DESIGNING CIRCULAR STRATEGIES FOR THE NEXT-GENERATION OF INSUFFLATION

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0.1 Preface

This thesis combines my interest in sustainability and healthcare, navigating the complexities of sustainable healthcare strategies. The challenge of balancing sustainability with prominent values such as patient safety, cost-efficiency and workload inspired me to explore strategic design thinking to help Spatium and potentially inspire similar companies and projects.

My personal motivations and learning goals are driven by my desire to contribute positively to the field of sustainable healthcare, designing solutions that serve a purpose beyond just monetary gain.

Enjoy reading!

Jelle Schilperoord

Master Thesis
Designing circular strategies for the next-generation of insufflation.

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0.2 Acknowledgements

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I'd also like to thank all hospital personnel and medical researchers who took time out of their enormously busy schedules to share their experiences, insights and ideas with me during the interviews. And my fellow design students who made time to sit and brainstorm with me over countless cups of coffee.

Finally, I'd like to acknowledge and thank my friends and family, who always believed in me and kept me motivated through my academic journey. I hope I have made you proud.

This thesis would not have been possible without you!!!

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0.3 Executive summary

The healthcare sector, while dedicated to promoting human well-being, is also a major contributor to declining environmental conditions, paradoxically adversely affecting health through resource-intensive and waste-generating practices. Laparoscopic surgeries using single-use insufflation devices, or disposables, exemplify the tension between healthcare delivery and sustainability. This graduation project addresses these challenges by exploring and proposing circular strategies to mitigate the environmental impacts of disposables inside a insufflation system through strategic design.

The research follows the Double Diamond Design Framework, beginning with an in-depth context analysis of the environmental impacts of an average laparoscopic patient journey and an extensive literature review on circular economy principles. Empirical studies, incorporating semi-structured interviews with relevant stakeholders, provide insight from the hospital perspective. Intermediate findings are combined into a design scope, guiding subsequent work. Environmental hotspots are identified by combining a self-executed fast-track life cycle analysis with insights from existing studies. Finally, conceptual circular interventions are developed to address identified hotspots and improve the environmental sustainability of the insufflation system.

This results in a strategic sustainability plan designed to help the client, a medical start-up, integrate sustainability and create a truly "future-proof" insufflation system. This plan includes company level strategies offering recommendations for actionable steps, commitments, and documentation, potentially leading to a competitive advantage in hospital procurement processes and product level circular strategies. These include redesigning devices to reduce material use, introducing reusable or hybrid devices, and exploring recycling opportunities. Applying strategic design thinking, the proposed strategies balance sustainability ambitions and both the complexity and practical constraints of healthcare systems and medical start-ups, offering a roadmap for implementing more circular and sustainable medical practices.

In conclusion, this project demonstrates the potential for applying circular strategies to complex healthcare settings. By integrating circular economy principles, it exemplifies how sustainable healthcare practices can reduce CO_2 emissions and waste from single-use devices. Ultimately, this thesis underscores the growing need for healthcare to adopt circularity, enabling it to continue improving human well-being while respecting the planet.

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Part C: Develop

Part D: Deliver

0.5 Methodology

Figure 1 showcases the structure of the MSc graduation project, including the different chapters of the report. The structure follows a Double Diamond Design Framework (Design council, n.d.), which splits the project into four parts: A) Discover phase, which explores the current environmental impact, existing sustainable frameworks and stakeholders. B) Define phase, which draws key insights from the discover phase and translates these into a design scope. C) Develop phase, quantifying environmental hotspots and designing viable, desirable and feasible sustainable strategies. D) Deliver phase, which combines all previous work and findings in a strategic sustainability plan for Spatium.

Medical device design controls

When developing medical devices, a company must adhere to several regulations and standards. One example is the Design Controls (FDA, n.d.). These Design Controls form a guide for the design process to ensure safety, effectiveness and quality of medical devices. The process can be easily compared to the Double Diamond Design Framework. It starts by mapping *User Needs* (Discover), then translates these into *Design Inputs* (Define). These inputs are used in the *Design Process* (Development), and ultimately, lead to delivering a *Medical Device* (Deliver). Each step requires constant *Review*. *Verification* and *Validation* cycles are added to make the process iterative.

A. Discover

1. Introduction
This chapter introduces the thesis, provides background information and lists the scope, research questions and method.

2. Context
This chapter explores the context of an average laparoscopic care pathway and looks at related environmental impacts.

3. Circular design
This chapter explores theories of the circular economy and how these can be applied to healthcare.

4. Stakeholders and values
This chapter explores key stakeholder and their values through desk research and empirical interviews.

B. Define

5. Design scope
This chapter translates findings from the discover phase into requirements and design guidelines.

C. Develop

6. Assessment current patient kit
This chapter quantifies the environmental impact of identified hotspots by combining existing research with the results of a self-executed fast-track LCA analysis.

7. Deep dives
This chapter explores applying identified circular strategies to the Spatium system, mitigating the impact of identified environmental hotspots and addressing identified opportunities for sustainability.

D. Deliver

8. Sustainability report
This chapter discusses the sustainability report deliverable, which accumulates all work into an actionable strategic overview for the future of Spatium.

9. Conclusions
This chapter concludes the thesis and discusses and reflects on the reached results.

Figure 1: Graduation project methodology

Abbreviations

ABS	Acrylonitrile Butadiene Styrene
CO_2	Carbon Dioxide
CO_2-eq	Carbon Dioxide equivalent
CSA	Centrale Sterilisatie Afdeling
DEHP	di(2- ethylhexyl) phthalate
EoL	End-of-Life
EPD	Environmental Product Declaration
ESG	Environmental, Social and corporate Governance
EtO	Ethylene Oxide
FDA	Food and Drug Administration
GHG	Greenhouse Gas(es)
GWP	Global Warming Potential
HDPE	High-Density Poly Ethylene
IFU	Instructions for Use
KPIs	Key Performance Indicators
LC	Laparoscopic Cholecystectomy
LCA	Life Cycle Assessment
LCI	Life Cycle Inventory
LCIA	Life Cycle Impact Assessment
MDR	Medical Device Regulation
ORs	Operating Rooms
PC	Polycarbonate
PET	Polyethylene Terephthalate
PETG	Polyethylene Terephthalate Glycol
PP	Polypropylene
PVC	Polyvinyl Chloride
SUDs	Single-Use Devices
UNIP	Infection Prevention Department
UNSDGs	United Nations Sustainable Development Goals
VHP	Vaporisid Hydrogen Peroxide

Glossary

Circular economy

A system where material never become waste and nature is regenerated. Products and materials are kept in circulations through applying the R strategies (MacArthur, E., 2010).

End of Life

The life cycle stage where products are discarded or disposed (Schulte et al., 2021).

Environmental hotspots

Hotspots are the locations within a supply chain or part of a product with the highest environmental impact (*Mérieux NutriSciences | Blonk | Environmental Footprinting & LCA*, n.d.).

Insufflation

The act of blowing air, a gas or powder into a body cavity to "inflate" ("Insufflation," n.d.).

Laparoscopy

A minimally invasive procedure that uses a laparoscope inserted through a small cut in the abdominal wall.
A laparoscope is a thin tube-like instrument (*Definition of Laparoscopy - NCI Dictionary of Cancer Terms*, n.d.).

Life cycle assessment

Compilation and evaluation of the inputs, outputs and the potential environmental impacts of a product system throughout its life cycle (ISO 14040:2006(En), n.d.).

Linear economy

Also referred to as the take-make-waste economy, a system where resources are extracted to make product that eventually end up as waste and are discarded (MacArthur, E., 2010).

Patient kit

Disposable part of the Spatium Insufflation System consisting of a cassette, insufflation tubing and trocar(s) (*Spatium Medical*, 2024)

Sterilisation

A cleaning method commonly applied to medical devices before use which destroys all microorganisms (Rutala & Weber, 2019) .

Sustainable Procurement

The pursuit of sustainable development objectives through the purchasing and supply process (“Call for Papers Special Issue: ”Sustainable Procurement”,"2010).

Trocar

A surgical instrument consisting of a sharp tipped obturator and a cannula placed inside an opening in the body ("Trocar," n.d.).

CHAPTER 01

Introduction

This chapter introduces the topic of the graduation project and provides background information on its context, specifically the medical application. The scope of the thesis project and final deliverables are stated. Finally, the research questions and topics are listed.

In this chapter:

1.1 Background

1.1.1 Laparoscopy and insufflation

Laparoscopy is a minimally invasive technique allowing surgeons to access a patient's abdomen without the need for large incisions. The operation is performed with long instruments that are inserted through trocars. Trocars provide access points for laparoscopic instruments guided by a camera (see Figure 2) and are inserted in small incisions (usually 0.5-1.5 cm) made by surgeons. During the procedure, a patient's abdomen is insufflated with carbon dioxide gas (CO_2), which elevates the abdominal wall above the patient's internal organs. This process is called insufflation and is done in order to create a working and viewing area for surgeons. CO_2 is used because it is non-flammable, colourless, dissolves in blood and is safe for patients.

Depending on the complexity of the operation, the surgery can last anywhere from 30 minutes to several hours. Standard laparoscopic procedures include gallbladder removal (cholecystectomy), appendix removal (appendectomy) and removal of all or part of the colon (colectomy) or kidney (nephrectomy). Surgical sub-specialities that have adopted laparoscopy in recent times are gastrointestinal surgery, gynaecological surgery and urology.

Minimally invasive surgeries (e.g. laparoscopy) offer several advantages when compared to open surgeries (e.g. exploratory laparotomy). These are: reduced pain due to smaller incisions, reduced haemorrhaging, and less scarring and operative trauma, which all combined should result in a shorter recovery time and hospital stay (Nguyen et al., 2011; Agha & Muir, 2003).

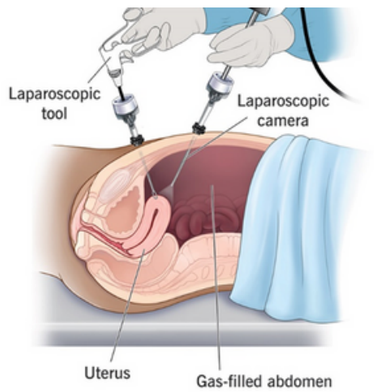


Figure 2: Abdominal laparoscopic surgery (Professional, 2024)

1.1.2 Spatium Medical

The client of this graduation project is Spatium Medical, a start-up spin-off from the Erasmus MC in Rotterdam. The company is developing a next-generation insufflator for laparoscopic surgery (see Figure 3), based on years of research and development by the inventors of the technology Frank Sterke, Willem van Weteringen, John Vlot and Raffaele Dellaca.

By implementing their innovative turbine technology, the Spatium insufflator makes use of reciprocal insufflation, enabling stabilised pressure and oscillation technology that allows selection for personalised pressure (*Spatium Medical*, 2024). These innovations are believed to improve patient recovery and surgical outcomes in laparoscopic surgeries.

Spatium Medical formulates its mission as follows:

"Our mission is to make insufflation for minimally invasive surgery more accessible and safer for all patients regardless of their indication, age or physical condition, while at the same time enhancing operating room (OR) workflows."

Accompanying the mission, they have the following vision:

"Our vision is that 10 years from now, our insufflation technologies will be the 1st choice for clinicians in ORs worldwide."

Figure 3: Prototype render of the next-generation insufflator and accompanying patient kit (*Spatium Medical*, 2024)

1.1.3 The next-generation insufflator

The next-generation insufflator that Spatium is currently developing uses turbine technology, allowing for three innovative advancements compared to regular insufflation technologies which are: Endoscopic Oscillometry, Reciprocal Insufflation and Pressure Stabilization. Each of these advancements creates benefits for both patients and surgeons.

Endoscopic Oscillometry

The next-generation insufflator uses Endoscopic Oscillometry to find the trade-off between insufflation pressure and workspace volume, which leads to optimal surgical conditions (Sterke et al., 2022). Endoscopic Oscillometry is a novel non-invasive method that provides real-time feedback which allows surgeons to estimate workspace compliance during laparoscopic surgeries. It can help surgeons tailor and optimise insufflation pressure for individual patients.

Reciprocal Insufflation

Respiratory conditions of a patient are of great importance during laparoscopic surgeries. The next-generation insufflator allows for real-time control of intra-abdominal pressures, adapting the CO_2 volume to match the tidal volumes generated by mechanical ventilation in surgery.

Reciprocal Insufflation between the Spatium next-generations insufflator and mechanical ventilation improves the patient's respiratory system compliance during laparoscopy, benefitting the patient while also reducing pressures needed for mechanical ventilation (Sterke et al., 2022).

Pressure Stabilisation

Finally, the next-generation insufflator can respond quickly to pressure deviations, accommodating for couching and mechanical ventilation during surgery. This allows for a more stabilised pressure during operations, benefiting surgeons. In addition to this Pressure Stabilisation, the technology also allows for continuous smoke evacuation without the need for additional equipment (Sterke et al., 2022).

Spatium refers to its product as the “Spatium Insufflation System”. This system comprises the device and the accompanying patient kit. Figure 4 provides a schematic representation of the Insufflation System.

The insufflator device is designed to have a ten-year lifespan, whereas the patient kit is designed for a single operation and contains various single-use devices (SUDs). Using the data provided by Spatium, it is estimated that in the most intense use scenario, over the ten-year lifespan of a single insufflation device, 16000 patient kits can be used, not accounting for reserve patent kits present as a backup at operations (Spatium Medical, personal communication, 2024).

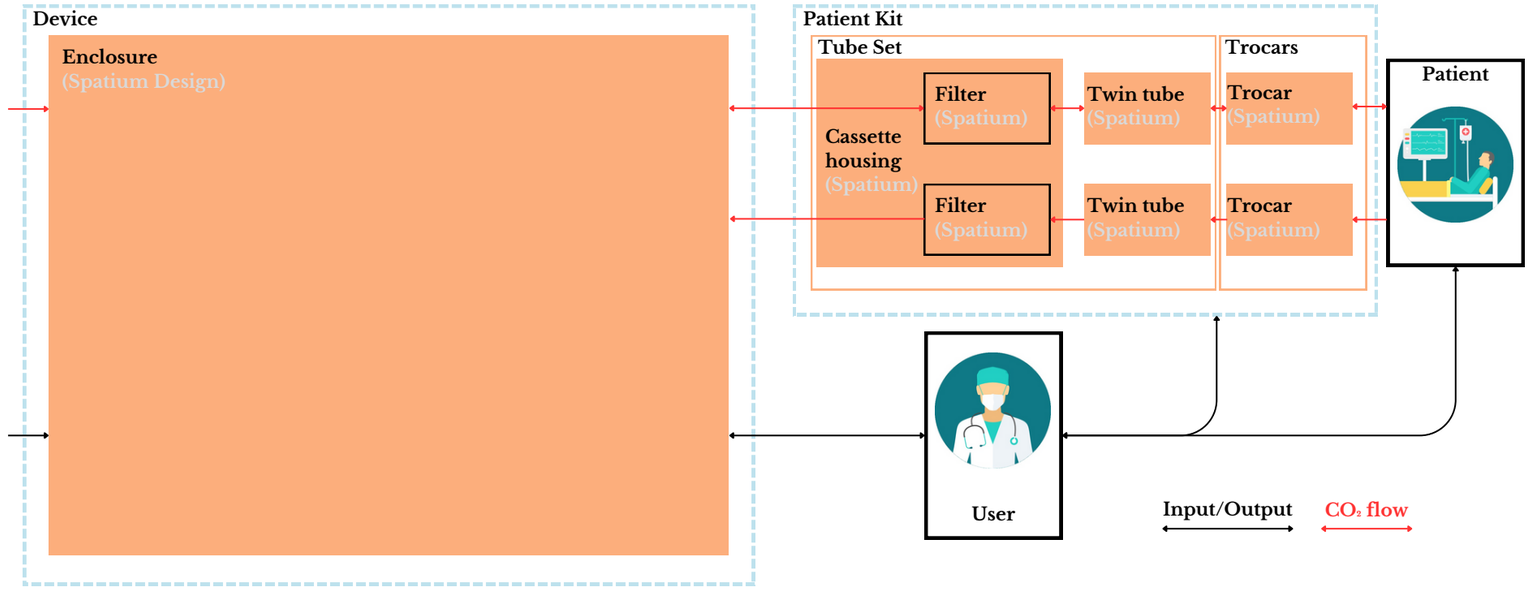


Figure 4: Spatium Insufflation System (Spatium Medical, personal communication, 2024)

1.2 Scope

This graduation project accumulates in a strategic sustainability plan for Spatium Medical. This plan outlines information and steps on how existing environmental hotspots can be addressed and circular interventions can be developed. Implementing the designed interventions will decrease the environmental impact and amount of waste generated by the Spatium Insufflation System.

This graduation project's main focus is to help Spatium assess its current design on sustainability and design actionable steps to plan and implement desirable, viable and feasible circular strategies.

As explored in the previous section, the current system design assumes a patient kit made up solely of SUDs. Moving away from this linear approach is challenging as issues such as safety related to sterility, regulation, hospital policies, logistics and business models dependent on continued sales of SUDs cannot easily adapt to more sustainable systems.

Nevertheless, Spatium recognises the increasing need and importance of sustainability in healthcare. Thus, the focus of this thesis project will cover the design of a strategic sustainable approach to be implemented by Spatium.

To achieve this, the following final deliverables will be developed:

- **An analysis of how the concepts and strategies of the circular economy can be applied to the Spatium products with a focus on disposables.**
- **An analysis of the current Spatium patient kit, highlighting and quantifying the environmental hotspots present within the system.**
- **An environmental impact comparison, fast-track LCA, comparing the impacts of the current system design with those of proposed interventions.**
- **A strategic sustainability plan which summarises the graduating project work and presents actionable steps Spatium can follow to lower their environmental impacts.**

Design Goal:

"Creating a truly future-proof insufflation system which is not only better for patients and surgeons but also respects the planet."

Research Questions

To achieve the projects design goal and reach the final deliverables outlined in the scope the following questions (Table 1) have been researched:

Overarching questions	Sub questions	Chapter
What environmental impacts relate to the context of the Spatium system and can be found along the care pathway of a laparoscopic patient?	What is the impact of an average laparoscopic surgery?	**2.2**
	What is the contribution of CO_2 used for insufflation within the scope of impacts caused directly by insufflation?	**2.3**
	What is the impact of the disposables required for insufflation?	**2.4**
	How much impact can be saved by decreasing the postoperative hospital stay?	**2.5**
	How does the impact of the Spatium insufflation system compare to standard surgery setup for laparoscopy?	**2.6**
	What are potentially interesting environmental hotspots for Spatium?	**2**
What theoretic strategies/models exist and are desirable, viable and feasible for Spatium to improve the environmental impact of their insufflation system?	How do the concepts of the linear and circular economy relate to healthcare?	**3.1** **3.2**
	What are circular strategies, and how can they be applied in healthcare?	**3.3** **3.4**
	What are the relevant and feasible circular strategies for the Spatium patient kit?	**3.5**
Which stakeholders need to be engaged to implement sustainable and circular interventions?	Which stakeholders play a role of importance in the life cycle of the Spatium insufflation system?	**4.1**
	What are the key values of the identified stakeholders and how do these relate and conflict with each other?	**4.2**
	What barriers and insights do these stakeholders experience in practice?	**4.5**
How can proposed sustainable strategies be evaluated?	What are the must-meet requirements for devised strategies?	**5.1**
	How can proposed strategies be compared and assessed based on potential gains and required investments?	***5***
What is the quantifiable impact of environmental hotspots inside the Spatium insufflation system?	How big is the impact of the Spatium tube set in line with relevant impact categories?	**6.3**
	What life cycle stages can be identified as environmental hotspots for the Spatium tube set?	**6.4**
	What components and parts can be identified as environmental hotspots inside the Spatium tube set?	**6.4**

Table 1: Overarching and sub research questions and linked chapters

Overarching questions	Sub questions	Chapter
What are strategies Spatium can implement to mitigate the environmental hotspots?	What are circular strategies and interventions Spatium can develop in the short, medium and long-term to lower their environmental impacts?	**7**
How should Spatium address and implement sustainability in the coming years?	Who is the intended target audience for the sustainability report?	**8.1**
	How can all reached results be translated into a concise and actionable sustainability plan for Spatium?	**8.1**
	What should similar reports developed by Spatium aimed at different target audiences look like/include?	**8.2**

Discover

CHAPTER 02

Context

This chapter aims to get a rough indication of the overall environmental impact of the care pathway of a single laparoscopic surgery and determine the environmental hotspots. Existing studies and online sources are used to estimate the data for an average laparoscopic surgery. Additionally, Spatium provides data to estimate and compare the impact of laparoscopic surgery using the Spatium insufflation system.

In this chapter:

Key topics:

- What is the impact of an average laparoscopic surgery?
- What is the impact of the disposables required for insufflation?
- How much impact can be saved by decreasing the postoperative hospital stay?
- What is the contribution of CO_2 used for insufflation within the scope of impacts caused directly by insufflation?
- How does the impact of the Spatium insufflation system compare to standard surgery setup for laparoscopy?
- What are potentially interesting environmental hotspots for Spatium?

2.1 Scoping

Due to its benefits compared to traditional surgery, the use of laparoscopic techniques has grown worldwide. Around 15 million laparoscopic procedures are performed annually (Boberg et al., 2022). Of this 15 million, laparoscopic cholecystectomy (LC), commonly known as gallbladder removal, is one of the most performed types of surgery (Adler et al., 2004). Because of this, coupled with the large amount of available research on LC, LC has been selected to represent the average laparoscopic procedure for calculating and comparing environmental impacts.

To draw a complete picture of the overall environmental impact of the care pathway and allow for a comparison of current reality and the proposed Spatium system, it is critical to define and assess the various factors contributing to it. To do this, three scopes have been formulated to create a big-picture indication of the overall impacts and a more zoomed-in representation of the impacts directly linked to Spatium.

Scope 1

Is defined as the average environmental impact of an LC expressed in kilograms of CO_2. Recent work comparing various LC surgeries across different hospitals in the Netherlands is used to get an impact estimation. The study uses data on disposables, reusables, transport, energy, anaesthesia and linen.

Scope 2

Is defined as greenhouse gas (GHG), CO_2 emissions directly linked to insufflation during laparoscopic surgery. This refers to the CO_2 gas used for insufflation, which, during surgery, escapes into the atmosphere because of two reasons. Firstly, the main amount of used CO_2 escapes via leaks or decompression at the end of surgery. Secondly, a small amount of used CO_2 is absorbed by patients during surgery. This amount can be calculated (Wolf et al., 1995), but is so minimal that it is not considered within the scope and confines of this project (Power et al., 2012). Additionally, scope 2 covers GHG emissions related to single-use equipment unique to insufflation, specifically trocar(s), insufflation tubing and filter(s) or, in the case of Spatium, a cassette. For this initial rough estimate of the environmental impact, data is gathered on the number of kilograms of plastic used in the disposables. Impacts of both production and End-of-Life (EoL) treatment of these plastic disposables is calculated.

Scope 3

Is defined as GHG emissions caused along the care pathway of a patient post-operation. Because of the minimally invasive nature of the operation, most patients post LC end up in a lower-intensity inpatient setting (acute care unit). This scope assesses the average environmental impact of a patient's single postoperative “bed day” at the acute unit using existing literature data from a large US hospital.

2.2 Impact surgery

Understanding the total impact of an average LC surgery can be helpful to Spatium in two ways. Firstly, if the innovative insufflation technique provided by Spatium decreases the mean duration of the procedure, an indication of the potential saving of impact through this decrease can be found. Secondly, defining an average of the total impact of an LC surgery can help contextualise the impact of insufflation within the big picture.

A recent study comparing the impact of fifteen LCs performed across three different hospitals in the Netherlands concluded that the average impact of a single surgery is 56.5 kilograms of CO_2 (Comes et al., 2024). The study applied a process-based Life Cycle Assessment (LCA) comparing multiple contributing factors: disposables, reusables, transport of personnel and patients, energy use, anaesthesia and linen (Figure 5).

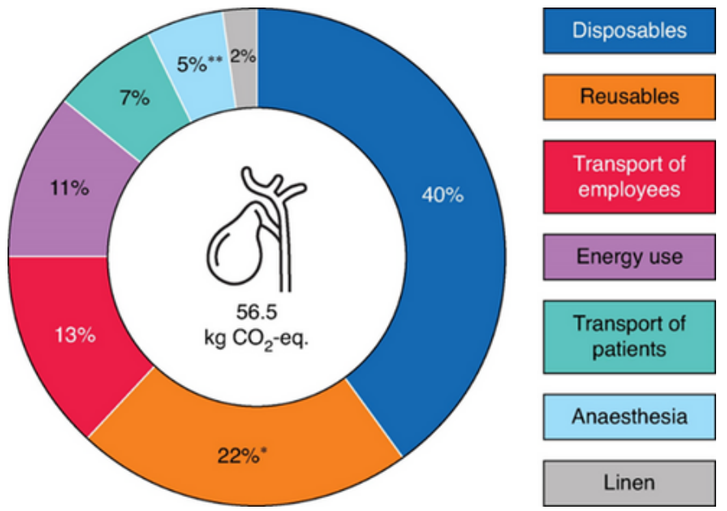


Figure 5: The average impact of an LC (Comes et al., 2024)

The reported average impact is based on measurements from fourteen of the mentioned fifteen surgeries. One of the surgeries turned out to be more complicated than expected and was left out of the assessment due to the large discrepancy in values compared to the others. The results show that disposables are the most significant contributor to the overall impact, accounting for 40% (22.7 kilograms of CO_2). Notably, reusables also contribute a significant portion to the overall impact, 22% (12.5 kilograms of CO_2), though it is reported that 81% of this portion is attributed to the sterilisation process. In total, 133 individual products were reported to have been used during procedures, of which 86% were disposable. Relevant to Spatium is that one of the identified environmental hotspots for disposables is trocars, accounting for up to 18% (4 kilograms of CO_2) of the overall disposable impact.

The average procedure duration of the fourteen surgeries used to calculate impacts was 75 minutes (Comes et al., 2024). This means that every minute of surgery emits roughly 0.75 kilograms of CO_2, since 56.5/75 = 0.753. While factors like transport of employees and patients (Figure 5) are not influenced by time and would, thus, remain the same assuming a shorter operating time, others like energy use, anaesthesia can be influenced by operating time. This means that a decrease in procedure minute(s) due to using Spatium's innovative insufflation, providing a more stable workspace for surgeons, is likely to decrease the overall impact of LC surgery as well.

2.3 CO_2 used for insufflation

This first part of Scope 2 looks at the amount of CO_2 used for insufflation in an average LC. The found data is translated from litres of CO_2 to kilograms of CO_2 emissions for comparison.

Insufflation for laparoscopic surgery uses medical-grade CO_2 gas. The amount of CO_2 used for insufflation during surgery can vary depending on the duration of the surgery and the CO_2 gas flow rate. Additionally, applied gas pressure can indirectly affect CO_2 consumption since a higher pressure requires the system to maintain flow for a more extended period of time to reach and sustain set pressure.

The following formula is used to calculate the amount of CO_2 used in litres:

$$\textit{Total } CO_2 \textit{ (L)} = \textit{Flow rate (L/min)} \times \textit{Operation Time (min)}$$

Using the Ideal Gas Law (Garrett, 2020), 1 mole of any gas equals 22.4 litres at standard (1 atmosphere) pressure. Furthermore, 1 mole of CO_2 is equivalent to 44 grams. This means that every litre of CO_2 used during surgery emits approximately 2 grams of CO_2 since 44/22.4 = 1.96 grams. By applying these calculations, we can find the kilograms of CO_2 emissions escaping into the atmosphere during an average laparoscopic surgery if we know the used flow rate and operation time.

Studies into CO_2 used during LC report different durations of operating time ranging from as short as 20 minutes to several hours (Akoh et al., 2011; Gilliam et al., 2007; Jacobs et al., 1999; Power et al., 2012; Yoshizawa, 2011). Regarding flow rate, most studies only report maximum flow limit as the flow rate consistency during surgery varies considerably. However, it can be assumed that the expected average flow rate during surgery would be somewhere between 1-2 L/min (Power et al., 2012).

A mean amount of 83 litre of CO_2 per average LC has been selected as it fits well within all reported ranges found in the literature (Jacobs et al., 1999; Power et al., 2012; Yoshizawa, 2011). Additionally, this number closely compares to the reported number of approximately 81 litres of CO_2 in the study comparing LCs in Dutch hospitals (Comes et al., 2024). Using this number, we can calculate that the average LC emits approximately 0.16 kilograms of CO_2 directly into the atmosphere. Because 1 mole equals 22.4 litre, then 83/22.4 = 3.7 mole, and 1 mole equals 44 grams of CO_2. Therefore, 3.7*0.044 = 0.163 kilograms CO_2. Additionally, we can find the average CO_2 use per hour of operating time since the reported amount of 83 litres is based on a mean procedure time of 87 minutes (Yoshizawa, 2011). Using this information, we can calculate that the average amount of CO_2 used for one hour of operating is 0.11 kilograms CO_2 since (((83/87)*60)/22.4)*0.044 = 0.112.

Comparing this data to a scenario using the Spatium system is currently impossible as no clinical data for the Spatium system exists yet. It is believed however, that applying Spatium's innovations will lead to an overall lower pressure average and a potential decrease in procedure time due to stabilised workspace. These factors would result in a lower total amount of CO_2 used for insufflation per surgery.

2.4 Insufflation disposables

The second part of scope 2 focuses on the production and EoL of disposables directly related to and used for insufflation during LC.

Looking at the impact caused by single-use equipment linked to LC, we are mainly interested in the amount of plastic in kilograms as this makes up the bulk of materials in current surgery setups and the proposed Spatium system. For the impact assessment, we consider both the initial emissions caused by the production of the disposables and emissions caused by EoL treatment, which, in this case, means incineration as this is the standard treatment for hazardous hospital waste.

Assuming a standard LC setup, common disposables related to insufflation are:

- A 3-meter insufflation tube, likely made from a plastic such as polyvinyl chloride (PVC), including a filter.
- One to two trocars based on operation complexity.
- In the case of the Spatium insufflation system, a cassette housing the filters.

The weight of these components can be calculated or found in existing literature studies. An existing tube was measured, resulting in an inner diameter (d_1) of 9 millimeters and an outer diameter (d_2) of 13 millimeters. We assume the market standard of 3 meters for the length (l) and the material PVC, as it is commonly used for insufflation tubing. Using this data, we can make the following calculation:

The volume of a hollow cylinder:

$$V = \pi \times l \times [(d_2/2)^2 - (d_1/2)^2]$$

Filling in the data mentioned above results in a volume of 207.36 cm^3. The density (ρ) of PVC is approximately 1.38 g/ cm^3, which means we can calculate the mass (m) of the tube:

$$m = V \times \rho$$

Filling in this formula results in a mass of approximately 286 grams. In a standard current setup, the filters and housing, as seen in Figure 6, and the connectors would be added to this weight. To account for this, after weighing samples of such items present at Spatium, a total weight of 316 grams is assumed for impact calculations and comparison. This only applies to the standard LC setup as the Spatium system has a separate component housing the filters, namely the cassette.

Looking at trocars, depending on the model used, the mass of a single average trocar can vary slightly. An average weight of 53 grams has been found in the literature and is assumed to be a good representation of reality as it is based on a large sample size (Boberg et al., 2022). Spatium plans to use minimally modified existing market-certified trocars. Thus, for comparison, the Spatium trocars are assumed to be equal in weight.

The number of trocars used during LC depends on the complexity of the operation. Four total trocars are commonly used in surgery (Adler et al., 2004; Boberg et al., 2022; Power et al., 2012; Rizan & Bhutta, 2021). However, in a standard situation, only one of these four trocars is connected to the insufflator and, thus, required for insufflation. This means that when looking at disposables directly related to insufflation, only a single trocar should be considered in the calculation. This leads to a total mass of 53 grams for the trocar.

The Spatium system uses a disposable cassette to house its filters and connect the tube(s) to the insufflation device. While the exact metrics of this cassette are not locked in yet, current prototypes are used to indicate the expected mass of the component, resulting in a weight of approximately 70 grams (Spatium, 2024).

