

TOWARDS A CIRCULAR TAVI PROCEDURE

A transition pathway for circularity in healthcare practice

Eleonore van Hees
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Figure 1: Delivery system

Towards a Circular TAVI Procedure

A transition pathway towards circularity in healthcare practice

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Eleonore van Hees
5033977

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Committee

Prof. Dr. Ir. Jan-Carel Diehl
Ir. Caroline Kroon
Department of Sustainable Design Engineering

Preface

This report marks the completion of my graduation project and, with that, the end of my studies. Over the past months, I have worked on the question of how the TAVI products could transition towards a more circular future. What started as a product-focused challenge gradually developed into a broader exploration of healthcare as a complex system, in which circularity depends not only on design choices but also the system around it.

This has pushed me beyond my usual way of thinking as a product designer. This made the project both challenging and rewarding.

I had the opportunity to work on this project in close collaboration with people from different backgrounds, each of whom brought valuable knowledge and perspectives. Their input helped me better understand the medical context, the practical realities of hospital care, and the broader systemic conditions needed to make circularity possible.

Looking back, this project has been a meaningful and educational final step in my studies. It has strengthened my interest in complex systems, sustainability, and real-world implementation. I hope this report contributes, even if only in a small way, to the ongoing discussion on how healthcare can move towards a more circular future.

Acknowledgements

I would like to thank my graduation committee, JC and Caroline, for their valuable feedback, support and encouragement throughout this project.

JC, thank you for always being fully engaged during our meetings and for providing sharp and valuable feedback.

Caroline, thank you for encouraging me to explore the systemic design and for introducing me to this completely new design field. I am very grateful for the time you took to explain the methods, for your detailed feedback, and for broadening my approach to this project.

A special thank you to Aysegül for the extra coaching and support throughout the process, and for helping to organise the co-creation sessions. Your help made a real difference.

I would also like to thank Jasper for sharing gis knowledge and expertise in the medical field, which were very valuable in helping me understand the context of this project. As well as your expertise in the waste audits. Thank you as well for the great lunches and the many good laughs along the way.

An, thank you for doing the research for this project together, I think we were a great team. And Cat, thanks to you for the coffee and the laughs throughout this journey.

Executive summary

Healthcare delivers major health benefits but also generates significant waste and emissions. In interventional cardiology, many products are used once and then incinerated as hazardous waste. This report focuses on the TAVI procedure as a representative example: a procedure in which high-value, single-use products containing high-quality polymers and precious metals are used. This results in a loss of material value and repeated demand for virgin resources.

The central problem addressed in this project is that improving end-of-life outcomes is not only a product challenge. Even if a device is technically recyclable, it can still be incinerated if the workflow, waste routing, contracts, and responsibilities remain unchanged. Circularity, therefore, requires system change.

This project aims to identify ways to improve the end-of-life of the TAVI products to reduce environmental impact and value loss while maintaining clinical safety and compatibility with the Cath lab. The work addresses this through a combined product-and-system approach. System-level analyses were done to understand how the end-of-life is shaped in practice.

Product-level analyses were done to identify environmental and material hotspots. These findings were translated into design requirements to identify realistic directions for intervention.

Based on these findings, a transition strategy is proposed. The near-term focus is on a recycling route that is compatible with the current system. This phase aims to reduce incineration and enable higher-quality material recovery through design-for-recycling and material transparency. The longer-term direction is partial reuse of the delivery system's handle, which offers higher value retention but requires additional conditions, such as validated sterilisation and inspection, traceability of use cycles, and a defined liability and quality contract. Co-creation sessions were used to test feasibility assumptions and to clarify what stakeholders need to implement such changes in practice.

The report concludes that a circular pathway for the TAVI delivery system is feasible only if product interventions and system interventions are developed together. The deliverable of this project is a booklet to help all stakeholders realise this transition.

List of abbrevations

ABS	Acrylonitrile Butadiene Styrene
Cath lab	Catheterisation laboratory
CO2	Carbondioxide
CSA	Central Sterilisation Department
EMS	Erasmus Medical Centre
EOL	End-of-life
ESCH-R	Evidence-based Strategies to create Circular Hospitals: Applying the 10-Rs framework to healthcare
IC	Interventional cardiology
LCA	Life Cycle Assessment
MLP	Multi-Level Perspective
OEM	Original Equipment Manufacturer
PaaS	Product-as-a-Service
SZA	Speciaal Ziekenhuis Afval
TAVI	Transcatheter Aortic Valve Implementation



