on profit and competition and the focus on sustainability are more variable criteria. This means they do not have an equal weight, and should maybe be visualised differently.

Also, the focus on profit and competition could be a driver of change in itself. For example, if laparoscopic devices would be more expensive, they would be too costly to discard and OEMs would work intrinsically to find ways to recover them.



the 3D context of the laparoscopic device industry

figure 7. *A three dimensional visualisation of the context of the laparoscopic device industry with the dimensions as constraints*

7. Context construction iteration 2

Context clusters

For this iteration I decided to name the different clusters as if they are factors instead of just using key words. This would help me in preserving the directions that different factors point towards.

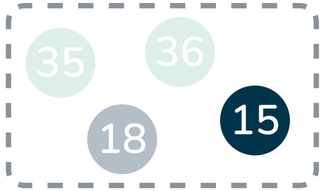
1. There is a complicated relationship between devices and their users

2. The use of SUDs is currently the standard.

3. The actions of medtech company are being watched closely

4. The current linear model of medical devices is costly for healthcare facilities

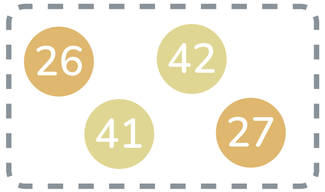
5. There is a lot of pressure on the healthcare sector to become more sustainable



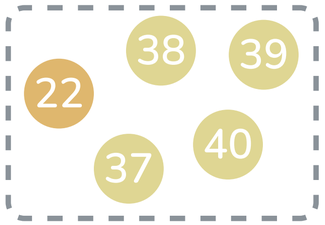
6. The medtech sector is highly competitive

7. Reusable devices seem to be more environmentally friendly than SUDs

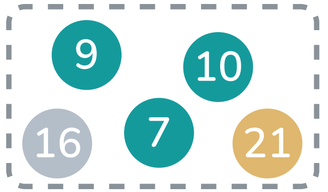
8. There is innovation in EoL technologies



9. Focus on functional improvements have made devices more complex and reuse more complicated

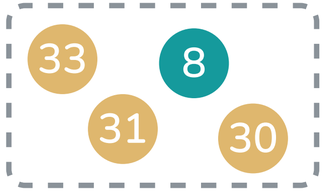


10. There is a safety first culture in healthcare



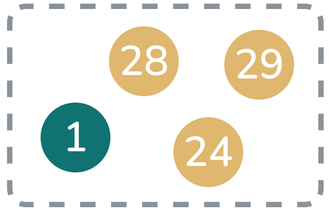
11. There are regulatory boundaries for the reuse of devices

12. Outsourcing reprocessing requires more time but allows hospitals to focus on their core business and is a good option for smaller facilities.



13. The healthcare sector has a high environmental impact

14. Hospital logistics are highly efficient and not easy to compromise on



Context mapping

From these new clusters I could see a matrix with two different axes on which the clusters could be mapped (figure 8). The matrix shows the meaning of sustainable solutions in the different possible futures of the MedTech industry. They are not meant to show the solution, but more so our attitude towards different solutions.

The axis of trust

One of the key concepts in this context is trust. There needs to be trust in the safety of the medical devices, that they are clean and that there can be no implications after use. This is trust between healthcare facilities and for example external reprocessors, but on a smaller scale the OR personnel needs to trust the safety of the individual devices that they use.

Another type of trust, or currently distrust, is that between different OEMs and between OEMs and 3rd party remanufacturers. They do not trust each other with the specifics of their products, and try to keep their secrets as best as possible.

Because these types of trust are so different, one is between different people and one is between people and objects, it made sense to me to try to map them both and look at the different matrices that would form.

The axis of change

One extreme on the axis of attitude towards change, is the feeling of the whole system being locked in. The other end represents the feeling of being open to change.

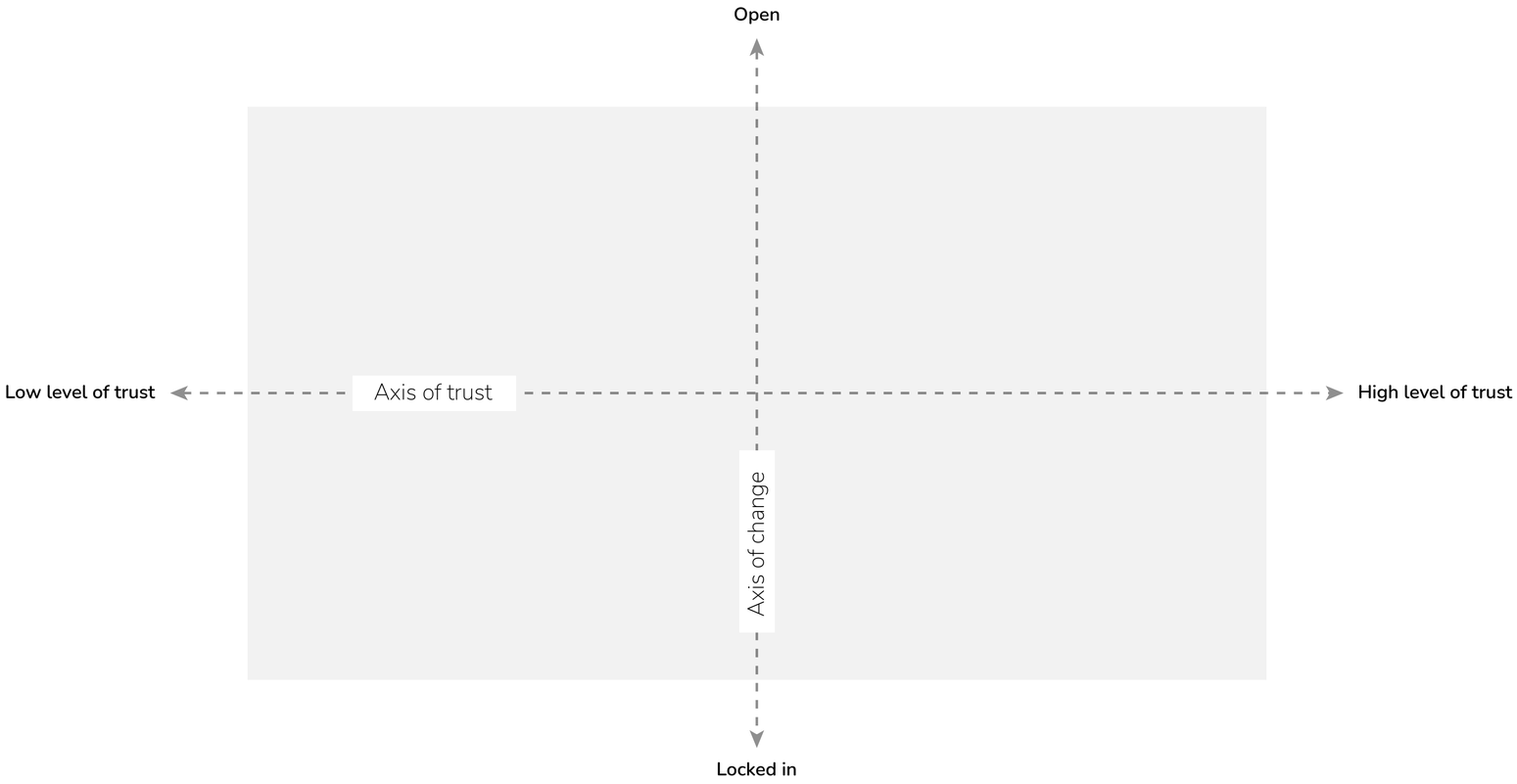


figure 8. *The empty context matrix*

Matrix 1 - trust between humans and objects

Here the axis of trust is more so an attitude towards safety. Currently the industry has a very low level of trust in devices, which is why the use of SUDs could grow so much. The industry also feels locked-in and not open to change. This means that currently there is only space for incremental design changes like changing a material to lower the environmental impact of a device just slightly, while still maintaining a linear perspective.

I think we need to move to a system based on trust that is open to change. This version of the future will be a big systemic change and still needs to be designed, but it will allow the healthcare industry to become less rigid and more open to the necessary sustainable solutions of the future. Questions we can then ask are: "Does the whole device really need to be that clean, or just parts of it?" and "How clean is clean enough?".

I do not think we can move from our current mentality directly to systemic change. We need to first develop trust in devices and systems before we can become open to change.

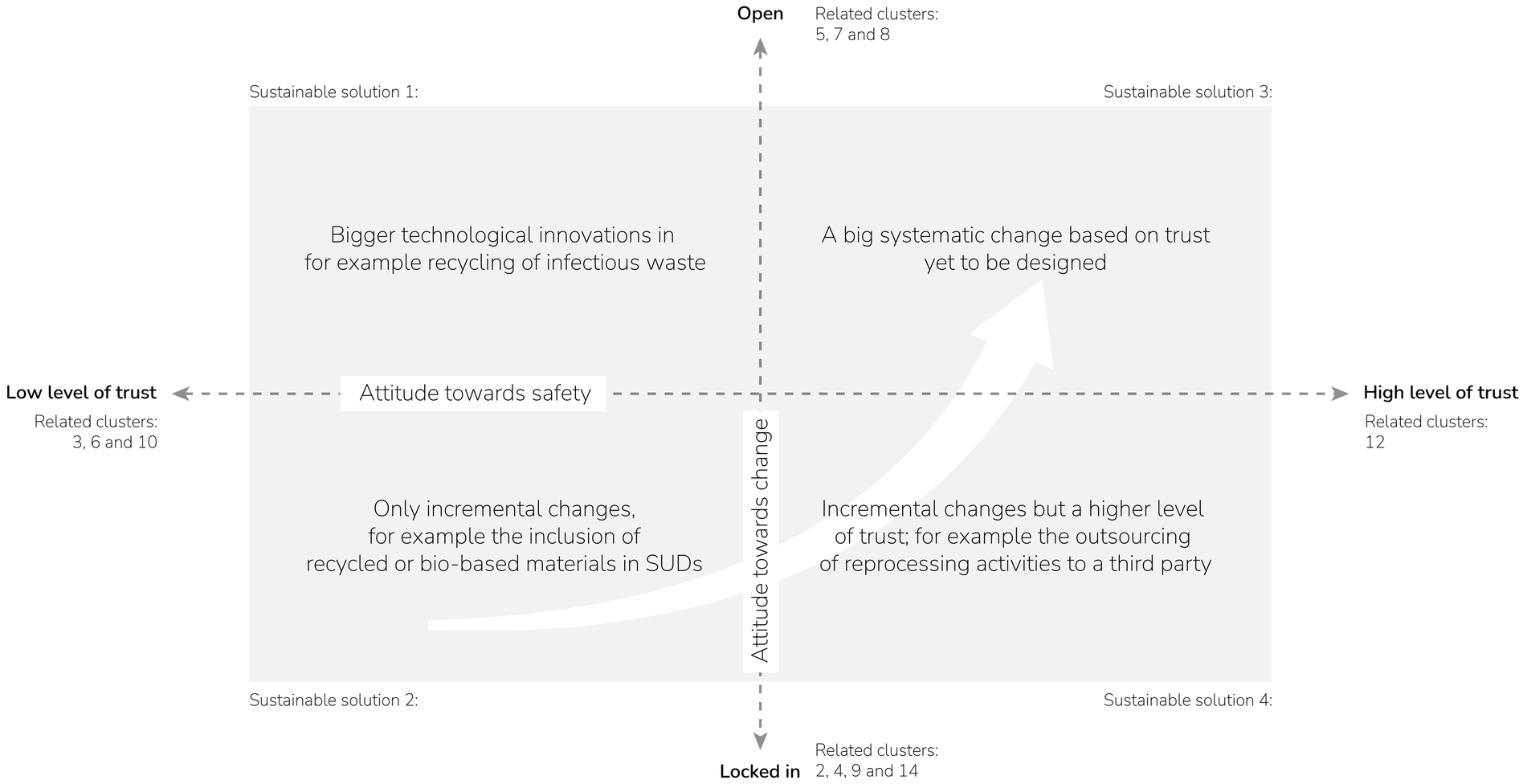


figure 9. *The context matrix of trust between humans and objects*

Matrix 2 - trust between humans

In this matrix the axis of trust is that of trust between people, or more specifically between companies. Currently there is very little trust between companies. Because of the high level of competition within the industry companies guard their secrets carefully and are not eager to share. Sometimes there are collaborations between companies but examples are scarce.

I think we need to move to a system where collaboration is the standard. This is hard to realise all at once so policymakers can help by changing regulations in a way that pushes companies in the right direction.

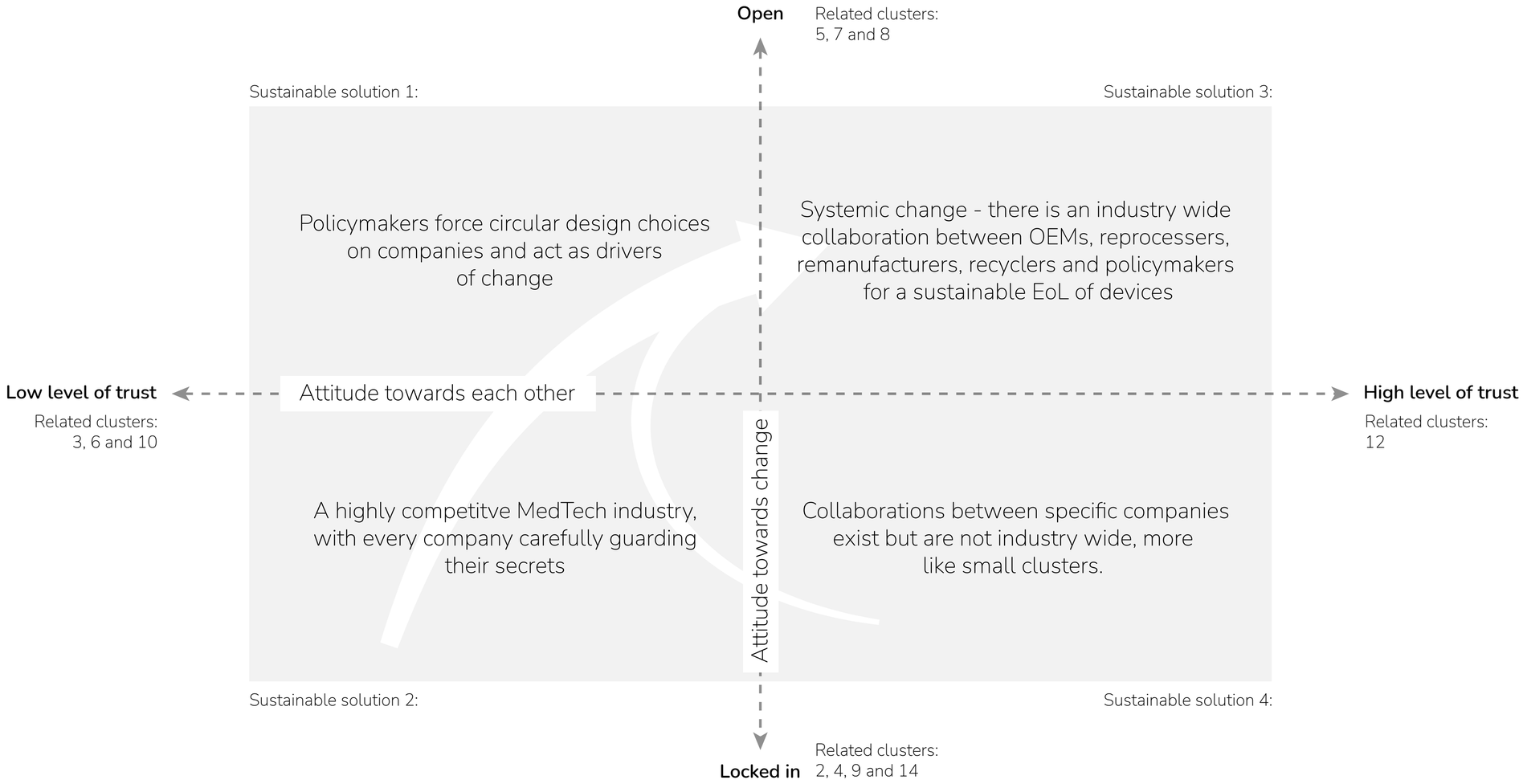


figure 10. *The context matrix of trust between humans*

8. Statement definition

The desired future scenarios from both matrices are a result of me taking a moral position. This position, or my own response to the context, is described in a statement. A statement is context based, and needs to show a new opportunity and the direction in which the design process is going without defining what the product is or does. In this case the statement should fit future scenarios of both matrices;

1. A big systematic change based on trust yet to be designed

2. Systemic change - there is an industry wide collaboration between OEMs, reprocessers, remanufacturers, recyclers and policymakers for a sustainable EoL of devices

My statement:

“I want to reshape the MedTech industry into a system based on trust and collaboration.”

9. Designing interaction

Now that the desired future context is defined, it is time to explore what kind of relationship or interaction fits with this context. For this step in the VIP process, you can simply trust your intuition. Another strategy is trying to come up with an analogous situation in another domain, this can help to see the appropriate interaction from a fresh perspective.
I am looking for an interaction between healthcare staff or facilities and an unspecified service model that laparoscopic devices are a part of. These are some of the possible interaction qualities:

- Trusting
- Transparent
- Easy
- Cooperative
- Preserving
- Careful
- Efficient
- Deliberate
- Accessible
- Systematic

I think the relationship between healthcare facilities and the envisioned service should be like our relationship with Dutch tap water. We blindly trust that there will always be enough for everyone and that it is safe to drink. Behind the scenes there are a lot of parties collaborating to make sure it stays this way, the water is carefully cleaned and tested and the process is entirely transparent.

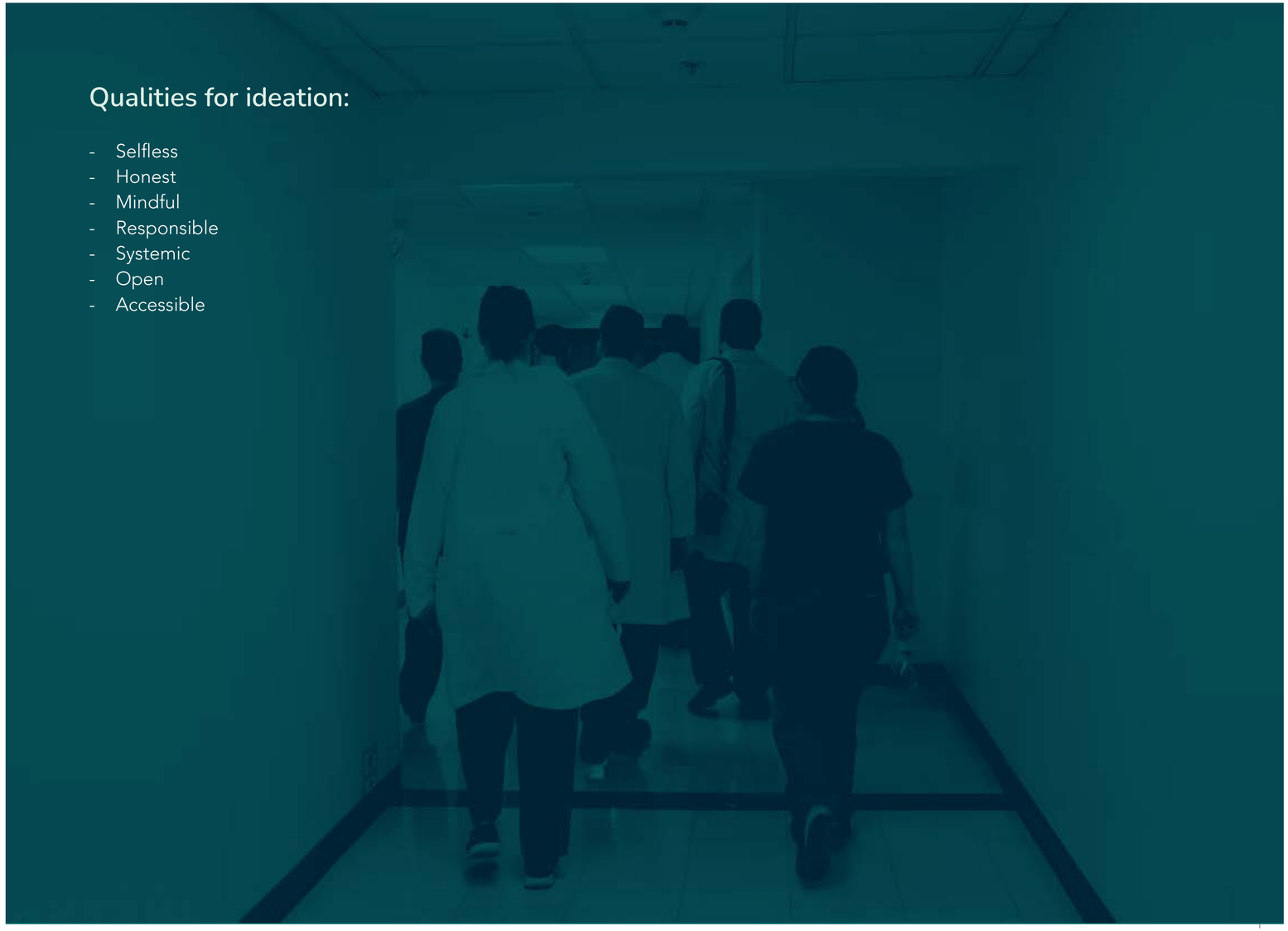
10. Defining product/service qualities

The last step of the VIP process is the translation from interaction to product, or in this case service, qualities. A product character metaphorically describes the “personality” of a product, but you can also think of what kind of actions a product calls for. Who should interact with the product and how? Some of the interaction characteristics can be used as product characteristics as well.

There are a few clusters of interaction qualities:
- **Collaborative** (Trusting, cooperative)
- **Trustworthy** (Trusting, careful, transparent)
- **Mindful** (Preserving, careful, deliberate)
- **Competent** (Efficient, deliberate, systematic)
- **Open** (Transparent, accessible, easy)

These clusters translate to the following product/service qualities
- Collaborative: Helpful, Loyal, Selfless
- Trustworthy: Genuine, Benevolent, Considerate, Dependable, Dutiful, Ethical, Honest, Reliable, Stable, transparent, good
- Mindful: Gentle, Caring, Cautious
- Competent: Articulate, Capable, Disciplined, Focused, Methodical, Responsible, thorough, systemic
- Open: Available, accessible, straightforward, uncomplicated, easy

My future context, interaction qualities and product/service qualities together formulate my vision for the laparoscopic device industry. This vision is the foundation for later design stages.



11. References

Hekkert, P., & van Dijk, M. (2011). Vision in Design: A guidebook for Innovators. BIS Publishers.

Microsoft support. (n.d.). The project triangle. Retrieved November 13, 2022, from https://support.microsoft.com/en-us/office/the-project-triangle-8c892e06-d761-4d40-8e1f-17b33fdcf810

How to ...

make the medical device industry open to change?

- Re-evaluate regulations
  - what are the barriers?
  - Challenge current barriers
    - proof when something is clear enough
    - show problems with current practices
    - show opportunities instead of barriers
      - give great examples
        - case studies + cost + LCA comparisons.
    - show a long term vision
    - using harmful ~~ways~~ method to sterilise products way more than necessary kills too!
- change on a bigger scale
  - drivers of change — challenge current regime
    - tackle problem from multi-level perspective
      - destabilize current regime
      - momentum of niches
      - landscape developments
  - niches — reusables
    - new sterilisation options
    - modulars
  - regime — ultra clean
    - safety first
    -
  - landscape influences
    - sustainability push
    - waste + resource problems
    - growing pressure on healthcare

How to...

Increase trust between OEMs?

and OEMs and third parties?

Use ~~rules on~~ regulation
- make OEMs share spare parts for EoL
- make OEMs take part in central EoL service
  - By EU?
    - subsidise or own? are there examples?
- make them share products specifications

Facilitate ~~speed~~ meetings & conferences
- make it personal

facilitate international contaminated device transport.

fee for labelling devices as single use?

SUP & reusable approval take same time + money

product design rules
- disassembly rules
  - for recycling
  - for cleaning.

transparency in pricing
- more natural competition
  - patients & doctors don't pick devices

is competition bad? why?

~~speed up~~

How to?...

have policymakers facilitate a high-trust med-tech industry?

How to...

Design for trust in the safety of devices?

STERILE

Have a control system in place + tracking

Scientific proof
- physical proof on the product of sterility — marker?
- physical proof on the product of max cycles — or just track+trace

good relationship between the people who clean and the people who use. — personal relationship?

consistancy

transport?

cleaning?
- What are exactly the parts of the process that people do not trust?
  - handling before surgery?
  - Sterilisation?

make the product look ~~durable~~
make the product look dependable
~~realize~~ avoid cavities → people will assume they can still be more dirty

Make the service as simple and transparent as possible → easy to understand = easy to trust.

How to...

design a transparent interaction?

be honest
- explain everything — know everything
- explain in simple terms
- be consistent
  - speed
  - quality
  - cost

Be personal
- tailor service to hospital
- standard contact person
- make it easy to start implementing the service

Be quick to reply to questions
- give a real time status report/ overview

Be specific
- what happens
- to which product
- how?
- when?

How to...

design a cooperative interaction?

make the benefits for all parties clear.

Be open for input

Let OEMs be a part of the design process

make the interface easy to use

minimise the change in workflow for hospitals

How to...

design an accessible interaction

How to...

design a selfless EoL service

non-profit – what does it take to be a non-profit organisation?

are waste management companies non-profit?

this should also be about OEMs

How to...

design an honest EoL service

what exactly do they need to be honest about?

do OEMs get part of the profit?

pricing?

do they resell devices?

how does it work icw new devices?

current distribution centers.?
how do orders work now?

Benefits for joining
- Liability sorted

any OEM can and should easily join

any hospital can and should easily join

Liability must be clear and traceable

full insight into its chain

Benefits of joining
- sustainable EoL for all devices
- less expensive waste

do they pay to get rid of devices?
or do they receive money for returning them?

How to...

design an open EoL service

How to...

design a responsible EoL service

Appendix 4.1.

Storyboard of the current situation (SUD)

TU Delft

ETHICON
a Johnson & Johnson company

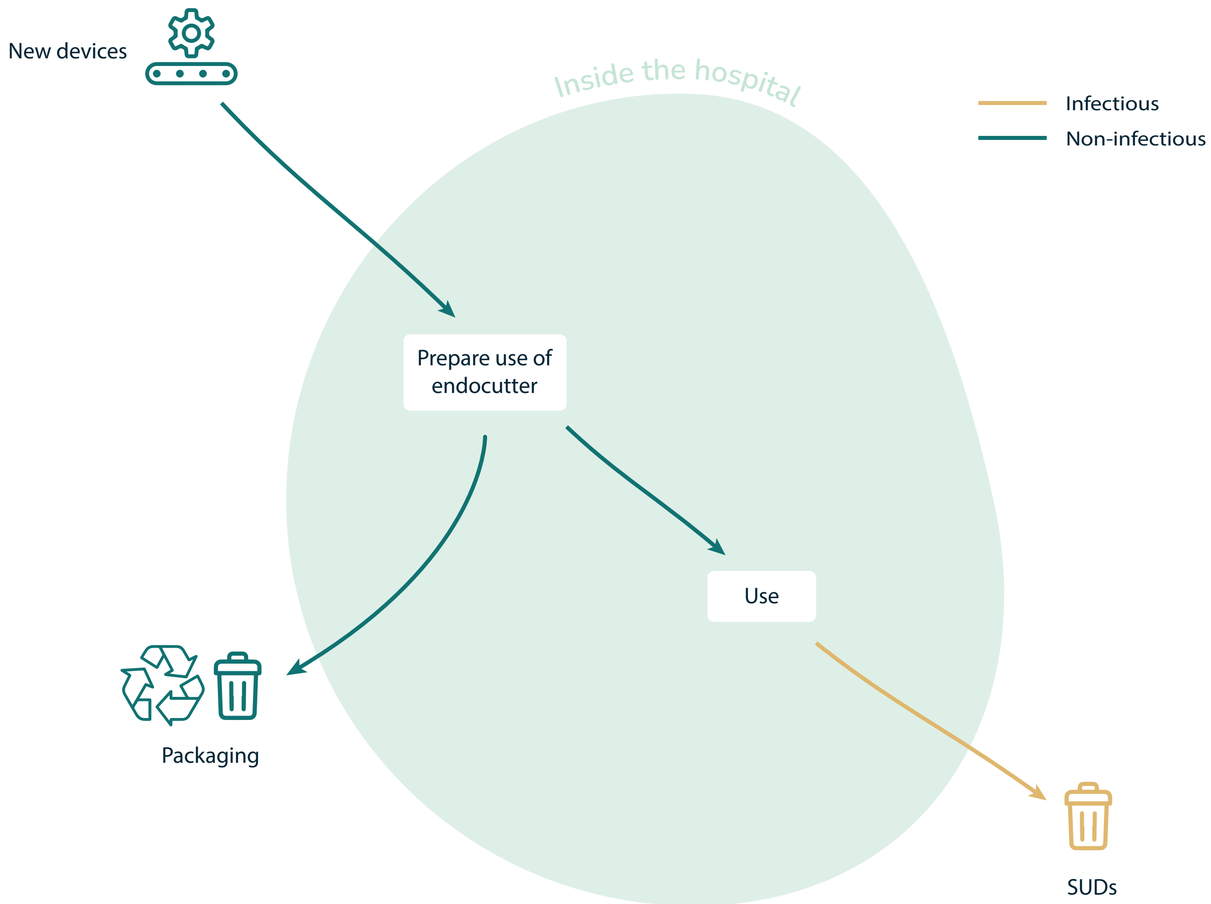
Faculty Industrial Design Engineering, Delft University of Technology,
the Netherlands