Having calculated the amount of plastic material, we can get a rough estimation of the impact of both the production and waste process. The total weight of plastic of the tube and trocars for the standard LC setup adds up to 0.369 kilograms. The total weight of plastic of the Spatium patient kit adds up to 0.409 kilograms.

Figure 6: Example of an existing insufflation tube with filter and connectors (*ORIS Insufflation Tubing Set*, n.d.)

The impact of producing 1 kilogram of plastic depends on various factors, such as the type of plastic, the applied process and the energy mixture used. For this comparison, polypropylene (PP) has been selected to use in the impact assessment as it is a commonly found plastic in many medical disposables. Based on the literature found, the average impact for producing 1 kilogram of PP has been set at 1.8 kilograms of CO_2 (COMET, 2022). This means that the production of plastic disposables in the standard scenario emits approximately 0.66 kilograms of CO_2 since 0.369*1.8 = 0.664 kilograms CO_2. In comparison, the production of plastic disposables for the Spatium patient kit emits approximately 0.74 kilograms of CO_2 since 0.409*1.8 = 0.736 kilograms CO_2.

All disposables will be incinerated at the EoL as they are part of the hazardous hospital waste stream. While impacts here can again vary depending on the context, a number of 5.26 kilograms of CO_2 emissions per kilogram of incinerated plastic is reported in literature (Cho et al., 2024). Assuming this number, we can calculate that burning all disposables used during standard LC emits approximately 1.94 kilograms of CO_2, since 0.369*5.26 = 1.941 kilograms CO_2. In comparison, burning disposables of the Spatium patient kit emits approximately 2.15 kilograms of CO_2 since 0.409*5.26 = 2.151 kilograms CO_2.

2.5 Postoperative stay

The third scope focuses on the impact of the care pathway post-operation. Here, the primary interest is in the hospital stay of patients post-LC. Getting an indication of the amount of CO_2 emissions caused by this stay can be of value for Spatium since, due to their innovative insufflation technologies, patients' postoperative stay can potentially be decreased as surgery should become less demanding.

The environmental impact (CO_2 emissions) of the postoperative stay of a patient after undergoing LC is mainly dependent on two variables: the average length of postoperative hospital stay and the average impact in kilogram CO_2 per bed day in an acute care unit.

Looking at the literature reporting on the postoperative stay length of LC, we can see a solid downward trend. Early papers report postoperative stays between 0-18 days, averaging around two days (Grace et al., 1991; McMahon et al., 2000). While later works report average postoperative stays of around one and even sub-one days (Chong et al., 2016; Ivatury et al., 2011; Ko-Iam et al., 2017). Using this data and considering that in some cases, the required hospital stay is significantly longer due to surrounding factors such as emergency and surgery complications, an average postoperative stay of approximately 17 hours (0.7 days) is assumed (Ivatury et al., 2011).

A recent study into the environmental footprint of regular and intensive patient care in a large US hospital reports that an acute care unit's average "bed day" emits 45.5 kilograms of CO_2 (Prasad et al., 2021). Using this number and the previously determined average postoperative stay, we can calculate that the average care pathway impact of patients post-LC is 31.9 kilograms of CO_2 since 0.7*45.5 = 31.85 kilograms.

Similar to CO_2 usage, comparing this standard scenario to the Spatium system is speculative, since no clinical data exists yet. However, it is believed that through the personalised innovations Spatium brings to insufflation, the mean postoperative time spent at the hospital can decrease, since the overall procedure will likely be less demanding and potentially shorter. Using the data found in the literature, we can calculate that reducing postoperative stay by a single hour would decrease CO_2 emissions by approximately 1.9 kilograms since (1/24)*45.5 = 1.895 kilograms.

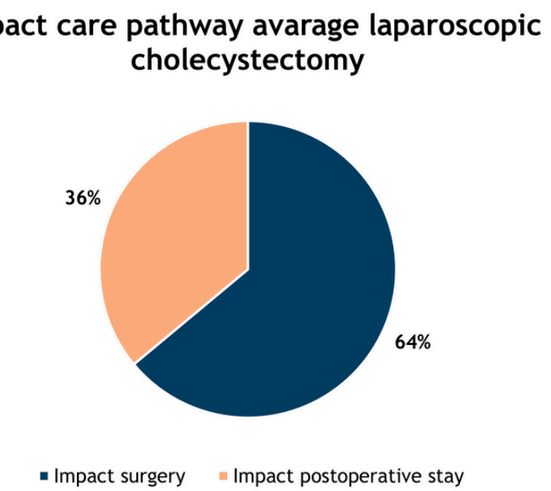


Figure 7: Analysis care pathway average LC

2.6 Impact comparison

Using all the gathered data, conclusions can be drawn on the overall impact of LC, the contribution of the different scopes to this impact and a comparison between the standard LC setup and the Spatium system.

Looking at the big-picture representation in Figure 7, we can see that the most impact can be credited to the surgery. However, the postoperative impact is still quite significant. In saying this, it should be noted that this aspect of the care pathway, postoperative stay, is more challenging for Spatium to influence directly as it depends on many more external factors.

In an earlier chapter, we looked at the various factors contributing to the total impact of LC. Here, disposables were identified as being the most significant contributor. While most of these disposables are unrelated to insufflation and thus out of scope, the previously mentioned tubing, cassette and trocar(s) are required to insufflate. Figure 8 showcases the impact of these disposables both for the standard LC setup, and the Spatium system, which uses a cassette to house the filters. Here, we can see that the total impact of the disposables for the Spatium system is slightly higher than the chosen standard market setup. This is mainly due to the cassette's considerable size and material requirement compared to the standard filters.

The Spatium scenario also shows that the impact of the insufflation tubing is more significant than that of the cassette and trocar(s). Thus, when trying to improve the impact of disposables, it could potentially be more interesting to focus on tubing specifically.

Next to disposables, the CO_2 used to insufflate the abdomen is another impact factor directly linked to insufflation. While the estimated average impact of this CO_2 amount is small in the big picture, looking within the scope of impacts directly linked to insufflation, the amount represents a noteworthy portion, as seen in Figure 9.

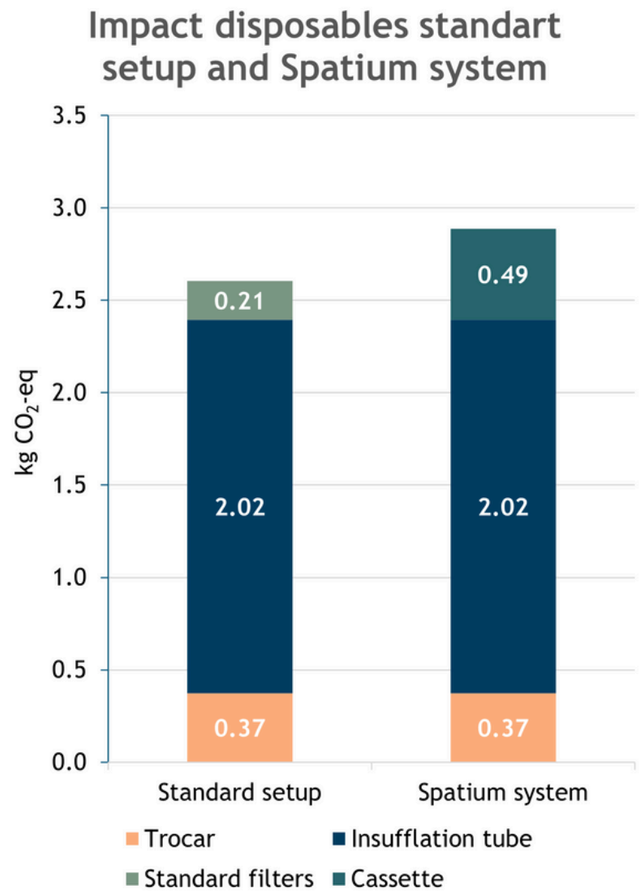


Figure 8: Comparison impact standard and Spatium disposables

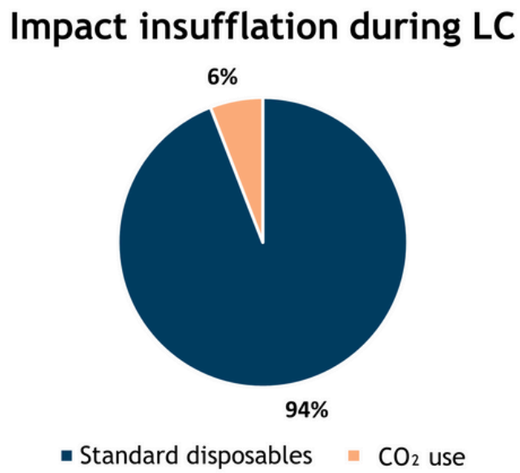


Figure 9: Direct impacts linked to insufflation during LC

While the impact of the Spatium disposables is higher than the standard LC setup, it was previously established that other impact factors, such as the amount of CO_2 used for insufflation, operating time and postoperative stay, are likely lower for the Spatium scenario due to the innovations present in Spatium's insufflator. Figure 10 visualises a speculative scenario accounting for these potential impact decreases. A decrease of 5% of the earlier mentioned impact factors was selected for the care pathway impacts of the Spatium system. The chosen value of 5% is not based on any research but purely an indication value selected to represent a difference between the two scenarios while remaining within potentially realistic boundaries.

Comparing the total impact amount of the two scenarios leads to a difference of approximately 4 kilograms of CO_2 in favour of the Spatium system. This means, assuming a 5% decrease in the stated factors, using the Spatium system, on average, saves 4 kilograms of CO_2 per patient. Using the use intensity numbers provided by Spatium, we can calculate that assuming this number, a single device can save up to 1600 kilograms of CO_2 annually (Spatium, 2024). Applying this number to estimated and projected sales numbers of the Spatium device, we can calculate this adds up to approximately 300 thousand kilograms of CO_2 saved annually by year 3 post-market introduction. This amount of CO_2 can be compared to driving an average gasoline-powered passenger vehicle around the world 30 times (*Greenhouse Gas Equivalencies Calculator | US EPA*, 2024).

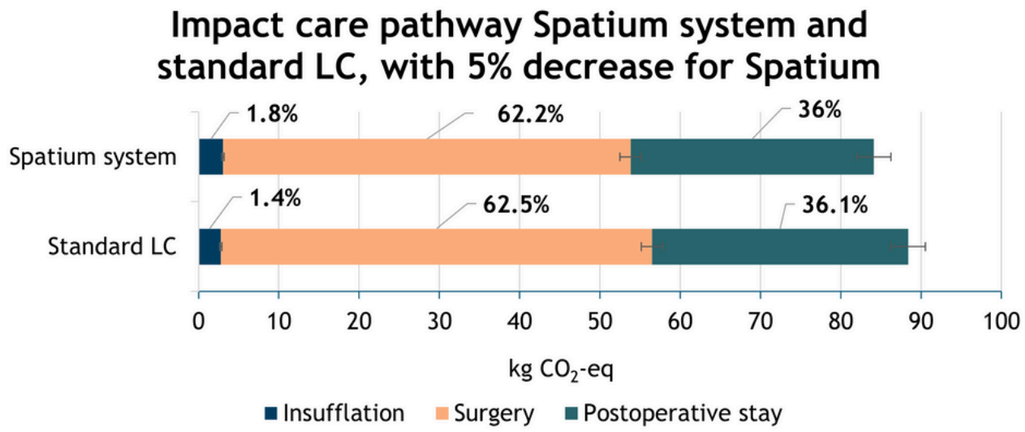


Figure 10: Total care pathway impacts for standard LC and Spatium system with a 5% decrease in CO_2 used, operating time and postoperative stay for Spatium

Key insights

What is the impact of an average laparoscopic surgery?
- The impact of an average LC equals 56.5 kilograms CO_2.

What is the impact of the disposables required for insufflation?
- Approximately 2.75 kilograms of CO_2 is emitted by producing and incinerating plastics used in disposables.

How much impact can be saved by decreasing the postoperative hospital stay?
- Assuming an average impact of 45.5 kilograms of CO_2 per bed day, approximately 1.9 kilograms of CO_2 per saved hour of postoperative stay.

What is the contribution of CO_2 used for insufflation within the scope of impacts caused directly by insufflation?
- Within the scope of the direct impact caused by insufflation, CO_2 gas used for insufflation is responsible for 6% of total emissions.

How does the impact of the Spatium insufflation system compare to standard surgery setup for laparoscopy?
- The impact of the Spatium system is approximately 0.28 kilograms of CO_2 higher than the standard setup due to more material used in disposables (cassette).

What are potentially interesting environmental hotspots for Spatium?
- Considering the scopes and factors on which Spatium can have the most influence. The disposables directly linked to insufflation pose an interesting environmental hotspot for Spatium since they contribute significantly to both the direct impact of insufflation scope, 94%, and the overall surgery scope, 40%.

CHAPTER 03

Circular design

This chapter explores the concept of the circular economy. Various frameworks, such as the Butterfly Diagram, 10R strategies and Value Hill, are discussed. As a conlusion of the theory assessment, relevant and feasible circular strategies are selected for Spatium and the project confines.

In this chapter:

Key topics:

- How do the concepts of the linear and circular economy relate to healthcare?
- What are circular strategies, and how can they be applied in healthcare?
- What are the relevant and feasible circular strategies for the Spatium patient kit?

3.1 The linear economy

As a consequence of the exponential growth of human population, post-war economic development and strong technological developments over the past century, we as humans have constructed a mass-consumption society (MacArthur, E., 2010). This society, also called the linear economy, follows a 'make-use-dispose' pathway, where recourses are extracted, used for production, and ultimately discarded as waste. While this approach has supported industrial growth and modernisation for decades, it has resulted in pressing challenges, especially in resource-intensive sectors such as healthcare. Over-extraction of finite resources, extensive waste generation, and increased GHG emissions are all consequences of the linear economy (MacArthur, E., 2010). In healthcare, these challenges are amplified by the growing demand for medical products and services, leading to increased production and disposal of single-use medical equipment. Additionally, there has been increased reporting on the adverse effects on human health due to declining environmental conditions and generated waste (Haines et al., 2000; Jameton & Pierce, 2001; Leaf, 1989; Solomon & Schettler, 2000). Meaning that the care sector intended to improve our health is also negatively impacting it.

Policy initiatives have stressed the need to tackle these challenges. On 12 December 2015, an international treaty was signed to combat rising earth temperatures by limiting global warming below two degrees Celsius (United Nations, 2015). To achieve this, the European Union introduced the European Climate Law (European Parliament & Council of the European Union, 2021), demanding that the union becomes climate-neutral by 2050. The aim is to decrease CO_2 emissions with 55% by 2030 (compared to 1990). In 2022, the Dutch government published the Green Deal on Sustainable Healthcare (Ministry of Health, Welfare and Sport, 2022) to ensure that the care sector benefits not only people but also our planet and does not cause more pollution and health problems. Objectives stated in the deal are subdivided into five different themes: promotion of health and lifestyle interventions, increase knowledge and awareness, carbon neutral by 2050, reduce use of materials and resources and reduce environmental burden of pharmaceuticals. Especially relevant to this project is the theme of reduction in the use of materials and resources as well as residual waste. Addressed points in this theme include adopting circular practices, efficient use of raw materials, and promoting sustainability and circularity as procurement policy objectives.

3.2 Butterfly Diagram

The circular economy, in contrary to the linear approach, is based on a 'make-use-reuse' model a system where product life cycles are extended by creating multiple layered loops. Waste is minimised while the extracted value of materials is maximised by keeping them in use for as long as possible. The system can be visualised using the Butterfly Diagram (Figure 11). It shows the continuous flow of materials through loops in a circular economy. The technical cycle of the diagram is most relevant to the project. The loops increase in energy from left to right. The smallest loop costs the least energy and the biggest the most (although still less energy-intensive than producing new products). Additionally, it has been argued that the smaller the loop, the more profitable it is (Stahel, 2010). This means that creating small loops is both environmentally and financially desirable.

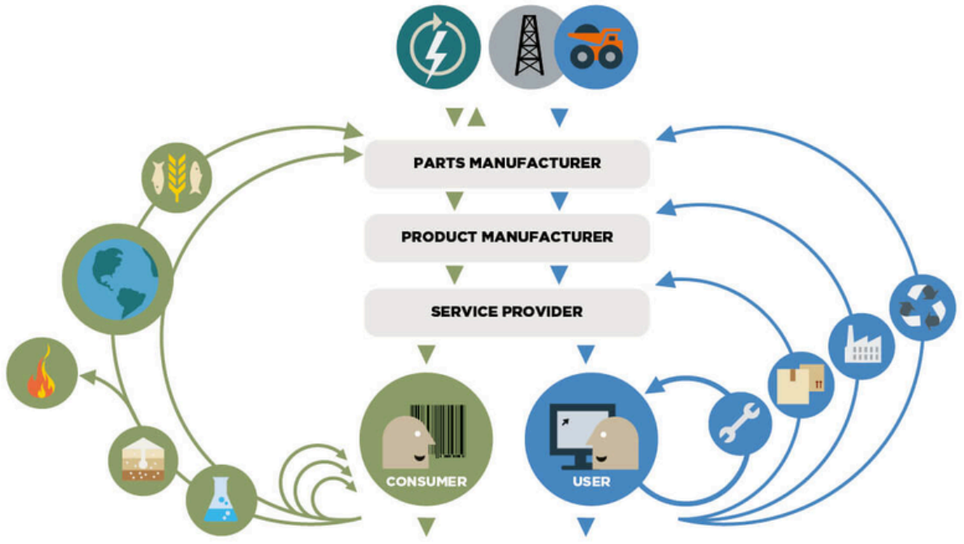


Figure 11: Butterfly Diagram of circular economy (MacArthur, E., 2010)

In the United States, approximately 85% of medical waste (of which 90% is made up of single-use medical devices) is non-hazardous and could, thus, potentially be cycled back (Kadamus, 2008). However, to apply these theories, a critical step needs to be added to the cycle: The (re)sterilisation of medical equipment (Figure 12). Depending on the applied method, such treatment could be linked to higher use of resources, energy, and costs. Thus, when deciding upon applying the discussed types of circular strategies, it will be critical to determine the required level, process, and impact of applied sterilisation methodologies.

Transitioning from a linear to a circular healthcare economy is essential to protecting human and environmental health and meeting the outlined sustainability goals. Frameworks such as the Butterfly Diagram help to gain a better understanding and suggest circular strategies to increase the level of sustainability and reduce CO_2 emissions. Adopting these strategies can ensure that the sector remains environmentally responsible and can deliver effective care well into the future. However, it is critical to remain mindful of the accompanying effects such strategies might carry.

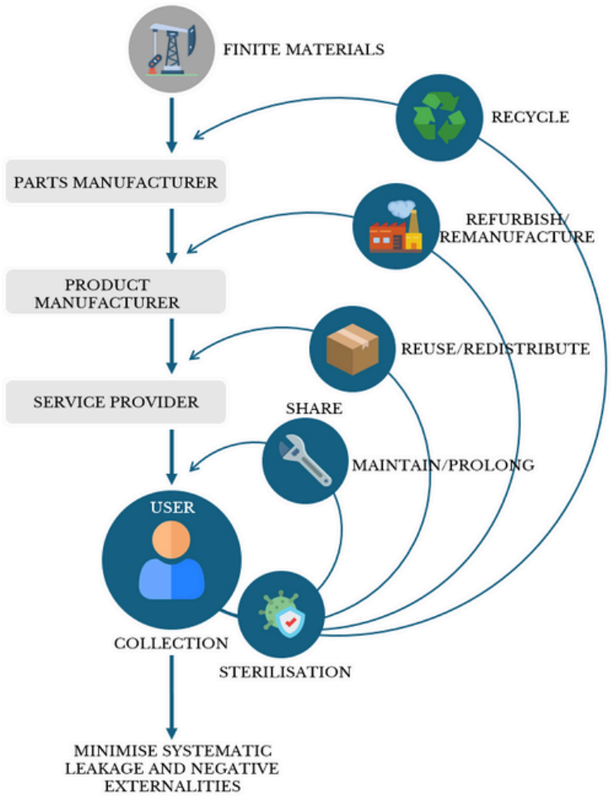


Figure 12: Technical cycle of Butterfly Diagram with added sterilisation step for healthcare, modified by Jelle Schilperoord (MacArthur, E., 2010)

3.3 10R framework

The 10R framework (Potting et al., 2017) introduces several circularity strategies to reduce the consumption of materials and resources and minimise waste. They can be ordered according to their level of circularity (Figure 13). The first category of strategies, efficient use of materials and resources, is referred to as short loops. These are preferred since they are strategies with overall high circularity. Life cycle extension is the next category, also referred to as medium loop strategies. Followed by maximisation of material usefulness through recycling and recovery, also called long loop strategies. Current healthcare practices see most medical equipment disposed of after a single-use cycle. A more circular healthcare economy can be realised by designing products whose life cycles can be extended by applying any of the 10R strategies. A more detailed description of each R strategy can be found in the following sub-chapters.

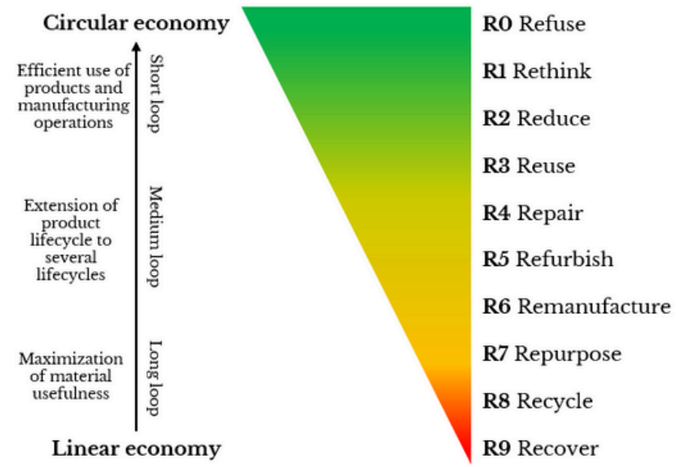


Figure 13: Graphical representation of the 10R framework (Potting et al., 2017)

3.3.1 Short loop R strategies

The first three R strategies, Refuse, Rethink and Reduce, comprise the short loop R strategies. These strategies are seen as the most idealistic and desirable strategies. This is because the strategies tackle waste and product impact in the crucial product design and development phase, allowing them to increase sustainability and avoid waste and environmental harm altogether. The three strategies are explained in the following sections.

Refuse

R0 refuse is seen as the most circular R strategy. This is because, when applied extensively, it would eliminate waste at the earliest point in the value chain. By refusing to use a harmful product or material and offering a more efficient or sustainable alternative in the early phases of development, one eliminates the potential impact this harmful product might have caused, thus, creating the shortest and most circular loop.

In reality, Refuse is one of the most complex R strategies. This is because it often requires the most innovative and extensive technological and systematic changes since making a product unessential through function removal or by including its function and abilities in other products is highly challenging.

An example of applying the Refuse strategy could be the replacement of single-use plastics in catering at Newcastle Hospital (NHS, n.d.). The pledge to no longer purchase single-use plastic straws, cutlery, plates and cups has prevented hundreds of thousands of these items from ending up in hospital waste streams.

Rethink

R1 rethink often refers to making a product more use-intensive by sharing products or creating multi-functional products. This strategy reimagines traditional product usage by minimising the natural resources and materials exhausted during use.

Unlike some R strategies, this strategy not only focuses on changes in the product itself but also reimagines how we approach and use products. As the concept of the sharing economy has been on the rise in recent years, more and more companies are rethinking their business models creatively to make more effective use of resources (Yaraghi & Ravi, 2017).

An example of the Rethink strategy in healthcare is the digital transformation of the care pathway. Rethinking the traditional approach and moving in-person visits such as postoperative follow-ups or patient monitoring to a remote setting. By doing this, emissions such as patient and health professional travel can be avoided, leading to more sustainable healthcare delivery (Fragão-Marques & Ozben, 2022).

Reduce

R2 reduce refers to the efficient use of resources during manufacturing and use. By minimising the weight, volume and expenditure, the use, manufacturing, and shipping of products can be made more environmentally friendly.

Reduce can be applied on a more systematic level, such as looking at the reduction of energy expenditure or on a product level by reducing the amount of materials in a product. Vital to both and particularly relevant to healthcare is that the reduction of these impacts should be made without altering the quality of the product/system.

An example of applying the reduce strategy on a product level in healthcare could be the redesigning of a syringe. An Erasmus MC study shows that the impact of syringes can be reduced by changing the material to sustainable alternatives and redesigning the shape for (partial) reuse (Honkoop et al., 2023).

3.3.2 Medium loop R strategies

Reuse, Repair, Refurbish, Remanufacture and Repurpose make up the medium loop R strategies. The main goal of these strategies is to help extend the lifespan of a product and its parts. As the strategies all take place inside the consumption phase of a product's life cycle, the user is a critical stakeholder. Important to note is that to maximise the effectiveness of these strategies, they should already be kept in mind when designing products. Creating more modular products, for example, benefits repair, refurbish and remanufacture. All medium loop strategies are discussed below.

Reuse

R3 reuse extends the lifespan of products by using them multiple times while maintaining the original abilities. The strategy aims to maximise the utility of existing items, reduce the need for new products, and minimise waste, thereby lowering environmental impacts.

In healthcare, this strategy becomes more complex as the reuse of medical devices often requires thorough cleaning and sterlisation. Thus, when applying this strategy, the impacts created by the cleaning and sterlisation process should be weighted against alternatives when creating a more sustainable care system.

An example of this strategy in healthcare could be the reuse of surgical equipment after sterlisation to ensure safety and compliance with standards and regulations. Studies show that depending on the applied sterlisation method, repeated reuse of such equipment is not only environmentally beneficial but could potentially save hospital costs (Boberg et al., 2022; Rizan & Bhutta, 2021; Unger & Landis, 2016; Van Straten, Ligtelijn, et al., 2021).

Repair

R4 repair focuses on fixing or restoring damaged or malfunctioning products to enable their original abilities to function correctly. Investing in repair can reduce waste and costs while maintaining reliable equipment.

Recent times have seen the rise of the rights-to-repair movement. This movement forces producers in specific industries to provide consumers with repair services or tools in case of product malfunction (Svensson et al., 2018). Legislative actions like these form examples of governmental stances or interventions created to promote sustainability.

A study on repairing ventilators in Brazil in response to shortages during the COVID-19 pandemic highlights the potential effects repair can have in healthcare (Cobra et al., 2023). By having volunteers repair malfunctioning and discarded ventilators, hospitals created greater resource availability and health system resilience while simultaneously progressing towards achieving sustainability goals.

Refurbish

R5 refurbish explores updating and renovating used products to restore them to original modernised conditions. This can be done by replacing obsolete or defective components within a product with updated parts.

The refurbishment of devices is often paired with EoL strategies, where intermediate trade replaces old parts with modern ones and allows refurbished devices to be sold. Unused or discarded older parts are then sent to recycling facilities.

An example of refurbishment in the healthcare industry can be seen when looking at Siemens AG (Plumeyer & Braun, 2011). The business unit focuses on refurbishing various medical devices while maintaining safety and adhering to regulations. Through refurbishing equipment, they help customers achieve more sustainable and financially beneficial outcomes.

Remanufacture

R6 remanufacture involves integrating product components that are still fully functional into new products with the same function. In contrast to refurbish, where an entire device is restored with the help of newer updated parts, remanufacture provides separate intact parts to be remanufactured into newer products.

Research by the Ellen MacArthur Foundation tells us that remanufacturing can save up to 80% less energy, 88% less water, 92% less chemical products and 70% less waste in some industries (*Europe's First Circular Economy Factory for Vehicles: Renault*, 2021). Additionally, consumers can access remanufactured parts as spare parts that might otherwise have been unobtainable due to products being discontinued.

An example of applying remanufacture in healthcare is Philips RS (Jensen et al., 2019). Philips takes back pre-owned equipment from hospitals, disinfects, disassembles, reviews all components, and remanufactures and refurbishes where possible. In doing this, they can extend the lifespan of products like their Interventional X-Ray systems by 5-10 years.

Repurpose

R7 repurpose takes products or materials that have reached their end of (intended) life and gives them a new purpose and function. This strategy helps reduce waste and often results in unique, innovative solutions that promote sustainability.

Important to note is the extent of reprocessing required to give the products or material this new purpose. This strategy's impact and sustainable benefits depend highly on the applied reprocessing level. If the reprocessing becomes too extensive, it can no longer be seen as repurposing and, instead, becomes a lower level of circular strategy, namely recycling.

An example of the repurpose strategy in healthcare, is a study at an American children's hospital (Bae et al., 2024). During this study, 960 clean single-use disposable items ranging from plastic trays to towels and gowns were collected and repurposed for schools, car washes, and moving companies over six weeks. It concludes that repurposing unused surgical items can provide environmental, societal and financial benefits.

3.3.3 Long loop R strategies

The long loop strategies, Recycle and Recover, act as fail-safes when other strategies can no longer be applied or fail to be applied. While through recovering valuable materials, energy, and heat, a positive impact can still be achieved, it comes at the cost of a much more complex and effort-demanding process than some shorter loop strategies.

Recycle

R8 recycle looks at reprocessing discarded products to recover valuable materials left within. Materials can be upcycled, making higher-quality materials, or downcycled, creating lower-quality materials.

In healthcare, recycling materials can only be done when products are not contaminated. Contaminated products must be cleaned and sterilised before recycling, but the accompanying costs and impact of this process are not always worth the benefits of recycling. This is why contaminated healthcare products which can no longer be used are often incinerated.

An example of applying recycling in healthcare, is a Dutch study focusing on the recycling of medical wrapping paper, also known as blue wrap (Van Straten, Heiden, et al., 2021). In the study, wrapping paper collected from the ORs was reprocessed into instrument openers for sterlisation processes. The study showcases an opportunity to reduce medical waste through recycling while allowing the material to serve an alternative purpose.

Recover

R9 recover is the last and lowest circular strategy. Here, electricity or heat can be generated through a waste-to-energy process where waste is incinerated and resulting heat or electricity is recovered through capturing produced steam.

While incineration still has some negative impacts, such as the emission of pollutants into the atmosphere and the production of slag and bottom ash, it is preferred and generally more environmentally friendly than other waste treatment alternatives, such as landfilling.

Some studies have explored the viability of waste-to-energy processes in a healthcare setting (Bujak, 2015). The study found that experimental waste-to-energy installations had little impact on the environment while adhering to emission and waste treatment standards.

3.4 Value Hill

The Value Hill is a model used to visualise the categorised life cycle phases of products (*Master Circular Business With the Value Hill*, 2023). To compare the concepts of the linear and circular economy and visualise the identified R strategies of the circular economy, two models have been made to represent a linear and circular system.

Figure 14 depicts the Value Hill model based on the principle of the linear economy, the make-use-dispose system. On the left side of the hill, the value of a product is built up from the extraction of initial resources, manufacturing, assembly and retail until it reaches the user. The top of the hill depicts the use phase of the product. The hill's right side represents the product's post-use, where in the linear economy, the value is destroyed as the product is discarded.

Figure 15 depicts the Value Hill model based on the principle of the circular economy, the make-use-reuse system. The previously identified 10R strategies are all represented in various phases of the product life cycle. By applying these strategies at either the use or post-use (see "prolonged use" in Figure 15), the product's life cycle is extended, as visualised through the lengthening of the right side of the hill. Various loops are created by applying the strategies each (re)increasing the product's value. A significant impact can be achieved by prolonging the product's life cycle and extending the time before products reach their EoL. Not only does this reduce the need for new products, but it can also save finances and resources over a product's lifetime.