Figure 2: Waste audit

Glossary

Co-creation	The collaborative process of involving stakeholders, such as customers, suppliers, employees, or the public, in creating or improving products, services, or experiences (Ertz, 2024).
End of life	Products, materials, or components that have served their intended purpose and are discarded by the final user (Abbaspour & Heydari, 2022).
Hazardous waste	Discarded materials with properties that make them potentially harmful to human health or the environment (Maowei et al., 2021).
Incineration	A high-temperature thermal treatment process used to combust waste produced by hospitals, clinics, and research facilities, converting it into inert ash, gas, and heat (EUROPEAN COMMISSION, 2006).
Infection Prevention	A practical, evidence-based discipline aimed at preventing the spread of infections, particularly healthcare-associated infections (HAIs), among patients, staff, and visitors (Costa et al., 2020).
Reprocessor	A reprocessor is an entity, system, or device that subjects used materials or medical instruments to specialized cleaning, disinfection, sterilization, and functional testing to enable their safe reuse (Van Drongelen et al., 2008).
Sterilisation	The process of making something free from bacteria or other living microorganisms (Korsman et al., 2012).
Transition	The process or a period of changing from one state or condition to another (Silva & Stocker, 2018).
Original Equipment Manufacturer	A company that designs, engineers, and manufactures specialized medical components, modules, or finished devices (Yang et al., 2022).
Point of use	The specific location where a product, service, or material is actually used, consumed, or treated (Eberhardt et al., 2024).
Product-as-a-Service	Abusiness model where customers access the functionality or outcome of a physical product through a subscription or usage-based contract (Hidalgo-Crespo et al., 2024).
Procurement	The strategic, end-to-end process of sourcing, negotiating, and acquiring medical supplies, equipment, pharmaceuticals, and services (Akabueze, 2025).
Reverse logistics	The process of managing goods moving backward through the supply chain—from the final destination (customer) back to the seller or manufacturer (de Brito & Dekker, 2002).

Table of contents

1 Introduction 7

1.1 Circular challenges in healthcare system 8
1.2 Analogy 9
1.3 TAVI case and context 10
1.4 Problem statement 11
1.5 Aim and research question 11
1.6 Approach 12
1.7 Involved parties 13
1.8 Context of the project 13

2 Background 14 14

2.1 Transcatheter Aortic Valve Implantation 15
2.2 The TAVI delivery system and its components 16
2.3 Clas III Medical Devices 20
2.4 Use in the Cath lab 22
2.5 Conclusion 24

3 Circularity in healthcare: a system perspective 25

3.1 Socio-technical system 26
3.2 Multi-level perspective 26
3.3 Healthcare system 27
3.4 Actors and roles in the healthcare system 27
3.5 From system perspective to system analysis 28
3.6 Stakeholder map 29
3.7 Trend analysis 31
3.8 Conclusion 32

4 Circularity in healthcare: a product perspective 33 33

4.1 Circular economy 34
4.2 Value hill 35
4.3 Circular economy in healthcare 36
4.4 From product perspective to product analysis 36
4.5 Life cycle overview 37
4.6 Product journey map 38
4.7 Waste audit 41
4.8 Disassembly 44
4.9 LCA 47
4.10 Benchmark 50
4.11 Conclusion 52

5 From insights to intervention 53 53

5.1 Translating hotspots to requirements 54
5.2 Idea selection 55
5.3 Conclusion 56

6 Collaborative creation with stakeholder 57

6.1 The need for co-creations 58
6.2 Co-creation OEM and ESCH-R 58
6.3 Co-creation hospital 60
6.4 Co-creation OEM 63

7 Designing the transition pathway 65

7.1 The transition goal 66
7.2 Shaping the transition 66
7.3 Future vision 67
7.4 Backcasting 68
7.5 Key challenges in the transition 69
7.6 Multi-level transition 71
7.7 Transition timeline 73
7.8 Parts for recycling and reuse 74
7.9 Stakeholders in the transition 75
7.10 Actions across the four levels 76
7.11 The transition map 80
7.12 Life cycle 82
7.13 Product interventions 83

8 Evaluation 88

8.1 Desirability 89
8.2 Feasibility 90
8.3 Viability 91

9 booklet 92

9.1 The booklet as communcation tool 93

10 Conclusion 94

10.1 Discussion 95
10.2 Conclusion 96
10.3 Recommendations 97
10.4 Personal reflection 98

11 References 99

12 Appendix 104

01

Introduction

This chapter introduces the context and scope of the project. It explains the circular challenges in healthcare, positions the TAVI procedure as the case study, and outlines the main research aim, questions, and project context.



Figure 3: Green Deal (Green Deal Duurzame Zorg 3.0, n.d.)

1.1 Circular challenges in healthcare system

In the Netherlands, healthcare accounts for about 7% of national CO_2 emissions (Steenmeijer et al., 2022), as well as 4% of all waste and 13% of raw material use, including metals and minerals (Krens, 2024).

This paradox, where the sector dedicated to health also affects the health, underscores the urgency of circular interventions.

This challenge cannot be solved by looking at products alone. In healthcare, environmental impact is shaped by a wider system of people, routines, regulations, infrastructure, and procurement. For that reason, this project takes a holistic and systemic approach. It looks not only at the product itself, but also at the system around it.

This broader direction is also reflected in Dutch healthcare policy. With the Green Deal Sustainable Healthcare 3.0, healthcare organisations committed themselves not only to reducing emissions and using fewer virgin materials, but also to changing the wider healthcare system through awareness, education, collaboration, and circular procurement (Green Deal Duurzame Zorg 3.0, n.d.). Erasmus MC is part of this deal.

This report builds on that context by exploring how circular system- and product-level interventions can contribute to a more circular healthcare.





Promote health among patients, clients and employees



Raise awareness and understanding of the impact of healthcare on climate and vice versa



Reduce CO2 emissions by 55% by 2030 and to be climate neutral by 2050



Reduce the consumptions of primary raw materials by 50% by 2030 and maximise circularity in healthcare by 2050



Reduce environmental harm caused by (use of) medication.

