Dorien van Dolderen
student number: 4541294
e-mail: dvdolderen@live.nl
Phone number: +31 623052024

Integrated Product Design
Faculty of Industrial Design Engineering
TU Delft

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Master's thesis

Designing a sustainable transition in the MedTech industry

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

Abstract

This graduation project explored how the circular economy could be implemented for single-use surgical devices like the endocutter. Design for reprocessing appears to be the best strategy, but modular solutions should be considered when reprocessing the entire device is not feasible. The project followed a transition management approach; a sustainable future is envisioned for the industry, and through backcasting a radical but short-term feasible solution is designed which could help us move towards this future. Conceptual service design "MedFlo" helps healthcare facilities overcome barriers in the implementation of modular devices into their workflow and logistics, by providing access to a safe and complete inventory of devices. MedFlo can help decrease the environmental and waste footprint of medical devices, create more resilient supply chains, stimulate circular design initiatives and serves as an example of how the circular economy can be implemented in the MedTech industry.

Preface

This is a master's thesis is written to fulfil the graduation requirements for the Master's degree Integrated Product Design of the Industrial Design faculty at the Delft University of Technology in the Netherlands. I worked on this graduation project full-time from September 2022 to February 2023.

When I was looking for a thesis subject, I knew I wanted to work on a combination of sustainable design and design for healthcare. Often the best course of action when designing circular solutions is simply finding ways a product is no longer needed at all. In healthcare, phasing out products not so straightforward. Medical products can have crucial functions in saving human lives, and we cannot simply choose not to use them. The constraints and complications of circular initiatives that exist in the healthcare sector intrigued me and seemed like a source of great design challenges. After all, aren't limitations an important driver for creativity?

This report will give you a complete insight into my journey from an unknowing student to a (by the time you read this) graduated design engineer with insight into the MedTech industry, the circular economy and the complexity of medical devices. It will show you my vision for a sustainable future, how I think we can get there and what you as a reader, depending of course on your background and function, can do to help us along the way.

Please enjoy,

Dorien van Dolderen

Acknowledgements

I want to thank my supervisors Conny and JC, as well as PhD candidate Tamara, for all the excellent guidance and support during my project and for challenging me whenever I tended to stay in my comfort zone. I could always reach out for feedback or questions, and our meetings gave me great new insights and direction. I also want to thank Kenneth for attending so many meetings, getting me into contact with experts from Johnson & Johnson and bringing great new perspectives and ideas to the table.

On top of that, I want to thank Associate professor Andrés Felipe Valderrama Pineda of Aalborg University Copenhagen for teaching a great course on transition theory and taking the time to proofread parts of my thesis, and Professor Paul Hekkert for helping me understand the VIP method and formulate a clear vision. I also want to thank all the experts from Johnson & Johnson, Philips, AMDR, Prezero, LUMC and Claaf for allowing me to interview them and for giving me new insights and great feedback.

I want to thank my family for the steady support and great questions, and my 15 housemates for providing distractions and entertainment at times whenever I needed a break, and for giving me an audience when I needed to practice a presentation. Finally, I want to thank all the students who work in the silent room on the second floor of the Echo building on the TU Delft campus every single day. I have no idea who you are and what you are working on, but it's great not to work alone and I appreciate the silent peer pressure. Even though I was very happy with your company, I hope I will not see you here again.

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Master thesis
Integrated Product Design
Faculty of Industrial Design Engineering
Delft University of Technology
The Netherlands

Author
Dorien van Dolderen
Student number: 4541294

Graduation Committee
Chair
Prof. dr. ir. Conny Bakker
Faculty of Industrial Design Engineering
Department of Sustainable Design Engineering

Mentor
Dr. ir. Jan Carel Diehl
Faculty of Industrial Design Engineering
Department of Sustainable Design Engineering

Design case
Kenneth Robertshaw
Office of Sustainability | Johnson & Johnson
Design for Sustainability Lead | Ethicon Front End Innovation

part of the DiCE project

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TU Delft

ETHICON
a Johnson & Johnson company

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Glossary

Access model: A business model archetype where instead of a physical product, access to that product is sold to a consumer [1].

Bioplastics: Plastics that (1) are biodegradable, or (2) may or may not be degradable but are produced from biological materials or renewable feedstock [2].

Circular business model: A business model that is closing, narrowing, slowing, intensifying, and dematerializing loops, to minimize the resource inputs into and the waste and emission leakage out of the organizational system [3].

Circular Economy: An economic system that replaces the 'end-of-life' concept with reducing, alternatively reusing, recycling and recovering materials in production/ distribution and consumption processes [4].

Decontamination: A cleaning method which destroys most bacteria [5].

Disinfection: A cleaning method which destroys all micro-organisms except high numbers of bacterial spores [5].

Economies of Scale: Cost advantages experienced by companies as they grow and become more efficient. An economy of scale is realised as a company increases in size and can spread out the cost of production over a larger number of units of a good [6].

End of Life: The life cycle stage when a product reaches the state of obsolescence and therefore, reaches the end of a functional life. The product then becomes waste in a linear economy, but this process can be reverted in a circular economy [7].

Extended Producer Responsibility: An environmental policy approach in which a producer's responsibility is extended to the post-consumer stage of a product's lifecycle [8].

Gap exploiter model: A business model archetype where the leftover value or lifespan of an existing product is exploited [1].

Laparoscopy: A type of surgery for which instead of a large open wound, one or more small incisions are made through which certain instruments and a laparoscope (camera) can access internal tissue [9].

Life Cycle Assessment: A methodology for assessing environmental impacts associated with all the stages of the life cycle of a commercial product, process, or service (also known as Life Cycle Analysis) [10].

Maintenance: Changing parts, cleaning and checking the device at regular intervals [11].

Medical Technology: Application of organised knowledge and skills in the form of devices, medicines, vaccines, procedures, and systems developed to solve a health problem and improve the quality of lives [12].

Obsolescence: A product becomes obsolete when it is no longer considered useful or significant by its user [13].

Product (life)cycle /Loop: The duration of the period that starts at the moment a product is released for use after manufacture or recovery and ends at the moment a product becomes obsolete [14].

Product lifetime: The duration of the period that starts at the moment a product is released for use after manufacture and ends at the moment a product becomes obsolete beyond recovery at the product level [14].

Product Service System: A value proposition oriented to provide satisfaction to customers/users through the delivery of an integrated system of products and services [15].

Recovery: Any operation with the primary aim of reversing obsolescence [14].

Recycling: In recycling the identity and functionality of the product and its components are lost, the purpose is to reuse materials instead of parts from used products and components [16].

Repair: A reconfiguration or replacement of parts to restore a product from functional obsolescence caused by a specific fault [11].

Reprocessing: A process carried out on a used device to allow its safe reuse including cleaning, disinfection, sterilisation and related procedures, as well as testing and restoring the technical and functional safety of the used device [17].

Remanufacturing: The complete rebuilding of a device already placed on the market or put into service, or the making of a new device from used devices, to bring it into conformity with regulation, combined with the assignment of a new life to the remanufactured device [17].

Societal regime: A dominant and stable configuration in a societal (sub)system at the meso level. A regime provides orientation and coordination of the activities of groups and accounts for the stability of the existing socio-technical systems [18].

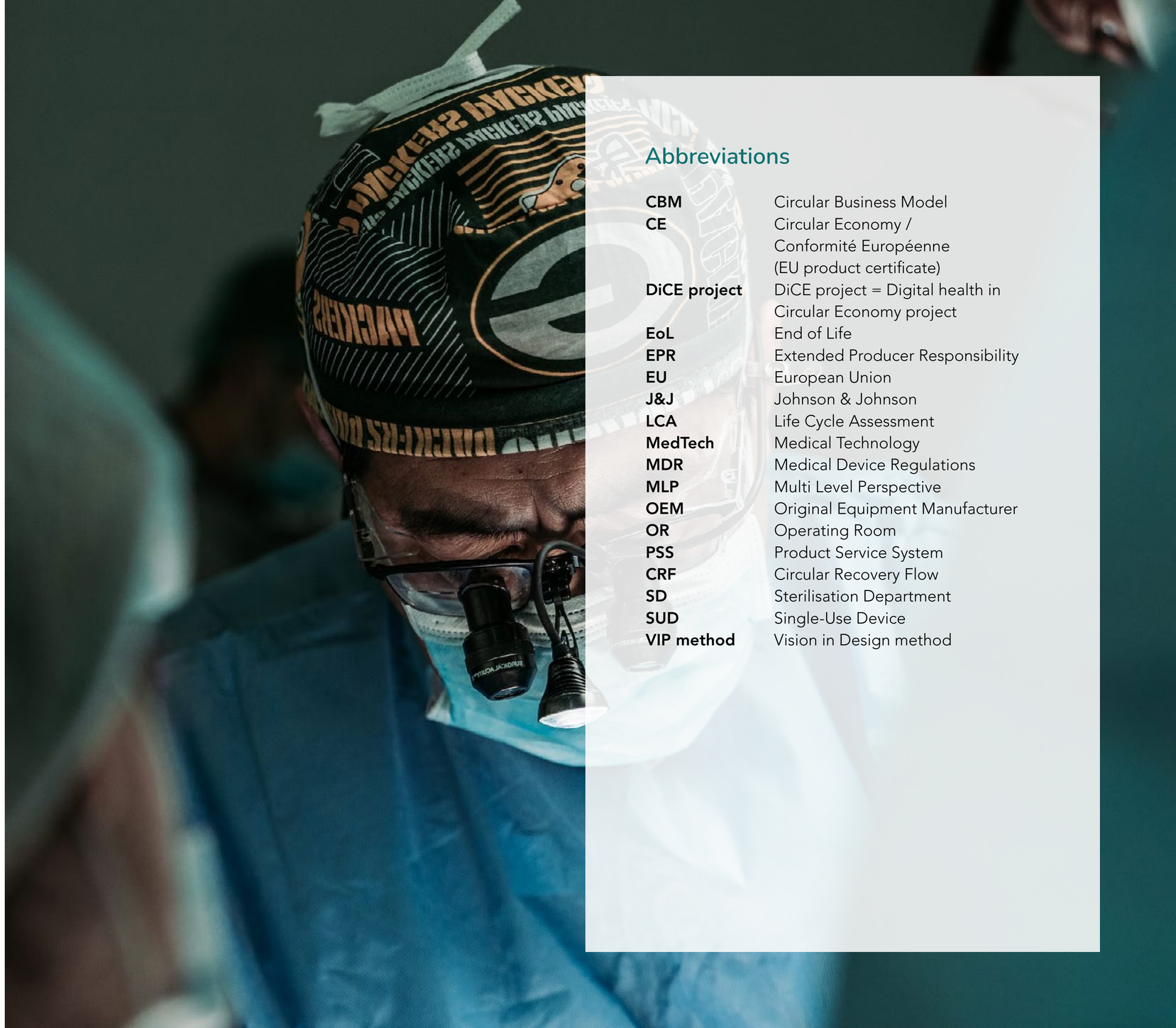
Socio-technical landscape: Material and immaterial elements at the macro level beyond the direct influence of actors [18], [19].

Sterilisation: A cleaning method which destroys all microorganisms [5].

Technological niche: Individual actors and technologies and local practices at the micro level [19].

Transition: A non-linear shift from one dynamic equilibrium to another through a set of connected changes [19], [20].

Waste: Any substance or object that the holder discards or intends or is required to discard [14].



Abbreviations

CBM	Circular Business Model
CE	Circular Economy / Conformité Européenne (EU product certificate)
DiCE project	DiCE project = Digital health in Circular Economy project
EoL	End of Life
EPR	Extended Producer Responsibility
EU	European Union
J&J	Johnson & Johnson
LCA	Life Cycle Assessment
MedTech	Medical Technology
MDR	Medical Device Regulations
MLP	Multi Level Perspective
OEM	Original Equipment Manufacturer
OR	Operating Room
PSS	Product Service System
CRF	Circular Recovery Flow
SD	Sterilisation Department
SUD	Single-Use Device
VIP method	Vision in Design method

Project introduction

This graduation project is part of the EU-funded DiCE (Digital health in Circular Economy) project; a project to innovate on the circularity of digital health devices as a way to enable a sustainable transition. Within the DiCE project, four digital health devices will be redesigned for improved circularity and will serve as an example for the medical technology industry. One of these devices, the endocutter, is the focus of this graduation project. Endocutters are surgical instruments used in laparoscopy, a type of minimally invasive surgery. This device can be used to cut tissue and seal it with the use of rows of tiny staples, all through a small incision. Currently, most endocutters follow a linear (take-make-waste) pattern and are only used once before they are discarded for the sake of patient safety. Figure FIXME shows the barriers to the circularity of a current (linear) endocutter design.

Scope

The main stakeholders in this project are Johnson & Johnson and their subsidiary Ethicon, but the project is aimed towards providing an example for the whole medical device industry and setting in motion a systemic change. Ethicon's ECHELON™+ Stapler (figure 1) is the endocutter analysed as the foundation for this project. However, the aim is not to provide guidelines for a circular redesign of this specific device, but instead to explore possibilities for improvements of a whole category of valuable but critical devices; costly devices which come into close contact with patients and pose a high risk of infection. The hope is that this project helps set in motion or advance a sustainable transition in the MedTech industry.

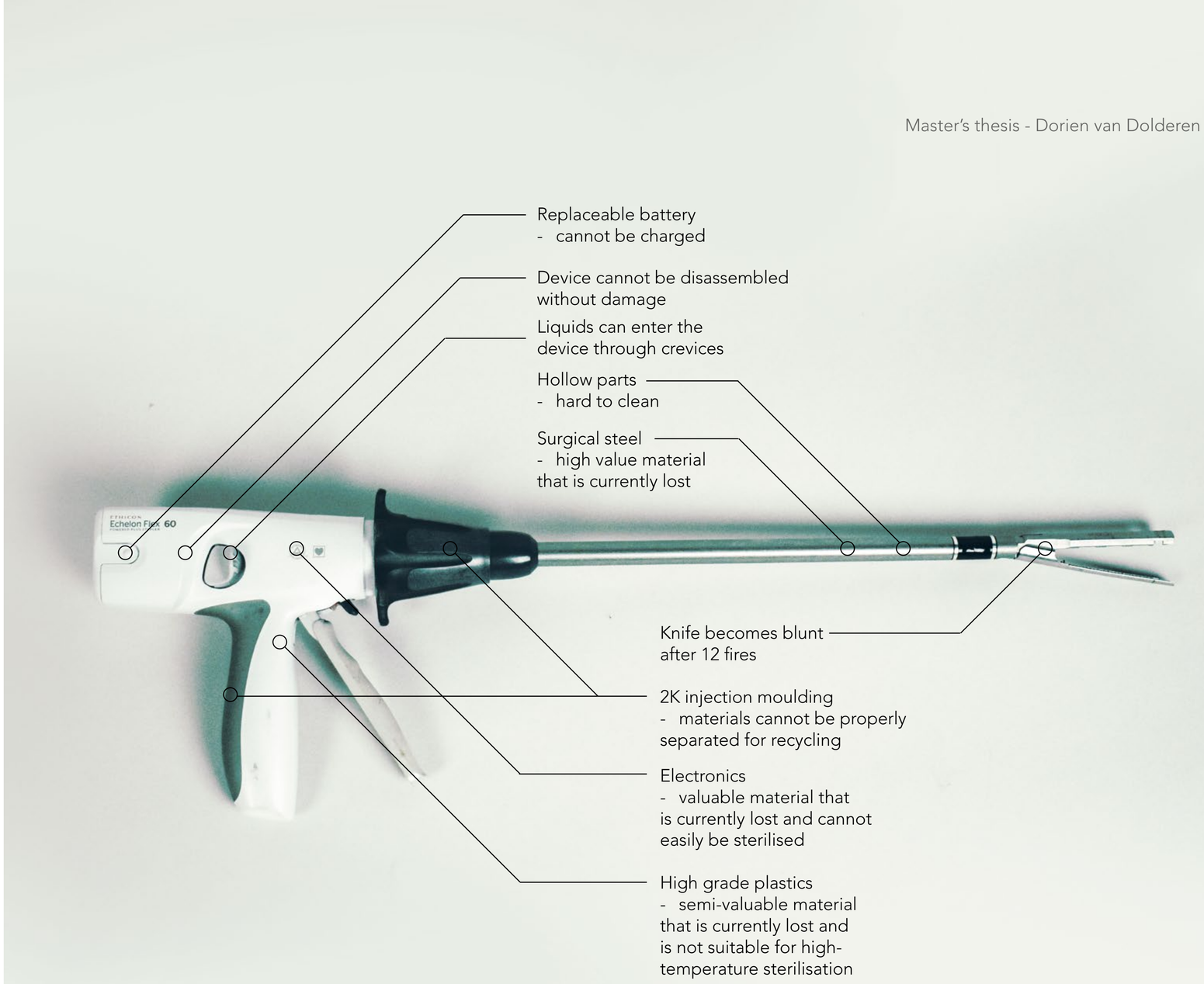


figure 1. *Ethicon's Echelon Flex 60 and current barriers to circularity*

Problem definition

Most endocutters are currently designed to be incinerated after a single surgery. Moving away from this linear model is complicated because of safety risks, as reusing potentially contaminated devices could cause infections and endanger patients. It is also regulatory very complex because of for example the medical device regulations [17], waste (transport) regulations [21]–[24], and hospital policies and logistics. On top of that, manufacturers depend on the continuous sales of single-use devices in their current business models and cannot easily adapt to more sustainable practices.

It is a challenge to identify the best and most impactful measures to take when the aim is to redesign for circularity. Measures can require End-of-Life (EoL) processes with a high environmental impact, complex Product Service Systems (PSSs) that can restrict healthcare activities, or drastic product redesigns which could limit the functionality of the device. Additionally, safety is crucial and the device cannot pose an infection risk to anyone involved.

Currently, there is no clear overview of the possible ways the life of the endocutter can shift from linear to circular, as well as their respective benefits and drawbacks. More knowledge on this subject could help us move towards a more sustainable model, and reduce the environmental and waste footprint of surgeries. This project will cover a design exploration of different possible circular recovery flows of the device in order to advance towards a sustainable future for the MedTech industry.

Aim and research questions

Within this project, different End-of-Life opportunities for the endocutter ¬which could reduce its environmental impact will be identified and explored through both qualitative research and explorative design. The different possibilities are then placed in the perspective of an envisioned sustainable transition in the industry, towards a future in which devices like the endocutter move away from their linear and polluting model. Through backcasting from the envisioned future, a service design is conceptualised which is both feasible on the short term and helps the industry move forward in the right direction. This project can serve as an example for a range of medical devices with similar barriers to circular design or circular business models, and can hopefully be used as a stepping stone for future design studies and projects in this field.

This thesis is guided by the following research questions:

1. What are the different circular paths (Circular Recovery Flows) a medical device like the endocutter could follow instead of its current linear model? And what are their benefits and drawbacks?

2. What could a sustainable transition in the MedTech industry look like? How do I envision the future?

3. How can the different Circular Recovery Flows (CRFs) of the endocutter be used to design an incremental but radical step in the envisioned direction?

The first research questions will be answered through a literature review, expert interviews and design sprints on each possible CRF. The second question will be answered through a visioning process using the Vision in Design (VIP) method [25]. The final question will be addressed through a design process and guided expert interviews.

Transition perspective

This project looks at the problems and developments in the MedTech industry from the perspective of transition theory because this approach can give great insight into the complexity of a problem as big as this one, and what it will take to solve it. A combination of research and design is used as a means to determine how we can shift from an industry dependent on single-use devices to a system based on circular design alternatives. The next chapter will explain transition theory in more detail, and the methodology chapter will elaborate on how it is used to guide this project. Figures 2 and 3 explain how the different sections of this report frame the different phases of a sustainable transition in the MedTech industry.

Part 1 Project background	Explore the system in which the endocutter exists. What are the barriers and opportunities for the implementation of the circular economy? Where are we now?
Part 2 Design sprints	What are the different routes we can follow towards more circular designs? What are their benefits and drawbacks?
Part 3 Envisioning a transition in MedTech	What could a sustainable future look like for this system? What should be the end goal of a transition?
Part 4 Idea generation and selection	What kind of solutions can help us get to this sustainable future? Which should we choose?
Part 5 Designing for a sustainable transition	What is a concrete example of a solution that brings us closer to a sustainable future and helps us advance in a transition?

figure 2. *The focus of report sections on different elements of a transition.*

Reading guide

Part 1: Project background

Where are we now?
what does the present look like?

The present

Part 2: Design sprints

What are the different
routes we can take from here?
Which should we choose?

The present

Part 3: Envisioning a transition in MedTech

A sustainable
future

What could a sustainable
future look like?

The present

Part 4. Idea generation and selection

A sustainable
future

What steps could get us to
that sustainble future?
Which should we choose?

The present

Part 5: Designing for a sustainable transition

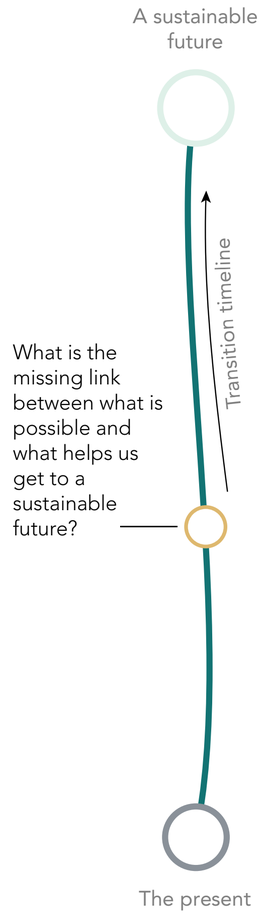


figure 3. *Reading guide - the implementation of transition theory on the planning for this graduation project*

Theoretical framework: Transition theory

Introduction to transitions

A transition is a shift from one dynamic equilibrium to another through a set of connected changes [19], [20]. It is a gradual, chaotic and continuous process of change in which society (or a complex sub-system of society) changes fundamentally. The direction, scale and speed of a transition can be influenced by governments, but cannot entirely be controlled [19]. Transition research aims to better understand transitions and use findings to predict and adapt to unfavourable transitions as well as support and accelerate desired ones [20].

Societal transitions are iterative processes of build-up and breakdown over generations, as visualised in the X-curve framework (figure 4) [20], [26]. The destabilisation and reformation of systems can be seen as a cycle: A new system develops and stabilises, goes into a period of optimisation, and after a few decades destabilises again. A stable regime is not open to change and is unable to deal with persistent internal problems, which makes it unsustainable in the long term. These problems create room for alternative innovations that in turn can contribute even more to the destabilisation of the regime [27].

Breakdown

Dominant cultures, structures and practices develop path dependency and resist any changes that fundamentally challenge the status quo, resulting in 'lock-in'. Path dependency can lead to reduced diversity and adaptability within the system. This is inevitable because of investments, economies of scale and internal regime dynamics [20], [26]. Innovation within a dynamically stable regime still occurs but is only incremental. Because of internal stabilising mechanisms, it is difficult to create radical innovations within socio-technical systems [28]. The dominant system experiences both internal and external pressures and, because of its inability to adapt, will over time destabilise [26].

Build-up

At the same time, alternatives become more attractive [27]. These alternatives are 'transformative innovations' that develop through experimentation in parts of the system shielded from dominant cultures, structures and practices. Innovations mature, develop and learn from each other, and they eventually form strong alternatives to parts of the old regime [20].

Transition

The actual transition is chaotic and disruptive with a sudden loss of security and stability. The system is out of its former balance, and future directions and configurations of the system are uncertain. New combinations of elements and innovations grow into a new regime, while elements of the old regime that cannot transform break down and phase out [20], [26].

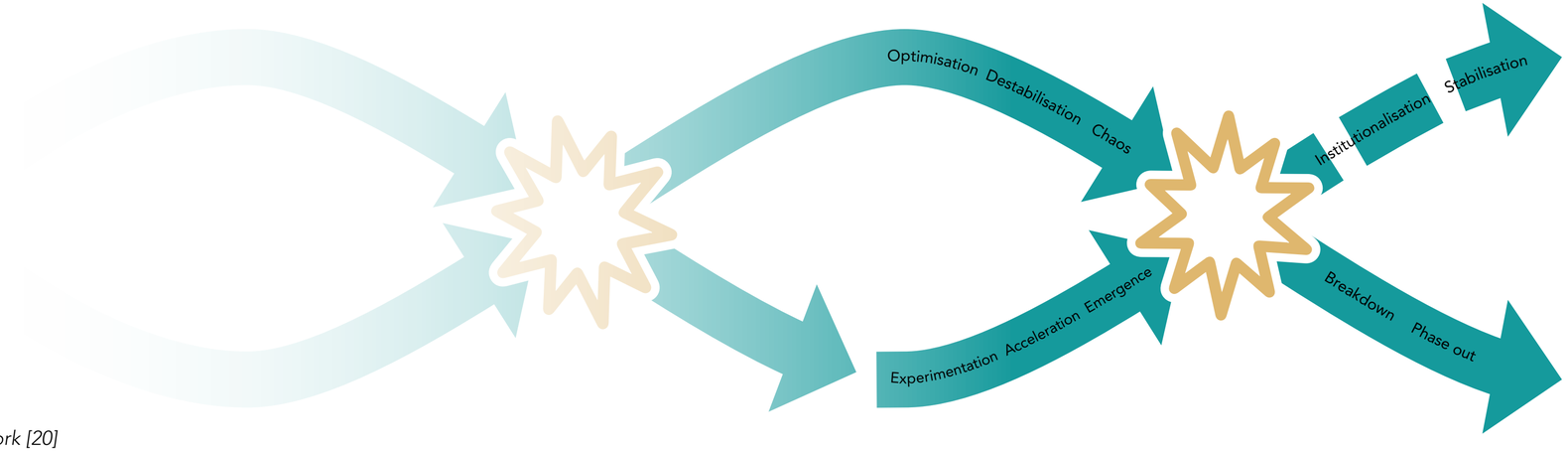


figure 4. *The X-curve framework [20]*

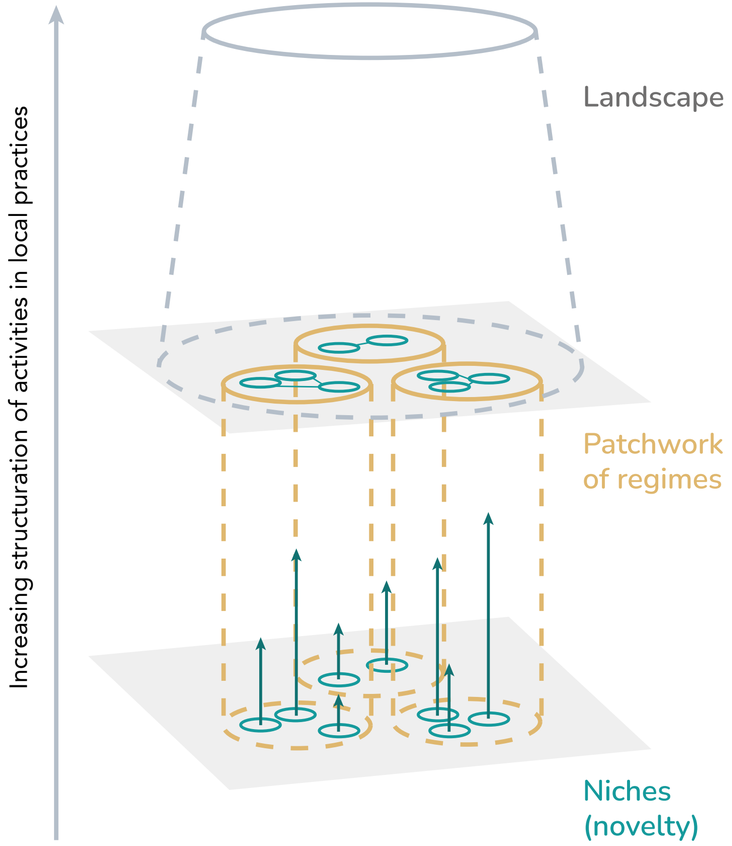


figure 5. *The multi-level model explaining the coevolution between the landscape, regime and niches [29].*

The multi-level perspective

Systemic change is the result of a variety of smaller changes in different domains and at different levels that interact and reinforce each other [20]. Transitions are nested as well; they are part of higher-level transitions and include lower-level transitions. There is an interplay of processes at different levels and there is no one cause for change. Developments shape and relate to each other and all happen simultaneously over longer periods of time [20], [28].

Transition levels

The three levels within the multi-level perspective are the landscape, regime and niches as shown in figure 5.

(Socio-technical) **Landscape** = Material and immaterial elements at the macro level such as infrastructure, political culture, social values and the natural environment [19]. The landscape is beyond the direct influence of actors and cannot be changed at will [28].

(Societal) **Regime** = A dominant and stable configuration in a societal (sub)system at the meso level. Societal regimes are made up of a set of e.g. dominant technologies, institutions, routines and cultures. They provide orientation and coordination of the activities of groups and account for the stability of the existing socio-technical systems [28]. Disruptive systemic change can be located at this meso level, but for the most part, a regime is geared towards optimising rather than transforming systems [19], [20].

Technological **Niche** = Individual actors and technologies and local practices. At the micro level, deviations from the status quo can occur [19]. Radical innovations cannot immediately compete in mainstream markets in the regime. Niches are actively created to provide a safe space for the early development of these innovations, with their own rules and selection criteria or provided investments and subsidies [28].

Transition phases

There are four different phases in a transition [19].

Phase 1. Radical innovations emerge outside the existing regime in niches. The connections between early innovations are fragile. There are no stable rules or dominant designs, and concepts may be competing. The innovations are no threat to the regime [28].

Phase 2. The innovations are used in market niches and have more access to resources supporting their development. Rules begin to stabilise and users develop experiences and preferences. The innovation still poses no real threat to the regime, as long as the regime remains stable [28].

Phase 3. The technology has a wider breakthrough and competes with the established regime. This competition depends on internal drivers within the niche, like prices and actor support, as well as external circumstances at the regime and landscape levels creating windows of opportunity, like landscape changes and internal problems within the regime. Wide diffusion occurs through niche accumulation, shares increase and more stable support structures are created, like infrastructures, regulations and user practices [28].

Phase 4. The new technology enters mainstream markets and it is now in direct competition with the established regime. This competition leads to replacement and in return wider socio-technical changes. The formation of a new regime takes time, but can eventually influence wider landscape developments [28].

The full multi-level and multi-phase model is visualised in figure 6 on the next page.

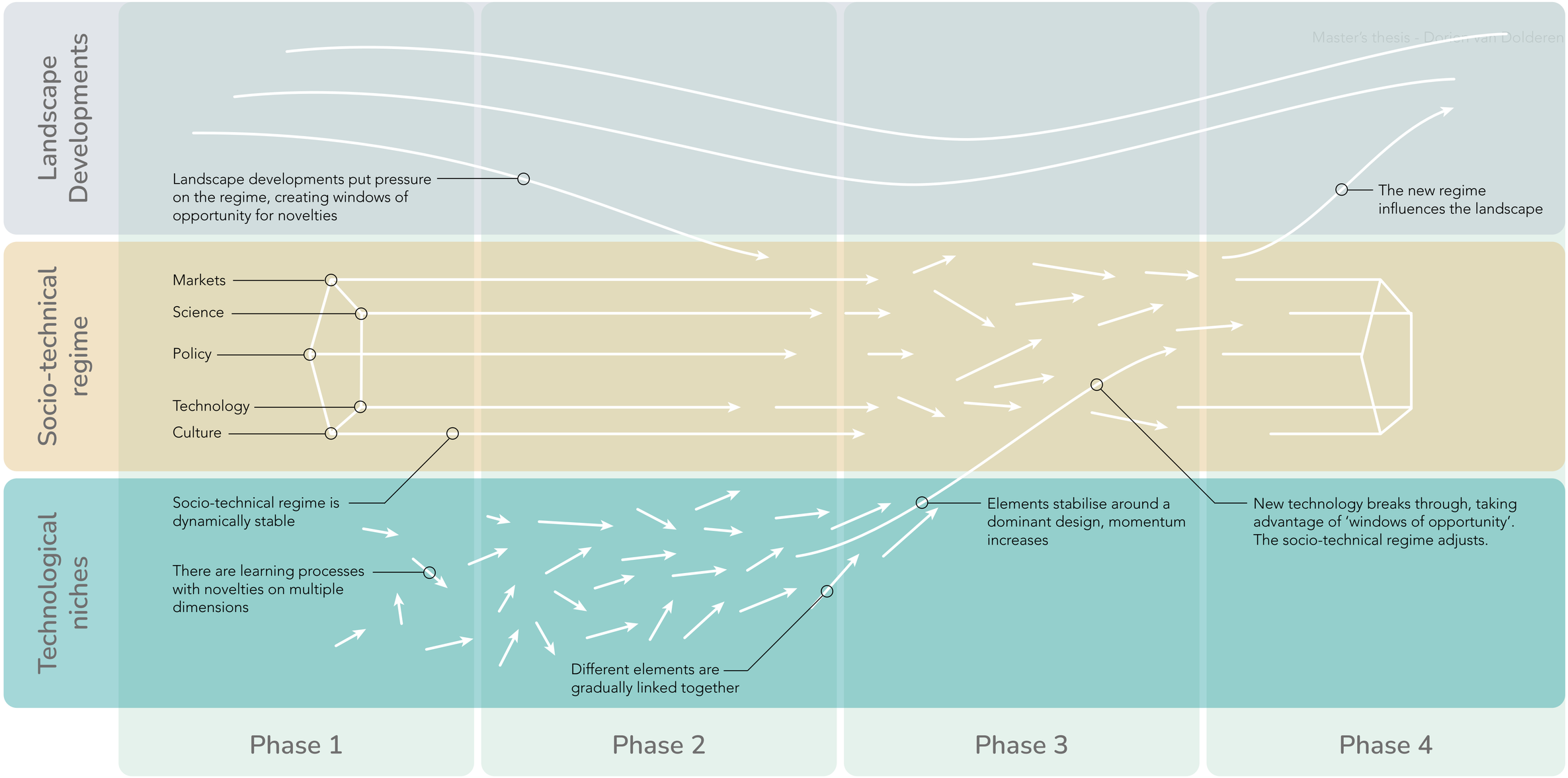


figure 6. *A transition as seen from the multi-leve and multi-phase perspective [28]*

Methodology

The transition management approach [30] offers methods to influence societal change dynamics towards sustainability. This process involves regular adjustment of goals to overcome conflicts between long-term ambition and short-term concerns [19]. Transition management can generate a sense of direction and inspire initiatives that contribute to the envisioned future [30]. It focuses on evolutionary societal change by working experimentally in an envisioned direction instead of towards a specific result [27]. This approach is characterised by long-term, multi-domain, multi-actor and multi-level thinking [19], and proposes the following project phases [30].

Because this method provides a structured approach to guiding and accelerating sustainable transitions, I chose this as a framework as a loose guide for my project. There are some deviations from this approach because of resource constraints and a limited timeframe. Firstly, it is recommended to form a transition team which manages the desired transition together. However, this is an individual graduation project, so instead, I follow this approach on my own. The final phase of transition management, the adaptation and implementation of the transition experiment, is outside of the scope because of time constraints.

This methodology section describes the first phase of transition management; setting the scene. It shows how subsequent phases are altered to this specific project and how they are used to address the research questions.

Exploring dynamics and framing the challenge

In this phase of transition management, the aim is to gain a thorough understanding of the system and the problem at hand. You explore which actors and domains are relevant to the issue, and how they relate to each other and interact. This baseline study should explain the current state of the system as well as the problems that have formed in it.

To gain a thorough understanding of the current system and its problems and challenges, a literature review was conducted on circular design in medical devices. This approach would answer the first research question and determine the Circular Recovery Flows (CRFs) that a medical device like the endocutter could follow instead of its current linear model. After that, the findings were visualised from a multi-level perspective to frame our current position on the transition timeline. Each transition level is described to provide an overview of the socio-technical system and the desired transition.

Four one-day design sprints were carried out to gain a deeper understanding of the challenges and opportunities of each possible circular recovery flow. The design sprints covered initial research into each CRF, as well as some rapid ideation and concepting to gain experience with the possible application of the CRF on a laparoscopic device like the endocutter. Each sprint was concluded with an evaluation, and after the four sprints, the results were compared to determine their suitability for this category of medical devices.

Envisioning

This phase focuses on setting a direction and creating a shared future perspective. A long-term vision functions as an anchor point for strategies and short-term actions. It can be used as a guide as well as a communication tool for broader audiences.

The Vision in Design (VIP) method [25] was used to envision a sustainable future for the MedTech industry. This design approach provides a structured framework that guides the designer from a focus on context to product qualities. The VIP method is subjective and can be adapted to fit the specific design assignment, context, and personal preferences of the designer. The result is a well-formulated vision that can serve as a starting point for idea generation in a deliberate direction.

figure 7. *The VIP book by Paul Hekkert and Matthijs van Dijk [25].*

Reconnecting long-term and short-term

From a long-term vision, you need to set short-term actionable goals. Through backcasting, it is possible to determine multiple possible routes towards the envisioned future, and see what is possible and needs to happen in the present to work towards that goal. You start the development of transition experiments that balance between radicality and feasibility – business as unusual – which should challenge the status quo but still be realistic.

In this project, idea generation using the how-to [31] and the morphological chart [31] methods helped in finding suitable short-term actions that work towards the long-term goal. The generated ideas were structured and compared using an adapted version of the Harris profile method [31], and then evaluated using design criteria and discussed from a transition perspective. The result is an actionable but radical concept which is iterated upon through storyboarding, expert interviews and further desk research.

Engaging and anchoring

In this phase, the goal is to inspire. You need to present your work to engage new actors to influence and accelerate societal change. This leads to increased momentum and helps to inspire other innovations.

This report and the defence of this graduation project represent this engaging and anchoring phase. The results will be shared with different relevant actors through the DiCE project and can be used to support other similar projects working towards a sustainable MedTech industry.

The final phase of transition management is called "getting into action". In this phase, a transition experiment will be further developed and sometimes even realised. It can be linked to innovations and activities which reinforce each other towards the envisioned future. This is unfortunately outside of the scope of this graduation project because of time constraints.

Figure 8 shows how the different sections of the report connect to different phases of the transition management approach.

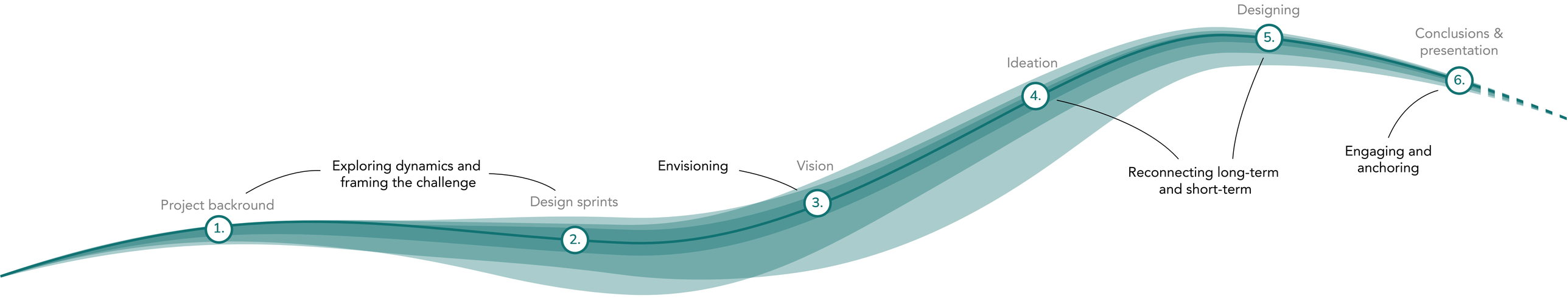


figure 8. *The different phases of transition management connected to different parts of this thesis*

This section of the report explains the assignment and the project behind this thesis. On top of that, it contains a literature review on the current state of healthcare, the MedTech industry and the circular economy. This section also answers the first research question: “What are the possible Circular Recovery Flows (CRFs) for the endocutter?” In the context of the transition management approach, the project background explores dynamics in the current system and frames the design challenge. As a conclusion of the literature review, the systemic transition is visualised from a multi-level perspective.

PART 1

Project background

1. Method

1.1. Collecting data

For the initial literature review, I used the academic platform 'Scopus'. This platform allows precise criteria and boundaries such as keywords, publication years and subject area to be included in the literature search. The search was focused on the opportunities and barriers in the implementation of circular business models on surgical devices. I also included waste management of surgical waste, material choices in surgical devices, regulation in the field and hospital policies around the operating room in my search strategy. The complete strategy is stated on the right.

This strategy provided 216 papers. The results that only mentioned healthcare as an example, as well as sources using the word "circular" in a way that did not refer to the circular economy, were excluded. After checking the titles for relevance, only 9 promising articles remained. These articles formed the base of the project background along with relevant master theses from the TU Delft repository. These theses covered design studies focused on moving away from single-use devices in a sterile hospital environment.

From this initial search, more specific research questions emerged and gaps in knowledge became evident. To fill those gaps I did some more specific searches and also looked into sources such as books, legislation, the DiCE project brief, and company websites.

1.2. Search strategy

ABS ((circular OR circularity) AND (surgery OR surgical OR "operating room" OR medical) AND (device* OR instrument) AND NOT radius AND NOT diameter AND NOT implant* AND NOT circularly)

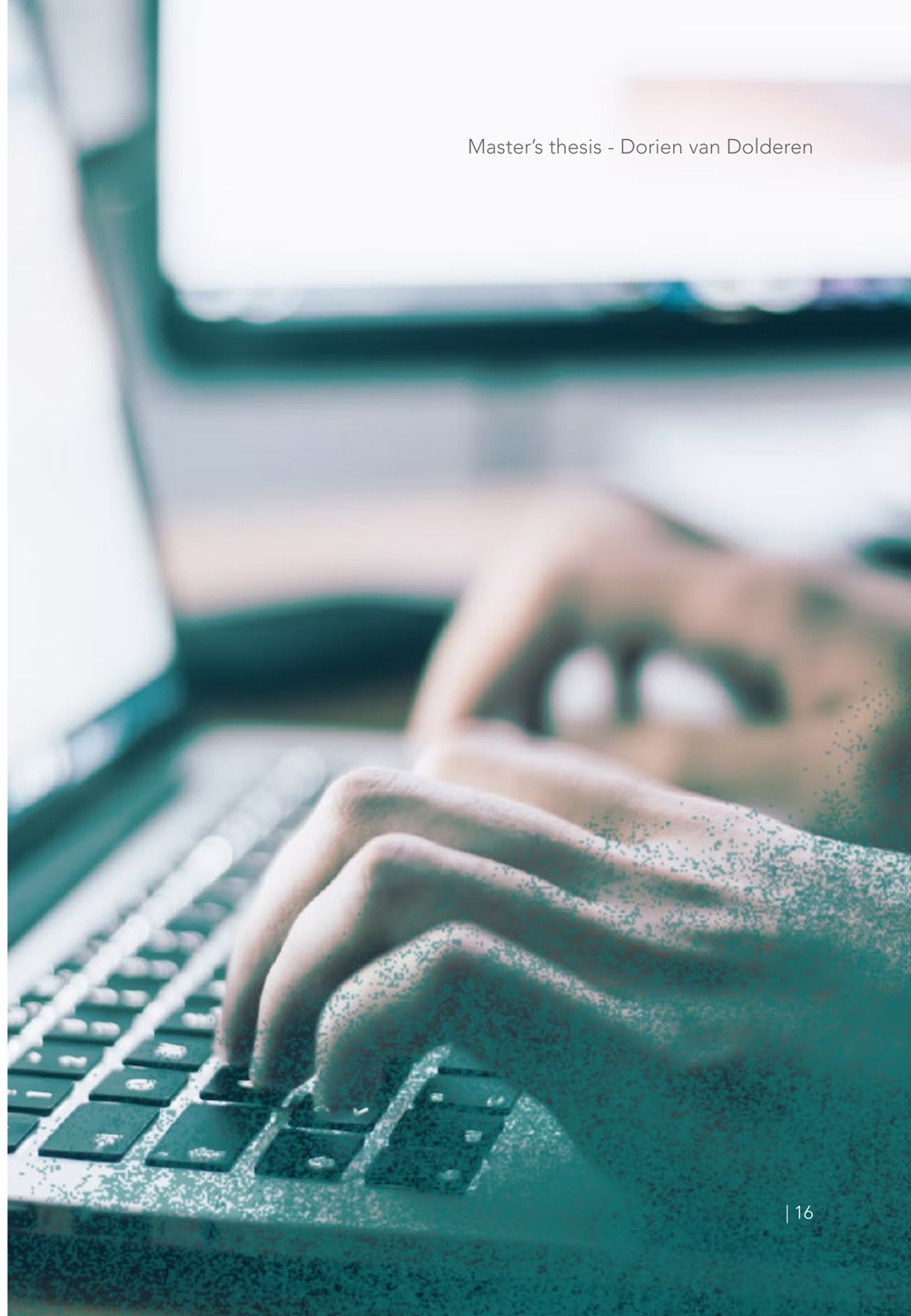
Within the subject areas of engineering, materials science, business and environmental science.