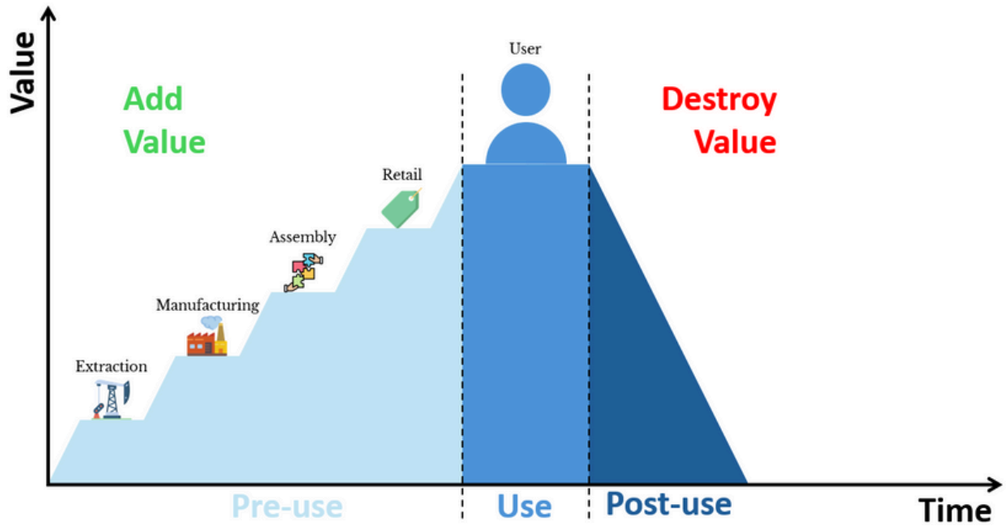


Figure 14: Value Hill of linear economy (*Master Circular Business With the Value Hill*, 2023)

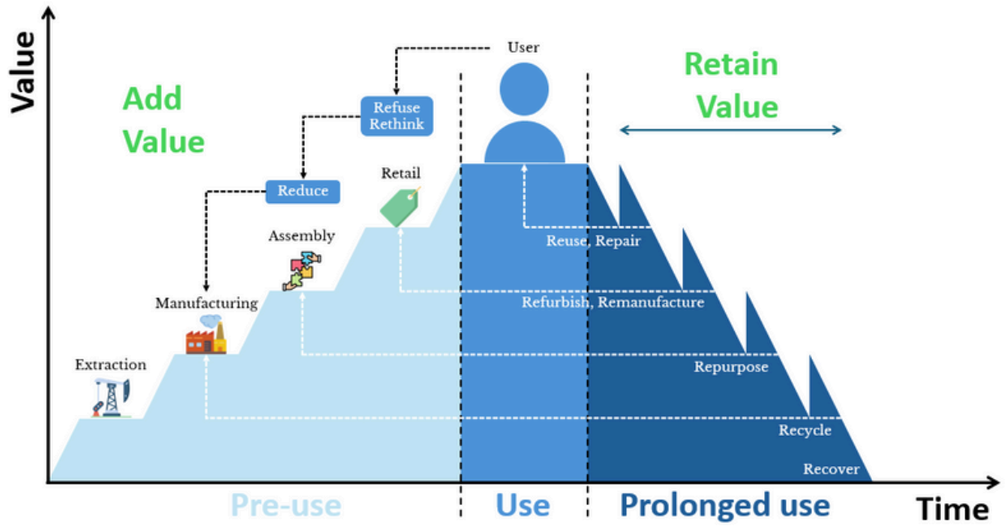


Figure 15: Adaptation of Value Hill for circular economy (*Master Circular Business With the Value Hill*, 2023)

3.5 Spatium strategies

Having discussed various circular frameworks and existing R strategies, conclusions can be drawn regarding the relevance and feasibility of specific strategies for the Spatium patient kit.

The value of the initial product is a determinant of which of the R strategies can be applied (Kane et al., 2018). Weighing this value against the cost of reprocessing and potential recovery can be grounds for selecting and refusing strategies.

Looking at the patient kit and accompanying packaging, it becomes clear that high-effort and high-cost strategies such as repair, refurbish, remanufacture and repurpose are not feasible. The infrastructure and scalability required to make these strategies profitable, both from an economic and environmental perspective, are far beyond the reach of a start-up like Spatium. This is also in line with findings from literature suggesting that some items will remain disposable in the end, as the cost of their recovery will always be greater than the cost of the device itself (Sloan, 2006).

Recover, being the lowest R strategy, is commonly not a strategy you would aim for. Since all contaminated medical waste is burned at the EoL, designing for recovery would likely mean selecting materials that do not cause harmful or toxic emissions when burned. However, it should be noted that the availability of energy recapture during recovery when burning medical waste is not something Spatium as a company can have much influence on and is more dependent on local infrastructure and governments.

The most apparent and highest potential R strategy which can be applied seems to be reduce. This could be done through multiple channels, like selecting the least environmentally impactful materials possible for the use case, optimising product aspects such as tube length and wall thickness, and selecting environmentally responsible packaging options. Additionally, reduce can be achieved through more big-picture effects like shortening the overall care pathway of patients by applying innovative insufflation technologies leading to a reduction of emissions and waste created by each patient's hospital stay.

Another promising R strategy for the Spatium patient kit is reuse. Various literature studies on different medical devices have shown that the reuse and reprocessing of items can be beneficial both cost and impact-wise (Boberg et al., 2022; Keil et al., 2022; Rizan & Bhutta, 2021; Sousa et al., 2020; Unger & Landis, 2016; Van Straten, Ligtelijn, et al., 2021). However, as concluded from the framework analysis (see chapter 3.2), the reuse of medical devices requires sterilisation and high-grade disinfection. Depending on the type of process applied, these can limit material selection, drive up environmental impacts, highly influence the cost, and, in the long run, lower the quality and functionality of medical devices. Thus, a more realistic and feasible strategy to explore as a solution to these challenges could be to design a device for neither a single-use nor an infinite number of cycles. Here, it would be essential to identify the number of reprocessing cycles needed to tip the environmental (and potentially economic) scales in favour of reuse without affecting the device's quality and performance.

Developing a hybrid device is a tactic with some prevalence in literature (Boberg et al., 2022; Rizan & Bhutta, 2021). A hybrid device can offer multiple advantages. They can be more interesting from a business perspective since the income from selling disposable devices is not fully removed while still leading to a lowering of the environmental impacts and overall costs of a medical device. Another benefit of hybrid devices is that often, not all medical device components enter a patient's body or require sterilisation and disinfection. If these pieces can be designed to, for example, be detachable, it can be a significant cost and impact saver compared to fully disposable or reusable devices.

Finally, while recycling contaminated medical waste requires prior sterilisation and disinfection, it can still be better than the alternative of incineration. However, due to the infrastructure and effort demand needed to realise this strategy, it will likely require a large number of devices in practice to become worthwhile, making it more of a long-term strategy. Design for recycling can be done by creating as many mono-material devices and components as possible and designing more complex devices to be easily deconstructed, allowing different materials and components to be separated without too much effort.

Key insights

How do the concepts of the linear and circular economy relate to healthcare?

- The current healthcare system is mainly built on a linear approach, but recent years have seen the rise and shift towards more circular practices. Circular frameworks like the Butterfly Diagram and Value Hill can be applied to healthcare but often require an additional step like sterilisation to create a more holistic view of reality.

What are circular strategies, and how can they be applied in healthcare?

- The 10R provides an overview of strategies categorised into short, medium, and long loops that can be applied to achieve more circular practices. Examples of applying all strategies in healthcare can be found in existing literature.

What are the relevant and feasible circular strategies for the Spatium patient kit?

- Due to the nature of the Spatium patient kit and Spatium's status as a start-up company, the most promising and feasible strategies to explore will be (rethink), reduce, reuse and recycle.

CHAPTER 04

Stakeholders and values

This chapter explores the different stakeholders involved in the project through literature research and empirical interviews. First, an initial overview of key stakeholders and accompanying values is formulated based on research, followed by reporting on the setup and an analysis of the results of executed interviews. Finally, key insights are formulated by revising the initial research overview with interview findings.

In this chapter:

Key topics:

- Which stakeholders play a role of importance in the life cycle of the Spatium insufflation system?
- What are the key values of the identified stakeholders and how do these relate and conflict with each other?
- What barriers and insights do these stakeholders experience in practice?

4.1 Stakeholder analysis

A power/interest matrix was used to map stakeholders in this complex healthcare project. The results of that mapping are presented in Figure 17 (Nguyen, 2018). All initial discovered stakeholders are divided in five groups: Hospital, Internal, External, Suppliers and Regulatory.

4.1.1 Hospital

Stakeholders inside a hospital system are involved in all phases of the life cycle of Spatium's medical devices. Because of this, many of these stakeholders can play key roles in realising circular strategies. Critical to discover is the level of involvement of each stakeholder in the decision-making, use, implementation and realisation of more sustainable medical devices. For this project, the focus was put on mapping stakeholders connected to proposing, developing and executing sustainable strategies and medical devices.

Central Sterilisation Department

The centrale sterilisatie afdeling (CSA) inside a hospital is responsible for reprocessing medical devices. The level of disinfection/sterilisation required for reprocessing is determined using the Spaulding classification (*Spaulding Classification | Nanosonics*, n.d.). Laparoscopic equipment such as trocars and insufflation tubing fall into the critical category (Figure 16) since they come into contact with sterile gas and tissue. This means that sterilisation is mandatory for the reprocessing of these devices.

When considering circular strategies, the required sterilisation of the devices must be kept in mind. The environmental impact and feasibility of reprocessing medical devices depend highly on the applied sterilisation process and circumstances (Adler et al., 2004; Davis et al., 2018; Leiden et al., 2020; McGain, McAlister, et al., 2012; McGain et al., 2017). This is why gathering a better understanding of sterlisation processes inside and outside, as well as acceptance criteria for reprocessing of hospitals, is critical to creating realistic circular strategies.

Green team

The formation of circular task forces, green teams, is an increasing phenomenon in hospitals. These teams are often made up of enthusiastic hospital staff such as nurses, doctors, management and members of other departments. They aim to further shape and apply circular strategies inside hospitals through, for example, starting pilots and communication changes (Voudrias, 2018).

Nowadays, green teams can be found in most hospitals in Europe and the US, including the Erasmus MC. Here, the setup of green teams has led to various achievements, such as a reduction in plastic weight equivalent to a Boeing airliner, discontinued use of disposable laryngoscope blades, a reduction of high emission load gas in ORs and further efforts towards reducing waste and promoting circularity (Erasmus MC, 2020). Involving green team members to discuss and explore further possibilities related to the project can be valuable in formulating actionable plans for Spatium.

Infection Prevention Department

The infection prevention department of a hospital (at Erasmus MC, coined the UNIP) ensures the existence of hospital protocols to minimise the risk of infection. This is especially important inside ORs, where patients often preside in critical conditions and are highly vulnerable and sensitive to infection.

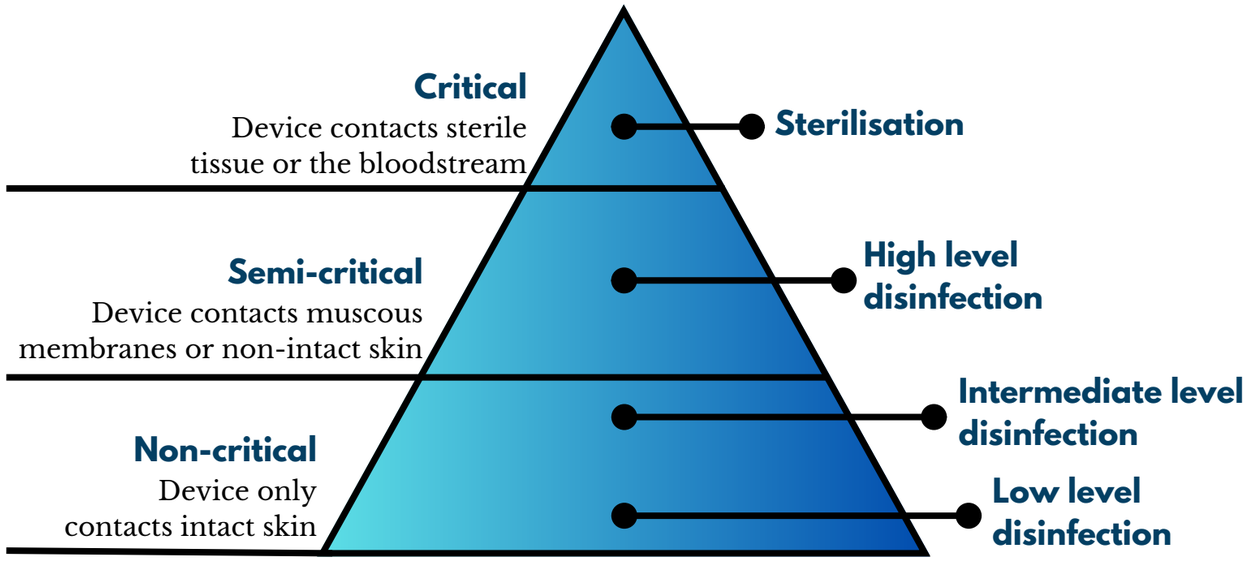


Figure 16: Spaulding classification (*Spaulding Classification | Nanosonics*, n.d.)

Because of this, changes in hospital procedures, waste stream or reprocessing practices often need to be examined and approved by the Infection Prevention Department. It is argued that a holistic approach to sustainable healthcare, including infection prevention, recognises health's environmental, cultural, and social aspects (Morgan & Synnott, 2024). Further exploring the involvement and importance of infection prevention in implementing circular strategies will be important in setting requirements for designed strategies.

OR nurses

Aside from the surgeons performing the actual procedures OR nurses play a vital role in interaction with medical devices during surgeries. Their primary objective is to support the operating team in their work. In doing this, they can interact with used medical devices. For instance, they are often the ones removing devices from their packaging, preparing them for use and even discarding the devices and packaging post-use. Because these handlings can be related to potential sustainable strategies it will be important to engage OR nurses and get a good understanding of their workflow.

Procurement

Procurement of goods has been found to make one of the most significant contributions to healthcare's carbon footprint (Lau et al., 2024; Tennison et al., 2021). As a consequence, sustainable procurement has become increasingly important. A hospital's procurement team plays a vital role in evaluating companies and products for hospital use, extending beyond the influence of most other stakeholders within the hospital.

Literature research showed that there are barriers to environmental supply projects, such as higher initial costs, lack of legitimacy, poor supplier commitment and industrial specificities (Oruezabala & Rico, 2012). It is valuable to explore these barriers and other decision-making criteria that procurement considers when selecting medical devices for a hospital during an interview.

Surgeon(s)

Surgeons are integral to many decisions made in the ORs. While their primary objectives are ensuring patient safety and achieving optimal surgical results, there has been an increasing awareness and desire for more sustainable OR practices among surgeons. Studies using surveys answered by medical practitioners from various fields indicate the recognition of excessive OR waste as a problem and the willingness to change workflow to reduce waste among surgeons (Chang & Thiel, 2020; McGain, White, et al., 2012; Meyer et al., 2022; Petre et al., 2018). However, there are current barriers to creating more sustainable ORs.

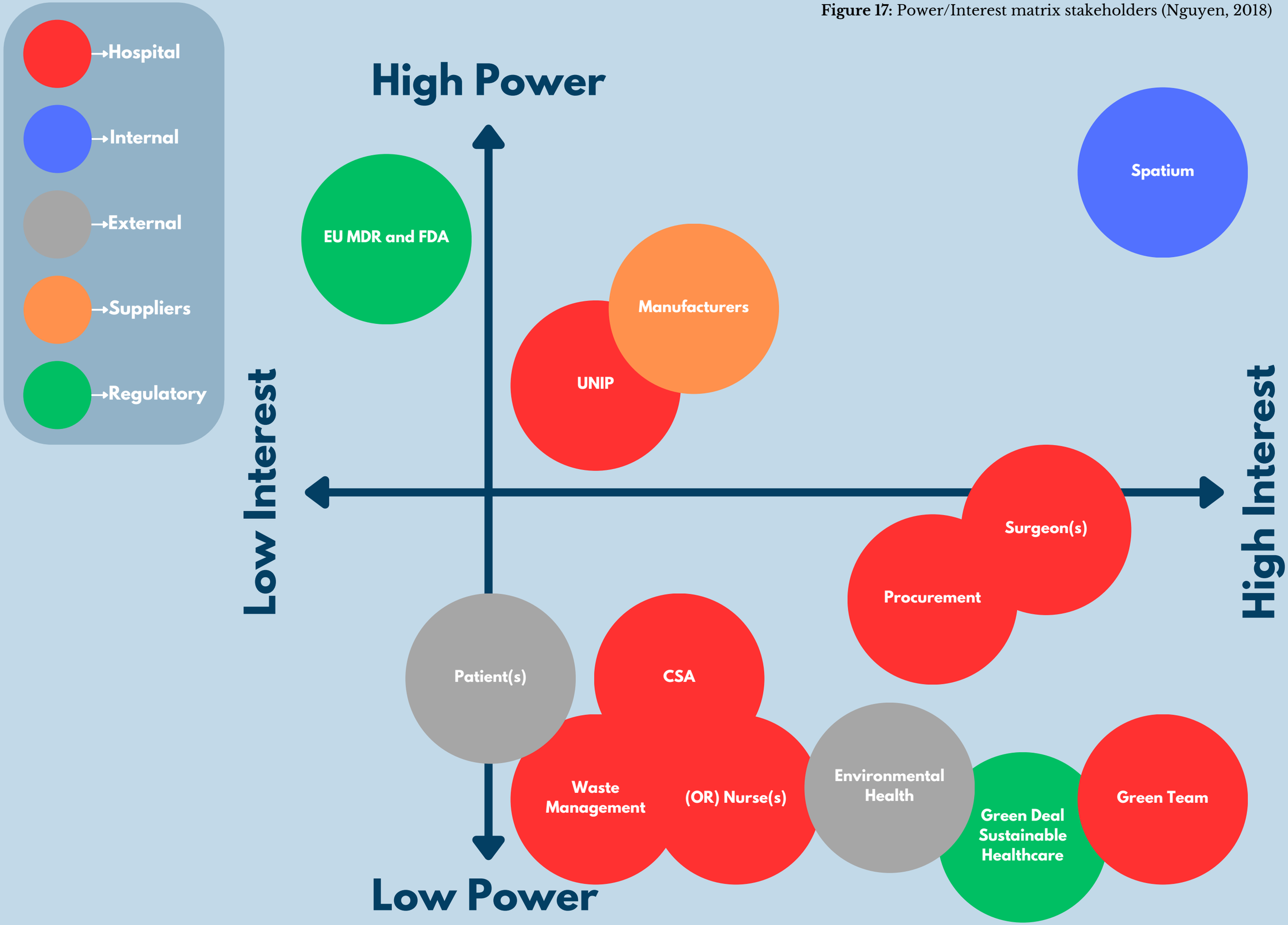
These barriers include uncertainty regarding the safety and sterility of reprocessed medical devices, unfamiliarity with new medical devices, investment of finances and time, lack of support from leadership, inadequate information and education, lack of facilities and negative staff attitudes (Chang & Thiel, 2020; McGain, White, et al., 2012; Meyer et al., 2022; Petre et al., 2018). It is critical to consider these barriers when developing circular strategies during the graduation project. Engaging surgeons about overcoming barriers in practice and balancing potentially conflicting values such as safety, efficiency, and sustainability will provide valuable insights for the project.

Waste management

A complete waste management system inside a hospital likely involves various sub-stakeholders from the moment of waste separation or allocation to bins present in ORs to the logistics of collection and transportation of waste, ultimately leading to the storage and disposal of waste through methods such as incineration. Mismanagement of healthcare waste can pose significant environmental and occupational health risks. Implementing effective waste management practices can be challenging due to system complexity, economic aspects and social impacts (Ranjbari et al., 2022).

Mapping hospital waste streams and sub-streams, such as infectious and non-infectious waste, from the OR to reprocessing or disposal sites can give more insight and a better understanding of involved key players and the possibilities of implementing circular strategies.

Figure 17: Power/Interest matrix stakeholders (Nguyen, 2018)



4.1.2 Internal

The internal stakeholder of this project is the client, Spatium Medical. They control choices that can impact all stages of the device life cycle. Additionally, the engineers and personnel at Spatium offer unique insights and expertise into the graduation topic.

Spatium Medical

As the client of this project and developer of the device, Spatium Medical is the most prominent stakeholder in the project. To develop a truly "future-proof" system, Spatium wants to ensure its product is not only better for patients and surgeons but also respects the planet (Spatium, 2024).

Having said this, while wanting a more sustainable product, Spatium needs to ensure the sustainability aspect of the device does not obstruct other values, such as usability, feasibility and profitability. To design a valuable output for Spatium these various aspects should be factored in when creating strategies.

4.1.3 External

While the external stakeholders are not directly involved with or influence medical device life cycles, they experience the benefits of more circular strategies in healthcare. Many external stakeholders exist, including extended families of patients, waste processing companies, the genera; world population and more. For this project, the focus has been put on the patients, who are the object of surgeries using Spatium devices and general environmental health, as they are directly linked to this thesis project.

Environmental health

While environmental health is included as a stakeholder, it remains without human attributes and thus, by definition, lacks any actionable power. Its main interests relate to potential environmental impact reduction by extension of overall product life cycles. As mentioned in earlier chapters, this impact reduction can have a positive influence on a global scale and is thus indirectly valuable to all stakeholders.

Patient(s)

While being the subject of surgery, patients are registered as external stakeholders. Other than some freedom in deciding specific approaches and treatments for their ailments, patients do not hold any power regarding the life cycle of specific medical devices.

While some might have strong preferences and beliefs that align with sustainability, it is assumed that, in general, all patients' principal value is a positive surgical outcome, and any solutions or innovations in the field of sustainability can, under no circumstance, negatively influence this outcome.

4.1.4 Suppliers

The various manufacturers Spatium enlists to develop its insufflation device make up the bulk of the supplier stakeholder group. This group mainly works and influences the pre-use phase of the device's life cycle. They hold a reasonable amount of power since choices made in this value build-up phase are decisive for the possibilities in later life cycle phases.

Manufacturer(s)

Spatium employs multiple manufacturers to develop the device and different components of the patient kit. Clear communication between Spatium and these manufacturers is key to developing the insufflation system.

Different manufacturers hold some power regarding material development possibilities and techniques. However, it should be noted that changing manufacturers, especially in the long-term prospects, is not impossible. The location of these manufacturers also influences sustainability aspects, as transport and local facilities can significantly influence environmental impacts.

4.1.5 Regulatory

The regulatory stakeholder group presents regulatory bodies and existing regulations and plans for sustainable healthcare development. While this stakeholder has no direct influence or involvement in product life cycles, to get their eventual medical device certified, Spatium has to comply with all existing regulations, including any regulations regarding reprocessing and circularity of medical devices.

EU MDR and FDA

As Spatium plans to introduce its insufflator to the global market, it must comply with different regulatory bodies. Most notable are the EU medical device regulation (MDR) and the US food and drug administration (FDA), which, for many global regions, set the standards and requirements for all medical devices and medical device manufacturers and designers.

Regulations on general device development and use, as well as specifics regarding reusability and sterilisation and disinfection of medical devices, are particularly interesting for the project confines and should be considered when designing strategies in later stages.

Green deal

The Green Deal for Sustainable Healthcare stakeholder represents the urgent need for more sustainable healthcare practices. The Green Deal is specific to Europe and the Netherlands, but similar plans have been proposed and accepted in regions across the globe.

While possessing little power currently recent policy changes in other fields and trends indicate the likelihood of sustainability becoming an increasingly important regulatory value. It is not unreasonable to assume that some minimum form of sustainability or circularity will be required of hospitals and medical device manufacturers and designers in the near future.

4.2 Stakeholder values

As preparation and discussion topic for the empirical interviews later, four core values are formulated for the identified stakeholders: Health outcome, Compatibility, Cost and Sustainability. The assumed importance of these values for all stakeholders has been visualised using radar charts. See Figures 18, where the outermost ring of the diamond represents the highest importance and the innermost lowest importance. The values for the surgeon(s) and OR nurses stakeholder groups were combined as literature findings showed these aligned (Chang & Thiel, 2020).

Health outcome

Health outcome is the most prominent shared stakeholder value. It relates to the patient's health during and after using the medical device. It is in the interest of all stakeholders to prioritise this value since any adverse health outcomes will have detrimental effects on all involved. In relation to the device, this is linked to performance and safety.

Compatibility

Compatibility of the device and drafted strategies with workflows is, to many stakeholders, a significant value. It refers to the conformity of the device with existing systems. Whether the device fits in with existing workflows or offers usability benefits can often be a key decider for adoption.

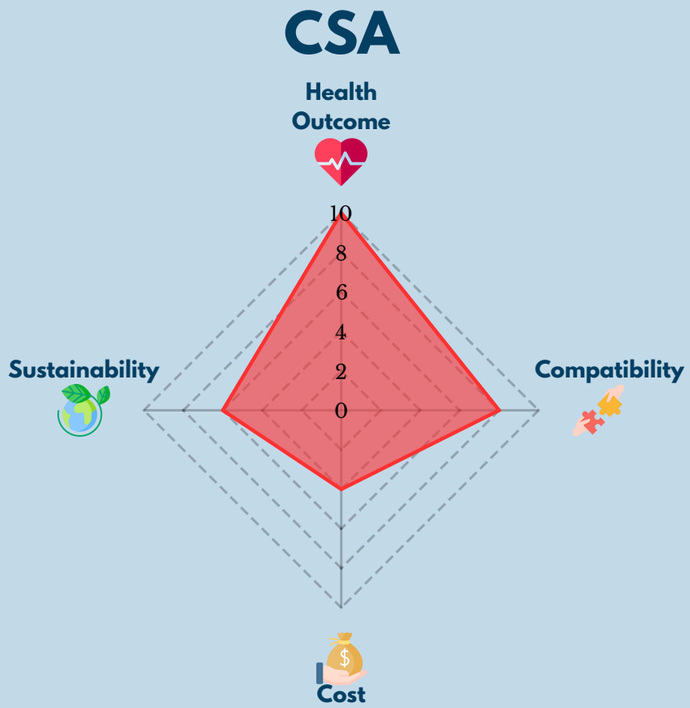
Cost

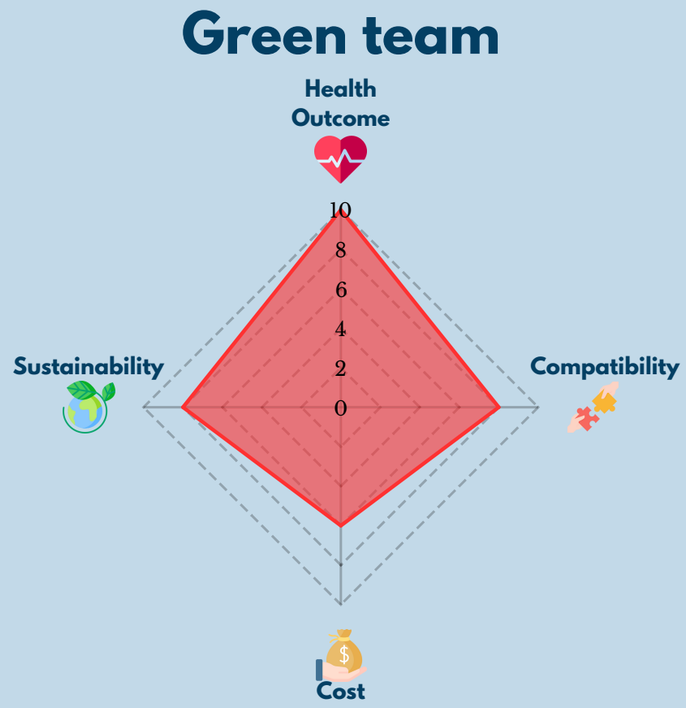
Cost is a self-explanatory value. However, its importance and prioritisation for various stakeholders might differ. While stakeholders such as Spatium, manufacturers and even hospital departments are more dependent and limited by cost and profit margins, others are less burdened by this pressure. The overall consensus, however, is to keep costs as low as possible without compromising other values to maintain the accessibility of healthcare in general.

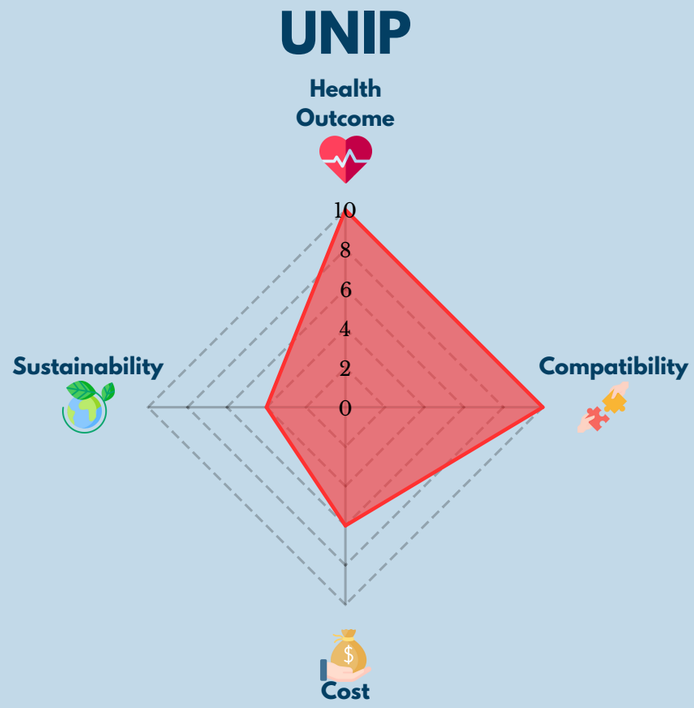
Sustainability

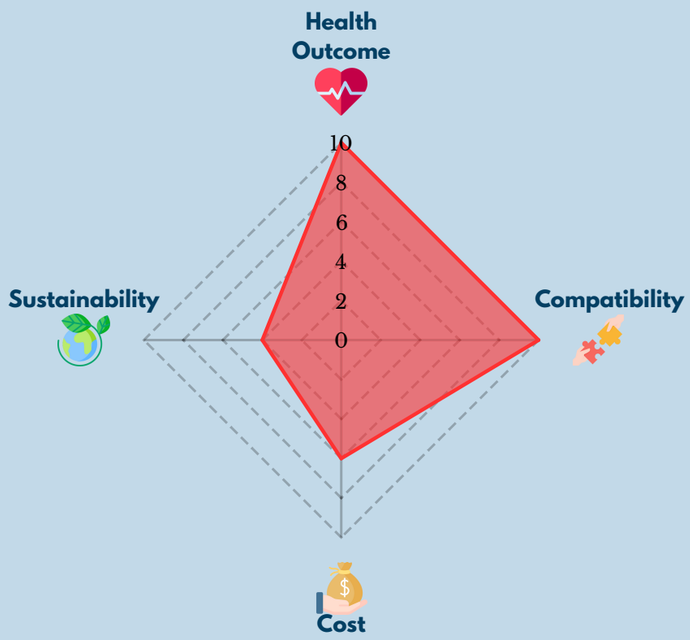
Sustainability has recently risen as a value in healthcare, becoming increasingly more important, as discussed in previous chapters. While most stakeholders agree and realise the need for more sustainable healthcare, its importance and place in relation to the other values is still unclear. Most stakeholders assume sustainability to conflict with values such as safety, cost and time.