1.2 Analogy

This transition can be explained through the metaphor of bicycle training wheels. Before more advanced circular strategies can work, the right system conditions need to be in place, such as reverse logistics, clear responsibilities, reporting, and transparency. Early interventions can help build this foundation in a gradual way, just as training wheels help build balance before riding without support.



Figure 5: Training wheels (Progear bikes, 2024)

1.3 TAVI case and context

Within this broader healthcare challenge, the TAVI procedure was selected as the case for this project. The TAVI procedure relies on several single-use products, including the delivery system, loading system, and packaging. After use, much of the value in this product set is lost, while new products are needed for each procedure.

Erasmus MC's carbon footprint reporting shows that a large share of its environmental impact comes from the purchase of goods and services (Lau et al., 2024). According to this report, around 60% of the hospitals CO_2 footprint is linked to procurement.

The TAVI procedure brings together several aspects of the wider healthcare challenge: a highly regulated and safety-critical context. This makes it a useful case for exploring how circular strategies can be combined with wider system-level change in healthcare.

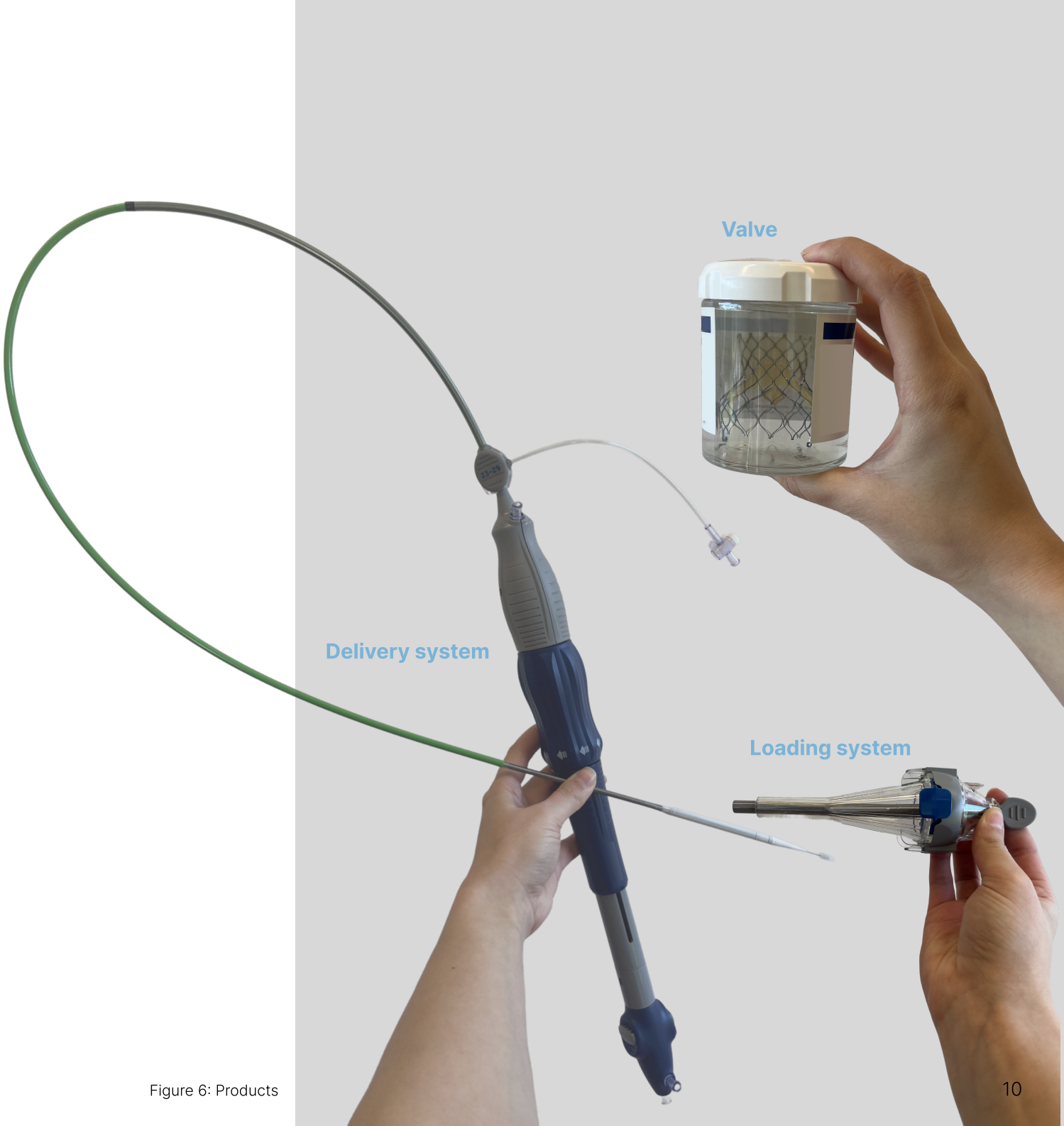


Figure 6: Products

1.4 Problem statement

The TAVI products currently follow a largely linear life cycle. After a procedure, the products are discarded, which creates repeated demands for virgin materials and leads to the loss of product and material value after a single procedure.