1.3. Structuring data

The data from the literature are summarised and structured into chapters 2-5:

2. The assignment
3. The state of healthcare
4. The circular economy
5. The circular economy in healthcare

Based on the findings from the literature, I could decide on the possible circular recovery flows (CRFs) for laparoscopic instruments like the endocutter. These CRFs are described in chapter 6. Chapter 7 frames the findings into a possible sustainable transition as seen from a multi-level perspective. This chapter sets the direction for the rest of the project.



2. The assignment

2.1. The DiCE project

This graduation project is a part of the EU-funded DiCE (Digital health in Circular Economy) project; a project for which numerous organizations, companies and universities throughout Europe collaborate to innovate on the circularity of digital health devices as a way to enable a circular transition. The DiCE project aims to mitigate the globally expanding health waste problem and critical material shortages while protecting global health and safety.

Within the 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 is the focus of this graduation project.

2.2. Laparoscopy and endocutters

Laparoscopic surgery is a type of surgery in which instead of a large open wound, one or more small incisions are made through which certain instruments and a laparoscope (camera) can access internal tissue. This type of surgery is a precise and effective way to perform various surgeries. Because the cuts are smaller, there is less blood loss, a lower chance of complications and a generally shorter recovery time after surgery. Depending on the procedure, laparoscopic surgery can also be significantly more cost-effective compared to open-wound surgery [9].

Working inside small spaces poses challenges; instruments can only have four degrees of freedom instead of the regular six. The focus of laparoscopic instrument design has been mostly on the steerability of the instrument's so-called "end-effector", which is the part of the instrument that interacts with tissue. This has made many laparoscopic instruments too complex for cleaning and maintenance, which is why they are often labelled as single-use [9].

An endocutter (a type of surgical stapler) is one of these laparoscopic instruments. It can be used to cut tissue and suture it with the use of rows of tiny staples, all through a small incision. Currently, most endocutters are only used once before they are discarded for the sake of patient safety. With their current market price of around 400 euros, they are some of the most expensive instruments used in laparoscopic surgery [32]. There is one example of a semi-reusable endocutter currently on the market. The handle is encased in a disposable plastic sleeve and does not need to be cleaned, the shaft can be sterilised up to 50 times and the end effector is disposable[33]. Even though the main device only needs to be purchased once, the disposable modules still contribute to a cost per surgery that is very similar to that of the disposable endocutter. The modular device is also quite complex to prepare, use and reprocess (appendix 5.3).

figure 9. *Ethicon's Echelon Flex 60, 45 and 35*

2.3. Ethicon and Johnson & Johnson

Johnson & Johnson is currently the world's largest and most broadly based healthcare company. The company was founded in 1886 in the US and develops medical devices, consumer packaged goods and pharmaceuticals [34]. Ethicon is a subsidiary of Johnson & Johnson with a focus on surgical and interventional solutions across different surgical approaches including laparoscopy [35].

3. The state of healthcare

"… I will do no harm…" is a key part of the Hippocratic oath. This text is a historical expression of medical ethics and is often recited by medicinal graduates in the so-called white coat ceremony. Why is it that, in trying to protect the health of society, the healthcare sector contributes so much to harming it?

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 [36], and even 7.3% of emissions in the Netherlands [37]. Development in this field has been mostly aimed towards patient and personnel safety and improving the quality of care. These values have such a high priority in the sector, that efforts towards more sustainable practices and minimizing environmental impact are put on the back burner. This has caused the healthcare industry to lag behind other industries when it comes to reducing the environmental impact of their practices [38].

The healthcare sector generates larger amounts of waste every year due to factors like rapid population growth, an increase in the number and size of healthcare facilities, and the systematic use of single-use devices (SUDs) [39]. Next to the proportion of this waste stream, especially the composition is a challenge. There is a complicated combination of non-hazardous waste and different types of hazardous waste, including medicine residues, sharp instruments, biological material and electronics [40], [41]. Because of a safety-first mindset, products that are uncontaminated sometimes still end up in the infectious waste stream. If separated correctly they could have been disposed of in an alternative way or could have been recycled [42].

The recent Covid-19 pandemic has also exposed problems in the system. One important weakness of the current MedTech industry is that of its supply chains. Closing borders led to shortages of certain medical devices, and especially the production of powered devices suffered because of a global shortage of semiconductor chips [43], [44].

Image from white coat ceremony 2018 of Washington University School of Medicine in St. Louis

figure 10. *The waste from one single mastectomy (breast cancer surgery), an artwork by Maria Koijck titled "This is the waste of one operation ,….my operation!" [49]*

3.1. The impact of the OR

An operating room (OR) must guarantee as much sterility as possible for the safety of patients. Approximately 20 to 30 per cent of waste from hospitals originates in the OR [45], [46]. To maintain the necessary level of sterility in the operating room, the whole room is treated as a contamination hazard after surgery. For medical devices this means all the instruments taken out of their sterile packaging, both used on patients and not used at all, either need to be sterilised or discarded as hazardous material [42], [47]. On top of individual disposables, sometimes disposable custom packs are used for surgical procedures. These packs are pre-sorted surgery kits with different disposables packaged together to reduce cross-contamination, time and human mistakes. This practice leads to even more unused products being disposed of after surgery [48].

Dutch spatial artist Maria Koijck underwent a 10-hour surgery to treat breast cancer. She collected all the waste and transformed it into a statement art film to create awareness of the impact of healthcare (figure 10) [49].

3.2. Single-use devices

Single-use devices (SUDs) are disposable products used in healthcare as an alternative to reusable devices that can be cleaned, disinfected, sterilised and sometimes repaired after use [48]. Lower purchase costs, perceived infection risks and potential for human errors in reprocessing have led to a surge in disposable products. Over the last few decades, medical devices that were traditionally reusable have now been redesigned for one single use [39], [50]. There are, however, significant drawbacks to the use of SUDs:

Even though purchasing prices are generally much lower, recent research suggests that SUDs are not actually cheaper compared to reusables in the long run [32], [39]. One study compared disposable versus reusable costs for laparoscopic cholecystectomy and found disposable set costs to be over 6 times greater compared to reusable set costs per surgery [51]. Also, a significant cost reduction in laparoscopic bariatric surgery and appendicectomy has been found [52], [53]. In general, evidence suggests that the use of SUDs is more expensive compared to the use of reusables, but there are exceptions and further research is needed to determine if this is the case for the endocutter as well. There is also a large variation in results between cases depending for example on the geographical locations of hospitals and even the level of experience of individual surgeons [32].

The environmental impact of reusables and disposables can vary significantly depending on materials, energy type and energy quantities consumed in for example reprocessing activities. Some cleaning agents used in disinfection and sterilisation also greatly contribute to waste pollution [32]. In a study comparing the environmental impact of SUDs and reusables used for laparoscopic cholecystectomy [54], evidence was found that disposable instruments impose a greater load on the environment. The impact of waste from disposable instruments contrasts with that of reprocessing reusable instruments, and in the case of reusables, the impact of the device's production is spread over many lifecycles. A life-cycle assessment (LCA) is necessary to determine the difference in impact per case, but generally, evidence suggests that limiting the use of SUDs holds environmental advantages [32].

Even though infection risk is perceived to be lower for SUDs compared to reusable devices, there is no compelling evidence that the use of SUDs reduces health-care acquired infections [55]. This is because cases are so rare that sample sizes needed to compare infection rates from single-use and disposable devices are too large for a study to be feasible [56].

Big corporations depend on economies of scale to keep product prices low [50]. This is why the income of manufacturers partly depends on continuous sales of SUDs, which makes a possible transition back to reusables slow. However, healthcare facilities aim to become more sustainable and cut costs as safely as possible. Solving this conflict will be a challenge since most solutions involve the design of a complex product-service system in which many more actors than just the manufacturer take part [42]. Currently,

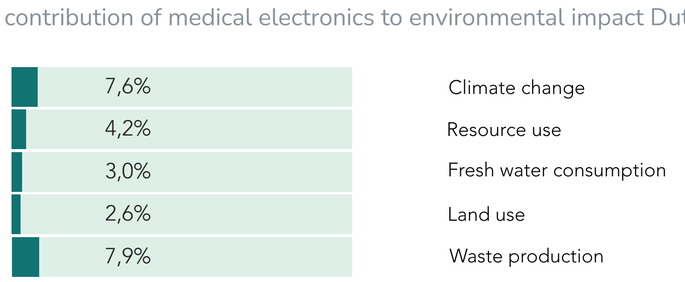


figure 11. *Contribution medical electronics to environmental impact Dutch healthcare [37]*

the manufacturer needs to prove that a device can be reprocessed safely to be able to market it as reusable, but there are no such requirements for marketing a device as single-use. This extra step to validate a reusable product leads many manufacturers to save time and resources by simply labelling a device as single-use [55].

One dimension missing from the literature altogether is that of the differences in convenience and ease of use between single-use devices and reusables. The reprocessing of devices requires hospitals to invest in or outsource specialised facilities, trained personnel, cleaning supplies, repair, tracking and accounting. Meanwhile, the use of SUDs only requires an infectious waste stream for their EoL, which is readily available in all healthcare facilities.

Figure 12 provides a summary of the comparison between SUDs and reusable devices and shows where evidence is still lacking.

	SUDs	Reusables	
Cost	High	Lower	Comparison depends on use cycles, geographical location, individual surgeons and cleaning processes. Needs more evidence because of hidden costs.
Environmental impact	High	Lower	Depends on materials, energy type and energy consumed by for example cleaning processes. Needs more evidence and LCAs.
(perceived) safety	High	Lower	Actual safety is impossible to prove because of large sample sizes. SUDs are however perceived to be safer compared to reusables.
Business case	Profitable	Less profitable	The continuous sales of SUDs is very profitable for OEMs. On top of that the design and approval of reusables is more expensive because of regulation.
Ease of use	Easy	Requires more time and resources	Reusables require cleaning infrastructure. However, evidence on this subject is lacking.

figure 12. *A summarising table comparing SUDs with reusable medical devices*

3.3. A need for change

SUDs are an example of products following a linear (take-make-waste) economy. This economy is often an unsustainable model which can contribute to global ecological destruction by depleting resources and generating immense amounts of waste and harmful emissions. A linear economy is not only harmful to the planet but also to human health through air pollution, water contamination, biodiversity loss and rapid climate change [55]. This leads to a vicious cycle; the healthcare sector contributes to climate change, which in its turn puts more pressure on the healthcare sector (figure 13).

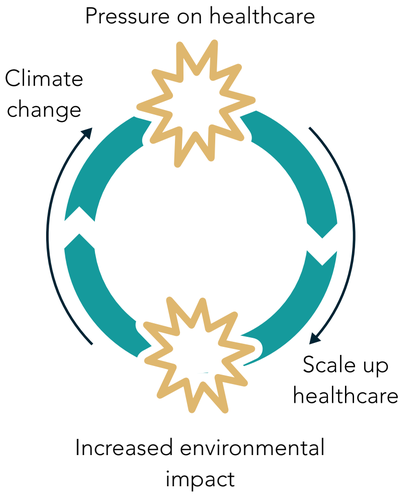


figure 13. *The vicious cycle of climate change and healthcare*

4. The Circular economy

In a linear economy, raw materials are extracted and then formed into products. These products at some point reach the end of their functional lives and are disposed of as "waste" [11]. The circular economy is an answer to this inherently destructive model.

The circular economy is described as "An industrial economy that is restorative by intention and design" [57] or more specifically as "an economic system that replaces the 'end-of-life' concept with reducing, alternatively reusing, recycling and recovering materials in production/distribution and consumption processes" [4]. The circular economy aims to eliminate waste by lengthening product life – slowing loops – or reintroducing the product, parts, or materials back into the system for reuse – closing loops [11], [55] (figure 14).

The Ellen MacArthur foundation visualized the circular economy as this butterfly diagram (figure 15), which shows the continuous flow of materials. They divided the diagram into two types of cycles; technical cycles and biological cycles. Through technical cycles, products and materials are kept in circulation through processes such as reuse, repair, remanufacture and recycling. Through biological cycles, the nutrients from biodegradable materials are returned to the Earth to regenerate nature [57].

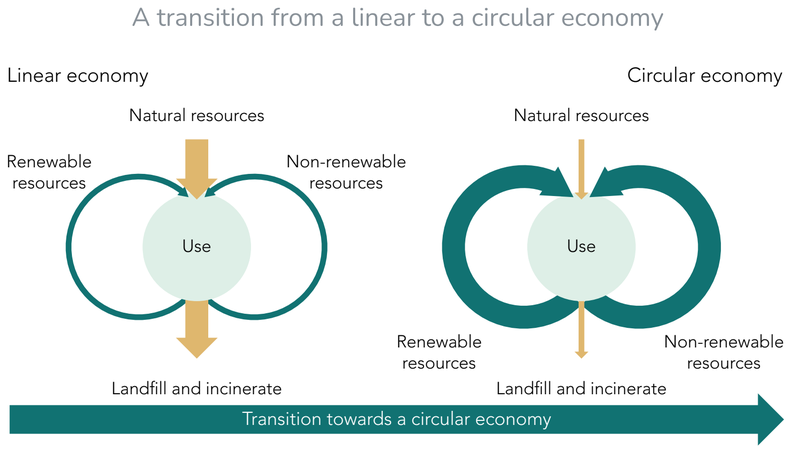


figure 14. *The transition to a circular economy, adapted from Potting et al. [58]*

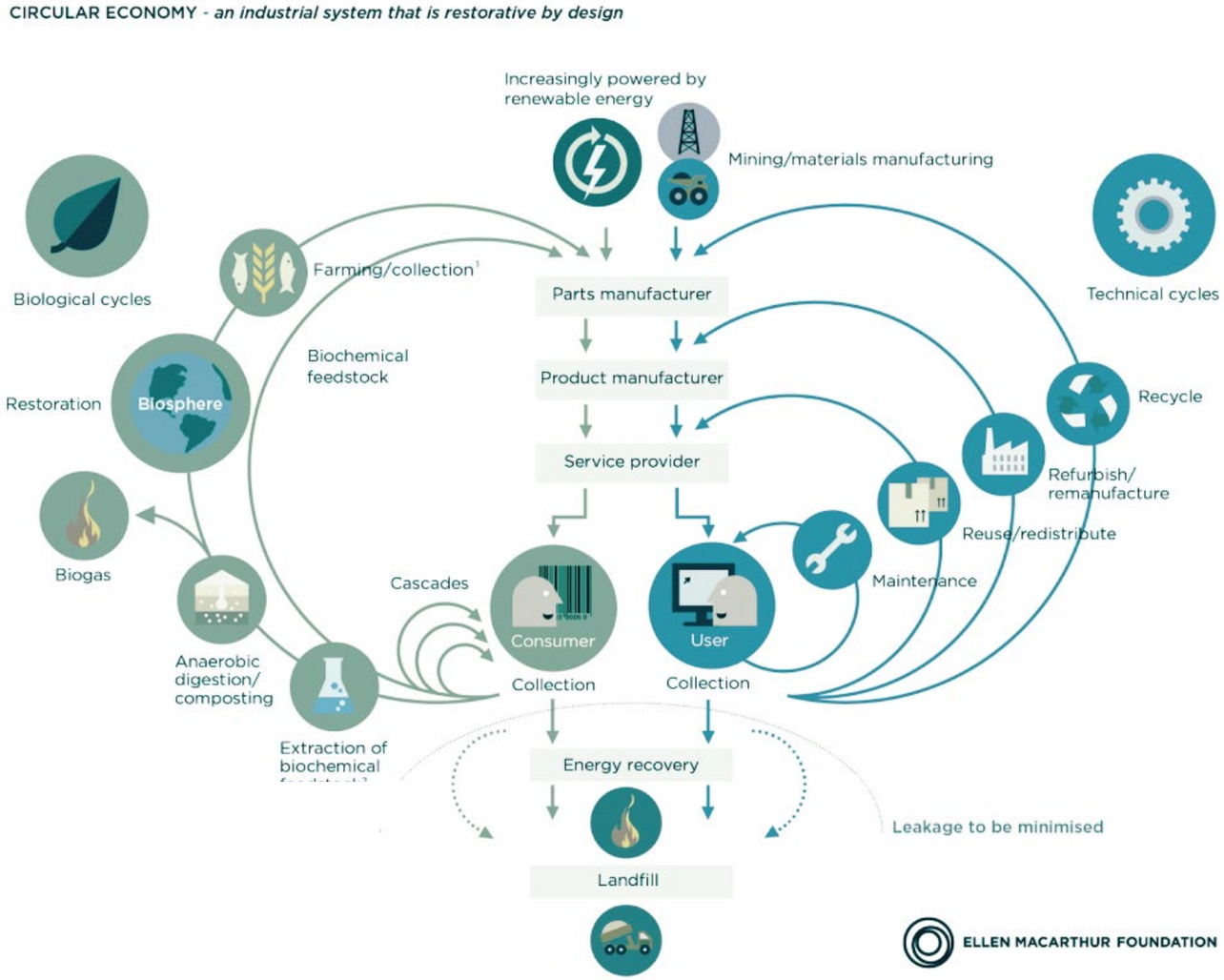


figure 15. *The butterfly diagram [57]*

4.1. Preserving product integrity

There is an order of priority to the cycles or "loops" a product can go through throughout its lifetime called the waste hierarchy. This is a priority order for managing waste, with the prevention of waste as the highest priority and the disposal of waste as the lowest priority [12]. The waste hierarchy ties together closely with the inertia principle: "Do not repair what is not broken, do not remanufacture something that can be repaired, do not recycle a product that can be remanufactured. Replace or treat only the smallest possible part to maintain the existing economic value of the technical system" [42]. Product integrity is the extent to which a product stays in its original state, or as close to that state as possible, over time. Retaining product integrity minimizes environmental impact from interventions to preserve or restore the value of a product over time [12].

As a rule of thumb; more circularity can be assumed to equal more environmental benefits. This is because a higher level of circularity means that the materials remain inside the system for longer, value is maintained, and the product retains a higher level of integrity (figure 17). As a result, fewer new materials are needed for the production of new products, and fewer materials leave the system as waste. There are however exceptions to this rule. Some strategies can require a lot of energy or for example dangerous chemicals to execute [43].

The order of priority of the different circularity strategies is visualized in the so-called 9R framework [43] (figure 16). The lower the R number, the higher the level of circularity. The R framework goes into a higher level of circularity compared to the butterfly diagram, because it also takes the beginning of cycles into account with its first three strategies.

Circularity strategies within the production chain, in order of priority

Circular economy

Increasing difficulty

Rule of thumb: Higher level of circularity = fewer natural resources and less environmental pressure

Linear economy

Smarter product use and manufacture	R0 Refuse	Make a product redundant by abandoning its function or by offering the same function with a radically different product
	R1 Rethink	Make a product's use more intensive (e.g. through sharing products, or by putting multi-functional products on the market)
	R2 Reduce	Increase efficiency in a product's manufacture or use by consuming fewer natural resources and materials
Extend lifespan of product and its parts	R3 Re-use	Re-use by another consumer of a discarded product which is still in good condition and fulfills its original function
	R4 Repair	Repair and maintenance of a defective product so it can be used with its original function
	R5 Refurbish	Restore an old product and bring it up to date
	R6 Remanufacture	Use parts of discarded product in a new product with the same function
	R7 Repurpose	Use discarded product or its parts in a new product with a different function
Useful application of materials	R8 Recycle	Process materials to obtain the same (high grade) or lower (low grade) quality
	R9 Recover	Incineration of materials with energy recovery

figure 16. *The 9R framework, adapted from Potting et al. [58]*

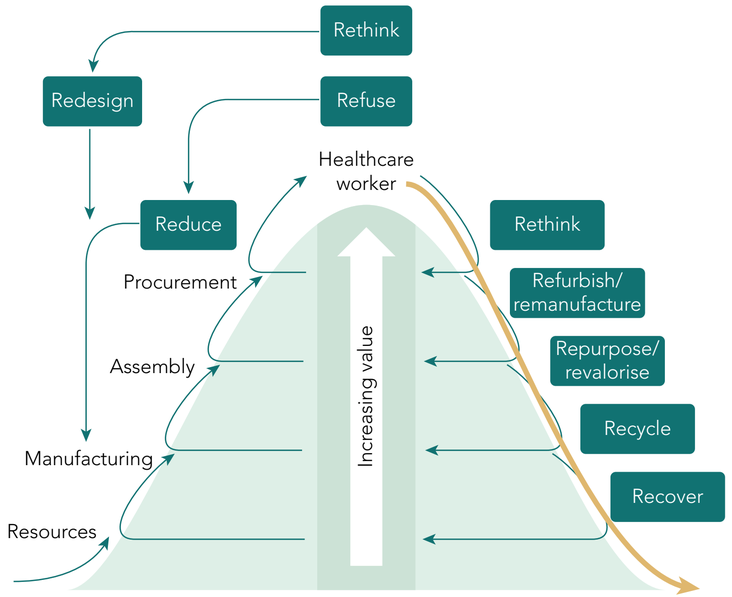


figure 17. *The value hill, adapted from Browne-Wilkinson et al. [59]*

figure 18. *Specialized hydrogen peroxide sterilisation machine for thermoplastics at LUMC*

5. The Circular economy in healthcare

Circular design in healthcare is particularly interesting. The impact of the sector is huge and there are a lot of design constraints due to the high level and complexity of regulations. For the redesign of medical products, you cannot simply take the same approach as for household appliances since there is way more risk involved. Everything that has a risk of contamination needs to be treated with extra care. This treatment includes extensive cleaning, disinfection and sterilisation processes and special handling in transport and storage, for the safety of everyone involved.

If a potential redesign negatively influences the functionality of the device or poses an increased risk, the product could endanger patients' health or even lives. Where normally the choice between reusable and single-use products is mostly based on cost and ease of use, in the medical industry the determining factor is often that of (perceived) infection risk [11].

Currently, there is already some level of circulation of products and materials in the sector. Remanufacturing of complex equipment is already quite advanced and widespread, but hygienic recovery of tools like the endocutter (medium/high value, high criticality) is often executed poorly and against manufacturers' intentions and designs, when it is done at all. Recycling is also a process that needs more research and exploration in the medical field [11].

5.1. Opportunities and challenges

Kane et al. [11] found that recovery opportunities for the medical sector primarily depend on hygienic criticality, product value and the environmental support structure. They mapped different products according to their product value and hygienic criticality and advised certain design strategies for recovery accordingly. Guzzo et al. [40] used the same axes to provide advice on possible circular business models (CBMs) around these medical devices.

5.1.1. Hygienic criticality

Hygienic criticality is defined by the Spaulding scale. Noncritical items only come into contact with intact skin and only need to be decontaminated before use. Semi-critical items come into contact with mucous membranes or non-intact skin and require a high level of disinfection before use. Critical items have a high risk of contamination, these are objects that enter human tissue or the vascular system. This category includes surgical instruments like the endocutter, which should be sterile before use [5]. Decontamination is a cleaning method which destroys most bacteria, disinfection destroys all micro-organisms except high numbers of bacterial spores, and sterilisation destroys all microorganisms [60].

5.1.2. Product value

Whether or not it is viable to recover a medical device largely depends on its economic value, and how much it would cost to discard the product compared to recovering it. If the cost of recovery is greater than the value of the device itself the item will probably remain disposable. However, there could still be value in material recovery through recycling [11]. The cost of recovery partly depends on economies of scale [61].

5.1.3. Environmental support structure

The opportunities for recovery of a medical device also depend on the infrastructure in the hospital it is used. For example; some devices need specialized sterilisation methods which might not be available in smaller hospitals, or require biomedical engineers for repair or remanufacture structures [11].

5.1.4. Opportunities for the endocutter

The endocutter is a medium-high-value, high-criticality device [11]. For this category of devices, the following opportunities show from the product map (figure 20).

Design strategies

Kane et al. [11] advise optimising devices like the endocutter for hygienic recovery as much as possible. This means choosing materials that can withstand high-grade sterilisation, and minimizing corners, sharp edges and moving parts in the design. This kind of redesign for repeated reprocessing can make devices more expensive. An alternative is to design for a fixed number of recovery cycles instead of an infinite number of cycles, to maintain a relatively low production cost. A way around some of the issues with reprocessing highly complex devices is to look into hybrid products in which some parts are reprocessable and others are not. This strategy also allows for different parts to be treated according to different levels of criticality, since they might not get into contact with the patient to the same extent. Lastly, because of a lack of trust, sometimes SUDs which could have been reused are discarded anyways. Designing for trust in the safety of the reprocessed or refurbished device could be a great opportunity to improve the circularity of the endocutter.

Circular Business Models

Guzzo et al. [40] advise providing a support system for in-hospital reprocessing for devices like the endocutter. Another option is to provide reprocessed devices and take away some of the risks and responsibilities from individual hospitals. Reprocessing facilities can verify, sort, reprocess, inspect and repackage devices all according to regulations. This system also creates a great business model opportunity and increases the chances of recycling at the product's EoL.

Map of circular medical products and business models

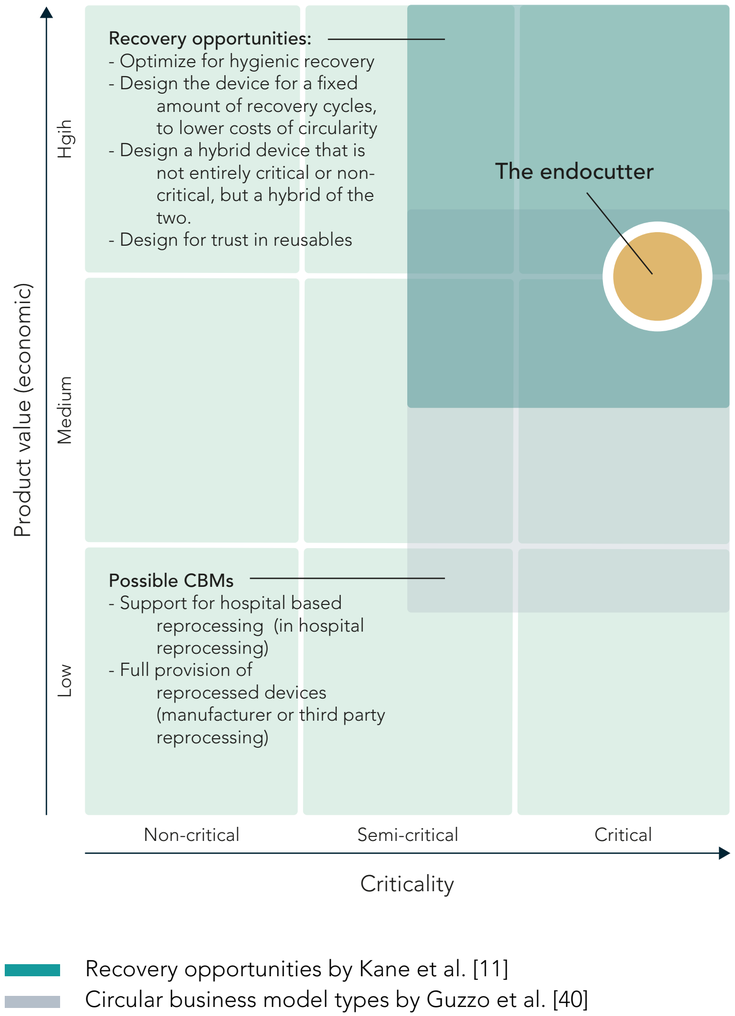


figure 19. *adapted from Kane et al. [11] and Guzzo et al. [40]*

5.1.5. Challenges for the endocutter

Perceived risk and cost of designing more sustainable devices and implementing them in hospital environments pose a roadblock to the implementation of circular strategies [42].

Hygienic criticality

The high criticality of the endocutter means they have to withstand more harmful sterilisation processes if they were to be reprocessed. The contamination hazard of a used endocutter also makes it subject to strict transport and waste regulations which limit external EoL opportunities like remanufacturing and recycling.

Product design

The endocutter has parts made from both metals and plastics and includes electrical components as well, which makes recycling a challenge. On top of that, the device's architecture is complex which poses problems for various cleaning processes and disassembly. The device currently cannot be disassembled without damaging or breaking certain components.

Regulation

Regulation in the medical device industry occurs via a complex network of organizations in which the division of responsibilities and roles is somewhat unclear. Opting for disposable devices helps hospitals avoid potential mistakes and liability [55]. However, study shows that good regulation could be the most impactful driver in the design of more environmentally conscious medical devices [42]. Currently, regulation focuses mostly on independent patient safety but fails to take into account the consequences of the environmental impact of the medical industry on population health [55]. In conclusion; regulation can be seen as a roadblock for the circular development of endocutters but could become a driver with the right alterations.

6. The possible Circular Recovery Flows for laparoscopic instruments

Kane et al. [11] did an extensive literature review on the existing Circular Recovery Flows via technical cycles within the medical device industry. As a result, they found the following forms of recovery: Repair, recycling, refurbishment/remanufacturing and reprocessing. These CRFs were also mentioned in other sources. A form of recovery via biological cycles is an addition to these four flows. This strategy was mentioned by Freund et al. [62] and Guzzo et al. [40].

6.1. Inconsistency in terms and definitions

A challenge in defining the Circular Recovery Flows is the inconsistency in the use of different terms and definitions. There is quite a lot of overlap and confusion between reprocessing, maintenance, repair, refurbishment and remanufacturing. To be able to properly define and frame the different CRFs, these inconsistencies need to be addressed first.

6.1.1. Reprocessing

Reprocessing is defined by the EU Medical Device Regulations as "a process carried out on a used device to allow its safe reuse including cleaning, disinfection, sterilisation and related procedures, as well as testing and restoring the technical and functional safety of the used device" [17]. This term is however used for refurbishment activities in some countries as well, like the "reprocessing" service of certain companies in the US. Northern American reprocessors recover devices from hygienic obsolescence but also go through a process of remanufacturing. They restore devices to be "Substantially equivalent to the FDA-cleared OEM device", and sell the devices as new after the recovery process [63].

6.1.2. Refurbishing and remanufacturing

The EU MDR defines refurbishing as "the complete rebuilding of a device already placed on the market or put into service, or the making of a new device from used devices, to bring it into conformity with this Regulation, combined with the assignment of a new life to the refurbished device"[17]. This definition is however inconsistent with the general definition of refurbishing; "Refurbishing brings used products up to specified quality, usually lower than new products. Products are disassembled into modules, which are inspected, tested, and sometimes fixed or replaced [16]. The EU MDR seems to discuss the process of remanufacturing instead; "Remanufacturing brings used products up to the same standard as newly produced products. Used products are completely disassembled and all parts are intensively tested. Approved parts are reassembled into new products" [16]. To meet the high product standards set by regulation, the concept of remanufacturing seems more relevant to high-risk devices like the endocutter compared to the concept of refurbishing.

6.1.3. Repair and maintenance

Repair involves a reconfiguration or replacement of parts to restore a product from functional obsolescence caused by a specific fault, and maintenance includes changing parts, cleaning and checking the device at regular intervals [11]. Different components could be repaired as a part of a remanufacturing process. Even when devices are cleaned in the internal sterilisation department of a hospital, they are checked and maintained and sometimes set aside for repair [64]. There can be no repair and maintenance of the endocutter without first performing different cleaning steps to combat infection risks. Because repair and maintenance activities are included in both reprocessing as well as remanufacturing processes, and are never stand-alone activities, I will not treat them as a separate CRF.

6.2. Defining the Circular Recovery Flows

I will define the CRF of **reprocessing** according to the EU MDR: "a process carried out on a used device to allow its safe reuse including cleaning, disinfection, sterilisation and related procedures, as well as testing and restoring the technical and functional safety of the used device" [17] Reprocessing focuses on recovery from hygienic obsolescence, the main form of obsolescence that SUDs like the endocutter experience [11], but can include repair and maintenance activities as well.

Remanufacturing is the complete rebuilding of a device already placed on the market or put into service, or the making of a new device from used devices, to bring it into conformity with regulation, combined with the assignment of a new life to the remanufactured device. This is an adaptation of the definition of refurbishing from the EU MDR [17]. Remanufacturing will also include cleaning, repair and maintenance processes.

In **recycling** the identity and functionality of the product and its components are lost, the purpose is to reuse materials instead of parts from used products and components [16].

The CRF of **biomaterials** explains recovery via the biological cycles instead of the technical cycles of the butterfly diagram [57]. Biomaterials are materials that (1) are biodegradable, or (2) may or may not be degradable but are produced from biological materials or renewable feedstock (adapted from Atiwesh et al. [2]).

These CRFs will be used as a basis for four design sprints, and are visualized in figure 22 on the next page.

This visual shows an adaptation of both technical and biological cycles of the butterfly diagram [58] for the life of highly critical and costly medical devices like the endocutter. Arrows of each color correspond with a defined circular recovery flow, and show which routes devices, components and materials can take and which parties are involved.

- Reprocessing
- Remanufacturing
- Recycling
- Biomaterials
- The linear model

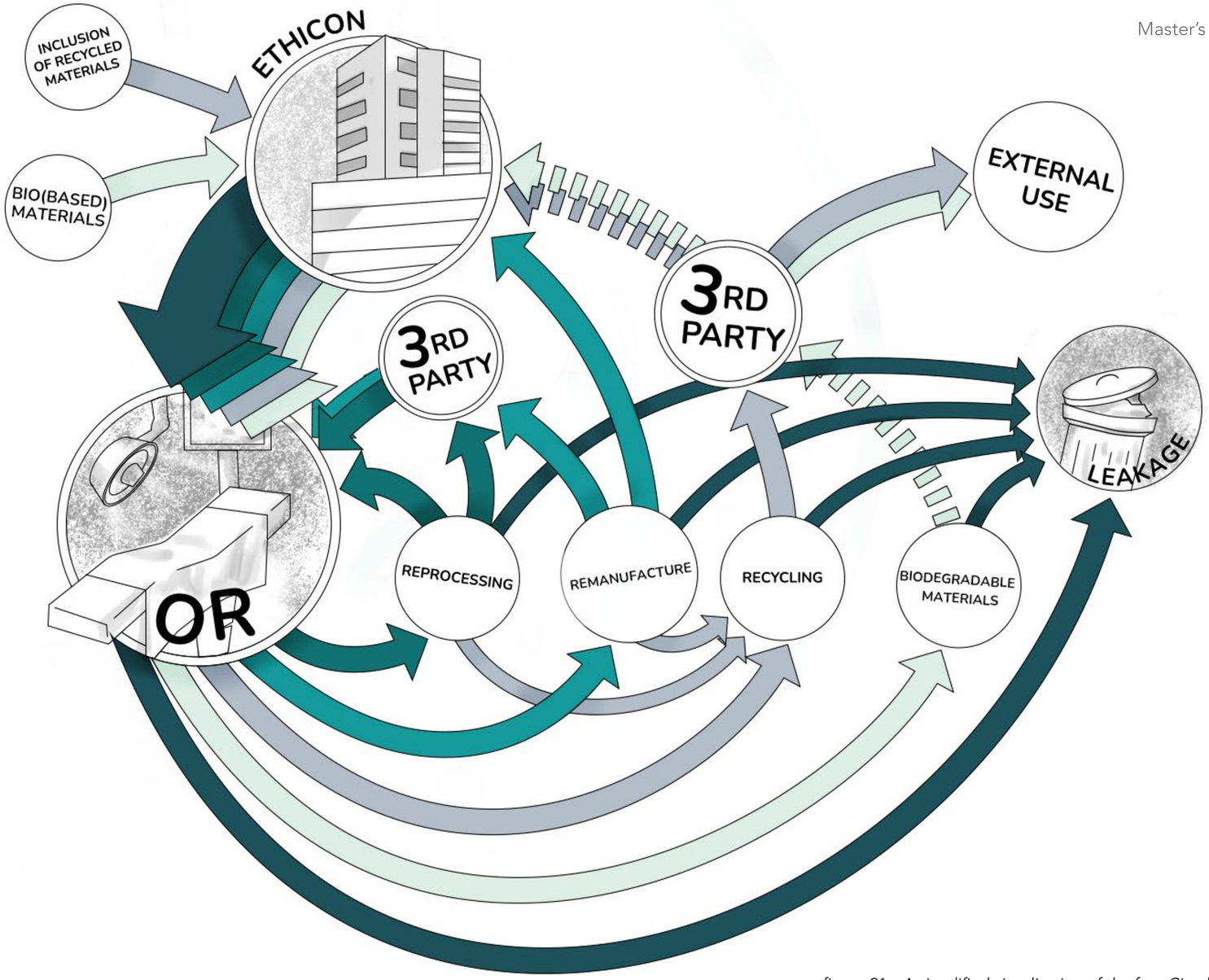


figure 21. *A simplified visualisation of the four Circular Recovery Flows*

7. The MedTech industry from a multi-level perspective

To be able to design a sustainable transition in the MedTech industry, it is crucial to take a step back and look at the system from a multi-level perspective. The full visual (figure 24) is shown on the next page.

7.1. The socio-technical regime

The socio-technical regime of MedTech includes actors like (inter) national governments, OEMs and hospitals. In the current regime, the regulation, production and use of SUDs is the standard. They are trustworthy, sterile per definition, accessible and regulatory sound. There is no need for cleaning processes and they provide a valuable business model for OEMs. In the design of medical devices, the focus is first and foremost on the functionality and safety of devices. There is a process of optimisation which leads to ever-increasing device prices and complexity. This focus on safety also extends to the existing culture around medical devices; risks are avoided at all costs. The increasing costs of healthcare as well as the large amounts of waste that this system generates are some of the regime's internal problems that contribute to its destabilisation.

7.2. Landscape developments

There are two important landscape influences that can contribute to the destabilisation of the current regime. The first is the growing demand for actors to act with planetary boundaries in mind and become more sustainable. Current practices need radical alterations to be able to keep up with this demand, which are hard to realise from within the regime. The other landscape influence is that of the covid-19 pandemic. This worldwide crisis exposed a level of supply chain vulnerability that cannot simply be solved by optimisation alone.

7.3. Technological niches

There are a few technological niches that allow space for innovation. In the Netherlands, the reprocessing of single-use devices is not allowed, but in some countries, this is a very common practice because of the high cost of new devices. This allows for more experience with and research into cleaning processes and design strategies for reuse. On top of that, smaller healthcare facilities sometimes do not have the space for their own sterilisation department and a large stock of medical devices, which leads them to outsource cleaning activities. Specialised companies have emerged with more space for innovation. Lastly, a version of the endocutter that is partly reusable already exists. It is unclear to which market niche this device belongs, but it provides a great example of an alternative to the dominant design of the device.

7.4. A sustainable transition in MedTech

The DiCE project is an initiative started by regime actors like governments, universities and OEMs, but it aims to create space in the regime for niches to break through. The destabilisation of the regime is evident, as well as some of the possible solutions (CRFs) that could take over. This leads me to believe we are already well into phase two of the four-phase transition model towards a sustainable transition in MedTech (figure 24). It is however still unclear what the dominant design will be that eventually breaks through and contributes to the formation of a new dynamically stable regime, and what a sustainable transition in the MedTech industry will look like. I will look into this through the envisioning of a sustainable future for the industry in part three of this report.