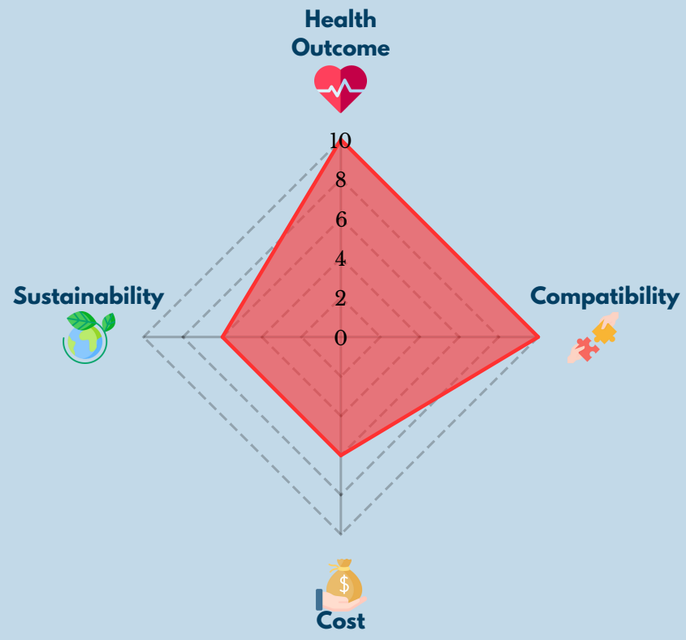
Figure 18: Radar chart assumed importance of core values from identified stakeholders











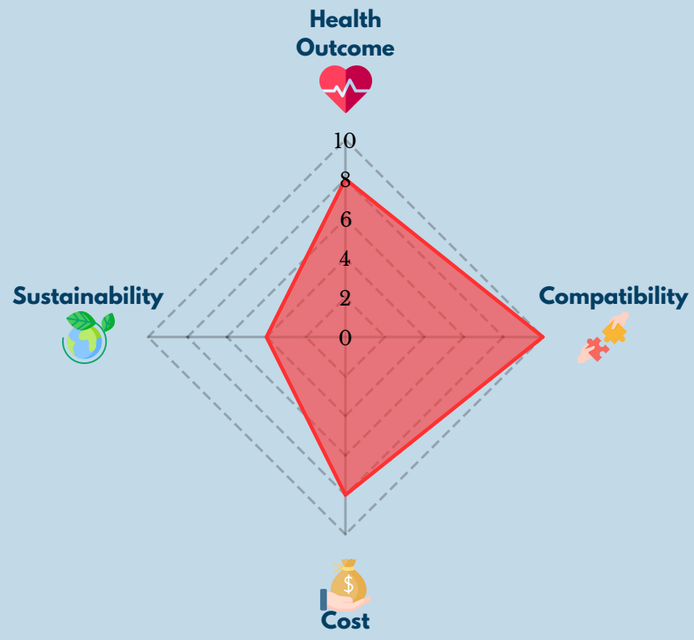
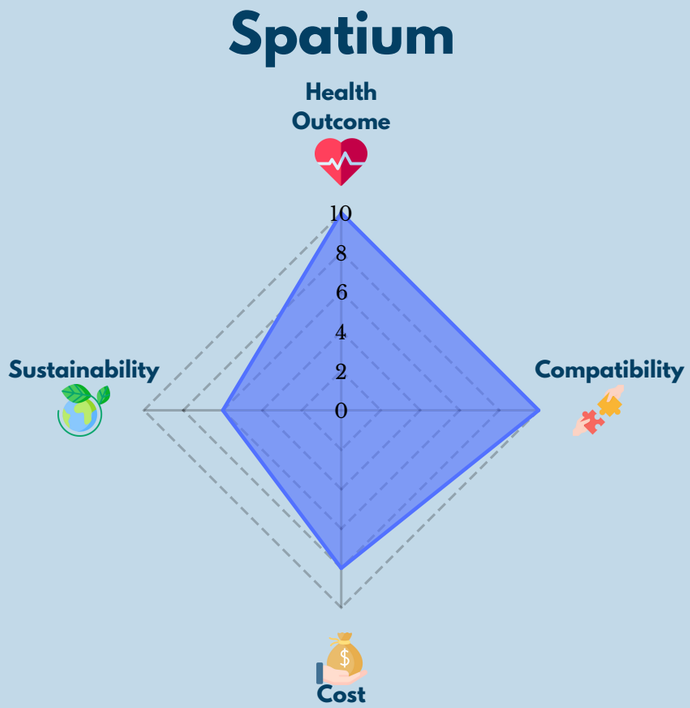
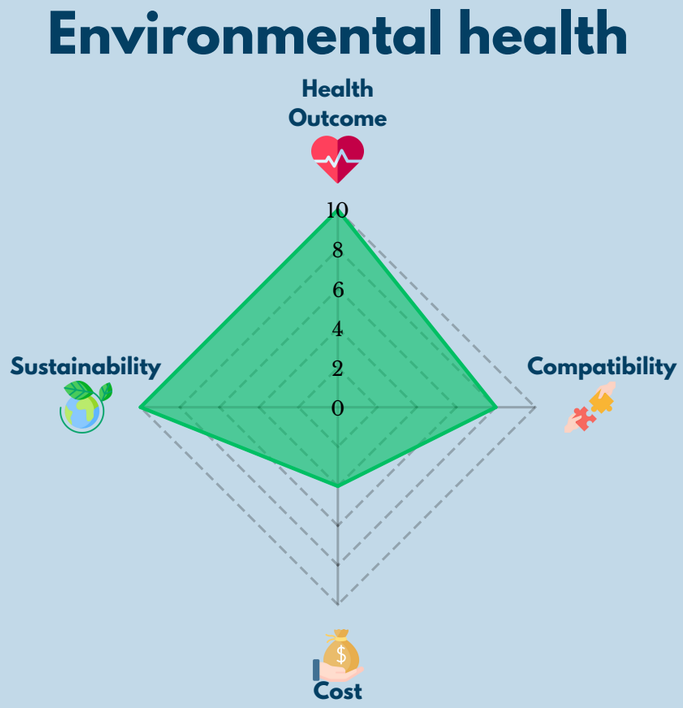
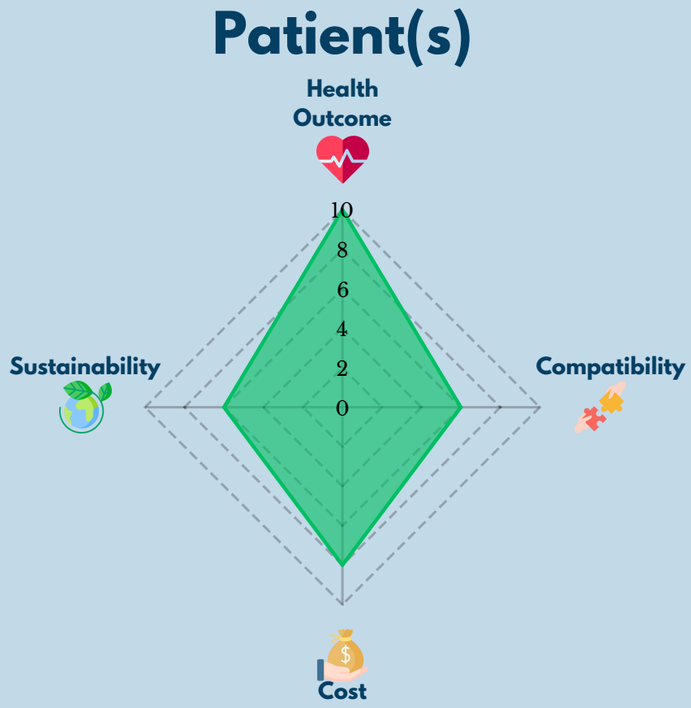
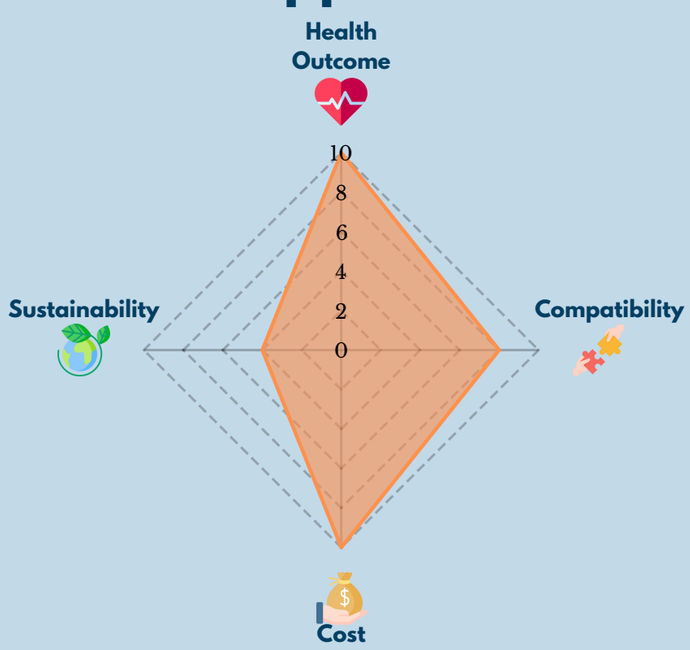


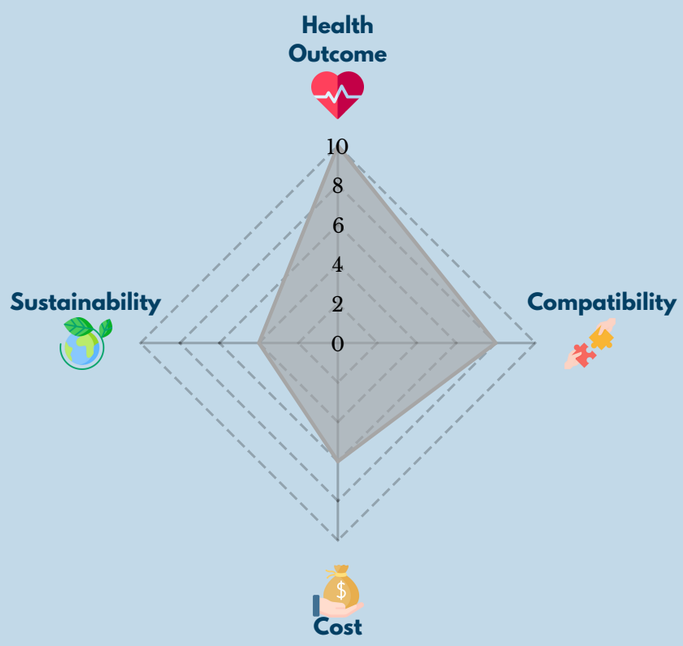
Figure 18: Radar chart assumed importance of core values from identified stakeholders

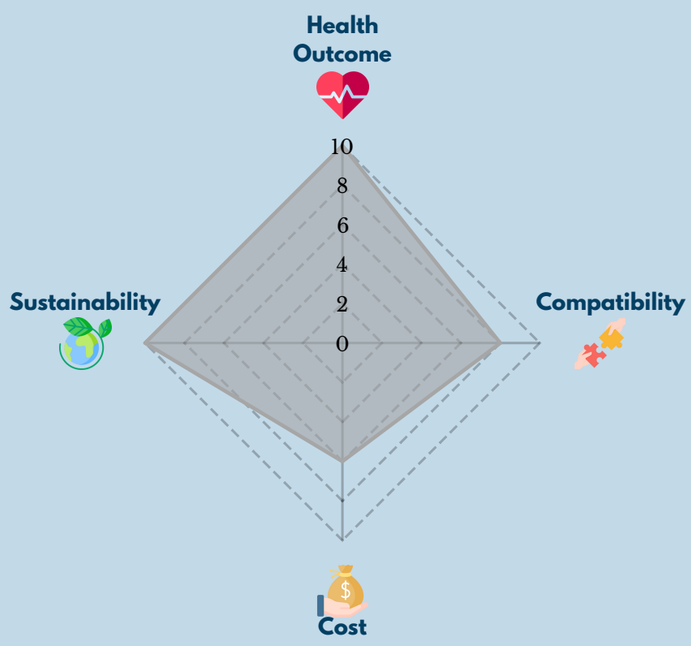












4.3 Interview planning

The main goal of the semi-structured interviews was to discover and gain more insight into the role of stakeholders, their core values and needs and any potential barriers they currently experience in their work, specifically relating to implementing more sustainable practices.

For this study, qualitative, in-depth, semi-structured interviews were selected as most appropriate due to this method's exploratory nature and (personalised) flexibility (Jain, 2021). The interviews used conclusions and findings from previous context and literature research as well as assumptions on the roles of stakeholders and the importance and presence of specific values as conversational tools. This is done to evoke responses and directly validate any findings and assumptions with the stakeholders. Additionally, when applicable, the application of identified circular strategies and ideas were discussed with stakeholders to receive thoughtful inputs, new ideas and constructive criticism. This feedback will be instrumental in developing and refining user needs and design guidelines and, in later stages, developing more detailed concepts. The key sub-research questions for the interviews are:

1. **What is the role/involvement of the stakeholder within the life cycle of a (sustainable) insufflator? (current practises)**
2. **What are the existing core values of the stakeholder? How does sustainability relate/rank within these values?**
3. **Are there any existing sustainable initiatives the stakeholder knows/has experience with? Do they foresee any future sustainable initiatives?**
4. **What are potential barriers to creating more sustainable practises the stakeholder experiences/foresees?**

Because of the variance in expertise, involvement and setting of the different stakeholders, stakeholder-specific interview guides were drafted and used as visible in the interview transcripts (Appendix B). Each interview guide started with a brief introduction to Spatium and the graduation project subject, followed by the following rough phases:

I. Role of stakeholder and current workflow (approximately 15 minutes): This section mainly focused on gaining insight into the existing workflows of the stakeholder and dealt with the first sub-research question.

II. Discussion on central values/criteria and importance of sustainability (approximately 20 minutes): Any relevant conclusions and reached results and assumed values with linked importance were discussed with a focus on the second sub-research question.

III. Current and foreseeable applications of sustainability in workflows and barriers to realisation/implementation (approximately 20 minutes): This part mainly looked at currently implemented sustainable initiatives, any future sustainable opportunities as foreseen by the stakeholder and potential barriers to creating more sustainable workflows. Here, sub-questions 3 and 4 were addressed.

The interviews were designed for a maximum length of 60 minutes to minimise interviewer and interviewee fatigue (Adams, 2015) while providing enough time for interviewees to respond thoughtfully to posed questions. The interviews were set up to allow for both online and offline settings to avoid limitations by geographical or time constraints and promote flexibility for interviewees. Some interviews included tours of departments within dedicated hospitals, offering unique opportunities for personal visual insights and experiences.

Table 2: Interviewee profiles

Interviewee number	Role	Hospital
Interviewee 1	Expert sterilisation and disinfection medical devices	ErasmusMC
Interviewee 2	Procurement and sustainability	ErasmusMC
Interviewee 3	Researcher	Esch-r project (ErasmusMC and UMC Utrecht)
Interviewee 4	Senior advisor procurement	UMC Utrecht
Interviewee 5	Operating assistant and green team member	ErasmusMC
Interviewee 6	OR nurse	ErasmusMC
Interviewee 7	Researcher and Anaesthesiologist	ErasmusMC
Interviewee 8	Pediatric surgeon	ErasmusMC(Sophia kinderziekenhuis)

4.4 Participants

Using connections provided by Spatium, various participants working in different hospital departments were selected for interviews. Due to time and network constraints, it was not possible to interview participants from all previously identified stakeholder groups. The focus was placed on interacting with participants from the procurement, OR staff (surgeons and nurses), green teams, and CSA stakeholder groups since these were identified as key to Spatium and the realisation and validation of potential sustainable strategies. Due to accessibility reasons, most participants worked at the Erasmus MC. However, some stakeholders from other hospitals were engaged to ensure that not all the data collected was biased to the setting of a single hospital.

To maintain their privacy, all participants are referred to as Interviewee X. Interviewees 1-5 all participated in full semi-structured interviews (transcript in Appendix B), while interviewees 6-8 were verbally engaged and questioned during usability tests or shorter meetings and interactions. No full transcripts are available for these later interactions, but relevant provided inputs are listed in the hereafter chapter. Table 2 lists the interviewee profiles.

4.5 Interview analysis

To analyse, compare and summarise the results from all collected stakeholder inputs a deductive thematic analysis approach was used (Braun & Clarke, 2012). The transcripts and interaction findings were reviewed, and as a result, identified themes were derived. Comparable themes were grouped and generated insights and relevant interviewee quotations have been listed.

As a result ten themes have been formulated. These themes are discussed in further detail in the following part of this chapter. All themes are listed in a similar format to improve readability.

4.5.1 Communication between hospitals and medical device manufacturers, and suppliers

While sustainability is becoming increasingly important in healthcare, for many stakeholders it remains relatively novel. This means that there are still a lot of unclarities between parties like hospitals and device manufacturers on what criteria are considered and looked at when evaluating or aspiring towards sustainability.

- **There is no current universal standardised process for evaluating/involving sustainability in medical device tenders.**

"So every hospital kind of gets to do their own thing. How do they want to do their tender? What type of criteria do they want to put in tenders? It's completely up to the hospital." (Interviewee 3)

- **Sustainable objectives, even when present, often remain quite vague and lack actionable parameters.**

"A lot of other hospitals state stuff like sustainable where practically possible, but then the question remains: what are you talking about? exactly what does sustainability mean for you? what are the parameters you are looking at?" (Interviewee 2)

- **Suppliers are unclear on what hospitals ask/want from them.**

"From my research so far, I get the feeling that suppliers are not very clear on what hospitals are asking from them." (Interviewee 3)

"My research is also about what hospitals are paying attention to. And I think that this is not very clear at the moment. One pays attention to this, the other to that. One does not care about sustainability at all, the other does, but in a different way. So yes, I often hear from suppliers that they find that very difficult." (Interviewee 4)

"But where is it exactly made of? Suppliers are not always used to that either. To make that very clear and very transparent." (Interviewee 4)

4.5.2 Roles and importance of specific stakeholders

Inside the hospital, the main initiative for requesting and obtaining more sustainable medical devices should come from the different surgical departments. The doctors and nurses are really the ones who request devices while procurement takes an advisory role in the process.

- **Initial proposals and requests for new devices are made by departments (doctors, surgeons and nurses)**

"You really have to assume that the most important stamp comes from the doctors and surgeons." (Interviewee 2)

"In the end, the doctor or the nurses that are asking for the product, they really have the power to decide, okay, do I want to put 20% for price and 10% for sustainability?" (interviewee 3)

- **Procurement takes an advisory role in the purchasing process and mainly looks at the argumentation.**

"Procurement does not say that's not allowed or no, but the argumentation for purchasing does have to be sound and correct." (interviewee 2)

"I found that the procurement department really just takes on an advisory role during a purchase. So they are there to help the doctors go through the tender process because there are legal considerations in terms of fairness, transparency." (interviewee 3)

- **A shift towards a more guiding and policy-based approach for involving sustainability during procurement can be observed in hospitals.**

"We do have to take that step now. To really go much more directly, Where are the contributions to our goals? What is needed for that? And then don't let it depend on the project team that is just deciding whether they think it's important or not. We really have to go more from policy. For example, now we said, you either comply or explain. So if you don't want to follow that direction, argue why not." (Interviewee 4)

4.5.3 Current and long-term mindsets

Momentarily, the mindset of stakeholders relating the different values is still very much focused on the short-term. When assessing devices on aspects such as costs and environmental impact, total life time amounts are often not considered. An effort is being made to change this mindset.

- **In terms of cost, often only the initial investment costs are considered.**

"There is a lot of looking at initial cost, people are tunnel visioned on that but don't take into account maintenance, reprocessing, and waste." (interviewee 2)

"Suddenly you have to spend 15.000 euros, to buy 10 reusables. That is an investment. But there is a thought mistake, that it is more expensive, or it seems more expensive. So they choose the disposable" (Interviewee 5)

- **The mindset on sustainability can still be very limited.**

"I do see is a very limited view on sustainability, so, for example, only looking at the CO_2 footprint of devices itself but not the full life time or processes around it." (Interviewee 2)

- **Long-term benefits are not always considered and really need to be presented well and be backed up by evidence.**

"Long-term cost savings, when it comes to being more sustainable, using more reusable and not disposable, sometimes need to be outlined to the point that the doctors can really be convinced by it. Then, they're more likely to get on board when it's sustainable." (Interviewee 3)

"There is a misconception that when we buy more sustainable, it's going to be more expensive. And that could be true in the beginning, but when you don't have to buy new product all the time, in the long run, you do save money. So that sometimes is not quite on people's mind and they need to be convinced a little bit." (Interviewee 3)

4.5.4 Expertise and knowledge of hospital workers

Hospital workers such as doctors and purchasers do not have the time and expertise to read, analyse and draw conclusions from detailed and often complex environmental reports such as an LCA. More readable alternatives such as EPD's are explored, and a growing interest in material sourcing can be observed.

- **People working in procurement do not have the experience to look at and evaluate LCA's.**

"In regards to the role of sustainability, yes, it's important, yes, we signed the Green Deal, and yes, we have ambitions, but these do not yet really translate into the action of procurement." (Interviewee 2)

- **The is an increase in awareness and requests for transparency on material sourcing.**

"I would be interested in is where this is produced, what factory, what circumstances, and where materials are sourced. I believe that is where we are going, not even only from a sustainability focus but also from a resource scarcity focus." (Interviewee 2)

- **For longer partnerships hospitals can require manufacturers to deliver an EPD, which is viewed as more accessible.**

"For example, when we sign a multi-year contract. The winner, within two years after the grant, must deliver an EPD, Environmental Product Decoration. Such an EPD is a little more readable and more summative of the underlying LCA. Which is then also better for us inside the procurement department" (Interviewee 4)

4.5.5 Tender process

In the Netherlands, each hospital can dictate how they structure their own tender processes (up to certain financial amounts). Regarding sustainability, common practice is to request (verified) reporting on the environmental impacts of manufacturers and products and propose future plans for more sustainable improvements.

- **Before starting a tender, the market is assessed on the prominence of various aspects, such as sustainability.**

"Before a tender is started, there is a period of market research. So, someone from the procurement department, like the purchaser involved with the project, can really go to the market and ask and search around to see what is possible, what is available, and what suppliers can provide." (Interviewee 3)

- **There is an increasing trend toward standardising sustainability as a fundamental value within tenders inside some hospitals.**

"A project almost always starts with a project initiation document. There we already pay attention that sustainability is also an important topic." (Interviewee 4)

4.5.6 Values

An effort is being made to develop a more holistic, value-based procurement process. The most critical and dictating values for selecting devices and tenders are (proven) patient and personnel benefits. Other considerable factors like availability, costs and sustainability are taken in account.

- **Involving different values can complicate the process and lead to losing sight of sustainable ambitions.**

"The best thing for me is if a company does not put sustainability as much in the foreground, they introduce a device and say this is the application. This is the advantage (this should really be a priority), and then next to that, you can also say, by the way, these are the facts about our impact." (Interviewee 2)

"Where it often goes wrong is the conflicts with interests. So, weighing up patient safety, functionality, ease of use, and costs. But what ultimately remains then of your sustainability ambition? That is sometimes the most difficult." (Interviewee 4)

- **As a company the most important value to communicate is patient benefit.**

"I think as a supplier, you kind of have to showcase how you provide better patient outcomes." (Interviewee 3)

- **Through a more value-based procurement approach (Figure 19) larger investments can be argued if proven benefits relating to values such as patient outcome and sustainability are present.**

"It's also about being able to substantiate that well. Like, it's a bit more expensive, but we think it's important to do it because it contributes to our sustainability goals." (Interviewee 4)

4.5.7 External partners

Examples of external partnerships to realise sustainable and circular strategies exist. However, these are often very specific and small in scale.

- **There are existing pilots between hospitals and third-party reprocessing companies.**

"We do have a pilot now, but that is very specific. With a party that recycles single-use medical disposables for us. And then we buy them back at a discounted price." (Interviewee 4)

- **Realising these kinds of strategies is often challenging due to the large scalability requirements.**

"You often see that you run into the economic reality that you actually have to have a lot more scale. To make an alternative really recyclable, for example." (Interviewee 4)

- **A big challenge is who takes on responsibility for required logistical steps.**

"You have to pre-sterilize and keep, and then they come and pick it up that's quite logistically challenging still. In short, there are still some hands that are missing in order to start such a process." (Interviewee 5)

4.5.8 Sterilisation/disinfection

Recent years have seen an increasing trend from disposable towards reusable medical devices. However, most hospitals do not have the facilities or personnel to accommodate this increase in reusables. Because of this, compatibility and ease of reprocessing are key factors.

- **Hollow medical devices are difficult to clean/sterilise.**

"The most difficult to clean are devices with hollow shafts. These are washed by connecting water jets to the mouthpiece, but depending on the length and diameter of the shafts, successful cleaning becomes difficult." (Interviewee 1)

- **Hospital-based sterilisation departments experience difficulties with capacity and personnel.**

"We see a new shift from disposable to reusable devices. We do not adjust temperatures and program times to specific devices." (Interviewee 1)

"Nowadays, there is a very acute shortage of staff. So the capacity of our CSA is basically very good. Because it is not that old yet. So we have really built our CSA with that trend that there will be more self-cleaning and sterilisation. But the staff shortage is quite high." (Interviewee 4)

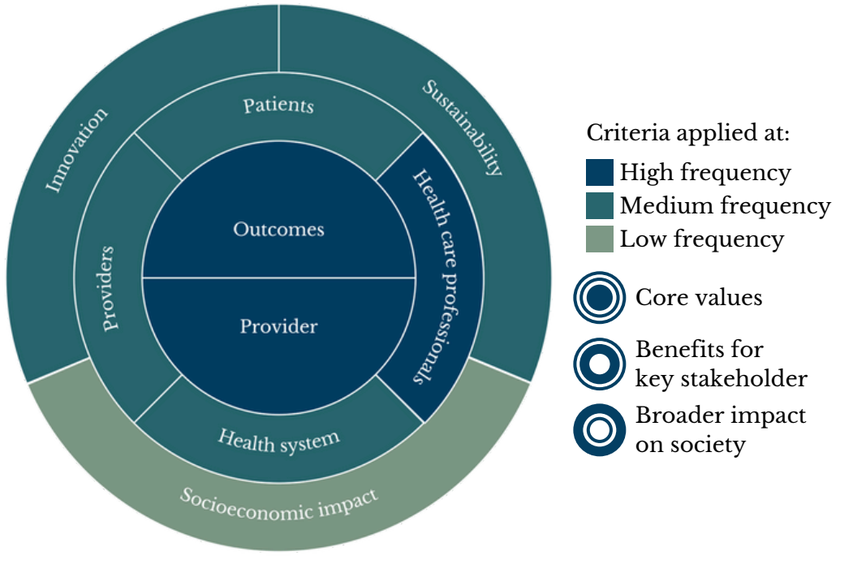


Figure 19: Value-based public procurement framework (Gerecke et al., 2022)

- **After processing, devices undergo manual checking and are repaired/discarded if appropriate.**

"Each device is manually checked on performance, damage and completeness. This allows workers to evaluate devices and log any damage or replacement of parts." (Interviewee 1)

- **Reusable trocars are used inside hospitals.**

"I generally work mostly with reusable trocars." (Interviewee 8)

4.5.9 Unused waste

The way certain medical devices are packaged or provided to hospitals can lead to an increase in waste due to the discarding of unused products.

- **A lot of unused devices are discarded because they come packaged together, but not all are required.**

"Sometimes, we get a box with six disposables. And we always use four. And then we have to throw away two. Because those are, for example no longer sterile." (Interviewee 4)

"Large manufacturers have one drive spring, and that is to sell as much as possible, with as much content as possible, so if there is a lot of stuff on it, that you don't use in the end. That is not their loss. They don't have a problem. You just have to throw it away." (Interviewee 5)

- **Complications with packaging, unclear labelling or contamination when opening, lead to the discarding of unused medical devices.**

"In terms of types of packaging, for smaller devices like trocars peel pouch packaging is quite standardised and works fine. For larger devices like the proposed tube set, blister packaging would be preferable due to contamination and handling difficulties when opening the package if using peel pouches for devices of this size." (Interviewee 6)

"The biggest issue and waste I foresee and encounter is the discarding of unused devices due to contamination when wrongfully opening the packaging or the opening of the wrong type of device due to bad labelling or confused personnel." (Interviewee 7)

4.5.10 Verification proposed strategies

There is potential for decreasing material waste and environmental impact by developing (hybrid) reusable devices, optimising device properties, creating mono-material recyclable devices and using recyclable packaging.

- **Most impacts can be avoided by implementing changes in the design phase.**

"It is good that you look at it straight from the design phase. Because there you already have 80% of the impact. If a product is well designed, or with materials that can be recycled well, or can be reused well, it can be a lot more sustainable." (Interviewee 4)

- **To convince users to adjust their workflow or slightly sacrifice usability, the gained benefit should be really clear and proven.**

"If you can really say things with integrity, with evidence backing saying okay, we can cut the tube a little bit shorter, and it really has a benefit for the environment, and it does not compromise patient safety and the quality of the instrument, then I think that's a good way to get hospitals on board." (Interviewee 3)

- **Tube length can potentially be shortened but should not go below 2.5 meters.**

"In terms of tube length, the standard size is 3 meters, but we do sometimes use tubes of 2.5 meters. These are, however, not optimal. Although a slight decrease in length +- 10 centimeters should be fine." (Interviewee 6)

"Interesting and fun to do a small study into different lengths of insufflation tubes. Could test various surgical setups and see what the minimal required lengths are." (Interviewee 8)

- **Thinner tube walls are more standard and can actually be preferable.**

"Thicker or thinner? That is certainly possible the only thing you have to look at is the nicking as long as it does not bend then everything is possible." (Interviewee 5)

"In terms of insufflation tubes, more flexible and lighter tubes are more attractive from a usability standpoint as the tubes are moved around the connected trocars during surgeries." (Interviewee 6)

- **Potential to recycle tube set since contamination risk is relatively low. However, should really be made mono-material.**

"This (tube) is not super contaminated, you could use this as recyclable plastic, but then you need to be able to remove different parts easily. But then you ask people to remove this or that, so if you could make it out of one type of material where the whole can be thrown away or recycled, I would say its better." (Interviewee 5)

- **Packaging materials are commonly recycled inside some hospitals.**

"Packaging material, when possible, gets separated for recycling at the Erasmus MC" (Interviewee 6)

Key insights

Which stakeholders play a role of importance in the life cycle of the Spatium insufflation system?

- Various stakeholders were identified and divided into five groups. Stakeholders belonging to the procurement, OR staff (surgeon(s) and nurses), green teams and CSA groups were engaged in empirical interviews as these were identified as vital for developing and implementing sustainable strategies.

What are the key values of the identified stakeholders and how do these relate and conflict with each other?

- Four key values were identified, health outcome, compatibility, cost and sustainability. Interview findings indicated that health outcome and compatibility are considered most critical by hospital staff when purchasing new devices, while the importance of sustainability is rising.

What barriers and insights do these stakeholders experience in practice?

- Some of the biggest barriers preventing sustainable developments are: lack of understanding between hospitals and device manufacturers on sustainability, lack of assessing costs and impacts on the long-term (full life cycles), capacity or staff limitations, lack of standardisation and difficulty of balancing potentially conflicting values.

B

Define

CHAPTER 05

Design scope

This chapter uses the key findings from the previous chapters 2-4 and chapter 6 to formulate and prepare evaluation requirements and design guidelines for the later design phase (chapter 7). The circular strategies identified as relevant in chapter 3 serve as a foundation to evaluate the current disposable patient kit and identify opportunities for improvement.

In this chapter:

Key topics:

- What are the must-meet requirements for devised strategies?
- How can proposed strategies be compared and assessed based on potential gains and required investments?

5.1 General findings

While later parts of this chapter discuss guidelines specific to selected strategies, some findings from research must be applied throughout all life cycles of the patient kit (Figure 20). These findings have been translated into general requirements and guidelines. Any selected strategy must meet all set requirements since not doing so would make the device a hazard or unsafe for patients and surgeons. Additionally, the guidelines serve as a way to compare different strategies and concepts. Scoring low on a set guideline does not necessarily mean a strategy cannot succeed. Instead, it indicates that the strategy is less desirable in line with these guidelines.