Dorien van Dolderen
4541294

Chair: Conny Bakker

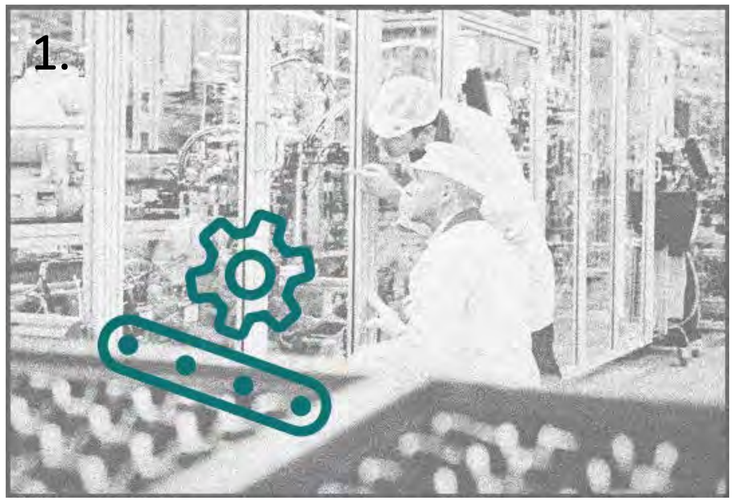
Mentor: Jan-Carel Diehl

Overview visual



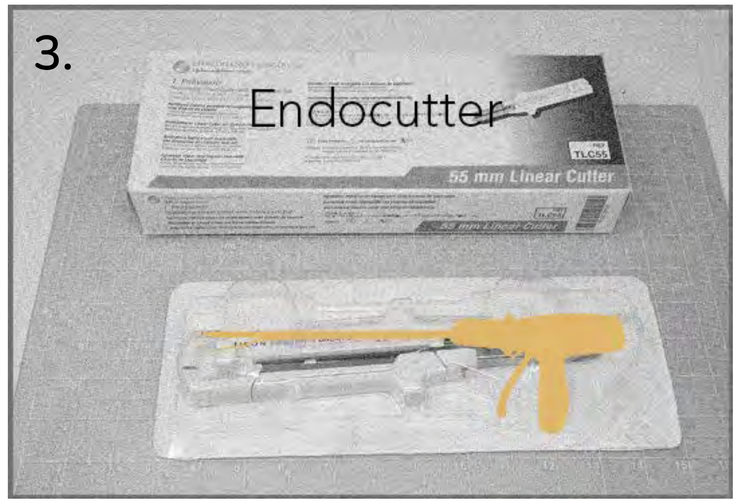
1. Device supply

Production



Sterilisation

Packaging



Distribution

Transportation

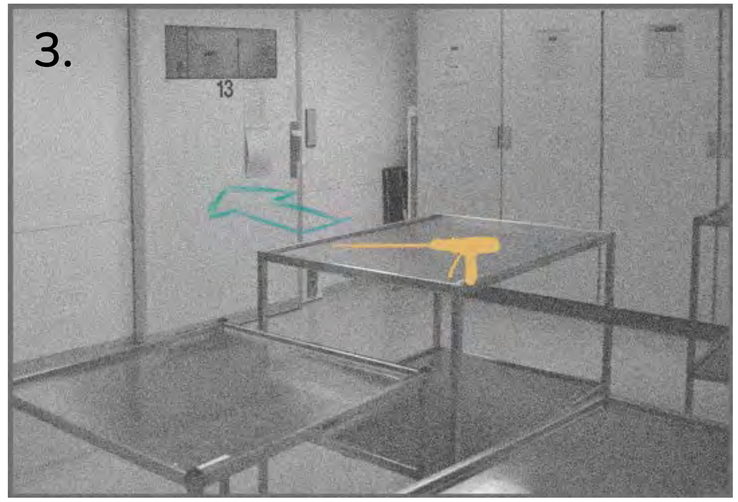
Hospital stock

2. Device use

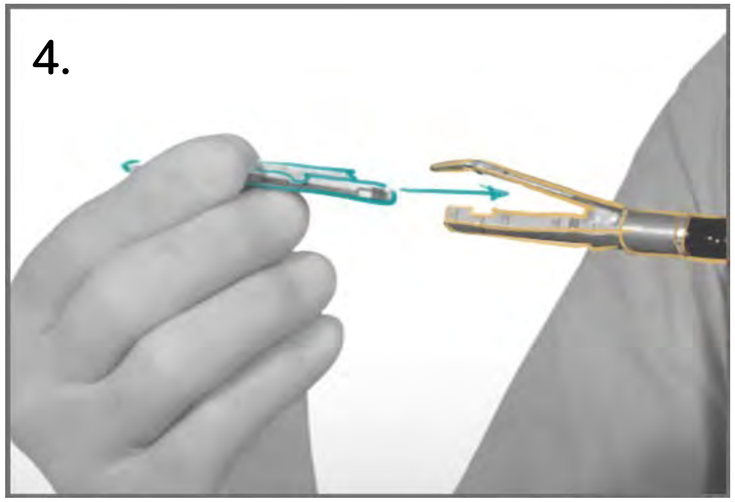
transport to preparation room

Unpack in preparation room

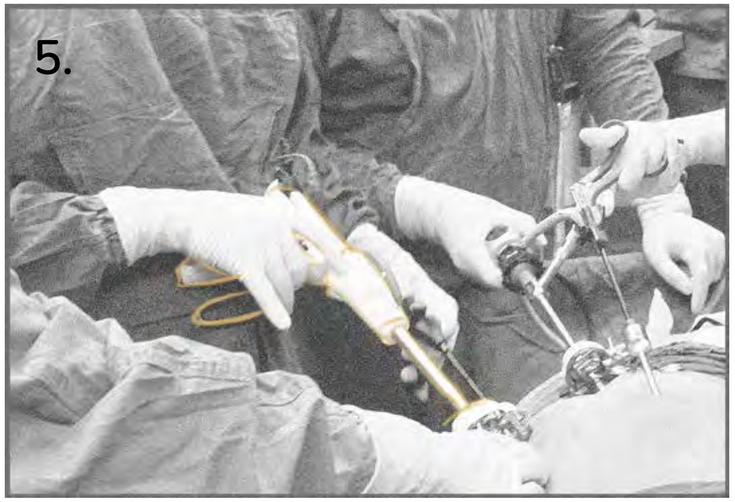
The device is placed on the surgery cart which is driven into the OR.



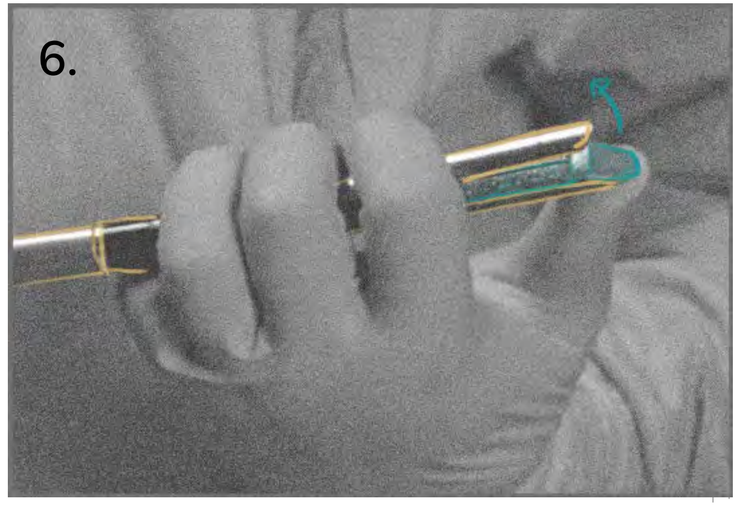
The assistant prepares the device for use (places a reload)



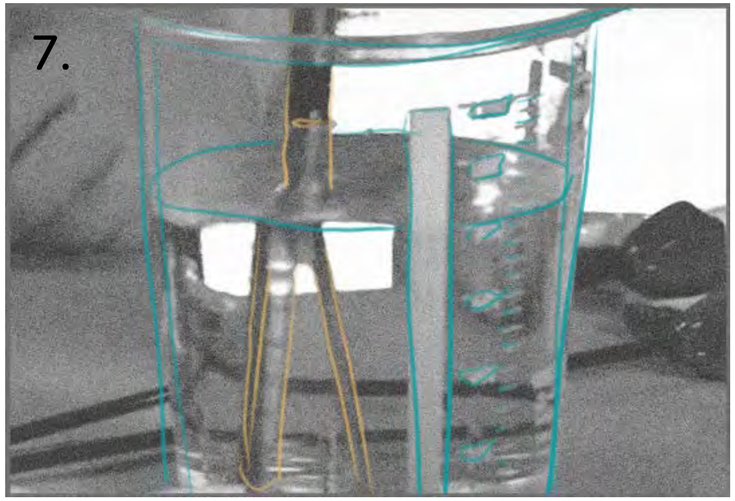
The surgeon uses the device



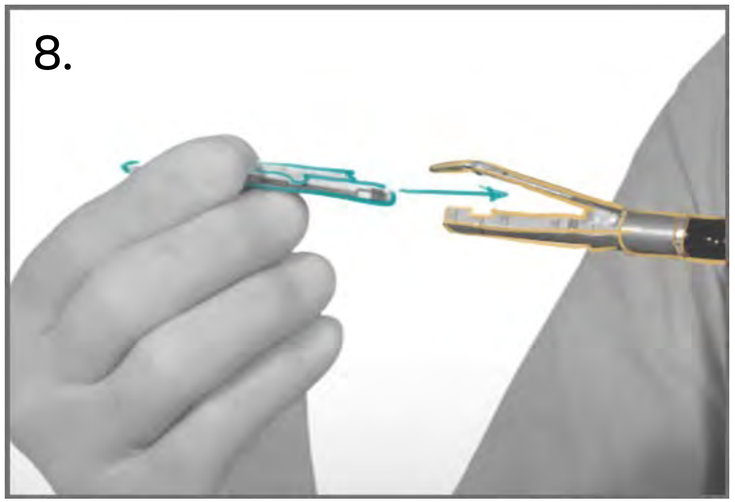
Assistant takes reload out and places it in contaminated waste bin



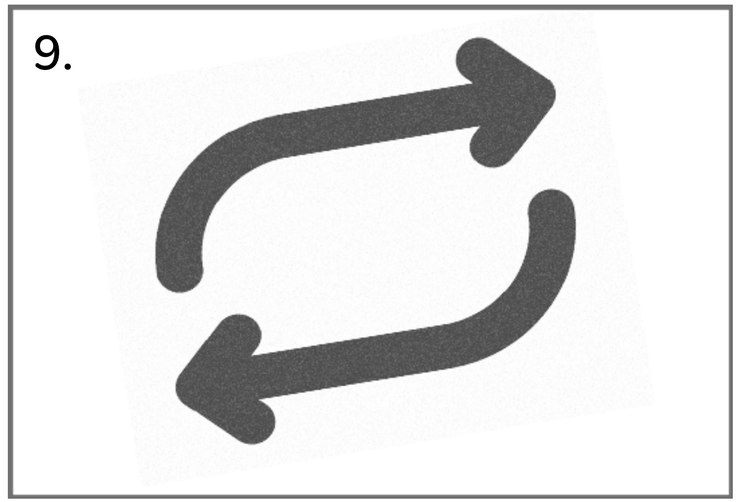
Assistant cleans the device (mild disinfectant)



Assistant reloads device

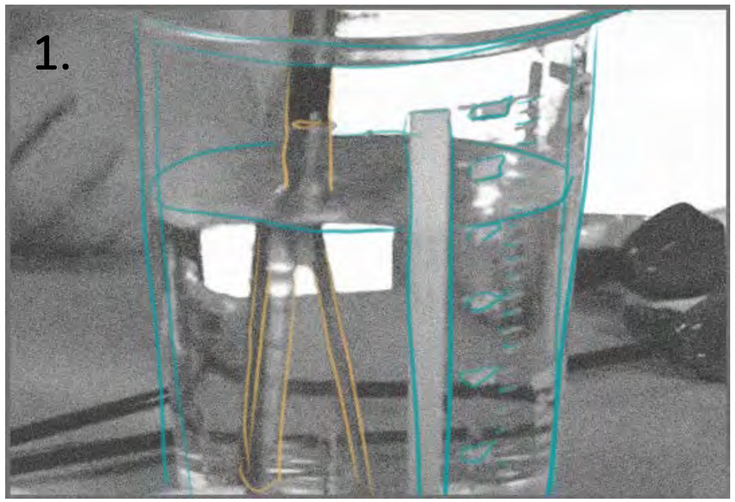


repeat steps 6 - 9 depending on number of necessary fires.

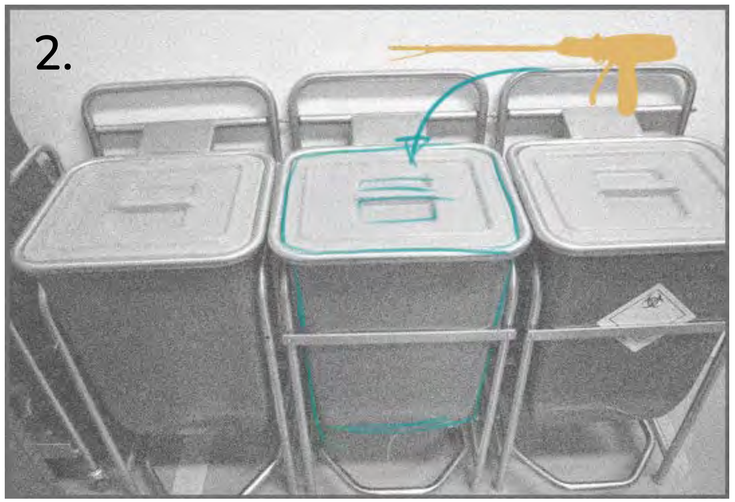


3. Waste

Assistant cleans the device with mild disinfectant after use



Assistant places device into contaminated waste bin

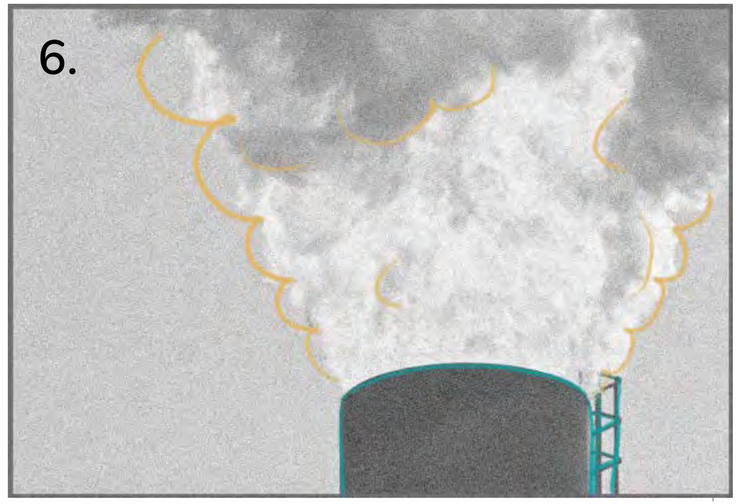


After surgery the waste bin is sealed

waste bin is transported to waste management area inside the hospital

When a container is filled with contaminated waste bins, it is transported to Zavin (Dutch contaminated waste processor)

At Zavin the sealed boxes are incinerated, energy is recovered.



Main benefits

- Easy for hospitals
- Continuous income for OEMs

Main drawbacks

- High environmental impact and very wasteful
- Over the longer term very expensive

Appendix 4.2

Storyboard of the current situation (internal reprocessing)

TU Delft

ETHICON
a Johnson & Johnson company

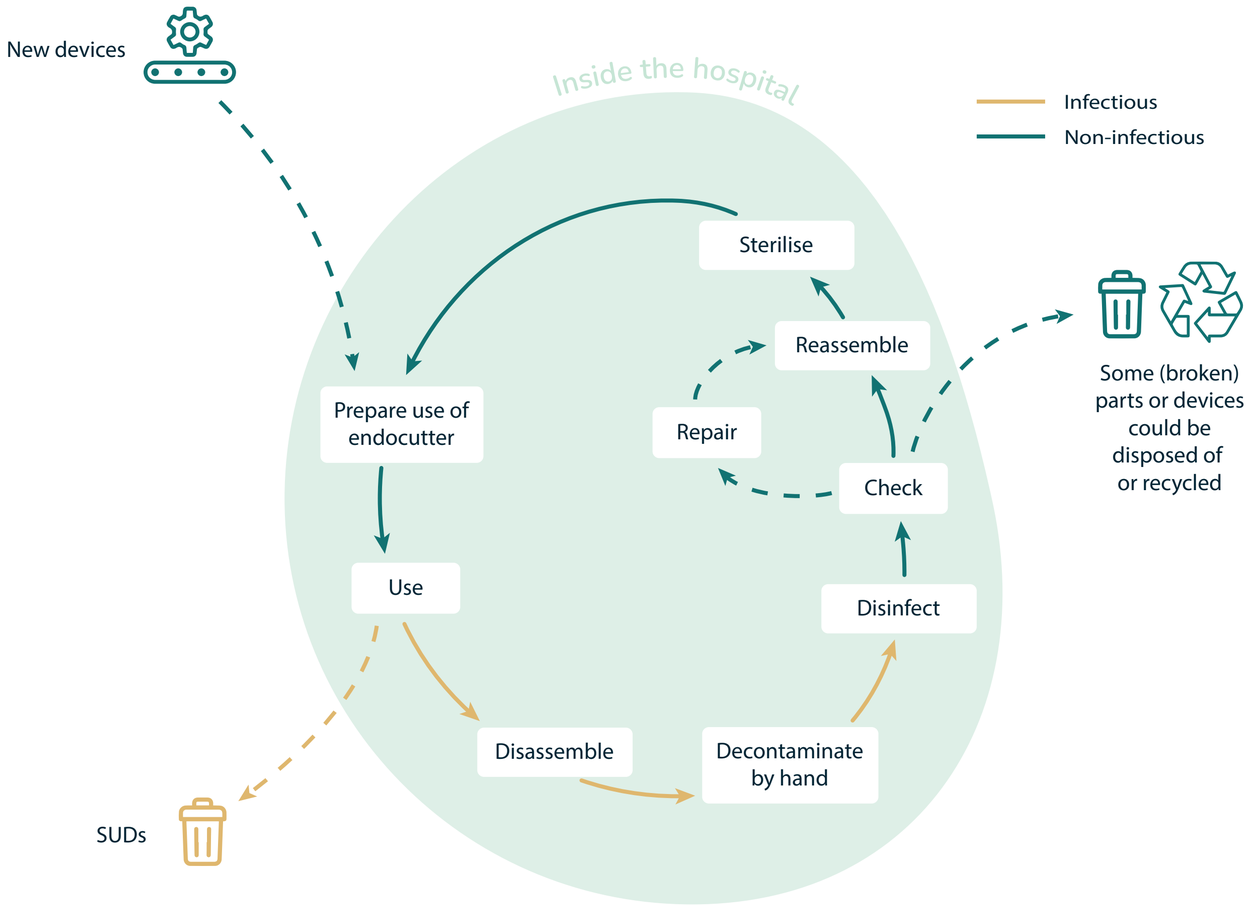
Faculty Industrial Design Engineering, Delft University of Technology,
the Netherlands

Dorien van Dolderen
4541294

Chair: Conny Bakker

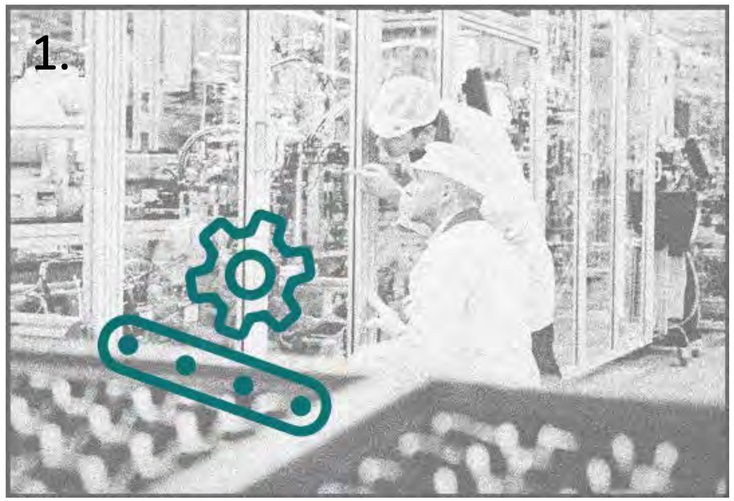
Mentor: Jan-Carel Diehl

Overview visual



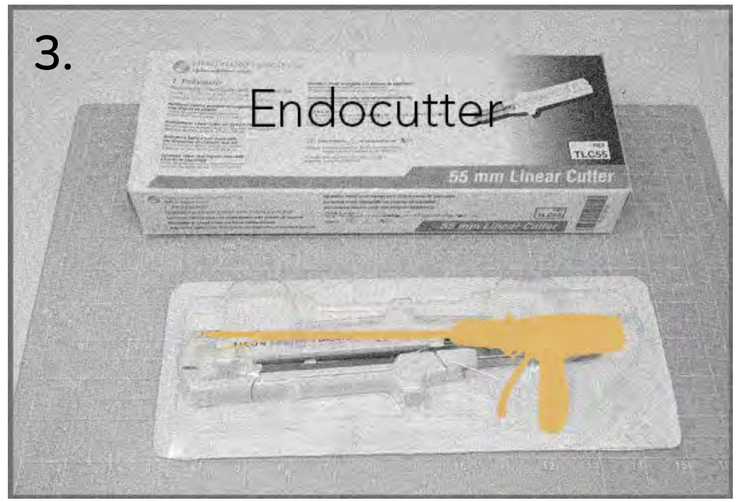
1. Device supply

Production



Sterilisation

Packaging



Distribution

Transportation

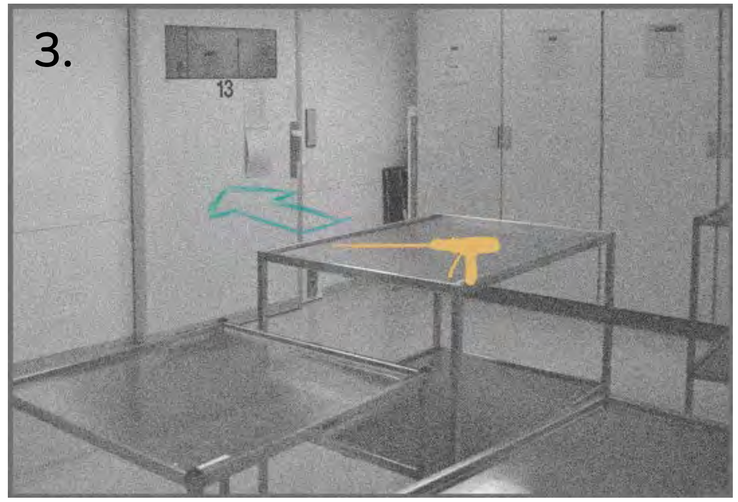
Hospital stock

2. Device use

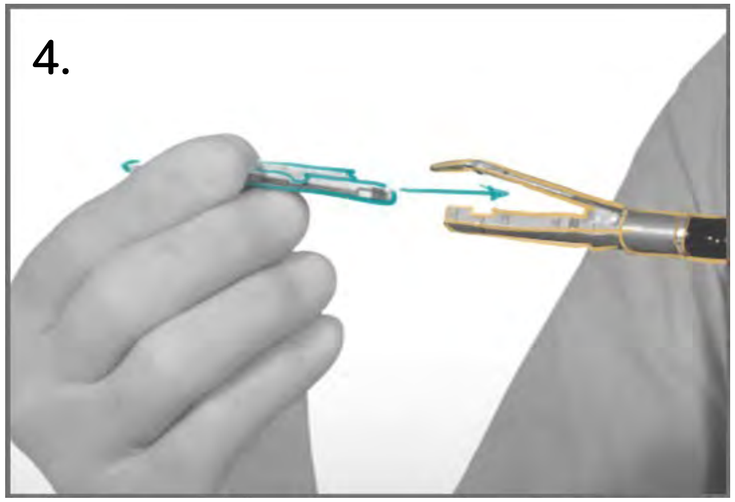
transport to preparation room

Unpack in preparation room

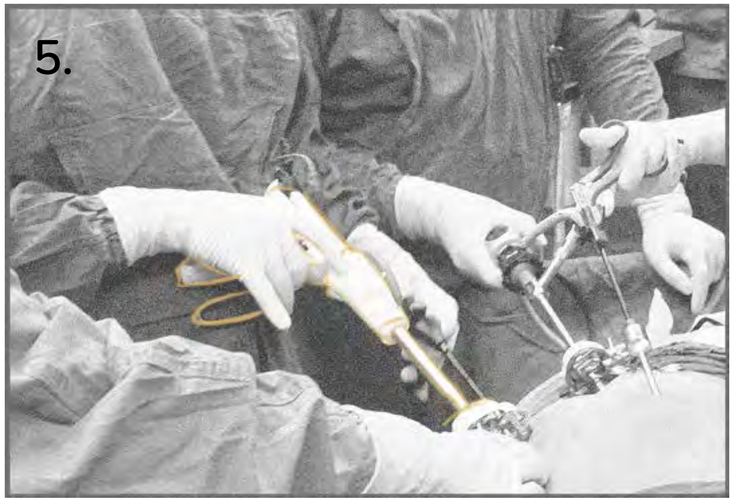
The device is placed on the surgery cart which is driven into the OR.



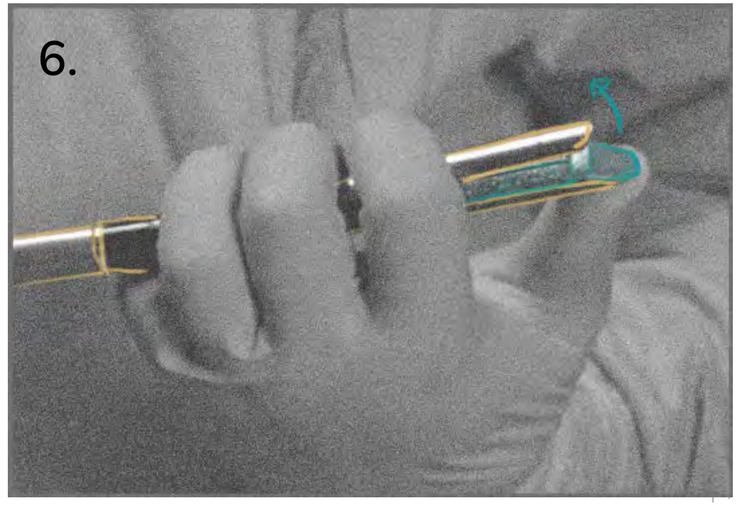
The assistant prepares the device for use (places a reload)



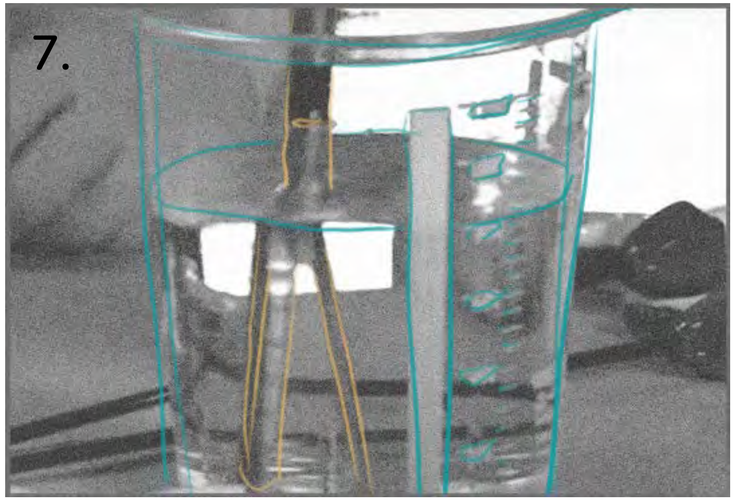
The surgeon uses the device



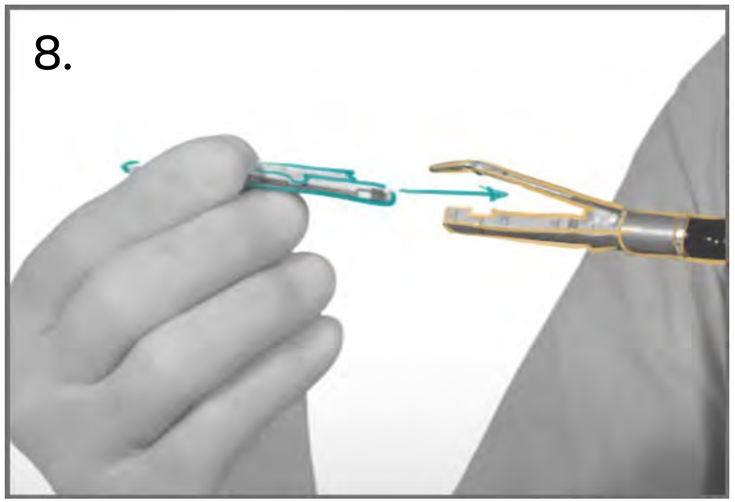
Assistant takes reload out and places it in contaminated waste bin



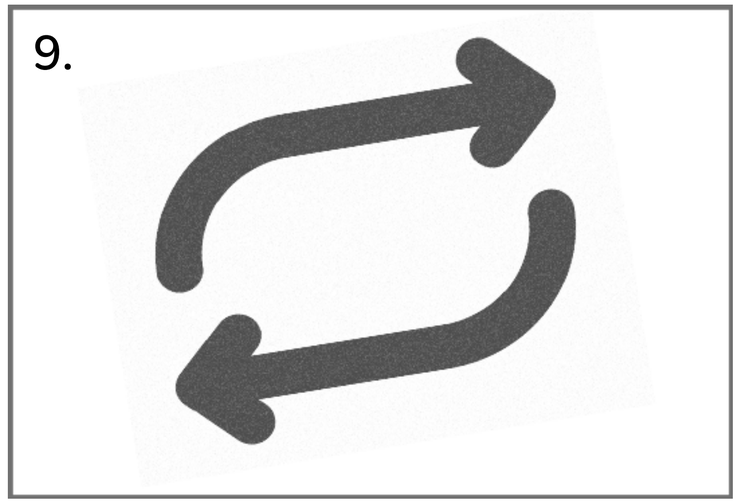
Assistant cleans the device (mild disinfectant)



Assistant reloads device

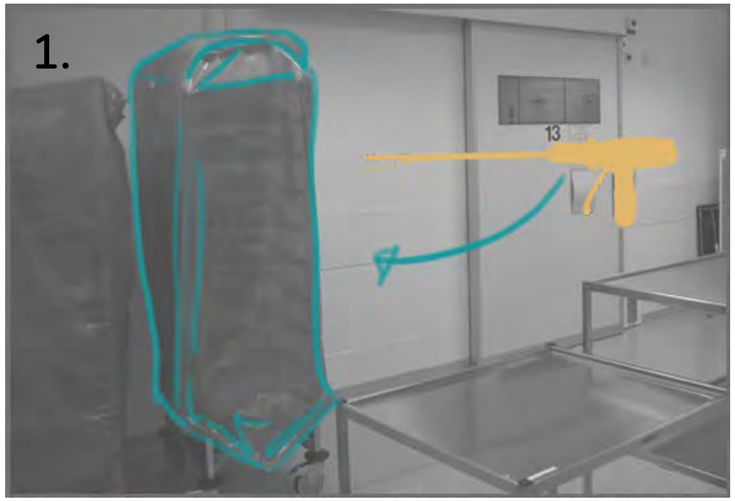


repeat steps 6 - 9 depending on number of necessary fires.