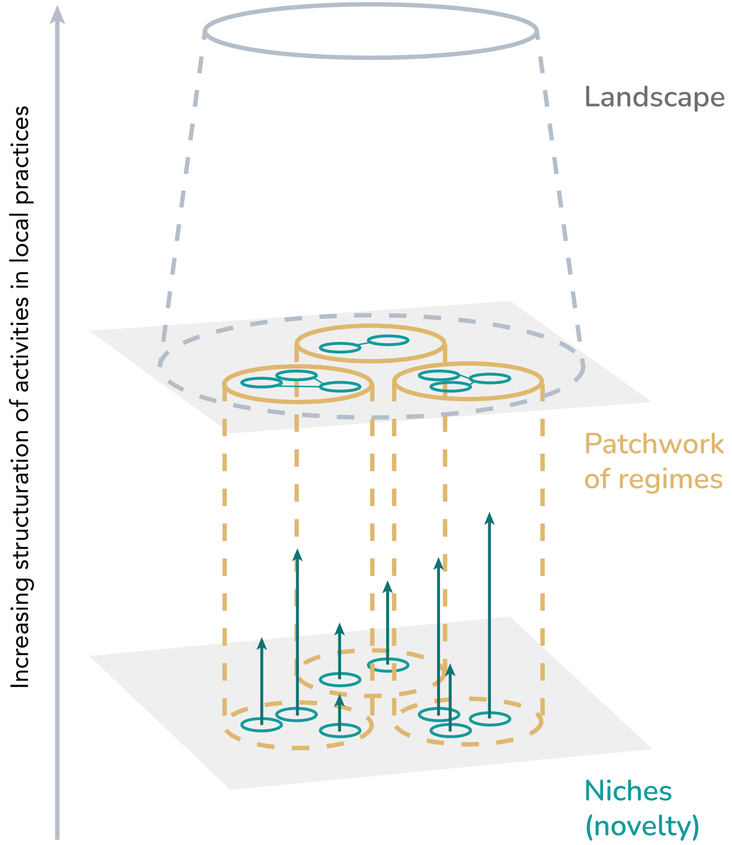


figure 22. *The multi-level model explaining the coevolution between the landscape, regime and niches, adapted from Rip [29]*

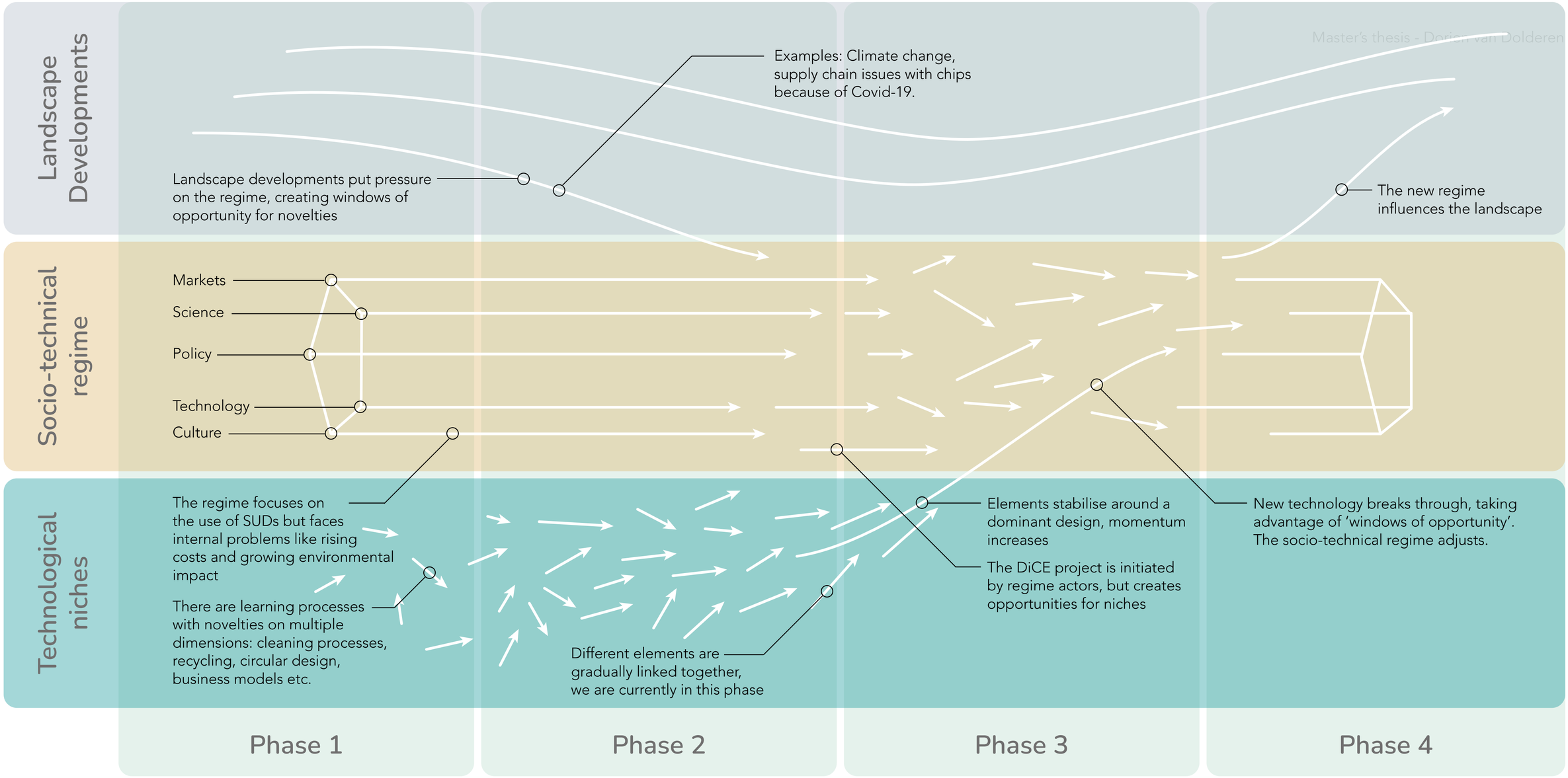


figure 23. *A transition in MedTech as seen from the multi-level and multi-phase perspective*

8. Conclusion

This section of the report described the exploration of system dynamics as well as problem framing within the transition management approach. First, a literature review was conducted describing the assignment, the current state of healthcare, and background on circular economy and circular economy in the healthcare sector. According to the literature, it would be best to redesign products like the endocutter for circularity by placing the focus on hygienic recovery, design for fixed reprocessing cycles, hybrid design or design for trust. Some of the most promising circular business models for these devices would be based on the support of in-hospital reprocessing and the full provision of reprocessed devices.

There are four possible circular recovery pathways for laparoscopic devices; Reprocessing, Remanufacturing, Recycling and recovery through the biological cycle. The CRFs form the basis for four design sprints exploring the strengths and weaknesses of each approach.

Lastly, the system is visualised as seen from a multi-level perspective to show a possible sustainable transition in the MedTech industry. The transition has already started but niches still need to build more momentum before they can take advantage of the destabilisation, and replace the current regime.

PART 2

Design sprints

This section of the report describes the method and execution of four design sprints exploring the different possible Circular Recovery Flows for laparoscopic devices like the endocutter. Each design sprint covers research into the CRF, idea generation on the possibilities within the CRF and an evaluation and reflection. All the different ideas from the design sprints are compared and tested against a set of requirements and criteria. This section of the report is a further exploration into the current dynamics of the system that builds upon the project background. Through quickly designing and testing the different CRFs, different barriers and opportunities for circularity in laparoscopic instruments can be identified.

1. Method

The original design sprint is a five-day Google Venture process meant to solve critical issues through ideating and prototyping with customers. The sprint is divided into five parts; understand and define, diverge, decide, prototype and validate [65].

Normally sprints are executed by an interdisciplinary team, but I will go through them on my own. The time this saves means that each sprint in this project can be done in one day. It takes one week to cover all the recovery flows and draw conclusions from the process.

There are examples of one-day adaptations of the five-day design sprint. For this to work you need to define the scope and goals beforehand, as well as understand the problem. The prototyping and user testing is done after the sprint [66].

For my project, I decided to prepare research questions, useful sources and design criteria per flow before the design sprints. I included knowledge I gained from visiting the Sterilisation Department (SD) at the Leids Universitair Medisch Centrum and the waste department of Erasmus MC in the design sprints as well. This way I could spend the day of the sprint as effectively as possible according to a set daily schedule. This planning can slightly vary per sprint since some sprints could be more research-based than others.

1.1. Planning

Morning
08:30 - 11:30: Research
11:30 - 12:00: Conclude findings

Afternoon
13:00 - 13:30: Ideation
13:30 - 15:45: Quick concepting
15:45 - 16:30: Concept presentation (conclusion/visual)
16:30 - 17:00: Reflection – evaluation according to criteria

1.2. Requirements and criteria

After the research and ideation of each sprint, I assume to have very little validation to compare concepts, since one-day sprints are too short to comprehend an entire recovery flow. I can, however, use these requirements and criteria as discussion points to elaborate on which benefits and drawbacks of each concept stand out to me. An endocutter concept needs to meet all the requirements set, otherwise, it could be a hazard to patients or other people involved. The criteria are a means to compare the different concepts. Scoring low on a criterium simply means a concept could in some way be less desirable than another. The first criterium has double the weight of the other ones since circularity is the main aim of this project.

Rq1: The endocutter retains its functionality after the redesign

Rq2: The endocutter is safe to use on patients (i.e. biocompatibility)

Rq3: The endocutter does not pose a contamination risk to anyone

Cr1: A high level of product integrity is preserved

Cr2: The endocutter fits within the current logistics and infrastructure of the hospital and OR.

Cr3: The redesign concept applies to more devices than just the Ethicon endocutter and sets an example for the MedTech industry

2. Design sprint reprocessing

Reprocessing is *a process carried out on a used device to allow its safe reuse including cleaning, disinfection, sterilisation and related procedures, as well as testing and restoring the technical and functional safety of the used device* [17].

This design sprint explores the different requirements and processes needed to properly clean and maintain the endocutter for another lifecycle. Reprocessing at LUMC is also described, as well as necessary product design alterations to adapt products for different cleaning processes. Next design opportunities and concepts for both in-hospital and external reprocessing are proposed and evaluated.

2.1. Research

In a comparison study between a single-use and reusable surgical stapler, depending on the type of surgery, the waste from a device could be reduced by up to 70% just by switching to a reusable alternative. This strategy could also reduce the total material requirement by over 90% [67]. However, this study compared two very specific devices and was highly impacted by the number of cycles the reusable device was able to withstand. Also, the sterilisation process itself has a notable environmental impact but was excluded from the analysis [55]. The sterilisation process can actually make the environmental impact of reusables larger than that of a single-use version of the same product, so the best course of action needs to be determined per individual case [68]. However, typically the use of single-use disposables results in higher petroleum use and higher greenhouse gas emissions compared to that of reusables [55].

Although a SUD is usually cheaper compared to a reusable device, reuse distributes the cost over many cycles which typically makes the lifetime cost of a reusable device lower. SUDs are also perceived to be safer compared to reusables, there is however no compelling evidence that they actually reduce the risk of infection from medical devices [55].

2.1.1. The Spaulding Scale

The Spaulding scale is a guideline for the disinfection and sterilisation of healthcare equipment. This scheme divides medical devices into three categories – critical, semi-critical and noncritical – based on the risk of infections from the use of the device [5].

Critical items

There is a high risk of infection if critical items are contaminated. These are objects that enter sterile tissue or the vascular system, and that must be sterile before use. Surgical instruments like the endocutter are examples of items that are labelled as 'critical'.

Semi-critical items

Semi-critical items come into contact with mucous membranes – like the inside of the mouth or the genital areas – or nonintact skin. These objects require high-level disinfection, which is generally defined as the complete elimination of all microorganisms in or on an instrument, except for small numbers of bacterial spores.

Noncritical items

Noncritical items only come into contact with intact skin, which is an effective barrier to most micro-organisms. Most of these objects may be decontaminated, even outside of the central reprocessing area and pose little risk of infection to patients.

figure 24. *An autoclave meant for steam sterilisation of critical medical devices at LUMC*

2.1.2. Sterilisation techniques

Critical items like the endocutter undergo a process of decontamination, disinfection and sterilisation as described by the RIVM [69]. There are however many different ways to sterilise medical devices, each with its benefits and drawbacks. The full overview of different techniques is shown in figure 26, but some of the most relevant and widespread techniques are:

Steam sterilisation

Steam sterilisation using saturated steam under pressure for sterilisation is the most widely used and most dependable process. It is also the preferred method for critical items, but not every device can withstand this process because of the heat and moisture involved. The use of steam is nontoxic, relatively inexpensive and fast [5].

Ethylene Oxide (ETO) sterilisation

This method is widely used as a low-temperature sterilisation technique. Devices that cannot withstand the heat or moisture from steam sterilisation are often treated using ETO. ETO sterilisation is far from ideal. The process takes a lot of time, is costly, and had been proven to be toxic and carcinogenic, with health hazards to staff and patients as a result. Because of this, ETO sterilisation is being phased out and should be avoided [5].

Hydrogen peroxide gas plasma sterilisation

The use of hydrogen peroxide gas plasma is another way to sterilize instruments that are sensitive to high temperatures or moisture. The by-products of this process are non-toxic, which makes it safer to handle sterilised devices [5].

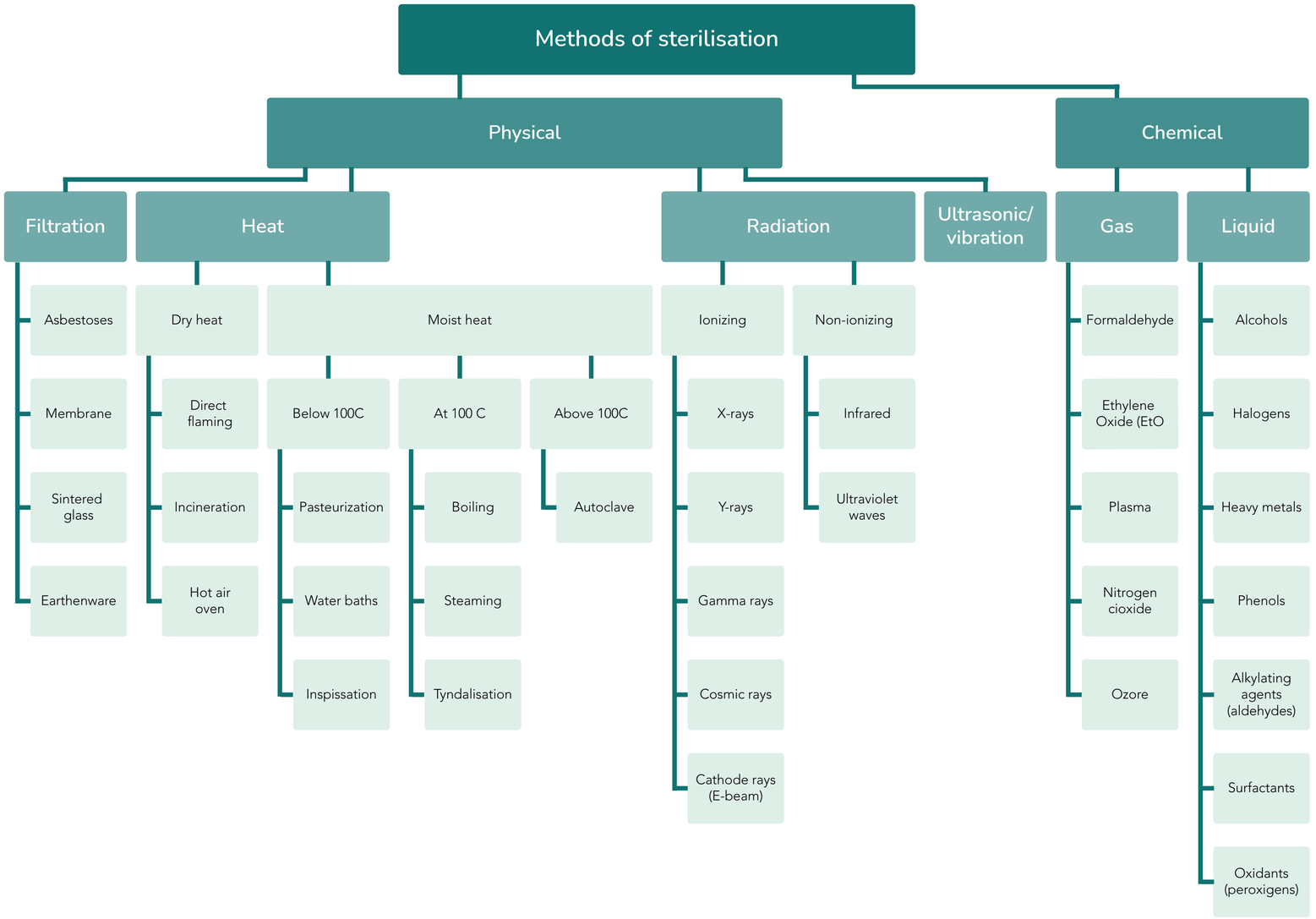


figure 25. *Different methods of sterilisation, adapted from Medical Plastics News [70]*

figure 26. *The clean room at LUMC*

2.1.3. Reprocessing at LUMC

I had the opportunity to get a tour of the ¬Sterilisation Department (SD) and OR of Leiden UMC, which gave me a good understanding of the practice of reprocessing in larger Dutch hospitals.

Different types of surgeries require different combinations of tools. All the tools are pre-sorted in so-called 'nets'; labelled metal baskets used for transport and storage. After surgery, the nets with contaminated equipment are brought to a designated contaminated room in the hospital, where everything is treated with extra care and employees are well protected. Here everything is first decontaminated by hand with water, specialised soaps and alcohol solutions.

Next, the nets are put into the disinfection machines in the contaminated room, and after the disinfection process taken out of the machines in the clean room on the other side. In this room, the nets are checked and re-sorted. Devices can be maintained, for example by lubricating hinges of moving parts, and broken items are set aside for repair. When everything is in order, the nets are packed in blue polypropylene (PP) wrap and stacked into carts, ready for the sterilisation process.

At LUMC, most instruments are sterilized by steam sterilisation. A cart with multiple nets is driven into an autoclave in the clean room, and taken out on the other side, where the sterile items are stored. LUMC also has a hydrogen peroxide gas plasma steriliser, which is used to sterilize thermoplastics. The cartridges used for this process make it very expensive in comparison, so this machine is used as little as possible. These machines are usually found in bigger hospitals with more resources, and which make use of more specialized tools that require different types of sterilisation.

Before surgery, the blue wrap is removed from the nets in a preparation room and everything is spread onto surgery carts, ready to be moved into the OR. The blue PP wrap is treated as general waste and separated for recycling.

2.2.2. Product design for reprocessing

One important factor in the possibility of recovering a medical device from hygienic obsolescence is the ability of the device to survive the disinfection and sterilisation processes. On one hand, there is the risk of incomplete sterilisation, on the other, there is the risk of material damage [11]. The product needs thermal stability, it must be possible to repeat the reprocessing cycle multiple times, and if the product is complex it must be possible to easily disassemble and reassemble the device during each cycle [71]. Currently, the electronics and complex components and design of the endocutter pose a barrier to steam sterilisation of the device.

Choice of materials

Depending on the type and process of sterilisation, there are different suitable materials for medical device design. Metals can withstand steam sterilisation, which is as mentioned before the preferred method of sterilisation. However, not all types of plastic are compatible with autoclaving. A useful resource to determine possible material choices is the book Sterilisation techniques for polymers by Wayne Rogers [72].

Electronics

Electronics can withstand steam sterilisation as long as they are encapsulated to be protected against moisture. However, high temperatures hurt the lifespan of batteries [73]. ETO sterilisation is better suited for electronic devices; only the vacuum could pose a risk to batteries. Hydrogen peroxide plasma sterilisation is not suitable for embedded electronics, especially for semiconductors [74].

2.2. Design opportunities

There are two main directions for reprocessing; internal, in-hospital reprocessing and external reprocessing. In-hospital reprocessing can be done by the SD of the hospital, where ownership of the devices remains with the hospital, or by a third party located inside the hospital. In this case ownership shifts to the third party which reprocesses the devices and then resells them to the hospital. This shift in ownership can be done externally as well. The product can be owned by the hospital and only be cleaned by a third party, but it can also be sold to this third party. This last option would mean any device resold to a hospital could be a different one from the device the hospital sold to the reprocessor for cleaning. These different routes are visualised in figure 35 on page 39.

2.2.1. Internal reprocessing

Internal reprocessing is already common practice for many surgical instruments, which means that sterilizing the endocutter internally could fit well within the current logistics and infrastructure of hospitals. There is less transport involved compared to external reprocessing so the process is more efficient and the loop is smaller. However, only a limited variety of sterilisation processes is available, which could mean that either the endocutter cannot be sterilized internally in many smaller hospitals at all, or that it needs a drastic redesign, possibly affecting the functionality of the device.

2.2.3. External reprocessing

With external reprocessing, a bigger change in logistics and infrastructure is necessary compared to internal reprocessing. It requires a separate collection of certain devices and a new form of infectious transportation. If the reprocessing is handled by the OEM that does mean they have full control over the quality and safety of reprocessed devices. When processing SUDs, taking into account liability is crucial [71]. Reprocessing with a shift in ownership could also serve as an extra revenue stream for the company since they have the chance to resell the same devices [40]. There are examples of external reprocessing services in the Netherlands [75].

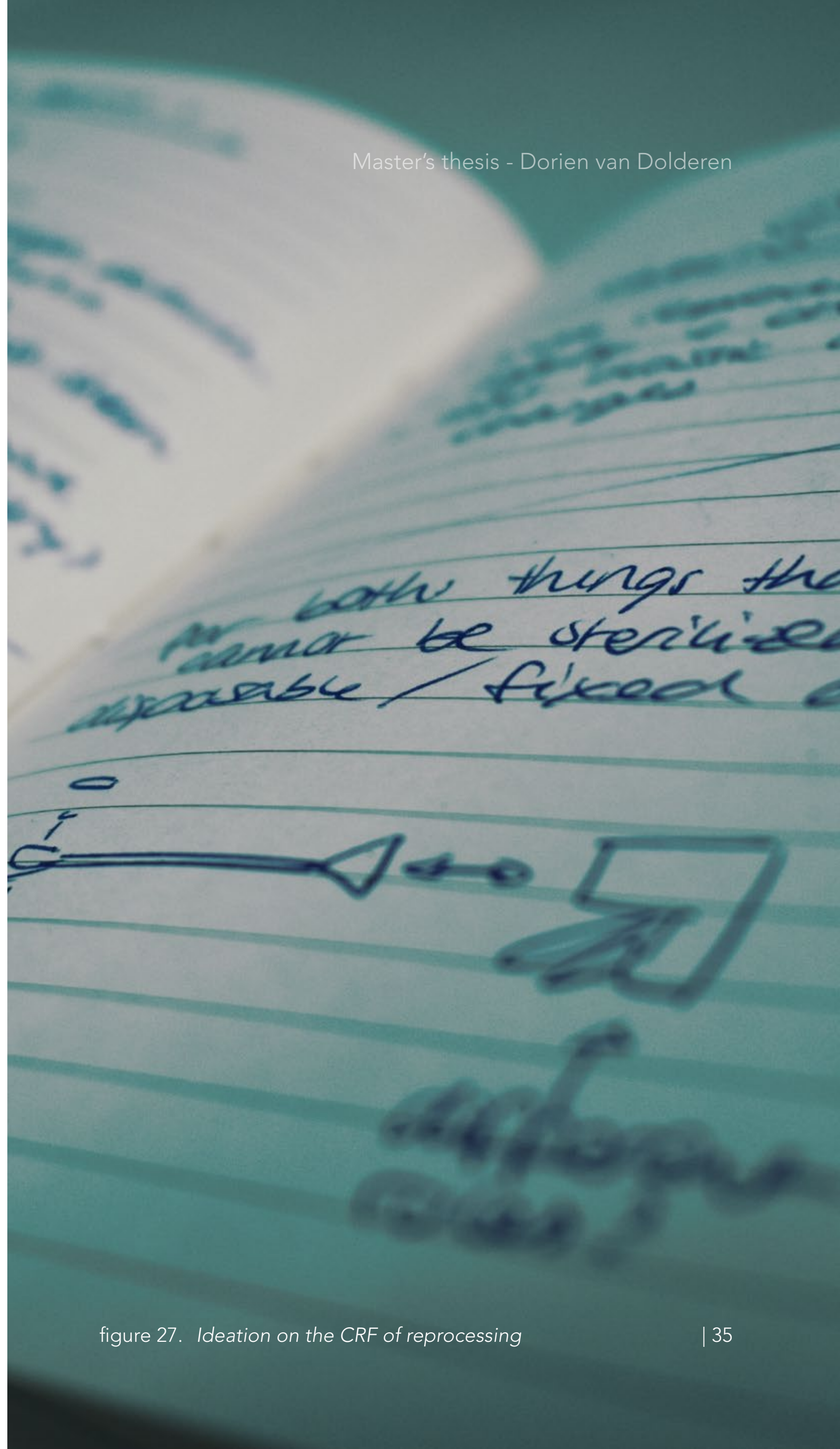


figure 27. *Ideation on the CRF of reprocessing*

2.3. Concepting

I came up with the following concepts during my design sprint.

2.3.1. Optimise for in-hospital sterilisation

Since steam sterilisation is possible in many different hospitals and is the preferred method of sterilisation because of the cost and safety of the technique, it makes sense to try to redesign the endocutter for this process. This means that it must be possible for hospital staff to partly disassemble the product so that everything is accessible for disinfection. Also, electronics must be either encapsulated to protect them from steam or removable before sterilisation and tested for resistance against high temperatures. Materials must be chosen to be steam resistant according to Rogers [72].

Steam sterilisation might not be the only means of sterilisation that hospitals have, especially when looking into the further future for solutions. More specialised hospitals that perform more laparoscopic procedures might also have more advanced sterilisation techniques at their disposal, which allow for less drastic redesigns.

Design for fixed cycles

If making the product entirely reusable (∞ cycles) makes it too expensive or impairs the function of the endocutter, it might be an option to design the product for a predetermined, limited number of cycles instead [11]. A way to make the safety of the device visual to the user is to include a sort of coating that dissolves after the maximum number of reprocessing cycles (figure 29).

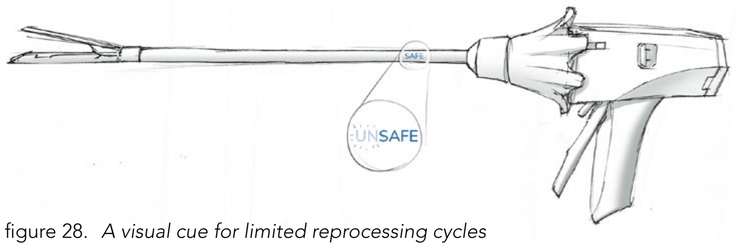


figure 28. *A visual cue for limited reprocessing cycles*

2.3.2. Modular design

Another option is to design the device to be modular. This has benefits for disassembly, remanufacture and recycling as well.

Hybrid design

If certain parts of the endocutter are especially hard to reprocess, or too complex to disassemble, it could be an option to dispose of some parts of the device while reprocessing others (figure 30). There is already an example of this hybrid design on the market; the Signia stapler from Medtronic [33]. This stapler has a reusable handle and a disposable shaft and shell.

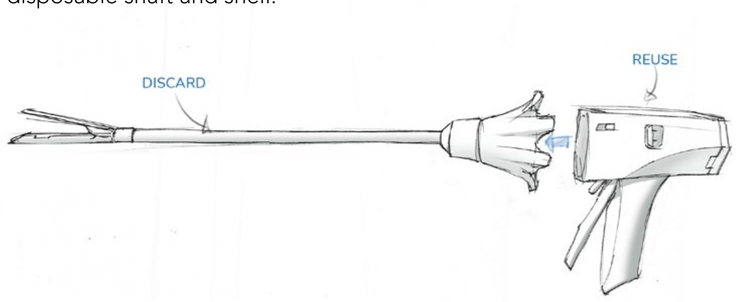


figure 29. *An example of a hybrid redesign of the endocutter*

Compatibility with other staplers

Ethicon manufactures different kinds of surgical staplers with different applications. If the handle were to be reusable, maybe it could be used in combination with other stapler end effectors. This could reduce the raw material needed for each surgery even further compared to the hybrid design (figure 31).

To quickly test this theory I documented the actions necessary to operate the device for the echelon flex endocutter as well as two other types of staplers from Ethicon based on their use guides (figure 32) [76].

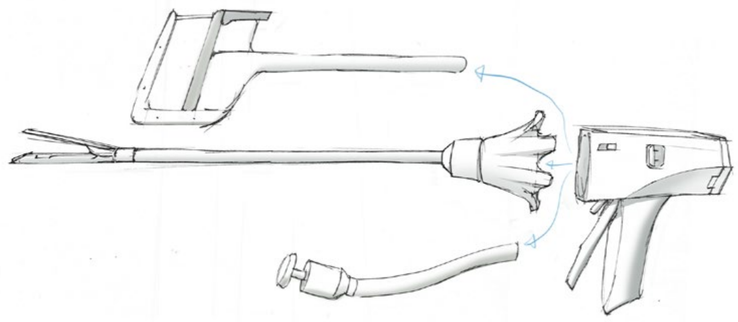


figure 30. *One multi-purpose handle for different staplers*

Type of stapler / Action on handle	Actuator/retaining pin	Close	Open	Articulation	Unlock	Fire	Knife return	Manual knife return	Adjustable to tissue
Endocutter		■	■	■	■	■	■	■	
Curved cutter	■	■	■			■			
Circular stapler		Speed not constant	■		■	■			■

figure 31. *A comparison of use actions for different Ethicon staplers*

Since there is quite a large variation between the operation actions necessary to control each device, and precision and efficiency are crucial in the operating room, the concept of a multi-purpose stapler handle does not seem feasible at this time.

Currently, the endocutter is a class 3 medical device according to the EU Medical Device Regulations [17]. Could it be possible to register the handle and the shaft as two different medical devices that are used together? This would mean the handle could be classified as 2b, and it would not be critical, but instead semi-critical on the Spaulding scale since it does not enter sterile tissue or the vascular system [5]. If this reclassification would be possible it would not be necessary to entirely sterilise the handle; high-level disinfection would be sufficient. It would also open doors for the redesign of many other laparoscopic devices of which the handle is operated outside of the patient's body.

2.3.3. Design for external reprocessing

If it would be possible to include endocutters in an existing external reprocessing service, it could be possible to design for many more sterilisation techniques compared to in-hospital sterilisation. There is already a CBM in place and the collection strategies have been proven. It is, however, unclear which devices are currently included in existing Dutch services, and if they are retrieved from the OR or just from more accessible parts of the hospital.

For a take-back system like this to work, enough devices need to be reprocessed for economic feasibility. The number of devices would increase if the service would collaborate with more hospitals, but it would also increase the distance of device transportation. Where lies the right balance between scale and distance?

figure 32. *Sorting and checking of disinfected devices*

2.4. Evaluation and reflection

For the CRF of reprocessing, there are two main directions; internal reprocessing and external reprocessing. The possibility of internal reprocessing mainly depends on the device itself, so an in-depth analysis of the different parts and materials is necessary to move forward. For external reprocessing, this product analysis helps as well, but there also needs to be a lot of attention on the product service system (PSS) and the business model around the endocutter, as well as in-hospital logistics. To gain a more in-depth understanding of the current reprocessing of medical devices and the infrastructure around them, I need to get in contact with a reprocessing service. Depending on the outcome of the product analysis and reprocessing service interviews, the reprocessing flow could be very realistic.

I graded each concept on the requirements and criteria determined before the design sprints (figure 34). This grading is an initial evaluation, but will not be used to definitively choose or exclude ideas. More research into the ideas is needed than can be covered in a one-day design sprint.

The only concept that does not meet a requirement is the concept of stapler compatibility. There would be such a drastic redesign necessary to make a handle compatible with multiple types of staplers, that the functionality of the endocutter will change. It would be hard to guarantee the same level of precision and ease of use as that of the original device. Also, the concept of separate classification is at risk, because making medical device classification rules more lenient could increase contamination risks from medical devices.

The reprocessing concepts of in-hospital sterilisation and fixed cycles score best on these criteria. This is because the full endocutter can be reprocessed via a standard hospital reprocessing procedure. The hybrid design, separate classification and external reprocessing score well as well, but either maintain a lower level of product integrity or do not currently fit into hospital logistics.

Possible further research into the topic of reprocessing includes an in-depth product analysis of the current design of the endocutter to explore problematic areas for different cleaning processes, as well as research into logistics and infrastructure around current reprocessing practices. It would also be useful to look into the approval of different parts of the endocutter as different medical devices, each with its criticality and cleaning guidelines. This possibility would open doors for different modular redesigns of the device.

Reprocessing

	Requirements and criteria:	Concepts: In-hospital sterilisation	Fixed cycles	Hybrid design	Stapler compatibility	Separate classification	External reprocessing
Rq1	The endocutter maintains its functionality after redesign	+	++	++	--	++	++
Rq2	The endocutter is safe to use on patients (i.e. biocompatibility)	+	++	++	++	++	++
Rq3	The endocutter does not pose a contamination risk to anyone	+	+	+	+	+-	+
Cr1	A high level of product integrity is maintained (this criterium weighs double)	++	++	+	+	+	++
Cr2	The endocutter fits within the current logistics and infrastructure of the hospital and the OR	++	++	+	+-	+	-
Cr3	The redesign concept is applicable to more than just the Ethicon endocutter and sets an example for the medical device industry	+-	+	+	+	++	+
	Total score concept:	6	7	4	2	5	4

++ = definitely (Rq) or 2 (Cr) | + = probably (Rq) or 1 (Cr) | +- = maybe (Rq) or 0 (Cr) | - = maybe not (Rq) or -1 (Cr) | -- = definitely not (Rq) or -2 (Cr)

figure 33. *Initial comparison of reprocessing concepts*

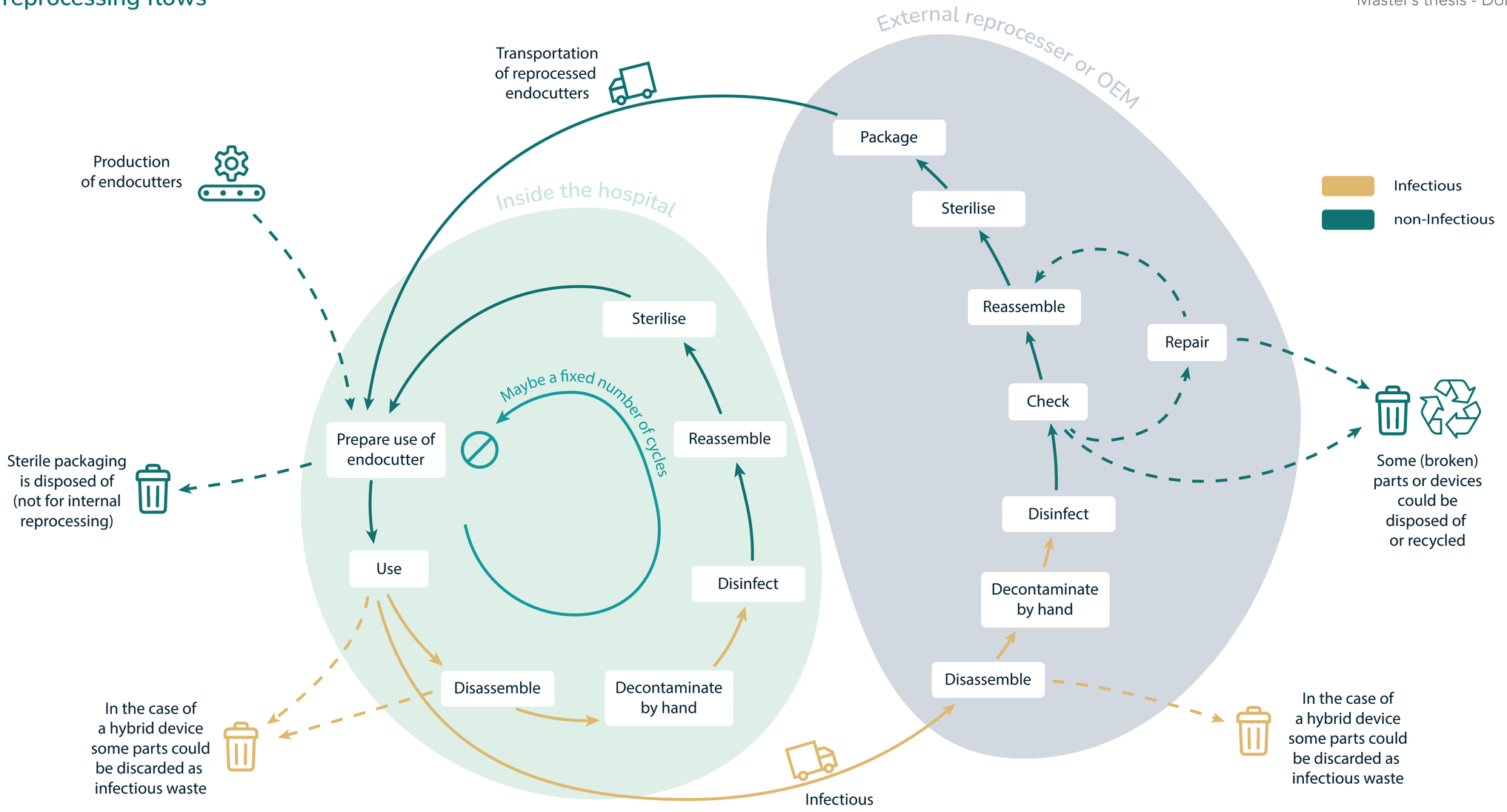


figure 34. *A schematic overview of different reprocessing flows*

3. Design sprint remanufacturing

Remanufacturing is *the complete rebuilding of a device already placed on the market or put into service, or the making of a new device from used devices, to bring it into conformity with regulation, combined with the assignment of a new life to the remanufactured device* [17].

This design sprint goes into product design for remanufacturing as well as examples from the medical industry. Opportunities and one concept for remanufacturing endocutters are proposed.

3.1. Research

3.1.1. How to remanufacture

Because remanufacture and refurbishment are sometimes used interchangeably, information on both has been gathered. Also, van den Berg & Bakker [77] propose the term "remaking" as an umbrella term for refurbishing and remanufacturing. Remaking consists of all actions performed when a product returns from the customer. They also provide a circular economy framework that serves as a tool for designers for applying circular product design in practice. For the remanufacture (here remaking) of products, the product disassembly needs to be non-destructive to preserve parts and materials. Van den Berg & Bakker [77] also recommend strategies within the categories of Modularity, Reliability Assessment and (reverse) logistics (figure 36).

In theory, everything that is manufactured can also be remanufactured, but the feasibility of remanufacturing depends on the business case. It is easier to remanufacture mass-produced items since product cores and spare parts are more readily available [78].

Design for remanufacture involves both the business model and the product design (figure 37). Product strategy includes sales, marketing, service and reverse logistics, while product design includes design for core collection, as well as functional design [79].

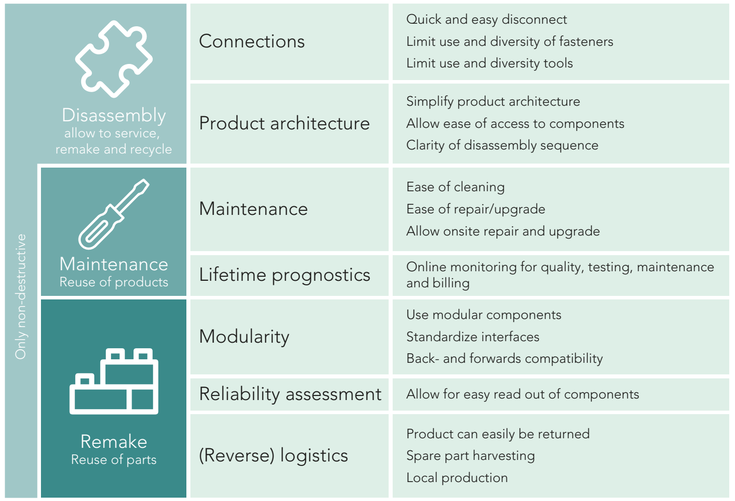


figure 35. *Part of the circulr economy framework adapted from van den Berg & Bakker [77]*

It is important to design for greater product durability, but there needs to be a focus on some parts of the product. Designing entire products for a long life could result in unnecessarily high production costs and a waste of resources [78]. Effective product design for remanufacturing can improve efficiency in disassembly, reassembly and inspection, which reduces costs.

In some cases, the strategies around the remanufacturing process might have a greater impact on remanufacturing possibilities than detailed product design [79]. However, the product design and circular business model need to be developed concurrently [80].

A limiting factor to remanufacturing is retrieving the product "core" in good condition and for a low enough price. There also needs to be a good relationship between possible 3rd party remanufacturers and OEMs to avoid competition. For the whole process to be viable, the cost of the process of remanufacturing should be less than that of the original manufacture, unless the disposal of the product is so expensive that a higher remanufacturing cost is justified [78].

Sometimes only some parts of the product can be reused. When 'part harvesting', the goal is to recover a limited set of reusable parts from a product, which in turn can be used to remanufacture other products or components [80].

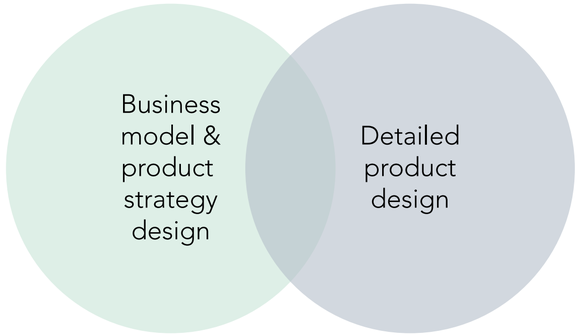


figure 36. *The two inter-related levels of design for remanufacture, adapted from Gray & Charter [79]*

Design for disassembly

Since disassembly is central to the extending or renewing of lifecycles, design for disassembly is an important strategy. Disassembly can be subdivided into connections and product architecture [77].

The efficiency of a product's disassembly is mostly determined during the design phase [77]. The cost of disassembly is determined by the EoL destinations of the materials recovered from the disassembly process, and the time and resources it takes to execute disassembly [81].

3.1.2. Remanufacturing of medical devices

Remanufacturing is already widespread in the medical industry but mostly happens with high-value, low-criticality products like MRI machines. The process often involves take-back schemes from OEMs and leads to a reduced cost for users [11]. It is possible to remanufacture instruments for surgery as well [47].

Various companies assist northern American hospitals in the "reprocessing" (but actually remanufacturing) of medical devices [40]. Some are subsidiaries of OEMs and only handle devices of a specific brand, others remanufacture a variety of brands. These companies provide dedicated bins for safe transport and train hospital staff on how and what to collect after procedures. Currently, used endocutters are not recovered through remanufacturing [63].

For the remanufacture of surgical instruments, devices first need to be disinfected and sorted before transport by hospital staff [40], or they need to be transported as infectious waste. Devices need to be sorted according to their manufacturer and destination, which is a process that does not currently fit into hospital logistics. At LUMC (appendix 1.1) they mentioned that the hospital purchases medical devices from many different OEMs so it would be a logistic nightmare to collect devices from each manufacturer separately. If remanufacture were to be implemented, good collaboration between OEMs – or between OEMs and a third party – would be essential. If there was a collaboration between many different manufacturers, the remanufacturing of medical devices would be easier to implement.

3.1.3. Design opportunities

Both product redesign and CBM design are crucial for the CRF of remanufacturing. At this point, I have not yet analysed the endocutter at a product level, so concepting on design strategies like modularity, interfaces and compatibility is inefficient. More information on the connections within the endocutter and its product architecture is needed first.

For the CBM it is necessary to look into the collection system, as it should fit in as seamlessly as possible in the current logistics around the OR.