This outcome is not determined by products alone. It is shaped by the wider healthcare system in which they are used. As a result, circular alternatives may be technically possible, but still difficult to implement in practice.

At the same time, manufacturers often still rely on business models based on the sale of single-use products. Moving to a circular model affects the current revenue stream, making change difficult for financial and strategic reasons.

The problem is therefore not only that value is lost, but also that the current system is not designed to keep that value. This report addresses that gap by examining where environmental impact and value loss occur in the TAVI product set, and what product-level and system-level changes are needed to support more circular alternatives.

This thesis addresses the problem that the TAVI products are currently embedded in a linear healthcare system that causes material value loss after one use, while circular alternatives remain difficult to implement due to product, workflow, and system-level constraints.

1.5 Aim and research question

The aim of this project is to create a pathway for transitioning the single-use TAVI products from its current linear “take-make-waste” model towards a more circular model. By researching the product, system, and regulatory barriers that shape this transition, the project aims to identify and propose feasible circular intervention strategies for hospital context.

Main research question:
How can the single-use TAVI products be transitioned towards more circular end-of-life strategies while maintaining clinical safety and compatibility with the hospital environment?

Sub-questions:

1. How is the TAVI delivery system currently used, handled, and disposed of within the context of Erasmus MC?
2. Which system-level characteristics create the main opportunities and barriers for more circular strategies for the TAVI products?
3. Which product-level haracteristics create the main opportunities and barriers for more circular strategies for the TAVI products?
4. What transition pathway could enable the TAVI products to move from its current linear model towards feasible circular strategies in practice?

1.6 Approach

This report uses a combined top-down and bottom-up approach, because the circular transition of the TAVI delivery system is not only a product issue, but also a system issue. The current linear outcome is shaped not just by the design of the device itself, but also by workflows, waste routing, safety requirements, responsibilities, infrastructure, and stakeholder interests. To identify realistic intervention opportunities, both levels need to be understood together.

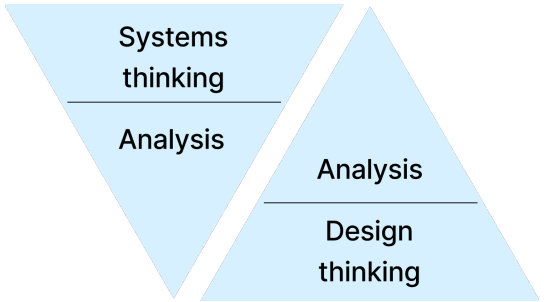


Figure 7: Top-down, bottom-up

The top-down perspective starts at the system level and is informed by systems thinking. It examines how the current end-of-life outcome is shaped by the wider healthcare context, including clinical routines, logistics, regulation, waste infrastructure, and the roles of different stakeholders. This perspective is important because it helps explain why the current linear system persists and under which conditions circular alternatives may become feasible.

The bottom-up perspective starts at product level and is informed by design thinking. It looks at the TAVI product to understand where environmental impact and material value are concentrated, and which product characteristics enable or constrain circular strategies. Methods such as life cycle assessment, disassembly analysis, and benchmarking help identify where value is lost and where product-level improvement opportunities may exist.

Together, these two perspectives are used to identify realistic intervention opportunities. The product perspective helps show where change could have value, while the system perspective helps show under which conditions that change could work in practice. Combining both makes it possible to move towards interventions that are both environmentally relevant and practically feasible.

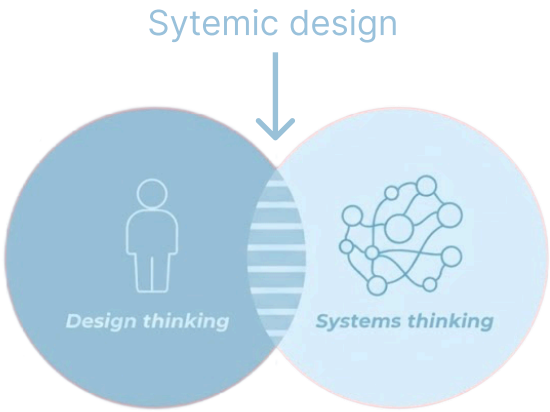


Figure 8: Systemic design

1.7 Involved parties

This graduation project was carried out in collaboration with several parties.

ESCH-R Consortium
This graduation project is part of the ESCH-R consortium. ESCH-R is a project funded by the Dutch Research Council. It stands for 'Evidence-based Strategies to create Circular Hospitals: Applying the 10-Rs framework to healthcare.' (Home - ESCH-R Consortium, 2025). Their aim is to "accelerate the adoption of circular intervention in hospitals and thereby lower the ecological footprint in healthcare" (Home - ESCH-R Consortium, 2025).

TU Delft
This project was conducted as part of the master's programme in Integrated Product Design at Delft University of Technology. The TU Delft provides the academic framework of this project, including supervision, methodological guidance, and design support.

Erasmus Medical Centre
Erasmus Medical Centre (EMC) is the hospital context in which this project takes place. It is the largest academic hospital in the Netherlands. Within this project, EMC contributes practical knowledge about the healthcare setting and helps connect the research to the daily context in which circular interventions would need to work.