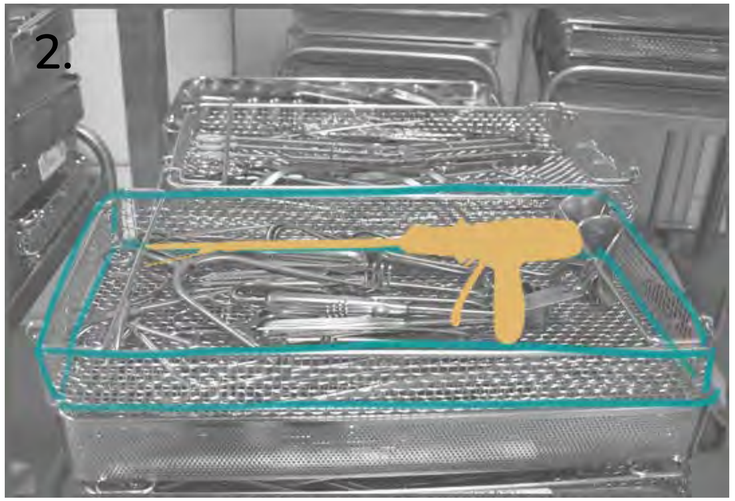


3. Reprocessing

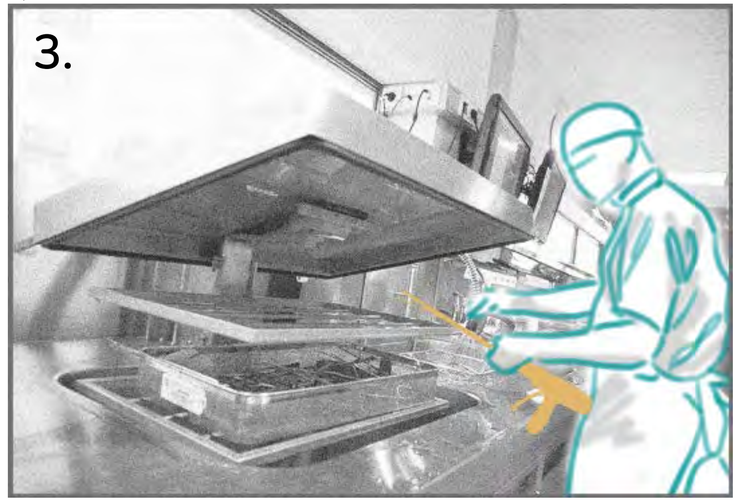
All reusable devices are collected for reprocessing



nets are moved to a dedicated contaminated room



Inside the contaminated room devices are disassembled and disinfected by hand

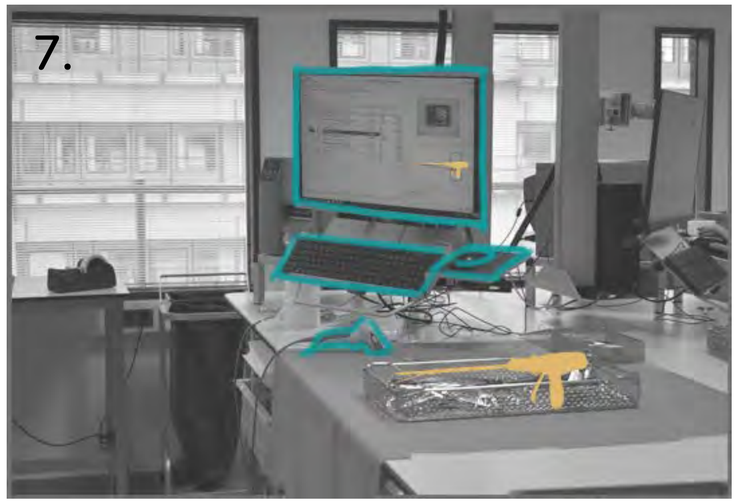


Devices are put into a washing machine for disinfection

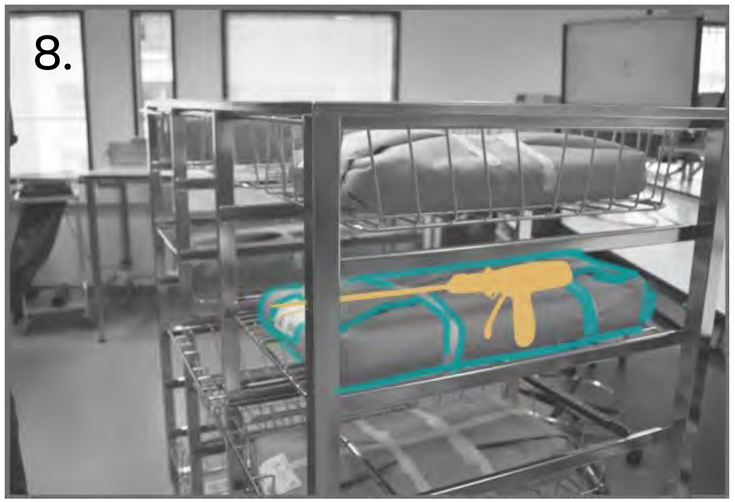
Disinfected devices and their parts are thoroughly checked.

devices with repairable faults are set aside for repair

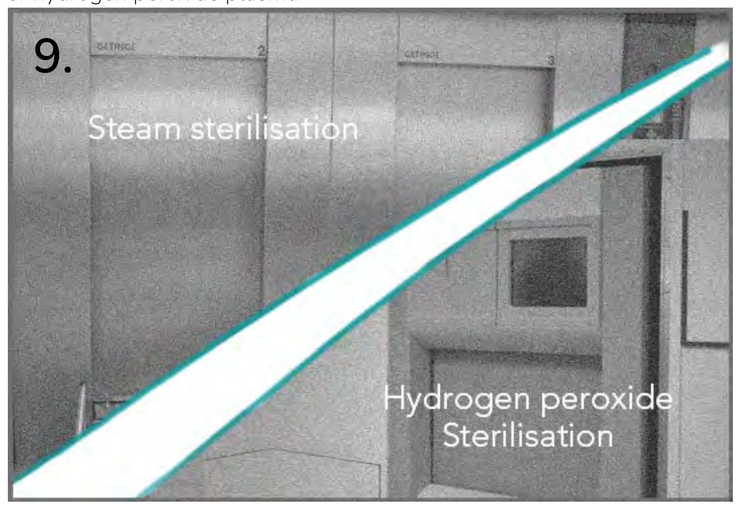
The devices are reassembled, scanned and sorted



The nets with devices are packaged in blue PP wrap and put into carts for sterilisation



Depending on the device, the device is sterilised through the use of steam or hydrogen peroxide plasma.



Sterilised nets are sorted and stored, ready for the next surgery

Main benefits

- No transportation, saves time
- (Probably) cheaper compared to external reprocessing for the larger hospitals
- More control over device safety compared to external reprocessing

Main drawbacks

- Extra work for hospitals
- Only possible for larger healthcare facilities
- No facilities for more drastic repairs or remanufacture
- Little return for OEMs for their circular design initiatives

Appendix 4.3.

Concept storyboard

TU Delft

ETHICON
a Johnson & Johnson company

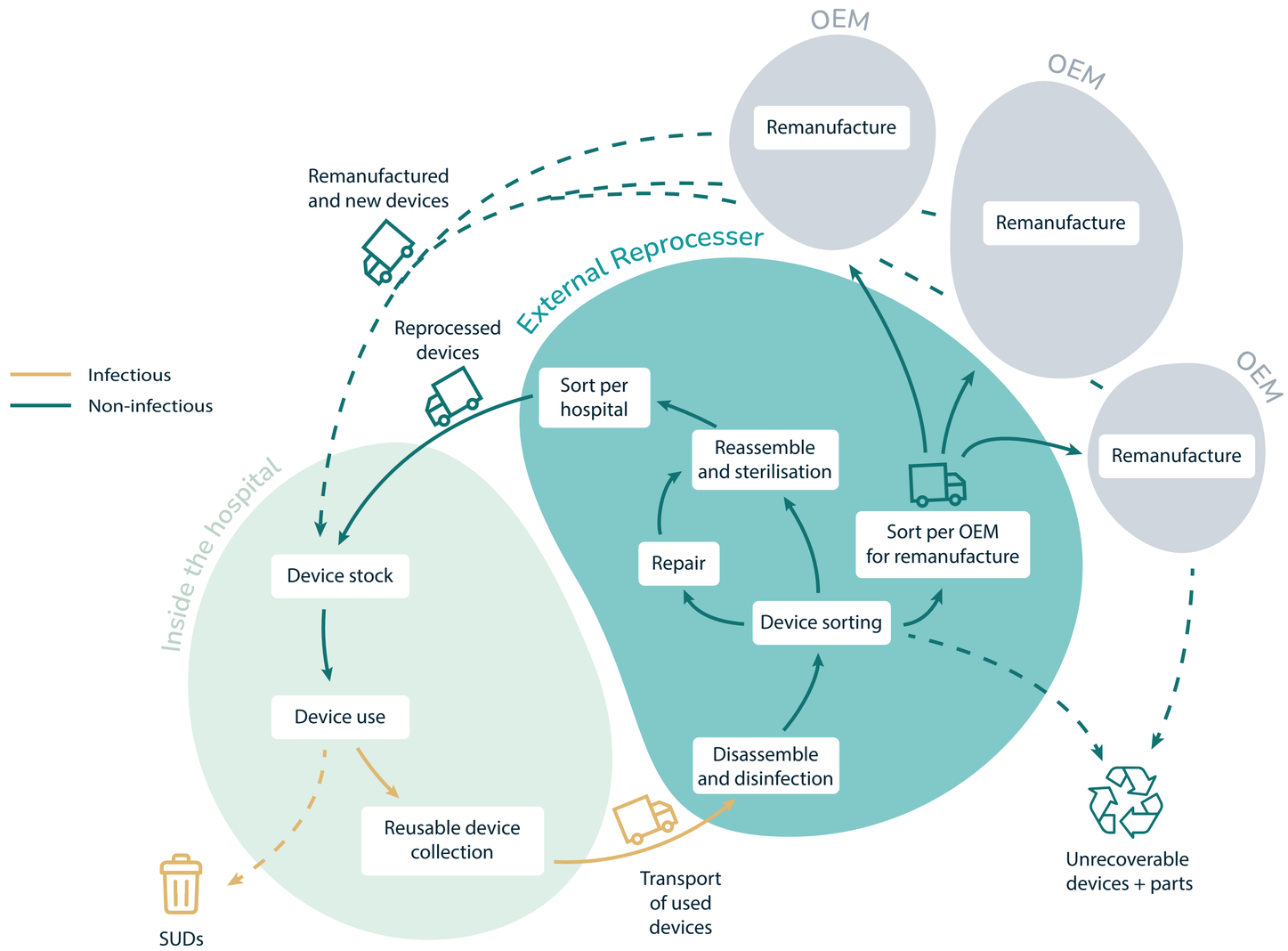
Faculty Industrial Design Engineering, Delft University of Technology,
the Netherlands

Dorien van Dolderen
4541294

Chair: Conny Bakker

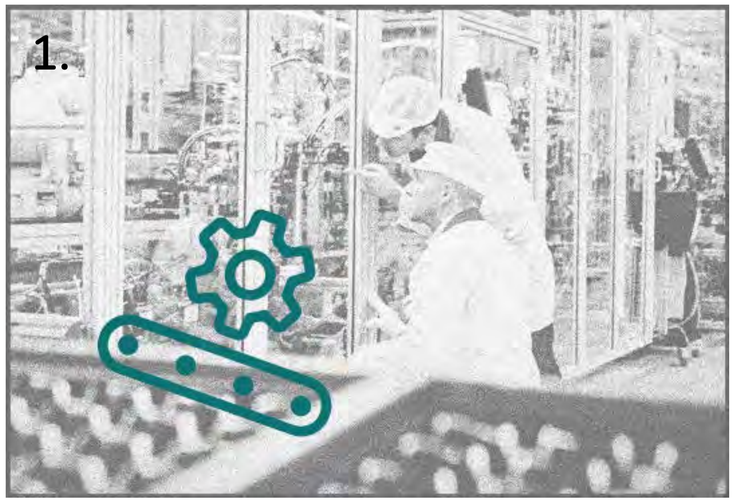
Mentor: Jan-Carel Diehl

Overview visual



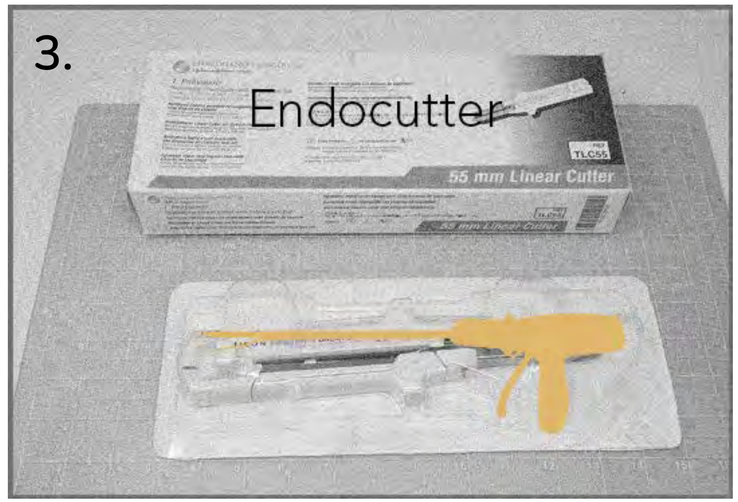
1. New device supply

Production at OEM



Sterilisation

Packaging



Distribution

Transportation

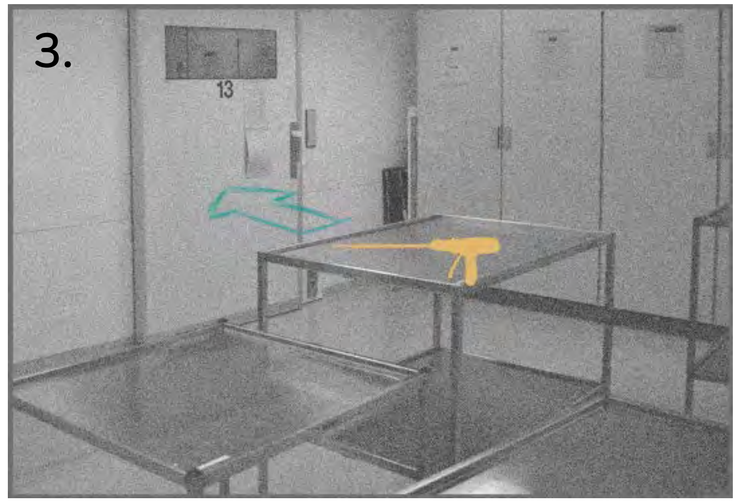
Hospital stock

2. Device use

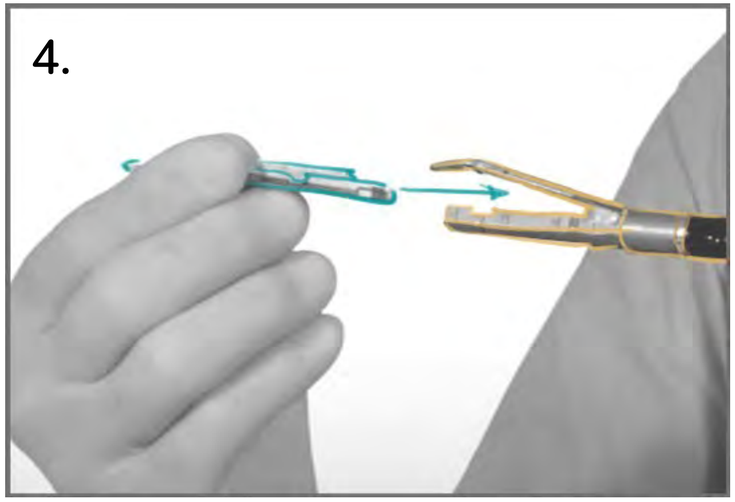
transport to preparation room

Unpack in preparation room

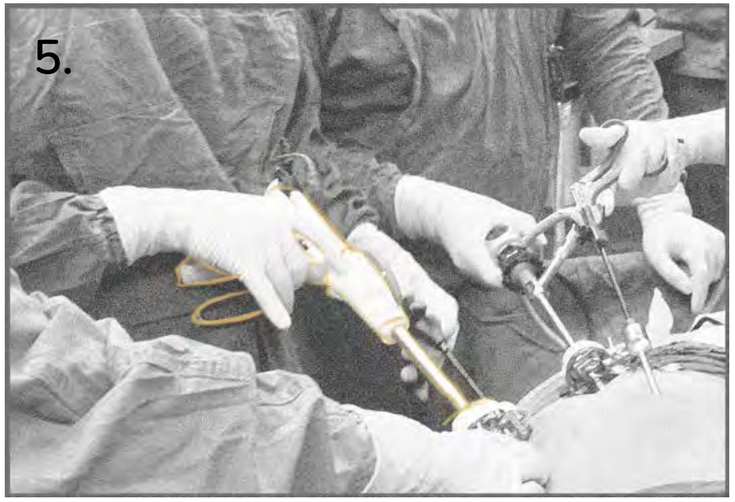
The device is placed on the surgery cart which is driven into the OR.



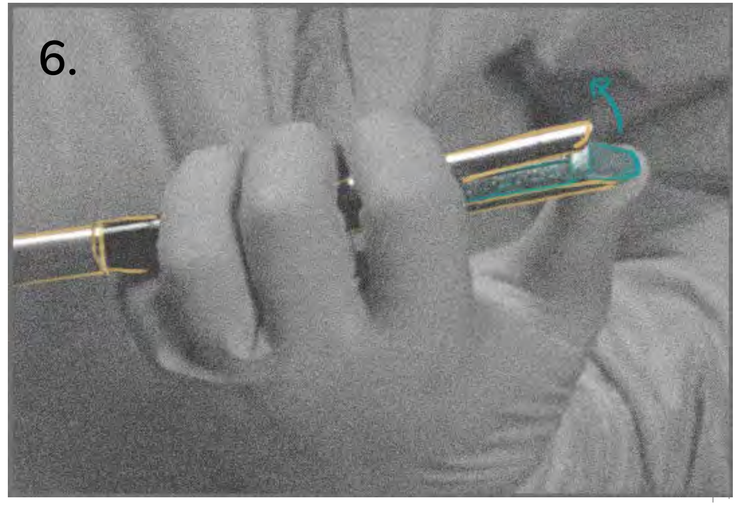
The assistant prepares the device for use (places a reload)



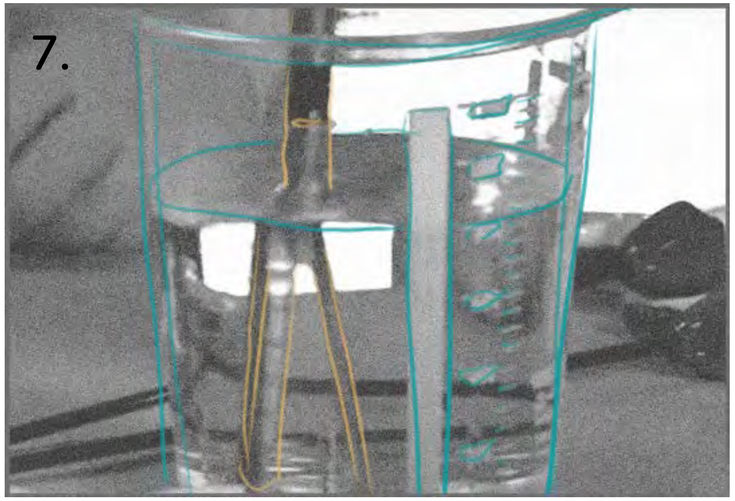
The surgeon uses the device



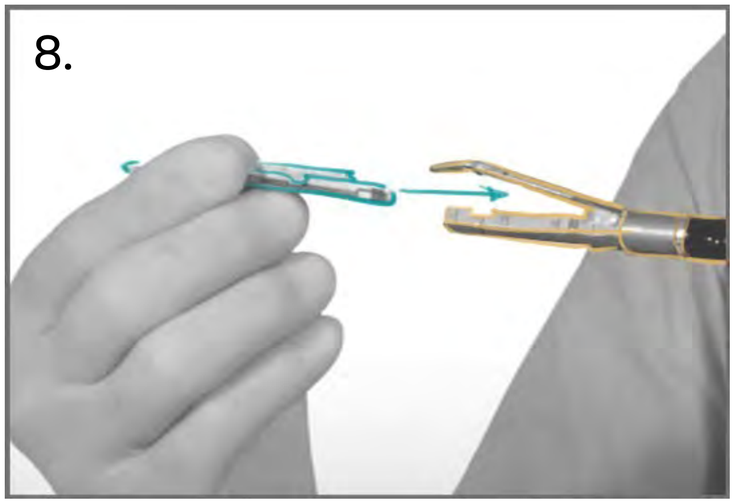
Assistant takes reload out and places it in contaminated waste bin



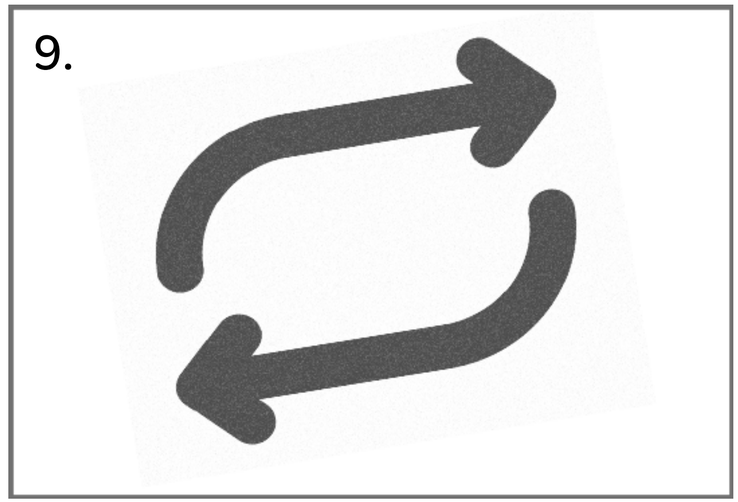
Assistant cleans the device (mild disinfectant)



Assistant reloads device

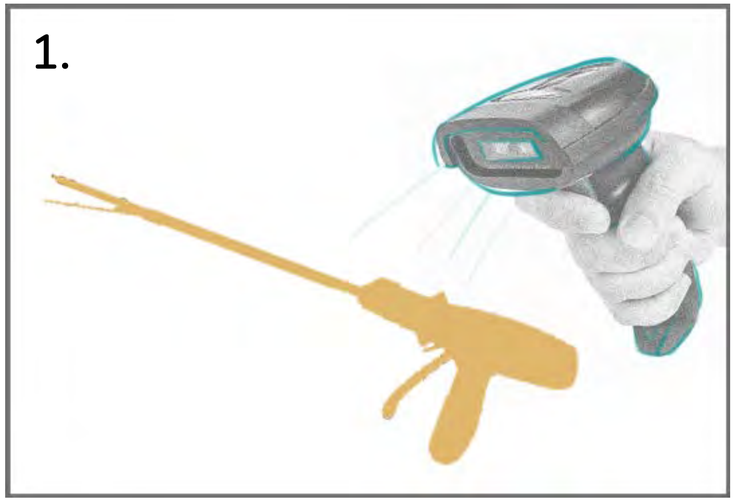


repeat steps 6 - 9 depending on number of necessary fires.

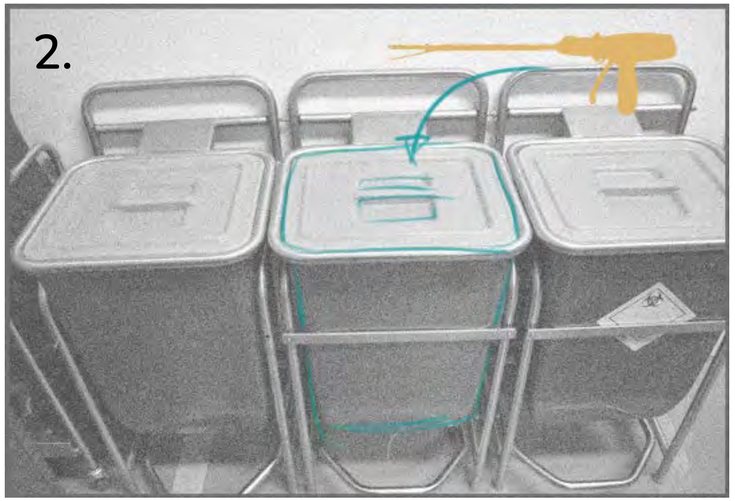


3 Reverse logistics

All used reusable devices are scanned for track and trace, notes are taken of faults in devices.



All the used reusable devices are collected together in special bins



bins are closed after surgery and scanned for track and trace

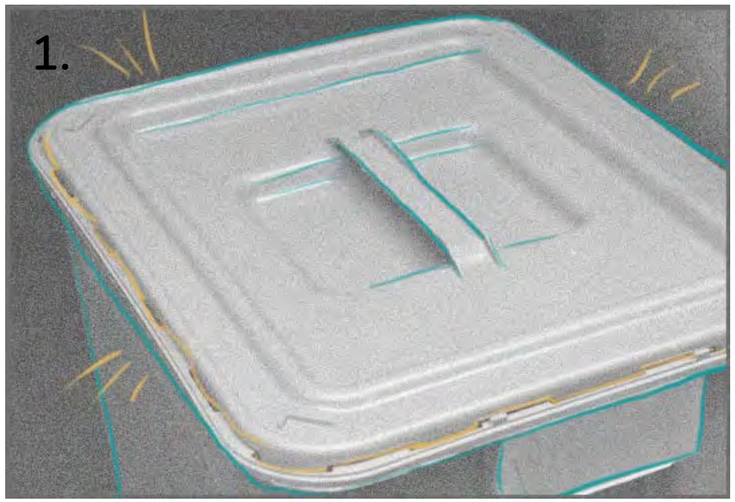
Bins are stored for transportation

Once a day (?) all the bins are transported to the reprocessing facility.

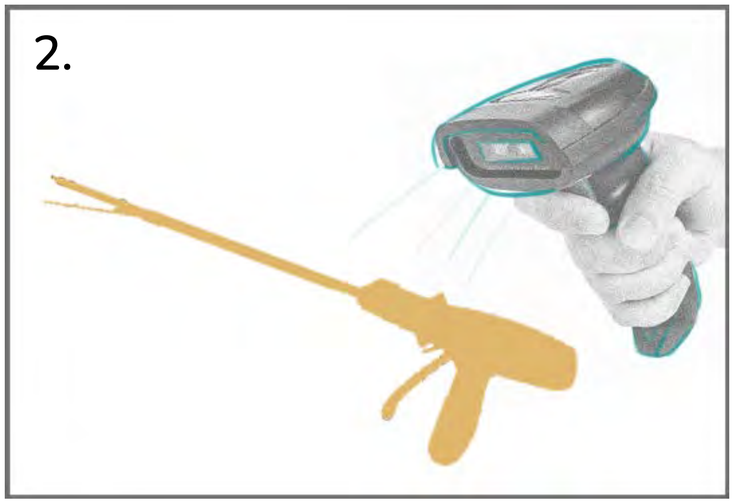
At the reprocessing facility bins are scanned and stored for reprocessing

4. Initial cleaning and selection

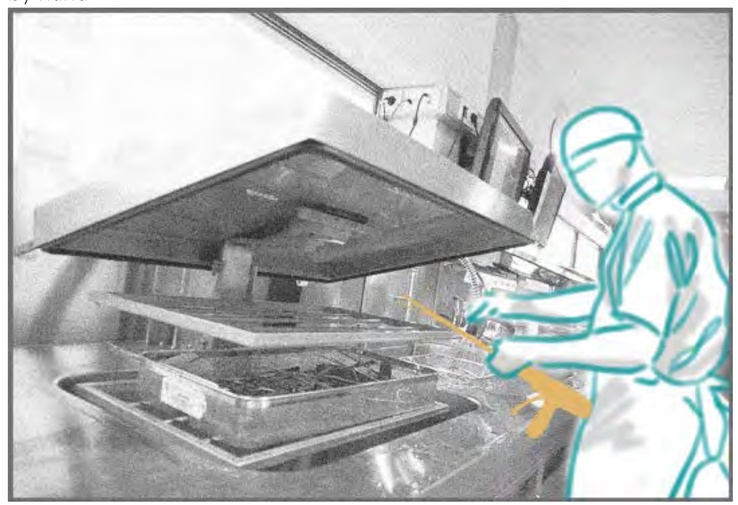
Boxes are opened inside the contaminated room of the reprocessing facility



Devices are scanned, notes about faults in devices are checked



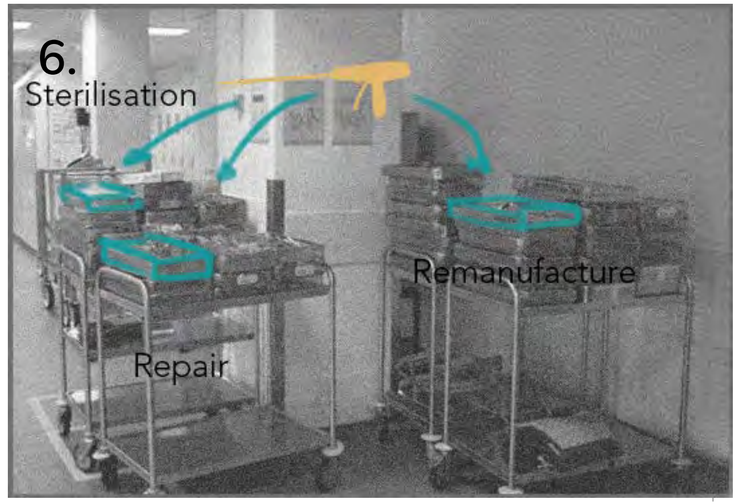
Inside the contaminated room devices are disassembled and disinfected by hand



Devices are put into a washing machine for disinfection

Disinfected devices and their parts are thoroughly checked.

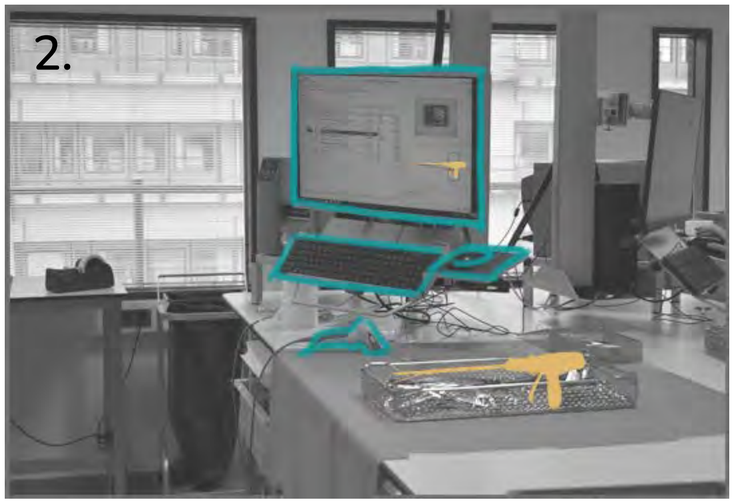
Devices are sorted for direct serilisation, repair and remanufacture.