Catagory	Finding	Requirement (Rq) and Design guidelines (Dg)
Safety	• Patient and surgeon safety (health outcome) is a key decider for use and adoption of medical devices	**Rq:** The patient kit is safe to use for both patients and surgeons
Performance	• Succes of the Spatium insufflator depends on the device performance	**Rq:** The functionality and performance of the patient kit and insufflator are not affected by implemented strategies
Work effort	• Surgeries are often time sensitive and all OR staff have specific dedicated roles	**Rq:** The implemented strategies do not hinder existing workflows of OR staff
Compatibility	• Compatibility with existing workflows can be a major benefit and key decider for adoption of devices	**Dg:** The patient kit is compatible with existing workflows inside hospitals and ORs
Wide application	• Available facilities and resources can very across different hospitals, creating standardised strategies is desirable	**Dg:** Devised strategies can be generalised for (many) different hospitals
	• Strategies which are applicable beyond Spatium can set an example for all medical device manufacturers	**Dg:** Devised strategies are applicable beyond the scope of Spatium
Circularity	• Shifting from linear to circular life cycles can help achieve sustainable healthcare goals	**Dg:** The lifetime of the patient kit is extended as much as possible
Business	• To implement sustainable strategies they must be viable from a (circular) business perspective	**Dg:** Devised strategies are profitable for Spatium

Table 3: Requirements and guidelines based on findings chapters 3 and 4

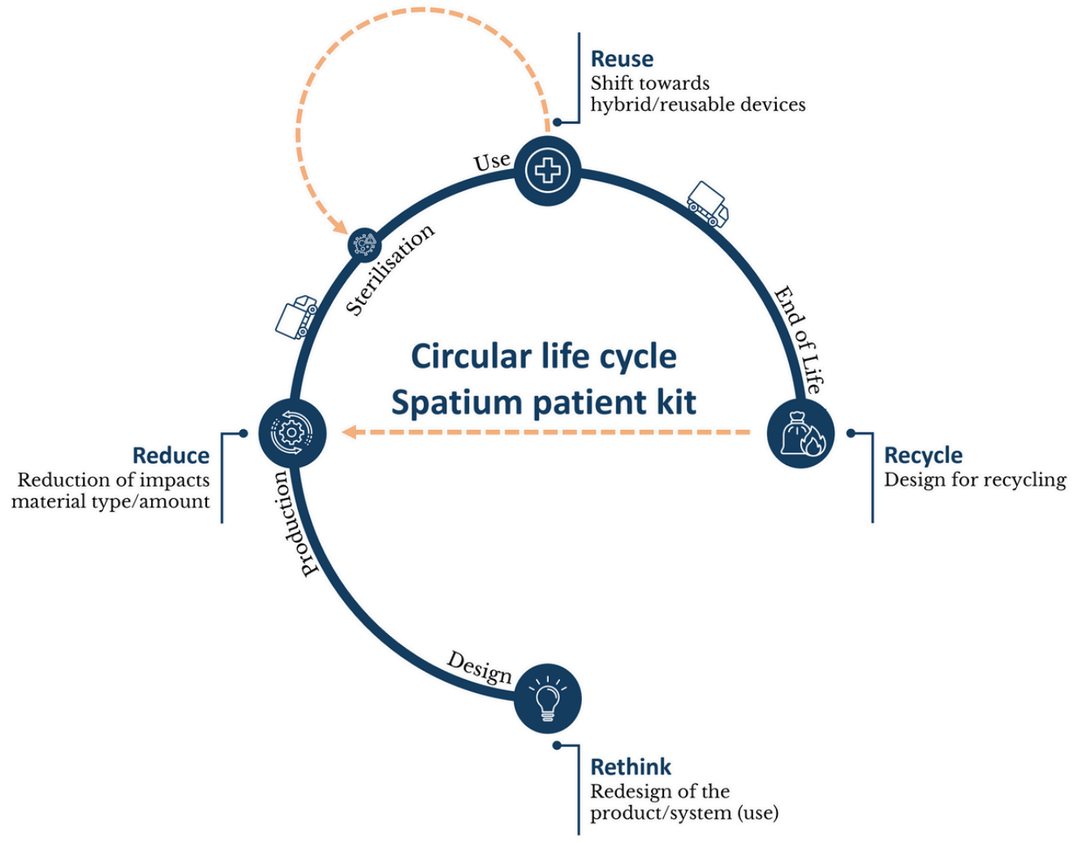


Figure 20: Circular analysis Spatium patient kit with selected strategies

5.2 Circular strategy rethink

The design phase is a critical step in the development of products. It is estimated that 80% of all product-related environmental impacts can be influenced during this phase (Su, 2020). Strategies from the rethink category can be applied here to redesign products and the way we approach products (Figure 21). This is also the life cycle phase where Spatium as a company can have the most control over the execution and application of selected strategies. Using findings from interviews and context research, the following guidelines were identified for evaluating rethinks strategies:

Catagory	Finding	Design guidelines (Dg)
Unnecessary use	• Misinterpretation of products and between users can lead to unnecessary opening (discarding) of products	**Dg:** Avoid unnecessary use (waste) of products/materials
Product lines	• Device properties are often tailored to the most extreme use scenario (setup)	**Dg:** Offer various product lines for different use applications/scenarios

Table 4: Design guidelines based on findings chapters 3 and 4

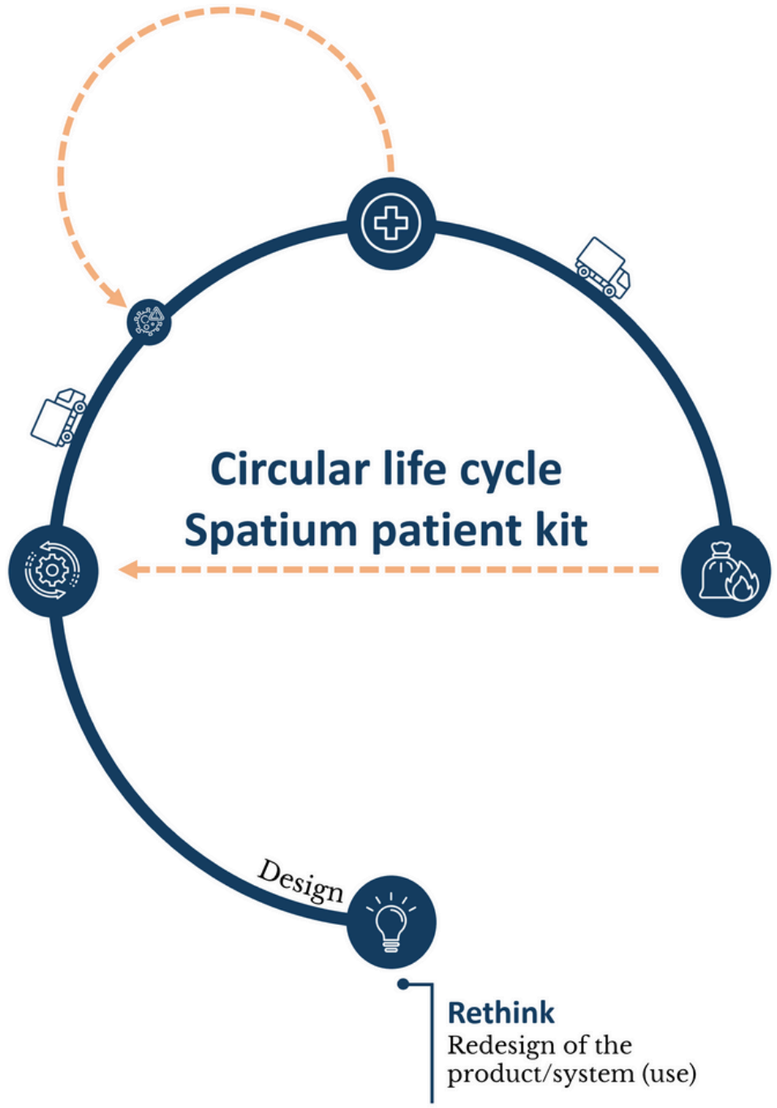


Figure 21: Rethink strategy within the life cycle of the Spatium patient kit

5.3 Circular strategy reduce

Reduce is another majorly impactful strategy since the effects of applying this strategy are primarily implemented in the production phase (Figure 22). By selecting lower-impact materials and decreasing the amount of material used, the overall impact of products in all following life cycles can be brought down. Using findings from the LCA assessment and context research, the following guidelines were identified for evaluating reduce strategies:

Catagory	Finding	Design guidelines (Dg)
Material impacts	• Producing the materials for the patient kit is one of the most impactful life cycle phases	**Dg:** Use low CO_2 impact materials
Material quantity	• Product properties such as tube length and wall thickness can be optimised to specific use cases to lower material input	**Dg:** Optimise product/component properties (minimal viable)
Packaging	• Sustainability can be a deciding factor when selecting packaging option for the tube set	**Dg:** Optimise impacts of packaging
Care pathway	• Spatium's innovative device can potentially lower the impacts across an avarege patients care pathway	**Dg:** Lower impacts overall care pathway

Table 5: Design guidelines based on findings chapters 2, 3, 4 and 6

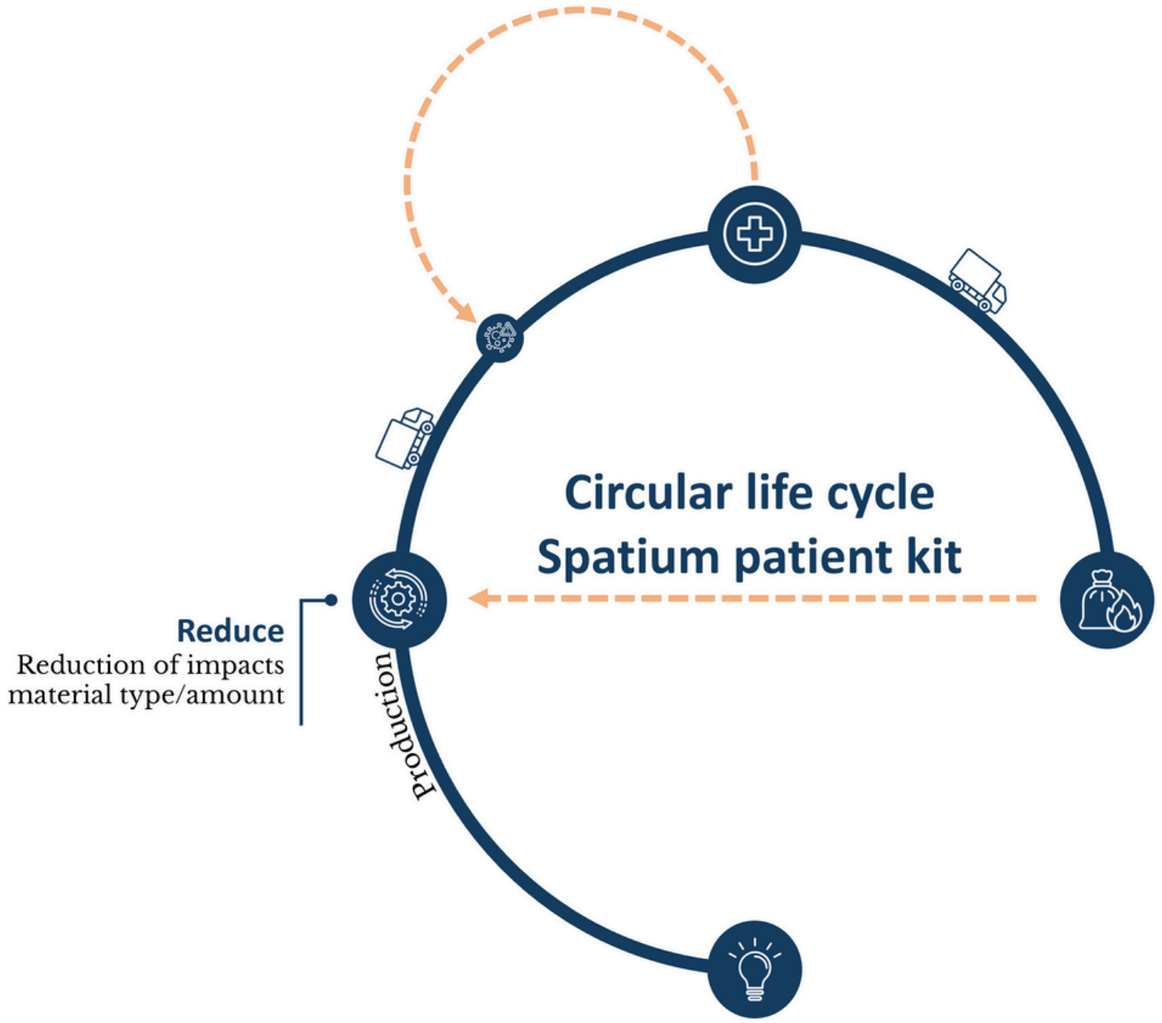


Figure 22: Reduce strategy within the life cycle of the Spatium patient kit

5.4 Circular strategy reuse

While reusing medical devices is becoming more prominent, the potential of these strategies is very context-related. Effects and results can heavily vary depending on reprocessing techniques and facilities. Still, implementing these strategies can greatly extend the use phase of existing products (Figure 23) and lower the need for new products. Using findings from interviews and literature research, the following guidelines were identified for evaluating reuse strategies:

Catagory	Finding	Design guidelines (Dg)
Sterilisation	• The cassette (filters), twin tubes and trocar are all require sterilisation before use	**Dg:** Sterilise or disinfect (reusable) parts according to Spaulding classification
Separation components	• Components requiring sterilisation or disinfection are separately sorted post use when possible	**Dg:** Critical components should be easily and safely separable for reprocessing
Trust	• When applying reprocessing stakeholders should keep trusting the product	**Dg:** Patient and surgeons trust the reprocessed patient kit

Table 6: Design guidelines based on findings chapters 3 and 4

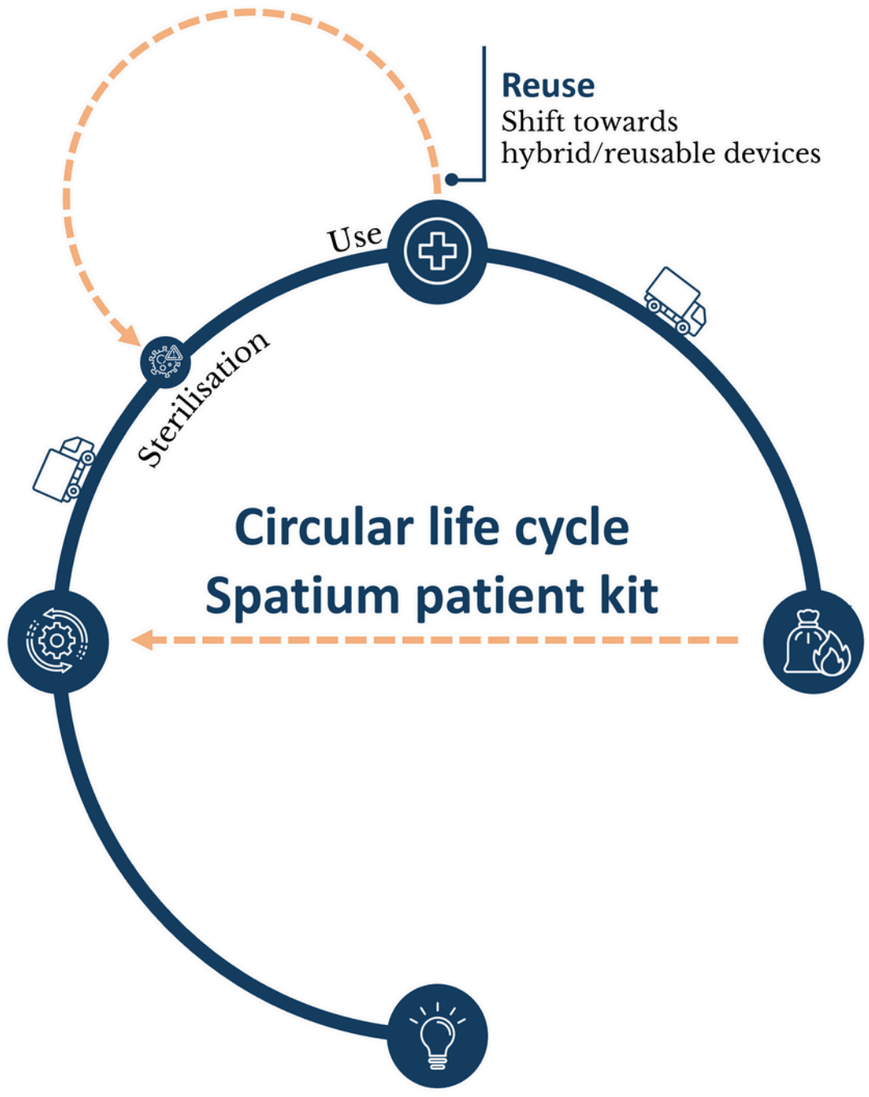


Figure 23: Reuse strategy within the life cycle of the Spatium patient kit

5.5 Circular strategy recycle

As previously established in chapter 3, recycling is likely a long-term strategy due to the more significant investment needed to create worthwhile effects than other strategies. However, by already implementing a design for recycling approach for the EoL phase of the current patient kit (Figure 24), the eventual realisation of such strategies can be made more accessible. Using findings from the existing tube set assessment and context research, the following guidelines were identified for evaluating recycle strategies:

Catagory	Finding	Design guidelines (Dg)
Mono-material components	• Current tube set designs use seven different and mixed plastic types, which makes recycling difficult	**Dg:** Reduce the variety of materials in the patient kit by making more (recyclable) mono-material components
Fixed connections	• Components such as the filters, twin tube and cassette are currently inseparable due to fixed connections	**Dg:** Avoid the use of fixed connections between different material components
Electronics	• Some tube set versions have glued on electronic components creating electronic (high value) waste	**Dg:** Make electronic components easily accessible for recovery

Table 7: Design guidelines based on findings chapters 3, 4 and 6

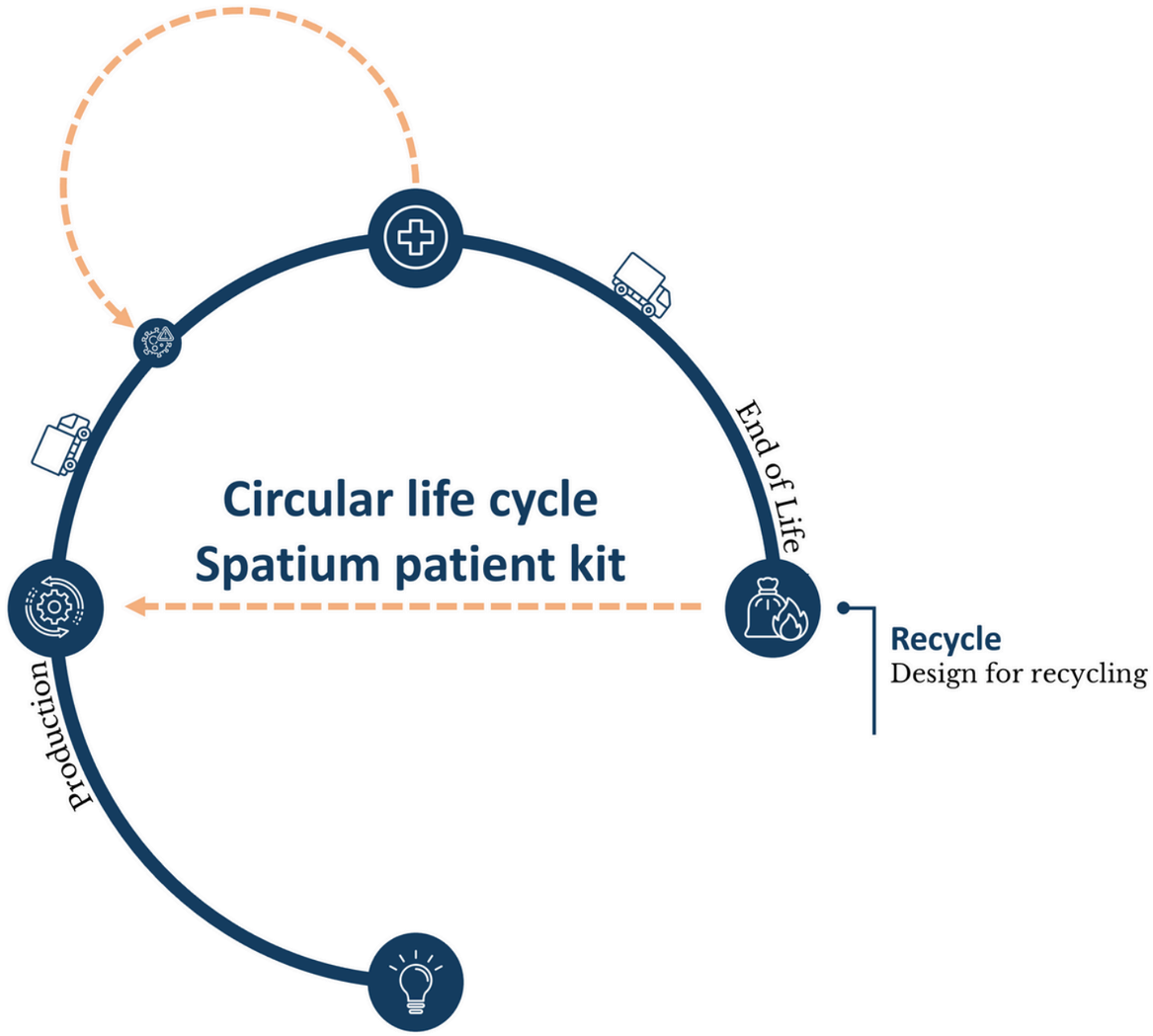


Figure 24: Recycle strategy within the life cycle of the Spatium patient kit

Key insights

What are the must-meet requirements for devised strategies?

- Three hard cut-off requirements for potential sustainable strategies have been identified. As a consequence of implementing any proposed strategy the device can under no circumstance become unsafe for patients and users, be effected in its performance or significantly hinder OR workflows.

How can proposed strategies be compared and assessed based on potential gains and required investments?

- Design guidelines for relevant R ladder strategies have been formulated. These guidelines will be used to compare strategies and select those with the highest potential.

C

Develop

CHAPTER 06

Assessment current patient kit

This chapter assesses the environmental impact of the current patient kit by combining existing LCA studies with a self-executed fast track LCA. The scope and boundaries are discussed. Finally, the results are presented for relevant impact categories, and the most significantly impactful life cycle steps and components in the tube set are identified. This assessment serves as a foundation for later development and circular intervention selection.

In this chapter:

Key topics:

- How big is the impact of the Spatium tube set in line with relevant impact categories?
- What life cycle stages can be identified as environmental hotspots for the Spatium tube set?
- What components and parts can be identified as environmental hotspots inside the Spatium tube set?

As concluded from the initial big picture assessment of laparoscopy and insufflation inside chapter 2, disposables were identified as the largest contributing factor to the overall environmental impacts. For this reason, a more extensive and detailed fast track LCA assessment of the disposables inside the Spatium patient kit has been conducted. The purpose of this LCA is twofold:

- First, the goal is to identify which components and life cycle steps of the patient kit are the largest contributors to the overall impact. Marking these as potential areas for improvement and using them as input for later ideation.
- Second, to serve as later validation of developed strategies and concepts. The results of this LCA will create a baseline with which potential impact-saving strategies can be compared to assess the gained benefit.

6.1 Life cycle assessment

ISO lists the following definition of LCA: “Compilation and evaluation of the inputs, outputs and the potential environmental impacts of a product system throughout its life cycle” (ISO 14040:2006(En), n.d.). The ISO standards outline a certified framework to follow when creating an LCA. This framework includes four main steps (ISO 14040:2006(En), n.d.):

1. Goal and scope definition:
“Phase of life cycle assessment in which the aim of the study, and in relation to that, the breadth and depth of the study is established”
2. Inventory analysis (LCI):
“Phase of the life cycle assessment involving the compilation and quantifications of inputs and outputs for a product throughout its life cycle”
3. Impact Assessment (LCIA):
“Phase of life cycle assessment aimed at understanding and evaluating the magnitude and significance of the potential environmental impacts for a product system throughout the life cycle of the product”
4. Interpretation:
“Phase of life cycle assessment in which the findings of either the inventory analysis or the impact assessment, or both, are evaluated in relation to the defined goal and scope in order to reach conclusions and recommendations”

Because the Spatium products do not yet exist on the market and are still undergoing design changes during development, the choice was made to combine the results of three existing LCA studies (Boberg et al., 2022; Lalman et al., 2023; Rizan & Bhutta, 2021) on comparable devices or processes present in the patient kit with a self-executed fast track LCA based on current prototypes and designs. The studies of Boberg (2022) and Rizan & Bhutta (2021) were used to gather results for comparing disposable, reusable and hybrid trocar systems, results are further discussed in chapter 7.4, and data on the impacts linked to autoclave sterilisation processes. This route was chosen since definitive trocar dimensions were unknown at the time of the project. However, the comparison between various trocar systems in the mentioned studies was deemed sufficient for the purpose of this project. Lalman's study (2023) was used to gather data on Ethylene Oxide (EtO) sterilisation since this is the currently assumed route of sterilisation for the disposable patient kit.

Spatium is currently developing five optional tube sets, Tube set A through E (see Appendix C for an overview and description of the proposed Spatium tube set options). For the purpose of this project two of these tube sets, tube set B and tube set D, were explored on the basis of their expected environmental impact. After discussion with Spatium tube set B was designated as the most representative and used as the baseline for the self-executed LCA (Spatium Medical, personal communication, 2024). For accessibility reasons, the OpenLCA 2.3 software and the Idemat2023 database were selected for modelling the fast track LCA as professional software and databases like SimaPro or ecoinvent were unobtainable.

6.2 Scope

The tube set LCA evaluates the environmental impact of a single tube set B used for laparoscopic surgery. The analysis covers the product life cycle from cradle to grave (Figure 25). The most important impact factor, global warming potential (GWP), is expressed in kilogram carbon dioxide equivalent (kg CO_2-eq). CO_2-eq is a metric which merges the emissions of different greenhouse gases based on their individual GWP and expresses them to the equivalent amount of CO_2 (Eurostat, n.d.). Noteworthy boundaries set inside the LCA are the exclusion of transport impacts from the raw material production site to the component manufacturing site since this data could not be obtained. The exclusion of impacts related to intermediate and final packaging since no definitive selection on the packaging was made at the time of executing the LCA (packaging options are separately assessed and discussed later in chapter 7.6). And the exclusion of impacts during the use phase of the tube set since these are assumed to be nonexistent.

Figure 25: Life cycle flow model LCA tube set

Using the Idemat2023 database means that inputs are primarily based on European data. However, since most of the life cycle processes take place in Europe, this was deemed acceptable. The Erasmus MC (operating location of Spatium) was selected as the location for the tube set to be used. In reality, this could be any hospital in the world, meaning the impacts of transport can vary depending on this. Some material data was adjusted since not all materials used in the tube set were represented in the Idemat2023 database. Any assumptions made here were supported by rationale and mentioned in the full LCA report, which can be found in Appendix D. Finally, for the EoL allocation, assuming incineration of all components. A manual calculation was made for the GWP of this life cycle step, as Idemat2023 only allows for modelling municipal incineration, and it was found that for specific hospital waste incineration, the CO_2 emissions are significantly higher (Leone et al., 2024).

LCA are heavily dependent on the quality of collected data. The input data used for tube set B in this LCA is derived from existing component prototypes at the time of execution. All prototypes were weighed, and linked input data was reported in the LCI (Appendix D). Impact categories for reporting results were selected to align with the mentioned impact factors in the "*Impact Programma van Wensen Erasmus MC*" document (Procurement Erasmus MC, personal communication, October 4, 2024) and the project objective of identifying environmental hotspots, reducing carbon footprint and designing circular strategies.

6.3 LCA results

Figure 26 shows the results of the fast track LCA analysis of tube set B for the selected impact categories. Looking at the figure, it can be observed that the life cycle step EoL (incineration) results in negative impacts for some of the selected categories. This is due to the way the Idemat2023 software calculates the EoL cut-off. The modelled process for these impact categories assumes heat recapture during incineration. Because of this, Idemat assigns "credit" in the form of a negative impact on these categories. Heat recovery during incineration processes is not uncommon, especially in more developed countries, so for this fast track LCA, it was deemed a reasonable assumption.

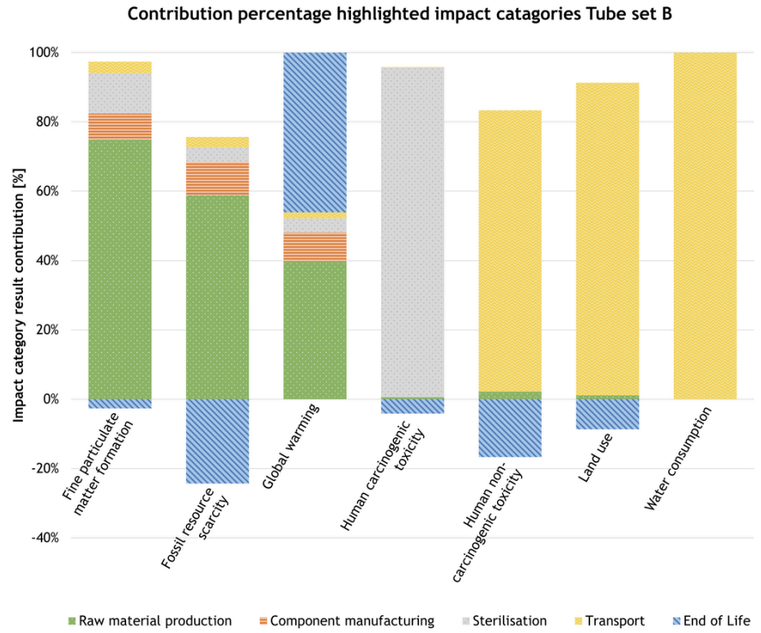


Figure 26: Contribution of life cycle steps to selected impact categories

The GWP impact category is the most interesting, as it aligns best with those selected in previous studies and this project's main objective of identifying environmental hotspots and opportunities for circular interventions. It can be observed that the majority of impacts within this category are linked to the life cycle steps of raw material production and EoL incineration. Thus, when aiming to improve this category, any thought of strategies and interventions should prioritise addressing the impacts caused by these life cycle steps.

Looking at some of the other impact categories like fine particulate matter formation and fossil resource scarcity, the raw material production step is logically the most significant contributor. Thus, when aiming to address these categories, developed strategies should focus on lowering the impact of this life cycle step. For the human carcinogenic toxicity impact factor, the sterilisation life cycle step is the most impactful. This is due to the use of toxic EtO gas. Optimising the sterilisation cycle or changing to another process like autoclaving should address this life cycle step's significant impact within this category. Finally, the transport life cycle is the most impactful for the human non-carcinogenic toxicity, land use, and water consumption categories. Thus, when aiming to address the impacts within these categories, a focus should be put on minimising or optimising the effects of transport through the lifetime of Spatium's products.

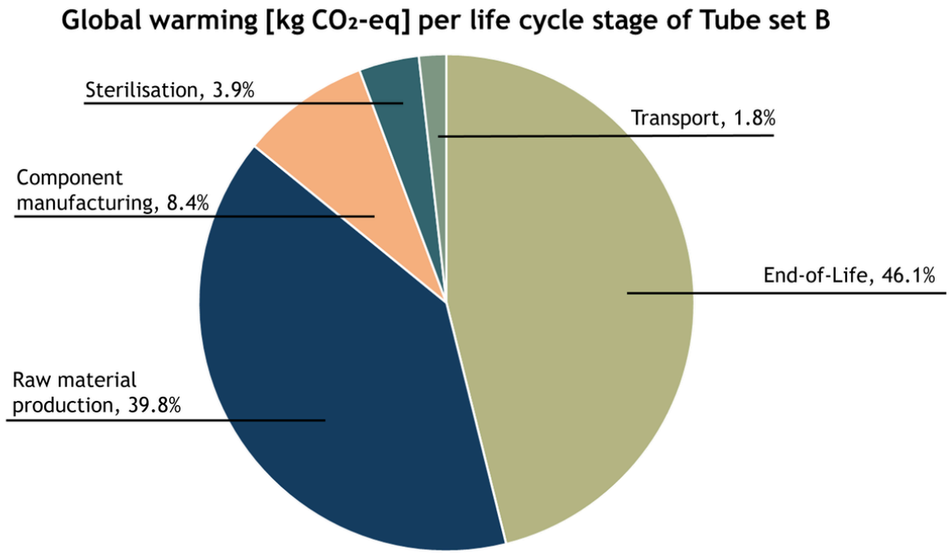


Figure 27: Contribution percentage of modelled life cycle steps to GWP tube set

6.4 GWP tube set

As stated, the main impact factor of interest is the GWP, as this was found to be the most reported and important for quantifying environmental impacts in communications. Figure 27 showcases the contribution of the five life cycle steps to the overall GWP of tube set B. It can be observed that EoL and raw material production are the two most significantly contributing life cycle steps. This is in line with the earlier identified high potential of applying strategies such as rethink, reduce and reuse to the patient kit, as all of these strategies often lead to a decrease in the initial amount of (high impact) raw material produced or required and the amount of waste material generated over a set period. It should be noted that decreasing the amount of impactful material used in the product also lowers the GWP of the other three life cycle steps, as all are calculated using inputs based on material weight and amounts

Beyond knowing what life cycle steps are most impactful, it will be valuable to determine which components and parts of the patient kit contribute most significantly to the overall impact of tube set B. Figure 28 shows the GWP impact of the components and parts inside tube set B. Notably, the connector components and RFID tag are left out of this figure as their total GWP impact was below 0.1 kg CO_2-eq due to their low material weights (their designated impacts are reported in the full LCA report in Appendix D). The results show that the twin tube is responsible for the majority, over 70%, of the GWP impact caused by the tube set. After this, the most impactful are the cassette housing, overmould, and filters in that designated order. These three individual components in the final design are all built into each other, so any potential designed or thought-off interventions would likely affect all three components. In line with Figure 27, the life cycle steps of EoL and raw material production contribute most significantly to the overall impact of the individual components and parts.