1.8 Context of the project

This project is positioned within a wider movement in Dutch healthcare to reduce environmental impact while maintaining clinical quality and safety. In recent years, sustainability has moved from a concern to a priority for healthcare organisations, driven by national agreements, targets, and growing awareness of the environmental burden of healthcare. Within this context, both Erasmus MC and the OEM are operating under increasing pressure to reduce emissions, lower material consumption, and explore more circular ways of delivering care.

Although this case is specific, the intention is not to develop a final redesign for one product. Instead, the TAVI procedure is used as an example of a broader category of similar single-use medical devices used in the interventional cardiology department. These devices often have the same structure as the delivery system (precious metal in the tip, complex wire design, and a handle) and are also incinerated.



Figure 9: Sterile storage EMC

02

Background

This chapter provides the clinical and operational context for the TAVI delivery system. It introduces the TAVI procedure, the associated product set, the functional role of the delivery system, its regulatory classification, and the Cath lab environment in which it is used.

Research question 1:
How it the TAVI delivery system currently used, handled, and disposed of within the hospital context of Erasmus MC?

2.1 Transcatheter Aortic Valve Implantation

Transcatheter Aortic Valve Implantation (TAVI), also referred to as Transcatheter Aortic Valve Replacement (TAVR), is a minimally invasive alternative to surgical aortic valve replacement for patients with severe aortic stenosis.

In aortic stenosis, the aortic valve becomes narrowed and restricts blood flow from the heart into the aorta (Figure 11). This can lead to symptoms such as shortness of breath, chest pain, dizziness, and reduced exercise tolerance.

Traditionally, these patients were treated with open surgical aortic valve replacement (SAVR), which is an open heart surgery.

Compared with open-heart surgery, TAVI is typically associated with a shorter hospital stay and faster recovery. Recent work also reports that the carbon footprint of TAVI performed in a Cath lab is lower than SAVR, with indicative ranges of 290–360 kg CO_2e for TAVI versus 620–750 kg CO_2e for SAVR (Blitzer et al., 2025).

TAVI avoids opening the chest by delivering a replacement valve through the vascular system via a catheter-based delivery system. In most cases, the delivery system enters the body through the femoral artery in the groin and is guided through the blood vessels towards the heart (Figure 10).

Once the system reaches the aortic valve, the prosthetic valve is positioned and deployed, after which it immediately takes over the valves function. In some cases, alternative access routes are used when transfemoral access is not suitable.

Approximately 3000 procedures are done per year, (Jaarcijfers Behandeling Van Aortakleplijden: Hart & Vaatcijfers, n.d.). The procedure is typically performed under local anaesthesia, has a duration of around 60 minutes and is performed by interventional cardiologists. The patient group is generally older, with an average age in the early 80s (Demal et al., 2023).

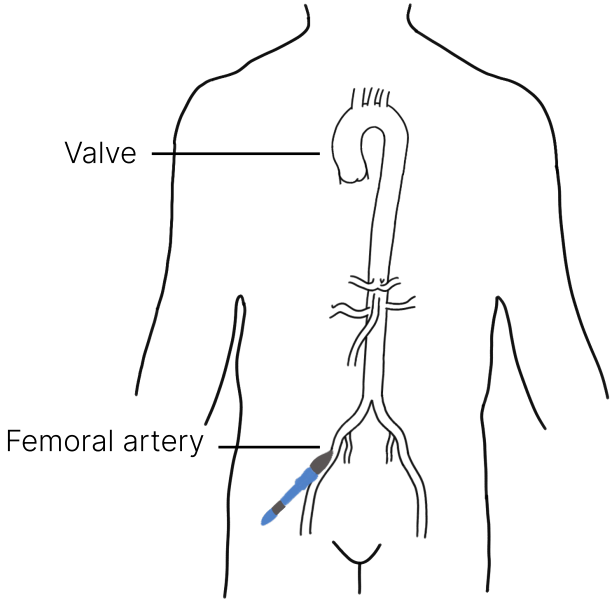


Figure 10: Delivery system in body

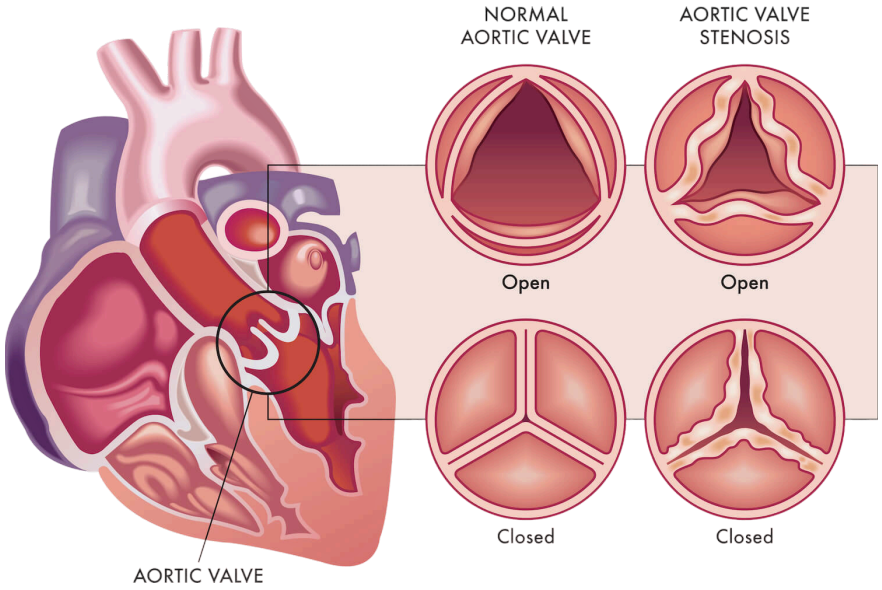


Figure 11: Diseased aortic valve (Keyhole & Robotic Heart Surgery Centre, 2024)