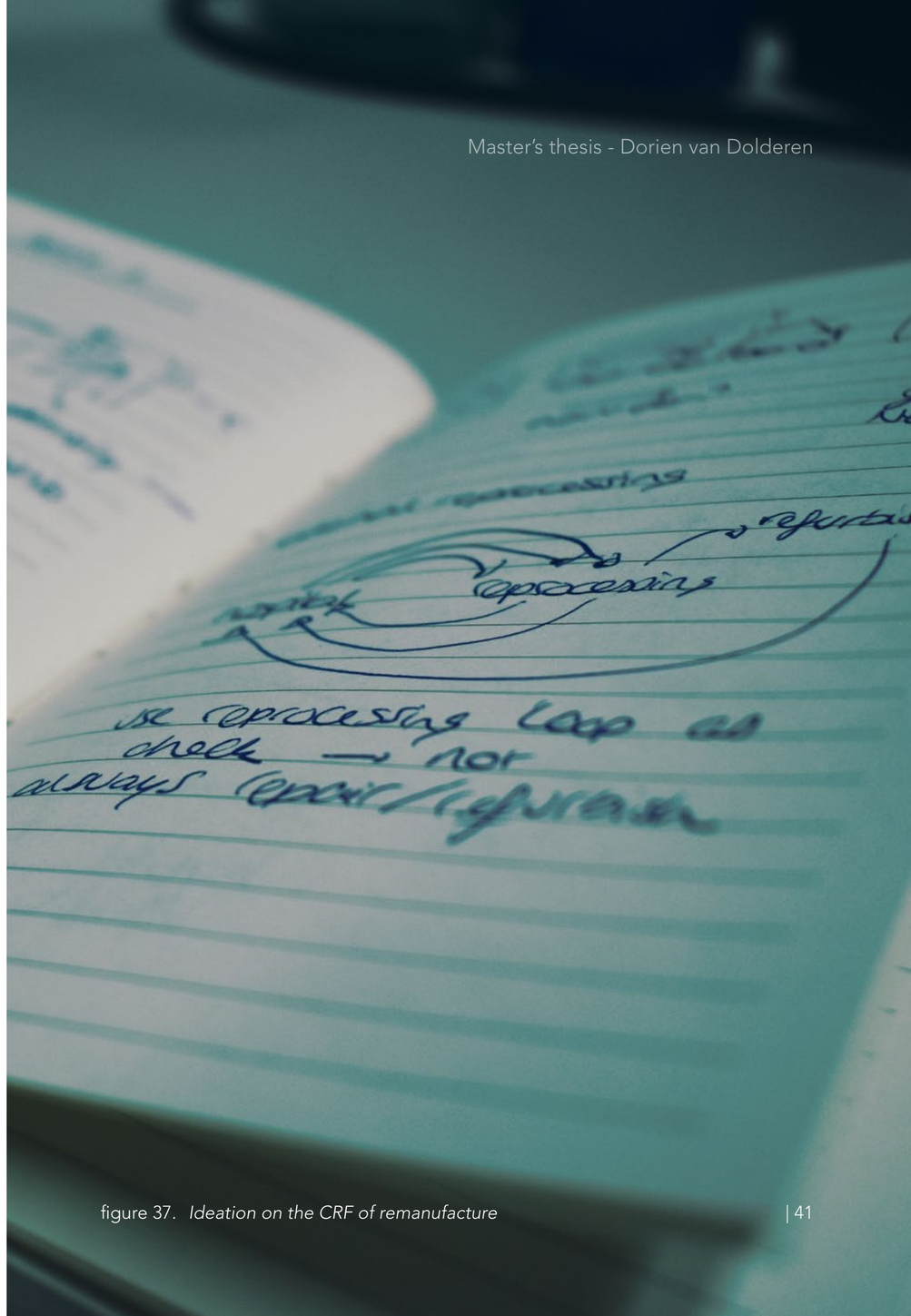


figure 37. *Ideation on the CRF of remanufacture*

3.2. Concepting

3.2.1. International collaboration

For remanufacturing to be possible, a large collaboration between different OEMs is necessary. This allows for one collection system for most of the devices used in the OR, instead of different collection systems for products from different manufacturers. If the remanufacturing of devices would be managed internationally, the design and management of these facilities would be more realistic since everything could be handled at a larger scale. When the collection system is in place, remanufacture can be combined with external reprocessing, repair services and EoL recycling to realize an all-encompassing circular strategy for medical devices. This approach would also generate extra revenue for OEMs, as they can resell recovered devices to hospitals.

International waste transport

For an international collaboration to be possible, infectious medical devices would need to be transported across borders. International agreements were made in the 'Basel Convention on the Control of Transboundary Movements of Hazardous waste', which currently has a nearly universal membership with 175 parties. Each member state can prohibit the import, export or transit of hazardous waste, and other member states must comply. Member states are responsible for their waste and it is prohibited to export hazardous waste to developing countries [21].

According to the Basel Convention, it is not allowed to transport hazardous waste across borders. There is, however, a distinction between the removal of waste and the useful application of waste. Useful applications could for example cover recycling or part harvesting strategies, but international transport for remanufacturing could fit within this category as well [23]. Parties who want to transport waste across borders need permission and a license from the ILT [22] (Inspection of Living environment and Transport). Through an interview with Prezero (appendix 1.2), the company handling the waste streams from Erasmus MC, I learned that it is probably possible to get an exception on the international hazardous waste regulations if the aim was to remanufacture devices and this way close medical waste loops. This process would, however, take quite some time.

If the contaminated devices were to already be disinfected inside the hospital where they are used, all these waste transportation rules would not apply. The devices could then be treated as non-infectious, and transport would be a lot less complicated [22].

figure 38. *Sealed boxes with infectious waste, ready for transport at Erasmus MC*

3.3. Evaluation and reflection

The Circular Recovery Flow of remanufacture could be really interesting. It is however highly dependent on the product design of the endocutter, which needs more research. It is very unclear what kind of redesign is necessary to make remanufacturing feasible. On the other hand, the business model could already partly exist, which is why I am very curious to learn more about existing remanufacture collection systems.

This concept was more challenging to evaluate according to my criteria than the reprocessing concepts because more in-depth information is needed (figure 40).

It is unclear if the endocutter would meet the first requirement because it is hard to determine how drastic a redesign needs to be for remanufacture without a good view of the current version of the endocutter. On the criteria, the remanufacture concept scores lower than the reprocessing concepts because a lower level of product integrity is maintained and devices need to be collected separately per OEM. This does not currently fit in with hospital logistics and infrastructure. If such a large-scale collaboration would be possible it could have a big impact on the medical device industry.

Possible further research into the field of medical remanufacturing includes research into existing services and collaborations, as well as an evaluation of the remanufacturability of the current endocutter design.

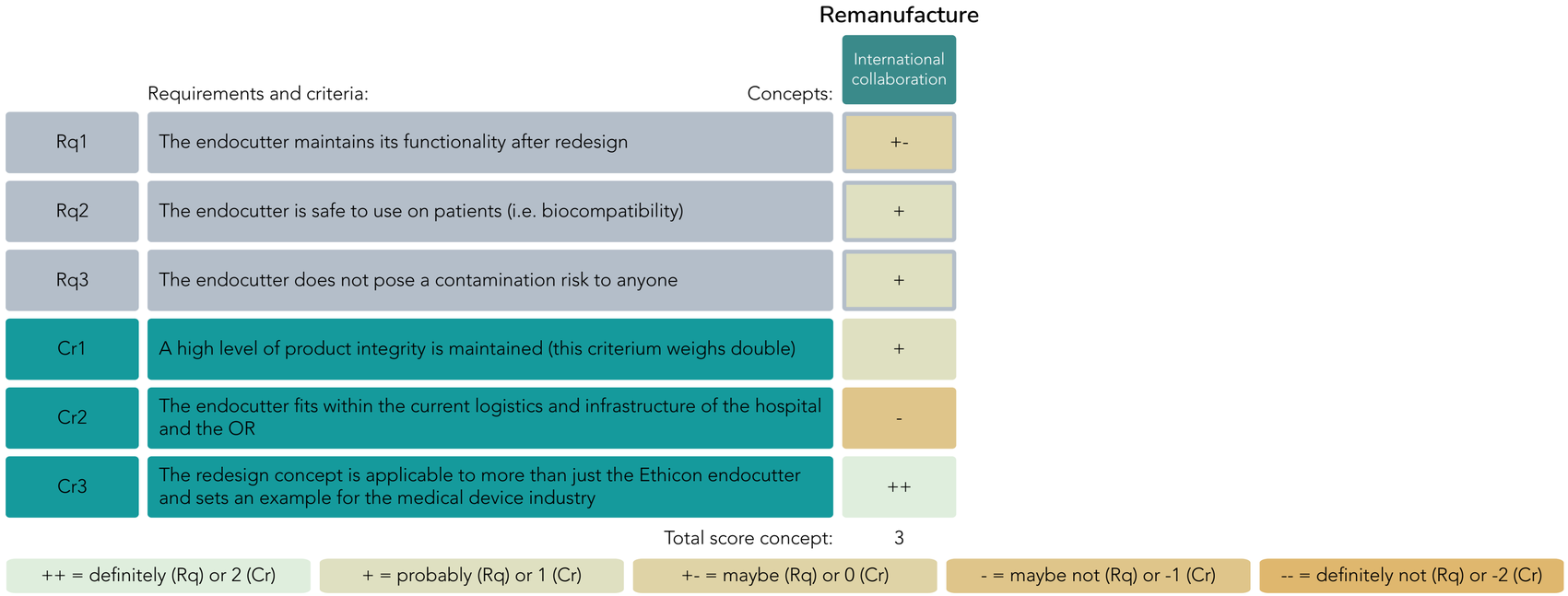


figure 39. *Initial evaluation remanufacturing concept*

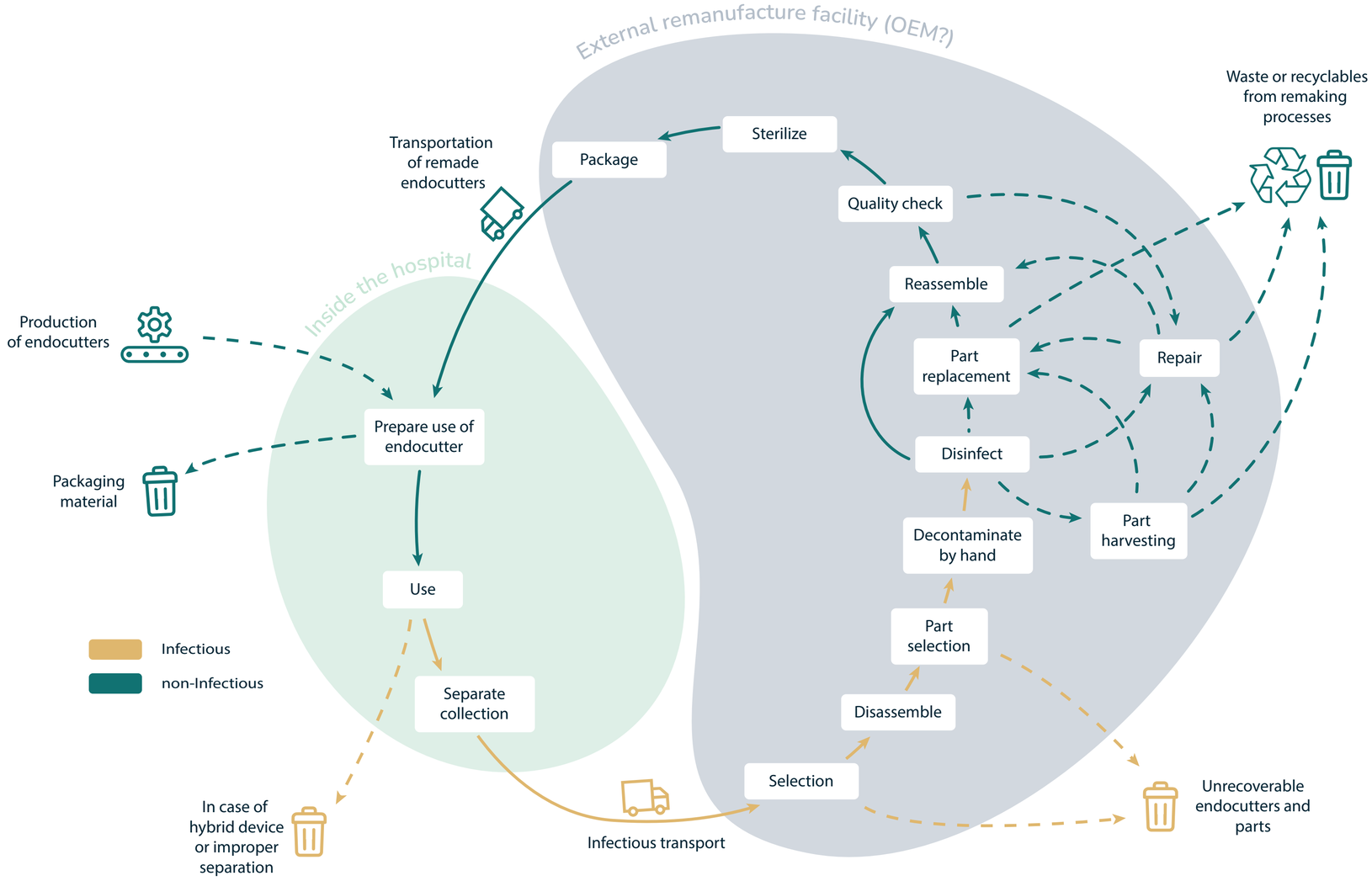


figure 40. *A schematic overview of a remanufacturing flow*

4. Design sprint recycling

In **recycling,** *the identity and functionality of the product and its components are lost. The purpose is to reuse materials instead of parts from used products and components [16].*

This design sprint goes into the different levels of recycling, the recycling of different types of waste and the viability of recycling. Also, design for recycling and the inclusion of recycled material is explored. Opportunities and two recycling concepts are proposed.

4.1. Research

Recycling is less desirable compared to previous flows because it often needs a large input of energy and needs transport to specific recycling centres [82]. Recycling is only preferred when maintenance, repair or remanufacture is not possible. There is proof that it is feasible to use medical waste as a source of raw material. The process of recycling could contribute to a reduction in the size of medical waste streams [83]. There are four main levels of recycling [84]:

1. Primary recycling – closed loop recycling; mechanical processing into a product with equivalent properties
2. Secondary recycling – downgrading; mechanical processing into products requiring lower properties
3. Tertiary recycling – recovery of chemical constituents. Composting of biodegradable plastics is an example of this and can also be referred to as organic or biological recycling.
4. Quaternary recycling – recovery of energy (The way medical waste is handled currently)

4.1.1. What can be recycled?

Contaminated waste

A specialised logistical setup is required to process contaminated medical devices, which also generates more costs for hospitals [83]. For this design sprint, I assumed that the endocutter is collected as a medical recyclable from the operating room and is not part of the general infectious waste stream. As mentioned in the previous design sprint, the devices could either be disinfected before transport or transported as infectious waste.

Contaminated waste used to not be considered for material recycling because of the infection risk [85]. However, technologies have been developed that can sterilize infectious waste by first shredding the material and subsequently treating it with high-temperature steam, microwaves or chemical treatment [82]. These techniques have been implemented in some Dutch hospitals (appendix 1.2). For example, at Erasmus MC a Pharmafilter [86] system has been installed. This is a system that shreds waste, transports it through the hospital's sewage system and then disinfects the waste mix. UMC Utrecht has another type of disinfection system which is capable of shredding infectious waste and microwaving the scraps for disinfection. After these processes, previously infectious waste can be treated as regular waste, which makes disposal significantly cheaper. The scraps can be recycled as well, but are so small that this is currently not economically feasible.

It is also possible to disinfect without shredding devices first, as long as the disinfection process can reach all contaminated parts. This would either require some level of disassembly or a drastic redesign of the endocutter. Disassembly makes the process very costly since employees must be trained to identify and disassemble individual devices on a small scale. The endocutter could also lose part of its functionality after a redesign that makes all contaminated parts accessible for disinfection. It could be interesting to look into shredding the device into larger pieces to improve the yield from the recycling process.

Surgical steels

Surgical instruments are often manufactured out of stainless steel [47] (figure 42), which is why I assume for this design sprint that the shaft and end-effector of the endocutter are made of SS. Stainless steel is recycled on a large scale by remelting scrap into new steels [87] and often has a significant recycled content [88].

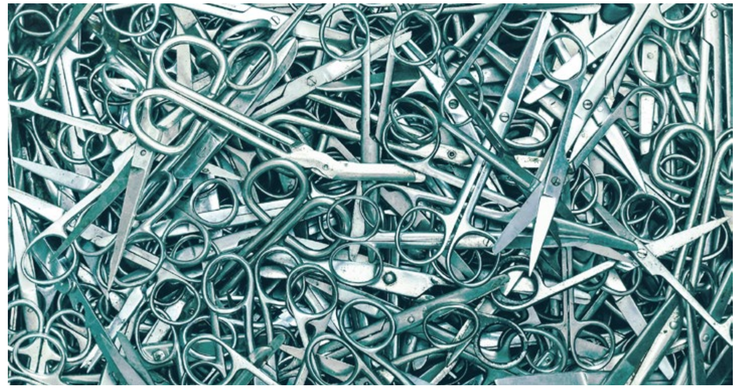


figure 41. *Stainless steel surgical scissors*

Medical plastics

Plastics can only be recycled a limited number of times before they become too contaminated and can no longer be used [2]. Most plastics can successfully be recycled (appendix 1.2).

Electronics

Electronics are highly complex and valuable. They can be recycled but should, if possible, be separated from the other materials of the device [77].

4.1.2. Is recycling viable?

To determine the viability of recycling a comparison needs to be made between the cost of recycling and the costs of alternative ways of disposal. The value of the reclaimed materials compared to the virgin material must also be taken into account, as well as the logistics behind the collection and disinfection of contaminated waste [83], [84]. The viability of recycling must be evaluated case by case.

Prezero explained that the business case does not always need to be airtight. Hospitals are sometimes willing to pay more for EoL processes if it means they reduce their environmental footprint. Also, the disposal of infectious waste is five times more expensive compared to the disposal of general waste, and this difference in cost does not even include the purchase of mandatory plastic transportation bins. If in-hospital disinfection installations become more widespread and efficient, it could become more economical for hospitals to treat their waste, which would make recycling more accessible as well (appendix 1.3).

4.1.3. Design for recycling

Unlike disassembly for the recovery flow of remanufacture, disassembly for recycling is usually destructive. Non-destructive, manual disassembly can be valuable due to better material separation but is only viable for bigger, more valuable products with specific valuable components and a lot of units being recycled. Recyclability is mostly determined by the choice of materials and how easily these can be separated from each other [81]. On top of that, a recycling industry of a larger scale makes the recycling of individual units more economically feasible. This is because of economies of scale; the cost of large investments can be divided over a greater number of devices [61].

According to the framework of van den Berg & Bakker [77], there are different design strategies for recycling which are separated into the categories 'materials', 'electronics' and 'connections' (figure 43).

Destructive or non-destructive disassembly	Recycle Reuse of materials	Materials	Avoid the use of (non-compliant) coatings Limit the number of different materials Only use materials that can be recycled Use preferred/pure materials
		Electronics	Get PCB out in one piece Easy/fast detection of materials Use SMD components
		Connections	Avoid fixed connections Break down by shredding/disassembly to: Pieces of uniform composition Pieces of relatively large size (>1cm)

figure 42. *Part of the circular economy framework adapted from van den Berg & Bakker [77]*

figure 43. *Electronics separated for recycling at Erasmus MC*

figure 44. *Waste separation at Erasmus MC*

4.1.4. Inclusion of recycled material

Whether or not virgin plastic can be substituted by recycled plastic usually depends on the purity of the recovered plastic and the property requirements of its destination product [84].

In the US, the FDA (Food and Drug Administration) is responsible for the approval of medical devices. The FDA considers the specific properties of the material like biocompatibility, the intended use of the device, and the function of the device when evaluating the safety of the device and its material constituents. They do not approve individual materials, but rather decide on their approval on a case-by-case basis [89]. For this design sprint, I assume the approval process of medical devices by notified bodies in the EU works similarly.

Especially for invasive medical devices like the endocutter, materials included in a device must be non-toxic and compatible with use on human tissue [17]. Generally in recycled plastics, different levels of material contamination are allowed depending on the application of the product. The use of recycled plastics with unknown composition is limited in high-purity applications [90].

In conclusion; It is a challenge to determine whether or not recycled material can be included in the endocutter. It depends on the patient contact of that specific part, which influences the material requirements, and the purity of the material that is used. In the end, the product needs to be legally approved to be sure.

4.2. Design opportunities

For simplicity, I divided the endocutter into four main parts; the handle, the shaft, the electronics and the reloads. Each part has different opportunities within this recovery flow. The number of different materials used should be minimised and the materials and connections between these materials must be suitable for recycling.

The handle

The handle is made from a type of plastic that could be recycled. It might even be possible to include recycled material in this part of the device since it does not come into direct contact with human tissue. It would be preferred to manufacture the whole handle from a single type of plastic for better material separation.

The shaft

The shaft is made from surgical steel which is a high-value material that can be recycled (if there is no need for a non-compliant coating). Since the shaft is hollow it could be a challenge to disinfect it without the need for shredding. This needs further research.

Since this part of the endocutter enters human tissue, it is subject to tighter regulation. Stainless steel usually partly consists of recycled material, how pure should the material be in this kind of application?

The electronics

The electronics inside the handle are treated as e-waste and should be recycled as long as they are not infectious. The battery needs to be separated from other materials as well.

The reload

The reloads are small, complex units with multiple different materials. They could be recycled but because of the small amounts of different materials, it would probably be less profitable compared to the other parts of the endocutter.

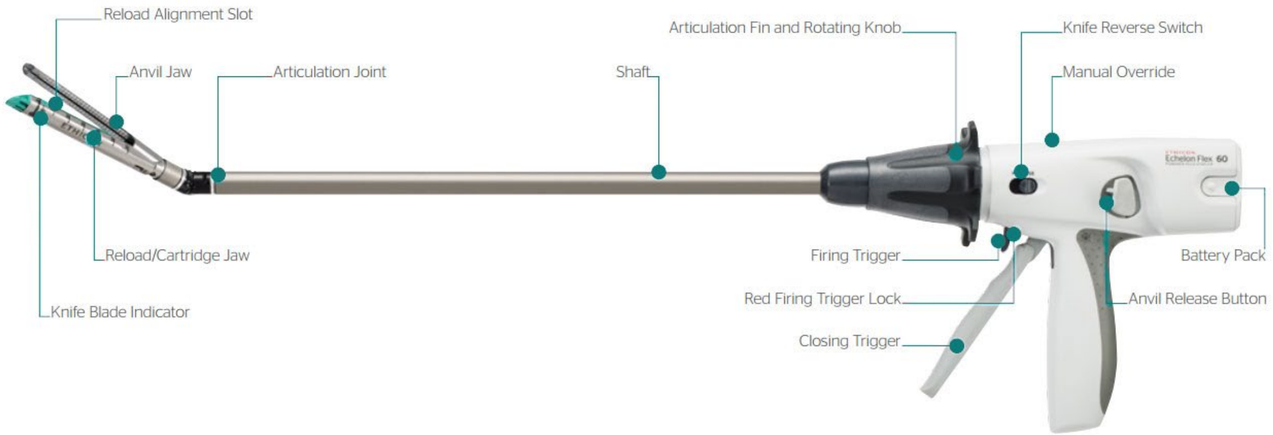


figure 45. *An example of the different parrts of an endocutter (Ethicon Echelon Flex 60 stapler) by Central Infusion Alliance (CIA) [91]*

figure 46. *Ideation on the CRF of recycling*

4.3. Concepting

4.3.1. Inclusion of recycled material

I assume that currently the parts of the endocutter made from stainless steel already have recycled content, but that the plastics are made from virgin material. This is why looking at recycled plastic content in the handle could be interesting.

One of the main barriers to recycling mixed plastics is polymer contamination in the result. Properties could be hard to predict because of impurities since the composition of the recycled plastic is not always clear [90]. This could be an issue for materials included in medical devices because there needs to be a high level of certainty that materials coming into contact with patients are biocompatible and non-toxic.

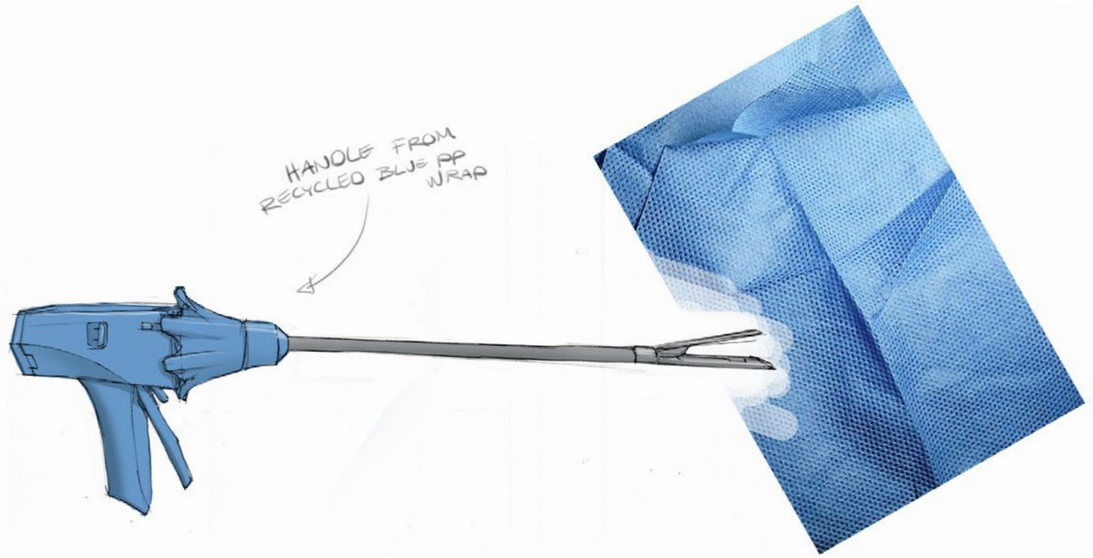


figure 47. *Concept inclusion of recycled material*

Hospitals have a large waste stream of polypropylene (PP), partly because of the large boxes some medical devices arrive in and partly because of the blue PP wrap used to pack the nets storing sterile surgical tools. This waste stream is uncontaminated, and the material is easily separated. This makes hospital PP a great resource for recycling and potentially a base material for new medical devices, as demonstrated by van Straten [83].

It might be possible to make the handle of the endocutter from recycled hospital PP. The handle does not enter human tissue, so maybe high-grade recycled PP would be approved in this application (figure 48).

4.3.2. Design for recycling

Designing for recyclability can be achieved according to different strategies, according to van den Berg & Bakker [77]. The materials included in the design need to be evaluated and may need to be reconsidered, and the number of different materials needs to be minimised. The connections between different parts need to be designed for recycling as well so that it is possible to shred the device into pieces large enough for proper separation.

This concept is an endocutter made of four main parts; the shaft from surgical steel, the handle from recyclable plastic, the reload, and the electronics (figure 49). These parts do not need to be designed for manual disassembly, but there should be no permanent fixtures between them to allow for proper material separation after shredding.

Whether or not this is possible needs to be evaluated after an in-depth product analysis.

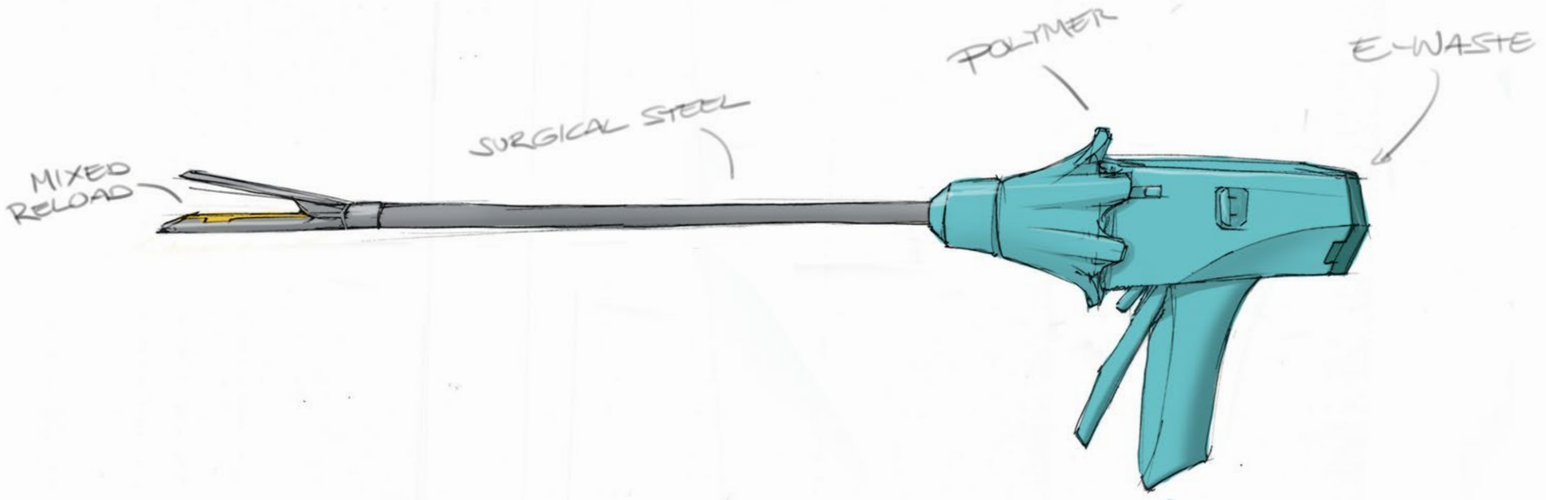


figure 48. *Concept Design for recycling*

4.4. Evaluation and reflection

Both concepts could be interesting but depend on hospital logistics and detailed product design. It might not be possible to reduce materials and choose non-permanent connections without compromising the functionality of the endocutter. On top of that recycling some materials require so much energy, that choosing incineration and energy recovery instead of recycling might be the more environmentally friendly option. This decision would require an LCA. The inclusion of recycled material depends on regulation and the approval of individual devices, which needs to be looked into further after this design sprint.

Both concepts need to be evaluated further to determine whether or not they meet all the requirements. They score lower on the criteria compared to the concepts from previous flows, because a lower level of product integrity is preserved. Design for recycling could apply to many similar products as well, which makes it worth investigating further, especially if it goes hand in hand with a scale-up of in-hospital medical waste disinfection for recycling. The inclusion of recycled material is not a very impactful direction but, if the device could get approved, relatively easy to implement.
Possible further research into medical device recycling includes finding example devices which include recycled materials and looking into the legal approval of these example devices. It would also be useful to look into the requirements and risks of including high-risk products like the endocutter in recycling schemes.

		Recycling	
	Requirements and criteria:	Concepts: Design for recycling	Inclusion of recycled materials
Rq1	The endocutter maintains its functionality after redesign	+-	++
Rq2	The endocutter is safe to use on patients (i.e. biocompatibility)	++	+-
Rq3	The endocutter does not pose a contamination risk to anyone	+	++
Cr1	A high level of product integrity is maintained (this criterium weighs double)	+-	-
Cr2	The endocutter fits within the current logistics and infrastructure of the hospital and the OR	+	++
Cr3	The redesign concept is applicable to more than just the Ethicon endocutter and sets an example for the medical device industry	+	-
	Total score concept:	2	-1

++ = definitely (Rq) or 2 (Cr) | + = probably (Rq) or 1 (Cr) | +- = maybe (Rq) or 0 (Cr) | - = maybe not (Rq) or -1 (Cr) | -- = definitely not (Rq) or -2 (Cr)

figure 49. *Initial evaluation recycling concepts*

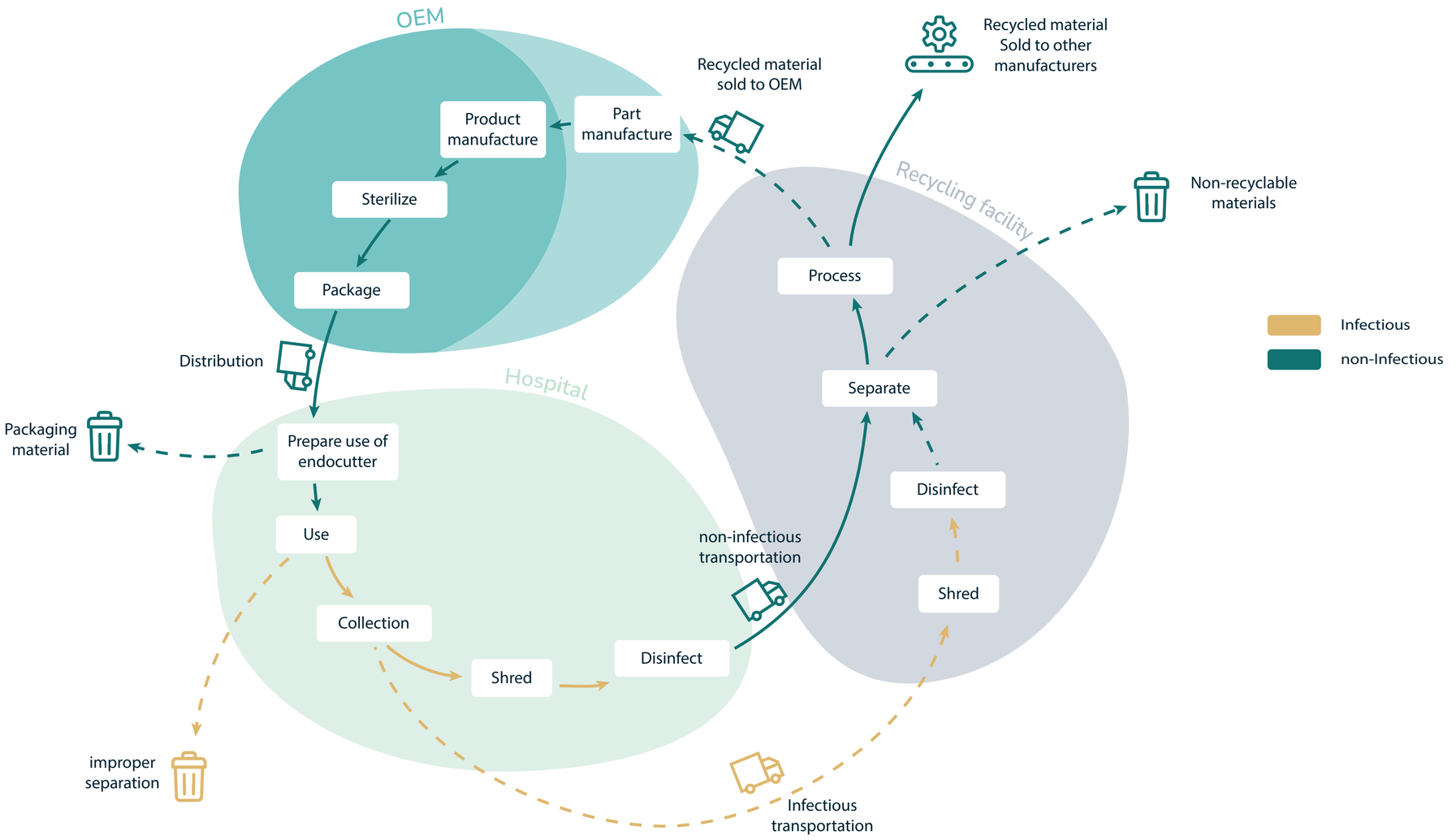


figure 50. *A schematic overview of different recycling flows*

5. Design sprint biomaterials

The CRF of **biomaterials** goes into *recovery via the biological cycles instead of the technical cycles of the butterfly diagram [57]. Biomaterials are materials that (1) are biodegradable, or (2) may or may not be degradable but are produced from biological materials or renewable feedstock (adapted from Atiwesh et al. [2]).*

For this flow, I made the assumption that only the handle and the reload could possibly be made from biomaterials because the shaft should be made out of surgical stainless steel. There are many different biomaterials, but for this application, I will only go into the bioplastics, because I assume these are the most suitable for use in the handle and reload.

Bioplastics are plastics that (1) are biodegradable, or (2) may or may not be degradable but are produced from biological materials or renewable feedstock [2].

5.1. Research

Bioplastics are plastics that (1) are biodegradable, or (2) may or may not be degradable but are produced from biological materials or renewable feedstock. Many petroleum-based plastics are not biodegradable, which means they don't deteriorate over time and remain where they have been disposed of, harming the environment. Nondegradable plastics can take decades or even centuries to break down [2].

Guzzo et al. [40] mention that the inclusion of bio-based plastics could be an alternative to recycling SUDs. Since bio-based plastics are made from renewables, fewer fossil fuels are used in production compared to fossil fuel-based plastics. This does however not guarantee a lesser environmental impact in return [92].

Just as not all petroleum-based plastics are nondegradable, not all bio-based plastics are biodegradable. Some bioplastics even contribute significantly to global warming, pollution and drastic change in land use. The source of the plastics and the needed facilities for possible composting has a great influence on the environmental impact of the device [62]. To know for sure if a bioplastic makes a good substitute, a lifecycle comparison is necessary [2].

There are four categories of biodegradability [92]:

1. Biodegradable; 90% of the material can be decomposed and the other 10% is non-toxic to the environment.

2. Compostable; the rests of decomposition form less than 10% of the original mass and have no toxic effects.

3. Bio-fragmentable; blends of synthetic and natural elements. The natural elements disappear over time and fragments of synthetic polymers remain.

4. Oxo-bio-degradable; thermoplastics with additives that can be decomposed or fragmented, but of which the toxicity is not evaluated.

Biodegradability is strongly determined by factors like humidity, temperature and micro-organisms, and conditions in nature are often very different from those in a laboratory [93].

5.1.1. Advantages of bio-plastics

Bio-plastics could have a lower carbon footprint compared to conventional plastics; generally, they are made from renewable resources, generate fewer greenhouse gases and the production requires less energy [93].

5.1.2. Disadvantages of bio-plastics

The bioplastic industry sometimes competes with agriculture for the resources necessary for production. A redistribution of farmland towards the production of bioplastics could lead to a rise in food prices, affecting mostly poorer regions of the world [2], [93].

At end-of-life, bioplastics are hard to separate from other plastics, which could lead to problems with recycling. Composting usually requires industrial treatment as well, sometimes at levels which are not widely available [93]. Dutch composting facilities often only handle biodegradable waste for 6 weeks, while bioplastics could take up to 12 weeks to decompose (appendix 1.3). According to European guidelines plastics that decompose after 12 weeks are still labelled as "biodegradable". This means after the industrial process, so-called biodegradable products could be still partly left intact. On top of that, decomposition produces methane, a greenhouse gas much more potent than carbon dioxide [2].

Currently, bioplastics are about two times more costly to produce compared to conventional plastics, but this difference in price could shrink in the future when production is expected to scale up.

It is important to evaluate the use and environmental impact of bioplastics compared to conventional plastics using an LCA [2].

5.1.3. Biodegradable medical waste

The Dutch company Pharmafilter developed a solution for the treatment of (infectious) hospital waste, a system that is installed at Erasmus MC in Rotterdam (figure 52). Next to the disinfection and shredding of waste mentioned in the previous recovery flow, the Pharmafilter is also designed to compost the biodegradable fraction of hospital waste [86]. This section of the installation is currently not functional, because there is a shortage of compostable waste coming through the system. The lack of nutrients kills the microbial cultures necessary for the composting process (appendix 1.3).

5.1.4. Bioplastics for medical applications

Most PHAs (polyhydroxyalkanoates) are suited for use in both medical devices and tissue engineering, because of their biodegradability without being toxic [94]. This material is made by microorganisms and can display similar thermal and mechanical properties to PP [95]. PHAs are the most widely used type of bioplastic in biomedical applications [96].

PLA (polylactic acid) is also biocompatible and biodegradable and has a wide range of applications in biomedical design. Devices containing PLGA (polylactic-co-glycolic acid), a synthetic biodegradable polymer, have also been approved by the FDA and the European Medicine Agency [96].

figure 51. *The pharmafilter system [86]*

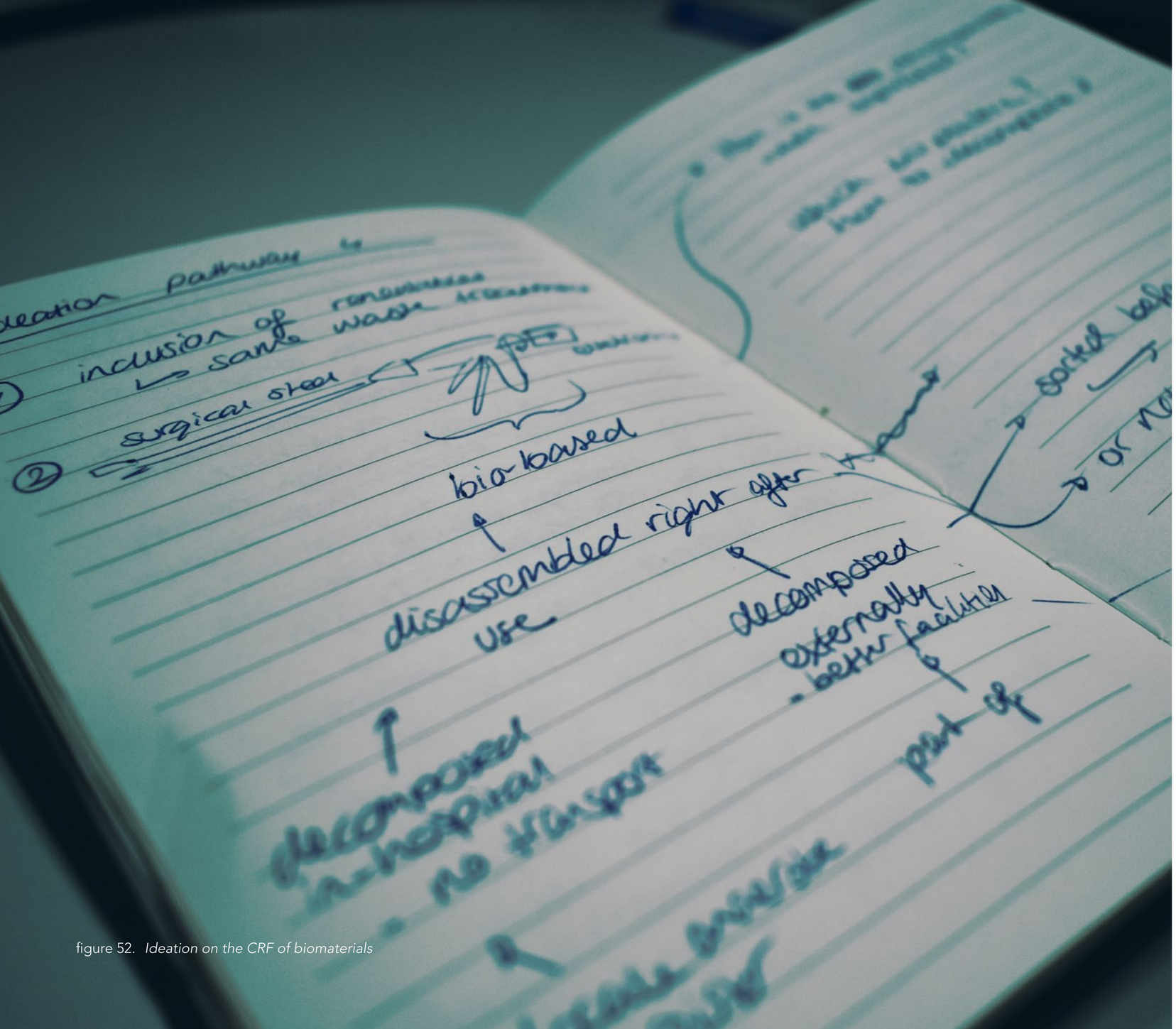


figure 52. *Ideation on the CRF of biomaterials*

5.2. Design opportunities

The in vivo (inside a living body) biodegradability of some plastics makes them interesting for use in implants. Maybe the staples could be redesigned to decompose into the sutured tissue. This technique has already been proven [94].

Apart from the reload, the handle is the only part of the endocutter that could be made from bioplastics. I assume the shaft needs to be manufactured from surgical steel to retain its functionality.