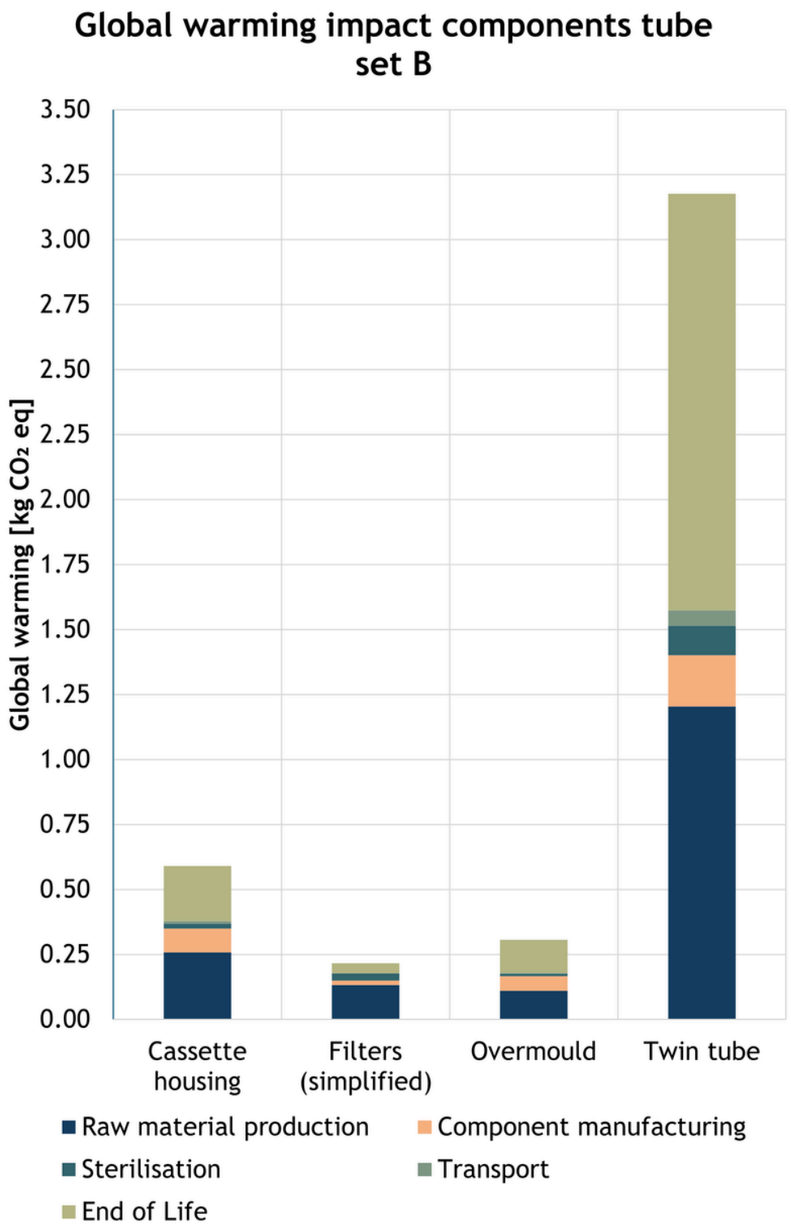


Figure 28: Environmental impact components of a single tube set B per life cycle (RFID and connector components were left out as their total impacts were < 0.1 kg CO_2-eq)

Key insights

How big is the impact of the Spatium tube set in line with relevant impact categories?

- The total impact for all relevant impact categories has been calculated and can be found in the detailed LCA report in Appendix D. The GWP of a single tube set B is approximately 4.44 kg CO_2-eq.

What life cycle stages can be identified as environmental hotspots for the Spatium tube set?

- The life cycles EoL incineration and raw material production have been identified as the most impactful, with a GWP of approximately 1.98 kg CO_2-eq and 1.71 kg CO_2-eq, respectively. Optimising the impact caused within these two life cycles will likely also lower impacts in the other three.

What components and parts can be identified as environmental hotspots inside the Spatium tube set?

- The twin tube most significantly contributes to the overall impact of the tube set with a GWP of approximately 3.18 kg CO_2-eq. Most of the remaining impact comprises the different parts in the cassette, including the housing, overmould, and filters.

CHAPTER 07

Deep dives

This chapter presents the designed strategies for Spatium based on findings from previous chapters, a creative session with engineers at Spatium and executed design sprints. First, the applied methodology is explained, followed by a deep dive into selected strategies for improving the environmental impact of the Spatium patient kit.

In this chapter:

Key topics:

- What are circular strategies and interventions Spatium can develop in the short, medium and long-term to lower their environmental impacts?

7.1 Method

The output and results from all project work so far, including the literature research, interviews and LCA assessment, have been used as input to generate ideas for sustainable interventions and solutions to be applied by Spatium. To do this a creative facilitation session (Heijne & Van der Meer, 2019) was hosted, participants included engineers and designers at Spatium. The session followed the following setup (the complete session plan with descriptions of all activities can be found in Appendix E):

- Introduction and background
- Purge on the provided problem statement
- Brainwriting 4.3.5 (Diverging)
- Spontaneous clustering (Reversing)
- Hits or dots (Converging)

Results from this session (Appendix F), mainly comprised of low-level descriptive ideas, were combined with self-thought-of ideas collected throughout the project and existing solutions discovered during research. Using the appropriate requirements and design guidelines outlined in chapter 5, a selection of ideas was discussed with Spatium (initial ideas that did not comply with the three must-meet requirements were excluded). Due to time constraints within the project, exploring or working out each of the resulting ideas was impossible. Thus, in agreement with Spatium, a selection of the six most promising ideas or directions for sustainable strategies were chosen to be developed further in dedicated deep dives.

Each deep dive provides a rationale for selecting or pursuing the strategy, a description of the strategy, research into the context of the strategy or similar existing strategies and validation for desirability, viability and feasibility of the strategy through findings from interviews or comparing proposed intervention impacts with results of the LCA assessment.

Additionally, strategies are mapped as either short, medium or long-term. A short-term strategy means potential for direct implementation. A medium-term strategy requires some level of development of existing technologies or innovations for implementation. In contrast, long-term strategies would require developing new technologies or systems to implement the strategy.

7.2 Twin tube optimisation

The LCA analysis of tube set B identified the twin tubs as a major environmental hotspot within the system. The combined life cycle impacts of the twin tube account for over 70% of the total global warming impacts associated with the tube set. These findings provided a strong basis for prioritising and developing strategies to reduce the environmental impacts of the twin tube. Two of the mapped circular R-strategies were considered:

- **Reuse**: Transitioning to reusable silicone tubing (see chapter 7.4).
- **Reduce**: Optimising the product properties.

Optimising the twin tube properties to reduce their overall impact offers a key advantage by directly addressing the source of the environmental impacts. This approach allows for impact reductions through design modifications, removing the need to implement additional circular flows. As a "short-loop" R-strategy, reduce is particularly desirable, as it is less energy-intensive and potentially more cost-effective than alternatives.

Two product properties were identified as actionable for optimisation. The first is the length of the insufflation tubing, currently set at 3 meters. The second is the wall thickness of the tubing, which is 2 millimeters in the current design.

Tubing length

The current standard length of 3 meters was determined based on existing market standards and a risk assessment conducted by Spatium. However, shorter tubing lengths are available and offered by various competitors (*Insufflation Tube | KARL STORZ Endoskope | United States*, n.d.; Richard Wolf GmbH, n.d.; *Wisap*, n.d.).

Insights obtained during a study with an OR nurse from the Erasmus MC revealed that a shortened tube measuring 2.5 meters is currently used inside the hospital. Further research and interactions with OR staff, including a surgeon, highlighted the importance of sufficiently long tubing to accommodate diverse surgical setups, with an optimal length of around 3 meters. Nonetheless, when asked multiple staff members suggested that a slight reduction in length would not compromise the viability of the tubes. Based on existing tubing lengths and feedback from OR staff, a minimum viable length of 2.5 meters was established.

Model scenarios were developed for tubing lengths ranging from 2.5 to 3 meters in 10-centimeter intervals to evaluate the potential reductions in environmental impacts and material usage (Figure 29).

Wall thickness

Unlike the tube length, where 3 meters is the common market standard, the Spatium tube thickness at 2 millimeters is slightly greater than that of the tubes commonly used at Erasmus MC, which measure 1.5 millimeters in thickness. The primary rationale for producing thicker tubes is to reduce the risk of kinking during transport, storage, and use.

While it is true that increased thickness mitigates the risk of kinking, there are more factors to consider. Insights from a usability study conducted with an OR nurse revealed that the current Spatium tubes were perceived as heavy and clumsy compared to the standard tubes they frequently use. Additionally, it was emphasised that during procedures, the tubing is often repositioned around the connected trocar by surgeons or other staff. Consequently, slightly lighter and more flexible tubing may be preferable. A solution to combat the risk of kinking at a lower wall thickness could be a conjoined double-tube design, where the twin tube are joined for a significant portion of their length. Such a design inherently reduces the likelihood of kinking, as both tubes must collapse simultaneously rather than a single separate tube. An additional advantage of this solution is that it limits the amount of separate tubes present in the OR during a procedure.

Two scenarios were modelled to assess the potential impacts of adjusting wall thickness. A base scenario with a thickness of 2 millimeters, as per the current Spatium design, and an alternative scenario with a reduced thickness of 1.5 millimeters more in line with tubes currently used in the OR (Figure 29).

Impact validation

The twin tube is modelled at two different wall thicknesses, a thickness of 2 millimeters and a thickness of 1.5 millimeters. Both configurations were analysed for tube lengths ranging from 3 to 2.5 meters.

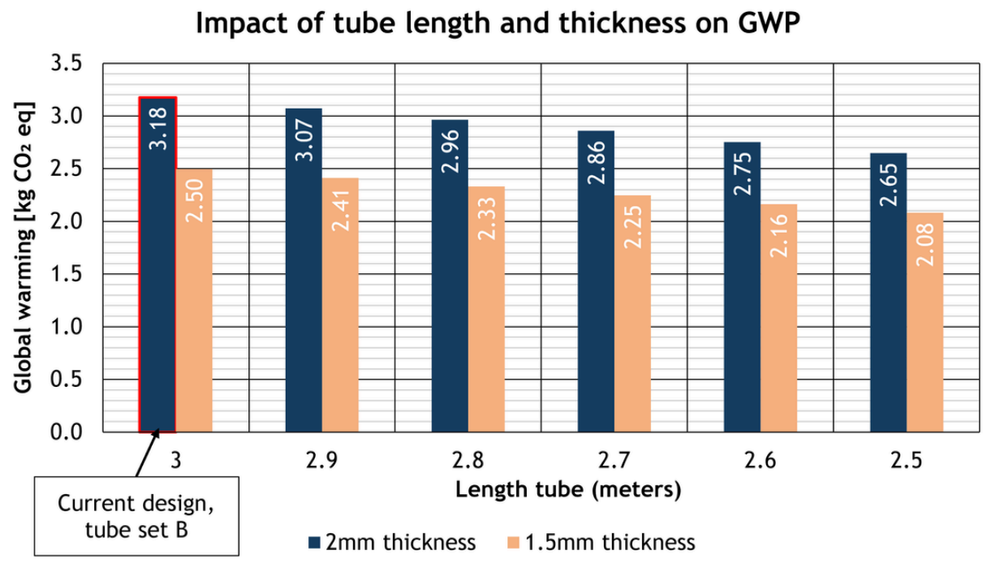


Figure 29: Bar chart comparison global warming impact (GWP) of varying tube lengths and wall thickness

Figure 29 illustrates the results of this analysis. The first bar represents the base scenario of tube set B, which is 3 meters in length and 2 millimeters in thickness. The chart indicates that the GWP impact of the twin tube decreases proportionally as the tube length is reduced. Notably, the reduction in wall thickness has a greater impact than a change in length. The 3 meter tube with a 1.5 millimeter thickness still results in a lower environmental impact than the shortest 2 millimeter thick tube. The change in wall thickness alone reduces the impacts of the twin tube by approximately 20%.

The most optimal scenario, featuring a tube length of 2.5 meters and a wall thickness of 1.5 millimeters, shows an overall reduction of approximately 35% in the twin tube impact compared to the base scenario. When considering the impacts of other components in the tube set, which remain unchanged, this optimisation results in a total decrease of around 25% in the overall impact of the entire tube set relative to the base scenario.

Another significant advantage of applying these strategies is the reduced amount of plastic waste generated. Using projected sales data provided by Spatium (Spatium Medical, personal communication, 2024), it is estimated that by the end of year 3 post-market introduction, the most optimal combination of tube length and thickness could save over 17,000 kilograms of plastic waste. This is equivalent to the weight of 12 average cars. Given the projected exponential growth in sales, this number is expected to more than double in year 4 alone.

Next steps

It has been established that the twin tube is a major contributor to the overall environmental impact of the patient kit. Furthermore, optimising component properties such as length and thickness has been demonstrated to be viable and desirable for impact reduction. Moving forward, testing and validating the feasibility of the proposed modifications is crucial. Three key actions have been identified for implementing the proposed strategy:

- **Validate and test product integrity (tube kinking) with the proposed thinner tube wall.** If necessary, strengthen the material to accommodate the reduced wall thickness.
- **Evaluate the usability of shortened tubes through scenario testing.** If feasible, determine the optimal tube length.
- **Finalise and agree on changes with manufacturers** to produce the newly modified twin tube.

A significant advantage of this strategy is its relatively low implementation complexity and costs. Apart from the tests and verifications listed above, making these changes does not require modifications to other components of the patient kit, making the strategy both achievable and potentially realisable in the short-term.

Finally, as previously highlighted, altering the tube's thickness has a greater environmental impact than adjusting its length, and therefore, this change should be prioritised. If shortening the tube length proves challenging, Spatium could consider offering tubes in varying lengths, allowing surgeons to choose the optimal tube length tailored to the specific requirements of their procedures. However, it should be noted that some interview findings indicated that offering various tube lengths could result in surgeons always requesting the largest available length for all scenarios since having one guaranteed option that always suffices is easiest for them.

7.3 Cassette optimisation

Following the twin tube, the LCA results indicated that different parts inside the cassette, the housing, overmould and filters caused the most considerable GWP impact. These parts' combined life cycle impacts accounted for approximately 30% of the GWP impacts associated with the tube set. Thus, solutions for addressing this large part of the overall impacts were ideated, and two intervention strategies have been explored:

- **Swappable filters:** Exploring a potential scenario where only the filters would be disposed of, and cassette housing would become reusable.
- **Material optimisation:** Selecting low-impact materials.

Creating a cassette design where users could swap out filters post procedures would allow the cassette housing to be reused after undergoing some level of disinfection. While such a solution is more challenging from an engineering and logistics perspective, implementation could lead to a reduction in the amount of generated waste and impact related to production as the cassette housing would likely be reused for a large number of procedures since it is unlikely to encounter wear and tear in its use function.

Alternatively, or in combination with the swappable filters, the impact of parts and life cycles can be reduced by optimising the cassette's component properties. The use of potentially lower-impact materials is interesting to explore here. Logically decreasing the size of the cassette itself would also reduce impacts related to this component, but this was not investigated during this project as no definitive sizing of the cassette was determined at the time of execution.

Swappable filters

In the current design, the filters are locked inside the cassette housing. However, since the filters are the only part of the cassette construction that comes into contact with the gas in and out flow, according to the Spaulding scale (*Spaulding Classification | Nanosonics*, n.d.), these would also be the only part that needs resterilisation before reuse. Resterilising filters through processes commonly present inside hospitals is currently impossible due to material and process conflicts.

A solution where filters could be swapped out post-procedure and replaced with new filters would allow the cassette to be reused and potentially even recycled at EoL. While this means that the filters themselves and potentially the overmould when present would remain single-use and disposable, the cassette housing would become reusable after undergoing some low-level disinfection, which is compatible with the current design and can be done inside most existing hospitals.

However, one of the considerable challenges of this strategy is introducing the additional step of removing the contaminated filters post-procedure and replacing these with new filters. This handling likely falls to either OR staff or CSA workers, who would remove contaminated filters post-procedure and place new filters inside the cassette housing post-low-level disinfection. Interactions with various stakeholders indicated that introducing new handlings or steps into the workflow of any of these stakeholders is not preferable. Thus, when doing this, these new handlings would need to be optimised to become as low effort as possible, and the potential of gained benefits would need to be proven and presented well to convince these stakeholders. A model scenario comparing the impact of a fully disposable cassette and a cassette where only the filters (and overmould) remain disposable was developed for use in up to 100 procedures at different intervals to evaluate the potential reduction in environmental impact and material usage (Figure 30).

Material optimisation

Another way to lower the impact of the parts and components inside the cassette would be to select lower-impact materials. While doing this for the filters and overmould is extremely difficult and likely impossible due to specialised material needs of these parts, the cassette housing material could be adjusted. The current design assumes virgin Polycarbonate (PC) will be used for the housing. Other commonly used plastics for medical devices, such as Polypropylene (PP), High-Density Poly Ethylene (HDPE), or Acrylonitrile Butadiene Styrene (ABS), could be considered. The cassette currently connects and locks onto the device through a snap fit connection. This means that the only requirement for selecting a cassette housing material would be that the material is compatible with such a design. This can easily be tested and explored by Spatium or partnering manufacturers. A model scenario for comparing the impact of producing the cassette housing with these different materials was developed, assuming the projected sales numbers for the end of year 3 post-market introduction provided by Spatium (Spatium Medical, personal communication, 2024) (Table 8).

Impact validation

Figure 30 compares two scenarios: a baseline scenario A, where the full cassette is disposable in line with the current design and an alternative scenario B, where the filters are swappable and the cassette housing can be reused.

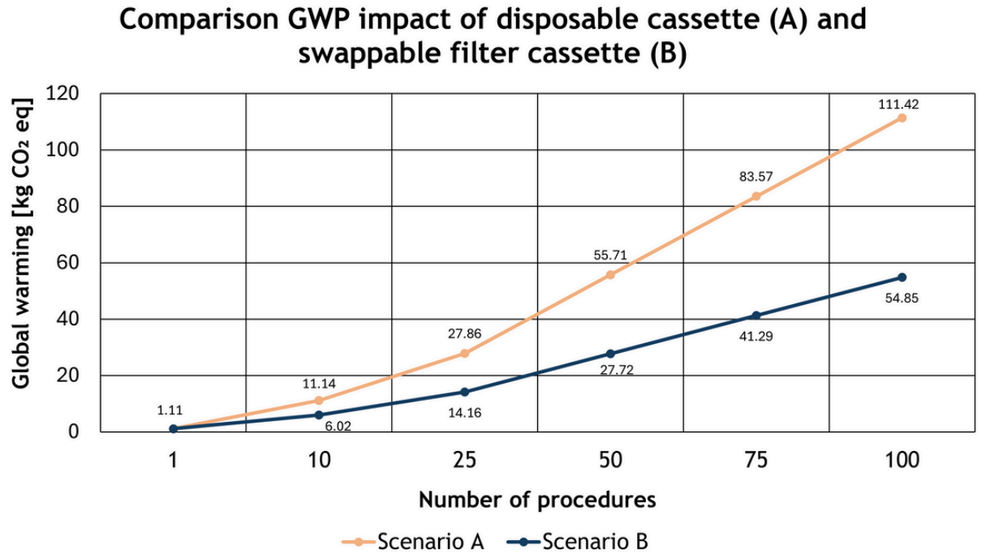


Figure 30: Comparison GWP impact of current cassette design with proposed swappable filter strategy for reuse up to 100 procedures

For the inputs of calculating scenario A, the total life cycle impact of the cassette housing, filters, and overmould were multiplied by the reported number of procedures. For the inputs of calculating scenario B, the total life cycle impact of the filters and overmould were multiplied by the reported number of procedures, while the total life cycle impact of the cassette housing was only counted once. For modelling the low-level disinfection of the cassette housing, as an assumption, the life cycle impact of sterilising the original cassette housing was multiplied by the number of procedures since the impact of the actual expected low-level disinfection is unknown. However, this low-level disinfection is expected to have a lower impact than the now-used impact since this is based on a complete EtO sterilisation cycle. This means potential results would only improve compared to those in Figure 30.

Looking at the figure, it can be observed that by reusing only the cassette housing, the cassette's total impact is approximately halved compared to the baseline scenario. Additionally, depending on how many procedures the housing can be reused for, this strategy can save up to nearly 7000 kilograms of plastic waste by the end of year 3 post-market introduction.

Table 8 compares the impact of the different discussed materials that can be used for the cassette housing. It can be observed that the current proposed design using PC leads to the highest impact. Depending on which alternative material is used, this intervention can save more than 10.000 kg CO_2-eq by the end of year 3 post-market introduction.

GWP impact material options cassette housing			
Material	Material impact ($kgCO_2$-eq)	Total impact per cassette housing ($kgCO_2$-eq)	Total impact end of year 3 post-market introduction ($kgCO_2$-eq)
PC	**3.4**	**0.59**	**53123**
PP	1.63	0.46	40991
HDPE	1.8	0.47	42148
ABS	2.69	0.54	48202

Table 8: GWP impact results for different material cassette housing

Next steps

It has been established that developing an alternative cassette design allowing for swapping out of the filters post-procedure could reduce environmental impact and generated waste. Furthermore, by adjusting the material used for the cassette housing, the overall impact of the cassette can also be lowered. However, to realise these discussed strategies and validate their feasibility, the crucial following actions will need to be undertaken:

- **Design and engineer an alternative cassette.** In this new design, users should be able to swap out and replace filters without affecting the performance of the insufflation system.
- **Usability testing new cassette concept.** Precise performance and usability testing should be executed to validate the use case of the new design and train users on how to remove and replace filters as effortlessly as possible.
- **Evaluation of new material with cassette design.** The proposed material alternatives should be tested and evaluated with partnering manufacturers, especially regarding the functionality of the snap fit connector.
- **Finalise and agree on changes with manufacturers** to produce the new cassette design.

While results indicated that implementing swappable filters would reduce environmental impact and generated waste, implementing and realising this strategy is highly complex, cost and time-intensive. Making this more of a medium to long-term strategy to consider. However, adjusting the material of the cassette housing is vastly less effort and cost-intensive, and could be a short-term intervention for Spatium to explore. Even though the effects of implementing this strategy are lower, it is more feasible and could thus be implemented in the short-term.

7.4 Reprocessing

Another high-potential and impact-saving strategy for the Spatium patient kit is switching some components from SUDs to reusables. Through reusing devices multiple times, the need to produce new devices is decreased, lowering the environmental impact and amount of waste generated. Two of the components currently present inside the patient kit have been identified as viable to become either fully or hybrid reusable:

- **Trocar:** Transitioning to a metal reusable or hybrid trocar
- **Insufflation tubes:** Transitioning to reusable silicone tubing

A comparison of the impacts of disposable, hybrid and reusable trocars can be found in the literature (Boberg et al., 2022; Rizan & Bhutta, 2021). Moreover, interactions with stakeholders inside hospitals have shown that reusable trocars have already been implemented and are used in some cases. This means developing and implementing reusable trocars for Spatium can be viable, desirable and feasible.

While some competitors offer reusable tubing (*CO2 Insufflator Flow 50 Accessories | AESCULAP Minimally Invasive Surgery*, n.d.; *Insufflation Tube | KARL STORZ Endoskope | United States*, n.d.; Richard Wolf GmbH, n.d.; *Wisap*, n.d.) during interactions with stakeholders inside hospitals, it was indicated that reprocessing tubes can be highly challenging and is currently not commonly done inside hospitals. While the existence of such tubes speaks to the realisability of the concept, alternative solutions like third-party reprocessing partnerships will need to be explored.

Sterilisation techniques

The most challenging aspect of implementing reusable medical devices is undergoing the required reprocessing steps. Items such as trocars and insufflation tubing are commonly designated as critical on the Spaulding scale (*Spaulding Classification | Nanosonics*, n.d.), meaning that they are required to undergo a process of disinfection and sterilisation. Various sterilisation techniques exist (Figure 31). Depending on the technique applied, the medical devices can be limited in material types, and the environmental impact of the process can differ. Through research and interaction with CSA workers and stakeholders, the three most relevant techniques have been identified and are discussed:

Autoclave (steam sterilisation)

Moist heat sterilisation in the form of saturated steam under pressure in an autoclave is the most widely adopted and dependable method of sterilising critical and semi-critical items. The major benefits of this process are that it is non-toxic, comparatively rapid and inexpensive (Rutala & Weber, 2019). Drawbacks, however, are that items require a high heat and moisture resistance to be compatible with the sterilisation process. This means that devices with built-in electronic components or devices made from plastic cannot be sterilised in autoclaves. Both metal trocars and silicone tubing can technically be reprocessed using this technique. However, interactions with CSA staff at Erasmus MC indicated that sterilising long hollow devices, such as tubes, can be challenging and is not commonly done.

Ethylene Oxide (EtO) sterilisation

EtO sterilisation is the most widely adopted low-temperature sterilisation technique, mainly applied to devices that cannot withstand heat or moisture from steam sterilisation. A common type of EtO sterilisation applied is mixed gas. Here EtO gas is combined with another gas (often CO_2) that acts as a stabilising agent. The EtO-carbon dioxide mixture consists of 8.5% EtO and 91.5% CO_2 (Rutala & Weber, 2019). While the compatibility with plastic and electronic devices offers a benefit compared to other techniques, EtO sterilisation is far from ideal. The process requires a larger time investment due to the aeration needed post sterilisation, is more costly and, additionally, EtO gas has been proven to be toxic and carcinogenic, causing health hazards to staff (Rutala & Weber, 2019). Because of these reasons, healthcare personnel have been exploring alternative and novel low-temperature sterilisation technologies. EtO sterilisation is the technique that is currently applied and used for the fully disposable Spatium patient kit.

Hydrogen peroxide gas plasma sterilisation

Hydrogen peroxide gas plasma sterilisation is an alternative low-temperature sterilisation technique, with one major advantage being that the process does not generate toxic by-products (Rutala & Weber, 2019). The process inhibits the introduction of hydrogen vapours inside a chamber, which are transformed into gas plasma by creating an electrical field through radio frequency (Rutala & Weber, 2019). The technique is relatively novel compared to the other two discussed sterilisation techniques and is mainly applied for sterilising high-value devices, which include electrical or plastic components. Insights from stakeholder interactions indicated that some hospitals can sterilise devices using this technique, although the capacity is often minimal. Applying this technique to the current Spatium kit is not feasible due to restrictions in availability and capacity. However, it could offer interesting possibilities in the future, especially regarding tube set alternatives that include electrical components for gas heating.

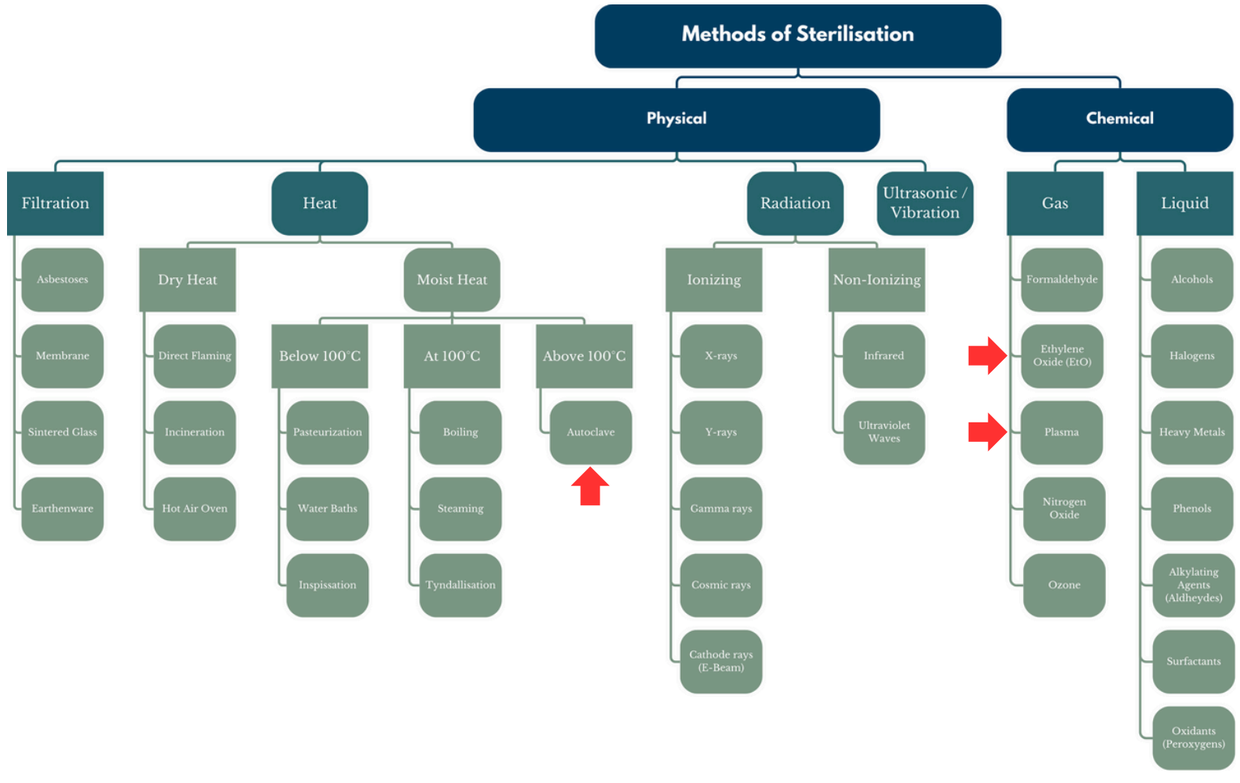


Figure 31: Physical and chemical sterilisation methods used in the medical industry (Medical Plastics News, 2022)

Trocar(s)

The current Spatium trocar design is based on an existing minimally modified disposable trocar. Because of this minimal modification, existing research and results on the environmental impact of disposable, hybrid and reusable trocars are assumed to be representative of the eventual Spatium trocar. The current design assumes a disposable trocar primarily made of plastics. Fully reusable trocars exist on the market, often made of metals and silicone (Boberg et al., 2022). Alternatively, examples of hybrid trocar designs combine reusable metal parts with disposable plastic parts (Rizan & Bhutta, 2021). Studies show that switching to reusable trocars can lower the environmental impact by up to 80% compared to single-use trocar systems (Boberg et al., 2022), while switching to hybrid trocar systems can lower the environmental impact by up to 70% compared to single-use trocar system (Rizan & Bhutta, 2021). Interestingly, interactions with OR staff and surgeons indicated that the reason for selecting single-use trocars over reusable or hybrid alternatives often comes down to the additional features present on the trocars. Assuming Spatium plans to design its own reusable or hybrid trocar to reduce its environmental impact, it will be vital to engage surgeons about what features should be included in the design.

Tubing

Unlike reusable trocars, even though reusable tubes are offered on the market, there is much less research and reporting on environmental impact comparisons between single-use and reusables. It can be concluded however that the material used in reusable tubing is silicone, as this is the listed material of existing reusable tubing offered by competitors and that tubes can be autoclaved up to 100 times (*CO2 Insufflator Flow 50 Accessories | AESCULAP Minimally Invasive Surgery*, n.d.; *Insufflation Tube | KARL STORZ Endoskope | United States*, n.d.; Richard Wolf GmbH, n.d.; *Wisap*, n.d.). Knowing these factors, the weight of such a silicone tube can be calculated and using reporting on the environmental impact of a disinfection and sterilisation cycle (Rizan & Bhutta, 2021), a comparison of impacts between a reusable silicone tube and the current single-use Spatium tube can be modelled (Figure 32).