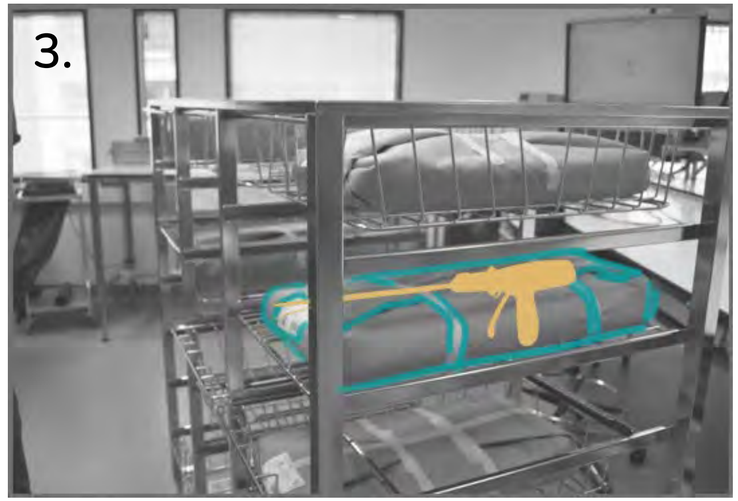
5. Reprocessing (and repair)

devices with repairable faults are set aside for repair

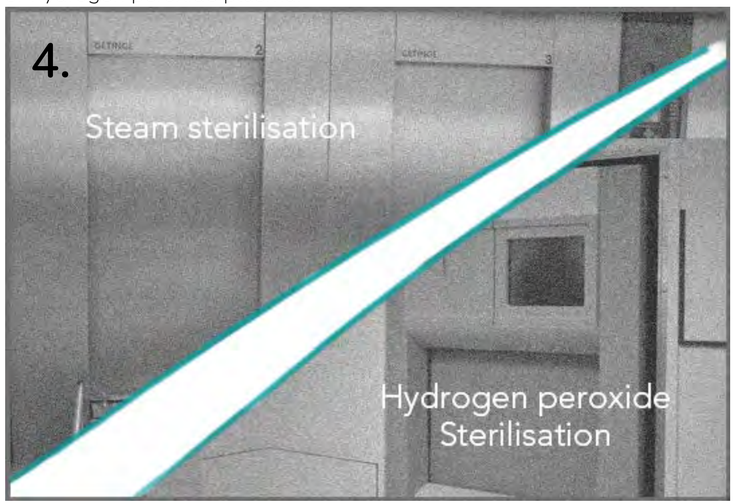
The devices are reassembled, scanned and sorted



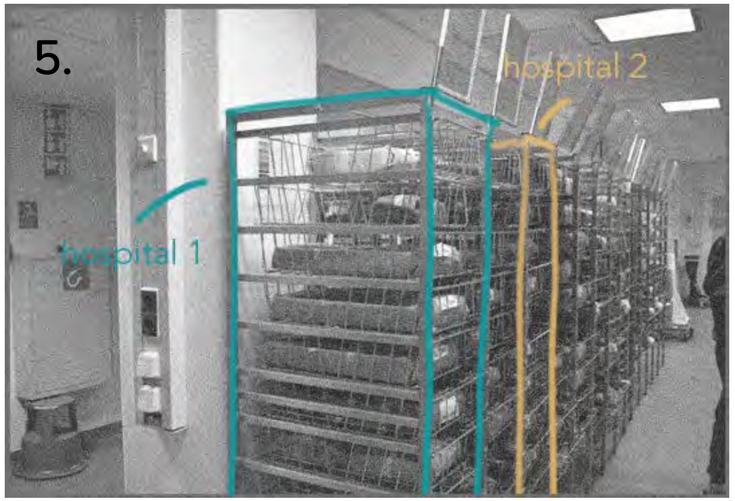
The nets with devices are packaged in blue PP wrap and put into carts for sterilisation



Depending on the device, the device is sterilised through the use of steam or hydrogen peroxide plasma.

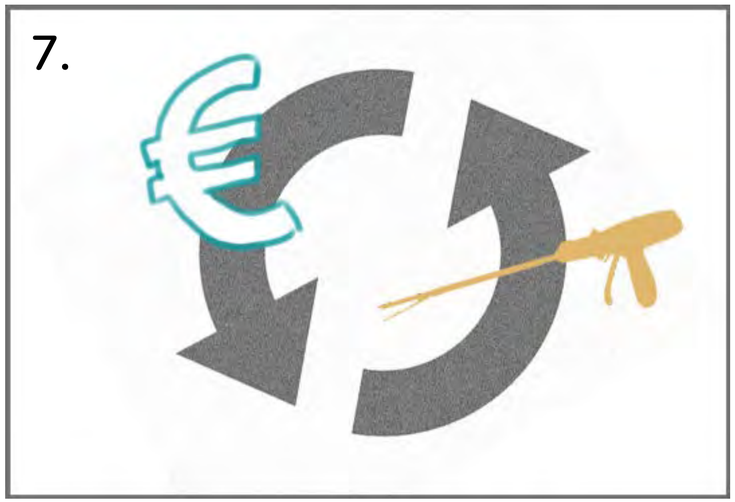


sterilised nets are packaged for transport to different hospitals



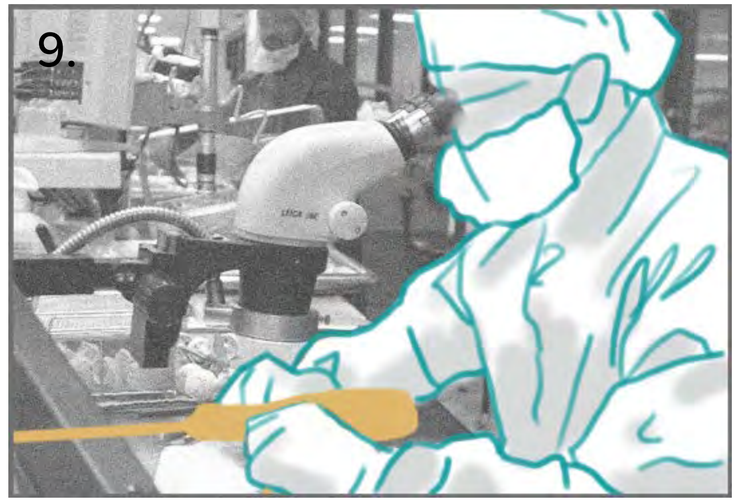
Nets are transported back to hospitals

Hospitals pay per device per reprocessing cycle



OEMs receive a small sum whenever one of their devices is reprocessed, this gives incentive to design for more reprocessing cycles.

After remanufacture the same device can be sold again. The reverse logistics of the new solution makes a collaboration more lucrative for OEMs

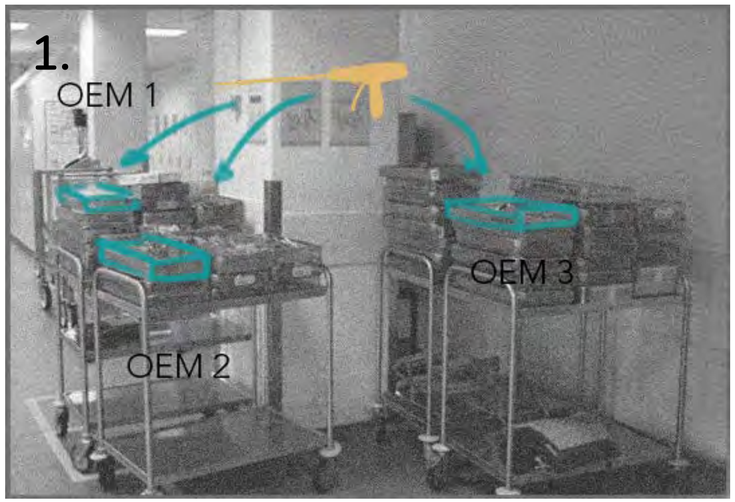


Parts or devices that are too damaged for recovery can be recycled.

There could be a reprocessing facility per province, but the remanufacturing collaboration is international

6. Remanufacture

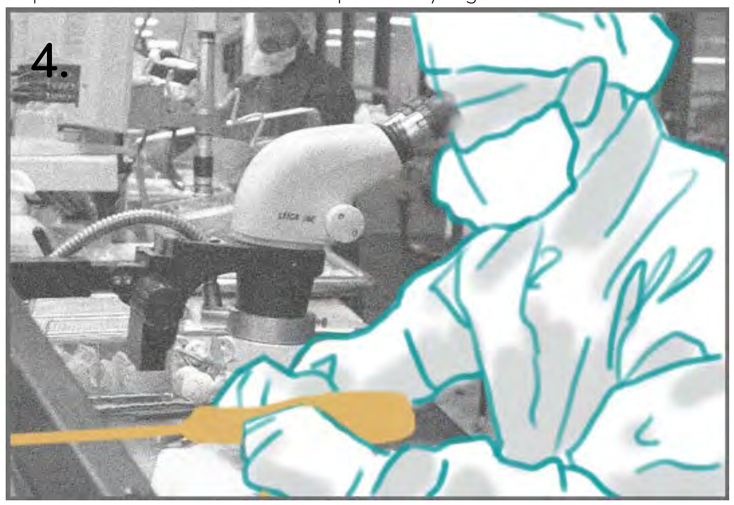
Devices that need to be remanufactured are separated per OEM



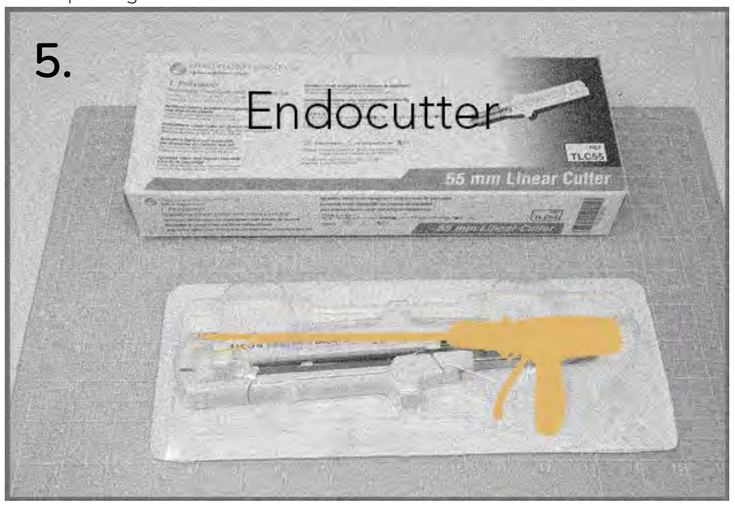
The hospitals that own those devices are notified that they cannot be recovered and need to be replaced.

Whenever there is a certain number of devices for a single OEM collected, they are sent back to their manufacturer.

Each OEM takes responsibility for the remanufacture of their own devices as part of Extended Producer Responsibility regulation



remanufactured devices are equipped with a new serial number, resterilised and repackaged



Devices are sold as new to hospitals

Main benefits

- No need for extra waste streams inside ORs
- EoL available for healthcare facilities of all sizes
- No issues with IP and confidentiality around spare parts for remanufacture (compared to one central remanufacturing facility)
- Because OEMs are responsible, they invest in facilitating EoL in the design of their devices
- Possibilities for recycling of broken parts
- Highest possible level of product integrity is maintained

Main drawbacks

- There is a delay in recovery of devices because of transportation to reprocessing facility
- OEMs need to design reusable devices with more value - alternate business model.
- There is a lot of transportation involved in remanufacture

Appendix 6.1.

Storyboard of the current situation (SUD)

TU Delft

ETHICON
a Johnson & Johnson company

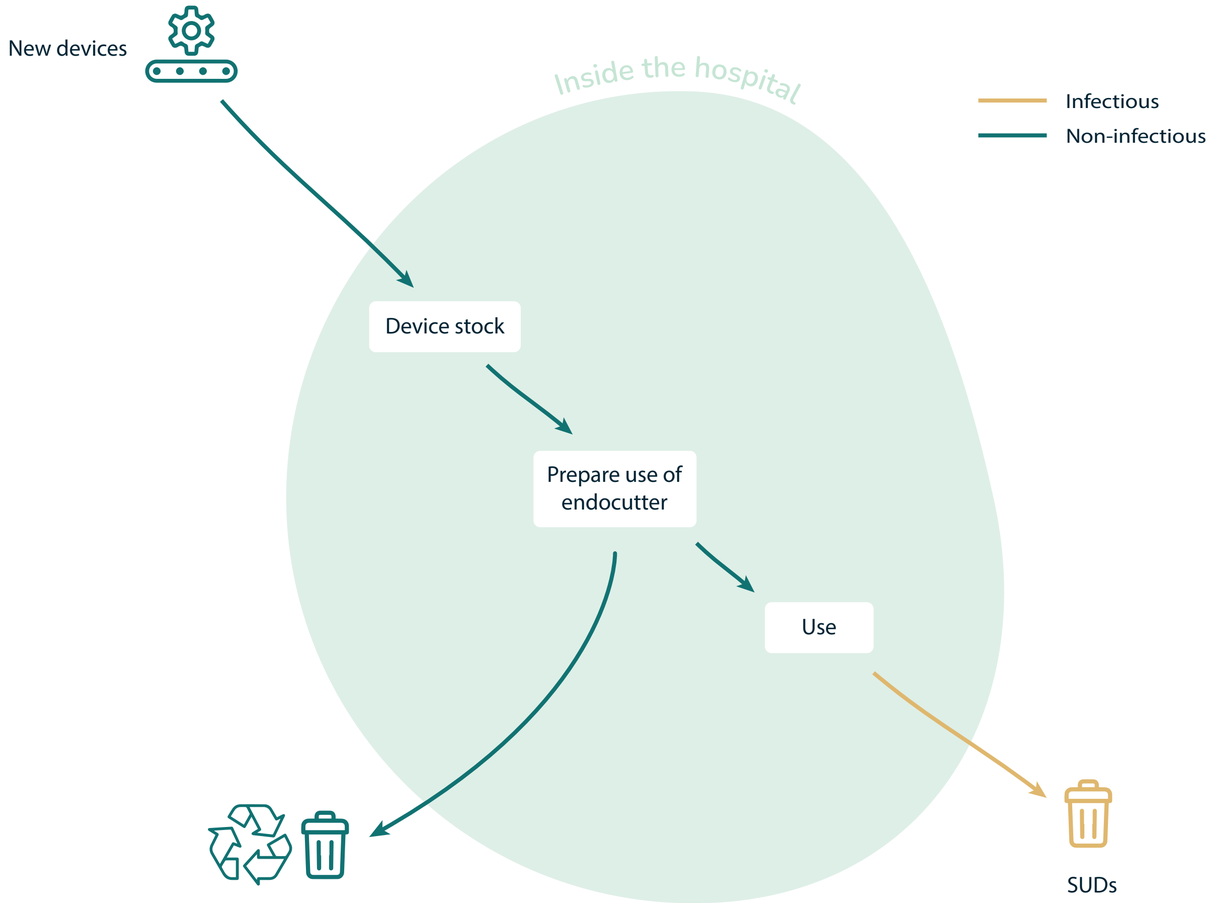
Faculty Industrial Design Engineering, Delft University of Technology,
the Netherlands

Dorien van Dolderen
4541294

Chair: Conny Bakker

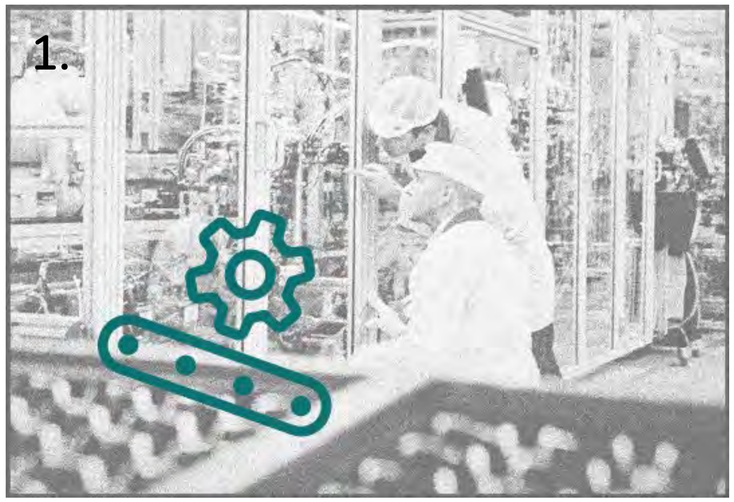
Mentor: Jan-Carel Diehl

Overview visual

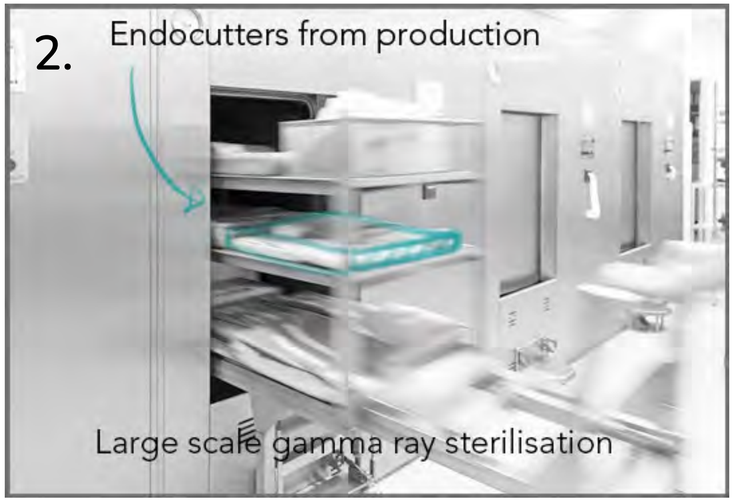


1. Device supply (disposable)

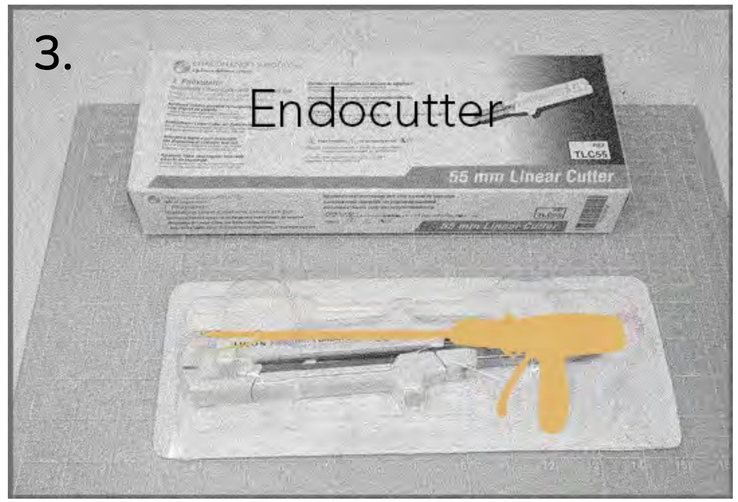
Production



Sterilisation - incl part of the packaging



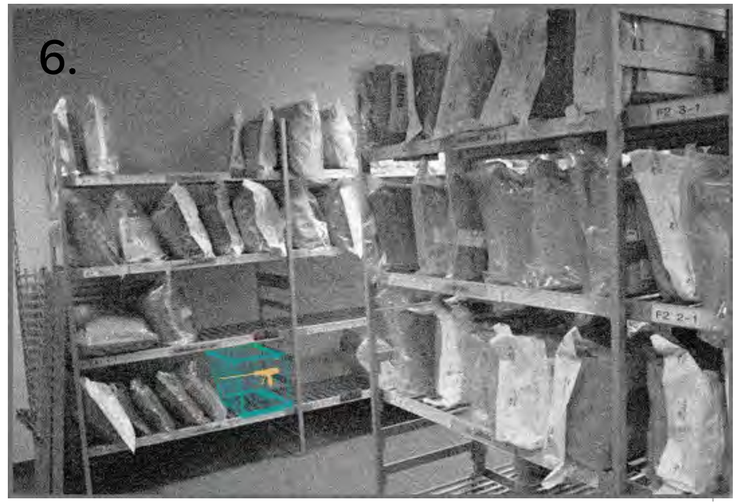
Further packaging



Distribution

Transportation

Hospital stock

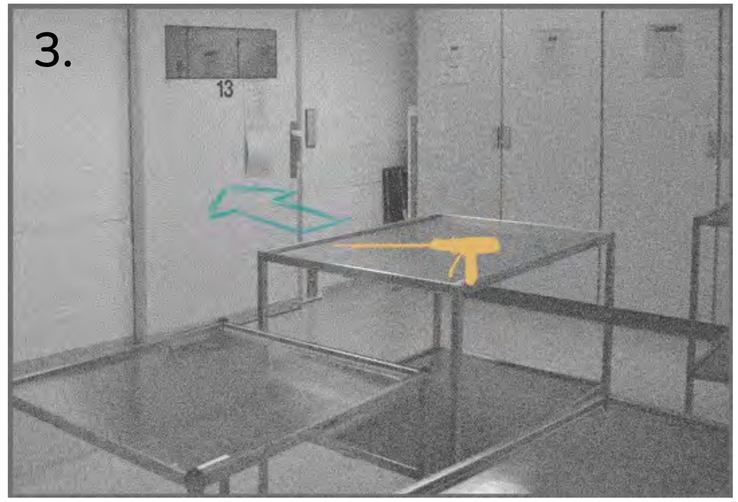


2. Device use

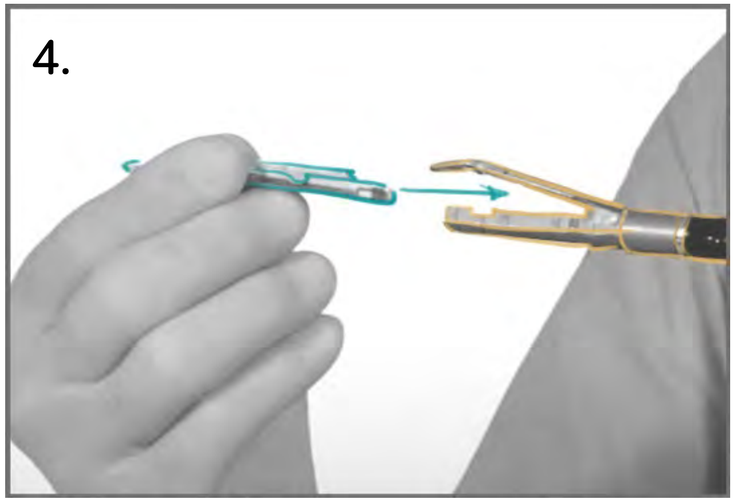
transport to preparation room or OR

Unpack in preparation room (sometimes happens in OR) - somewhere where the air is clean

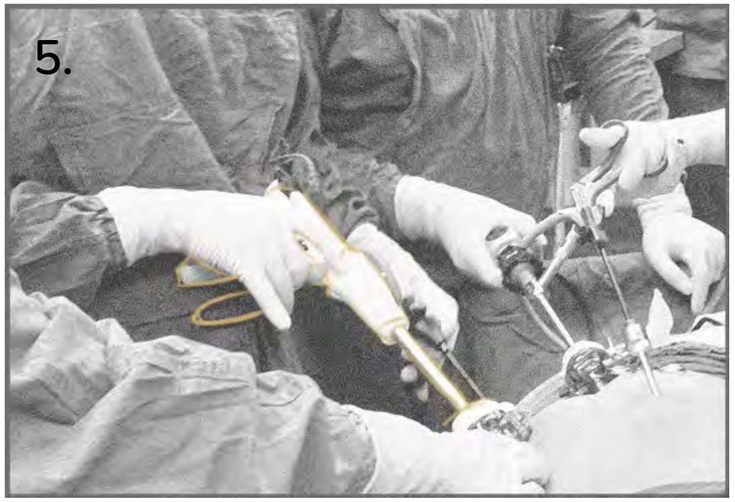
(The device is placed on the surgery cart which is driven into the OR.)



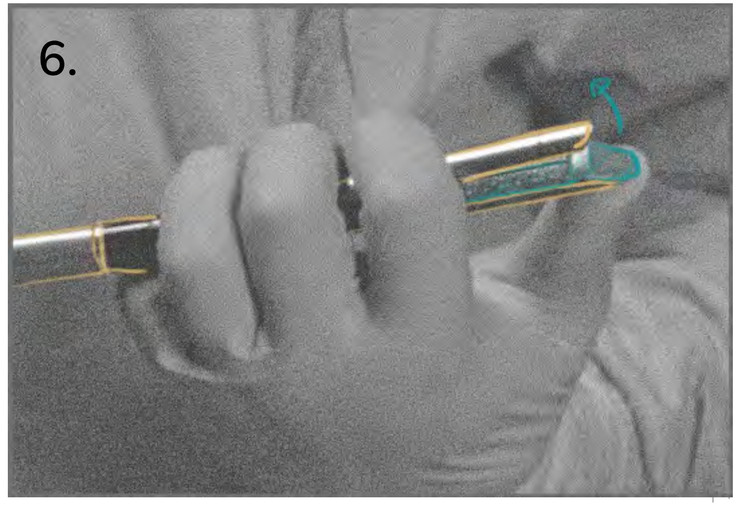
The assistant prepares the device for use (places a reload)



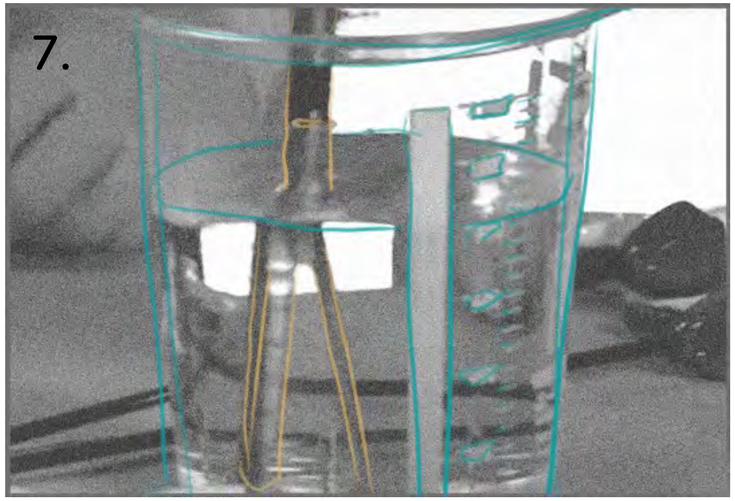
The surgeon uses the device



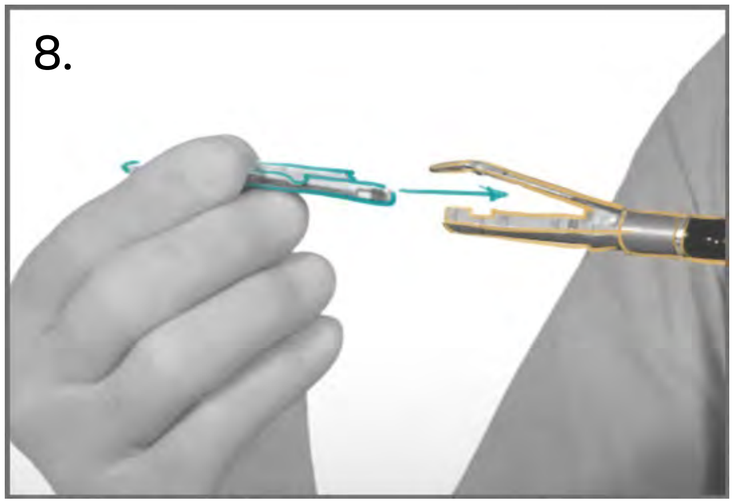
Assistant takes reload out and places it in contaminated waste bin



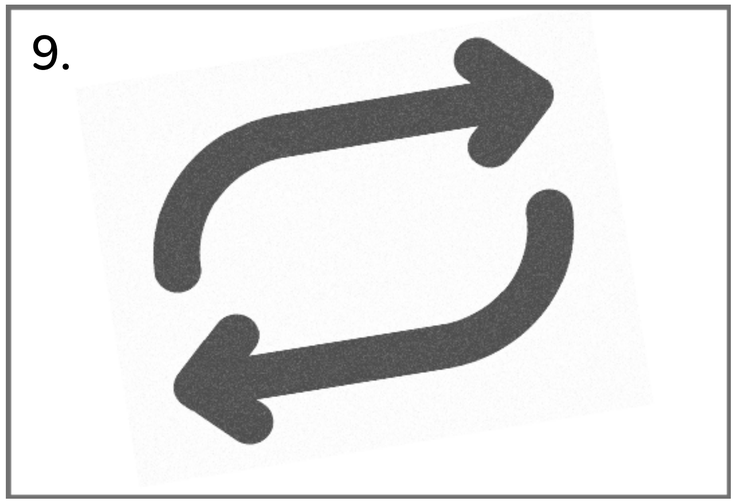
Assistant cleans the device (mild disinfectant)



Assistant reloads device

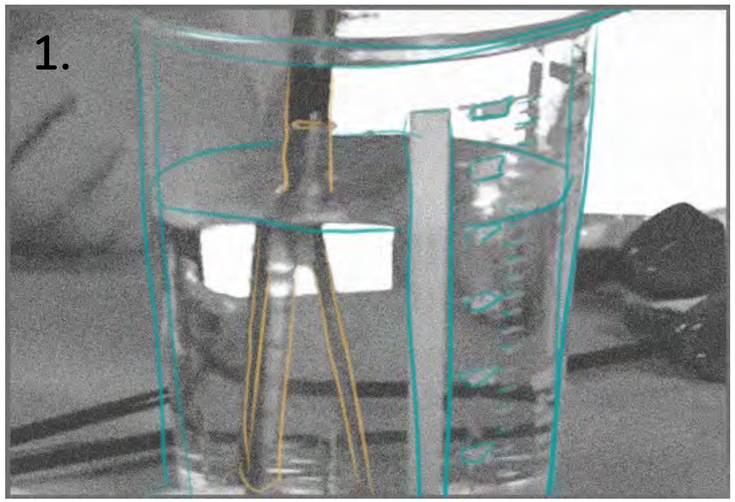


repeat steps 6 - 9 depending on number of necessary fires.

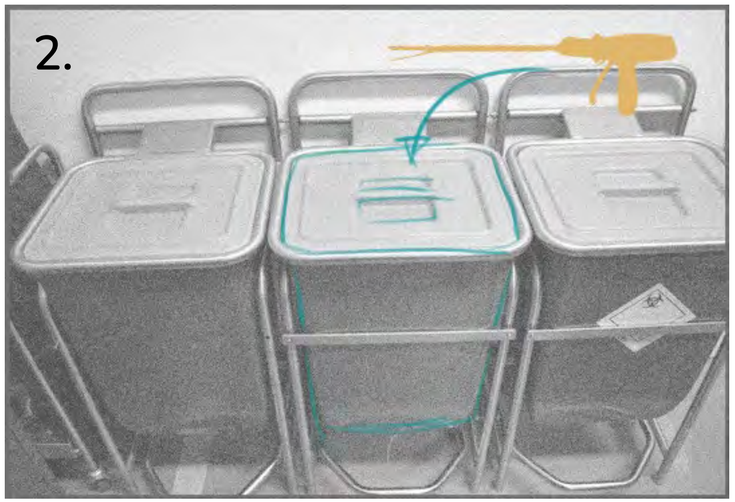


3. Waste

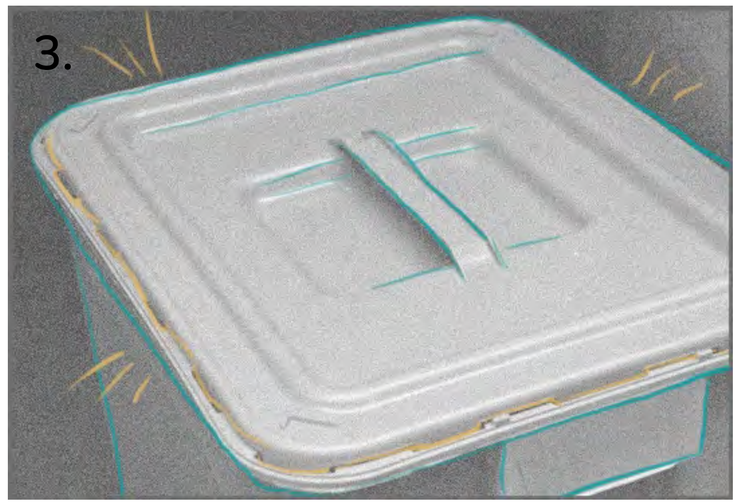
Assistant cleans the device with mild disinfectant after use



Assistant places device into contaminated waste bin



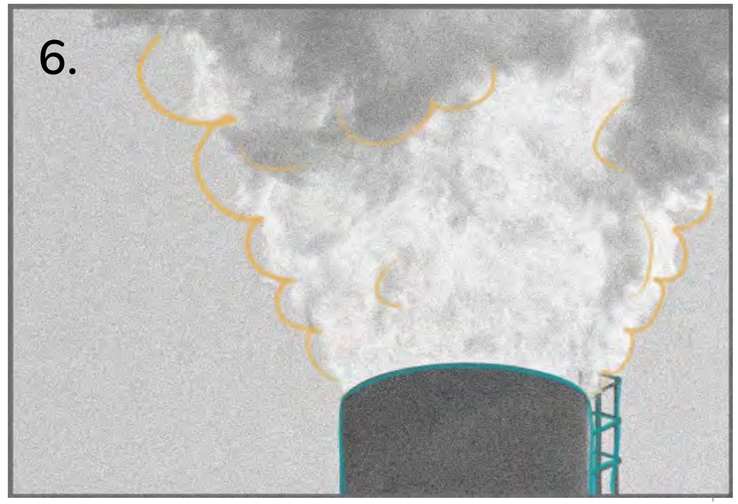
After surgery the waste bin is sealed



waste bin is transported to waste management area inside the hospital

When a container is filled with contaminated waste bins, it is transported to Zavin (Dutch contaminated waste processor)

At Zavin the sealed boxes are incinerated, energy is recovered.