5.3. Concepting

5.3.1. Biodegradable plastics

Biodegradable plastics could either be decomposed inside the hospital or externally. Inside the hospital, they would be decomposed by for example a Pharmafilter installation, which unfortunately currently is unable to do so. This strategy would require less infectious waste transportation, which is a huge advantage, but would only be suitable for larger hospitals. External decomposing would be a bigger challenge since the waste would either need to be disinfected before transport or need to be transported according to hazardous waste regulations. There is only one infectious waste processing facility in the Netherlands; Zavin in Dordrecht [97]. Zavin currently incinerates infectious waste along with the bins it is transported in and would need to drastically alter its waste handling process to include composting facilities. If the waste was disinfected before transport, it could be sent to a regular composting facility, where composting could maybe be combined with regular recycling of other components of the device. As shown in figure 55, the CRF of bioplastics is not actually a closed circular flow. Maybe the recovered nutrients from the composting process could contribute to new growth of bio-based feedstock, but this is unlikely.

5.3.2. Biobased plastics

The inclusion of biobased plastics in the handle is relatively easy to implement but would require an LCA for validation.

5.4. Evaluation and reflection

Since both concepts stay very close to the original endocutter, and biobased materials are already approved in medical applications, both concepts meet all the requirements. However, they score very low on the criteria.

Biodegrading plastic is a type of tertiary recycling, where only chemical constituents of materials are recovered [84]. This means that a very low level of product integrity is maintained which makes this recovery flow quite undesirable from a circular economy point of view.

The non-degradability of plastics in landfill is not a concern for hazardous waste, since this type of waste is not sent to landfill but incinerated instead. I think I can safely assume that endocutters do not contribute to lingering plastic in oceans or on land, which takes away one of the main benefits of including biodegradable plastics in the design. This strategy would have minimal impact and require quite the logistics alterations to implement.

The inclusion of renewables is easy to implement, it is however unclear if this strategy is actually an improvement compared to the use of fossil fuel-based plastics. If no other CRFs are possible for the endocutter this could be an option, but it would depend on the results of an LCA.

		Biomaterials	
	Requirements and criteria:	Biodegradable plastics	Biobased plastics
	Concepts:		
Rq1	The endocutter maintains its functionality after redesign	++	++
Rq2	The endocutter is safe to use on patients (i.e. biocompatibility)	++	++
Rq3	The endocutter does not pose a contamination risk to anyone	+	++
Cr1	A high level of product integrity is maintained (this criterium weighs double)	--	--
Cr2	The endocutter fits within the current logistics and infrastructure of the hospital and the OR	+-	++
Cr3	The redesign concept is applicable to more than just the Ethicon endocutter and sets an example for the medical device industry	--	--
	Total score concept:	-6	-4

++ = definitely (Rq) or 2 (Cr) | + = probably (Rq) or 1 (Cr) | +- = maybe (Rq) or 0 (Cr) | - = maybe not (Rq) or -1 (Cr) | -- = definitely not (Rq) or -2 (Cr)

figure 53. *Initial evaluation bioplastics concepts*

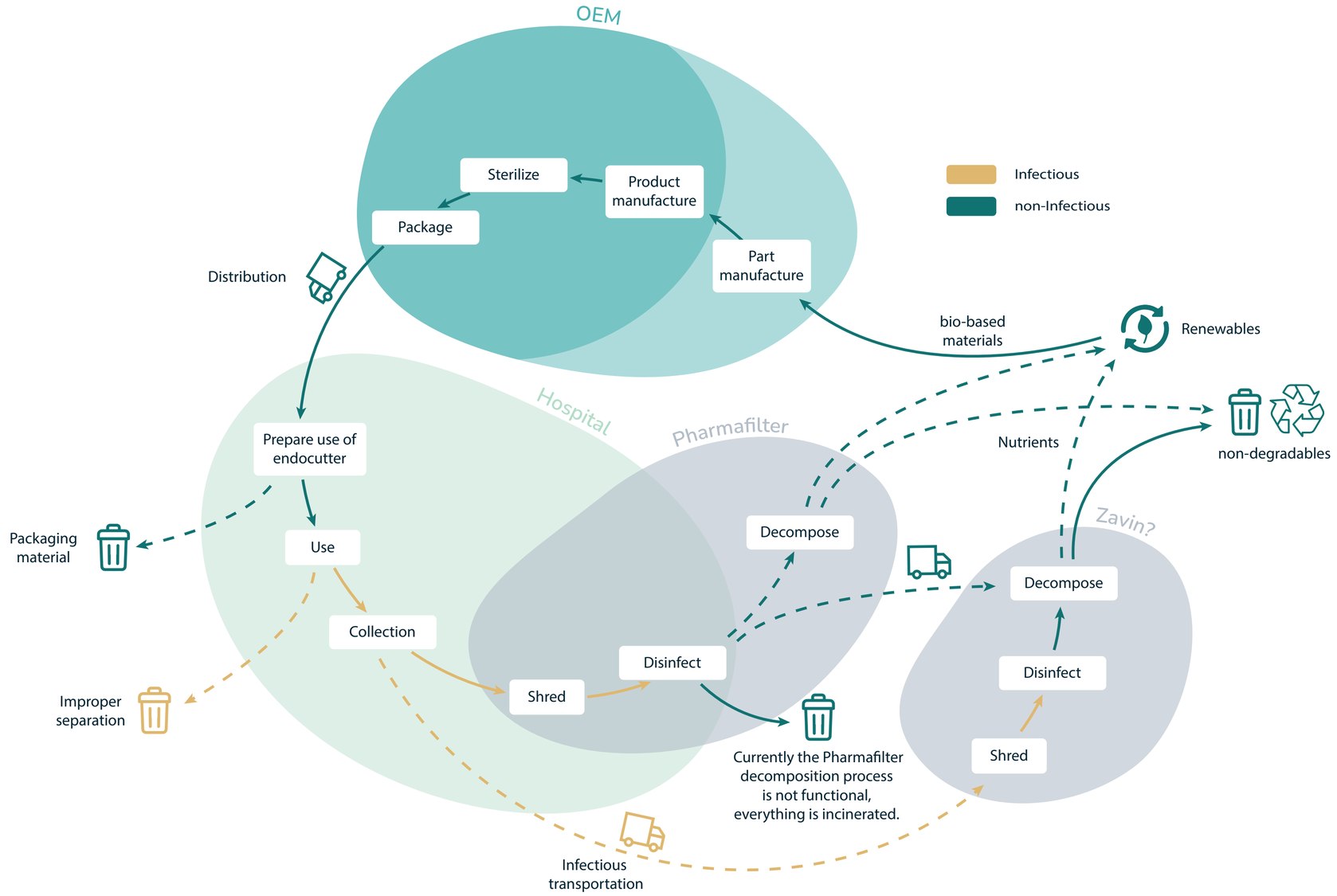


figure 54. *A schematic overview of different biomaterial flows*

6. Conclusion

			Reprocessing						Remanufacture	Recycling		Biomaterials	
	Requirements and criteria:	Concepts:	In-hospital sterilisation	Fixed cycles	Hybrid design	Stapler compatibility	Separate classification	External reprocessing	International collaboration	Design for recycling	Inclusion of recycled materials	Biodegradable plastics	Biobased plastics
Rq1	The endocutter maintains its functionality after redesign		+	++	++	--	++	++	+-	+-	++	++	++
Rq2	The endocutter is safe to use on patients (i.e. biocompatibility)		+	++	++	++	++	++	+	++	+-	++	++
Rq3	The endocutter does not pose a contamination risk to anyone		+	+	+	+	+-	+	+	+	++	+	++
Cr1	A high level of product integrity is maintained (this criterium weighs double)		++	++	+	+	+	++	+	+-	-	--	--
Cr2	The endocutter fits within the current logistics and infrastructure of the hospital and the OR		++	++	+	+-	+	-	-	+	++	+-	++
Cr3	The redesign concept is applicable to more than just the Ethicon endocutter and sets an example for the medical device industry		+-	+	+	+	++	+	++	+	-	--	--
		Total score concept:	6	7	4	2	5	4	3	2	-1	-6	-4

++ = definitely (Rq) or 2 (Cr) | + = probably (Rq) or 1 (Cr) | +- = maybe (Rq) or 0 (Cr) | - = maybe not (Rq) or -1 (Cr) | -- = definitely not (Rq) or -2 (Cr)

figure 55. *The comparison of all concepts from the design sprints*

Figure 56 shows a comparison between all the concepts from the four design sprints. The scores and evaluations are highly subjective because of the limited research that can be done in a one-day sprint, so further validation will be necessary. The results of the design sprints are in line with the findings of Guzzo et al. [40] and Kane et al. [11]. They advise focusing business models and instrument design of high-criticality and high-value devices like the endocutter on hygienic recovery, and the concepts originating from the CRF of reprocessing score best according to the criteria. Because of this level of uncertainty, choosing a few promising design directions instead of one single concept is preferred.

6.1. Design directions

These directions are combinations of multiple concepts that add to or build on each other. They are sorted in order of desirability and can be used as a base for designing innovation in technological niches.

6.1.1. Design for in-hospital reprocessing

This direction stems from the concepts of steam sterilisation, fixed cycles, hybrid design and separate classification. The first focus should be to design for regular in-hospital (preferably steam) reprocessing. If the changes to the product are too severe to maintain its function or keep the product cost low, I should look into the design for fixed cycles and hybrid designs. I think it is interesting to look into a separate classification of the handle and the shaft since this could bring new possibilities to the table for the redesign of other laparoscopic instruments as well.

6.1.2. Design for an external remanufacturing or reprocessing service

This design direction combines the concepts of design for external reprocessing, international collaboration, and design for recycling. A collaboration between many OEMs across borders could make the collection of devices more streamlined and make external reprocessing, repair and remanufacturing more accessible, all within one single service. Devices which are not fit for another life can also be effectively recycled since they are already collected separately from other infectious waste. A redesign of the endocutter for this kind of service would mostly focus on design for disassembly principles, as well as standardisation and modularity.

6.1.3. Design for recycling

This design direction focuses on the separation and disinfection of contaminated recyclables inside hospitals, to allow this waste stream to be recycled along with the general hospital waste. This would require a change of hospital logistics around the operating room and a disinfection machine for waste treatment, as well as a redesign for disassembly and recycling. This direction is significantly less attractive compared to the previous two because a lot of value of the device would be lost and a low level of product integrity would be preserved.

6.1.4. Design for inclusion of recycled or renewable material

The inclusion of bioplastics or recycled plastics in the handle is a minimal design change and mostly depends on individual device approval. This is the least preferred direction, and should only be looked into if the earlier-mentioned directions turn out not to be feasible, viable or desirable.

figure 56. *Used and contaminated medical devices, stored before reprocessing.*

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, I need to take a step back and look at the bigger picture before moving forward to the design stage of this project. Visioning alternate system futures is an important tool in transition management as it gives direction and enables actors to work more strategically [20].

Designing is a subjective practice at its core. The Vision in Design (VIP) method provides an approach for designers to structure this subjectiveness and explain and understand their views and considerations in the process. Unlike the research phase of this project, visioning is a lot more fluffy and personal. It is not centred around facts and figures but is 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.

The whole VIP process for this graduation project is explained and documented in appendix 2, this part of the report is simply a concise summary of the results.

PART 3

Envisioning a transition in MedTech

1. 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. You first need to take a step back and look at the bigger picture, before you can 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 followed the method as described in the book Vision in Design – a Guidebook for Innovators [25].

Designing is the act of defining a vision of what you want to create, instead of simply creating something in response to demand. This is why the process of designing needs to start with analysing why a design should exist in the first place. 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 58 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 at 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 to 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.

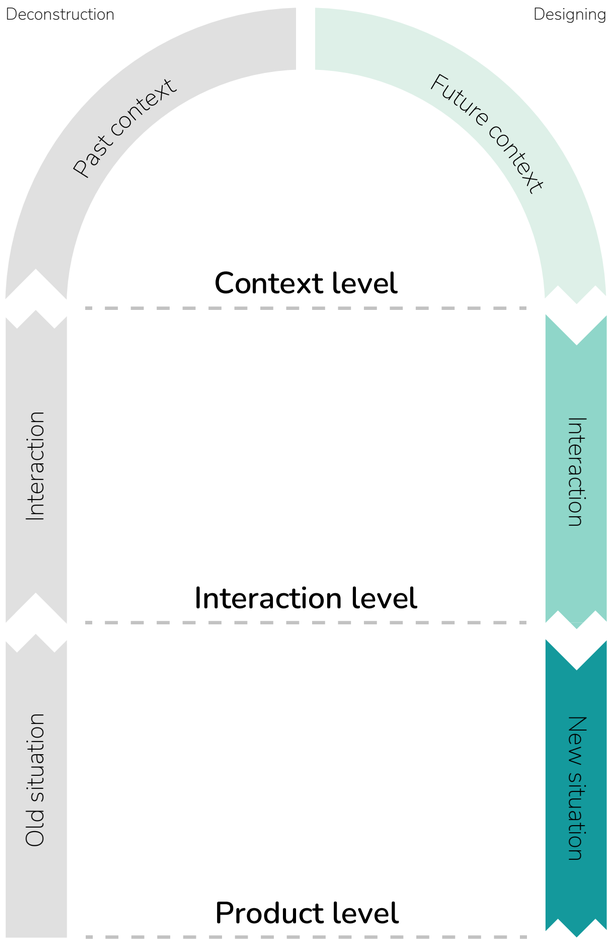


figure 57. *The VIP process [25]*

2. Designing the context

The context design is based on a deconstruction of the current situation on a context, interaction and product level. From this point, many context factors are collected, sorted and clustered within the domain 'The life of a laparoscopic device'. The clusters of factors point in certain design directions, but still do not explain the relationships between different developments, trends, states and principles. To explain a full future context, clusters need to be mapped to show patterns or conflicting dimensions.

I visualised the future context as shown in figures 59 and 60. These matrices show 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.

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 will 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 the kind 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. Another factor in this context is people's attitude towards change. Do they feel locked-in in their current system or do they see possibilities for change in the future?

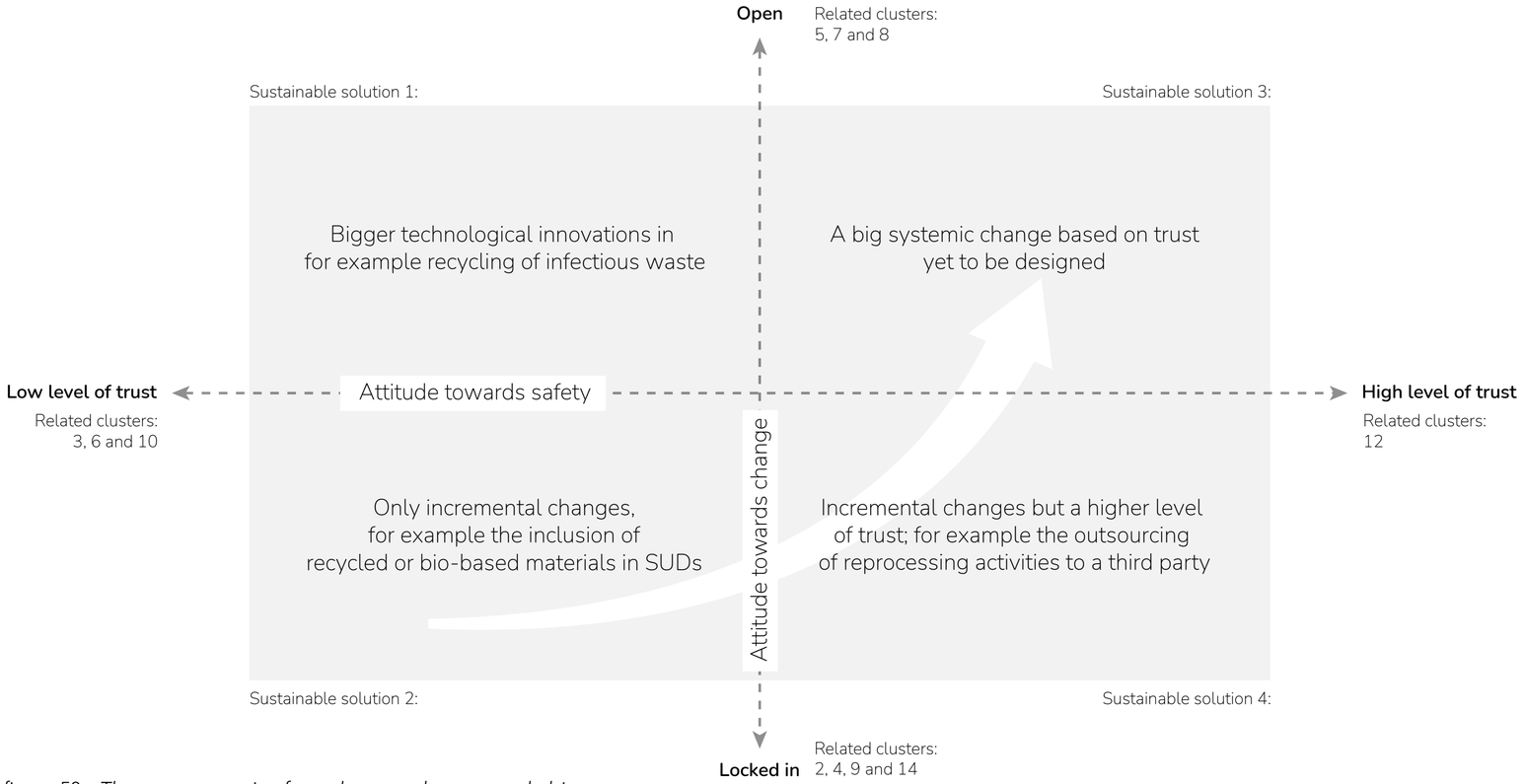


figure 58. *The context matrix of trust between humans and objects*

2.1. Trust between humans and objects

Currently, the industry has a very low level of trust in devices, which is why the use of SUDs could become the standard. 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. 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.

2.2. Trust between humans

In this matrix (figure 60), 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 companies can collaborate but there are not many examples.

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.

2.3. Statement definition

The desired future scenarios from both matrices are a result of my taking a moral position within the design process. 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 systemic change based on trust yet to be designed

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

My statement:

"I want to reshape the MedTech industry into a more circular system based on trust and collaboration."

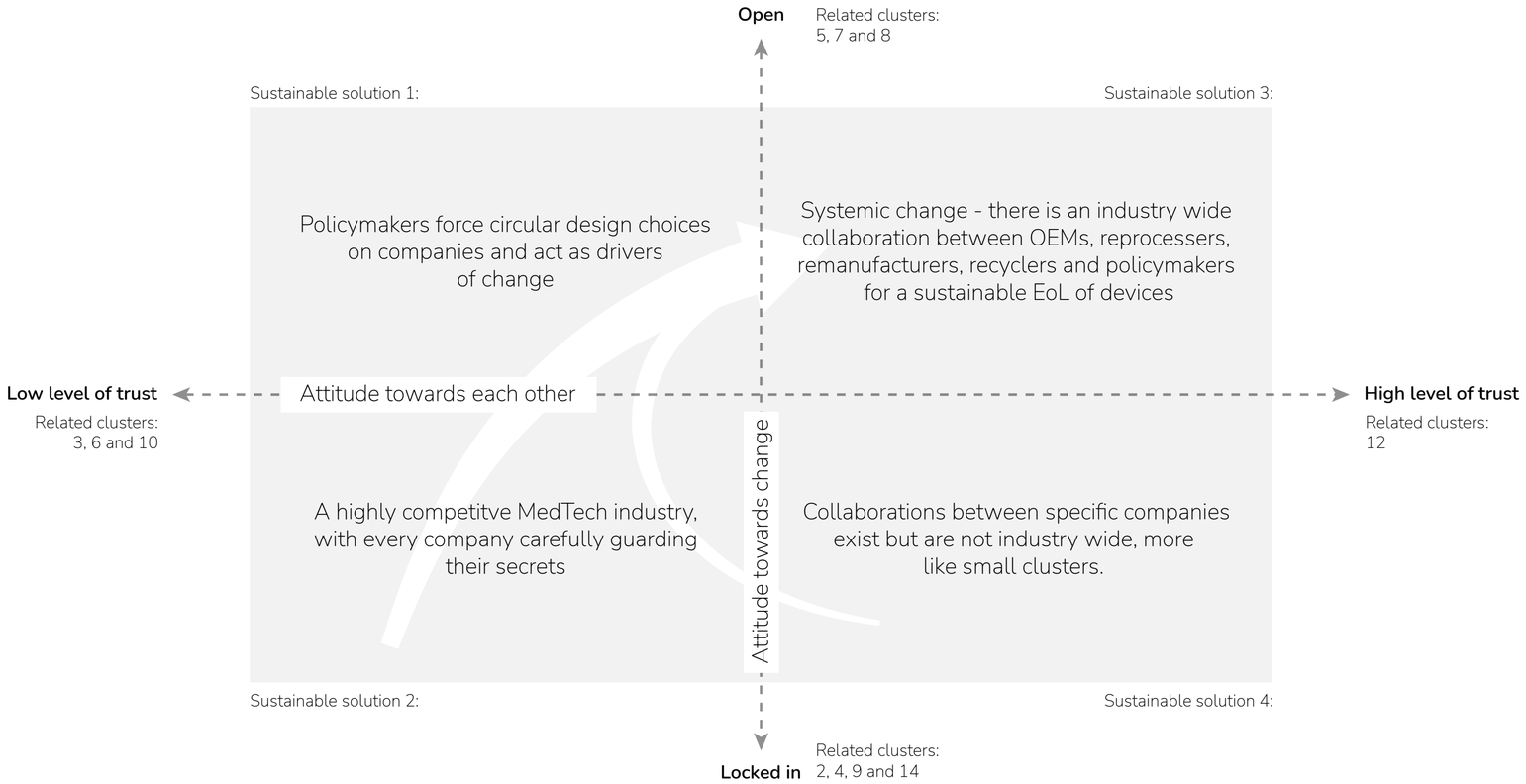


figure 59. *The context matrix of trust between humans*

3. Translation to interaction and product qualities

To translate context qualities to interaction qualities, you need to explore what kind of relationship between people and the final design fits the envisioned context. One way to do this is to simply trust your intuition, another is to think of an analogous situation in another domain to see the appropriate interaction from a new perspective.

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 (figure 61).

The last step of the VIP process is the translation from interaction to product qualities, which in this case could also be the qualities of a service model. A product character metaphorically describes the “personality” of a product, but you can also think of what kind of actions a product calls for. Some possible characteristics of my design are;

- Selfless
- Honest
- Open
- Responsible
- Cautious
- Affordable

figure 60. *interaction qualities*

4. Conclusion

This section of the report described the envisioning of a future for the MedTech industry. I see a sustainable future for MedTech as a more circular system based on trust and collaboration. There needs to be trust both on a contextual level between different OEMs, as well as on a conceptual level between a possible product or service system and its users. This vision on the context level was then translated to more specific interaction and product qualities that can help achieve the desired future context. The backcasted qualities serve as a starting point for later design stages of an experimental design supporting a sustainable transition in MedTech.

This section of the report describes the process of generating and comparing ideas for different types of service designs for the End of Life of laparoscopic devices. I decided to focus on the redesign of structures around the endocutter instead of the endocutter itself, because I think the endocutter design should be adjusted to the structure that it is a part of. If I first design a service model that fits my vision, The product design can later be altered to fit this service.

Ideas are generated through different methods based on the previously described vision and earlier research. The most promising one is selected by testing the ideas on different requirements and criteria. The selected idea will be developed further into a service concept, which will be discussed in the next part of the report.

Concept design in the context of transition management is a connection between long-term vision and short-term goals. I aim to design a possible route to the envisioned future, something that is almost feasible in the present but still radical in nature. Experimenting through design is a way to unpack complexity and find out what hinders or supports the desired transition [20].

PART 4

Idea generation and selection

1. Method

For the idea-generating phase of this project, a combination of two methods was used. The first is the 'How to' method, and the second is the 'Morphological chart' method. The how-to method allows for initial free thinking and the generation of a lot of ideas to reach quality through quantity. This is ideal for ideating on an abstract vision and for the exploration of the whole design space. The Morphological chart method is a way more structured and analytical method and is used to narrow down after taking full freedom with the How to's.

After the idea generation, a set of requirements and criteria were formulated which were used to test and select the ideas. The best idea is developed further in later design stages.

1.1. How to's

How-to's are problem statements formulated as questions to support idea generation. They are most suited for the beginning of idea generation and can be used to for example ideate on elements of a vision. It is important to determine the how-to questions from a variety of perspectives and on varying scopes for the best result [31].

1.2. Morphological chart

The Morphological chart is a method that helps generate solutions analytically and systematically by deconstructing the overall function of a product or service into sub-functions. The goal is to generate a matrix of the different sub-functions and their possible solutions (parameters and components). From the matrix, you can combine different solutions to sub-functions to describe possible principle concepts [31]. Normally morphological charts are made for physical products, and sub-functions are very practical. In this case, I decided to describe the sub-functions more as elements of a possible service and keep them a bit more abstract.

1.3. Idea selection

Ideas were selected by evaluating and comparing them according to different criteria.

1.3.1. Requirements and criteria

A list of requirements can be composed based on all the gathered information on the design problem. This list is a living document, and during different stages of the design process, different requirements and criteria play roles of varying importance. As the design becomes more detailed and concrete, so does the program of requirements. Requirements need to be met, otherwise, an idea is simply not feasible, viable or desirable. They serve as simple yes or no questions. Criteria are not as binary and can be used as a kind of scale to compare and select ideas [31].

1.3.2. Harris profile

The Harris profile is a method to visually compare ideas based on design criteria for your design. A Harris profile consists of an assessment of to which extent each idea meets each criterium, usually, a four-point scale is used [31].

figure 61. *The morphological chart method described in the Delft Design Guide [31]*

2. How to's

The how-to questions are based on keywords from my vision. I worked from a higher level of abstraction towards more specific ideas, so the questions will be sorted from context level to product level. How-to's can be part of a group brainstorm, but require all participants to have sufficient insight into the design space. This is why I decided to use this method on my own for this graduation project.

2.1. Questions

2.1.1. Context level

How to... Make the medical device industry open to change?
How to... Design for trust in the safety of devices?
How to... Increase trust between OEMs? And between OEMs and third parties?
How can... Policymakers facilitate a high-trust MedTech industry?

2.1.2. Interaction level

How to... Make the interaction between an EoL service and healthcare facilities transparent?
How to... Make the interaction between an EoL service and healthcare facilities cooperative?
How to... Make the interaction between an EoL service and healthcare facilities accessible?

2.1.3. Product level

How to... Design a selfless EoL service?
How to... Design an honest EoL service?
How to... Design an open EoL service?
How to... Design a responsible EoL service?

figure 62. *How to's on the circular life of a laparoscopic device*

2.2. Ideas

The complete How-to worksheets can be found in appendix 3. The most interesting directions are grouped, connected, and summarised below. They are separated by context level, interaction level and product level.

2.2.1. Context level

Currently, there are a lot of barriers in place that hinder the MedTech industry from opening up to change. We should find these barriers and challenge them. For example, can we re-evaluate when a device is safe to use? How clean is clean enough? Are the current practices for safety necessary, or are they going way too far with no regard for their environmental impact? If possible, we should focus more on opportunities instead of barriers. What kind of good examples for the implementation of the circular economy can we set for the industry through case studies, LCAs and cost analyses? Can we show what is possible, instead of just showing what is not?

What if the EU would play a central role in the EoL of medical devices? They could set up a non-profit, international service taking responsibility for the reprocessing, remanufacturing and, if necessary, recycling of medical devices. Maybe the EU could change the European Medical Device Regulations in a way that would make it mandatory for OEMs to let their products be part of this service if they aim to sell their products on the European market. The EU could demand OEMs to share spare parts and product specifications, and make them design devices with disassembly in mind. In return, OEMs could receive some of the returns of the service per reprocessed device.

The EU could also look into the facilitation of international infectious device transportation. Another interesting direction is looking into the rules for approval of SUDs compared to reusables. Currently, it seems to be easier for OEMs to label devices as single-use instead of reusable, can this be turned around and support companies that are looking to bring reusable devices on the market?

2.2.2. Interaction level

Since it is difficult to trust something you don't understand, design for ease and accessibility could possibly increase trust in devices. The service should be as consistent and user-friendly as possible. Maybe trust can be generated by designing an almost personal relationship between the sterilisation department personnel and the users of devices. If you know the person who cleans the device in your hand, it would be easier to trust that it has been handled with care. Another solution is to provide some sort of proof of the safety and sterility of a device. This could be done through a track and trace system, which is already implemented, but maybe also through the use of physical markers on the devices showing the number of cycles a device has gone through or whether or not it has been sterilised. Certain product qualities could evoke a sense of trust as well. If a device looks durable and dependable it is easier to assume it can withstand a lot of reprocessing cycles. A polished design without many crevices in which dirt can stick could give the impression to be cleaner compared to rougher designs.

Maybe a transparent interaction could be realised by making the interaction personal. The service should be tailored to each hospital, made as easy as possible to sign up for and start its implementation, and the contact person should be consistent. At the same time, the service should be easy to reach, quick to reply to questions and make real-time insights or status reports available. The information provided should be accessible and specific; what happens to which device, when and how?

In a cooperative interaction, it should be clear to all parties involved what they get out of the collaboration. Everyone should be open to feedback and input, and if possible even part of the design process. There should be multiple parties involved, each with their unique role to play, their contribution and their intrinsic motivations for participating. Parties should be aware and considerate of each other's motivations and reservations and aim to help come to the best shared results possible.

2.2.3. Product level

One characteristic that would make a service selfless by definition, is to make it a non-profit organisation. This would communicate clearly that the only goal for this service is to provide a responsible end-of-life for medical devices, with no conflicting interests. An honest service has full insight into its work so that it can share these insights with clients too. It needs to be responsible and should be aware of its entire impact and responsibilities in all different parts of its system. Liability must be clear and traceable. A responsible service is fully aware of and transparent about the safety of the medical devices they handle. An open EoL service is accessible for both hospitals and OEMs and makes it as easy as possible for actors to implement the service in their way of working.

2.3. Knowledge gaps

The ideation did not just result in new ideas, but also a lot of new questions and research directions.

First, it is clear that the MedTech industry is highly competitive, but why is that? Is this level of competition between OEMs a bad thing? Are there examples of successful collaborations between OEMs? It is not like the market of medical devices cannot be called a free market, since it is highly regulated and consumers are often not aware of, and influenced by, the price of a device. If there was more transparency in the pricing of devices, how would the nature of the competition between OEMs change?

Also, if I want to design for trust it would be useful to find out what the least trusted part of the reprocessing process is; is it the cleaning, the sterilisation, the transportation or the handling of devices before surgery? It could also be interesting to look into the track and trace system and see how OR personnel experience insight into the safety of devices.

Lastly, I wonder if interesting examples exist of for example non-profit waste management companies or EU-funded EoL projects that push OEMs to contribute by sharing product details or spare parts.

3. Morphological chart

Usually, a morphological chart describes the sub-functions of a physical product, but in this case, I have adapted the method for service design. The first step is to decide on the variable parameters or sub-functions, and next on the components or solutions that could fit each parameter. From there you can make interesting combinations and generate possible solutions.

3.1. parameters

The key parameters that I decided on are:

- Location and scale; on what scale will the EoL strategy be executed?
- Reverse logistics; how will the devices be collected and separated?
- Liability; Who is responsible for the EoL?
- EoL strategy; Which strategies are included in the service?
- Business model archetype; What kind of circular business model is connected to the service [1]?

For each parameter, I brainstormed on possible solutions. Some components are connected and some cannot be combined, which means not every combination of components is possible (figure 64).

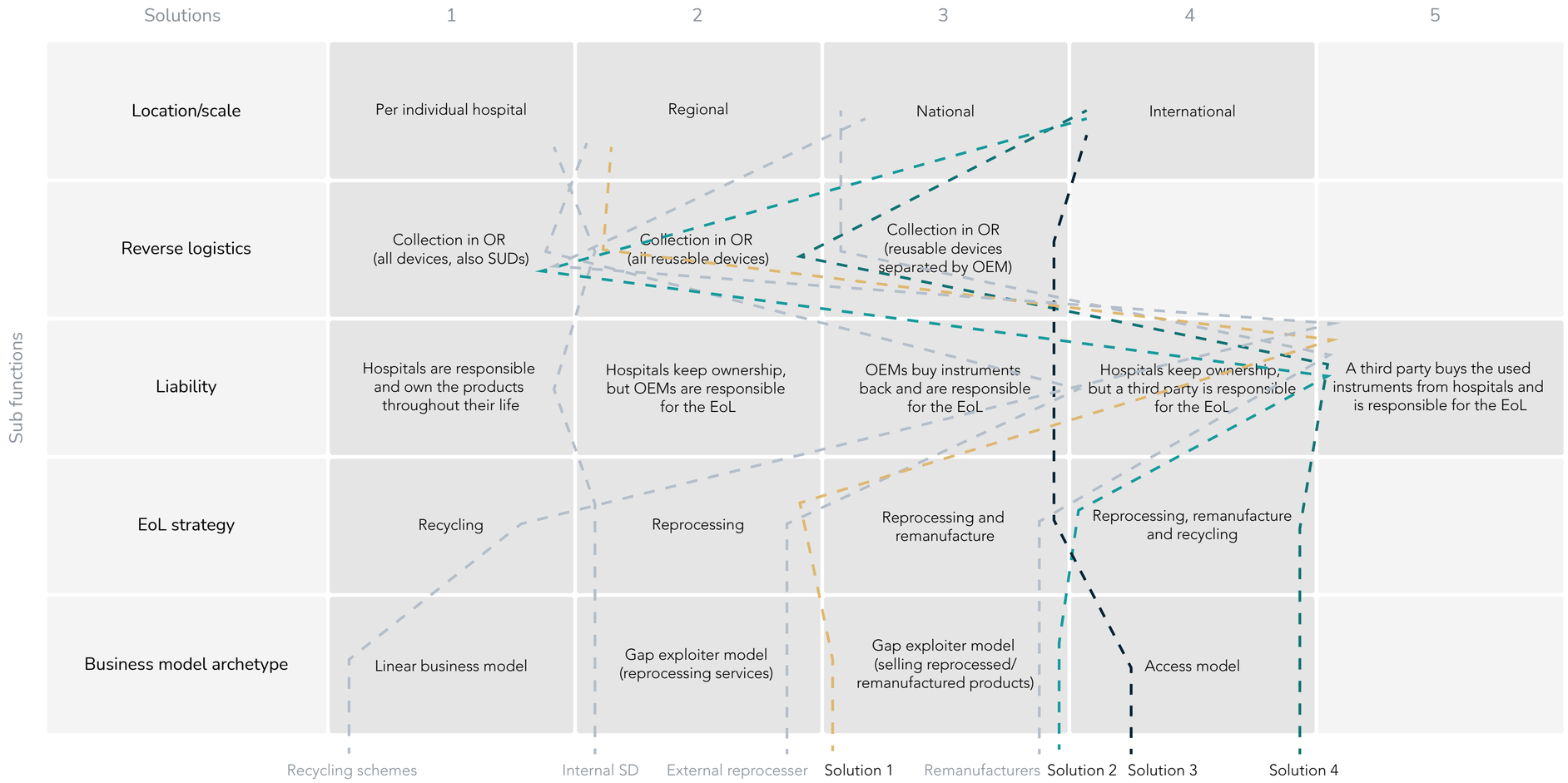


figure 63. *The morphological chart for the circular life of an endocutter*

3.2. Results

From the morphological chart method, eight possible solutions emerged from which at least four already exist in some form in the industry (figure 64). The existing solutions are all largely explained in previous sections of the report, so only have a small description in this chapter. The possible new solutions require a more extensive and visual explanation. Some initial benefits and drawbacks of each solution are summed up as well.

3.2.1. Existing solutions

The dotted grey lines in the morphological chart represent some of the solutions that already exist in some shape or form for other medical devices, but currently do not exist for the endocutter. It is good to be aware of these solutions, and they are useful examples, but new directions could be more interesting.

Internal Sterilisation Department

An internal sterilisation department inside hospitals is usually managed by the hospitals themselves. However, the internal reprocessing can be outsourced and follow a gap exploiter model. Currently, endocutters are not included in this solution because they are labelled as single-use and not designed for cleaning processes (Appendices 1.1 and 1.5).

External reprocessor

An external reprocessor operates on a regional level. They can collect both single-use and reusable devices together, or only collect the reusable devices from the OR. Hospitals retain ownership of the devices, but the third party is responsible for reprocessing. The service works according to a gap exploiter model and offers cleaning services to hospitals. Currently, endocutters are not included in this solution because they are labelled as single-use and not designed for cleaning processes (Appendix 1.5).

Remanufacturer

A medical remanufacturer operates on a national or international level and collects devices only from specific OEMs. They collect or buy used devices from hospitals and take up complete responsibility for their EoL. Their services include both reprocessing and remanufacturing, and they resell the devices they buy for a lower price compared to the set prices of OEMs. Reprocessors work according to a gap exploiter model. There is a European medical remanufacturing company based in Berlin that remanufactures single-use laparoscopic instruments, but endocutters are not (yet) part of their product portfolio [98].

Recycling scheme

Recycling schemes for SUDs do not yet exist, but J&J is currently a part of a recycling pilot for the recycling of single-use endocutters in collaboration with seven Dutch hospitals, the Delft University of Technology and waste handling company Greencycl (appendix 1.4). They operate on a national level, collect only specific devices from ORs, dismantle them and recycle the separate components. Because of the individual collection of devices and the manual dismantling, it is unclear if this kind of recycling scheme will be viable in the long run.

It is also possible to downcycle infectious waste inside hospitals through the use of specialised waste handling machines (Appendices 1.2 and 1.3). However, because of its metal components, the downcycling of endocutters in this way could damage these machines.

figure 64. *Recycled scraps from infectious waste at UMC Utrecht (appendix 1.3)*

3.2.2. Solution 1

Regional – All reusable devices collected together – Third party buys used instruments and is responsible – reprocessing – gap exploiter model (selling reprocessed devices)

The first possible solution is an external reprocessing service in nature. The main difference between this solution and existing reprocessors is that this service purchases contaminated devices from hospitals instead of just taking up the responsibility of cleaning them. In this case, there is a shift in ownership. Clean devices are later sold back to hospitals, so hospitals do not receive the same instruments that they sell.

There are several potential benefits to using this external instrument reprocessing service. One advantage is that it can be a cost-effective option for hospitals, as they can sell their used devices rather than paying high fees to dispose of them. Additionally, the waiting times for clean instruments do not depend on the reprocessing process, as they are with regular external reprocessors. This service can also be flexible in terms of which OEM devices can be included, as there is no access to spare parts required.

However, there are also some potential drawbacks to consider. One concern is that the level of trust in reprocessed devices may be lower than that of fully remanufactured devices because reprocessed instruments could have visible damage. Additionally, each surgeon and hospital may have individual preferences for the contents of their surgical nets, which can be better met by receiving their instruments after cleaning. Finally, only purchasing used devices would not meet the entire demand of hospitals, so they would need to purchase from multiple different platforms.

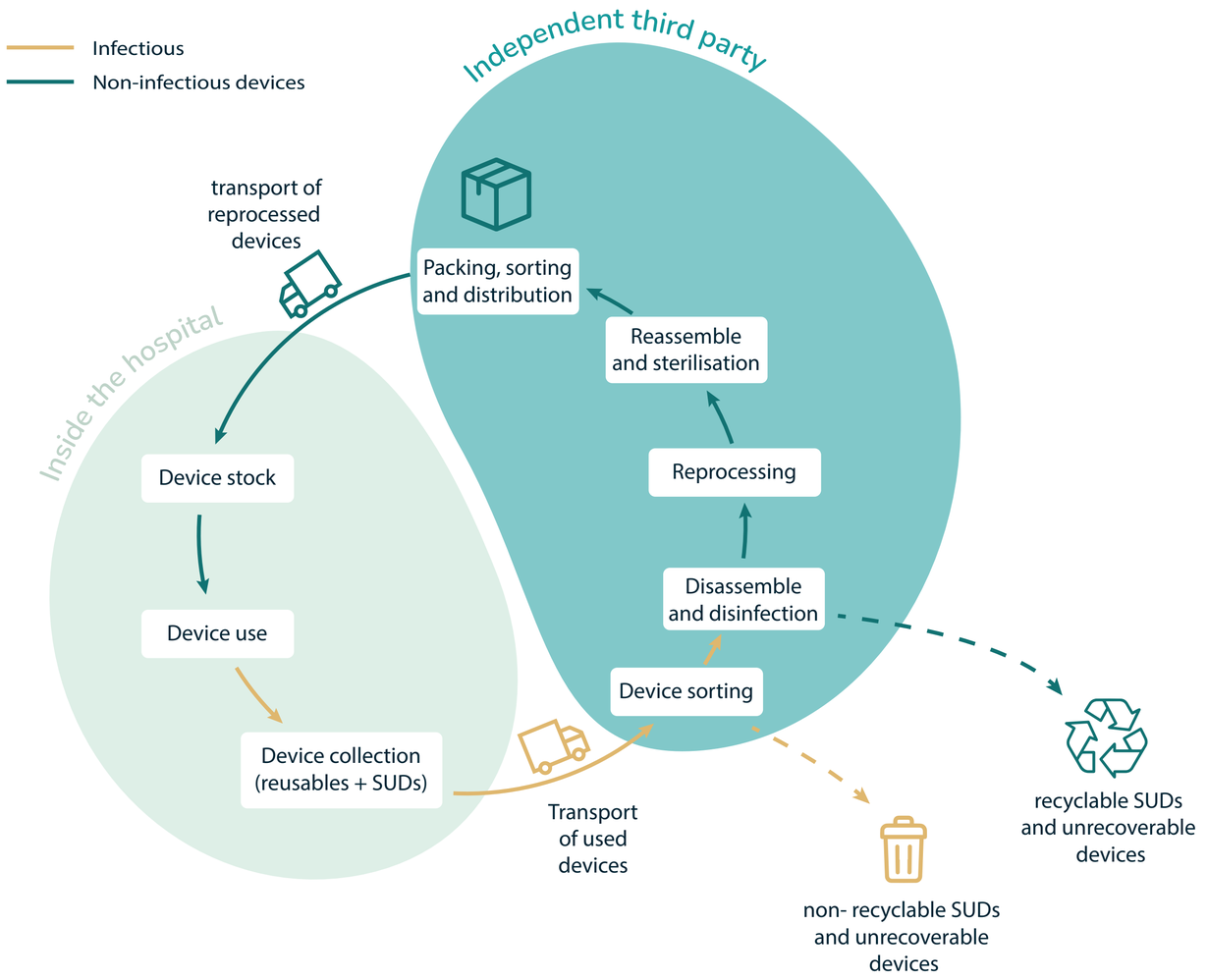


figure 65. *Solution 1*

3.2.3. Solution 2

International – All devices collected together – Third party buys used instruments and is responsible – reprocessing, remanufacture and recycling – gap exploiter model (selling remanufactured devices)

This solution is very similar to existing international remanufacturers. However, on top of cleaning, repair and remanufacturing services, products or components which are too damaged to withstand another lifecycle can go through a recycling scheme instead. This makes this solution one complete EoL service. Also, all devices are collected from the OR together, and reusables are separated from SUDs at the EoL facility so there is no need for extra waste streams inside the OR. This would open more doors for the recycling of SUDs as well since there is more space for material separation in a specialised facility compared to waste systems inside hospitals. It would be ideal if there is a collaboration between this service and OEMs so that the remanufacturer has access to all the necessary spare parts.