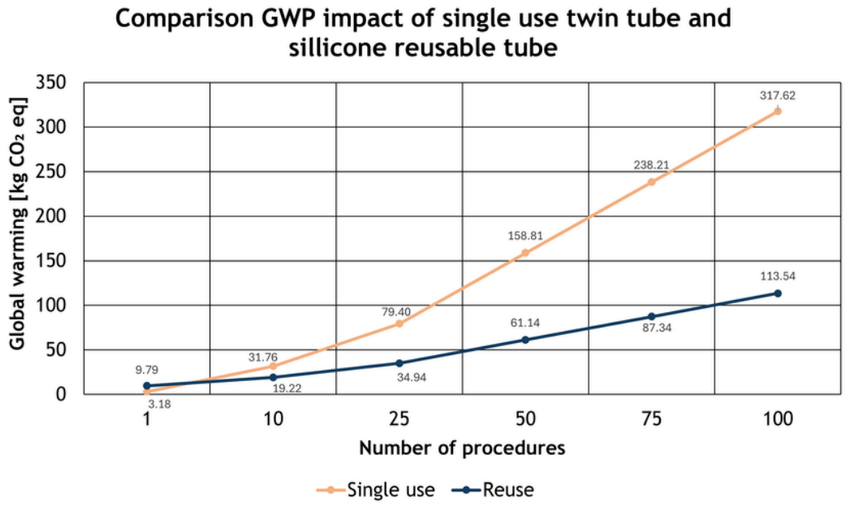


Figure 32: Comparison GWP impact of single-use and reusable twin tube for up to 100 procedures

Impact validation

Figure 32 compares the impact of a single-use twin tube to using a reusable silicone twin tube for up to 100 procedures. It can be observed that even though the initial impact of producing a single twin tube is higher for the reusable alternative due to the larger material impact of silicone compared with PVC, within the first 10 reuse cycles the impact of the disposable twin tube becomes larger than that of the reusable.

Additionally, by switching to reusables, a large amount of material waste can be avoided since, as mentioned, the need for newly produced products decreases. Assuming the reusable twin tube can be autoclaved up to a hundred times maximum, this can save more than 50.000 kilograms of plastic waste compared to the current single-use design by the end of year 3 post-market introduction.

Regarding the trocar, it is reported that the reusable alternative can be used for up to 500 procedures (Boberg et al., 2022). Using the weights reported in the study (Boberg et al., 2022), switching to a reusable trocar can save up to 4700 kilograms of medical waste by the end of year 3 post-market introduction, assuming a single trocar is used per procedure.

It should be noted that switching from single-use to disposable medical devices can lower impact factors such as GWP and human carcinogenic toxicity due to switching away from toxic sterlisation techniques such as EtO. However, other impact factors, such as water use, will likely increase due to alternative sterilisation techniques for reprocessing reusables, such as autoclave sterilisation.

Next steps

Through the existence of current reusable alternatives for both trocars and insufflation tubes and the highlighted potential for a decrease in environmental impact and generated waste, the desirability, viability and feasibility of these reusable have been established. However, when wanting to realise these strategies, crucial next steps remain:

- **Development and certification of reusable trocar by Spatium.** Having demonstrated the environmental benefits, using a reusable or hybrid design should be considered.
- **Discussion on trocar features with surgeons.** Interactions with OR staff and surgeons indicated that specific trocar features often decide whether a certain trocar is used. Thus, Spatium should engage users on what features they would like to be implemented when developing their trocar.
- **Sterilisation validation of reusable insufflation tube.** Interaction with CSA workers indicated that sterilising long tubes like those used for insufflation is highly challenging; thus, proper testing should be done regarding the reprocessing capabilities of such tubes.
- **Partnering with external reprocessing facilities.** Due to the difficulties of reprocessing devices such as insufflation tubes inside a hospital. An alternative solution of outsourcing reprocessing to a third-party company could be explored as interaction with stakeholders indicated that such practices exist, although only on a smaller scale.

Implementing reusable trocars is a proven and widely adopted solution that can reduce environmental impacts and waste. However, due to the effort required to develop or modify a reusable or hybrid trocar design, this strategy, although realistic, is designated as medium-term.

Reusable tubing, although potentially leading to a larger impact reduction, is a more complicated strategy due to the challenges of reprocessing tubes. As mentioned, an alternative solution could be for Spatium to partner with a third-party reprocessor such as VANGUARD (Köhler, 2024). Another potential solution to consider would be for Spatium to offer both reusable and single-use insufflation tubing so that hospitals that possess the facilities required to reprocess the tubes can purchase and use reusables. Nevertheless, it would likely be a long-term strategy due to challenges in development, certification and scaling.

7.5 Sterile barrier

The filters inside the cassette function as the sterile barrier of the insufflation system, separating the “contaminated” patient kit and the insufflator device. This means that by moving these filters closer towards the patient, any components, parts, and materials placed between the filters and the device would technically no longer be considered contaminated and could be reused without extensive disinfection and sterilisation. During interaction with stakeholders and Spatium, two potential intervention ideas were proposed:

- **Filter trocar(s):** Finding a way to integrate the filters in the trocar. In this scenario, only the trocar and the now-implemented filters would be considered contaminated.
- **In-line cassette on the edge of the operating table:** Placing the cassette within the insufflation line at a length that can be anchored to the edge of the operating table. In this scenario, the new cassette, any remaining tubing between the cassette and the patient and the trocars would be considered contaminated.

Implementing the filters inside the trocar will be highly challenging from an engineering standpoint. However, it would lead to the largest environmental impact reduction as the tubes could be reused without extensive disinfection and sterilisation. Furthermore, the cassette will no longer be required as the filters are now integrated into the trocar, saving additional impact and material. While the feasibility of this strategy would need to be explored and proven, requiring considerable time and financial investments, the potential for impact reduction is largest.

Integrating the cassette inside the insufflation line is more feasible, as examples of filters and filter housings within such tubing lines exist (*ORIS Insufflation Tubing Set*, n.d.). While the potential for impact reduction of this strategy is lower, so are the required time and cost investments, making the strategy potentially more viable.

Filter trocar(s)

As indicated, integrating filters inside a trocar poses an engineering challenge. An example of a study exploring the idea of a trocar with a built-in smoke filter does exist (Hahn et al., 2017). While this strategy is unlikely to be realisable with current technology, it can potentially be interesting to explore in the future. Assuming a scenario where implementing the filters inside the trocar would be successful, the potential environmental impact and waste reduction would be considerable. The impact of the current disposables, the entire tube set and two accompanying trocars (impact based on literature (Boberg et al., 2022)), can be calculated at approximately 6.56 kg CO_2-eq (see chapter 6). The impact of the disposables when integrating the filters inside the trocar(s) would be approximately 2.69 kg CO_2-eq. In reality, this number would likely be lower since the filters would need to decrease size to fit inside the trocar. However, for simplicity reasons, the assumption is made that the impact of the filters in both scenarios is similar. Comparing these totals shows that the new scenario reduces the environmental impact by nearly 60% per patient kit. Furthermore, since the twin tube will no longer need to be disposed of, as it not contaminated, and there is no longer any need for a cassette to house the filters, implementation of the strategy would lead to saving nearly 100.000 kilograms of plastic waste by the end of year 3 post-market introduction.

In-line cassette

Creating an in-line cassette design is a more feasible strategy direction. One of the challenges of implementing an in-line cassette would be the added tension the weight of the cassette places on the insufflation line. A potential solution to this issue could be to anchor the in-line cassette to the operating table. While this would resolve the issue of putting weight on the tube line, the optimal length at which the cassette should be placed in the line must be determined. Interaction with OR staff indicated that the insufflation tubes from the trocars are often guided down towards the foot end of the operating table and, from there, move down towards the floor and then towards the tower on which the insufflator sits. To compare the environmental impact reduction caused by placing the cassette at different lengths inside the insufflation line,different scenarios have been modelled (Figure 33)

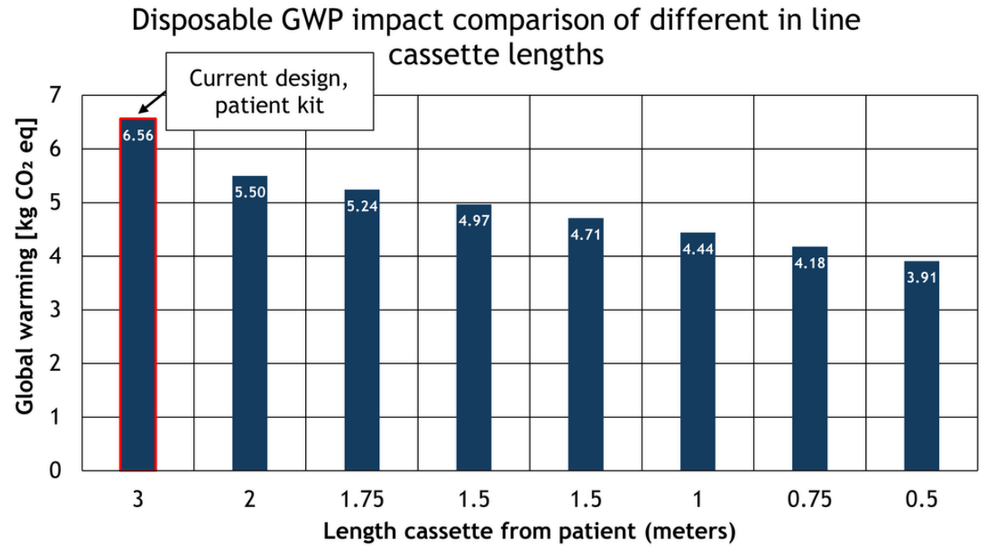


Figure 33: Comparison GWP disposables when placing the in-line cassette at various lengths

Impact validation

Figure 33 visualises the potential impact reduction caused by disposables when placing the cassette at different lengths inside the insufflation line. This figure does not account for any potential decreases in cassette size. However, since the cassette no longer needs to be locked inside the device, the dimensions can be expected to decrease, thus potentially adding to the impact reduction.

To realise this strategy, two additional pairs of connectors would need to be introduced since the cassette will need to connect to the insufflation tubes both at the front and back. However, since the LCA analysis concluded that the impact of such connecters is smaller than 0.1 kg CO_2-eq this should not significantly affect the presented results.

Finally, the numbers presented in Figure 33 do not account for any impact caused by the low-level disinfection of the “saved” tube length between the new cassette position and the device. However, contamination of these tube parts should be near zero since the gas inside is filtered and the outside is placed at a reasonable distance from the patient and operating table, making the expected impact of disinfection minimal.

Next steps

Having highlighted the potential decreases in caused environmental impact and waste and discussed the challenges of the interventions, the following steps for potential implementation will be:

- **Research and explore filter trocar(s).** Potential ideas and concept for integrating filters can be developed over time as this solution indicated the highest potential for impact and waste reduction.
- **Validate in-line cassette position.** Using an OR and existing in-line cassette design, different positions for the in-line cassette concept can be tested to determine the optimal length from the patient.
- **Develop an in-line cassette system.** Using existing examples, Spatium can develop its own in-line cassette system. The new system would require some modification compared to the existing design, namely the pocket inside the device, adding extra connectors and an alternative to the current RFID tag setup.
- **Performance testing in-line cassette system.** It will be important to test the performance of the insufflator when placing the cassette at different lengths in the insufflation line. However, it should be noted that a discussion with Spatium indicated that moving the filters closer to the patient is likely to improve the system's performance (Spatium Medical, personal communication, 2024).

While implementing filters inside the trocar leads to the highest decrease in environmental impact and produced waste, it is currently not feasible due to the strategy's engineering challenges. This makes the potential implementation of this strategy a long-term prospect.

The in-line cassette concept, although less impactful, is more feasible as similar examples already exist in the current market. However, due to the large amount of required development and changes to the current Spatium insufflation system, implementing the strategy is considered medium-term.

7.6 Packaging

The trocar(s) and tube set, both part of the patient kit, are suitable to be sold and offered either together or separately. Such devices must be placed inside specified packaging before sterilisation and ending up inside a hospital. For this packaging, Spatium can consider a flexible medical peel pouch or a rigid blister packaging. A decision on the most suitable packaging will need to be made. Factors to consider are:

- **Usability** (ease of opening and retrieving the device from packaging without contamination)
- **Risk** (risk of punctures and damage to packaging before use)
- **Look** (visual appeal of product inside packaging)
- **Environmental impact** (impact of packaging options in kg CO_2-eq)
- **Cost** (Financial cost of producing packaging)

Peel pouch

A peel pouch, or sterilisation pouch, is a disposable package that can be used in a steriliser to allow penetration of the sterilant to devices placed inside. Commonly, there are two types of combination peel pouches (*Guide to Sterilization Pouches in Healthcare | STERIS*, n.d.):

- Paper and plastic peel pouches are used in steam (autoclave) or EtO sterilisation.
- Tyvak and plastic peel pouches are used in Vaporised Hydrogen Peroxide (VHP) and EtO sterilisation

A peel pouch consists of two main materials: medical grade paper or Tyvek and a transparent plastic film held together by either a heat seal or an adhesive. Spatium's proposed peel pouch design uses Tyvak over medical grade paper since the material is much stronger and difficult to tear.

Blister packaging

A blister, or tray, is a disposable package made from a hard plastic film custom-fitted to the device placed inside. Depending on the type of plastic film used, blister packaging can undergo various forms of sterilisation, including steam (autoclave) and EtO.

A blister package consists of two main materials : a plastic film, commonly made from PET (polyethylene terephthalate) or PP, and a Tyvak lid held together by either a heat seal or adhesive (*Blister/Tray Packaging for Medical Devices and Pharmaceuticals &Ndash; Früh Verpackungstechnik AG,* n.d.). Spatium's proposed blister design uses a Tyvak lid and PETG plastic film.

Evaluation

- **Usability:** Usability is an essential factor to consider since any problem that arises during the opening of the packaging and removal of the device from the packaging can lead to contamination of the sterile device inside. When this occurs, the whole device must be disposed of as it can no longer be used since it is not sterile. This can mean a significant amount of wasted material and costs and thus must be avoided. Interactions with an OR nurse at Erasmus MC gave insight into some of the currently proposed Spatium packaging. Regarding the trocar, it was mentioned that either packaging option, peel pouch or blister, should work fine. Both types of packaging are already used for trocars inside the hospital and cause no large issues. For the tube kit, however, it was indicated that a blister packaging could be preferable. Placing a larger device, such as the tube kit, inside a peel pouch and then opening it is reasonably complex and clumsy while removing such a device from blister packaging is much easier. For this reason, it was noted that most comparable products currently used in the hospital are provided in blister packaging.

- **(puncture) Risk:** Damage or punctures to the packaging must be avoided since, similarly to contamination, when occurring before use, the product inside must be discarded. Comparing the two options, a clear advantage for the blister packaging arises. Firstly, the hard plastic film used in blister packaging is stronger and, thus, less likely to puncture or be damaged than the plastic film used for peel pouches. Secondly, the hard plastic is custom-fitted to the device placed inside the packaging. This means that the item within is restricted from moving around during, for example, transport, lowering the chance of punctures or damage. It should be noted that inside peel pouch packaging for trocars, there is often an additional hard plastic holder piece to keep the trocar components in place and guard off the sharp tips. This part lowers the puncture and damage risk for peel pouches regarding trocars.

- **Look:** While this factor might be the less critical, the product's visual appeal can still be important, as creating something that looks cheap or unappealing might influence use and sales numbers. This factor is also more challenging to evaluate since looks and visual appeal are, by nature, subjective. However, interaction with OR staff has indicated that overall blister packaging looks more “professional” and would thus be preferable.

- **Environmental impact:** Since both options are disposable and, as previously established, a large number of trocars and tube sets will be produced, it is essential to factor in the environmental impact of the packaging when deciding upon the design. For this reason, an impact comparison of the various options has been made to allow Spatium to make an informed choice. See Impact validation for a more detailed description.

- **Costs:** The final factor to consider is the costs of producing and developing the packaging options. Here, the peel pouch option is preferable as the material costs are lower than those for the blister packaging. Additionally, producing the custom-fitted blister packaging would require an additional investment for developing a mould to form the part made of hard plastic film.

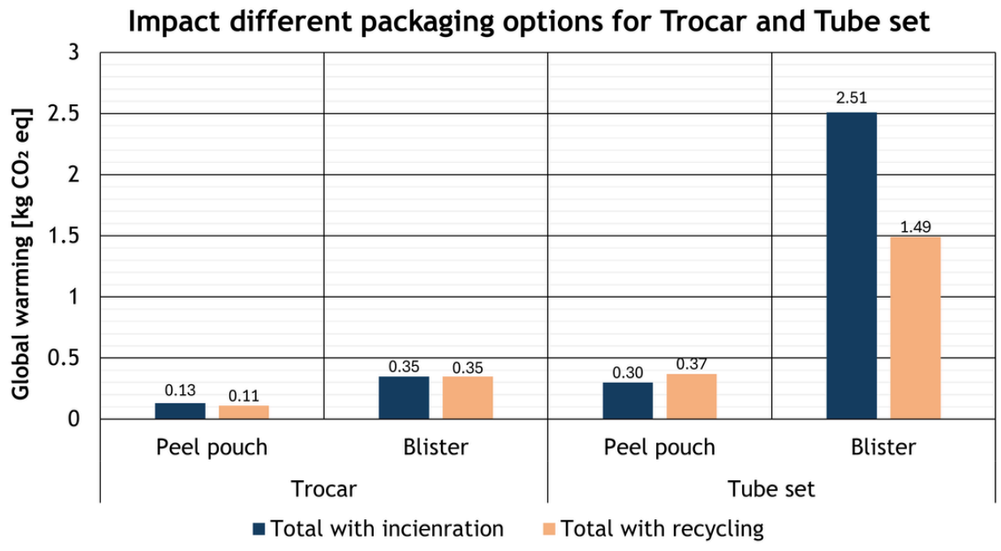


Figure 34: Comparison GWP impact of different packaging options for the trocar and tube set and different EoL scenarios

Impact validation

A calculation of the GWP of each option across the various life cycles was modelled to compare the impact of the different packaging alternatives. The total impact across all life cycles was calculated for each option, as seen in Figure 34. To gather the input data for this comparison, existing sample packaging available at Spatium was weighed. Knowing the weight of the various components, the GWP was calculated by finding the CO_2-eq amount for production, manufacturing, incineration and recycling of each identified material using Granta Edupack 2024. For the life cycle stage of transport and sterilisation, a similar approach as for the fast-track LCA on tube set B was used (see Appendix D). For the peel pouch option for trocars an additional plastic holder piece was modelled and included in the impact calculations as these are commonly present in trocar peel pouch packaging.

Looking at the results in Figure 35, it can be seen that from an impact perspective, the peel pouch options are more desirable as their impact is lower than blister packaging due to using a lower amount and less impactful materials. Furthermore, recycling at EoL generally leads to lower total impacts. A potential solution to combat the lower score on (puncture) risk and usability when using peel pouch packaging for the tube set would be to double sleeve the tube set. This will decrease the contamination risk of the tube set during transport and opening while still being less environmentally impactful than the blister packaging alternative.

Next steps

Using the findings described above, a Harris Profile (*Harris Profile*, n.d.) was made to advise Spatium on which packaging options to use for their devices. The usability and risk criteria were identified as the most important, as any complications here would lead to discarding the entire packaging and devices inside. For this reason, these criteria were weighed double. Visual appeal, as mentioned, plays a role but not to the same extent as the other criteria, so this criterion is weighed half.

This results in packaging advice for the trocar being peel pouches, scoring 12.5, compared to the blister, scoring 11. For the tube set, Spatium is also advised to use peel pouch packaging, scoring 10.5, compared to the blister, scoring 9. However, as described Spatium is advised to double sleeve their tube set in peel pouch packaging to combat the lower score on (puncture) risk and usability.

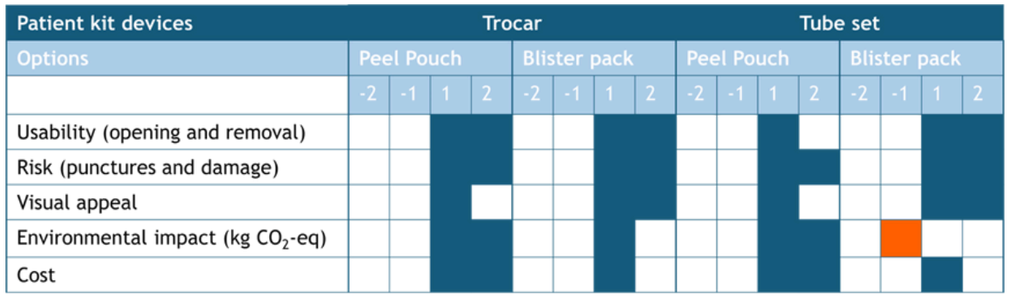


Figure 35: Harris profile for packaging options, Usability and Risk are weighed double while Visual appeal score is halved

7.7 Design for recycle

Insights from an interview with a green team member inside the Erasmus MC highlighted the potential for recycling the most impactful component inside the tube set, the twin tube. It was noted that since the inside of the tubes only come in contact with the gas, there is a large likelihood that the component can be recycled at EoL without intensive disinfection or sterilisation requirements. While recycling is one of the lower R ladder strategies, it was indicated that current practices inside the OR do allow for the separation of recyclable medical waste. However, it was stressed that if applied, the recyclable parts should be able to be separated with minimal effort since introducing extra steps or handlings, especially if involving tools, would likely hinder the strategy application. To lower the boundaries of recycling high-impact components such as the twin tube, the following factors should be considered:

- **Fixed connections:** In the current design, the twin tube is fixed onto the cassette. To lower the boundary for recycling, this should be adjusted to a detachable connector.
- **Mono-material components:** The connectors used to attach the twin tube to the trocars are made from different materials than the tubes. To lower the boundary for recycling, these should be adjusted to be the same material.

When applied successfully, the EoL environmental impact of the twin tube can be reduced. Granta Edupack 2024 lists the environmental impact of recycling DEHP-free PVC at 0.67 kg CO_2-eq per kilogram of material. This is considerably lower than the reported impact of 2.8 kg CO_2-eq per kilogram of material caused by incinerating specialised hospital waste (Leone et al., 2024). This means that when implemented successfully, the strategy can save more than 100.000 kg CO_2-eq emissions by the end of year 3 post-market introduction.

Disassembly

As discussed, vital to the success of this strategy will be to lower the effort boundary for separating and recycling the twin tube. A disassembly map (De Fazio et al., 2021) mimics the scenario post-operation inside an OR (Figure 36). While the different components of the patient kit are not nested very deep, they require multiple product manipulation and non-reusable connector steps to be separated. To get to the twin tube, the OR staff must first disconnect the cassette and trocars using multiple hand motions. After this, they will need a sharp object, such as a knife or scissors, to cut the tubes and separate them from the cassette. Then, they must repeat this step again to separate the tubes from the connectors fixed onto the tube at the outlet (VinylPlus, 2023). After going through these steps, the tubes can be separately disposed and potentially recycled. The effort and tools some of these steps require, especially cutting the tube, will likely hinder this strategy's feasibility.

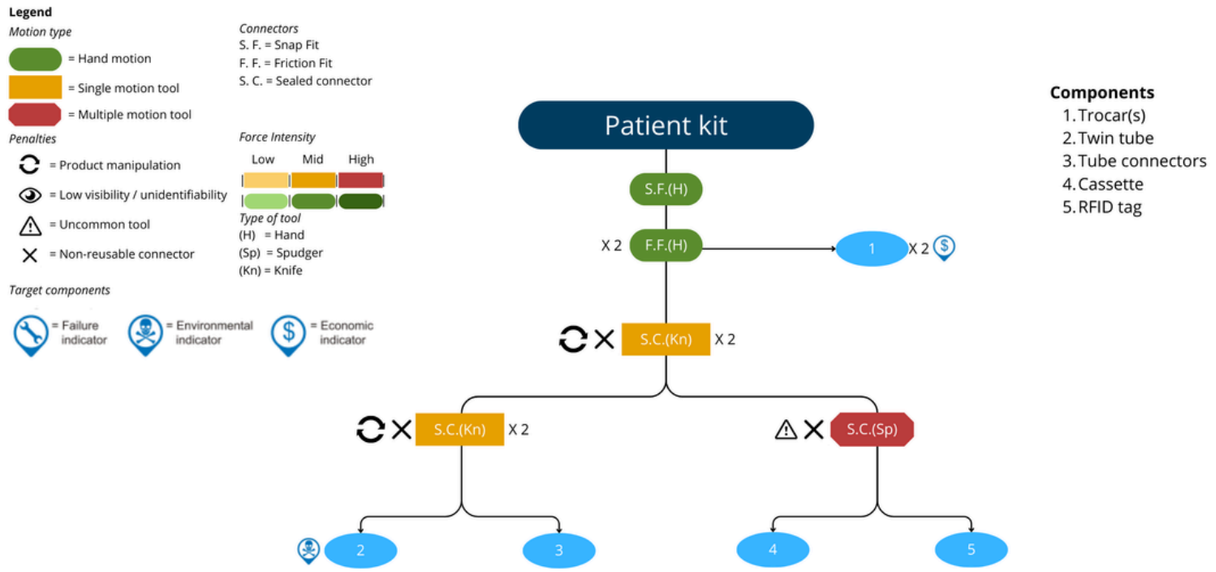


Figure 36: Disassembly map patient kit for current scenario OR post-operation

By integrating the discussed adjustments, the disassembly process can be improved by changing the material of the connectors to that of the tubes and introducing an extra set of detachable connectors to attach the tubes to the cassette (Figure 37). In the new scenario, OR staff is no longer required to cut the tube as the tube can be disconnected from the cassette similarly to the trocars. Moreover, since the connectors and twin tube now exist out of the same material, DEHP-free PVC, these components can be disposed of together without the need to separate them, lowering the overall effort required to be put in by OR staff. Making these changes increases the likelihood and feasibility of this strategy and could lead to a higher potential for recycling the twin tube.

Next steps

To implement this strategy and realise the potential highlighted decrease in environmental impact, the following next steps will need to be undertaken:

- **Adjustment components patient kit.** The described adjustments, extra connectors and material changes would need to be applied to the current system design. These changes, however, are minimal and should not affect the current system or performance.
- **Education OR staff on recycling.** The importance of recycling the twin tube and the steps needed for recycling should be communicated in the patient kit's Instructions for Use (IFU). Additionally, potential training for OR staff on correctly separating the twin tube for recycling could be proposed.

In conclusion, recycling is a more effort-intensive strategy often dependent on local hospital infrastructure. Due to the highlighted potential environmental impact reduction and minimally required design changes, the strategy implementation is expected to be reasonably feasible, making it a short to medium-term intervention.

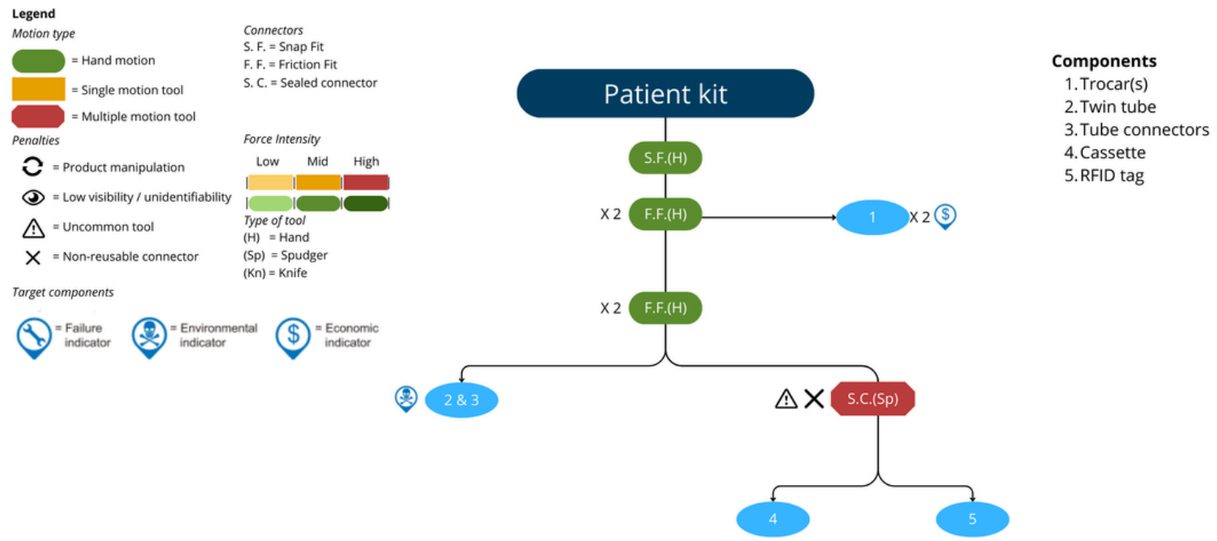


Figure 37: Disassembly map patient kit for improved scenario OR post-operation

Key insights

What are circular strategies and interventions Spatium can develop in the short, medium and long-term to lower their environmental impacts?

- Short-term strategies for Spatium to consider are: optimising the twin tube length and thickness, adjusting the material cassette, packaging and design for recycle.
- Medium-term strategies for Spatium to consider are: reusable trocar(s) and in-line cassette (moving sterile barrier).
- Long-term for Spatium to consider are: swappable filters, reusable tubes and filter trocar(s).

Deliver

CHAPTER 08

Sustainability report

This chapter focuses on the sustainability report deliverable (Appendix G), which summarises and presents the results and advice of the thesis research in a concise format for Spatium. The purpose and topics of the report are presented. Finally, the value of Spatium developing a similar report in the future for alternative target audiences and suggested changes to contents when doing so are discussed.

In this chapter:

Key topics:

- Who is the intended target audience for the sustainability report?
- How can all reached results be translated into a concise and actionable sustainability plan for Spatium?
- What should similar reports, developed by Spatium, aimed at different target audiences look like/include?

8.1 Purpose

A summative sustainability report, see Appendix G, was created as an accumulation of all gathered research and results. The purpose of this report was to aid and inform Spatium and any relevant stakeholders within the company, such as management and potentially the investors, of the main findings, conclusions, and advice for the company to address sustainability in the coming years.

The report's main goal is to clearly and concisely communicate and inform Spatium on the current role, importance and potential value of integrating sustainability into the company's core values and future plans. As a guideline and inspiration for drafting the report and deciding on the topics to include, various sustainability reports of medical device manufacturers and a hospital were used as a comparative benchmark (2023 *Comprehensive Report*, 2023; Erasmus MC, 2020; *Johnson & Johnson Health for Humanity Report 2023*, 2023; Metabolic, 2022.; *Our Sustainability Report*, 2024; *Sustainability Reporting | Asker Healthcare Group*, 2023).

The report includes a company level evaluation, highlighting the importance of sustainability from a procurement and tender perspective using results gathered mainly from stakeholder interactions. It outlines actionable steps, documentation, and commitments Spatium can make to integrate sustainability and reach its vision of a truly "future-proof" insufflation system. These steps and documents are advised to be taken on either a short, medium or long-term basis, further helping Spatium prioritise its future developments and linking them to the expected growth of the company and related products. While results from stakeholder interviews showcased that patient and personnel benefits are the main drivers for selecting medical devices in the procurement process, it also indicated that sustainability can be a deciding factor when choosing between multiple devices offering similar features and advantages, thus further substantiating the value of integrating sustainability from a potential business and customer perspective.

Next, the report outlines findings and results relating to sustainability on a product level. Here, the identified environmental hotspots inside the current Spatium system are listed starting from a big-picture perspective, summarising the impacts related to an average laparoscopic surgery followed by a more zoomed-in assessment of the identified disposable hotspot looking specifically at the Spatium patient kit. As a conclusion significantly impactful components, parts and life cycle steps are linked to three R ladder strategies which Spatium can apply to address these environmental hotspots. Some of the specific developed circular interventions using these R ladder strategies are highlighted later in the report, these interventions are again advised to be implemented on a short, medium or long-term basis to help Spatium prioritise and plan their development into the future.

A complete one-page overview of all life cycle steps of Spatium's products, starting in the design phase, with integrated circular flows based on the 10R ladder strategies, is included. The primary purpose of this overview is to showcase which R ladder strategies can be applied throughout the various life cycle steps while simultaneously linking potentially actionable steps needed to realise these strategies. The overview is a summative result of the literature research into the circular economy and links these findings directly to Spatium's case and products. Furthermore, it could be used as a potential brainstorming tool for Spatium to inspire and help them decide on applying specific circular interventions.