Main benefits

- Easy for hospitals
  - in terms of safety guarantee
  - in terms of use
  - no need for cleaning facilities

- Easy for OEMs
  - Continuous income
  - production optimisation - move production to cheaper markets because there is no reverse logistics

- Is perceived to be more sterile because it is new

Main drawbacks

- High environmental impact and very wasteful

- Over the longer term very expensive (compared to reusables)

- Supply chain vulnerability

Appendix 6.2.

Storyboard of the current situation (internal reprocessing)

TU Delft

ETHICON
a Johnson & Johnson company

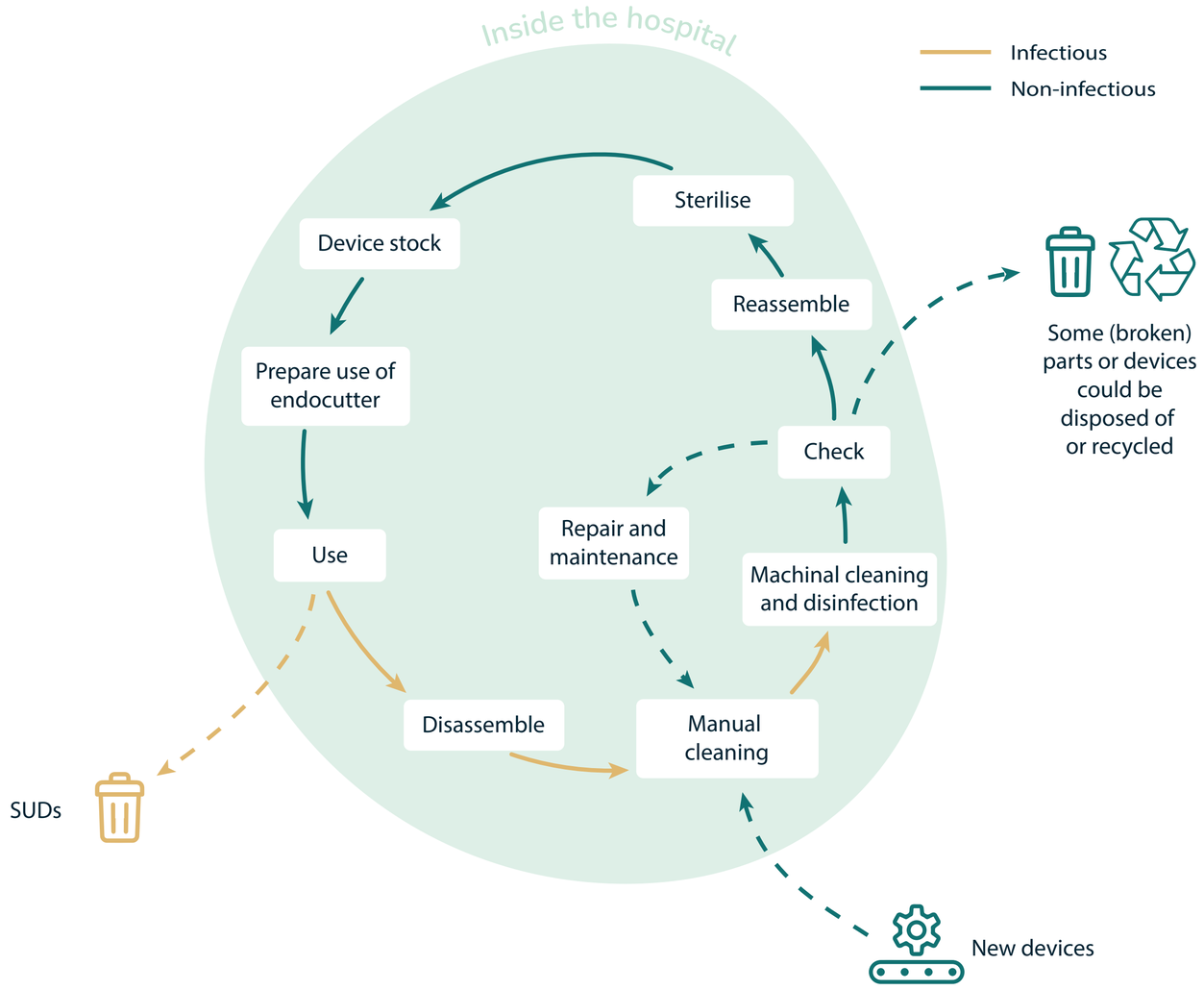
Faculty Industrial Design Engineering, Delft University of Technology,
the Netherlands

Dorien van Dolderen
4541294

Chair: Conny Bakker

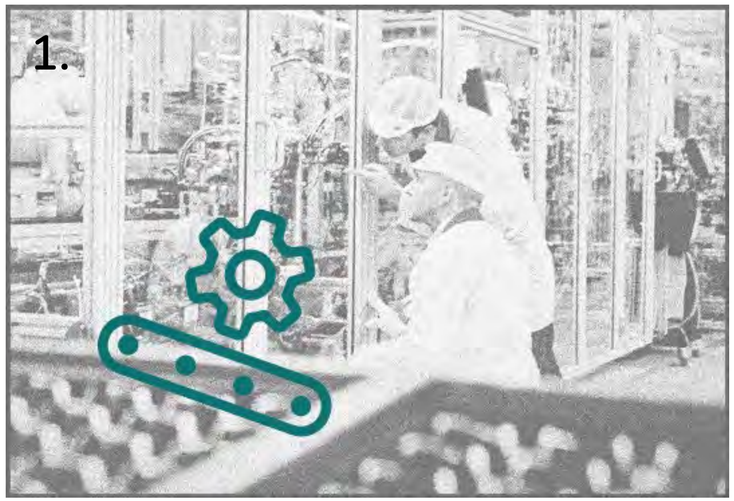
Mentor: Jan-Carel Diehl

Overview visual

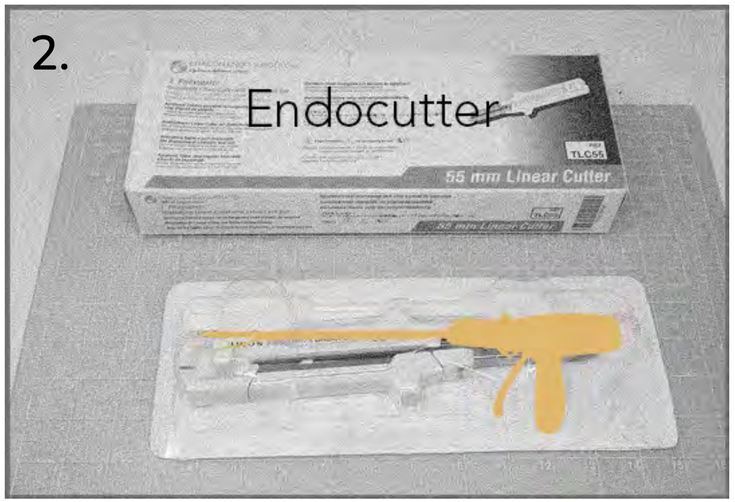


1. Device supply (reusable)

Production



Packaging

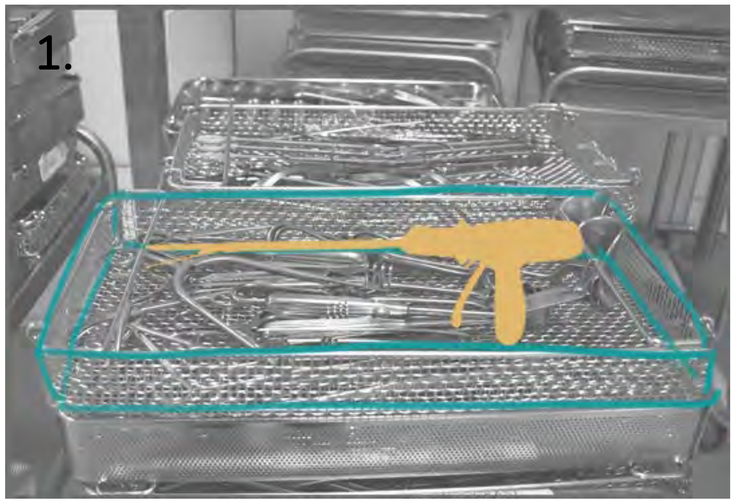


Distribution

Transportation

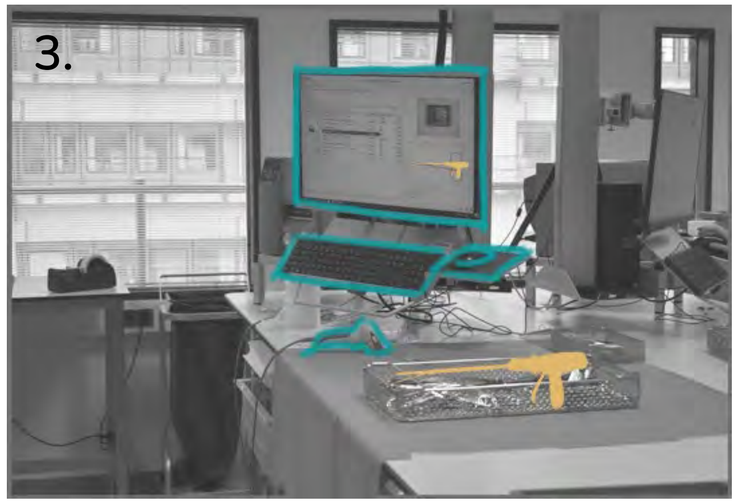
2. Initial cleaning of new devices

New devices are moved into the contaminated room for initial cleaning

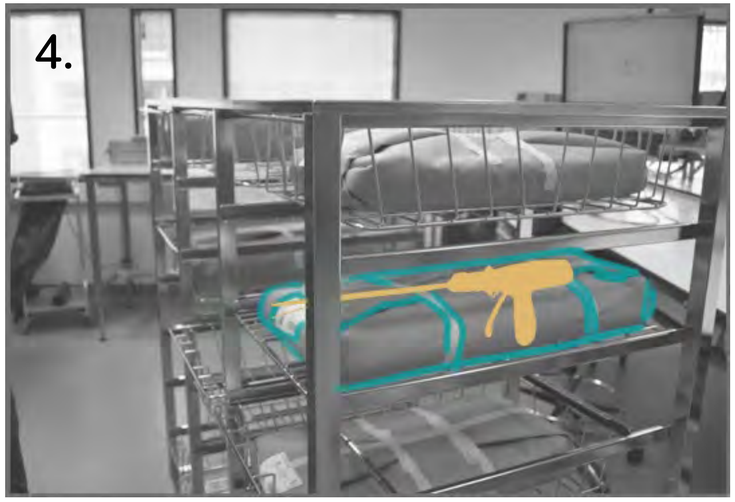


Devices are put into a washing machine for machinal cleaning and disinfection

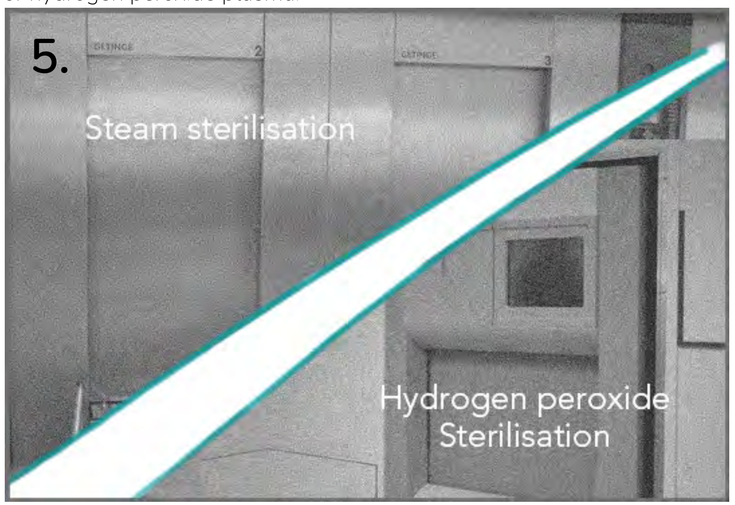
The devices are reassembled, scanned and sorted



The nets with devices are packaged in blue PP wrap and put into carts for sterilisation



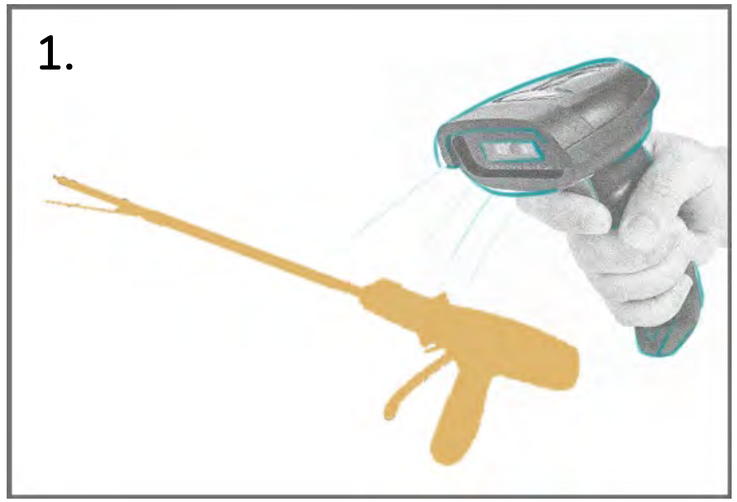
Depending on the device, the device is sterilised through the use of steam or hydrogen peroxide plasma.



Sterilised nets are sorted and stored, ready for the next surgery

3. Device use

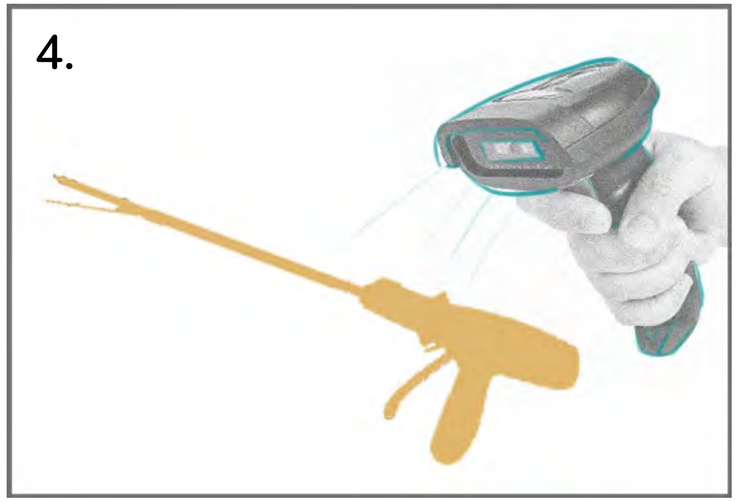
Nets are scanned



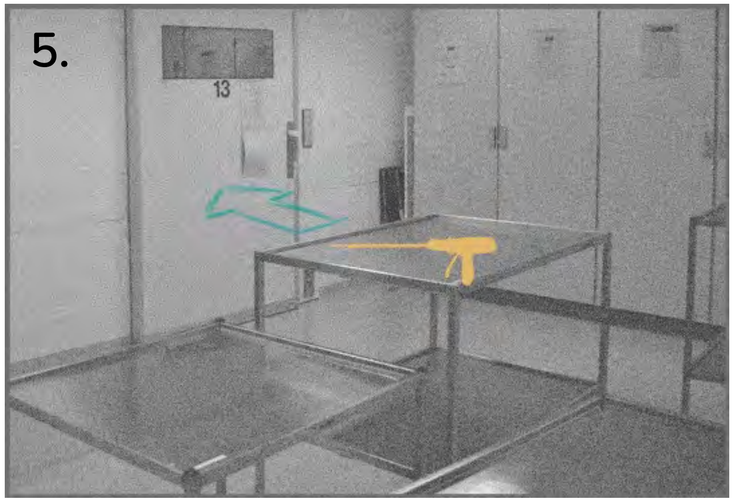
transport to preparation room or OR

Unpack in preparation room (sometimes happens in OR) - somewhere where the air is clean

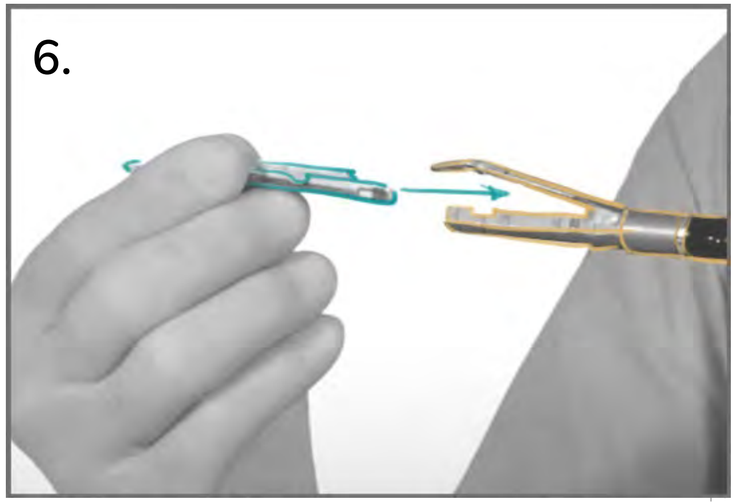
Some devices are scanned



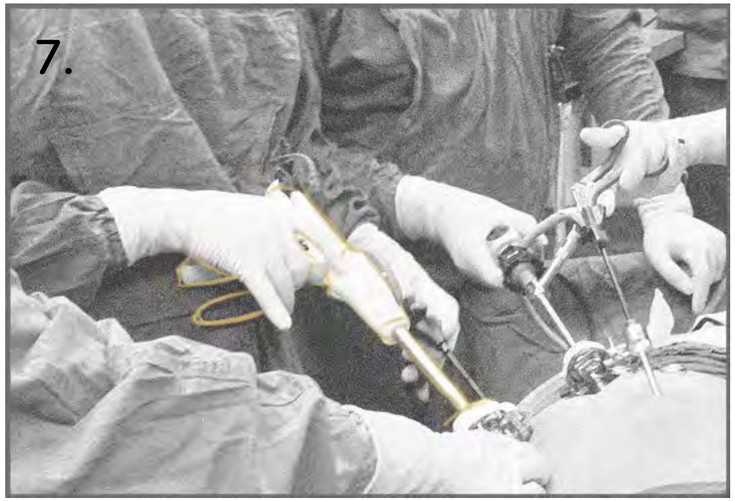
(The device is placed on the surgery cart which is driven into the OR.)



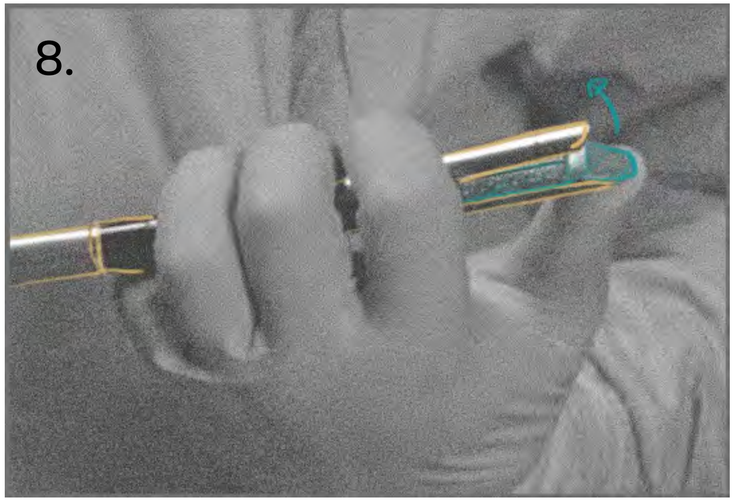
The assistant prepares the device for use (places a reload)



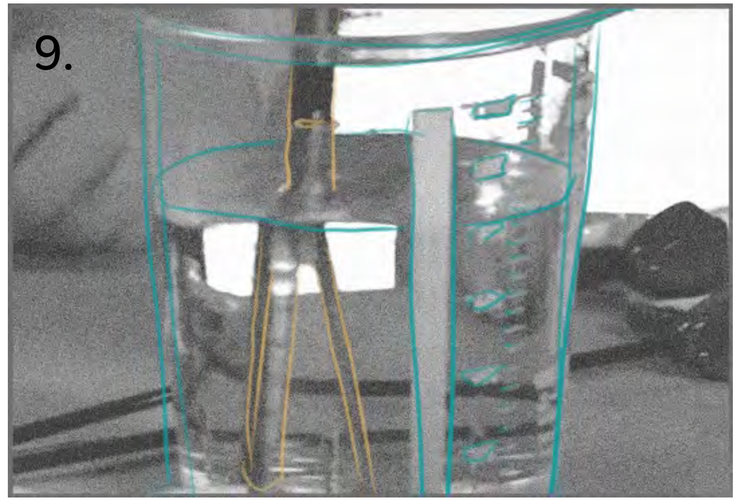
The surgeon uses the device



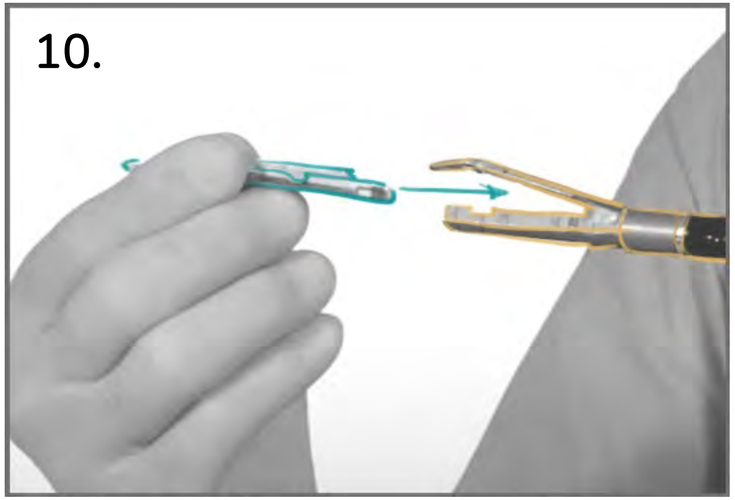
Assistant takes reload out and places it in contaminated waste bin



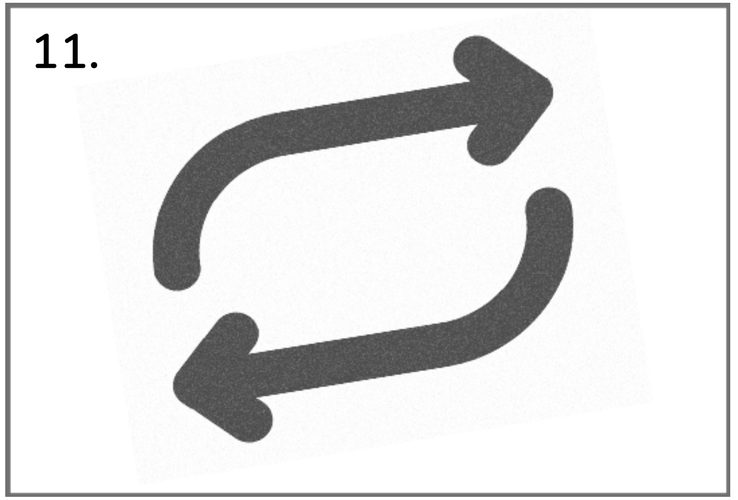
Assistant cleans the device (mild disinfectant)



Assistant reloads device

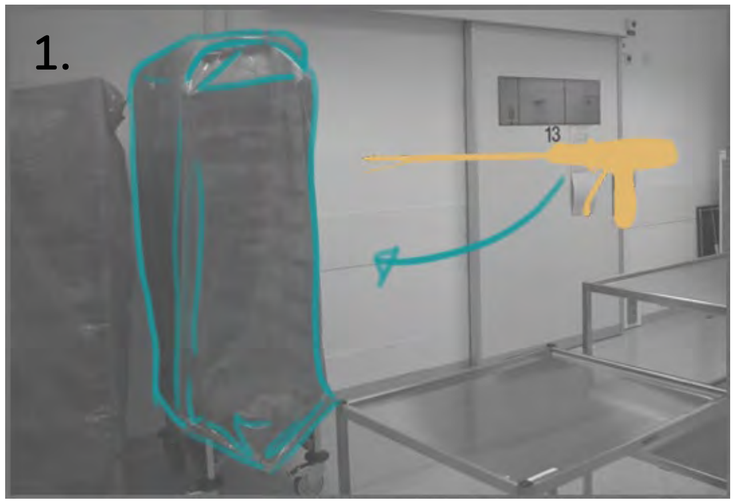


repeat steps 6 - 9 depending on number of necessary fires.

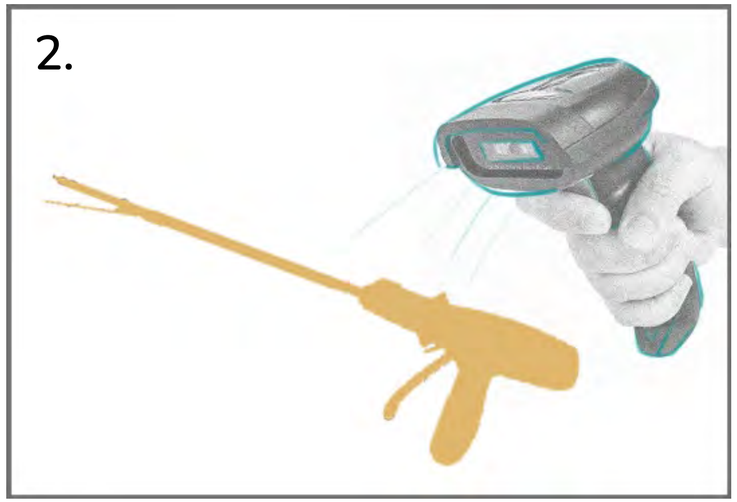


4. Reprocessing

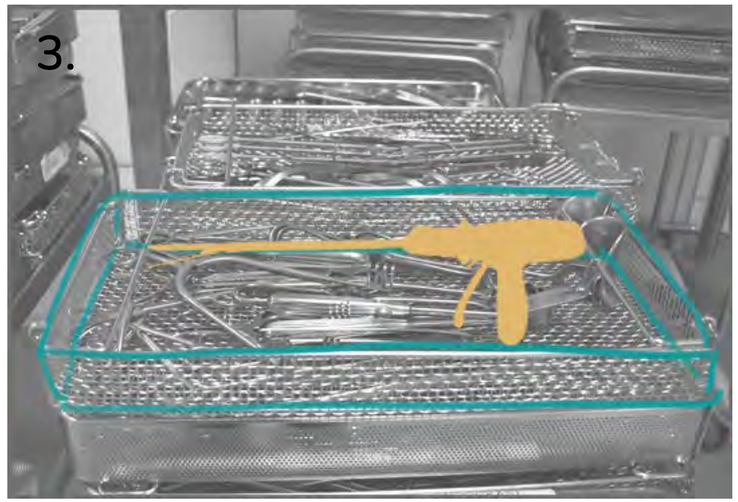
All reusable devices are collected for reprocessing



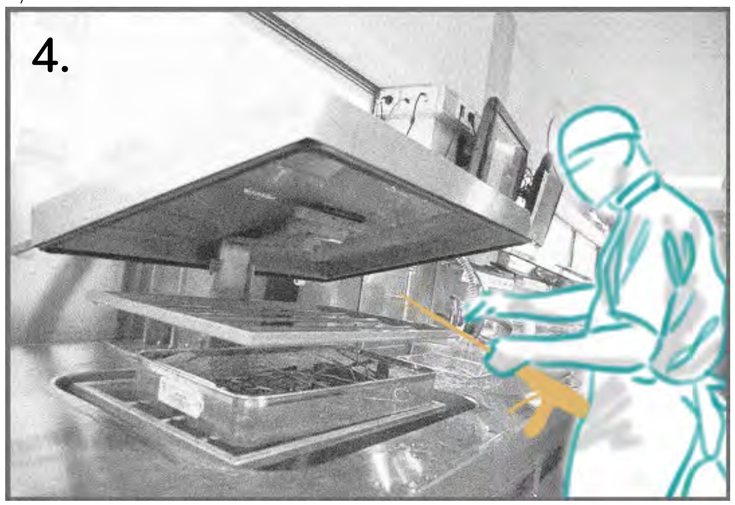
Nets are scanned



nets are moved to a dedicated contaminated room

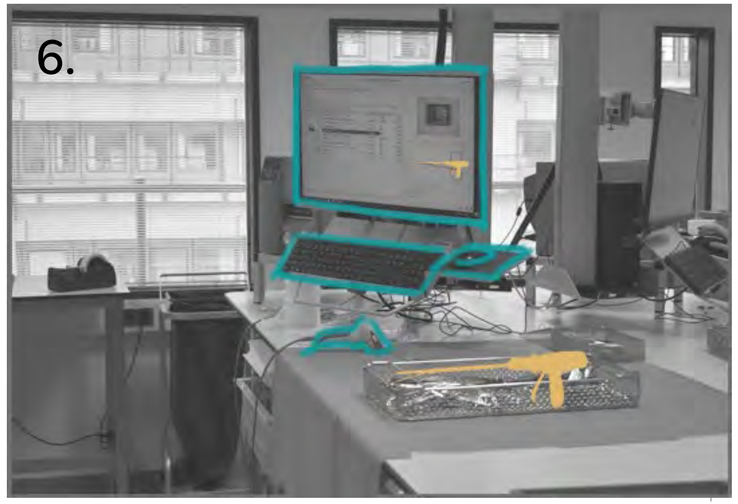


Inside the contaminated room devices are disassembled and disinfected by hand



Devices are put into a washing machine for disinfection

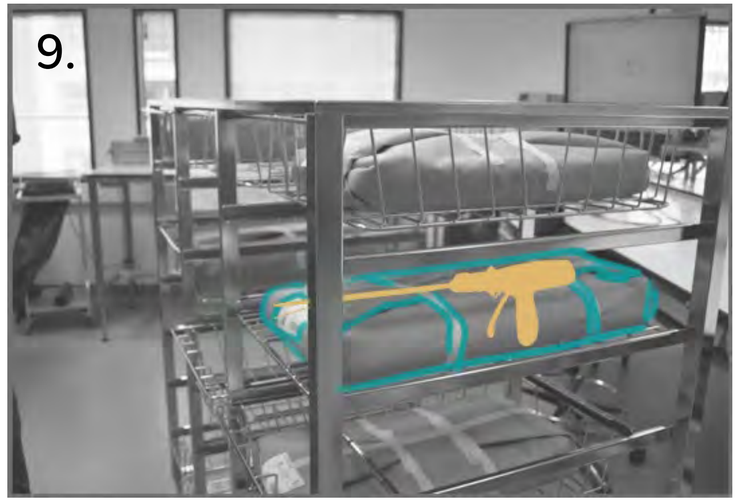
Disinfected devices and their parts are thoroughly checked.