One advantage of this solution is that it can maintain a high level of product integrity by combining different CRFs. The large scale of this service may also make it economically viable, as a collaboration between hospitals and OEMs could make the life of almost any device circular. In addition, placing the responsibility for remanufacturing on an impartial third party could make it easier for OEMs to share product details and spare parts.

However, there are also some challenges to consider when implementing this solution. One limitation is that this solution may only be feasible with a large number of participating healthcare facilities, as it would require a significant amount of transportation. Additionally, designing and implementing this service would likely require a systemic change and a large collaboration between the remanufacturer, waste management and recycling companies, policymakers, and hospitals. It may also be necessary to create a financial construction that shifts the position of the remanufacturer from competitor to collaborator to get the support of OEMs. Finally, the supply of remanufactured devices would completely depend on the participating healthcare facilities and their waste streams.

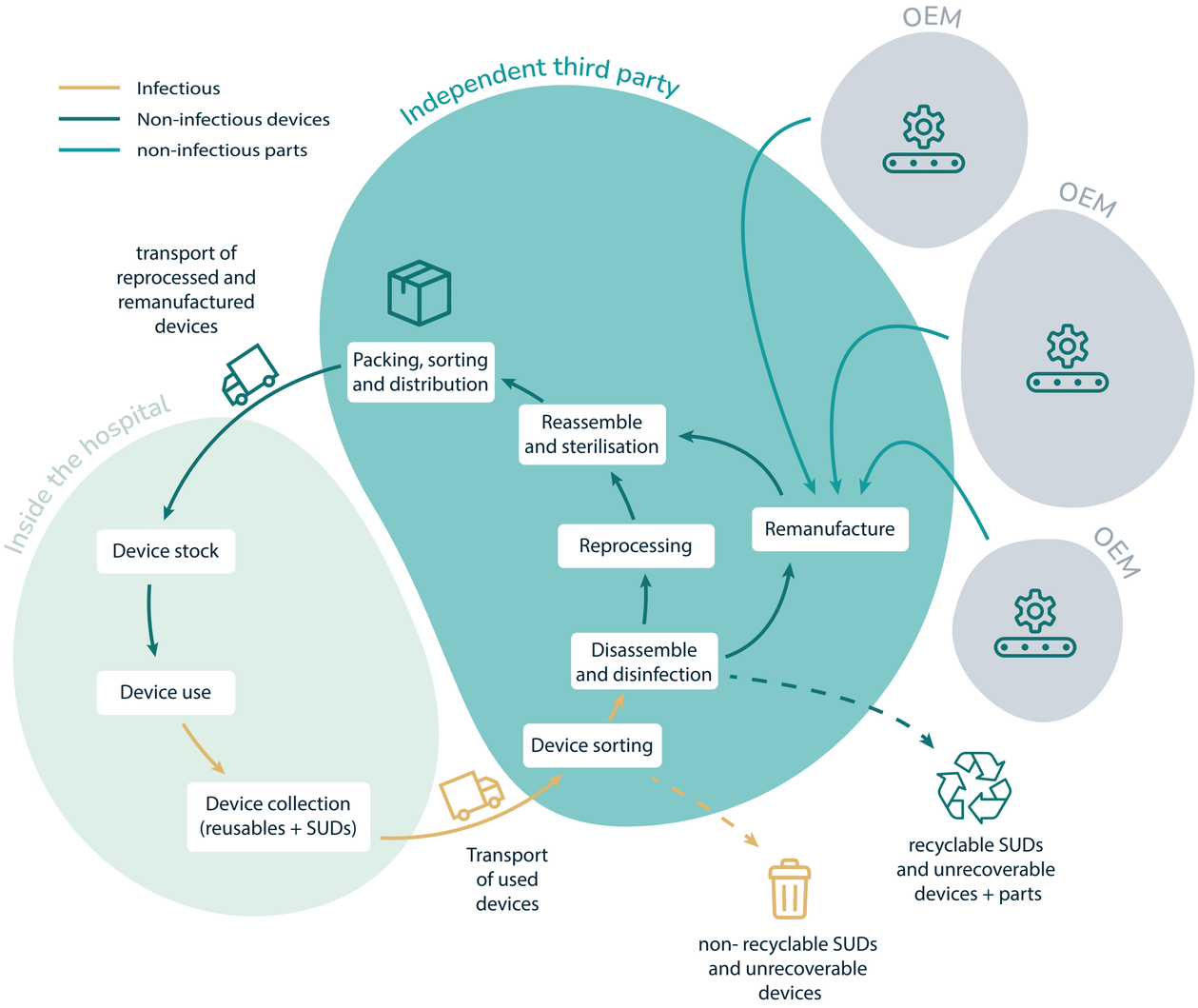


figure 66. *Solution 2*

3.2.4. Solution 3

International – Reusable devices collected separated by OEM – OEM buys used instruments and is responsible – reprocessing and remanufacture – Access model

This solution would require each OEM to take responsibility for the EoL of their own devices. This does not only require more work and effort from each OEM, but also from hospitals since they would need to collect devices and separate them according to their respective manufacturers. This service would be an access model, which means that hospitals buy access to clean and safe instruments. Whether these instruments are reprocessed, remanufactured or brand new is not of their concern and can be decided by the OEM based on their available stock.

One potential benefit of using a centralized remanufacturing service for medical devices is that it allows for easy access to product specifications and spare parts, without any issues related to confidentiality. This model also provides an opportunity for OEMs to profit from the circular life of their devices, which may give them the incentive to design for durability and end-of-life strategies.

However, there are also some challenges to consider when implementing this service. One potential drawback is that it requires hospitals to separate used devices by OEM, which can be an extra burden in the operating room. Additionally, this solution is only suitable for a small range of devices, as many devices from smaller or other OEMs may still follow a linear model. The transportation of just a few devices per hospital can also make this solution relatively expensive. Finally, OEMs may not currently be able to remanufacture devices, so they would need to make significant adjustments to their business model and value chain to participate.

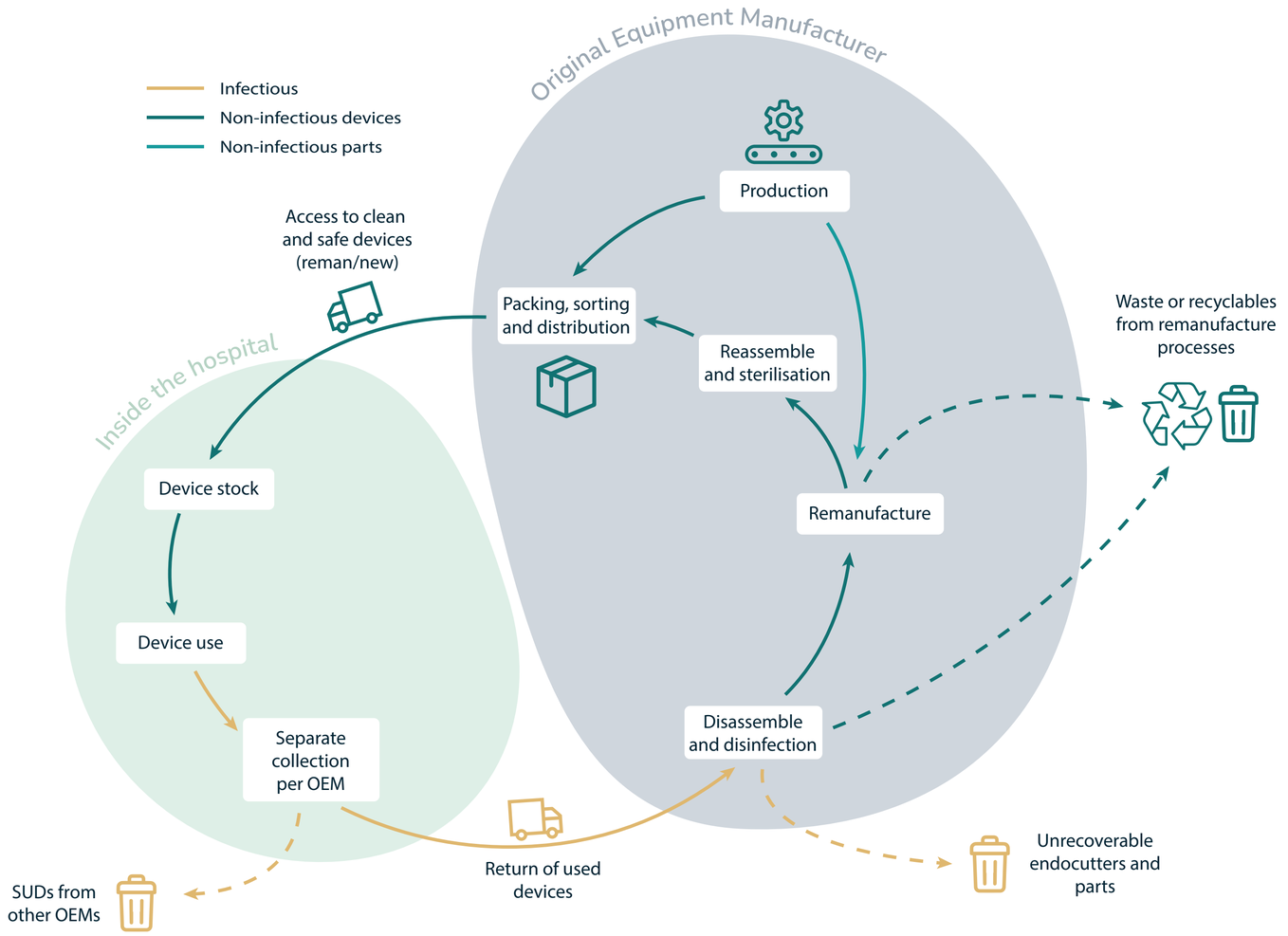


figure 67. *Solution 3*

3.2.5. Solution 4

International – All reusable devices collected together – Third party buys used instruments and is responsible – reprocessing, remanufacture and recycling – Access model

This solution is a combination between the second solution and the third solution. It is based on an access model where hospitals pay for access to clean and safe instruments but is managed on an international scale through a large collaboration between OEMs. The service includes reprocessing, remanufacturing and recycling. OEMs supply spare parts for remanufacturing and new devices to be distributed along with the stock of reused devices.

An advantage of this solution is that it can maintain a high level of product integrity by combining different CRFs. This service would also be very accessible to hospitals, as orders and EoL are simplified to one central platform and one waste stream, respectively. Additionally, this solution could potentially have a significant impact on the sustainability of the MedTech industry, as it represents a systemic change. Placing the responsibility for remanufacturing on an impartial third party could also make it easier for OEMs to share product details and spare parts.

However, there are also some challenges to consider when implementing this EoL service. One limitation is that it may only be feasible with a large number of participating healthcare facilities, as it would require a significant amount of international transportation. Additionally, designing and implementing this service would require a complicated collaboration between the remanufacturer, waste management and recycling companies, policymakers, and hospitals. It may also be necessary to create a financial construction that shifts the position of the remanufacturer from competitor to collaborator to get the support of OEMs. Finally, this service could potentially require OEMs to collaborate on the distribution of new devices as well, which can be very time-consuming and resource intensive.

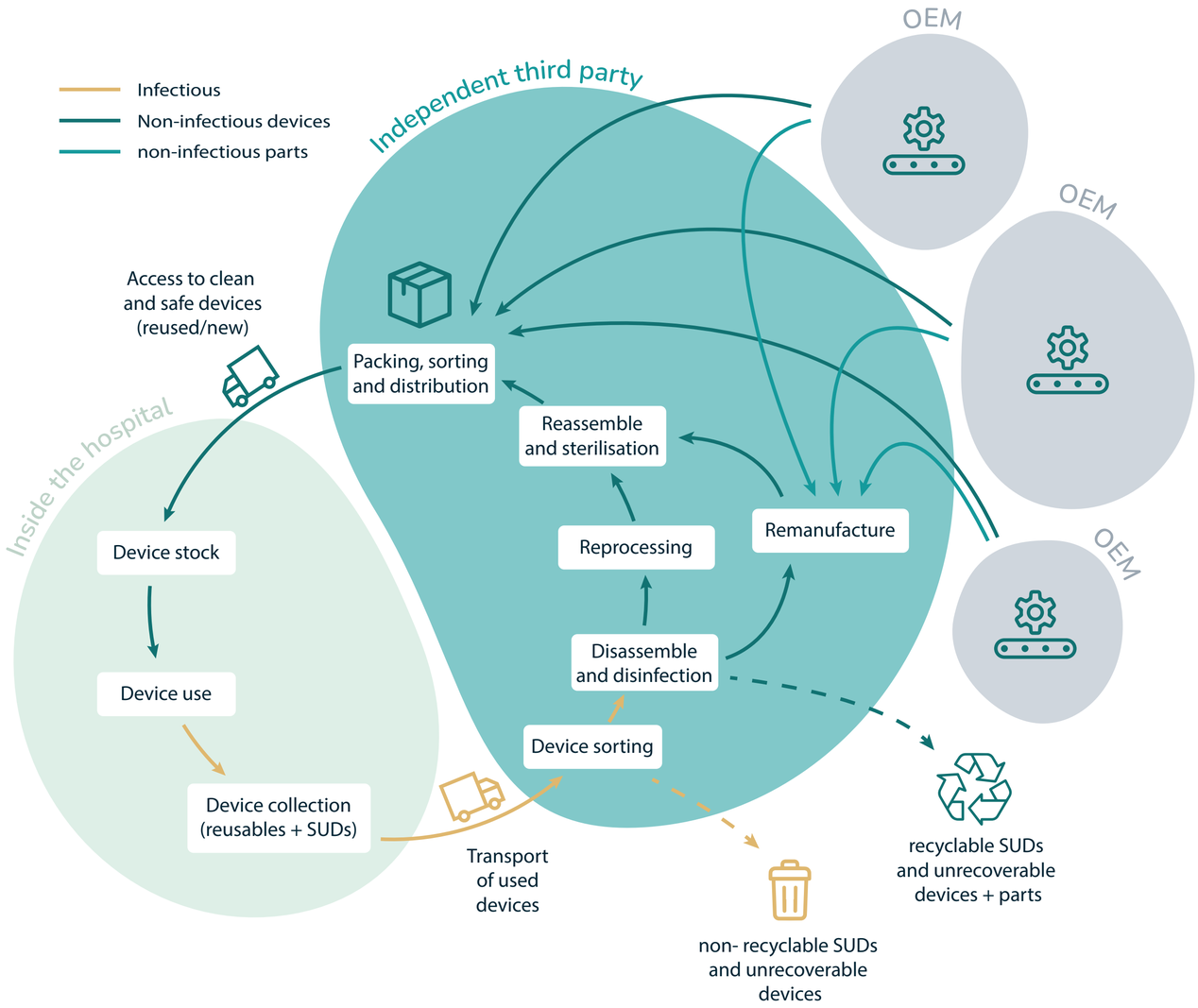


figure 68. *Solution 4*

4. Idea selection

4.1. Design criteria

The first three criteria were already formulated to test initial ideas in the design sprints described earlier in this report. These are now slightly altered to fit a service design specifically since they will be used to test and compared the generated service ideas instead of endocutter redesigns.

Cr1: The service allows for a high level of product integrity to be maintained
Cr2: The service fits within the current logistics and infrastructure of the hospital and OR.
Cr3: The service can be implemented on a large scale, could work for the EoL of a large variety of devices and sets an example for the medical device industry.

The How-to method did not result in many service design ideas, but more so in points of attention for later design stages and new research questions. This method was useful to determine a set of new design criteria based on a design vision which can be used to compare possible solutions from the morphological chart.

Cr4: The device goes through as many lifecycles as possible
Cr5: The service is collaborative in nature and improves trust between OEMs
Cr6: The service enables hospitals and OR personnel to blindly trust the safety of the medical devices they use
Cr7: The service is easy to understand and accessible for all parties involved.
Cr8: The service can easily be implemented by OEMs
Cr9: Medical devices need to be transported as little as possible
Cr10: The service is profitable for OEMs
Cr11: The service comes across to healthcare facilities as honest, transparent and selfless.

4.2. Idea selection

For the selection of the best fitting service design, there should not just be a comparison between the four new solutions, but also a comparison between the new solutions and the already existing service designs. One of these existing models could be more favourable than new ideas, and even though it already exists in some form, it could still serve as a foundation for the design of a new EoL service.

I adapted the Harris profile method in the same way as for the evaluation of the design sprints. Each solution can score ++, +, +-, - or - - on each criterium (visualised in figure 70 on the next page). These scores represent points, which are added up to show a final score for each solution.

The three solutions that score best according to the criteria are solution two, solution four and the already existing internal sterilisation department solution. Internal sterilisation departments seem to be highly valuable for the EoL of devices, but the possibility of scaling up and realising a systemic change in the MedTech industry makes solutions two and four very interesting.

These two solutions are very similar, and score the same according to the criteria. The main difference between the two is the business model archetype, with solution two following a gap exploiter model and solution four following an access model. Also, for solution two OEMs only provide spare parts for the remanufacturing process, while for solution four manufacturers provide new devices to be centrally distributed by the third party along with reused devices. For solution two, healthcare facilities have to purchase devices from separate manufacturers on top of purchasing reused devices from the third party, while in solution four healthcare facilities pay the third party for all their devices, and receive a combination of new and reused devices.

The choice between concepts is highly subjective. The designer generates the ideas, chooses the criteria, and scores the ideas according to the criteria. There is no way to be sure one solution is better than another at this stage in the design process. Solutions two and four seem to be the most interesting, but need to be evaluated in a transition management context before moving on to later design stages.

++ = 2 points	+ = 1 point	+- = 0 points	- = -1 point	-- = -2 points

		Existing solutions				New solutions			
		Internal sterilisation department	External reprocessing service	Independent remanufacturer	Recycling scheme	Solution 1	Solution 2	Solution 3	Solution 4
Cr1:	The service allows for a high level of product integrity to be maintained	++	++	+	-	++	+	+	+
Cr2:	The service fits within the current logistics and infrastructure of the hospital and OR	++	++	-	+-	+-	++	--	++
Cr3:	The service can be implemented on a large scale, could work for the EoL of a large variety of devices and sets an example for the medical device industry.	+-	+-	+	+	+-	++	+-	++
Cr4:	The device goes through as many lifecycles as possible	+-	+-	+	--	+-	++	+	++
Cr5:	The service is collaborative in nature and improves trust between OEMs	-	+-	+	-	+-	++	--	++
Cr6:	The service enables hospitals and OR personnel to blindly trust the safety of the medical devices they use	+-	+-	+	++	+-	+	+	+
Cr7:	The service is easy to understand and accessible for health-care providers involved.	++	+	+	+-	+	+	-	++
Cr8:	The service can easily be implemented by OEMs	+	+	+-	++	+	-	--	--
Cr9:	Medical devices need to be transported as little as possible	++	+	-	+-	+	--	--	--
Cr10:	The service is profitable for OEMs	+-	+-	-	+-	+-	+	++	+
Cr11:	The service comes across to healthcare facilities as honest, transparent and selfless.	++	+-	+-	++	+-	++	--	++
	Score:	10	7	4	3	5	11	-7	11

figure 69. *The adapted Harris profile comparing different service solutions*

5. Conclusion

5.1. Ideas as part of a transition

First, we determined the problems in the MedTech industry, and then the direction we need to go to solve those problems. I want to reshape the MedTech industry into a more circular system based on trust and collaboration, as stated in my vision. Now it is time to translate this direction to short-term solutions. Because the solutions described before need to contribute to a MedTech sector moving in the envisioned direction, it is important to reflect on both their radicality as well as how realistic they are in the short term. The goal is to design an incremental but radical step in the right direction which can serve as an example for future projects moving closer to the envisioned future of MedTech (figure 71).

Solution one is incremental, but maybe too small of a step to be an interesting design challenge. Solution two is very interesting, but the movement of contaminated devices across borders makes it not very feasible in the short term. It also requires OEMs to share spare parts and product details, which is not very realistic within the current regime. Solution three is possible in the shorter term, but because it does not promote a collaboration between OEMs it does not get us further on course to the envisioned future. Solution four is very interesting as well, but way too radical for the short term. It does not only require OEMs to share spare parts but also needs them to collaborate with the distribution of new devices through one shared platform.

We need a solution X that is both radical and incremental. We can derive this solution from solution two, and look into changing some of the elements that make it less feasible in the short term. The main two barriers to solution two in the short term are the international transportation of infectious devices, and the sharing of product details between different organisations.

5.2.1. Solution X

Solution X is a regional reprocessing service similar to existing companies in the Netherlands (appendix 1.5). However, this service has a collaboration with OEMs. Whenever a device is too damaged for cleaning processes alone, it is sent back to its manufacturer, which will take care of remanufacturing and can resell the device as new. Devices are cleaned and disinfected before international transportation, and because OEMs are responsible for the remanufacture of their own devices there is no need for them to share product details with third parties. This solution is radical and a step into the envisioned direction, but feasible in the shorter term as well.

The storyboard in appendix 4.3 explains the first version of solution X in more detail. This storyboard serves as a starting point for later design stages.

This section of the report describes the process of generating and selecting ideas for an end-of-life service for laparoscopic devices. Through the how-to method, a lot of new insights were gained on different levels of abstraction which can be useful in later design stages. The method was unfortunately not very fruitful for the generation of actual service concepts.

The morphological chart method did result in several possible solutions based on different combinations of elements of an EoL service. Four existing and four new solutions were found, explained and visualised. The eight solutions were then measured and compared against eleven criteria. Solutions two and four scored received the highest score.

The four new solutions were evaluated in a transition management context. This led to the conclusion that a new solution was needed, to provide a concept that is both realistic in the short term, but still radical and which sets an example in the direction of the previously envisioned future. This solution X is summarised and explained further in appendix 4.3 in a storyboard and will serve as a starting point for later design stages.

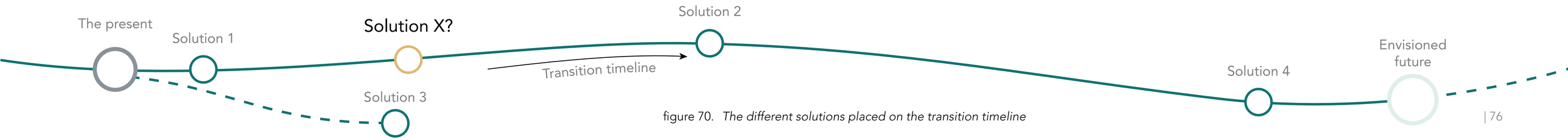


figure 70. *The different solutions placed on the transition timeline*

Experimentation is a means for unpacking complexity and gathering evidence on the new roles and relations that a sustainable transition requires [20]. Experimenting and finding new boundaries and necessary actions to advance the desired transition can be done through a conceptual design process.

This section of the report elaborates on the design process of a product-service system that could be part of a sustainable transition in the MedTech industry. The final service design is explained and the current barriers to its implementation are summarised. These barriers are contextual factors which need to be altered by different central actors to create space in the regime for such a service to develop and grow.

PART 5

Designing for a sustainable transition

1. Method

With the aim to iterate towards an ideal service design, concept storyboards were used as guides for expert interviews. After each interview, the storyboards were updated and altered, and additional desk research helped to elaborate on results, confirm findings and fill any crucial knowledge gaps left after the interview process.

1.1. Storyboards

I described the concept using the storyboard method because this method allows me to detail and visualise the concept in a way that gives sufficient information during interviews but is still straightforward and comprehensible. Storyboards are visual representations of a narrative about a design in its context of use over time [31].

I made three storyboards to show the different routes a medical device could follow in a hospital. The first storyboard explains the life of an existing, single-use endocutter. The second storyboard shows what a life of a completely reusable endocutter would look like when reprocessed inside a Dutch hospital, with the assumption that it is possible to design the entire device for reprocessing. The third storyboard explains the life of an endocutter recovered by the to-be-designed service model.

The storyboards first show an overview visual of the different steps in the life of the device, and then go into these steps frame by frame. Frames are separated into sections like "Device supply", "Use" and "Reverse logistics", and numbered to allow for correct referencing during interviews. The storyboards function both as a guide for expert interviews and as a visual representation of the concept. The initial storyboards can be found in appendix 4.

1.2. Expert interviews

Expert interviews are a method used to gather qualitative data with the aim to explore a specific field of interest. They are interviews following a guide with a focus on the knowledge of an expert. Experts are considered to be knowledgeable of a particular subject, they have specific knowledge, an important community position or a certain status. An expert is seen not as an individual person but instead as a representative of a specific group or field [99].

There are two types of expert knowledge; technical knowledge and processual knowledge. Technical knowledge is highly specific knowledge in a field related to subjects like technical applications, information or data. Processual knowledge is based on practical experience and the institutional context of actions [99].

In this case the interviews are not only used to gather information on the field, but also for gathering feedback on and validating my service concept [31].

Figure 72 gives an overview of the selected experts and the value of their knowledge for this design process.

Organisation	Function	Expert knowledge	Selected because...
Johnson & Johnson	Local product manager endo	Technical and processual knowledge	Knowledge on endocutter in Dutch context
	Design engineer	Processual and technical knowledge	Knowledge on considerations and choices in endocutter design
Philips	Senior supply chain consultant	Technical knowledge	Knowledge on different CBMs in the MedTech industry
AMDR (Association of Medical Device Reprocessors)	President	Technical knowledge	Knowledge on third party remanufacturers
LUMC (Leids Universitair Medisch Centrum)	Manager OR facilities & SD	Technical and processual knowledge	Knowledge on internal reprocessing and inventory management of a hospital

figure 71. *Overview of the selected experts and the value of their knowledge.*

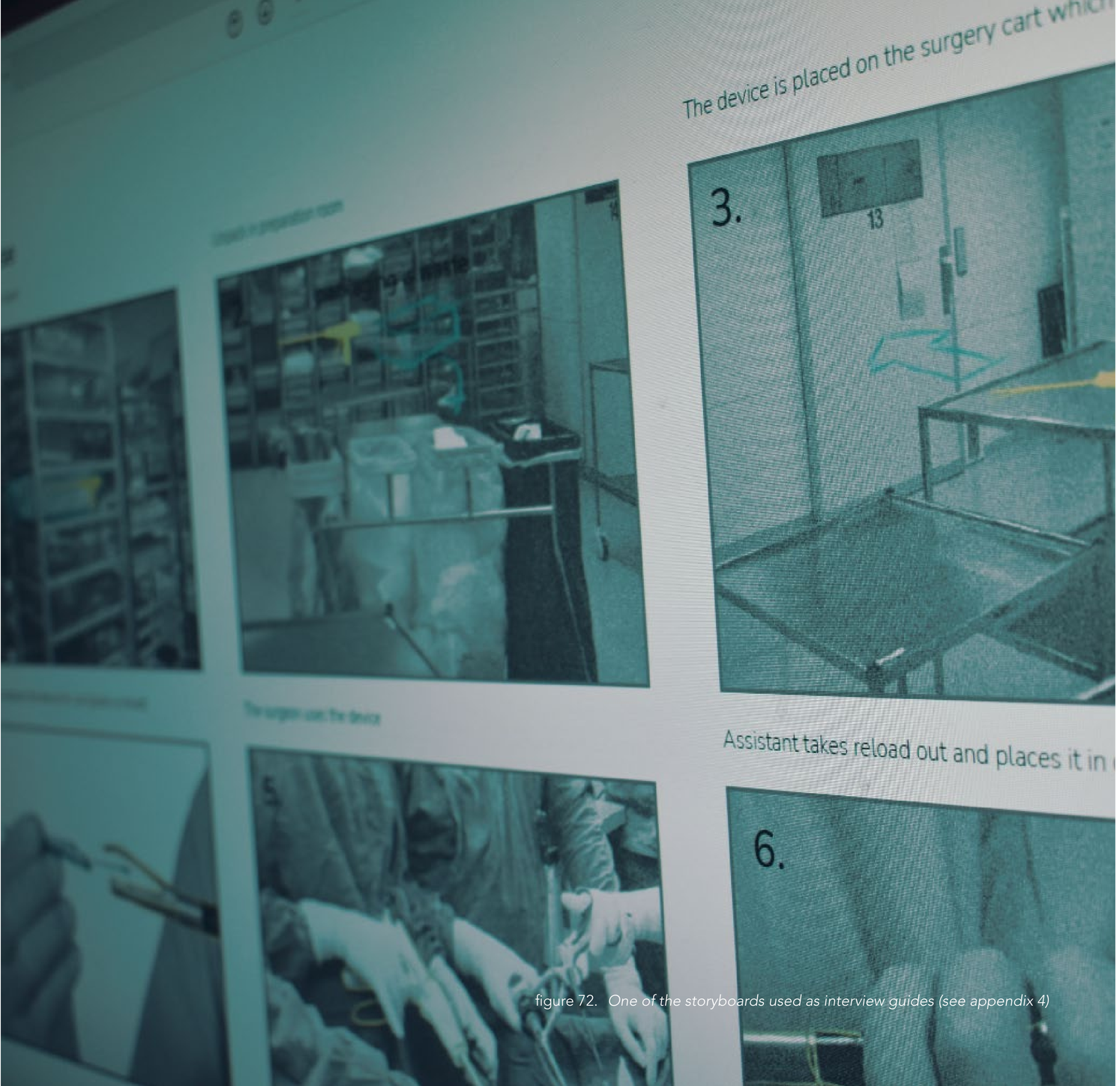


figure 72. *One of the storyboards used as interview guides (see appendix 4)*

1.2.1. Research design

A semi-structured interview usually follows a topic list with a few (mostly open-ended) questions per topic [100]. In this case, all the interviews started with a short explanation of the graduation project and the work so far. Next, the three storyboards were discussed frame by frame starting with the storyboard of SUDs, leading to the storyboard of internal reprocessing and ending with the storyboard describing solution X. Interviewees were asked to elaborate on any mistakes, barriers or opportunities they found in the storyboards and jump in with new ideas at any time. questions specific to each expert were prepared beforehand to add to specific details in data or ask for more in-depth information in the expert's field. After the storyboards and questions were covered, there was time for a concluding discussion. Each interview lasted between 45 and 90 minutes and most of them were conducted online via Microsoft Teams.

One exception to this interview setup is the interview with the design engineer of the endocutter. Since his expertise is on the product itself, an interview guide was constructed that was entirely focused on the design of the device. The storyboards were not discussed.

1.2.2. Structuring data

Each interview was recorded, reviewed and summarised. After each interview, the storyboards were adjusted according to feedback and new design considerations. All the summaries of the interviews conducted during the design phase of this project can be found in appendix 5.

2. Design process

2.1. Initial service idea - Solution X

At the end of the idea generation and selection phase of this graduation project, I proposed an incremental but radical "Solution X". The storyboard of this initial proposal can be found in appendix 4.3.

Solution X is an external reprocessing service for healthcare facilities in close collaboration with medical device OEMs. All devices are collected by the service and go through a process of disassembly, cleaning, disinfection, checking and sorting. The devices that are not reprocessable are sorted by their respective OEMs and sent back when enough devices are collected. The OEMs take full responsibility for the remanufacturing of their own devices and have the possibility to sell the same products again. This shift of responsibility also gives them the incentive to take EoL into account in their product design. The external reprocessing and sorting of devices per OEM allows hospitals to allocate more time, space and resources to their core business.

Figure 74 shows the different device recovery steps and the responsibilities of different actors within solution X.

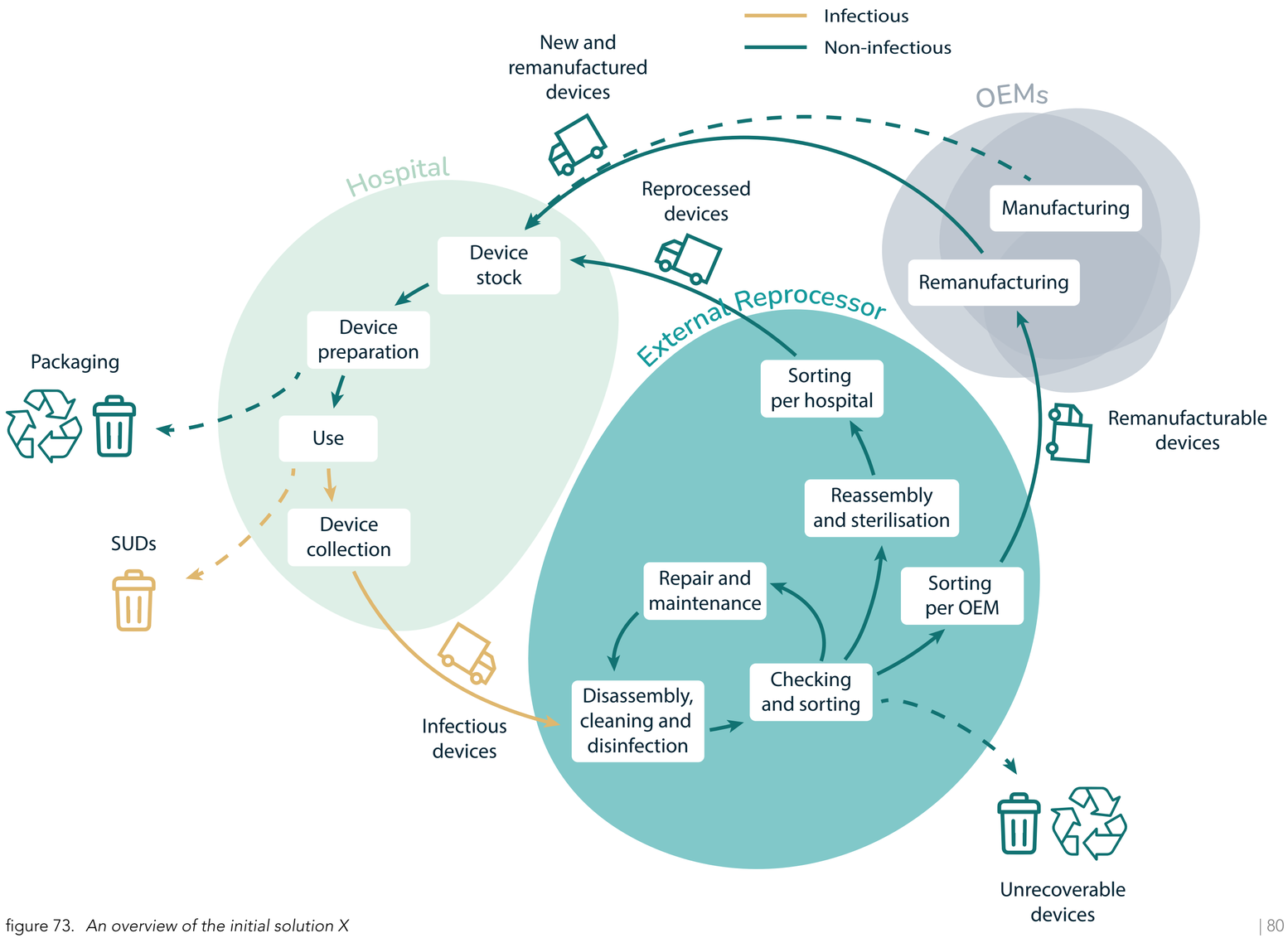


figure 73. *An overview of the initial solution X*

2.2. Expert feedback and iterations

Through the different conducted interviews I iterated upon the concept, its overview visual and the storyboards. Here I will discuss the main considerations that shaped the initial solution X into my final concept proposal; MedFlo.

figure 74. *An example of a mechanical endocutter*

2.2.1. Reprocessing or remanufacturing - product design

If it is possible to design an endocutter for reprocessing without losing usability, safety and cost, reprocessing is the more favourable option compared to remanufacturing. This redesign would mean the device can be cleaned inside a hospital through existing infrastructure and logistics, and that a high level of product integrity can be retained. But is complete reprocessing even a possibility for a device as complex and critical as the endocutter?

There are a lot of challenges to cover when redesigning the single-use endocutter to a product service system. First, the function of the endocutter is highly critical. It is used to operate on the most important vessels in the human body, and a malfunction of the device can easily be fatal. This means that safety standards for this type of device need to be exceptionally high. Also, the size of the end-effector limits the possibilities for a circular redesign. The end-effector needs to go through a trocar (a sort of portal device used during laparoscopic surgery) and needs to operate with high precision at its final destination. Because it is so small, the designers have really pushed the material boundaries in terms of strength and safety factors. Especially the end of the device is often deformed during surgery. On top of that, the design of the endocutter includes a lot of small and intricate parts, which are especially hard to clean (appendix 5.3).

In the past, the endocutter was a mechanical device (figure 75). The mechanical version functions in a very similar way to the powered device, but the force of the surgeon's hand translates directly to the closing mechanism, and determines how well the device can close around tissue. Surgeons are using the endocutter on progressively thicker and thicker tissue, which can require almost 400 N of force from a surgeon's hand. The struggle of closing the device with this much force can lead to shaking of the end-effector and increases the risk of tearing fragile tissue. The powered design allows the surgeon to cut thick tissue while keeping the device absolutely still. Technology is still evolving and endocutters will only become more complex in the future. These innovations improve patient safety and surgery results, but they are a major barrier to reusability (appendix 5.3).

How to design an endocutter for reprocessing

Designing an endocutter entirely fit for reprocessing is very difficult. Its complexity, user interface and small end-effector with lots of moving components are some of the barriers to an entirely sterilisable redesign.

Because the distal part is so small, complex and fragile, it is unlikely that this part can be redesigned for reprocessing. However, the handle could be made reprocessable but should preferably be designed for hydrogen peroxide sterilisation, which is less harsh on the device, instead of steam sterilisation. Designing for steam sterilisation would require thermal protection of components like batteries. This shielding of components adds a lot of bulk and weight and hurts the useability of the device. On top of that, you would need to minimise any points where fluid can be trapped after the cleaning process. This would mean a redesign of some of the controls in the current endocutter. It is possible to design a hybrid device in which some parts are single-use and others are reusable, but there are a lot of trade-offs to be made with this kind of strategy (appendix 5.3).

How to design an endocutter for remanufacturing

Compared to design for reprocessing, design for remanufacturing is a lot more straightforward. One of the main weaknesses with regard to remanufacturing the current endocutter is that in production, the shrouds of the device are press-fit together instead of connected by screws. Fortunately, changing this design element is not a huge obstacle. The parts inside the handle should be able to withstand multiple lifecycles and contain most of the higher-value components. However, the distal part of the device is heavily damaged during surgery because of its size and is a lot more challenging to recover (appendix 5.3).

For the remanufacturing of endocutters, the redesign of the device is not the main barrier. The business case and logistics will determine whether or not this is realistic. Another challenge is that there are a lot of small components inside the endocutter which individually do not contain much value. As a whole, the value of these components adds up, but some thorough calculations are needed to determine if remanufacturing is economically viable (appendix 5.3).

The best fit for solution X

Design for reprocessing is more of a challenge compared to design for remanufacturing. However, it is definitely possible with a modular approach. There are some uncertainties around the option of remanufacturing the endocutter since the individual parts are not very valuable, and the device is very complex to remanufacture, it is unclear if the business case for this strategy is valid. On top of that, reprocessing allows for a higher level of product integrity to be preserved. This is why I think reprocessing is the best course of action for solution X, given that (parts of) the endocutter can be redesigned accordingly.

There are a lot of redesign possibilities for the endocutter, but each comes with a tradeoff. Some of the tradeoffs are visualised in figure 76.

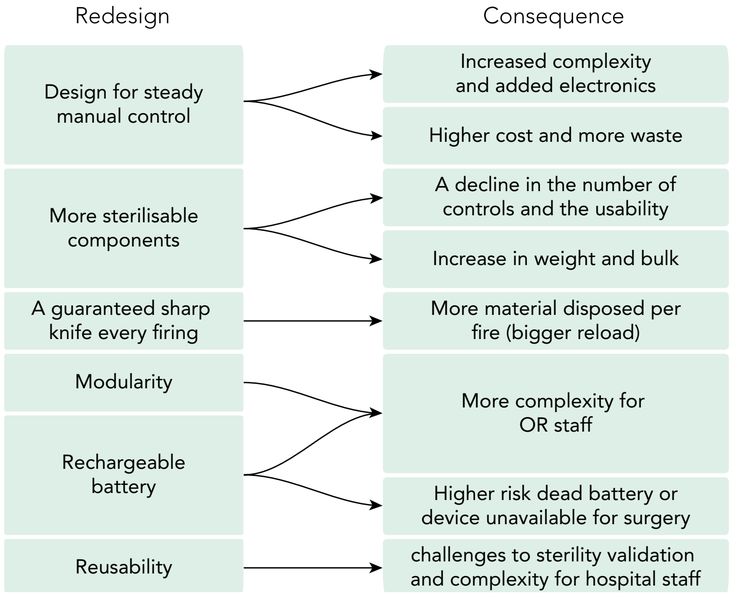


figure 75. *Trade-offs in endocutter design (appendix designer)*

2.2.2. Green servitisation

Servitisation is a strategy where manufacturers extend their business into services as a way to develop new revenue streams and generate greater value for their customers. The focus shifts from just developing and selling physical products to extending the business proposition to value-added services that support customer processes throughout the product lifecycle. They cal also choose to outsource this strategy to a third party. Servitisation can contribute to more environmentally friendly solutions and more resilient supply chains. The term 'green servitisation' refers to servitisation with ecological sustainability in mind [101]. Research into green servitisation around single-use medical devices is unfortunately scarce and relatively new (appendix 5.1).

A product-service system (PSS) can be product-oriented, use-oriented or service-oriented. A product-oriented system is a system where ownership of the product is transferred to the consumer, but additional services are provided. A use-oriented PSS is a system where the ownership of the product is retained by the service provider, who sells the function or functions of the product. A result-oriented system is a system where products are replaced by services entirely [102].

In the single-use medical device industry, product-oriented systems are the most common. This means that hospitals own their own devices and pay for example for cleaning and repairing services. There are also examples of use-oriented services where the OEM retains ownership of the device through its entire life and the hospital purchases access to it, with no distinction between new and remanufactured products. There are no examples of result-oriented models in this industry, as the choice for a device to use on a patient needs to be made case-by-case and cannot be outsourced to the OEM because of the possible impact on patient safety.

Servitisation can lead to a dematerialisation of the economy; it can reduce the material flows in production and consumption and lower the environmental burden while still offering the same level of performance to consumers [103].