Figure 12: Products

2.2 The TAVI delivery system and its components

The TAVI product set used in the procedure consists of four main products: the valve, the delivery system, the loading system, and the delivery system packaging.

The valve is the implant that stays in the patient. The delivery system is used to position and deploy the valve. The loading system supports preparation by enabling the valve to be mounted onto the delivery system. The packaging protects the delivery system during transport and storage and helps load the valve onto it.

Function and features of the delivery system

The function of the delivery system is to support controlled navigation through the vascular system and allow the device to be advanced through the body. The device can be divided into three functional parts. First, **the handle** enables the user to control the system during the procedure. Second, **the catheter shaft (the wire)** provides a flexible connection between the handle and the distal end of the system, allowing the device to be advanced through the body. Third, **the distal end (the tip)** holds the valve and deploys the valve. Although the exact configuration differs per brand, these functional groups are present in all systems.

There are two types of delivery systems: self-expandable and balloon-expandable. This distinction describes how the valve expands once positioned (Wang et al., 2023). Both types are used at Erasmus MC.

- **Self-expandable:** uses a valve with a frame that expands once the constraint of the delivery system is released (Figure 13).
- **Balloon-expandable:** uses a balloon to expand the valve (Figure 14).

The choice between these types depends on patient-specific factors and the balance of risks and benefits, including differences in complication profiles (Mack et al., 2015).

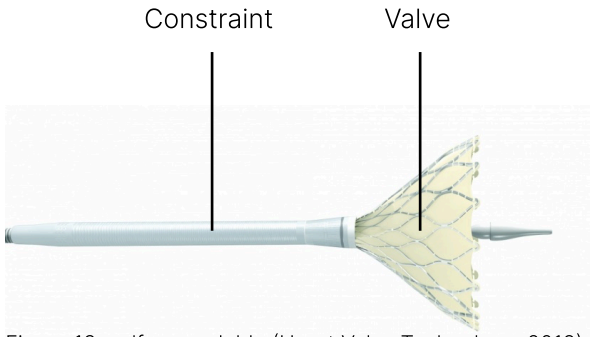


Figure 13: self expandable (Heart Valve Technology, 2018)

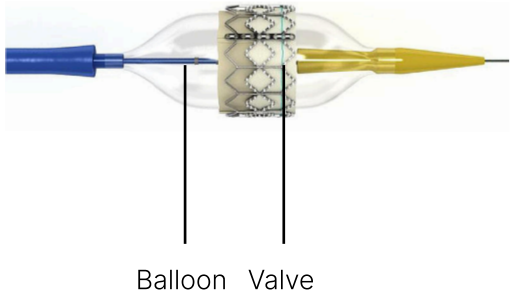


Figure 14: balloon expandable (Webb, et al., 2009)

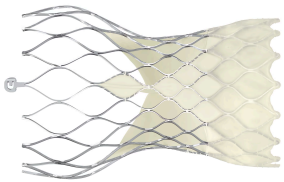


Figure 15: valve (Medtronic, n.d.)

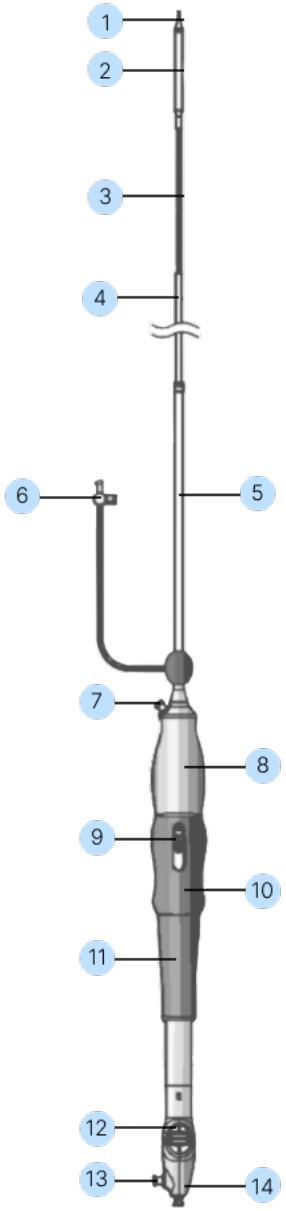


Figure 16: Functions and features of delivery system

Features and functions of the delivery system (Figure 16):