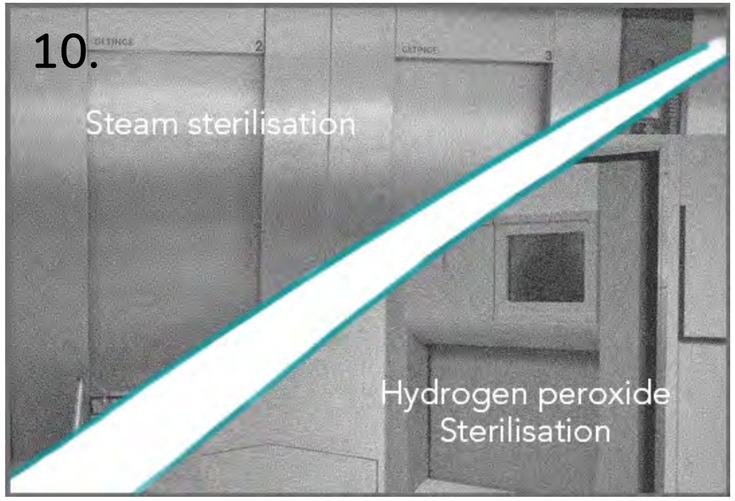
devices with repairable faults are set aside for repair, some devices are set aside for maintenance (not performed at the SD but at the tech. service)

The devices are reassembled, scanned and sorted

The nets with devices are packaged in blue PP wrap and put into carts for sterilisation



Depending on the device, the device is sterilised through the use of steam or hydrogen peroxide plasma.



Sterilised nets are sorted and stored, ready for the next surgery

Main benefits

Compared to SUDs

- Less vulnerable supply chain
- Less wasteful - maintain a high level of product integrity
- Cheaper

Compared to external solutions

- No transportation, saves a lot of time
- (Probably) cheaper for the larger hospitals
- More control over device safety and availability
- Smaller device stock needed

Main drawbacks

- Extra work for hospitals
- Only possible for larger healthcare facilities (it requires a lot of time, educated personnel, investments and space)
- Little return for OEMs for their circular design initiatives
- Liability for hospitals

Compared to external solutions

- Investments in internal SD needed

Appendix 6.3.

Concept storyboard

TU Delft

ETHICON
a Johnson & Johnson company

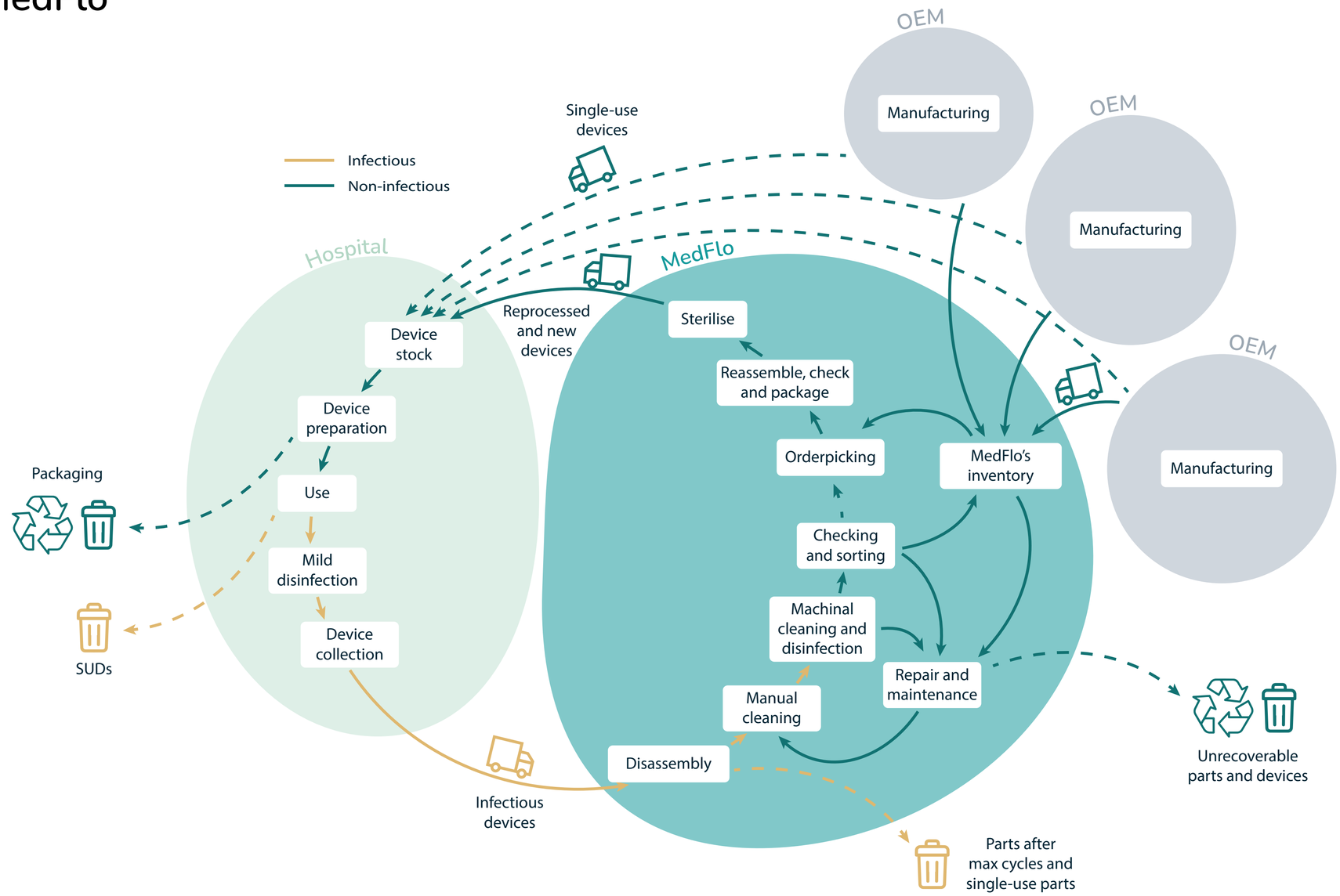
Faculty Industrial Design Engineering, Delft University of Technology,
the Netherlands

Dorien van Dolderen
4541294

Chair: Conny Bakker

Mentor: Jan-Carel Diehl

The service of MedFlo



1. What the future looks like (setting the scene)

Concept storyboard

It's 2030

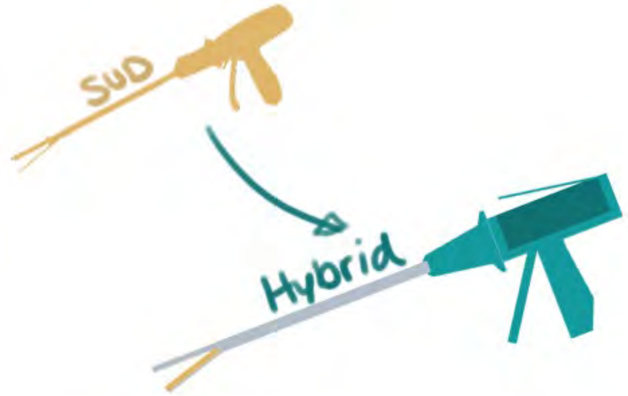
1.

There is EPR regulation in place for medical devices and additional fees are charged for branding devices as single use. SUDs are very expensive.

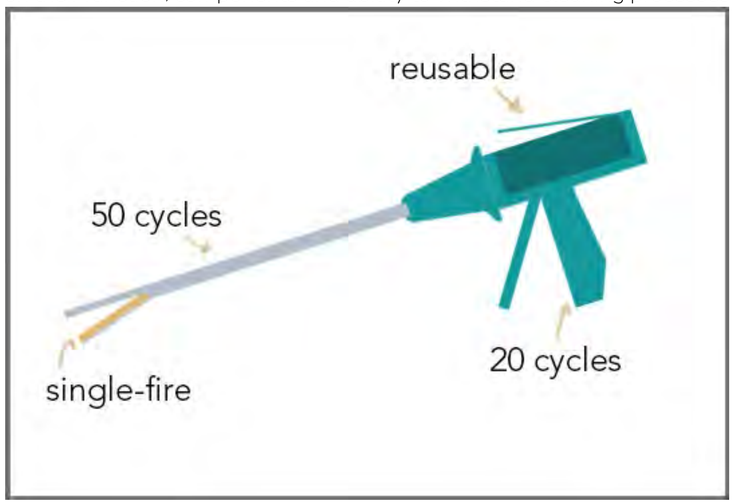
2.

Hybrid/semi-reusable devices are slowly replacing SUDs.

3.

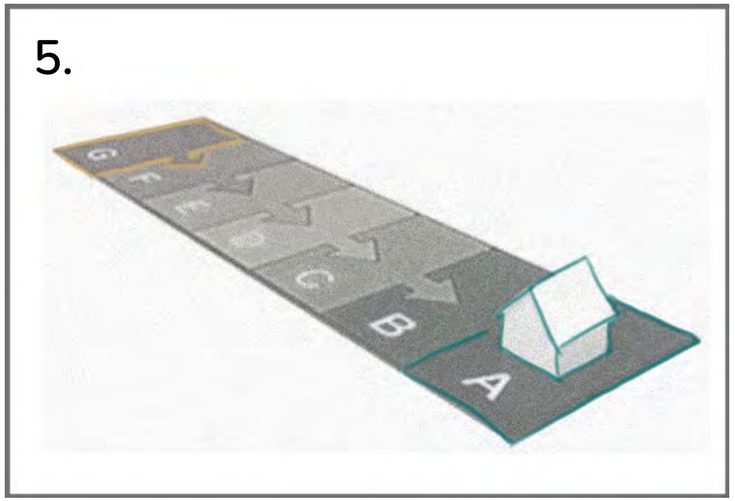


These devices have different modules with different lifespans depending on their function, components and ability to withstand cleaning processes



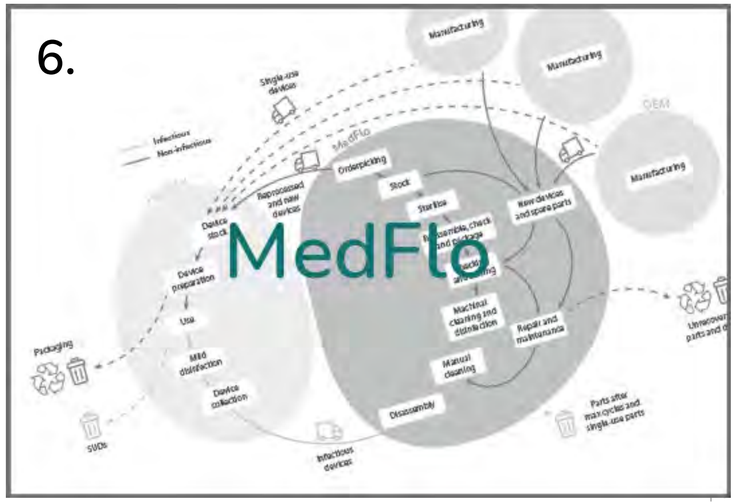
Hospitals are feeling the pressure to become more sustainable, OEMs as well

5.



Reprocessing service MedFlo steps in to help.

6.

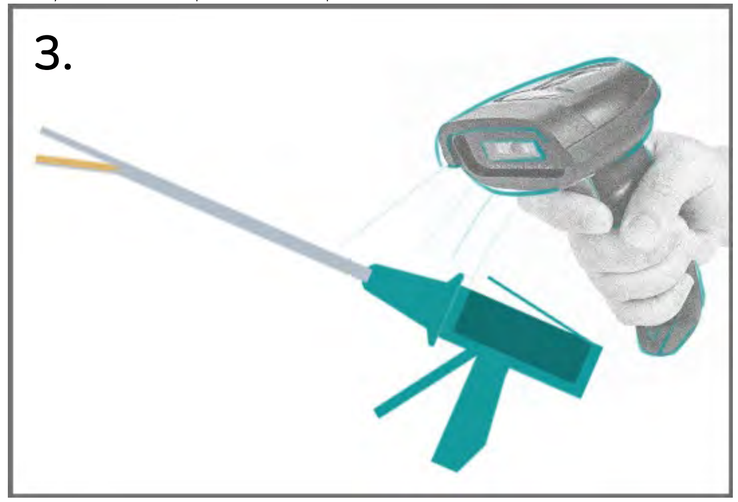


2. Device supply to hospitals

Each hospital specifies the exact stock of medical devices they need to function to MedFlo through their platform.

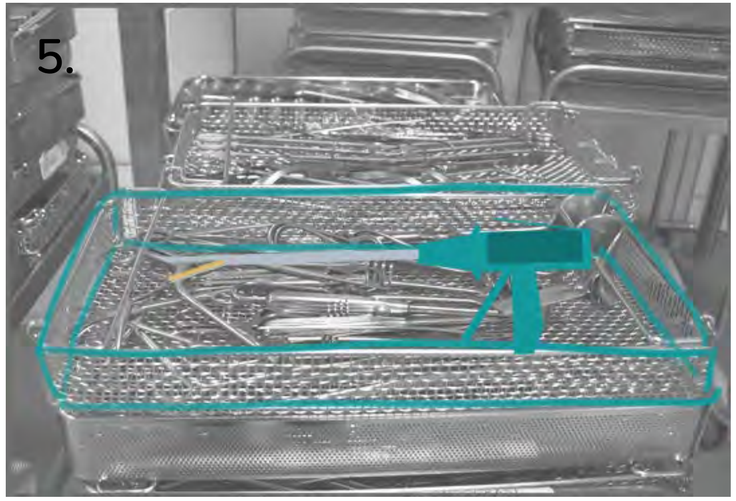
This stock is available in the hospital in consignment (MedFlo owns the devices but they are stored in the hospital's inventory)

Before a surgery all the nets that are going to be used are scanned to notify MedFlo to replete the hospital's device stock.



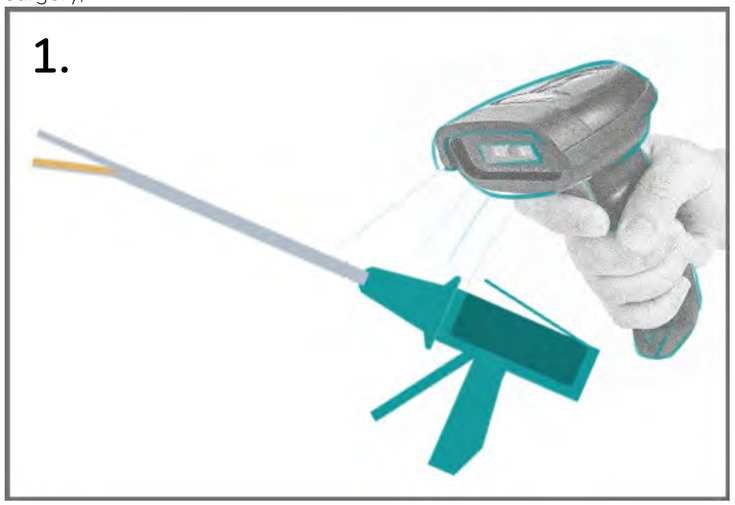
Once a day MedFlo provides the hospital with safe, functioning and clean medical devices.

The provided devices are a combination of new devices ((semi-)reusable) and reprocessed devices.



3. Device use

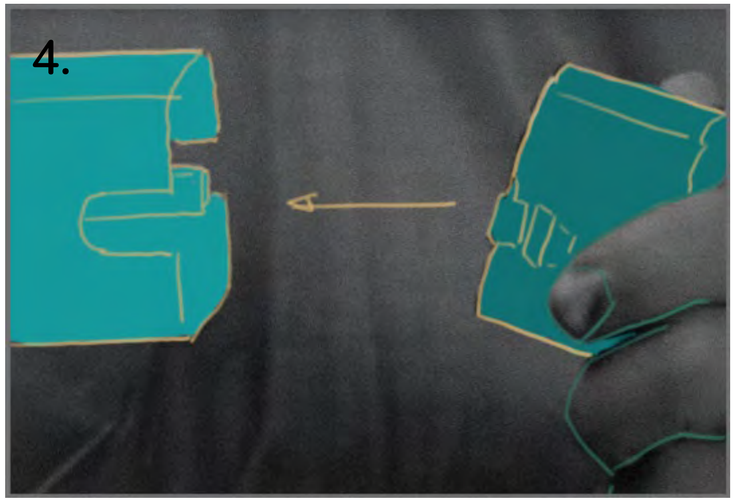
Nets with devices are scanned --> which nets are used for what kind of surgery,



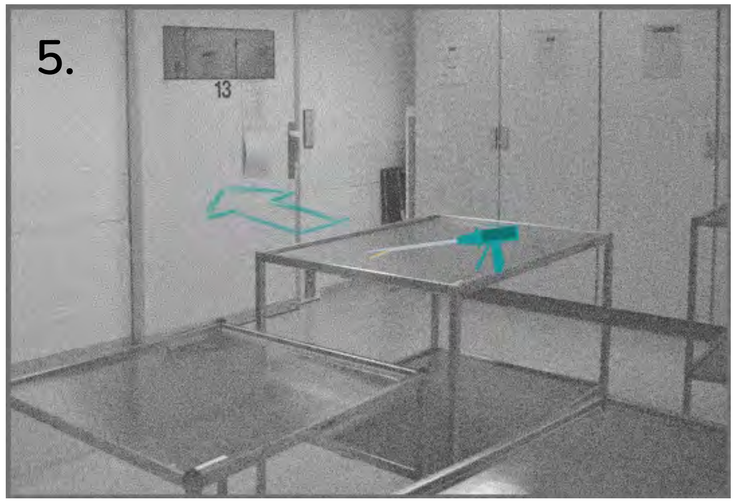
The correct nets (including some necessary SUDs) are moved to the preparation room

Nets and SUDs are unpacked in a room with clean air (preparation room or OR)

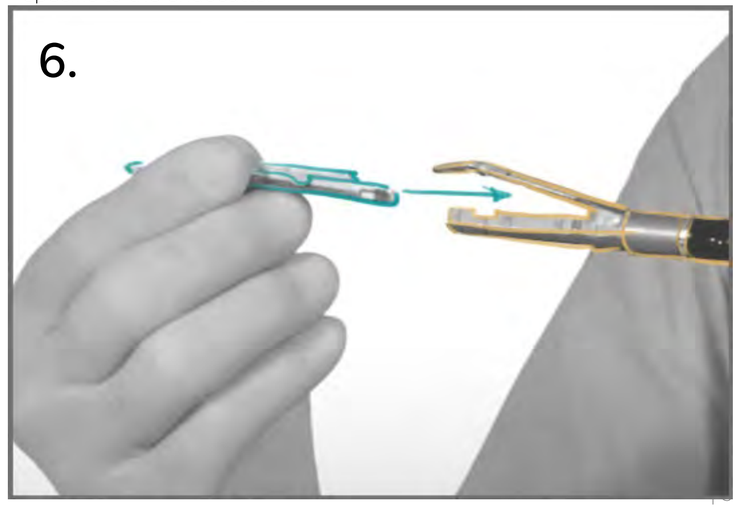
A charged battery (or other non sterile module) is placed in the device which functions as a sterile barrier.



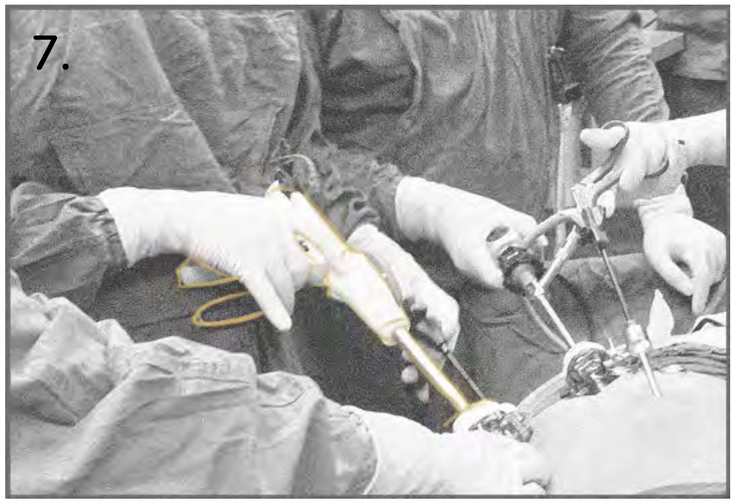
(The device is placed on the surgery cart which is driven into the OR.)



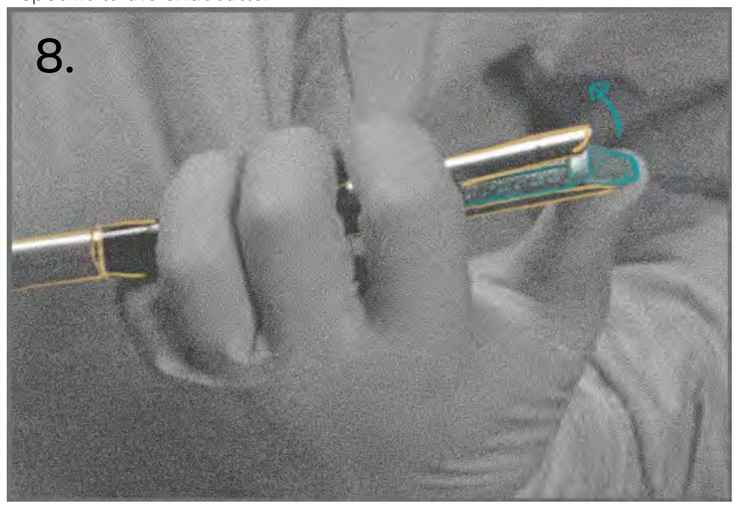
The assistant prepares the device for use (places a reload)
- specific to the endocutter



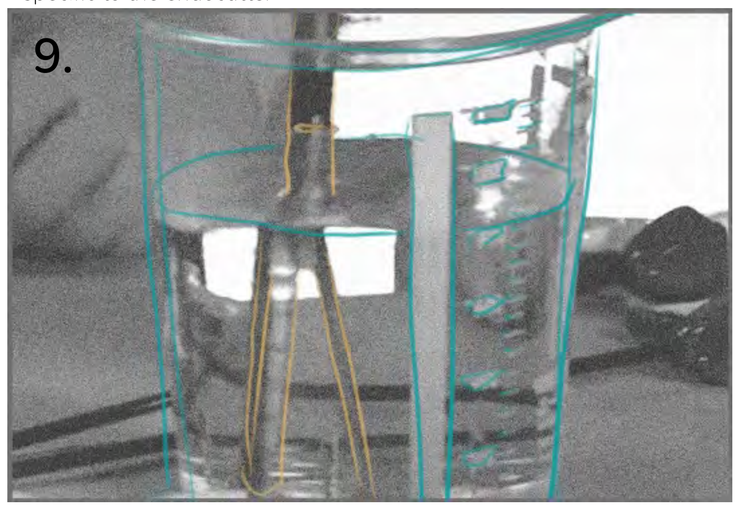
The surgeon uses the device



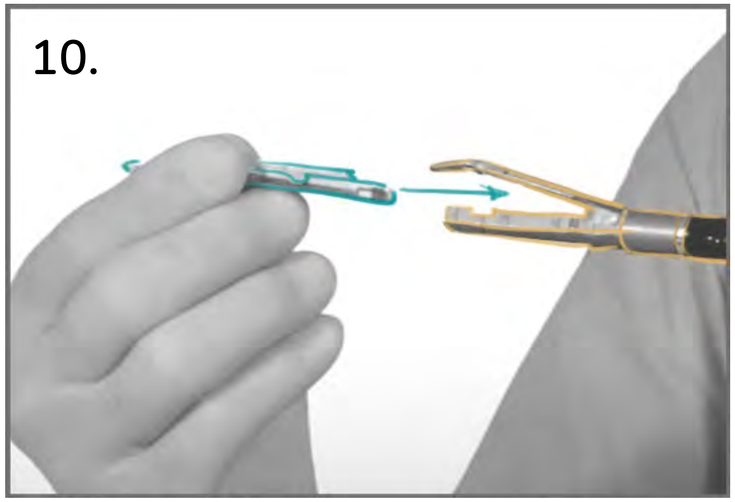
The assistent takes out the reload and places it in the infectious waste bin
- specific to the endocutter



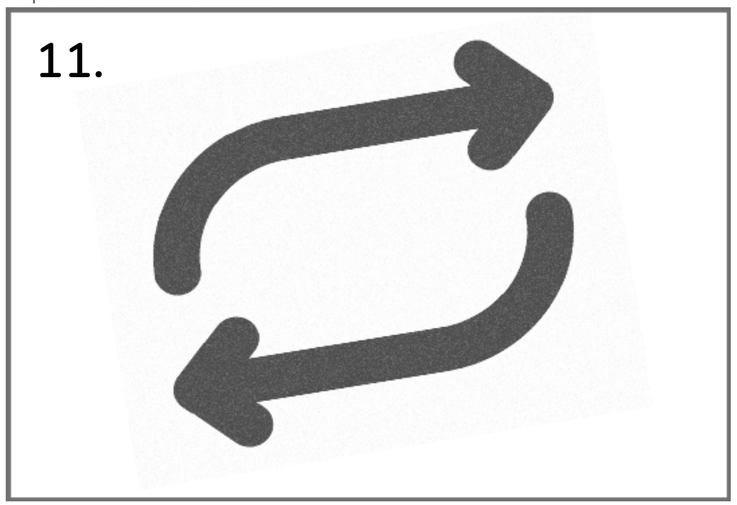
The assistant cleans the device with a mild disinfectant
- specific to the endocutter



The assistant reloads the device
- specific to the endocutter

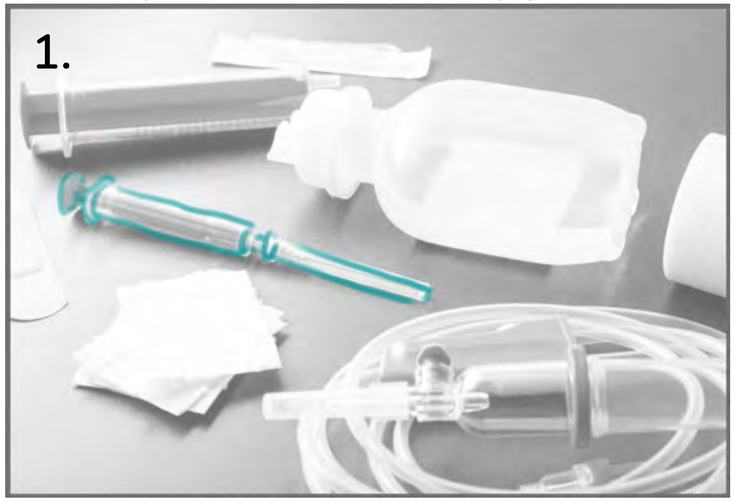


repeat steps 7 - 10 depending on number of necessary fires.
- specific to the endocutter

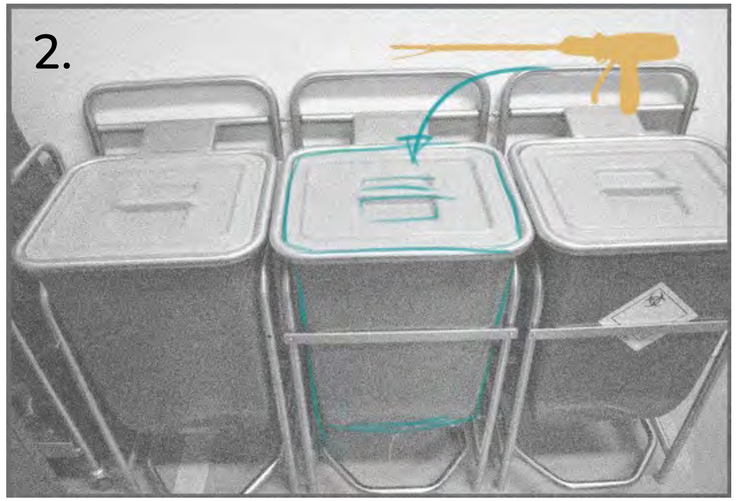


4. Disposal

Single-use devices still exist (needles for example). The SUD waste stream is however expected to have decreased drastically by 2030.



Used SUDs are disposed of through the infectious waste stream

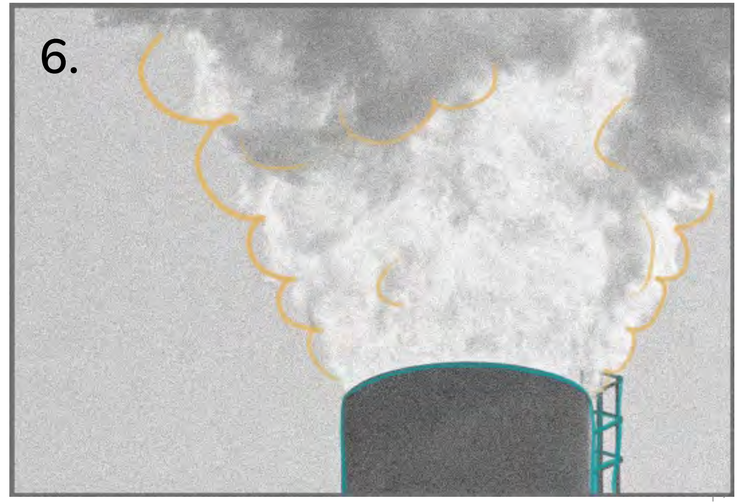


After surgery the waste bin is sealed

The waste bin is transported to waste management area inside the hospital

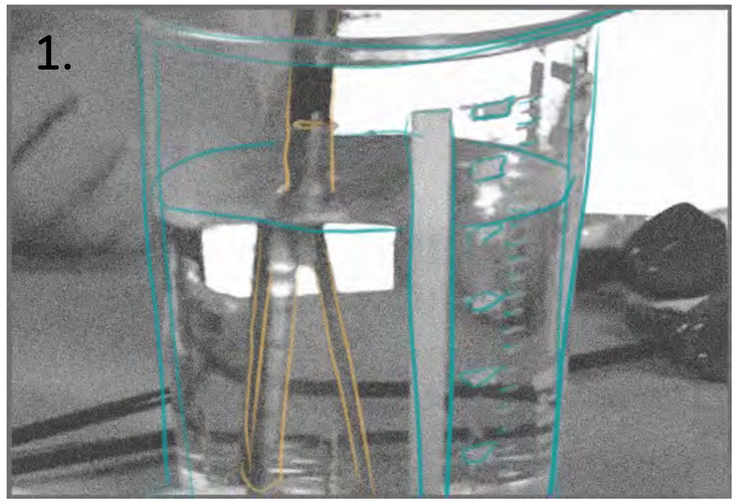
When a container is filled with contaminated waste bins, it is transported to Zavin (Dutch contaminated waste processor)

At Zavin the sealed boxes are incinerated, energy is recovered.