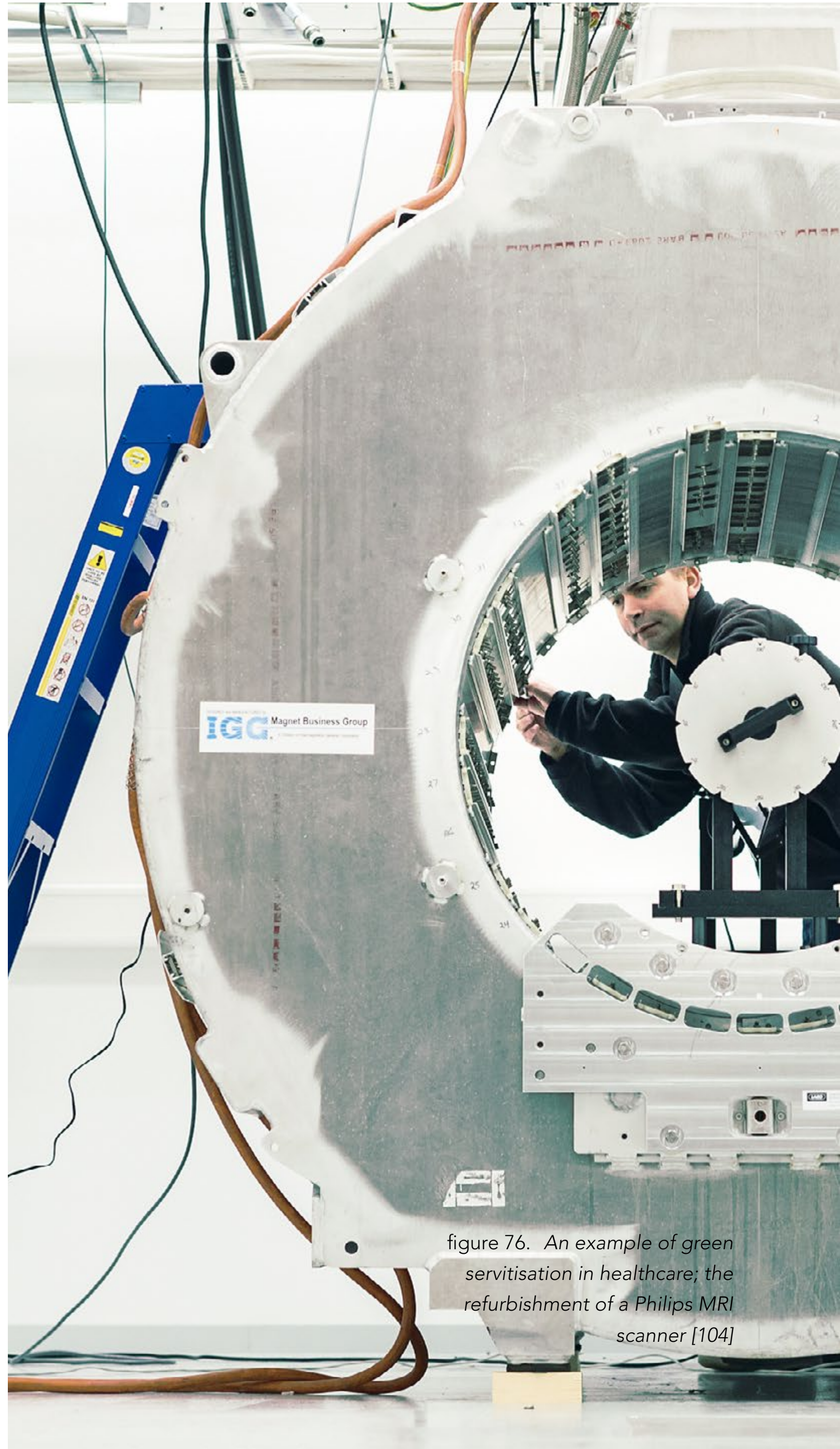


figure 76. *An example of green servitisation in healthcare; the refurbishment of a Philips MRI scanner [104]*

Barriers to green servitisation of SUDs

In the EU, a medical remanufacturer must assume the same obligations as the device's OEM and take full responsibility for a remanufactured device's quality and performance [17]. Remanufacturers are required to provide validation data regarding cleaning, sterilisation, and functional performance to show that the remanufactured device is "substantially equivalent" to the original device [105]. Devices must be approved and receive a CE certificate just like new devices before they are sold (appendix 5.3).

Additionally, the current business model of OEMs depends on selling as many new, single-use devices as possible. This makes third-party remanufacturers direct competitors of OEMs since remanufacturers cut into new product sales. This competition has led some OEMs to interfere with remanufacturing of their devices through restrictive technologies, forced obsolescence and contracting restrictions [105]. There is a lack of collaboration amongst different OEMs and between OEMs and remanufacturers. A collaboration could increase the scale of a service, and provide easier access to necessary competencies for a successful remanufacturing model. Some of these capabilities include remanufacturing technologies, testing procedures, device design, software skills and logistics [101].

The barriers to servitisation around reprocessing are less straightforward. In the Netherlands products that follow this CRF are designed to be reusable, and the business models of OEMs are adjusted accordingly. When substantially altering devices through repair or maintenance, you start to enter a grey area. At which point are you changing the original product so much that you enter the domain of remanufacturing instead? What levels of repair and maintenance would require the device to be revalidated before use?

The best service model for solution X

Since result-oriented models are not suited for the MedTech industry and Product-centred service systems already exist in the Netherlands (appendix 1.5), it might be interesting to look into an access model for solution X. There are examples of access models where an OEM retains ownership over a device, but sells access to it to hospitals, but this model is limited to devices or surgical nets which are very costly and highly specialised (figure 78). Hospitals pay for access to these devices whenever they plan the specific surgery that the device is designed for. The OEM retrieves the used device after the surgery for reprocessing (appendix 5.5). What if there was an access model managed by a third party instead of by individual OEMs, and if it would provide more than just highly specialised devices?

figure 77. *A specialised surgical net following an access model*

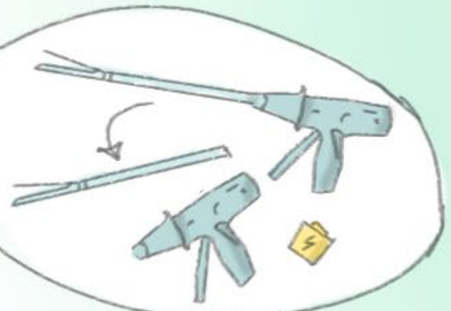
2.2.3. Track and trace

In existing internal reprocessing systems, reusables are traced throughout the cycle. The hospital needs to know exactly where they are at all times. This tracking is usually done by scanning the nets that devices are stored in. Individual devices are not often tracked, and SUDs, except for implants, are not tracked at all. If more and more products that are currently disposable are redesigned to be (semi-) reusable or modular, the tracking system needs to change. Instead of tracking the nets of devices, there needs to be information available on all the individual modules within a product because they would all lead separate lives. It needs to be clear for how many cycles a module is designed, after how many cycles maintenance of the module is planned, and how many cycles a module has already gone through to determine follow-up reprocessing actions.

One company that can help create detailed product passports with information on all the different parts and materials, is Circularise [107]. They use blockchain to combine information from raw materials and different production processes to give a detailed overview of the composition and impact of a product. This information can be used to for example optimise recycling because you know exactly what kind of materials with which composition make up a product and can decide what is possible at end of life with all that available information. Blockchain allows companies to refer to a shared ledger of information that they know cannot be tampered with, which creates a whole new level of value chain transparency.

3. MedFlo - the final design

Devices have become even more complex. Regulation has made SUDs very expensive, which is why reusable devices have gained popularity. In cases where reusing the entire device is not possible, modular design is the norm.

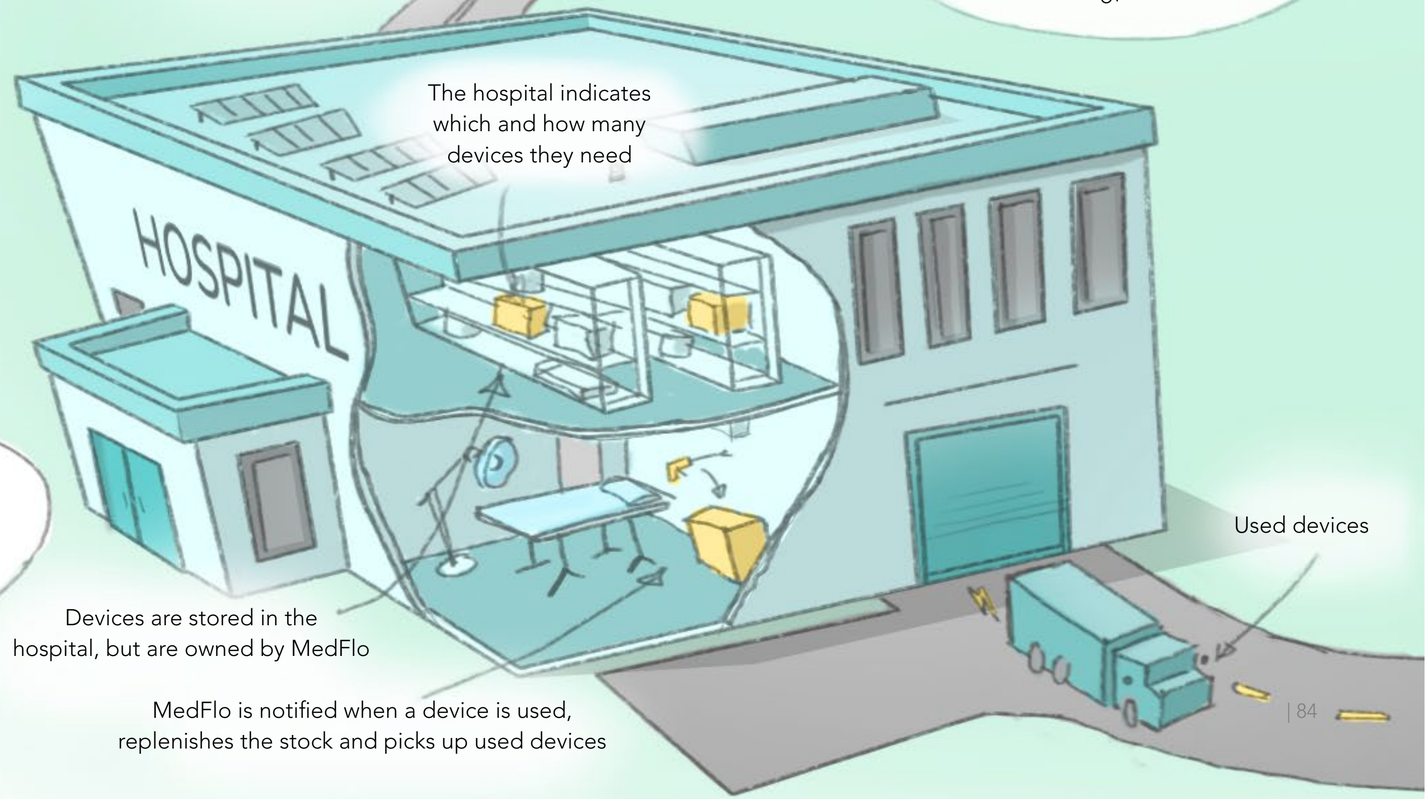


Modular devices contain parts with different planned lifetimes, with the aim to preserve as much product integrity and value as possible

Clean devices replenish used device stock

To deal with this complexity, hospitals partner up with MedFlo; a service that provides access to a clean and safe inventory of devices

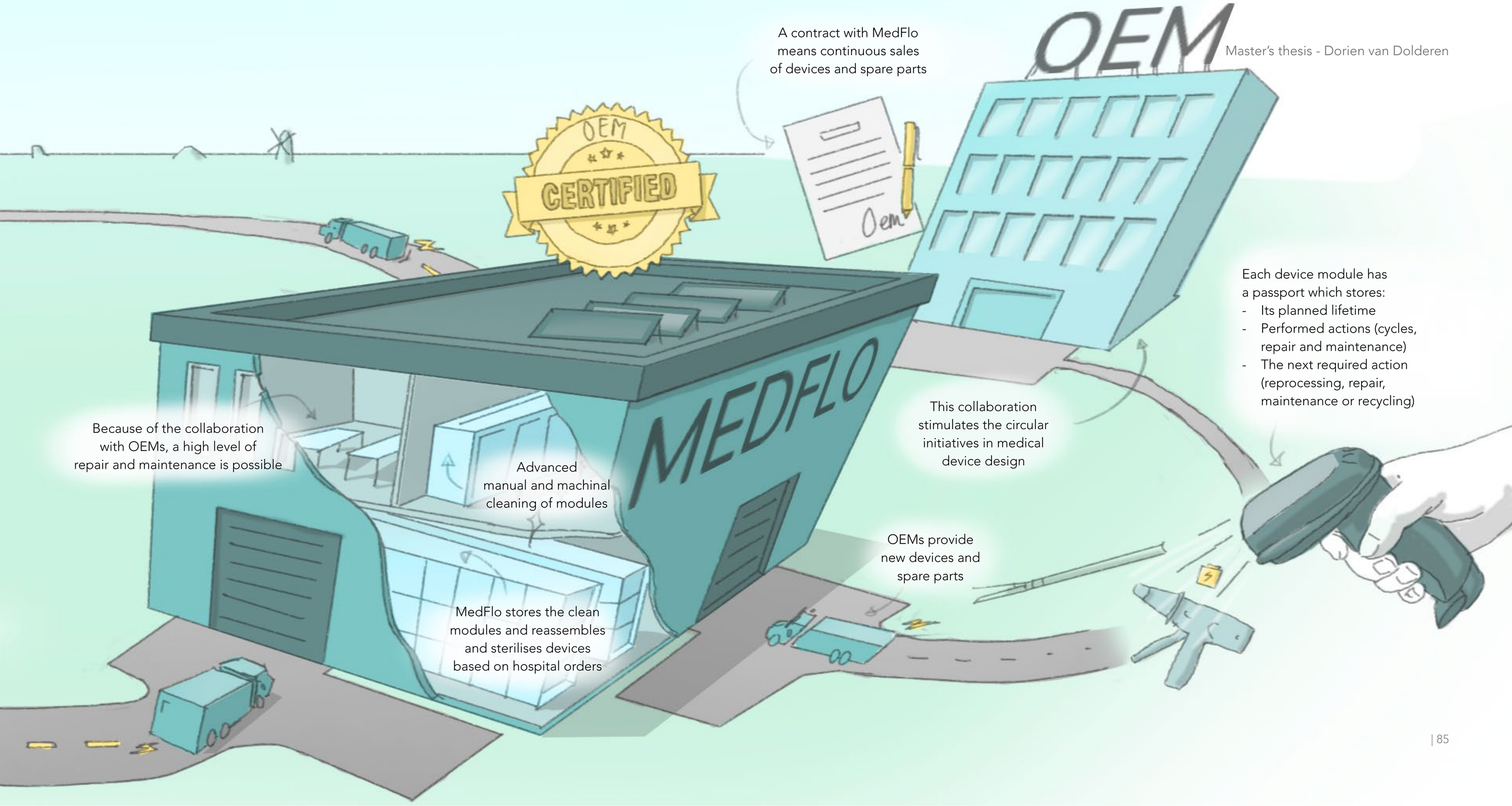
The hospital indicates which and how many devices they need



Used devices

Devices are stored in the hospital, but are owned by MedFlo

MedFlo is notified when a device is used, replenishes the stock and picks up used devices


A contract with MedFlo means continuous sales of devices and spare parts
OEM
OEM
CERTIFIED
Oem
MEDFLO
Each device module has a passport which stores:
- Its planned lifetime
- Performed actions (cycles, repair and maintenance)
- The next required action (reprocessing, repair, maintenance or recycling)
This collaboration stimulates the circular initiatives in medical device design
Because of the collaboration with OEMs, a high level of repair and maintenance is possible
Advanced manual and machinal cleaning of modules
OEMs provide new devices and spare parts
MedFlo stores the clean modules and reassembles and sterilises devices based on hospital orders

MEDFLO

MedFlo is a product-service system following an access model. It offers hospitals and other healthcare facilities access to an inventory of clean, safe and more circular medical devices. It is adapted to a future in which SUDs have become too expensive for hospitals because of regulatory boundaries, and a shift back towards reusables is taking place.

Devices have become more complex, and it is not always possible to reuse all their components. In cases like this, devices are designed to be modular. Different modules have different planned lifetimes to preserve as much product integrity as possible. This can however lead to an increased level of complexity in reprocessing and inventory management that hospitals cannot always handle by themselves. A collaboration with MedFlo is the solution.

MedFlo has the capability to reuse types of devices that are currently not suited for reprocessing because they have the facilities, expertise and connections with OEMs to handle a higher level of complexity in reprocessing, repair and maintenance. Figure 79 shows an overview of the cycle devices follow through MedFlo, and the storyboard explaining the entire service can be found in appendix 6.3.

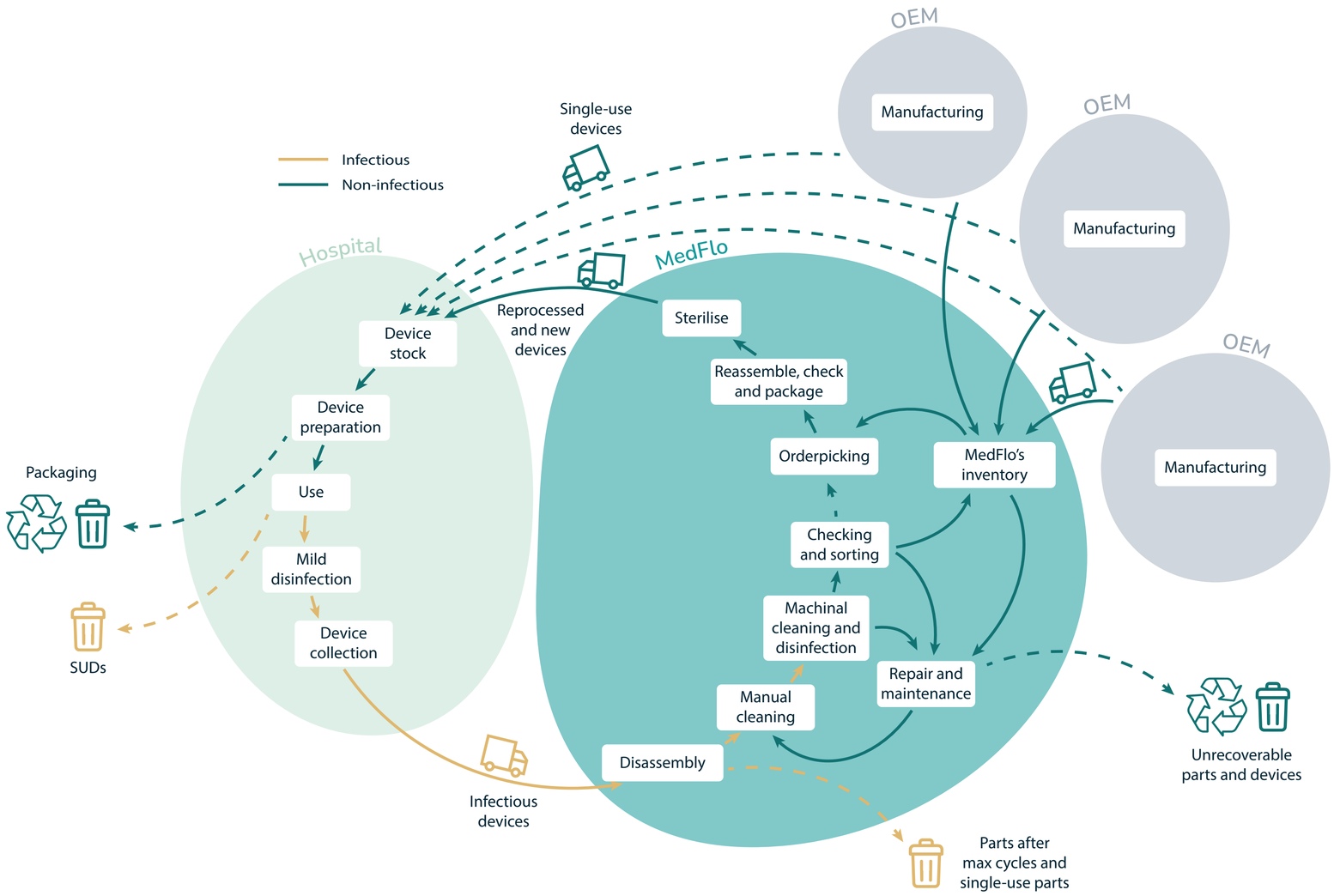


figure 78. *A schematic overview of MedFlo's service*

3.2. How does MedFlo work

Hospitals indicate exactly how many and which devices or device nets they need to have available in their inventory at all times. MedFlo offers this stock on consignment, which means MedFlo still owns the devices, but they are stored in the hospital's inventory. Whenever a device is prepped for surgery, MedFlo is notified to deliver a newly cleaned product the next day to restock the inventory. Once a day, a truck delivers new devices and picks up the used ones for reprocessing.

MedFlo closely collaborates with device OEMs. OEMs sell new (semi-) reusable devices, device modules and spare parts to the service which allows MedFlo to repair devices more efficiently. A contract with MedFlo also stimulates circular design initiatives because MedFlo creates a new market for devices with longer lifetimes, and offers stability for OEMs which aim to move away from a dependence on SUDs.

A blockchain product passport system is used to track the lifecycles of individual product modules. The passport shows the planned lifetime of each module, how many reprocessing cycles it has already gone through, when the module needs to be sent to repair and maintenance and when it is time for disposal or, if possible, recycling.

3.2.1. Logistics

The allocation of one box truck per hospital per day should be sufficient for the transportation of devices from and to most hospitals (figure 80). Only the largest medical centres may need a larger truck or multiple deliveries per day. Rush deliveries to any hospital within the Netherlands can be accomplished within one to three hours (appendix 7). This is significantly faster than internal reprocessing, where it takes around five hours to process a device (appendix 5.5).

A possible floor plan for the MedFlo facility is visualised on the next page in figure 81. It shows the dedicated areas for different parts of the reprocessing logistics, as well as possible routes that a device module can follow from arrival at the facility to departure back to a hospital. There are a few key differences with an internal reprocessing department (appendix 5.5).

From the manual cleaning area, there are two sets of washing machines for machinal cleaning and disinfection. One set leads to the checking and sorting area, and one to repair and maintenance. This separation early on saves time, since MedFlo already knows whether or not a module needs to move to repair and maintenance by checking the product passport before manual cleaning. After repair and maintenance, a device always moves back to manual cleaning first, for example for the removal of oil residue from the lubricating of hinges in mechanisms.

Also, there is a large storage area located before sterilisation instead of after sterilisation. In a regular internal sterilisation department, devices are stored in their nets after sterilisation. However, to reduce the number of modules needed in storage, devices are only assembled, sorted, packaged and sterilised after a hospital order comes in. This is why separate module storage before sterilisation is needed.

Non-sterile modules often contain batteries, which are charged in one central area. Some batteries are sterilisable and can follow the route of regular modules. Non-sterile modules are added on the outside of packaged nets after sterilisation in the cart storage area where hospital orders are completed. These modules are damaged if they go through sterilisation along with the rest of the net.

figure 79. *For most hospitals, one box truck for device transportation per day should suffice.*

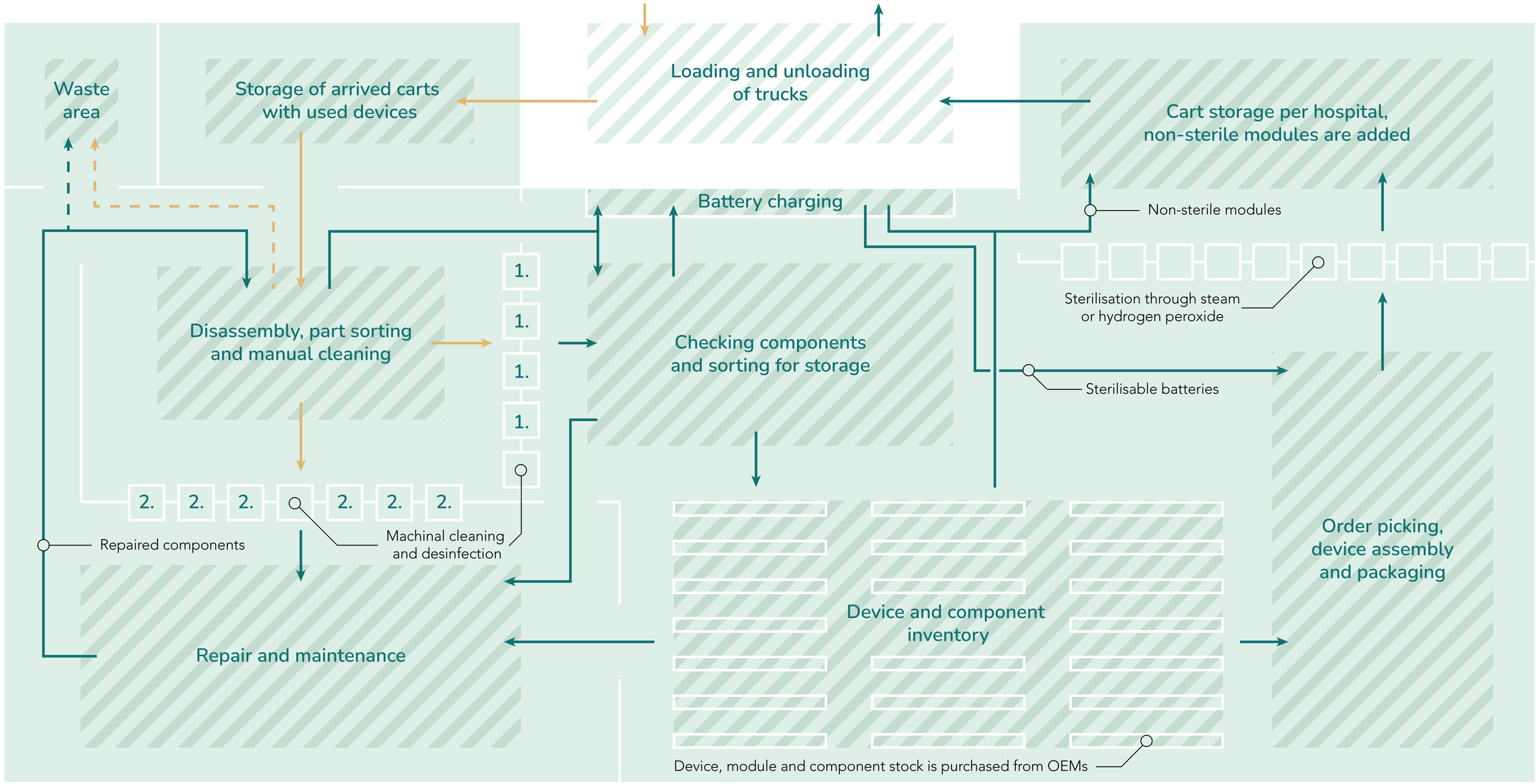


figure 80. *A possible floorplan of the MedFlo reprocessing facility*

3.2.2. Product lifecycle management

MedFlo works with a blockchain product passport system that tracks the medical devices and the modules within these devices. The product passport shows how many reprocessing cycles are planned for a module and how many cycles it has already gone through. Based on this information MedFlo can decide to reprocess it again, first perform repairs or planned maintenance, or if it is time to dispose of the module because it is at the end of its planned life.

The regular scanning of devices or nets can help MedFlo keep track of their exact locations and the next steps to take in reprocessing. Modules are combined into devices, which are combined into nets, which in turn can be stored together for transportation in carts. If you scan such a cart you should be able to find all the information on its contents. Figure 82 shows all the points in MedFlo's process where there is an interaction with the product passport, whether it is to find information, add to it, or if it is a combination of both.

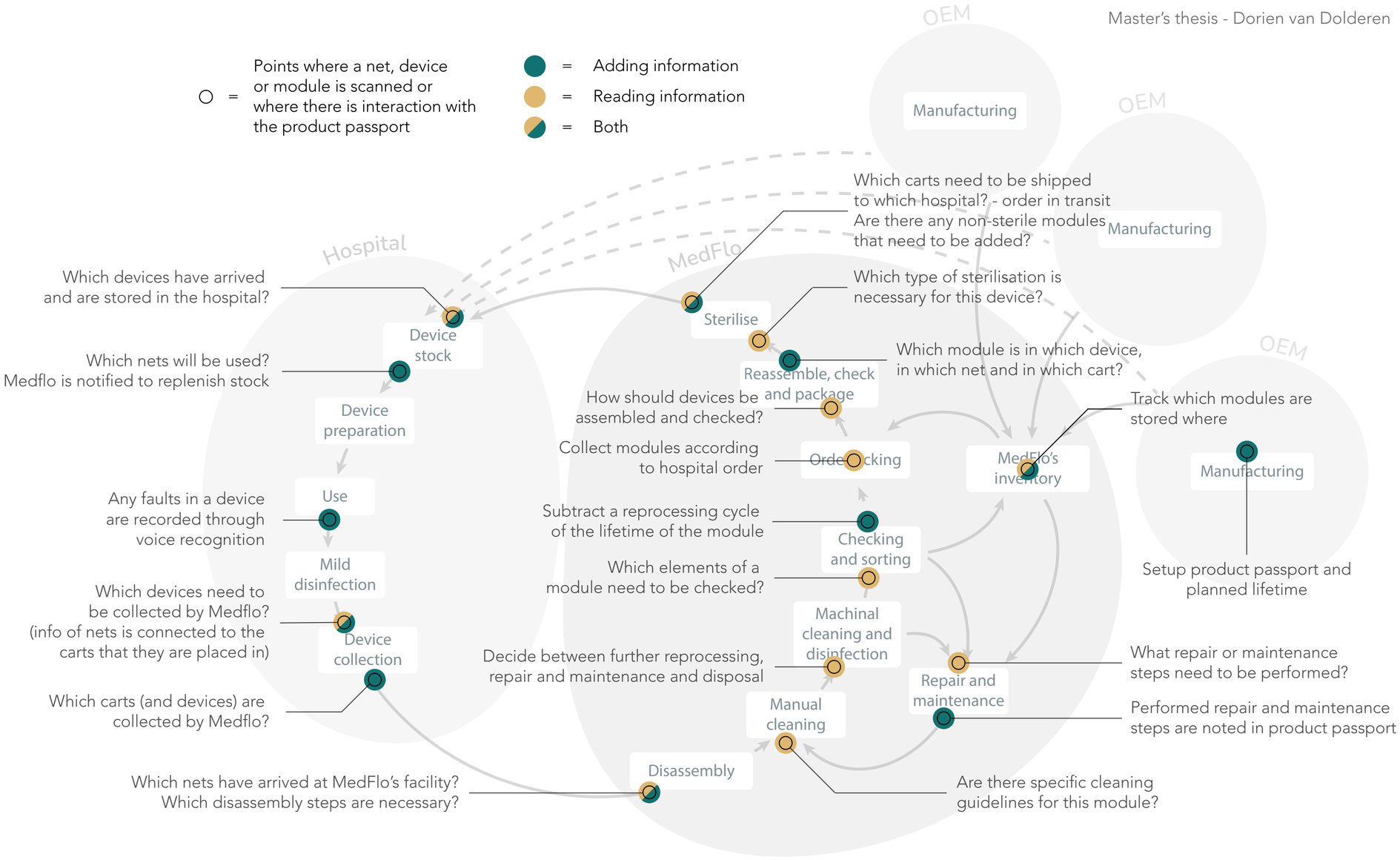


figure 81. *Product passport interactions visualised*

4. Barriers to the implementation of MedFlo

There are a lot of external factors to take into account and changes to the regime to be made before a service like MedFlo is realistic. These include regulatory changes, product redesigns, the rethinking of OEM value chains and business models, and adjustments to hospital organisation. Without taking the necessary steps in these fields, MedFlo does not have a chance to develop and grow.

4.1. Policy

Regulation is currently a roadblock for the circular development of endocutters but could become a driver with the right alterations [55]. There are a few key possible alterations to current policies and regulations that could contribute to a sustainable transition in the MedTech industry.

4.1.2. The "free" market of MedTech

"The free market doesn't exist. Every market has some rules and boundaries that restrict freedom of choice. A market looks free only because we so unconditionally accept its underlying restrictions that we fail to see them." – Chang [106]

The government is always involved in markets to a certain extent. The level, strictness and visibility of regulatory restrictions are the factors influencing how free we perceive a market to be. State involvement is actually a way towards more sustainable practices, goods and services. Without the state, a market would only strive to cut costs and increase profits. The state sets the boundaries for markets; it enforces humane working conditions and sets limits to environmental damages, which is crucial for a healthy, sustainable economy [106], [107].

The MedTech industry is heavily regulated, but highly competitive. In a free market, theory suggests that competition will deliver the best possible outcomes for both buyers and sellers, but others see competition as having no place in an industry aimed at protecting the sick [108]. The current system continues to reward companies based on volume sales, which leads them to protect their product details and restrict circular EoL possibilities. OEMs seem to be stuck in their business models and have no choice but to compete (appendix 5.1).

Companies know that the market is changing and that their current practices are unsustainable. Adjusting to the changes to come is a necessary preparation (appendix 5.1). failing to do so will mean they are caught off guard, and in the worst case, will be phased out after the transition. Changing in a competitive environment is not easy, but the right regulatory incentives can provide companies with the necessary support and direction.

4.1.1. Reusable device approval

The approval process for medical devices in the EU is regulated by the European Medicines Agency (EMA) [109]. The EMA is responsible for evaluating the safety, quality, and effectiveness of medical devices before they can be placed on the market.

In the EU, medical devices are classified according to their intended use, risk level, and duration of use. Classification determines the level of regulatory oversight and the requirements that must be met for a device to be approved [17]. New medical devices then undergo a conformity assessment to ensure they are safe to use. This involves a review of the technical documentation from the OEM on the safety and performance of the device, after which they receive a CE certificate. Medical devices need to meet the EU Medical Device Regulations [17] but are also validated according to different ISO and IEC standards.

It is easier to market a device as single-use compared to reusable. If an OEM wants to market a device as reusable, they need to be able to show a cleaning validation, a sterilisation validation and a functional performance validation. On top of that, they need to write instructions for reuse and validate those instructions. Even after the marketisation of a new product, there will be check-ups to see whether or not the test results correspond with practice. All of these checks and validations make it very costly to develop a reusable device compared to the development of a single-use device. (appendix 5.1).

Could it be possible to alter the device approval system in a way where the marketing of SUDs becomes less attractive than the marketing of reusables? Maybe companies could be charged a fee for the approval of a single-use device, or receive a subsidy for the approval of a reusable one. We need to reward behaviour that is more circular and discourage behaviour that is wasteful (appendix 5.1).

4.1.3. Extended Producer Responsibility (EPR)

Extended Producer Responsibility is an environmental policy approach in which a producer's responsibility is extended to the post-consumer stage of a product's lifecycle [8]. There is a transfer of the financial and sometimes organisational burden of the management of the EoL of products from public authorities to producers, in line with the Polluter Pays Principle [110]. EPR schemes involve a combination of requirements set by policymakers that producers should meet, and producers taking steps to fulfil these obligations.

The main aim of this type of scheme is to increase the amount of product recovery and minimise the environmental impact of waste materials. However, it also provides incentives for manufacturers to design their products for more effective and less costly EoL recovery [111].

One example of EPR closely related to medical devices is that of the directive of Waste Electrical and Electronic Equipment (WEEE or E-waste). WEEE is one of the fastest-growing waste streams, with a complex mixture of materials. Improper management of the EoL of these products leads to a waste of expensive and rare resources, as well as environmental and health problems [112], [113]. Electrical or electronic medical equipment is a part of this regulatory framework, but an exemption still exists for medical devices which could be infectious at EoL like the endocutter [114]. In some EU member states EPR is already implemented on medical waste, and it seems more states are moving in this direction [8].

For this project, it is crucial to take into account the regulatory boundaries which already exist as well as the direction that policymakers will take in the future. EPR policies are currently expanding to higher R-strategies and new product categories [8]. It is only a matter of time before EPR will be introduced for medical devices in some shape or form.

Individual versus collective EPR

In some cases, legislation requires manufacturers to join a collective recovery system, and in some cases, individual recovery strategies are allowed. Preferences vary and there are benefits and drawbacks to both strategies [111].

Individual producer responsibility (IPR) means that each producer manages the collection and recovery of their own products [8]. In this case, manufacturers see the return of their design for recovery efforts immediately, which gives a great incentive for more sustainable design practices. However, most producers still choose to join forces and carry their obligations together through third-party entities. These entities, the so-called producer responsibility organisations (PROs) are financed by OEMs to manage the collection, sorting and treatment of post-consumer products on their behalf. This collective producer responsibility (CPR) is usually more cost-effective. However, it is easier for producers to "free-ride" on the design for recovery of others, because recovery costs can be divided equally among participating manufacturers [111]. Fees that manufacturers pay to PROs can also be calculated by product volume or mass and can be used to incentivise the production of more sustainable products [8].

IPR generally gives a bigger incentive for OEMs to design for recovery [8], [111]. However, IPR can be more difficult to enforce compared to CPR because a larger variety of actors (PROs) per sector need to be monitored. If the aim is to support the design for product recovery and create a level playing field in competitive markets, EPR legislation should be based on individual producer responsibility [111].

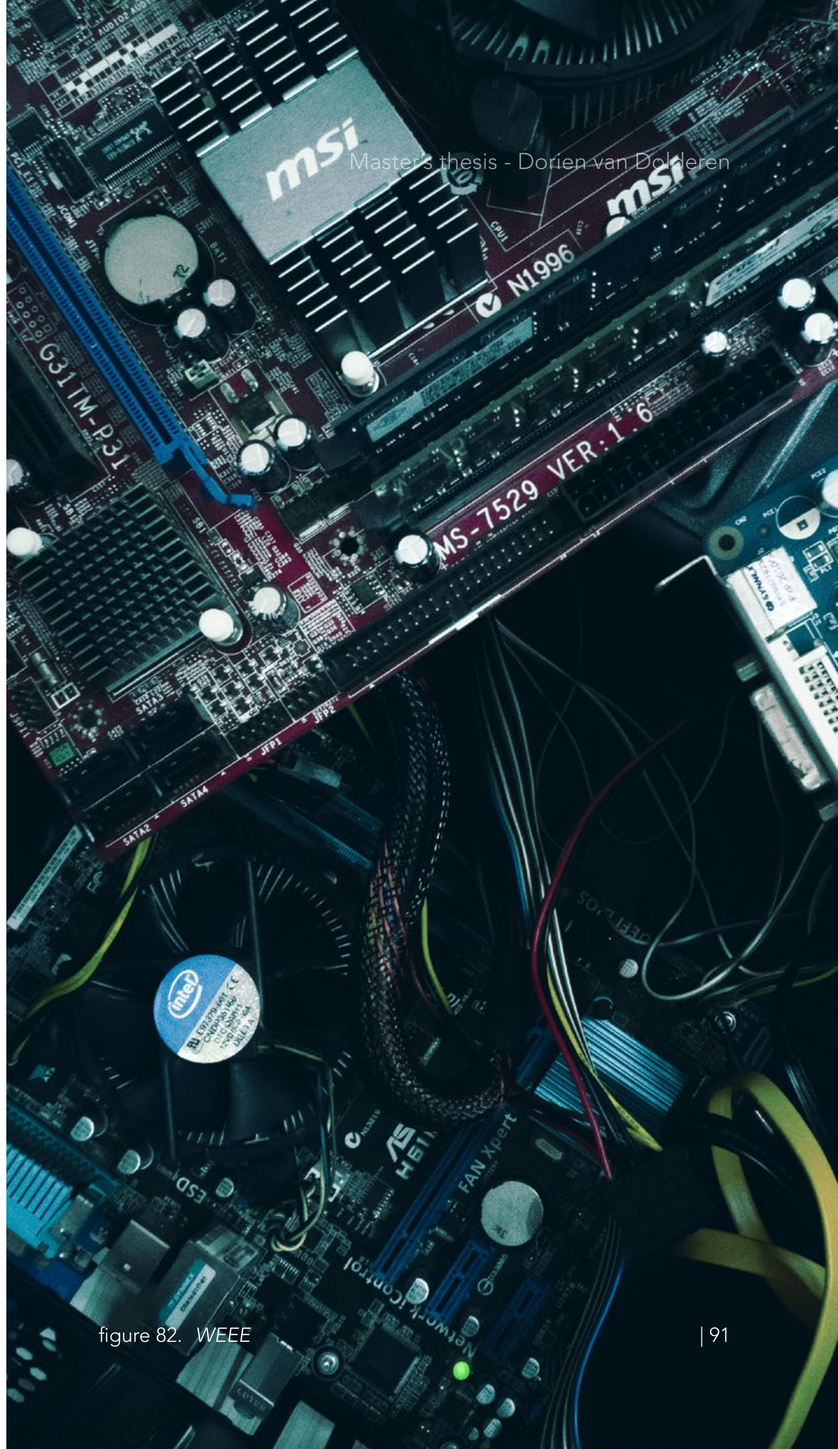


figure 82. *WEEE*

The EPR framework is flexible and there are different instruments that can be applied, both individually and combined.

Take-back requirements

Take-back requirements (figure 84) are the most common regulatory instruments. This strategy sets requirements or quantified targets for producers to collect products at the EoL and treat them appropriately. Targets are usually set as percentages of produced or collected products measured in weight, volume or units [8].

Advance disposal and recycling fees

An advance disposal or recycling fee (figure 85) requires producers or consumers to pay the EoL treatment costs of a product upfront. One main advantage of charging the fee in advance instead of at disposal is to reduce the risk of illegal dumping of products. This fee does however not promote the proper disposal of products [8].

One way to use this instrument as a promotor of eco-design is to differentiate it according to the level a product is designed for recovery. If the fee is lower for products that are for example easy to disassemble, it would provide an incentive for manufacturers to design their products in this way [8].

Deposit-refund system

Under a deposit-refund system (figure 86), consumers pay a deposit when they buy a product and receive a refund when they return it. This provides an incentive for consumers to sort and return products in a good state [8].