1. **Catheter tip**: leads the system through the vessels and across the valve.
2. **Capsule**: holds the valve and constrains it until deployment.
3. **Catheter shaft:** transmits push/pull, torque and rotation from the handle and carries internal lumens.
4. **Stability layer:** extra outer reinforcement that improves the strength and keeps the system coaxial while advancing / deploying.
5. **Sheath**: integrated protective / hemostatic sheath that reduces the insertion profile and shields the valve during advancement.
6. **Sheath flush port:** port to de-air/flush the sheath with saline.
7. **Stability layer flush port:** port to de-air/ flush the stability layer with saline.
8. **Gray front grib:** distal handhold for the doctor.
9. **Trigger**: safety/actuation control that enables or initiates the deployment
10. **Deployment knob**: knob that precisely advances/retracts the capsule for positioning of the valve.
11. **Blue hand rest:** proximal handhold for the doctor.
12. **Tip-retrieval mechanism**: built-in control that lets the doctor recapture/repostion the valve.
13. **Capsule flush port:** port to de-air/flush the capsule.
14. **Wire lumen flush port**: port to de-air / flush the wire lumen.

Supporting products: packaging and loading system

The packaging has a protective and sterile function. It forms the sterile barrier of the product set and protects the delivery system during transport and storage. In addition, the packaging includes a rinsing bath to rinse the valve in sterile saline. It also has a loading bath that is used to load the valve on the delivery system.

It exists of the following features and functions (Figure 17):

15. **Loading bath:** used to load the valve onto the delivery system in saline.
16. **Mirror**: integrated mirror that shows the underside of the loading for visual control.
17. **Folding section**: hinge area that allows the packaging to be folded for handling and space efficiency.
18. **Blue tab**: multiple blue tabs fit in the entire packaging to hold the valve in place or to keep the packaging secure when folding double.
19. **Rinsing bowls:** removable cups originally integrated in the packaging where the loading bath is, used to rinse the valve with saline.
20. **Handle section:** part of the packaging where the handle of the device sits.

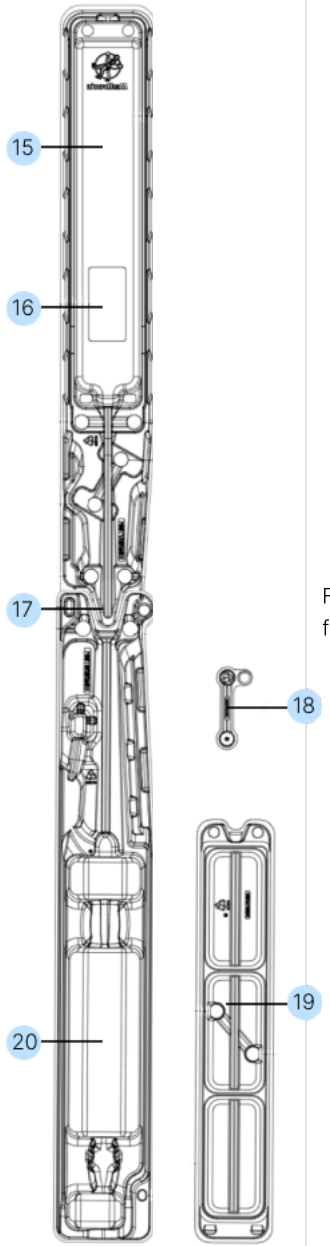


Figure 17: Functions and features of packaging

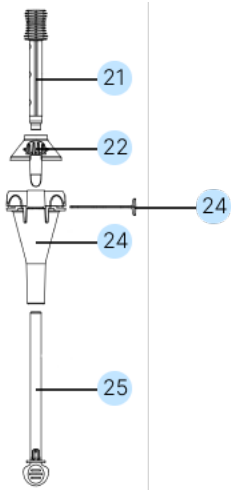


Figure 18: Functions and features of loading system

The loading system is used to place the valve on the delivery system before entering the body. It exists of the following features and functions (Figure 18):

20. **Capsule guide tube:** keeps the capsule of the delivery system aligned while the valve is loaded so it can slide in without catching or twisting.
21. **Outflow cone**: centers and supports the end of the valve during loading to prevent the frame or leaflest of the valve to damage.
22. **Backplate**: gives a stable surface to push against so parts don't move while crimping/advancing.
23. **Inflow cone**: centers and the other end of the valve and guides it smoothly into the capsule, keeping the valve orientation correct.
24. **Catheter tip guide tube:** holds and protects the catheter tip of the delivery system.

The Figures on the right show the rinsing of the valve (top) and the loading of the valve onto the delivery system (bottom)

Takeaways

- The delivery system is the central product of the procedure.
- Changing the delivery system's design might also influence the loading system and packaging, as they all work together.
- The presence of different delivery systems suggests that circular strategies cannot be automatically standardised across all brands at the hospital.



Figure 19: Rinsing of valve



Figure 20: Loading the delivery system

2.3 Class III Medical Devices

The delivery system is a Class III Medical device under the European Medical Device Regulation (EU MDR) (Medical Device Classification, 2024.). In the EU, medical devices are divided into three risk classes based on their intended purpose and associated risks, with Class III being the highest-risk category.

For cardiovascular delivery systems, this high classification is linked to the intended use and level of risk. Surgically invasive devices intended for short-term use are classified as Class III when they come into direct contact with the heart or are used to monitor, diagnose, or correct defects there.

Class III devices are subject to the strictest regulatory scrutiny: conformity assessment involves strong notified-body oversight, and clinical investigations are required.