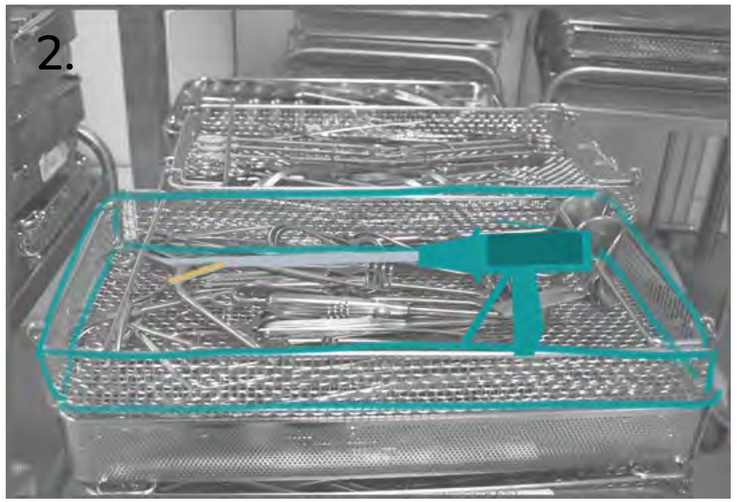


5. Reverse logistics

All the (semi-)reusable devices are after use cleaned with a mild disinfectant to remove most of the blood.



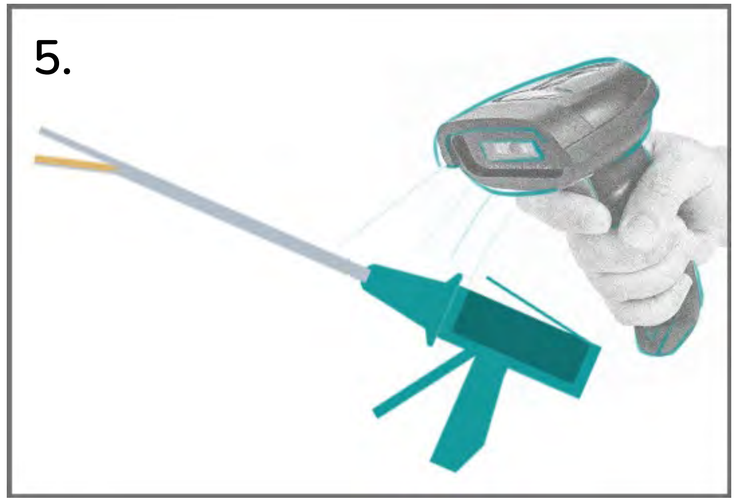
All the (semi-)reusable devices are after use put back into their nets inside the OR



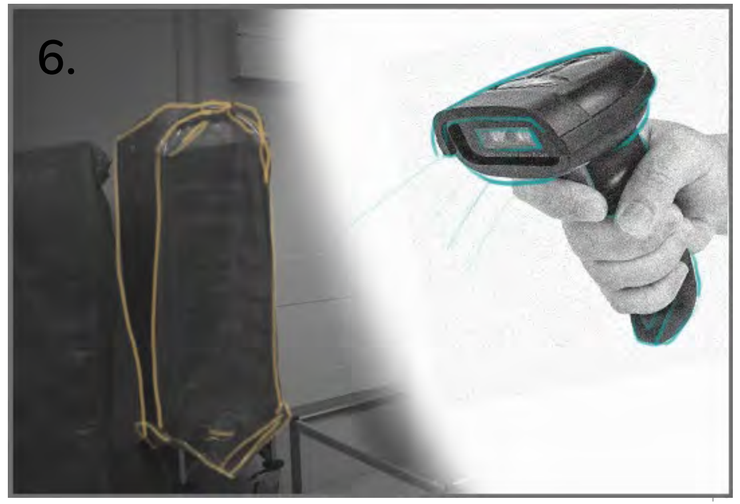
If there is anything wrong with a device the surgeon takes a note of that by naming the device and its fault out loud. - no need to touch anything

MedFlo's platform uses voice recognition to connect the surgeon's comment to the device's product passport

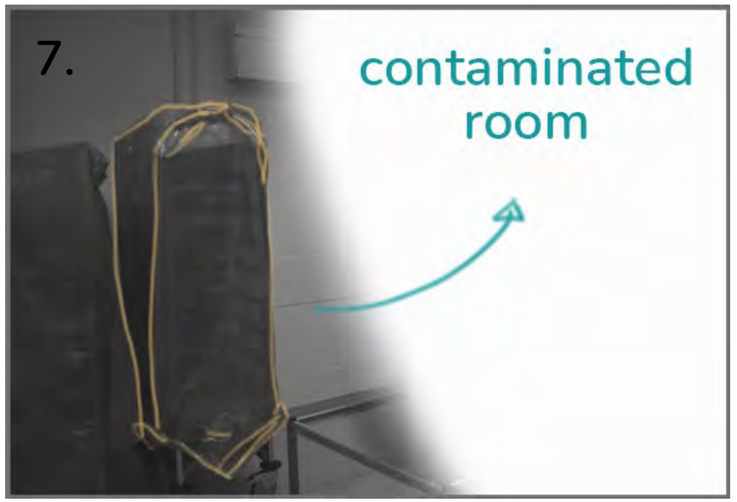
Nets are scanned to mark them as used devices for collection by MedFlo



Carts are covered up and scanned to mark which nets are in the cart.

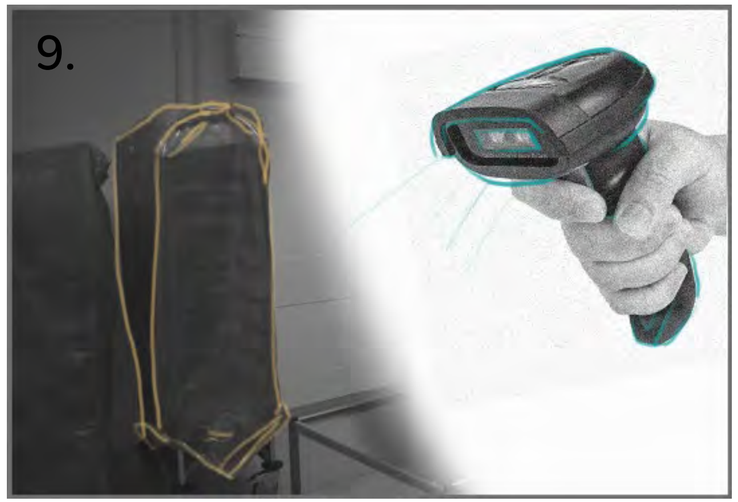


Carts are moved to a dedicated room for contaminated devices



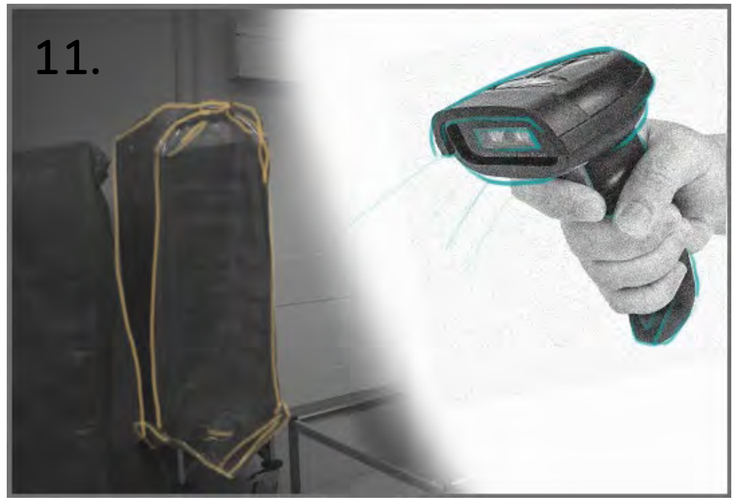
Once a day the used devices are collected by MedFlo, with the same truck the reprocessed devices arrive at the hospital.

All the carts placed in the truck are scanned to confirm them as collected.



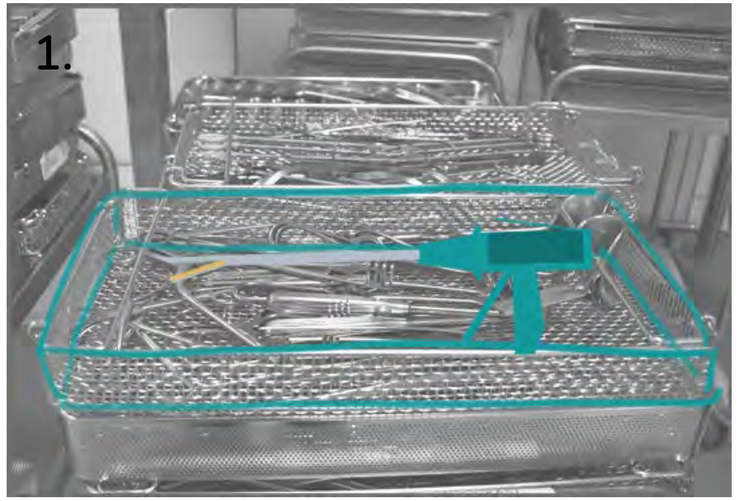
The devices are transported to the MedFlo reprocessing facility in Utrecht

At arrival the carts are scanned again

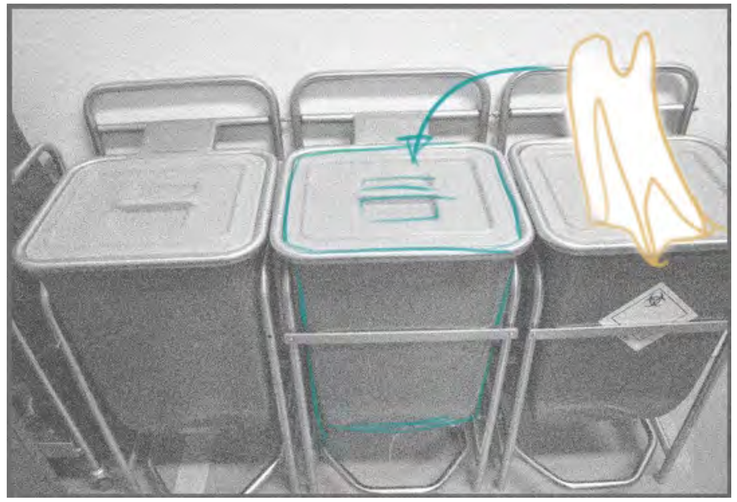


6. Reprocessing part 1

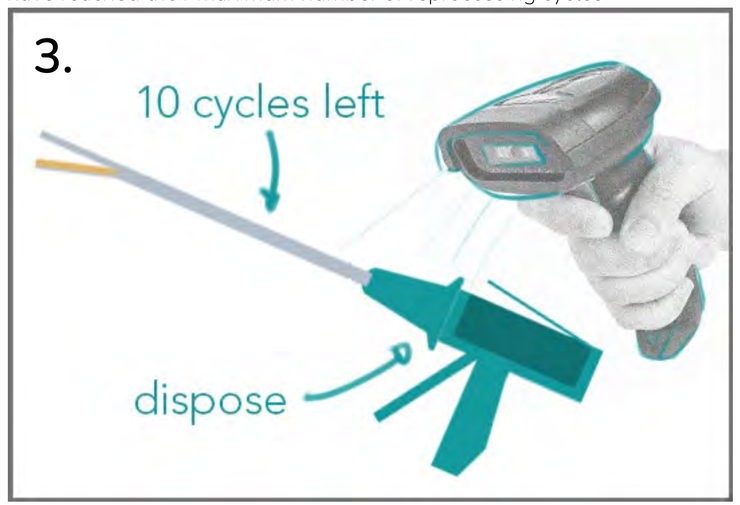
Nets are removed from the carts in a dedicated contaminated room.



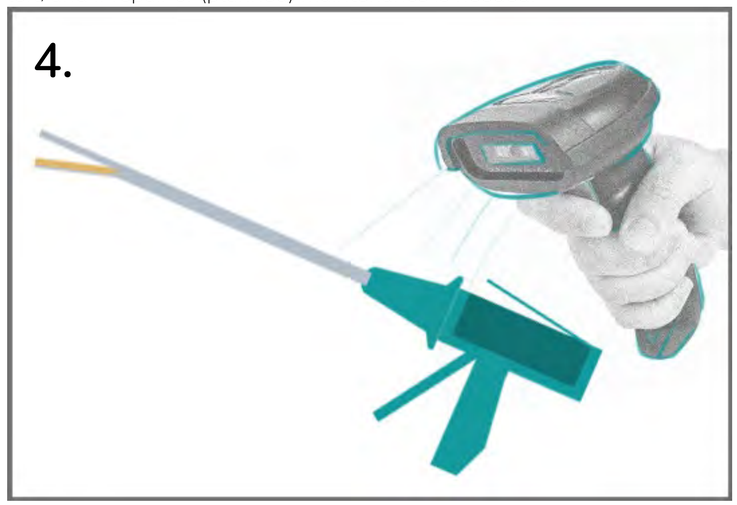
the bag used to cover the cart is placed in the infectious waste bin.



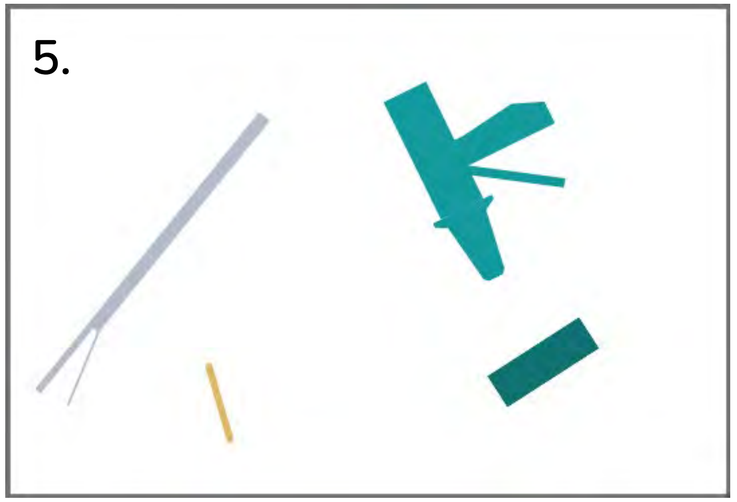
The product passport can show components that cannot be cleaned or have reached their maximum number of reprocessing cycles.



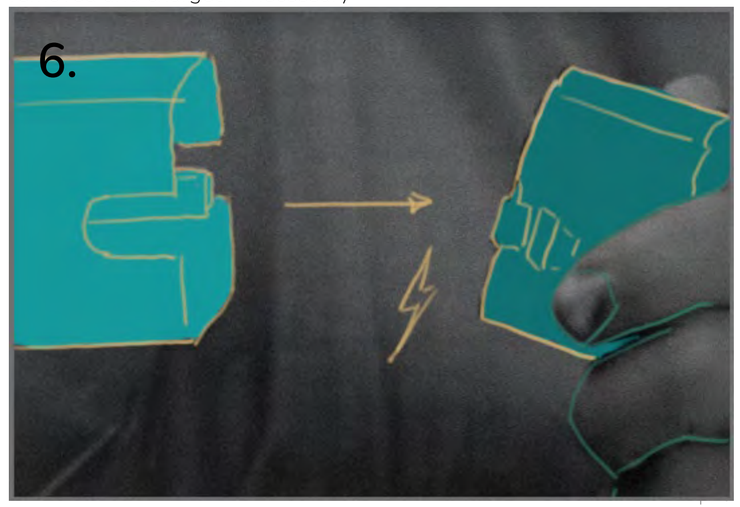
The product passport shows the number of cycles each component has left, and if repair or (planned) maintenance is needed.



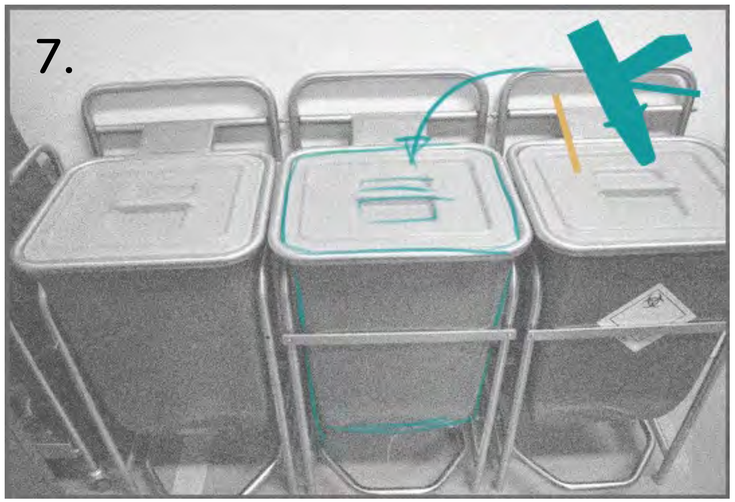
Devices are disassembled for manual cleaning



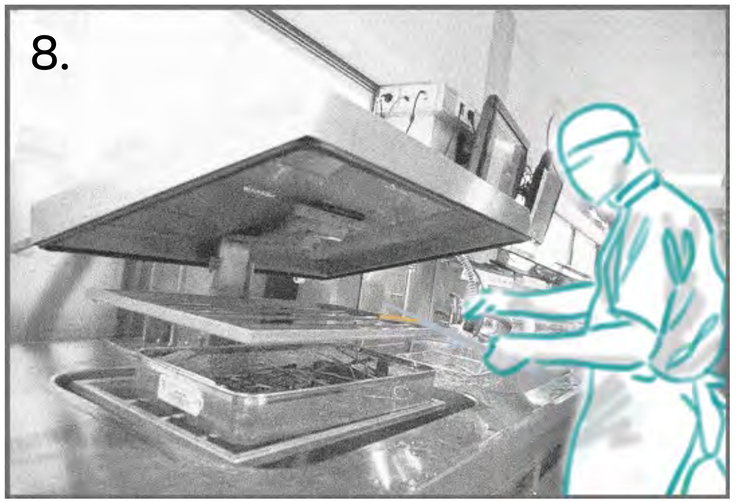
batteries (or other non reprocessable but reusable components) are removed and charged if necessary



components marked as single-use or which have reached their maximum reprocessing cycles are placed in an infectious waste bin.

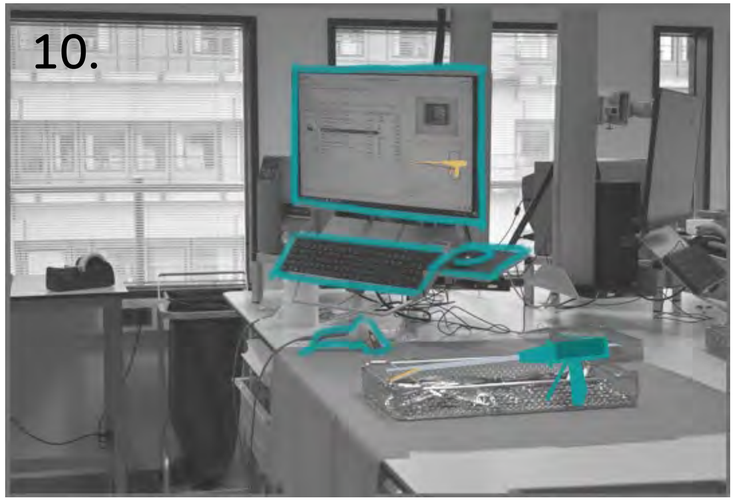


Other components are cleaned manually.

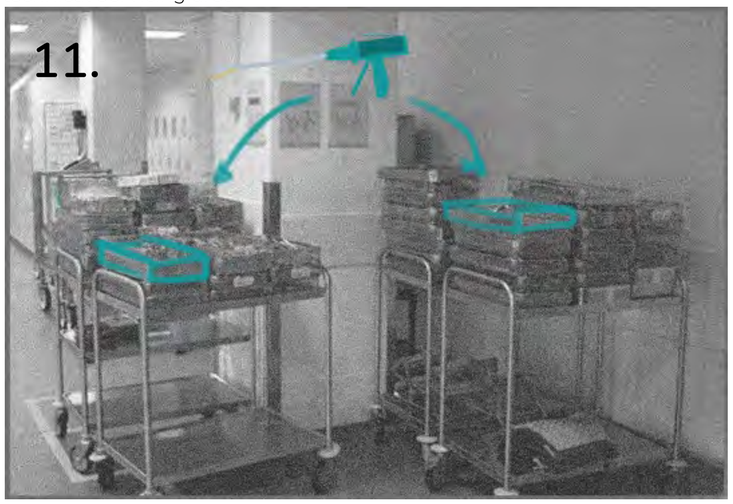


components that do not need to be repaired are put into washing machine set 1 for machinal cleaning and disinfection.

Disinfected parts are thoroughly checked and scanned

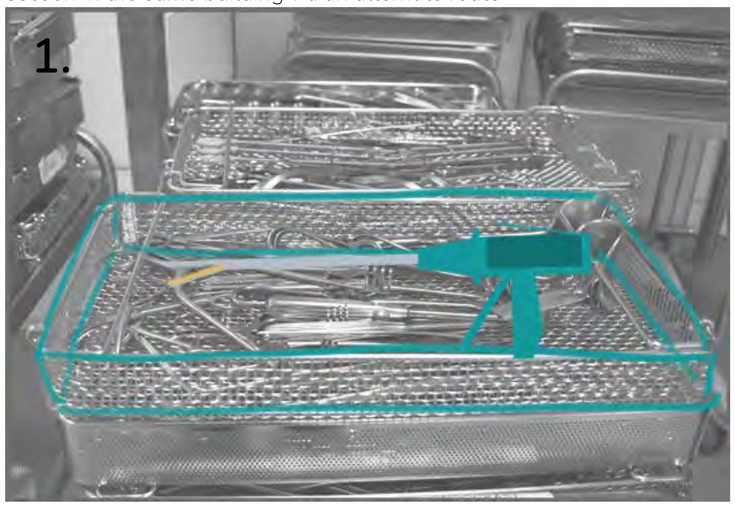


If there are any faults not noticed before, the parts are moved to the technical servicing area



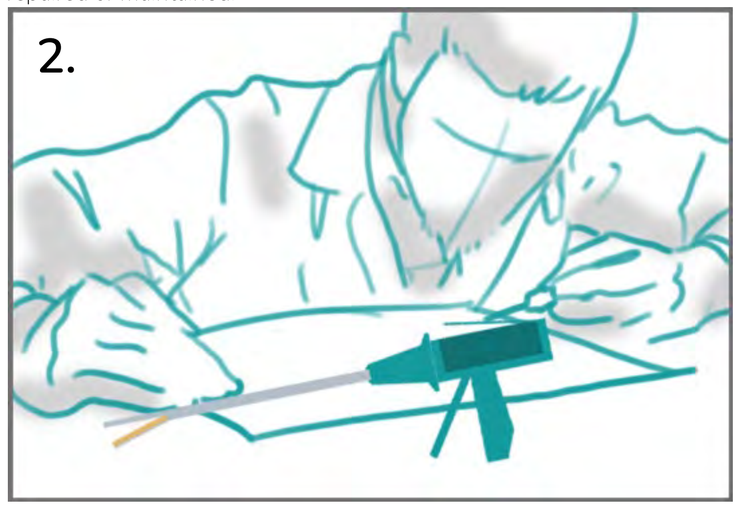
7. Repair and maintenance

Nets set aside for repair and maintenance are moved to a technical service section in the same building via an alternate route



These devices are put into washing machine set 2 for machinal cleaning and disinfection which takes them to technical servicing area.

Depending on the issue the device (or specific modules or parts) are repaired or maintained.

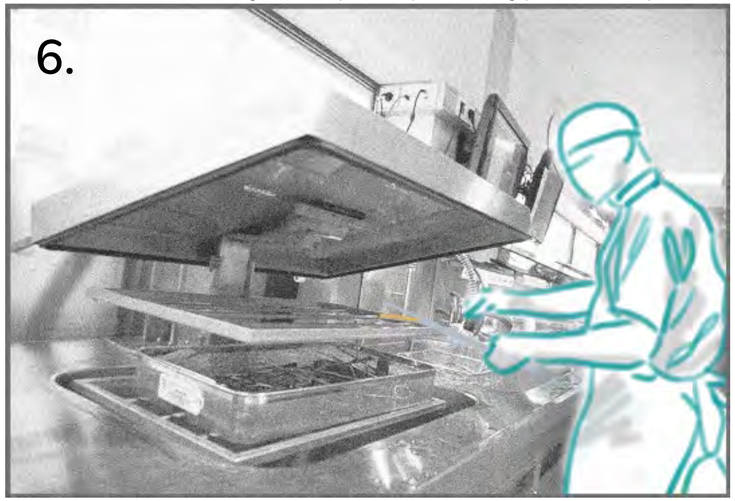


In the product passport, notes about all the parts are stored for future cycles.

MedFlo purchases spare parts from OEMs, this makes repair and maintenance on a higher level possible.

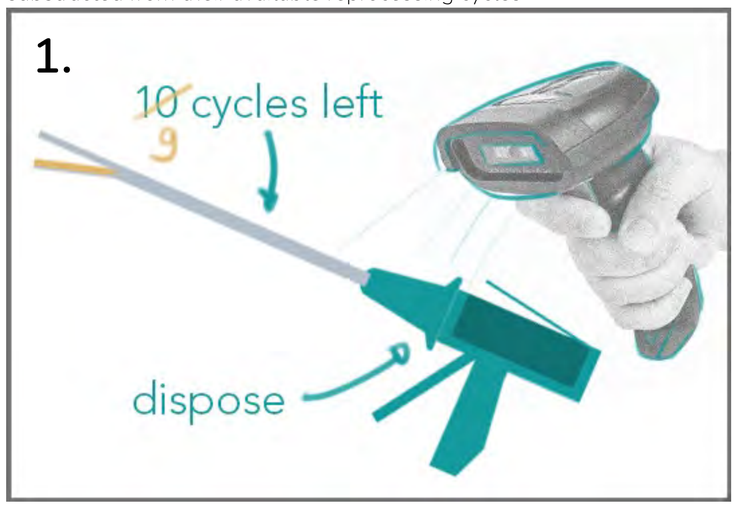
If a part is too damaged for repair, it can be recycled.

After repair and maintenance, the nets are brought back to the contaminated room for manual cleaning, the steps in reprocessing part 1 are repeated.



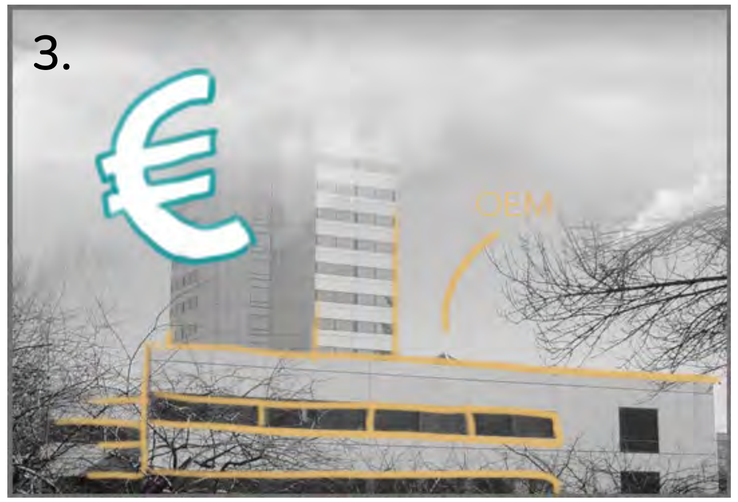
9. MedFlo inventory

reprocessed parts or modules are marked in the system --> one cycle is substracted from their available reprocessing cycles

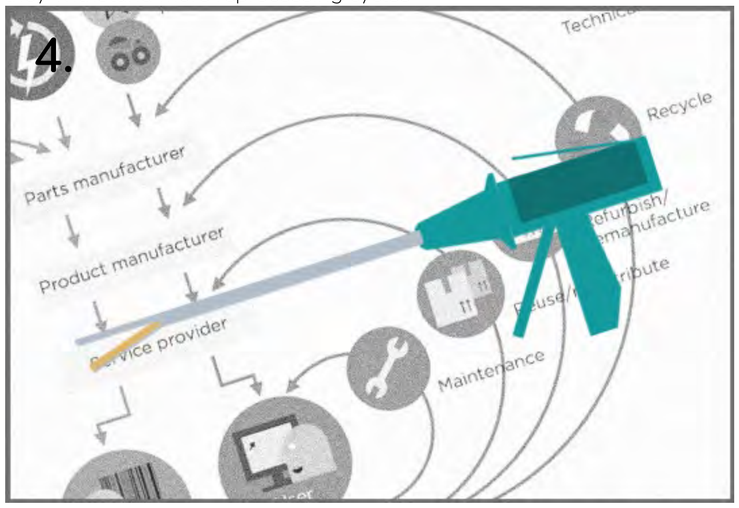


If there is nothing wrong with a component, it is stored in MedFlo's inventory

Medflo has contracts with different OEMs and purchases parts, modules and new reusables from these selected OEMs.



MedFlo values circularity in devices, because they are more valuable if they withstand more reprocessing cycles



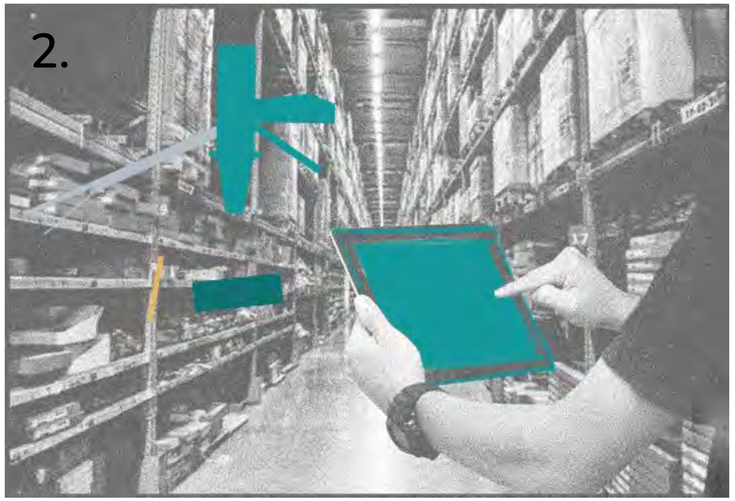
The scale of MedFlo provides incentive for OEMs to keep innovating on circularity in their devices.