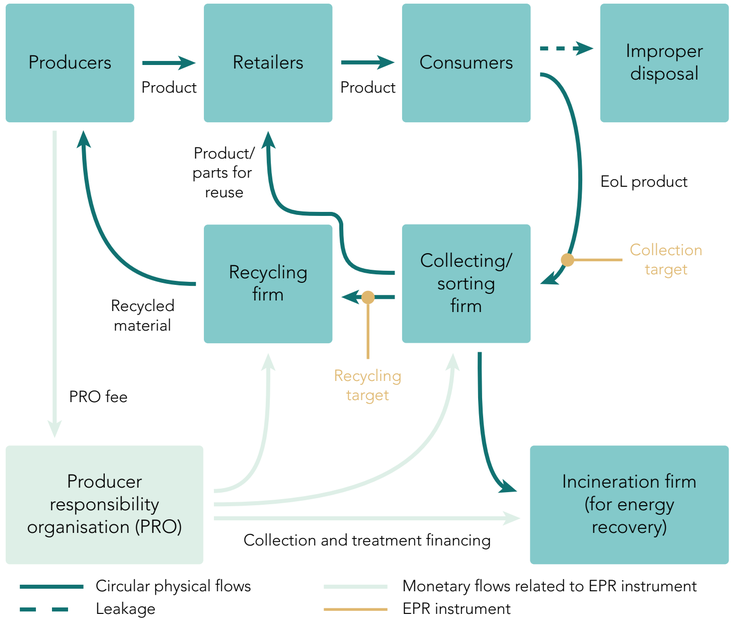


figure 83. *Systematic overview of take-back requirements for EoL products [8]*

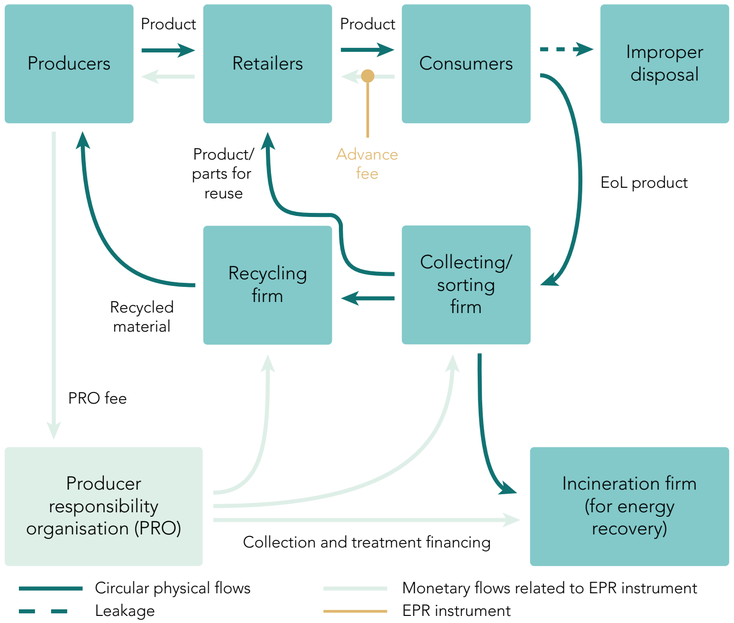


figure 84. *Systematic overview of advance disposal fees for EoL products [8]*

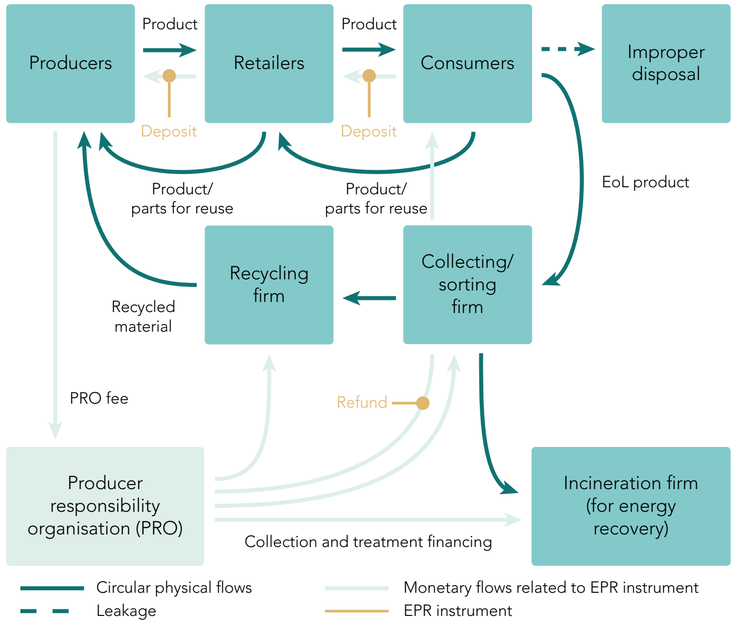


figure 85. *Systematic overview of a deposit-refund system [8]*

EPR for medical devices

EPR instruments are determined per member state. National regulation, but also cultural and social differences, make some more suited than others. The goal for the introduction of EPR on medical devices should be to incentivise a more circular design strategy and promote reusable devices over disposable ones. In this case, EPR should ensure that the contribution of each OEM reflects the environmental and social cost of recovery of their own products as closely as possible [8].

Individual vs collective EPR

The choice between individual and collective EPR for medical devices partly depends the desired CRF for the EoL of devices. Recycling or reprocessing can be handled collectively for example through a service like MedFlo. However, individual EPR is probably more realistic for the CRF of remanufacturing because of the confidentiality around product details in the industry. Individual EPR will also reflect the circular design initiatives of OEMs more closely compared to collective EPR.

Take-back requirements

A collection target could be an option for medical devices. It however does not incentivise OEMs to push past the set target, since they do not see a return on extra recovered devices. Take-back requirements are not really suited for reprocessing, but can maybe be altered by setting a requirement for the cycles each product needs to go through.

Deposit-refund system

A deposit refund system could promote collection for recovery instead of incineration, but in a B2B setting like that of medical devices this extra incentive might not be needed.

Advance EoL fees

Charging EoL fees in advance is not a very interesting model for medical devices, since there is no risk of illegal dumping because of the tight regulation around infectious waste. It could however be a way to differentiate the use of reusable products from single-use ones. If disposables would become more expensive because of these fees, hospitals would be motivated to opt for more circular designs instead. There could also be a differentiation between products by through their disassembly times, which would incentivise OEMs to look into their design practices towards circularity.

Discussion EPR

There are many ways to incentivise circular design or the purchase of more circular products. Further research will need to determine which EPR instrument or combination of different instruments could best suit the medical device industry, but advance EoL fees seem to be a good option.

OEMs could be motivated to design for more recovery cycles through a fee for each incinerated product, or through the promotion of a system where OEMs see extra returns per recovery cycle. They could also be held accountable for the EoL of all of their products through legislation. There is also the question of which CRF should be promoted. Reprocessing is not suitable for every device but would be the most sustainable option. Remanufacturing is the next best thing and relatively straightforward to hold OEMs accountable for. Recycling is a lot closer to the WEEE EPR policy but would waste a lot of valuable components. Which EPR targets would be both impactful and realistic? Is there a way to incentivise modular design in medical devices?

figure 86. *A deposit refund system implemented on plastic bottles in the Netherlands*

4.2. Product design

The current design of the endocutter cannot be included in a service like MedFlo. First, a significant redesign is needed. There are a few main factors to consider.

4.2.1. Design for reprocessing cycles

The main goal in the redesign of the endocutter should be to design it for as many reprocessing cycles as possible. On top of the environmental benefits, more cycles per device also create stability for MedFlo. There is not much value in buying new devices and reprocessing them once or twice before they are at the end of their planned life. Modules designed for many, or even an infinite number of cycles are way more attractive.

4.2.2. Modular design

Since it is unlikely that the entire endocutter can be redesigned for reprocessing, a redesign should be modular. This means that some components might still be single-use, like the reloads, some will be reprocessable, and some might not be sterilisable but will instead be encased in a sort of sterile barrier. The different modules should each have their optimal planned lifetime to preserve as much product integrity and value as possible. These modules should be easy to connect and disconnect from each other for efficient reprocessing. Overall design for disassembly could be useful for repair and maintenance but does not have to be the main focus of the redesign.

I brainstormed on some possible modular designs for the endocutter, each with its own benefits and drawbacks. Three options are shown on the next page in figure 88.

4.2.3. Battery design

Batteries are some of the components that are the most sensitive to cleaning and sterilisation techniques. They do not withstand heat well, and can only be autoclaved when properly shielded which adds a lot of weight and volume to the medical device [115] (appendix 5.3). If a device has a non-sterilisable module, the batteries are probably a part of it. More innovation around sterilisable batteries would help simplify reprocessing and decrease the number of modules in a device.

It would be ideal if the batteries of medical devices were rechargeable, which is not the case in the current endocutter. On top of that, Medflo could have a central charging area (figure 81 page 88), and it would be very useful for batteries to be standardised to simplify logistics. If this is not possible at least the charging ports should be standardised.

4.4. Industry

The OEMs need to change the way they work to become a part of this access model. MedFlo requires a level of collaboration that currently does not exist in the MedTech industry.

4.4.1. Provision spare parts and modules

Existing medical remanufacturers do not have access to spare parts of devices. They first need to go through a process of reverse engineering before they are able to repair or remanufacture a device. The collaboration between MedFlo and OEMs should enable EoL strategies without the need for the reverse engineering of components. OEMs need to become more open to sharing spare parts and modules for MedFlo to work.

4.4.2. Alternate business models

OEMs also need to drastically change their business models around surgical devices. Instead of depending on the continuous sales of SUDs to individual hospitals, they need to work towards contracts with bigger services that provide devices for many hospitals collectively. For the duration of such a contract, they provide new (semi-)reusable devices, modules and components. In this business model, the lifetime of devices is key.

4.3. Hospital organisation

A collaboration with MedFlo could be relatively expensive for hospitals which are used to managing the reprocessing of devices themselves. However, when device complexity increases further internal reprocessing, repair and maintenance will become a bigger challenge. So; the more complex the device, the more attractive MedFlo becomes. MedFlo has more space, expertise, time, and access to spare parts, and could even use sterilisation techniques that are not available in hospitals.

However, hospitals which have just invested in a new sterilisation department might not be too eager to make the shift to external reprocessing. Most hospitals in the Netherlands manage device reprocessing internally, so switching to MedFlo can be quite a big step.

It will take some changes within hospital organisation to implement MedFlo's services. Inventory management will change, as well as the supply and pickup of devices. The desired device stock needs to be reconsidered, as there are probably fewer devices needed inside hospitals because the reprocessing is outsourced, and newly reprocessed devices can be provided last minute. There will also be a more restricted catalogue of devices to pick from because only collaborating OEMs will provide devices through MedFlo. This means surgical nets will probably need to be more standardised than they currently are.

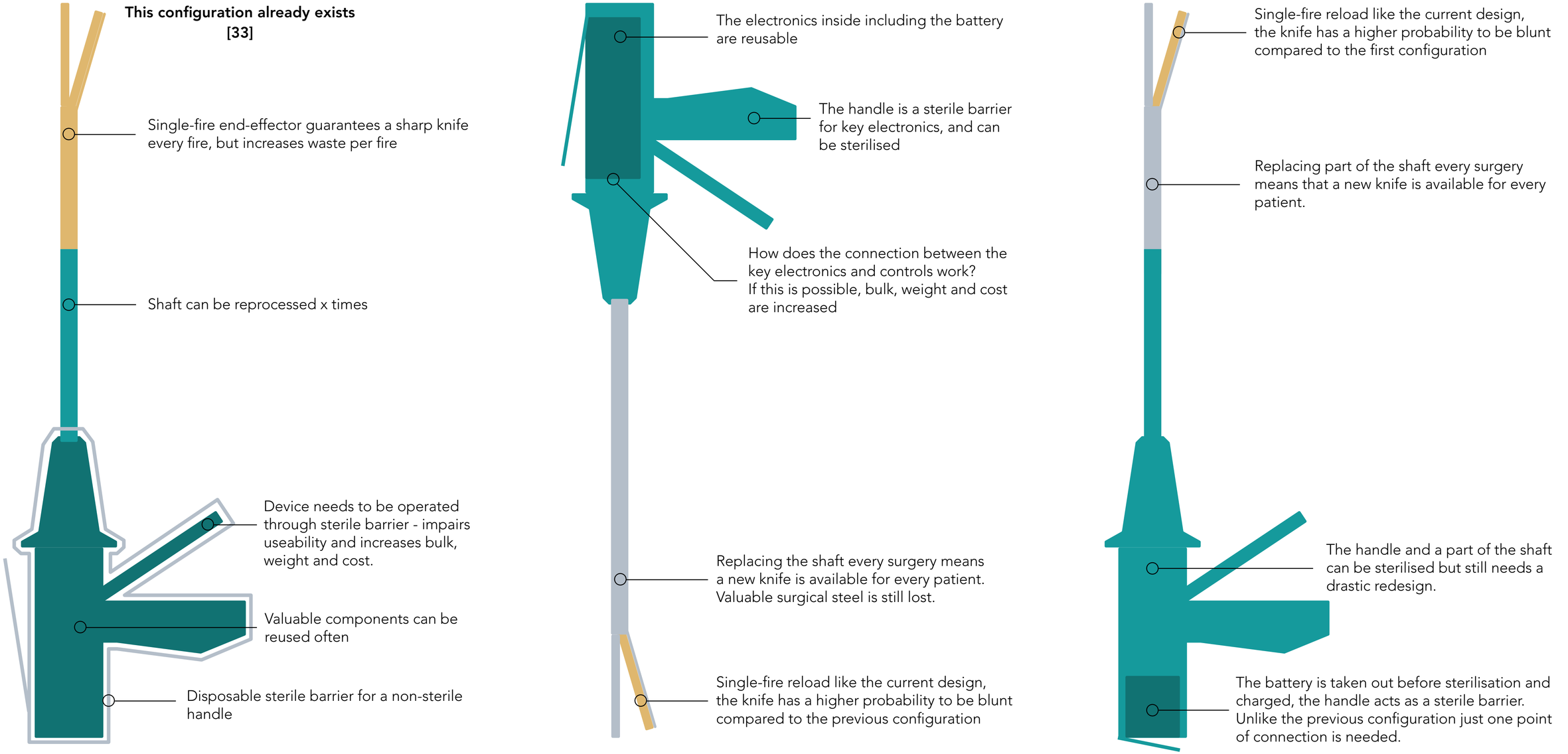


figure 87. *Different possible hybrid configurations*

figure 88. *An example of a non-sterile module within a sterile barrier*

5. Conclusion

Through desk research and expert interviews guided by storyboards, I iterated on an initial service idea towards my final design named MedFlo. I found that it is more straightforward to redesign an endocutter for remanufacturing, but that a design for reprocessing would be more impactful in terms of preserving product integrity and value. Reprocessing the entire device is probably not possible, even after a drastic redesign, but a modular design in which different modules have different planned lifetimes certainly is.

In terms of circular business models, a result-oriented model is not suited for medical devices, but product- and use-oriented models are great options. A use-oriented model creates a lot of possibilities for handling higher levels of complexity in reprocessing, repair and maintenance, which makes it attractive for a future where device complexity will increase even further.

MedFlo is a service which offers hospitals access to a complete, clean, safe and high-quality inventory of medical devices. A collaboration with MedFlo helps hospitals deal with the increasing complexity of medical devices, and allows the reuse of devices that are currently disposable. MedFlo is a partner of device OEMs and continuously purchases spare parts and device modules. This collaboration allows for more efficient and higher levels of repair and maintenance.

There are, however, a few barriers that need to be overcome before a service model like MedFlo is realistic. First, SUDs need to be more expensive to produce, sell and use to create room for the development of (semi-)reusable devices. This can be realised through interventions like EPR and marketisation fees for SUDs. Also, products need to be redesigned for reprocessing, and if that is not an option, for modularity. On top of that, OEMs need to change their business models and move away from their dependence on SUD sales. Lastly, hospitals need to adjust their organisation to access models and review their device inventory needs.

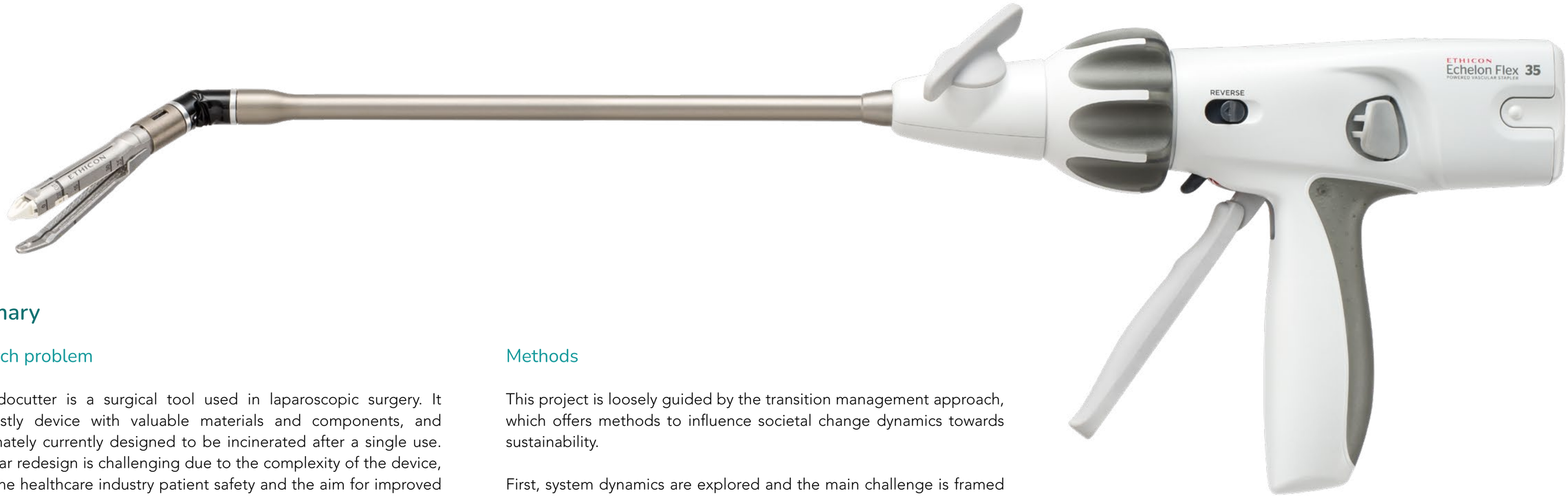
When all these external factors are taken into account there will be space to develop and implement a circular medical access model like MedFlo, and we will move a step closer to a sustainable future for the MedTech industry.

PART 6

Conclusions

This section of the report contains a summary of the project, an evaluation of the findings and the final design. It also contains detailed recommendations for policymakers, OEMs and healthcare facilities to follow if they want to contribute to a sustainable MedTech industry.

Discussion



Summary

Research problem

The endocutter is a surgical tool used in laparoscopic surgery. It is a costly device with valuable materials and components, and unfortunately currently designed to be incinerated after a single use. A Circular redesign is challenging due to the complexity of the device, and in the healthcare industry patient safety and the aim for improved surgery outcomes have been de main drivers for innovation.

Healthcare is a highly pollutive industry with a massive waste footprint, partly because of its dependence on single-use devices like the endocutter. The aim of this project was to look at a possible transition in the MedTech industry, envision what a sustainable future could look like and explore a possible route towards that vision through a case study of the single-use endocutter, its possible circular recovery flows, and an experimental design process.

Methods

This project is loosely guided by the transition management approach, which offers methods to influence societal change dynamics towards sustainability.

First, system dynamics are explored and the main challenge is framed through a review of the existing literature on the possible circular recovery flows for medical devices, the MedTech industry and the circular economy. Once the possible CRFs were defined, a one-day design sprint was executed per CRF to gain a better understanding of their individual opportunities and barriers and to decide on a preferred circular design direction.

Next, a vision for a sustainable future for the MedTech industry was formulated using the VIP method. This vision served as a starting point and a deliberate direction for idea generation and selection. The final service design took shape through the use of storyboards, expert interviews and additional desk research.

The MedTech industry from a multi-level perspective

When looking at the MedTech industry from a multi-level perspective, it is clear that there is increasing pressure on the regime to become more sustainable. Internal forces contribute to the destabilisation of the regime as well; the industry's dependence on SUDs is extremely wasteful and contributes to rising healthcare costs. It is time for a sustainable transition away from these harmful practices. The DiCE project is set up by regime actors (OEMs, universities, governments), but aims to create a niche where sustainable experiments have room to develop and grow. This project is an example of such an experiment and could hopefully contribute to a sustainable transition away from SUDs.

The Circular Recovery Flows for devices like the enocutter

The different Circular recovery Flows fit for devices like the endocutter are: Reprocessing, remanufacturing, recycling and biomaterials. The CRF of repair is not included because it is an integral part of both reprocessing and remanufacturing processes, and does not occur isolated in this field. Refurbishing is also excluded because it is not fit for high-criticality devices. This is due to the high safety standards that need to be met before a device is allowed to be reused.

Reprocessing is the CRF in which the highest level of product integrity can be retained. However, this strategy requires a drastic redesign of the endocutter. Depending on the sterilisation techniques available, different components need to be shielded against heat and moisture, and the device needs to be designed for partial disassembly. Reprocessing also requires complex logistics and infrastructure, either inside the hospital in a specialised sterilisation department or managed separately by an external reprocessor. If the reprocessing of the entire device is not possible, modular design options should be investigated in which different components have different planned lifetimes.

Remanufacturing is the best alternative to reprocessing, but the financial viability of a process like this depends on infrastructure, the value of product parts and the required disassembly and repair steps before a device can be resold. In the MedTech industry, a remanufacturer assumes responsibility for the quality and safety of the remanufactured device. This means that testing and the creation of technical documentation must be taken into account in the cost of the process as well. It is unlikely that remanufacturing is viable for the endocutter since it is highly complex and requires a lot of work to remanufacture while none of its individual components is very valuable.

The recycling of materials within an endocutter is an option but still requires the device to be decontaminated after use. This CRF does not help retain much product integrity, and with the extra work of device decontamination and disassembly, it is unclear if a recycling scheme could be financially viable. Waste handling company Greencycl is currently conducting a pilot for the recycling of endocutters in the Netherlands, the results should provide more clarity on the feasibility of large-scale recycling.

The CRF of biomaterials is the least interesting. It is relatively straightforward to include bio-based plastics in the design of the endocutters since there are plenty of examples where this has been approved in medical devices. However, a design choice like this has minimal impact on the entire footprint of the device.

In conclusion, if redesigning the endocutter for reprocessing is a possibility, this should be the goal. The best alternative to reprocessing is remanufacturing, the other two CRFs are less attractive. The two main design directions that resulted from the four design sprints are "design for internal reprocessing", and "design for an external reprocessing or remanufacturing service".

These directions are in line with the best strategies found in the literature. Kane et al. and Guzzo et al. [11], [40] advise optimising highly valuable and critical devices for hygienic recovery, and where necessary designing a fixed number of cycles or a hybrid configuration. In terms of business models, they advise either supporting internal reprocessing or offering an external reprocessing service.

A possible sustainable transition

A possible sustainable transition is not set in stone. It requires a personal view of the current state of affairs and developments in the system to formulate a vision for the future. I think a sustainable future for the MedTech industry involves a lot more circular design, so an implementation of (a combination of) the previously mentioned circular recovery flows. On top of that, I think the system should move to a higher level of collaboration. There should be trust between different actors like OEMs, governments and EoL organisations, but at the same time, there should be trust in the safety and availability of medical devices.

"I want to reshape the MedTech industry into a more circular system based on trust and collaboration."

An incremental but radical step in the right direction

MedFlo is a service concept designed through backcasting from my vision for the MedTech industry. It offers healthcare facilities access to a complete, high-quality, safe and clean inventory of medical devices and helps them tackle the increased complexity of (semi-)reusable devices and reprocessing logistics and infrastructure.

MedFlo is an OEM-certified reprocessor, which allows for a high level of trust between all parties involved. The close collaboration between MedFlo and OEMs also provides the service with access to necessary spare parts for improved repair and maintenance. The service works with a product passport system which tracks all individual device modules, their planned lifetimes, their performed reprocessing cycles and required consequent actions. This helps in retaining as much value as possible and in minimising the waste from medical devices.

Implications

The value of the project

This project shows what a sustainable future in the MedTech industry could look like. It helped provide insight into the different possibilities for implementation of the circular economy on highly critical and valuable devices like the endocutter. On top of that, the project shows how these possible circular product redesigns could be implemented in practice through an access model, and how a context can be created where services models like this can exist.

The value of MedFlo

MedFlo can help decrease the environmental and waste footprint of healthcare. It provides the possibility to reuse (parts of) medical devices for which incineration is currently the only EoL option. The complexity that MedFlo can handle as well as their partnership with OEMs provides possibilities for reprocessing, maintenance and repair that are currently not available for individual hospitals.

On top of that, the possible reuse of devices can contribute to more resilient supply chains as fewer raw materials are needed. When we shift to modularity and reuse, for example a computer chip shortage like the one caused by Covid-19 would be less damaging to the industry.

MedFlo could also stimulate sustainable innovation. As soon as the company grows and starts managing the device inventory of enough hospitals, they provide a generous market for more circular product designs. OEMs will start to compete for contracts, and devices will be selected based on their planned lifecycle and modular design.

Value for hospitals

For a hospital, the implementation of more modular medical devices can lead to a lot of complications in sterilisation department and operating room logistics. MedFlo Offers to manage many of these complications instead and supports them in a transition away from SUDs. On top of that, MedFlo is a service in close collaboration with medical device OEMs. Their activities are OEM-certified, so hospitals can trust the quality of the devices they receive.

Outsourcing most of the management of device inventory, reprocessing, maintenance and repair, also allows hospitals to focus more on their core business. This could especially be attractive for smaller healthcare facilities, which may not have the capability to deal with the increased complexity by themselves. On top of that, hospitals do not need to invest in a large device inventory or modern sterilisation department, they can cut down on inventory space, and rush deliveries by MedFlo are faster than a device can be reprocessed internally.

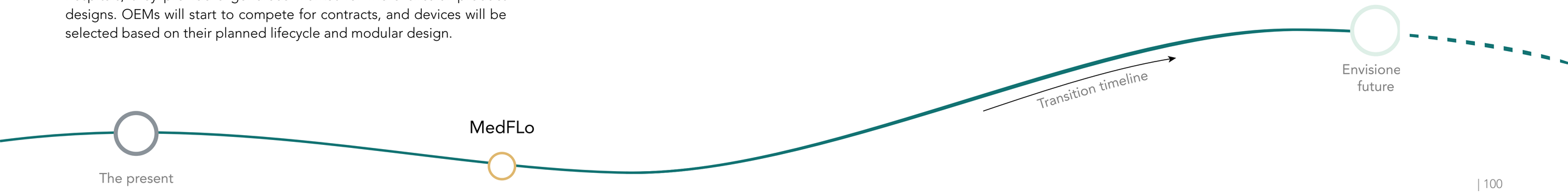
Value for OEMs

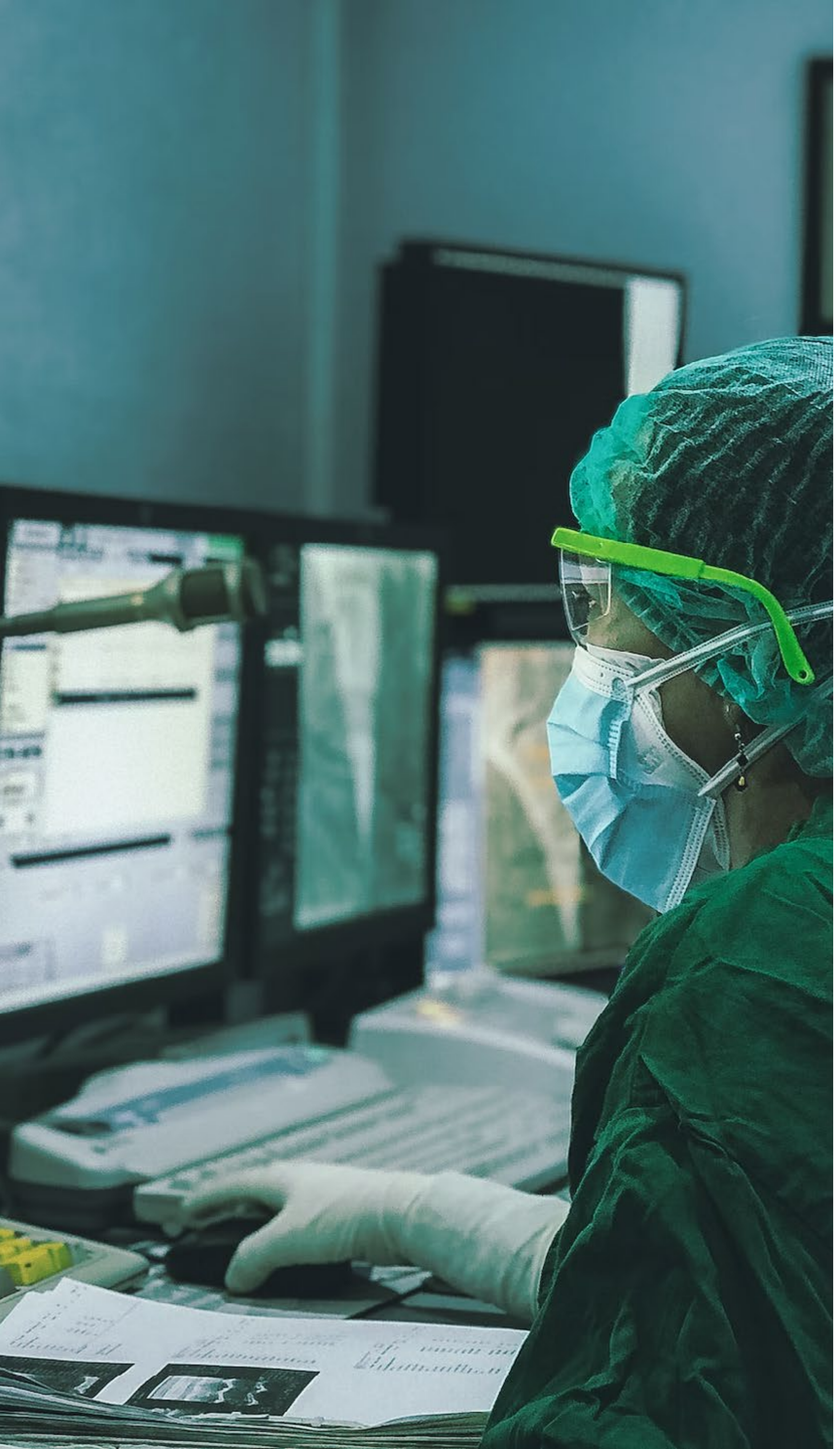
Depending on the specific regulatory changes implemented in the future which could impact the EoL of medical devices, OEMs could be forced to take responsibility for the entire life of their products. They will probably have no choice but to move away from SUDs, and MedFlo can help create a bigger market for their circular initiatives.

Also, unlike existing medical remanufacturing companies, MedFlo is a partner instead of a competitor. A contract with MedFlo means that an OEM can continuously sell new modules and spare parts to the service on top of the initial sales of (semi-)reusable devices, for the supply of many hospitals at once.

Value in a sustainable transition

A concept design can support a transition if it challenges existing norms within the regime and provides possibilities for further, perhaps more radical changes. I think that MedFlo can do both. MedFlo challenges the idea that complex and critical devices cannot be reprocessed at all, by showing how modular designs could be implemented in hospital logistics. It also challenges the high level of competition in the MedTech industry and shows how OEMs can be partners of an EoL service instead of rivals. Further possible developments for MedFlo could include international expansion, which is currently not possible because of tight infectious transportation regulations. Another possibility is the inclusion of the CRF of remanufacturing in the service for modules at the end of their planned lifetime. This would help to preserve an even higher level of product integrity.





Limitations

Project

The main limitation of this project is its scope. This is a graduation project spanning 20 weeks, with the aim to first understand and then solve a massive systemic problem. Societal transitions can take generations and require efforts from tons of different actors in different sectors. One master's thesis is like a drop in the ocean, it can only contribute so much. The transition management method helps, but is a deeply collaborative process intended to be followed by a large transition team. I used this approach as a guide, but it is not the most applicable to short, individual projects like this one. Still, it provided a great project framework, even if the project was too small to contribute to a sustainable transition.

Also, one-day design sprints can only give you so much insight into the complete picture of a circular recovery flow. The results from these sprints are inconclusive, and cannot be used to exclude a CRF, or definitively pick one over the others. This would require more insight into the possibilities for endocutter redesigns, as well as the execution of detailed LCAs, to compare different solutions.

It is not possible to conclusively answer the research questions within the available timeframe, but I have met the main goal of this project; to explore circular possibilities and define a sustainable future to work towards. This design exploration can be detailed further and iterated upon in future projects, and hopefully inspires others to work towards a sustainable MedTech industry.

Concept Design

MedFlo is at this point very conceptual and needs a lot more research and detailing before its real impact can be determined. I am no expert in the design of a business case, dealing with regulations, or planning out logistics. MedFlo needs input from professionals in these fields to determine its feasibility. On top of that, an LCA needs to be conducted to determine if MedFlo actually lowers the environmental and waste footprints, as well as the costs, of medical devices compared to those with a linear model.

There are also a lot of contextual factors that need to be taken into account. MedFlo's success depends on alterations in regulation, OEM business models and value chains, product designs and hospital organisation. It also needs to reach a certain scale to be viable. You need enough hospitals to collaborate to be able to afford the necessary facilities and device stock, and enough partnering OEMs to provide a wide enough range of medical devices. The setup of MedFlo will require a large effort from a variety of stakeholders.

Recommendations

Implementation of findings

To make MedFlo realistic, the barriers to its implementation explained in part 5 chapter 4 need to be overcome.

Policymakers

Policymakers need to incentivise the circular design of medical devices or the collaboration between OEMs and EoL services like MedFlo. They need to look into extended producer responsibility for medical devices, fees for the marketisation of single-use devices, and other ways to financially level the playing field between SUDs and (semi-)reusables. It needs to become more expensive to produce, sell, use and dispose of single-use devices. On the other side, the approval of reusable devices could become more streamlined or subsidised. The right regulations could become an important driver for sustainable design initiatives.

Medtech

The MedTech industry should aim to become more collaborative and collectively work towards a sustainable future. OEMs should aim to join forces with each other and with EoL organisations, instead of competing with them. This could streamline circular initiatives and allow products to be designed with their end-of-life in mind.

If OEMs want their devices to be a part of MedFlo's service offer to hospitals, they need to look into the possibility of sharing certain product details and spare parts with the service. This allows for higher level and more efficient repair and maintenance of devices and helps preserve value. They also need to adjust their business models. They could move to sell product modules instead of complete products, and prices need to be adjusted to longer lifetimes.

They also need to invest in circular redesigns of single-use devices. Devices should be designed for reprocessing if possible, and otherwise, they should be separated into modules with different planned but individually maximised lifetimes. These modules need to be easy to connect and disconnect in order to streamline logistics around reprocessing. Batteries of powered devices should be rechargeable and preferably standardised.

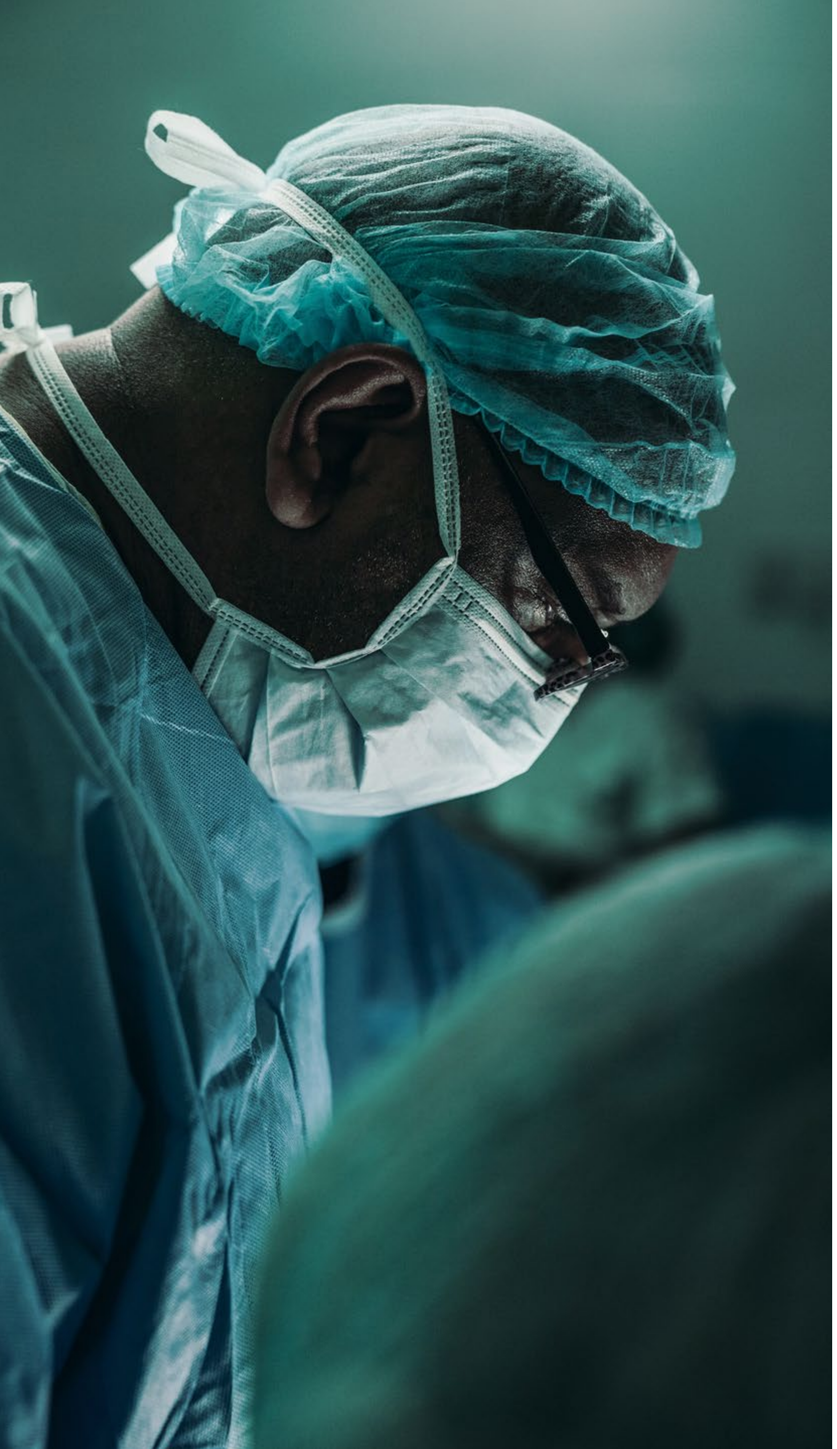
Healthcare facilities

Hospitals need to re-evaluate their required device inventory. Do they need the same number and variety of devices when collaborating with MedFlo as they would when managing their own sterilisation department? They also need to look at their side of the logistics, for example, what kind of route should contaminated devices follow inside the hospital? Is there a designated contaminated elevator down, as there would be in case of an internal sterilisation department? Lastly, they will not have access to the same variety of devices they would have when managing their own inventory. They will have to implement standardised surgical nets for different procedures if they have not done so already.

Summary of necessary actions

Actor	Action
Policymakers	Incentivise circular design and place (financial) restrictions on SUDs
OEMs	Collaborate with each other and EoL organisations – become open to sharing certain product details
	Adjust business models and value chains to module contracts instead of SUD sales
	Redesign SUDs for circularity - if not reprocessing, then modularity
Healthcare facilities	Re-evaluate inventory management and logistics for the implementation of an access model

figure 89. *A summary of the needed actions for key stakeholders*



Suggestions for further research

Product design

The redesign of the endocutter for compatibility with a service like MedFlo will require a lot of work. There needs to be investigated which components can be grouped together in a module, what the ideal planned lifetime for each module is, and how all the modules will be connected. At the same time, the modules fit for sterilisation should be designed to withstand the chosen sterilisation method, without hindering the useability of the device as a whole in terms of weight, size and controls.

Concept design

The concept of MedFlo needs a lot of detailing. In terms of logistics, there needs to be an investigation into which rules for infectious transport apply here, what route trucks follow to hospitals, and if deliveries for different hospitals can be combined in a single truck. I would also advise reaching out to circularise, the company specialising in blockchain product passports for a circular economy. They are growing quickly at the time of writing this thesis and did not have the capacity for external research interviews, but they could have great insight into how product modules can be tracked throughout their lifetimes.

One key unknown in the current version of the concept is the business model. There needs to be a thorough investigation into the viability of the concept, the scale necessary to make it realistic, the necessary investments, and MedFlo's cost structures and revenue streams. Does a contract with MedFlo provide enough incentive for OEMs to design their products for as many cycles as possible? Can MedFlo affort to select products according to their planned life or do they need to take other factors into account as well?

Finally, there needs to be an evaluation of which products could be included in this service, as well as which sterilisation methods should be available in MedFlo's facilities.

Policy

In terms of policy, there needs to be an investigation into the best ways to incentivise a more circular design of medical devices. What needs to change in the approval process of medical devices to make SUDs less attractive compared to reusables? Would collective or individual EPR be more suitable for the MedTech industry? And which (combination of) EPR instruments could help in a sustainable transition?

Also, MedFlo's repair and maintenance could be more thorough compared to existing activities implemented in internal reprocessing systems. When does repair become so drastic that it starts to enter the field of remanufacturing? Because different regulations apply to these two CRFs, there needs to be investigated where we draw the line, and how this line influences MedFlo's repair and maintenance capabilities.

Finally, since the products will be subdivided into different modules, would it be possible to classify each module separately according to the medical device regulations? If each module were to have different requirements for disinfection and sterilisation according to their respective level of patient contact, this could reduce the energy and material input in the system even further. Do we need to treat an entire device as highly critical when only a small piece enters the body?

Trust

The one advice from the literature that was not covered in the final concept, was the suggestion by Kane et al. [11] to design for trust in reusables. An investigation on the current state of trust in reusables would be very valuable. This kind of research should look into what makes people feel a sense of distrust in reusables, which part of the reprocessing process they trust the least, if it impacts the type of medical devices they choose, and how trust in reusables can be improved.

Conclusion

This thesis explored how the circular economy could be implemented in complex, critical, costly and currently single-use surgical devices like the endocutter. The best circular recovery flow for these devices appears to be the CRF of reprocessing, but modular solutions should be implemented where the reprocessing of the entire device is not possible. Conceptual service design “MedFlo” helps healthcare facilities overcome barriers in the implementation of modular devices into their workflow and logistics, by providing access to a safe and complete inventory of devices.

The project followed a transition management approach. First, the socio-technical system, the barriers to circular design and possible circular recovery flows were explored through a literature review and multiple design sprints. Next, a vision was created for a sustainable future for the MedTech industry, and finally, through backcasting from this vision, a conceptual service was designed. This design is a big step towards a sustainable future, but still actionable and within reach.

MedFlo can help decrease the environmental and waste footprint of medical devices, create more resilient supply chains and stimulate circular design initiatives. However, it will require effort from multiple different key actors to shape the context in favour of such a design. Policy needs to incentivise circular initiatives and discourage the production, sales and use of SUDs, OEMs need to alter their business models and invest in circular product designs, and hospitals need to adjust their logistics to the implementation of an access model. Hopefully, MedFlo can serve as an example of the implementation of the circular economy on highly valuable and critical medical devices, and be an inspiration for future projects.

Personal reflection

As I mentioned in the preface of this report, the constraints and complications of circular initiatives that exist in the healthcare sector intrigue me and are a source of great design challenges. In this regard, this project has really met my expectations. It is easy to get lost in all the rules, constraints and reasons for why a circular solution is impossible, not feasible, unsafe or too expensive, but whenever I found a small opportunity through all the barriers, it was extra rewarding and really pushed me to investigate further.

This project started as an analysis and redesign of a single product, but it grew out to be a system analysis and redesign instead. I've noticed that a systemic approach really suits me, way more than detailed product design, so I am happy with this development and the results. This approach also allowed me to implement insights and experiences I gained on my Erasmus+ exchange to Copenhagen, and helped me to combine some very different elements of my education.

I sometimes struggled with the balance between radicality and feasibility when making design choices. I could be a bit hesitant to try new things, especially when someone had already explained all the possible negative implications this new thing might have. Following what is known might make a design realistic, but at the same time it leads to a reduction of its potential positive impact. This project taught me to step outside of my comfort zone, and sometimes make choices that someone else might not agree with.

I also noticed that I could easily get lost in research. I really enjoy the process of finding and reading the right papers, talking to experts and interpreting new information, but it also distracts from the design challenge at hand. I have learned that there is such a thing as too much research, and this project has taught me when it is time to start making choices and actually start designing. The same can be said about my style of writing. I prefer to explain everything I do and include every single consideration in a design process. Unfortunately, this has resulted in a very lengthy graduation report. In the future I want to learn to get more to the point, and be careful to be aware of the priorities in my story.

Overall I am proud of the work I have done and the final concept I have presented. I think I have grown as a researcher and a designer over the past months, and I am looking forward to my next big challenge.

Dorien van Dolderen
student number: 4541294
e-4

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