Several concepts described in chapter 7, Deep dives, have been included in a one-page per-concept visual layout. Each page provides a short description of the concept, lists the findings on which the concept is based and validated, mentions actionable next steps for Spatium to realise the intervention and presents the environmental impact and amount of waste savings that can be achieved through implementation. Since the report's purpose, as previously described, is to inform management and potential investors, the selection of concepts included in the report was mainly based on the perceived realisability of the interventions. Because several developed concepts are more reliant on assumptions and require yet-to-be-developed technologies to be implemented, these were left out of the report to avoid communicating “abstract” plans or promises.

The final page of the report is a tactical roadmap. This roadmap uses the outputs of the earlier described company and product level assessment and strategies and links these to values for users, customers and Spatium. The roadmap maps all developed strategies and linked actions and resources of Spatium on the earlier described short, medium or long-term basis. The short-term horizon focuses on pre-market to market introduction actions. It mainly looks at optimising the current system and design and setting and communicating clear future sustainability goals and commitments. The medium-term horizon introduces an initial shift to more circular products inside the system while communicating on existing impact compared to set targets to validate commitments and build trust. The long-term horizon aims to optimise the circularity of products within the system while continuing to communicate and validate sustainability goals and commitments. Interlinking connections between strategies and values are shown by arrows. Additionally, to aid Spatium in exploring alternative concepts to those highlighted in the single-page report format, all resulting concepts of chapter 7 are plotted on the roadmap.

8.2 Target audience

The developed sustainability report's current purpose and target audience align with the project's main focus of helping Spatium assess its current design on sustainability and designing actionable steps to plan and implement circular strategies. However, in the future, as indicated in the results from stakeholder interaction, it will be valuable for Spatium to develop their own sustainability report aimed at alternative target audiences. Depending on the intended audience, the general public, hospital procurement or suppliers, the communicated information, tone, and language can differ.

Using the benchmark orientation executed on existing sustainability reports (2023 *Comprehensive Report*, 2023; Erasmus MC, 2020; *Johnson & Johnson Health for Humanity Report 2023*, 2023; Metabolic, 2022.; *Our Sustainability Report*, 2024; *Sustainability Reporting | Asker Healthcare Group*, 2023) and findings from stakeholder interviews. Spatium is advised to use the following communication and reporting formats.

When drafting a report for the general public, likely for marketing purposes, the report's main focus should be how Spatium addresses and already implements recognised values such as the United Nations Sustainable Development Goals (UNSDGs) or verified Key Performance Indicators (KPIs). Progress towards achieving set targets can be reported yearly, and environmental, social and corporate governance (ESG) initiatives can be communicated.

When drafting a report explicitly aimed at hospital procurement, the main focus should be on communicating the identified critical values of patients and personnel benefits Spatium's devices offer. Interaction with multiple procurement experts during the project indicated and verified this focus. Additionally, regarding sustainability, the documentation listed in the communication plan of the sustainability report (Appendix G) should be included. Furthermore, interview findings indicated that completed tenders, especially multi-year contracts, can require medical device manufacturers to provide a hospital with specifically requested documentation, such as an EPD, after an agreed amount of years.

Finally, when communicating with potential suppliers, clear commitments and a code of conduct outlining ethical and environmental expectations should be reported. Planned and known circular interventions can be mentioned to evaluate the feasibility of producing and implementing such strategies from a supplier perspective. Additionally, requirements for addressing the suppliers carbon emission scopes can be discussed. An example of such a requirement could be to power a percentage of their facilities with renewable electricity by a given year.

Key insights

Who is the intended target audience for the sustainability report?

- In line with the project's main focus, the sustainability report's purpose is to help and inform Spatium as a company. For this reason, the report is structured and intended as a concise summary of the project results. It also gives actionable advice to Spatium, specifically aimed at management and potentially the investors.

How can all reached results be translated into a concise and actionable sustainability plan for Spatium?

- Using a benchmark orientation of existing sustainability reports linked to the outcomes of the project, a format was drafted to communicate the main findings and advice to Spatium. Chapter 8.1 describes the various contents of the report. The full report can be found in Appendix G.

What should similar reports developed by Spatium aimed at different target audiences look like/include?

- In the future, it can be valuable for Spatium to develop its own sustainability report. Depending on the intended audience, general public, hospital procurement or (partnering) suppliers, the contents and purpose of such a report can differ. Chapter 8.2 proposes contents, formats, and changes for reports aimed at these identified target audiences.

CHAPTER 09

Conclusions

This chapter concludes the design project. It formulates a thorough summary of the addressed research problem, applied methodology and key findings. A definitive conclusion is given, and broader implications of the executed work are discussed. Additionally, the limitations of the project are addressed and potential avenues for future research are recommended.

In this chapter:

9.1 Discussion

Research problem

Spatium is developing a next-generation insufflation system to lower patient strain and improve surgical conditions during laparoscopic procedures. Although the system offers advantages compared to existing insufflator technology, the accompanying patient kit wholly consists of SUDs, potentially generating considerable amounts of waste and CO_2 emissions.

Healthcare is a highly polluting industry, responsible for 7% of all greenhouse gas emissions in the Netherlands alone (Steenmeijer et al., 2022). This is partly due to the vast use and dependence on single-use medical devices such as those in the Spatium patient kit. Results of the self-executed fast-track LCA analysis indicated that the tube set alone would emit approximately 400.000 kg CO_2-eq by the end of year 3 post-market introduction, equivalent to circumnavigating the world 40 times with an average gasoline-powered vehicle (*Greenhouse Gas Equivalencies Calculator | US EPA*, 2024). More than 90% of these CO_2 emissions stem from linear life cycle steps in the supply chain, like the raw material production, component manufacturing and incineration of the tube set components.

The focus of this project was to help Spatium assess their insufflation system on sustainability, identify environmental hotspots and problems, and design circular strategies to decrease waste and CO_2 emissions to create a truly "future-proof" insufflation system which is not only better for patients and surgeons but also respects the planet.

Methods

The project was structured to fit a double diamond framework (Design council, n.d.), allowing for diverging and converging steps and methods.

In the initial **Discover** phase, a big-picture assessment of the context in which Spatium operates was paired with a review of existing literature on healthcare and the circular economy and empirical interviews with identified relevant stakeholders.

The following **Define** phase used the gained insights, the disposable hotspot, user needs and R strategies applicable to the patient kit to formulate the design scope for creating and selecting the circular strategies.

Next, the **Develop** phase quantified environmental impacts specific to Spatium products and reported outcomes of the design sprints focussed on developing circular strategies for six selected idea directions.

Finally, the **Deliver** phase introduced the Sustainability report deliverable (Appendix G), which accumulates all relevant project results for Spatium and combined these in a summative document advising Spatium on addressing sustainability in the coming years.

Findings

Sustainability and hospital procurement

One of the key insights of this project was the current methodology used to evaluate and apply sustainability from the hospital procurement perspective. Interaction with procurement experts from the Erasmus MC and UMC Utrecht indicated that sustainability is increasingly integrated into the tender process, with the level of inclusion varying based on the type of product and market availability. This variability is likely also present between different hospitals.

Currently, hospitals in the Netherlands mainly assess medical device manufacturers and suppliers based on provided documentation and verified commitments to reducing the CO_2 impact of dedicated scopes. However, it was indicated by expert stakeholders that procurement practices are expected to shift toward a more result-oriented assessment approach in the future. This would involve evaluating manufacturers and suppliers based on their products (lowered) environmental impacts, internal operations and supply chains. The adoption of such an approach is currently limited by the novelty of the concept, both for procurement teams and manufacturers and suppliers.

R ladder circular flows

The R ladder circular flows identified as most suitable for the Spatium patient kit are: Rethink (often applied in combination with other R strategies), Reduce, Reuse and Recycle. Other explored R strategies were excluded due to their reliance on larger scalability or higher-value products to become financially or environmentally viable.

Rethink and Reduce are the most preferable circular flows because they are implemented during the critical design phase of a product's life cycle. By applying these strategies, the natural resources and materials exhausted and the amount of emissions and waste generated across all life cycles of products can be minimised. Furthermore, since these strategies are executed in the design phase, Spatium retains greater control over their implementation, reducing reliance on external infrastructure.

Reprocessing disposables within the Spatium patient kit allows devices to be reused for their original function while maintaining high product integrity. However, the disinfection and sterilisation procedures required before reuse present challenges, as they often warrant redesigns and material changes depending on the sterilisation technique. While the existence of reusable trocars and insufflation tubes on the market demonstrates the feasibility of such products, reprocessing medical devices at larger scales requires complex logistics and infrastructure that many hospitals struggle to manage. If reprocessing complete devices within the Spatium patient kit is not feasible, alternative design solutions should be investigated, such as modular designs or hybrid devices where specific components remain disposable while others become reusable.

While recycling materials used in the patient kit offers an environmental improvement compared to the current EoL incineration treatment, the circular strategy still requires the decontamination of critical devices after use. Given this additional step and the logistical waste streams needed for implementation, the strategy is likely only viable at large scales and when applied to high product volumes. Although currently unviable, adopting a design for recycling approach now can provide long-term benefits for Spatium by reducing the need for costly design changes in the future and helping promote circular usage practices.

Impact assessment

The results of the self-executed LCA on the tube set indicated that over 90% of the CO_2 emissions are attributed to linear life cycle steps (Figure 38). This is mainly due to the high environmental impacts associated with incinerating specialised hospital waste and the production of plastics used in the disposables. Furthermore, existing literature on the environmental impact of disposable, reusable and hybrid trocars suggests that reusables can reduce environmental impacts by up to 80% (Boberg et al., 2022), and hybrid systems can lower impacts by up to 70% (Rizan & Bhutta, 2021) compared to single-use designs. These findings align with the identified R ladder strategies of Rethink, Reduce, Reuse and Recycle, as these circular flows minimise the amount of (high impact) raw material used and reduce waste generation over time.

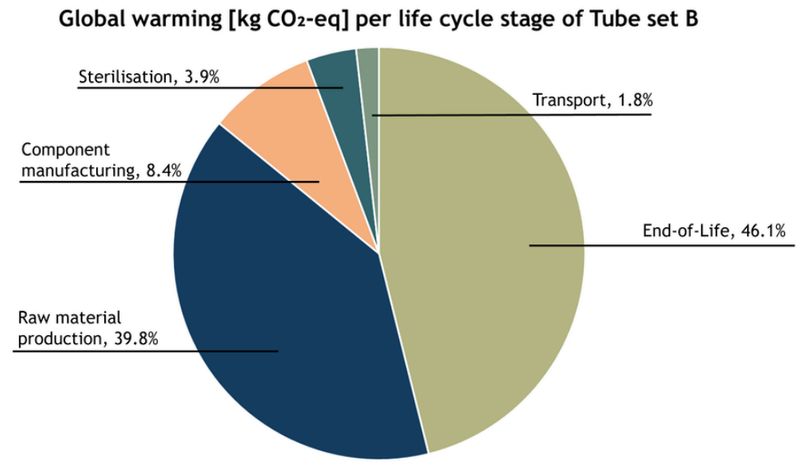


Figure 38: Contribution percentage of modelled life cycle steps to GWP tube set

Chapter 7, Deep dives, explores various concepts for implementing these circular strategies within the Spatium system. One such strategy focuses on optimising the twin tube component, which is identified as the major environmental hotspot within the tube set. By optimising product properties such as tube length and wall thickness, CO_2 emissions associated with this component can be reduced by up to 35% (Figure 39), and the amount of waste generated can be lowered by up to 28% per twin tube.

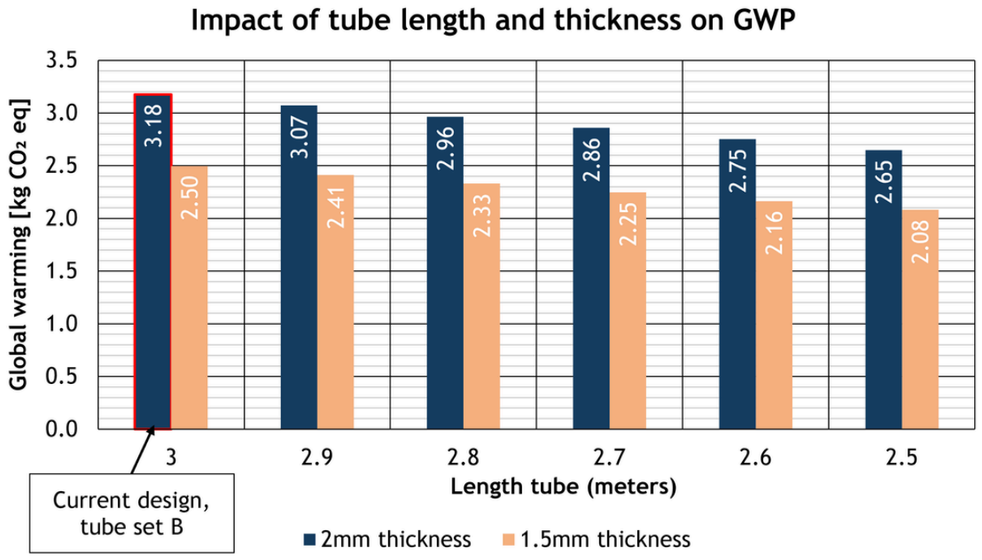


Figure 39: Bar chart comparison global warming impact (GWP) of varying tube lengths and wall thickness

Another concept looks at the potential environmental impact savings of implementing reusable silicone tubing by comparing the impact of using the current disposable twin tube with a reusable alternative for up to 100 laparoscopic procedures. It can be concluded that the reusable option reduces CO_2 emissions by over 50% (Figure 40), even when accounting for the impacts of reprocessing. Furthermore, transitioning to a reusable twin tube can save up to 50.000 kilograms of plastic waste by the end of year 3 post-market introduction.

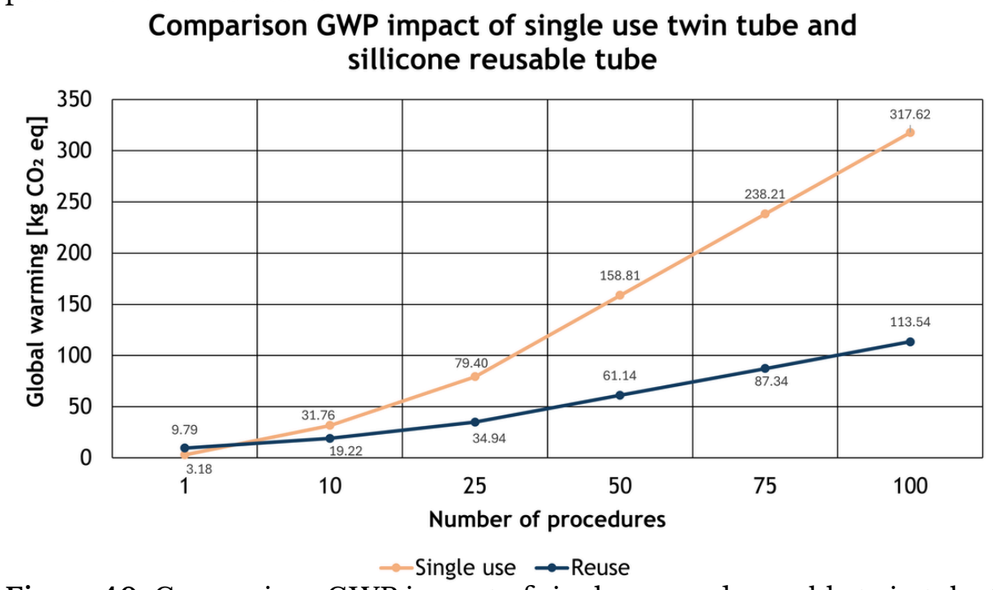


Figure 40: Comparison GWP impact of single-use and reusable twin tube for up to 100 procedures

Proposed actions and potential consequences of adopting a design for recycling approach have been explored. This concept mainly focussed on replacing the fixed connection currently present in the Spatium system with reusable alternatives and reducing material variety to simplify component and material separation for users. An expert interview suggested the potential to recycle the twin tube component without extensive decontamination. If realised, this approach could reduce emissions by more than 100.000 kg CO_2-eq by the end of year 3 post-market introduction.

Advice to Spatium

As a medical start-up, Spatium is limited in time and resources. For this reason, project results have been organised into three future horizons to guide and prioritise a strategic approach for the coming years.

The first short-term horizon focuses on optimising the current design, aligning sustainable and ethical values with Spatium's identity and committing to verified sustainable targets. Strategies in this horizon require minimal design changes and financial investments, targeting reductions in CO_2 emissions and waste generation associated with the current proposed designs.

The second medium-term horizon focuses on developing initial circular products and product flows while communicating progress on sustainability targets and building trust with customers. Strategies for this horizon integrate existing circular solutions into Spatium's system, extending product life cycles and expanding the product range.

The third long-term horizon focuses on optimising the circularity of Spatium's products, communicating achieved and future sustainability goals, and establishing Spatium as a sustainable example in the MedTech industry. This horizon develops innovative circular interventions to enhance product circularity and explores strategies previously limited by higher product volumes and scalability.

9.2 Implications

The findings of this project have implications for various stakeholders, including the environment, Spatium, the MedTech industry, hospitals and the academic research field.

Environment

The implementation of the proposed circular strategies has environmental implications. By reducing the waste generated during laparoscopic surgery and lowering the CO_2 emissions associated with disposable medical devices, the project demonstrates the potential for creating a more sustainable healthcare system. Additionally, it aims to inspire stakeholders to adopt environmentally responsible design approaches, showcasing that applying circular strategies in healthcare can yield significant environmental benefits.

Spatium

The gathered insights into the role of sustainability in the procurement process, alongside the proposed sustainability plan, can guide the company to becoming more environmentally responsible and provide a market-competitive position. Additionally, the hotspot impact assessment and applied methodology provide a foundation for Spatium to develop and refine their circular strategies in the future.

MedTech

For the broader MedTech field, this project can serve as both an inspiration and a practical example of applying circular design principles to healthcare. It accentuates the urgent need for a more sustainable healthcare system and sets the stage for more comprehensive circular design projects within the industry.

Hospitals

The findings of the project can also assist hospitals, particularly green teams, in further understanding of the environmental impact and waste linked to laparoscopic procedures and disposables. Furthermore, adopting circular strategies that reduce waste or introduce reusable medical devices offers a more cost-effective alternative to the current linear approach, creating value through sustainable healthcare solutions.

Academia

Lastly, this project creates academic value by applying existing circular design strategies to a case study. The reported results and methodology can inspire and guide future designers and researchers, demonstrating the integration of LCA results as input and validation for conceptual design. It also provides an example of how to apply theories of the circular economy to design and, by doing so, explore more sustainable medical solutions.

9.3 Limitations

Although this project comprehensively assesses the current Spatium design, identifies environmental hotspots, and proposes actionable circular strategies, it does have its limitations. These limitations primarily arise from constraints in the generalisability of the findings and the reliance on partially undefined inputs used in the assessments.

Project scope

One of the most considerable limitations of this project was the challenge of addressing a broad and complex topic, such as sustainable healthcare interventions, within the timeframe of a 20-week graduation project. Gaining a deep understanding of complex healthcare systems and products while aiming to address a massive systemic problem proved to be a limiting factor. Although the project successfully addressed the stated research questions and objectives, its complexity inevitably impacted the depth, validation and generalisability of some findings. For instance, insights gathered from stakeholder interactions were primarily based on engagements with Erasmus MC and UMC Utrecht personnel. While these interactions provided key insights for addressing the research questions and designing circular strategies, the findings are limited to the practices and perspectives of these two Dutch hospitals. Given Spatium's intention to enter global markets, further research must validate these findings and explore how sustainability is approached in healthcare systems worldwide.

As Spatium is still developing its final products, many of the findings and results presented in this project are based on intermediate prototypes and anticipated product developments. While this offers some advantages, as the majority of the environmental impact of products is decided in the design phase (Su, 2020), it also means that inputs used for environmental calculations were necessarily more assumptive due to the lack of definitive and final product dimensions.

Concept design
The resulting designed strategies and interventions proposed in this project largely remain conceptual, with varying degrees of development and detail. Most strategies require further extensive research, development, refinement and validation before successful implementation can be achieved. This will require input from and collaboration with professionals and experts in the MedTech field. Furthermore, as discussed, several strategies depend on developing new technologies and achieving sufficient scale to ensure their desirability, viability, and feasibility. Realising these strategies will require coordinated efforts from a range of identified stakeholders.

LCA validation
The environmental assessment conducted in this project combines results and inputs from existing LCA studies on similar products with a self-executed fast-track LCA on the tube set. While this approach was sufficient for the internal hotspot identification and for comparing the current design with the proposed strategies, several limitations to the environmental impact calculations should be acknowledged.

Firstly, the assessment assumes the use location of the tube set to be the Erasmus MC. In reality, the product may be used in hospitals worldwide. To improve the accuracy of the LCA results and validate the findings, a sensitivity analysis considering different use locations is recommended. Such an analysis will further determine the significance of the transportation life cycle within the total impact results.

Secondly, due to the restricted access to supplier data and reliance on open-access LCA software and datasets, the calculations and resulting emissions have been limited to available information. This has led to making simplifications, which likely do not fully represent real-world scenarios.

Lastly, the fast-track LCA conducted in this project focused exclusively on tube set B (see Appendix C for an overview and description of the proposed Spatium tube set options), as it is expected to capture the largest market share and includes all basic functionalities. It is important to note, however, that tube set D is anticipated to have the highest environmental impact. Performing an LCA for tube set D would necessitate additional assumptions as the electronic components could not be modelled using the available datasets and software, rendering the results unrepresentative of actual conditions. Consequently, tube set D was excluded from further analysis within the scope of this project.

9.4 Recommendations

Implementation of strategies
To realise the circular interventions proposed in this project, Spatium will need to explore the next steps and actions outlined in chapter 7.

Concept development
While the short-term strategies have been developed sufficiently for implementation testing, several medium and long-term strategies require further detailing and design changes. Strategies such as reusable trocars, a reusable insufflation tube, the in-line cassette and swappable filters are primarily inspired by existing solutions and approaches. As such, Spatium is advised to conduct further research and evaluations of these alternatives based on their implemented examples. This approach will help avoid unnecessary investment in “reinventing the wheel” and ensure efficient use of resources.

Validation testing
Conducting rigorous validation testing is a critical next step for implementing any proposed strategy. Depending on the strategy, this may include performance testing of the insufflator device with the implemented strategies, usability testing in the operating room through simulating use cases, and sterility testing to validate the proposed circular flows of products and materials. For example, one such test could involve simulating multiple surgery setups in an operating room to determine the minimal viable length needed for the insufflation tube, as suggested during interaction with a surgeon.

Supplier alignment
The proposed design changes must also be aligned with partnering suppliers and manufacturers to assess their feasibility in production. For instance, if reducing the wall thickness of the twin tube proves to be challenging, alternative solutions, such as switching to a stronger material to enable the reduction in thickness, must be explored.

Third-party collaboration

A potential direction mentioned, though not further explored in this project, is collaborating with third-party manufacturers or sterilisation facilities. Such collaborations could reduce CO_2 emissions and waste by enabling the packaging and sterilising of multiple devices used in the same procedures together or by facilitating the reprocessing of medical devices, such as reusable tubing, which the in-house capacity and facilities of hospitals currently limit. While existing examples of such systems were identified, further research is needed to explore the logistics and feasibility of these solutions.

Circular business models

The primary focus of this project was to assess Spatium's current design on sustainability and to propose designed circular strategies to address identified environmental hotspots. However, the consequences of implementing such strategies on Spatium's business model were left largely unexplored. For example, transitioning from disposable to reusable devices will likely impact sales volumes and potentially reduce profits under traditional business models. Hybrid solutions, which combine disposable and reusable components, may offer a compromise by partly maintaining sales volumes while improving the environmental impact. Nevertheless, it is recommended that the implications, market viability, and potential for circular business models that align both environmental and economic values be investigated further.

Life cycle analysis

While the fast-track LCA conducted during this project suffices to identify internal environmental hotspots and compare potential strategies, it is recommended that Spatium commissions an independently validated and certified LCA for its final products when publicly publishing or communicating environmental impact results. This recommendation aligns with findings from stakeholder interactions with hospital procurement experts, who indicated that possessing a verified LCA can also provide a competitive advantage in the tendering process.

9.5 Conclusion

This thesis has explored how circular economy principles can be integrated into the complex domain of single-use medical devices, specifically those present in the Spatium insufflation system. The primary focus of this project was to assess and quantify the environmental impact of the current system, identify environmental hotspots, and design a strategic plan suggesting various circular interventions to help create a truly "future-proof" insufflation system.

The project followed a Double Diamond Design Framework, beginning with an exploration of the project context, identifying the initial disposable hotspot, and a literature review of the principles of the circular economy, selecting four viable R ladder circular flows for Spatium's insufflation disposables. This was followed by empirical interviews with relevant stakeholders, resulting in insights, ideas and user needs. Subsequently, all intermediate findings from the Discover phase were translated into requirements and design guidelines for future strategies. A fast-track LCA analysis of Spatium's products was then conducted to quantify the environmental impact, identifying the twin tube component and the life cycle phases of raw material production and EoL as significant hotspots. In the final phase, nine conceptual circular strategies were developed through six dedicated deep dives and design sprints. These strategies will guide and help Spatium in achieving their sustainability goal.

The resulting designed strategies implement the R ladder circular flows Rethink, Reduce, Reuse, and Recycle to lower CO_2 emissions and waste generated by the Spatium disposables. Insights gained from stakeholder interactions were also instrumental in informing Spatium on the value of implementing sustainability, as doing so can give the company a competitive advantage in the tendering process. As conclusion and final deliverable for the client, a strategic sustainability report was created to guide Spatium in addressing sustainability by mapping all findings into three future horizons. This thesis provides Spatium with actionable steps towards a more circular and sustainable system while also aiming to inspire and serve as an example for future research on applying the circular economy to healthcare.

Thank you for joining my graduation journey!

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Appendix A project brief

Project title:
Design sustainable strategies for the development of the Spatium Insufflation System

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

Introduction

Describe the context of your project here; What is the domain in which your project takes place? Who are the main stakeholders and what interests are at stake? Describe the opportunities (and limitations) in this domain to better serve the stakeholder interests. (max 250 words)

As the healthcare sector continues to grow, the importance of implementing sustainability within the sector rises. In 2022 the RIVM estimated that the healthcare sector is responsible for 7% of the national carbon footprint in the Netherlands (Steenmeijer et al., 2022). This means that the sector that works to preserve our health is also polluting the world and indirectly making us less healthy. Movements and projects such as the Green Deal on Sustainable Healthcare are gaining momentum and focus on making healthcare more sustainable through, for example, reducing the amount of waste produced in operating rooms.

Spatium Medical is a spin-off of the Erasmus MC hospital. They are working on the development of the next-generation insufflator meant to improve the experience of patients and surgeons during laparoscopic surgeries. In addition, they are now looking into ways in which their product is not only better in terms of surgical purposes but also respects the planet. I will collaborate with designers at Spatium Medical with the goal of designing strategies to lower the environmental impact of the Spatium Insufflation System consisting of an active medical device and a disposable tube set.

The primary stakeholders include patients and surgeons who come in contact with the device, as well as Spatium Medical, who, as a startup, are highly dependent on the feasibility, viability and desirability of the Insufflation System. A thorough analysis of the stakeholders and their relationships will occur in the initial stages of the project.

It will be interesting to explore the limitations and opportunities of creating a more sustainable medical device. While it is clear that a more sustainable healthcare sector is desirable, sustainability in healthcare specifically is a challenging topic as it needs to be carefully balanced with other values such as costs, work pressure and safety.

Problem definition

What problem do you want to solve in the context described in the introduction, and within the available time frame of 100 working days? (= Master Graduation Project of 30 EC). What opportunities do you see to create added value for the described stakeholders? Substantiate your choice. (max 200 words)

The assignment stated the following challenge: How can we (Spatium Medical) reduce the environmental impact of the Spatium Insufflation System? To address this challenge, the following topics will be explored:

- Analyse the importance of sustainability within the life cycle of the Insufflation System. How to balance the sustainability value with surgical and patient needs? Where can the biggest impact be adverted? Explore strategies across the entire care pathway.

- Identify parts and/or processes of the Insufflation System that have the biggest impact in relation to its environmental footprint.

- Quantify and propose strategies for environmental improvements of the system, which may encompass innovations in the design of the device or tube set, manufacturing, marketing processes or other areas pertinent to sustainability.

- Propose a strategic plan for the implementation of the largest identified impact strategies.

Appendix A project brief

Assignment:

This is the most important part of the project brief because it will give a clear direction of what you are heading for. Formulate an assignment to yourself regarding what you expect to deliver as result at the end of your project. (1 sentence) As you graduate as an industrial design engineer, your assignment will start with a verb (Design/Investigate/Validate/Create), and you may use the green text format:

Create a strategic plan for evaluating and improving the sustainability of the Spatium Insufflation System for Spatium Medical with the goal of reducing the overall environmental impact of the system.

Then explain your project approach to carrying out your graduation project and what research and design methods you plan to use to generate your design solution (max 150 words)

Literature research and, if possible, expert interviews will be conducted to first get a better understanding of the need to reduce the product's footprint. The resulting findings will be analysed on their ties with the needs and values of identified stakeholders along the care pathway of the device. After which, the impact of the actual device will be determined through environmental and/or circulatory assessment methods such as, life cycle assessment or health technology assessment. The specific and most suitable method for doing this will be explored and determined within the graduation assignment. After assessing the impact, strategies for environmental impact improvement will be constructed, and an implementation plan for such strategies will be proposed. Depending on the outcome of this research and the product's development time, the implementation of such a proposed strategy might be included as part of the graduation project.

The project's ultimate output will take the form of a report in which the proposed implementation strategy for decreasing the environmental impact of the device is quantified and the outcome of the research will be included.

Motivation and personal ambitions

Explain why you wish to start this project, what competencies you want to prove or develop (e.g. competencies acquired in your MSc programme, electives, extra-curricular activities or other). Optionally, describe whether you have some personal learning ambitions which you explicitly want to address in this project, on top of the learning objectives of the Graduation Project itself. You might think of e.g. acquiring in depth knowledge on a specific subject, broadening your competencies or experimenting with a specific tool or methodology. Personal learning ambitions are limited to a maximum number of five. (200 words max)

During my SPD master and electives I have completed multiple courses with both sustainable and medical topics or a combination of both. I am personally very interested in strategizing the balance of making a product/service more sustainable while keeping it affordable/safe/convenient. I believe this graduation project is a great opportunity to learn more about what work like this looks like in a real-world scenario. Furthermore, I personally like designing/strategizing for medical purposes as it makes me feel that the work I do contributes to more than just financial gain.

Some of the competencies I aim to learn and develop through this project are:

- Experiencing what it is like to do real-world design work
- Designing within the medical landscape and how to work within these set-out processes.
- Developing and improving skills surrounding documentation of the detailed environmental impact of a device's life cycle

Appendix A project brief

Planning

The Gantt chart below depicts the planning as is for the project. The overall project is split up into two main phases: The research and exploration phase, which encompasses all blue boxes. And the execution and evaluation phase, which encompasses all the orange boxes. The phases are split around the midterm point as I plan to conclude most of the research and exploration phase by then.

The academic two week Christmas break is included in the planning since I will also be on holiday around that period. Furthermore, the key moments and major dates are included in the planning. The midterm presentation forms the barrier between the two phases and offers a nice evaluation opportunity. While the Green Light meeting is planned ahead of the holidays so as to leave enough time to finish the project. Near the end, I have also left open a couple of weeks, which I plan to dedicate to writing and finalizing my report.

Additionally, Spatium works with a monthly sprint system of which the dates are visible at the bottom of the chart. I have tried aligning the sprint reviews and start dates at Spatium with my various project phases as much as possible so that I can use these moments to present my preliminary results to the Spatium team and get feedback on my work.

Since I will be working most days at the Spatium offices, I can readily get feedback there. During the kickoff, I plan on agreeing to weekly or bi-weekly meetings with my supervisors at the TU. On these agreed-upon days, I will work at the TU faculty of industrial design so that I can not only meet with my supervisors but also work together with other graduating students.