When new reusables arrive they first go through an entire reprocessing cycle before being stored in MedFlo's inventory

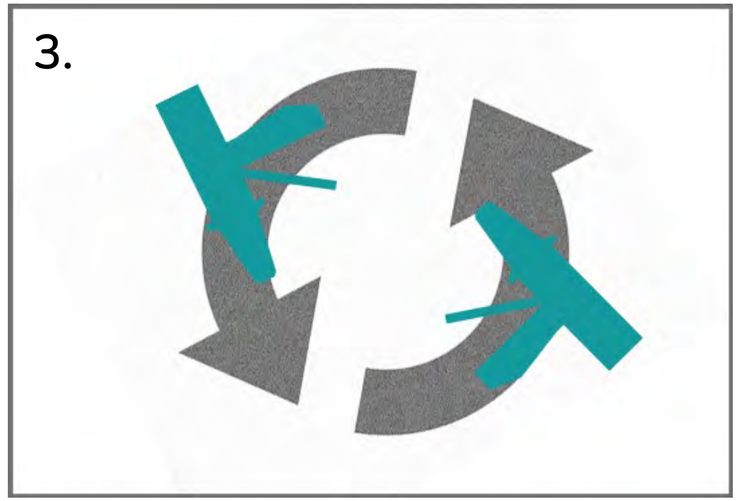
8. Order picking

MedFlo receives updates from hospitals on necessary nets for the next day, and can continuously work to assemble hospital orders

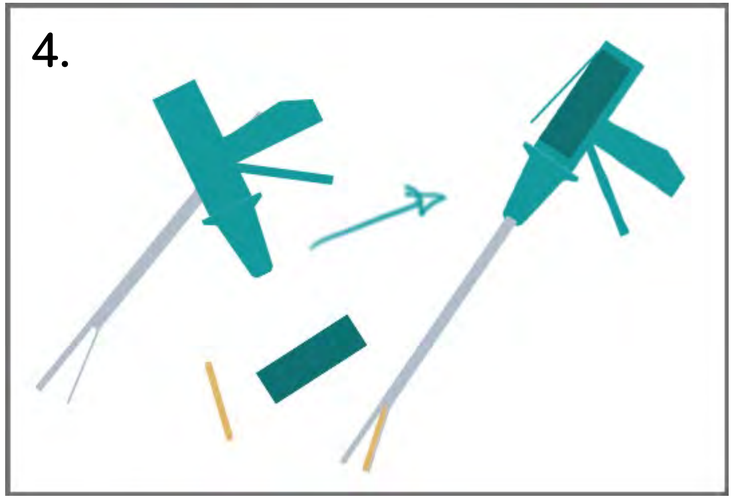
When an order for a net appears, the different necessary components are gathered from the inventory



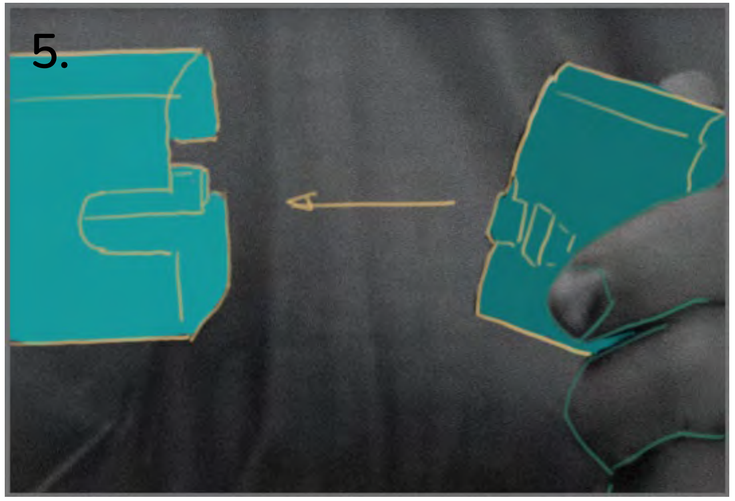
Some components have been through multiple cycles, some are new



Devices that consist of multiple modules are reassembled

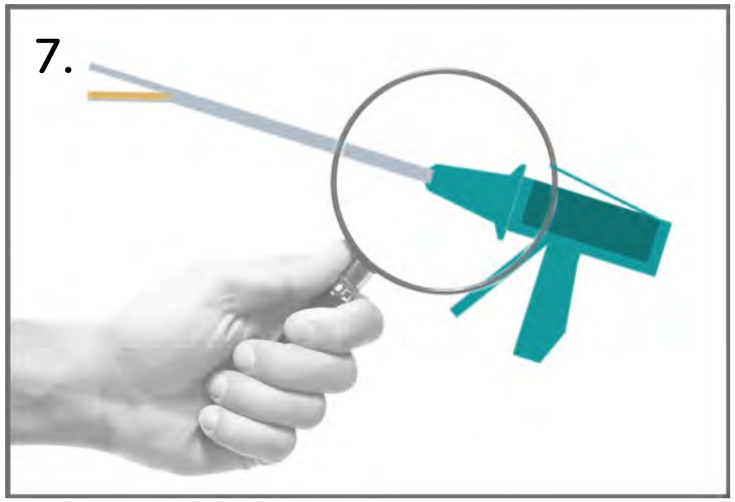


If the device contains batteries that can withstand sterilisation processes, charged batteries are inserted.

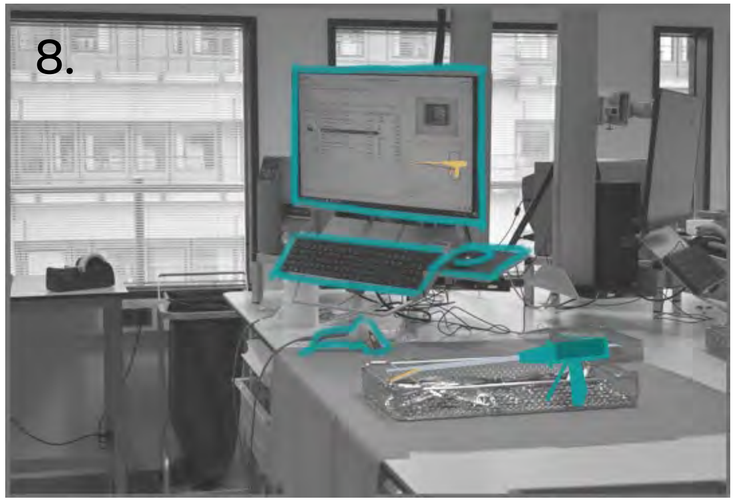


A new product passport is made for the combination of modules, information on each separate module is saved as well.

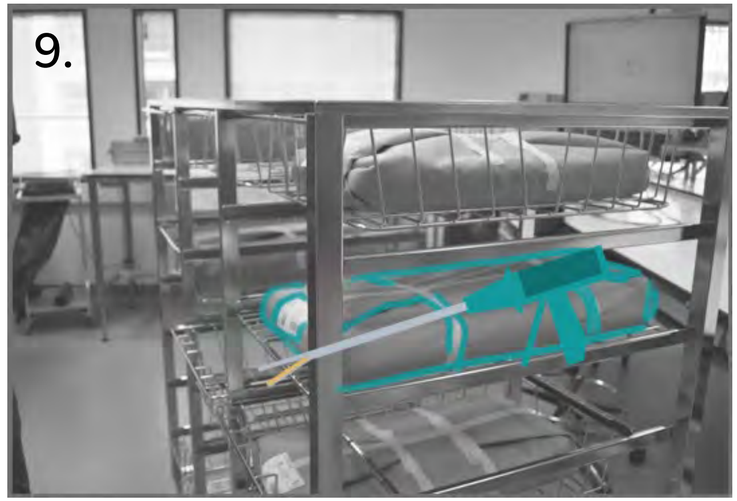
The device is checked one last time, does everything work?



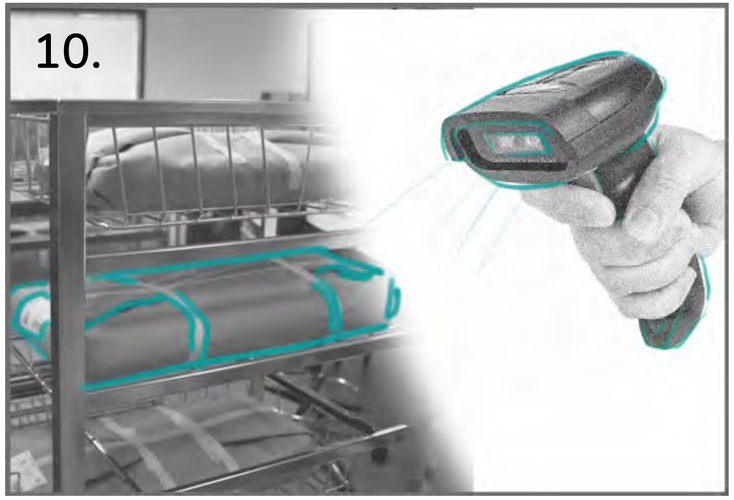
Devices are sorted in their nets.



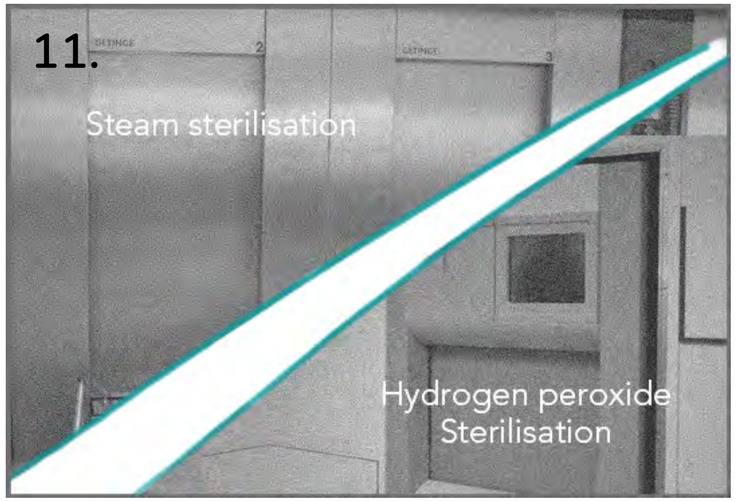
Nets are packaged in blue PP wrap and scanned



Nets are placed in carts, the carts are scanned to mark their contents.

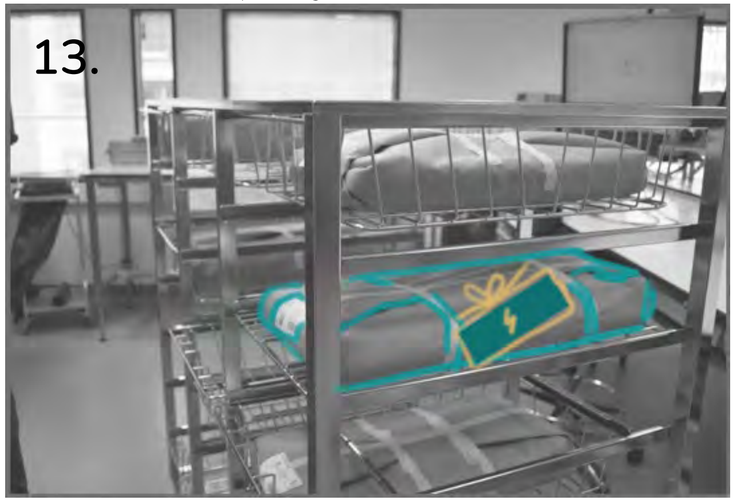


carts are sterilised using steam or hydrogen peroxide.

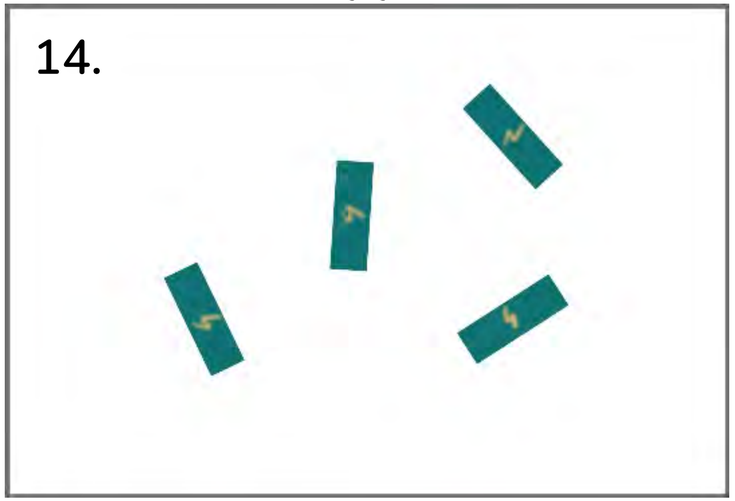


Carts are now stored in a final sterile room, sorted per hospital and ready for pickup.

after sterilisation optional non-sterile modules are attached on the outside of nets with their corresponding devices



this includes necessary charged batteries, MedFlo owns more batteries than devices to allow time for charging



10. Distribution

In the morning, all the carts with nets necessary to replenish hospital stocks are stored in the sterile room ready for pickup.

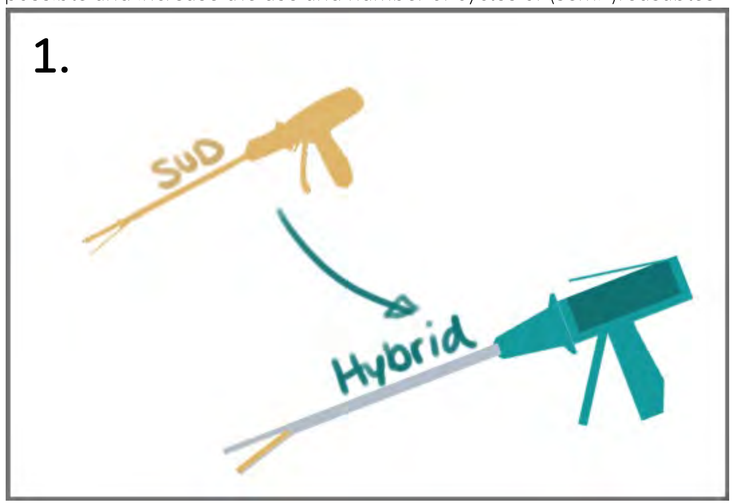
One small electric truck per hospital per day is enough to supply and retreive devices for most hospitals.

Once nets arrive at the hospital, they are scanned again and sorted by hospital staff.

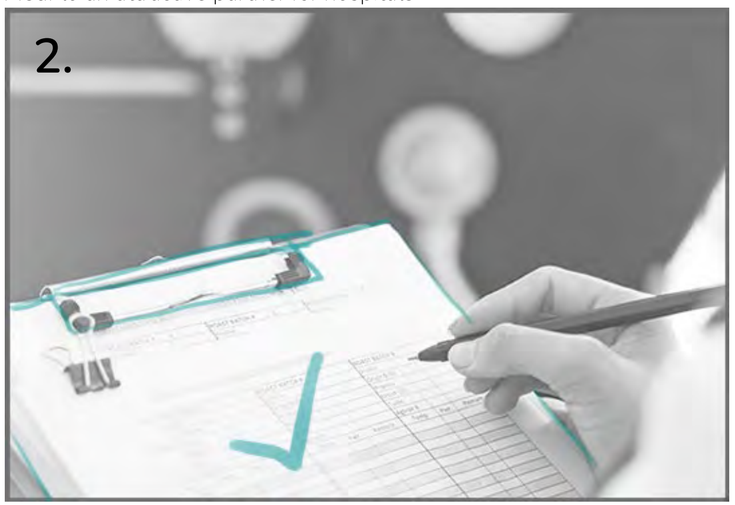
Rush deliveries are possible, these take between 1 and 3 hours - internal reprocessing would require 5 hours.

11. Final notes

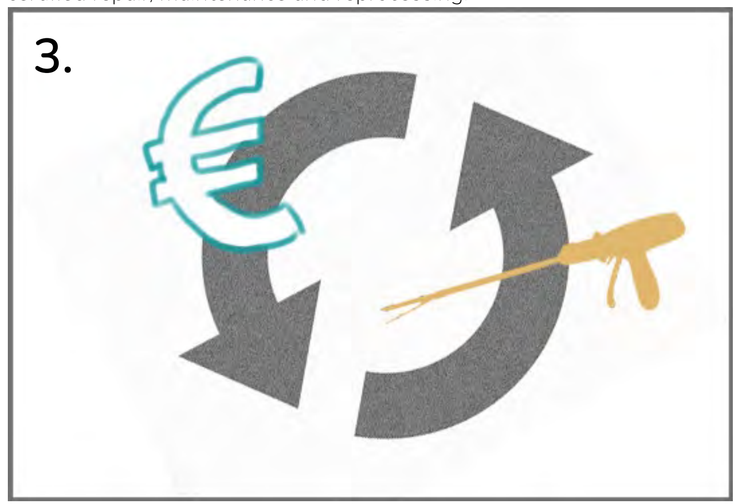
The goal is to reduce the number of SUDs used in the OR as much as possible and increase the use and number of cycles of (semi-)reusables



MedFlo is a certified reprocesser for the collaborating OEMs, this makes MedFlo an attractive partner for hospitals



Hospitals pay for access to clean and safe devices, inventory management, certified repair, maintenance and reprocessing.



MedFlo pays OEMs for new devices and device parts

MedFlo reprocesses and distributes over 4000 nets per day

Main benefits

- MedFlo helps decrease the environmental and waste footprint of healthcare

- MedFlo helps decrease supply chain vulnerability in MedTech

- MedFlo stimulates sustainable innovation

- MedFlo creates local jobs

For hospitals

- They are working with a certified reprocessor

- Simplified value chain. this allows focus on their core business (stock management is sorted, repair and maintenance are centralised and sustainability is taken into account)

- Reprocessing by MedFlo is faster than internal reprocessing

- They are supported in a transition away from single-use devices

- There are no big investments needed for a sterilisation department or own device stock

For OEMs

- They save on EPR costs because of advanced repair and maintenance

- MedFlo is a partner instead of a competitor like most third party reprocessers.

- A contract with MedFlo means selling devices on a larger scale compared to contracts with individual hospitals. They also keep selling devices and parts to MedFlo for the duration of the contract.

Main drawbacks

For hospitals

- Working with MedFlo is probably more expensive compared to managing reprocessing internally (?). This might shift when devices become even more complex and SUDs become more expensive.

- Hospitals do not get to choose the brand of devices they use entirely freely, they have to pick between collaborating OEMs

- There are some more actions needed around the use of devices (battery placement, pre-transport cleaning)

For OEMs

- They need to change their business model - move away from SUDs

- They need to compete for bigger contracts

- A redesign of their devices is necessary

Appendix 7. calculations MedFlo

	waarde	
Service Schaal		
aantal ziekenhuizen NL	74	ziekenhuizen
percentage ziekenhuizen dat meedoet	50%	
aantal ziekenhuizen die meedoen	37	ziekenhuizen
gemiddeld aantal OKs per ziekenhuis	12	OKs
aantal netten LUMC per jaar	70000	netten
aantal operaties LUMC per jaar	12000	operaties
Aantal netten gemiddelde ingreep LUMC	5,8	netten
Aantal operaties per OK per dag	1,6	operaties
Aantal netten per dag per gemiddeld ziekenhuis	115	netten
Aantal netten per dag per klein ziekenhuis	58	netten
Aantal netten per dag per groot ziekenhuis	211	netten
aantal netten per dag LUMC	192	netten
Aantal netten die totaal binnenkomen elke dag	4258	netten
Transport		
hoeveel netten passen er in een kar	10	netten
karren per dag per gemiddeld ziekenhuis	12	karren
karren per dag per klein ziekenhuis	6	karren
karren per dag per groot ziekenhuis	21	karren
lengte kar	1	m
breedte kar	0,5	m
lengte vrachtwagen	4,2	m
breedte vrachtwagen	2,2	m
aantal karren in de lengte	4	karren
aantal karren in de breedte	4	karren
aantal karren max in vrachtwagen	**18**	**karren**
Afstand verste ziekenhuis van MedFlo	210	km
afstand gemiddeld ziekenhuis van MedFlo	84	km
tijd gemiddeld transport	60	min
tijd langste transport	135	min
tijd order picking en in en uitladen	30	min
Maximale duur spoedlevering	**165**	**min**
gemiddelde duur spoedlevering	**90**	**min**
Voorraad		
gemiddelde voorraad in ziekenhuizen nu	1750	netten
nodige voorraad in ziekenhuizen	1634,932	netten
duur sterilisatie instrument	6	uur
duur reparatie instrument (+ extra deel sterilisatie)	4	uur
totale voorraad in ziekenhuizen aanwezig	60492,47	netten

opmerking

https://nl.wikipedia.org/wiki/Lijst_van_Nederlandse_ziekenhuizen
gok iets hoger omdat er ook nog onafhankelijke klinieken zijn (voor bijvoorbeeld maagverkleiningen)

https://nl.wikipedia.org/wiki/Operatiekamer (tussen de 6 en 25 Ors)
input van anne
input van anne

LUMC (20 Oks) heeft vrij lange operaties vergeleken met perifere ziekenhuizen, maar gebruikt ook meer net

dit is een check --> zit dus ongeveer goed

van foto LUMC

van foto LUMC
van foto LUMC
https://www.bta-international.com/nl/informatie/afmetingen-vrachtwagens-trailers/ --> bakwagen
https://www.bta-international.com/nl/informatie/afmetingen-vrachtwagens-trailers/ --> bakwagen

ik ga ervanuit dat karren niet gestapeld worden --> naast elkaar gezet
(op de heenweg moeten dus ook SUDs mee)
MedFlo zit in utrecht, verste ziekenhuis is Ommelander Ziekenhuis Groningen
aanname; gemiddeld ziekenhuis zit op 0,4 x afstand verste ziekenhuis

70% van de voorraad van LUMC (dat is wel een groot ziekenhuis) - ik ga er vanuit dat er dan ook meer (semi·
instrumenten in reprocessing tellen niet meer mee
langer dan nu omdat instrumenten gemiddeld complexer worden

Conclusie

input
output

ten per operatie. Komt dus waarschijnlijk ongeveer gelijk uit

alleen de grootste ziekenhuizen hebben misschien niet genoeg aan 1 bakwagen per da

dit is dus een stuk sneller dan internal reprocessing- dat duurt ongeveer 5 uur

-)reusables zijn, dus ook meer netten

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: van Dolderen
initials: D. C. given name: Dorien
student number: 4541294
street & no.:
zipcode & city:
country:
phone:
email: dv

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

IDE master(s): ★ IPD ☐ DfI ☐ 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: Conny Bakker dept. / section:
** mentor: Jan-Carel Diehl dept. / section:
2nd mentor: Kenneth Robertshaw
organisation: Ethicon
city: London country: United Kingdom

comments (optional): JC Diehl specializes in medical design and has a lot of contacts in different hospitals, while Conny Bakker is an expert in circular product design. The combination seemed perfect for my supervisory team and fit my project brief.

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 _____ date 13 - 09 - 2022 signature _____

CHECK STUDY PROGRESS

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

Master electives no. of EC accumulated in total: 36 EC

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

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

★ YES all 1st year master courses passed

○ NO missing 1st year master courses are:

name C. van der Bunt date 16 - 09 - 2022 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

- explanation team members same section is missing

comments

name Monique von Morgen date 20 - 09 - 2022 signature _____

Initials & Name D. C. van Dolderen Student number 4541294

Title of Project A redesign of the single-use endocutter for circularity

A redesign of the single-use endocutter for circularity 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 13 - 09 - 2022 14 - 02 - 2023 end date

INTRODUCTION **

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

Full title:
"A redesign of the single-use endocutter for circularity – An analysis of the current challenges for the implementation of circular business models on surgical devices."

The medical industry is one of the most polluting industries in the world, with the climate footprint of the healthcare sector being equivalent to 4.4% of global net emissions. (Karliner et al, 2020)

This graduation project is a part of the EU funded DICE (DIgital health in Circular Economy) project; a project with the goal to innovate on the circularity of digital health devices as a way to enable a circular transition. Within the DICE project four digital health devices will be redesigned for improved circularity, and will serve as an example for the industry. One of these devices is an endocutter designed by Ethicon, a company underneath the Johnson & Johnson umbrella, which will be the focus of my graduation project.

Endocutters are surgical instruments used in laparoscopy, a type of minimally invasive surgery. In this type of surgery the techniques and instruments used are less harmful to the body compared to open surgery, generally patients need a shorter recovery time and experience less pain after laparoscopic surgery compared to open surgery. An endocutter can be used to cut tissue and seal it with the use of rows of tiny staples, all through a small incision. Currently endocutters are only used once before they are discarded for the sake of patient safety.

The main stakeholders in this project are Johnson & Johnson and Ethicon, but the project is aimed towards setting an example for the whole medical industry.

Karliner, J., et al., Health care's climate footprint: the health sector contribution and opportunities for action. European Journal of Public Health, 2020. 30: p. 165-843.

space available for images / figures on next page

introduction (continued): space for images

image / figure 1: Ethicon Laparoscopic Endocutter (ECHELON FLEX ENDOPATH stapler)

TO PLACE YOUR IMAGE IN THIS AREA:

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

PLEASE NOTE:

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

image / figure 2:

PROBLEM DEFINITION **

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

Endocutters are currently designed to be single-use only. Moving away from this linear model is complicated because of potential safety risks to patients. It's also regulatory very complex because of for example medical regulations, waste regulations and hospital policies and logistics. It is a challenge to identify the best and most impactful measures to take when the aim is to redesign for circularity, and there is no clear overview of the options as well as their benefits and drawbacks.

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.

I aim to deliver a conceptual redesign of the endocutter, either in the form of a product or of a product-service combination. The concept will show the best approach to make high value single use surgical devices more circular and sets an example for the redesign of a whole category of medical products.

This project should not just benefit Ethicon and Johnson & Johnson, it should set in motion a systematic change in the healthcare industry. Endocutters are part of a product category of high value Single-Use medical Devices (SUD's) meant for surgery. A new approach to circularity in an endocutter could possibly be implemented in many similar products as well.

I aim to make a visual overview of the different possible recovery pathways for (parts of) the device, figure out the different barriers and opportunities that arise within each pathway and elaborate on the best course of action in the case of the endocutter. I will also look into the endocutter from a materials and recovery perspective and generate an understanding of the limitations of the current design in relation to different recovery pathways.

Together, an understanding of the recovery pathways and of the current product give me a starting point for the redesign of the endocutter. I will develop multiple concepts, and this design process will show me the barriers that are currently in place through tangent examples.

Initials & Name D. C. van Dolderen Student number 4541294

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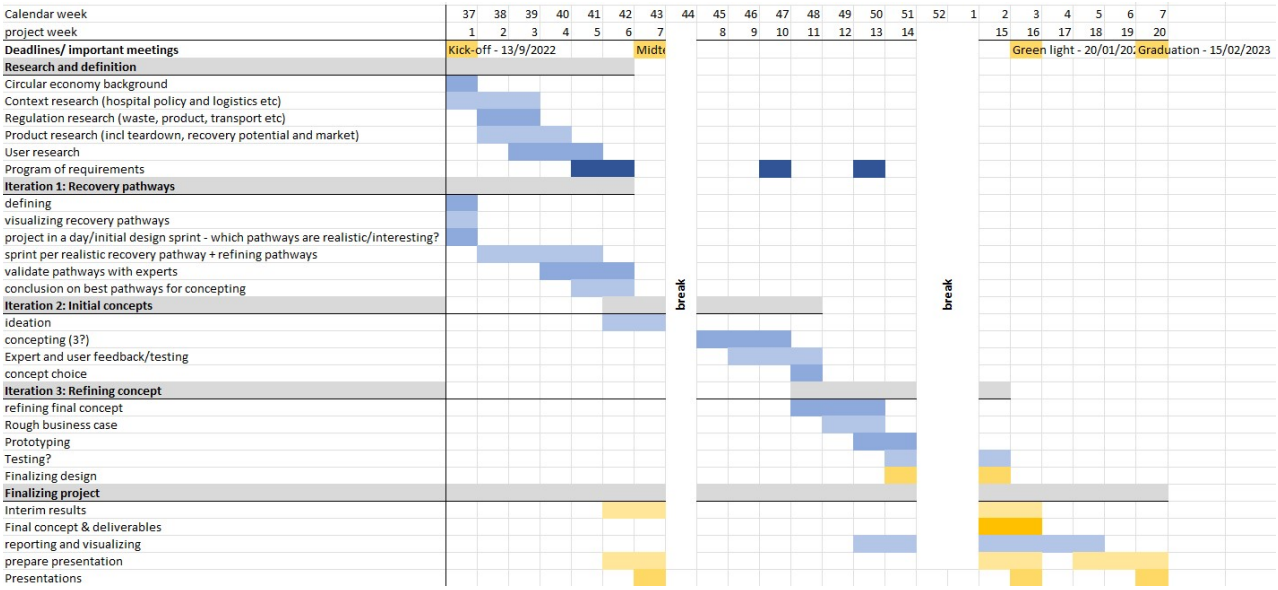
PLANNING AND APPROACH **

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 13 - 9 - 2022 14 - 2 - 2023 end date



Kick-off: 13/09/2022
Midterm: 28/10/2022
Green light: 20/01/2023

I will start my project by defining the different possible recovery pathways for the endocutter, and will do a design sprint where i go through my entire project in the first week. Here some pathways will be eliminated and in the weeks after I will go through sprints for each pathway that seems realistic. I will find supporting literature on the different scenarios, including other students' master theses on similar topics, and define the opportunities and barriers I find. I aim to interview sources at Ethicon itself but also hospital employees in surgery, logistics, sterilization and (third party) waste management. Parallel to this I will do research on endocutters, hospital context, user behaviour, competitors and (waste/medical device/transport) regulation. I will also dive deeper into the materials and recovery potential of a current Ethicon endocutter. I will then determine the best pathway(s) to further explore according to criteria like:
- How easily can this recovery pathway be implemented in the current OR environment?
- What level of product integrity can be maintained?
- By how much does this pathway extend the current lifespan of the endocutter?
- How much logistical restructuring, third party involvement or new facilities are necessary for this pathway to be realistic?
- How limiting are the legislative barriers that are in place for this pathway?
I will Ideate on the best pathways and present the best pathways and initial ideas during the midterm meeting. After this meeting I will work on three different endocutter concepts. A few weeks before my green light I will choose between these three and continue with the best one, which I will further refine and finally present during my defense.

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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.

My motivation for this project is to work on making a product more sustainable where the most obvious design solutions are not possible, or have big drawbacks. The healthcare sector was my first choice because the focus is and should stay on saving lives, any implementation of the circular economy needs to fit within that frame. This sets some really interesting boundaries and makes a challenging assignment. Medical design is also a field I have been interested in for a while, but I have not had the chance to work on related projects yet. I am looking forward to learning more about the challenges of designing medical instruments, and would like to see if this is the field I want to work in after I graduate.

I also want to learn to break down a complex problem and structure it in a way that is useful and actionable for other parties. I want to show that I can distinguish the importance of different factors, derive realistic design criteria from them and create a valid concept from those criteria.

I have followed some electives on sustainable design and I spent a semester abroad focused entirely on that topic, and I am happy that my graduation project reflects those experiences.

FINAL COMMENTS

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

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