Takeaways

- Safety and regulatory compliance are central to any circular intervention.
- Redesign and implementation timelines are long.

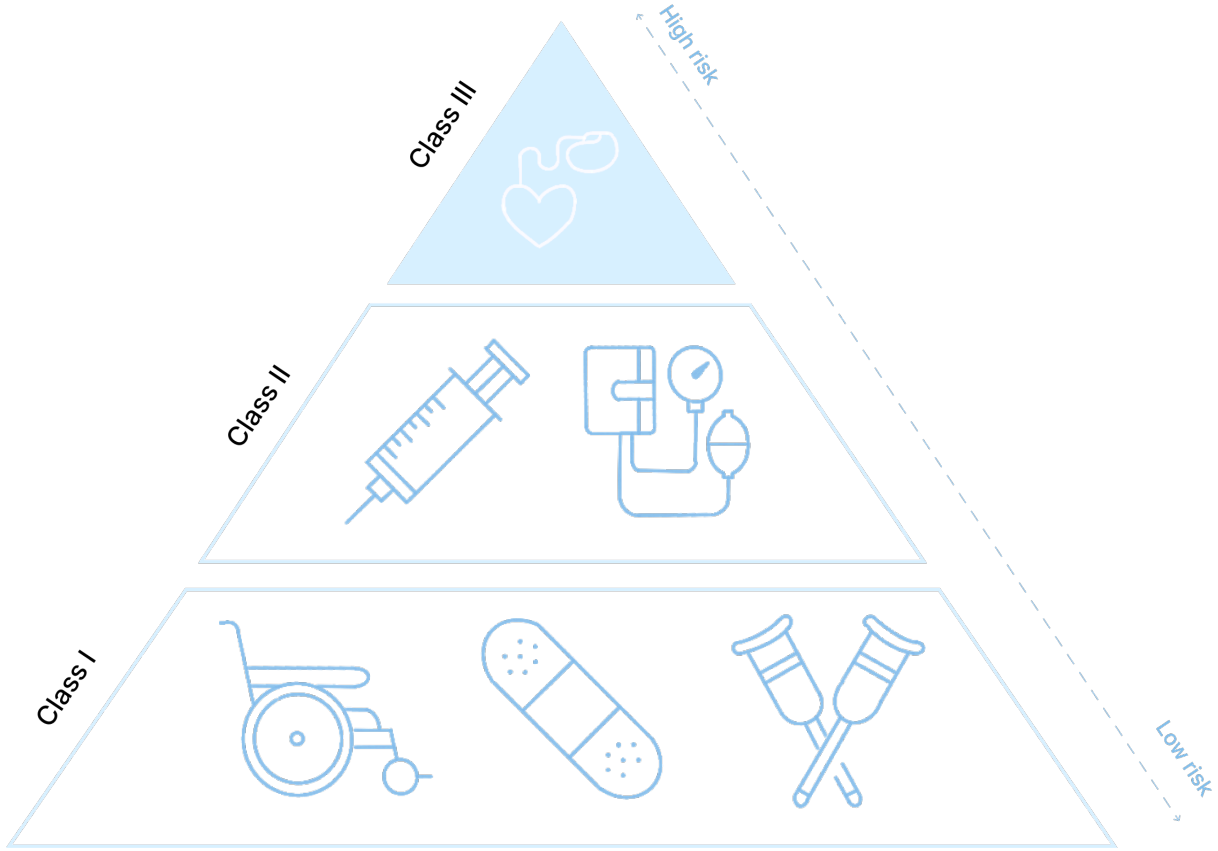


Figure 21: Class III Medical device



Figure 22: Cath lab Erasmus MC

2.4 Use in the Cath lab (workflow and roles)

The TAVI procedure takes place in a Cath lab. This is a specialised hospital department where minimally invasive procedures are performed with imaging and monitoring equipment.

Connected to the Cath lab is a sterile storage for most products required during procedures. The TAVI delivery system is stored separately and is brought in from a different room. Before the procedure starts, logistics staff set up the TAVI table (Figure 23), ensuring the required materials are already in the room.

Waste from the Cath labs is brought to a nearby drop-off point ("the slot"), where it is collected before internal transport.

The Cath lab is a time-critical and safety-focused environment. After the procedure is completed, the room is quickly cleaned, and the next patient is already waiting outside.

During a standard TAVI procedure, there are seven people in the Cath lab:

- **Two interventional cardiologists** work together to insert the delivery system. One mainly stabilises the handle, while the other controls handle movements during positioning and deployment.
- **One sterile nurse** who loads the valve onto the delivery system and hands instruments to the cardiologists.
- **One circulating nurse** supports the procedure by retrieving additional items from sterile storage, scanning all products used, and communicating with the patient.
- **Two technicians**: one positioned near the patient to support measurements and monitoring, and one behind the lead screen operating the imaging equipment and viewing the scans, which are also shown on the cardiologists' screens.
- **The patient**

Takeaways

- As the Cath lab is a time-critical environment, any circular intervention must fit this environment.
- The physical organisation of the Cath lab, along with its storage and waste infrastructure, shapes what is practically possible. There is limited space in the slot, and there are already many bins, so any intervention should fit within this space.



Figure 23: TAVI table

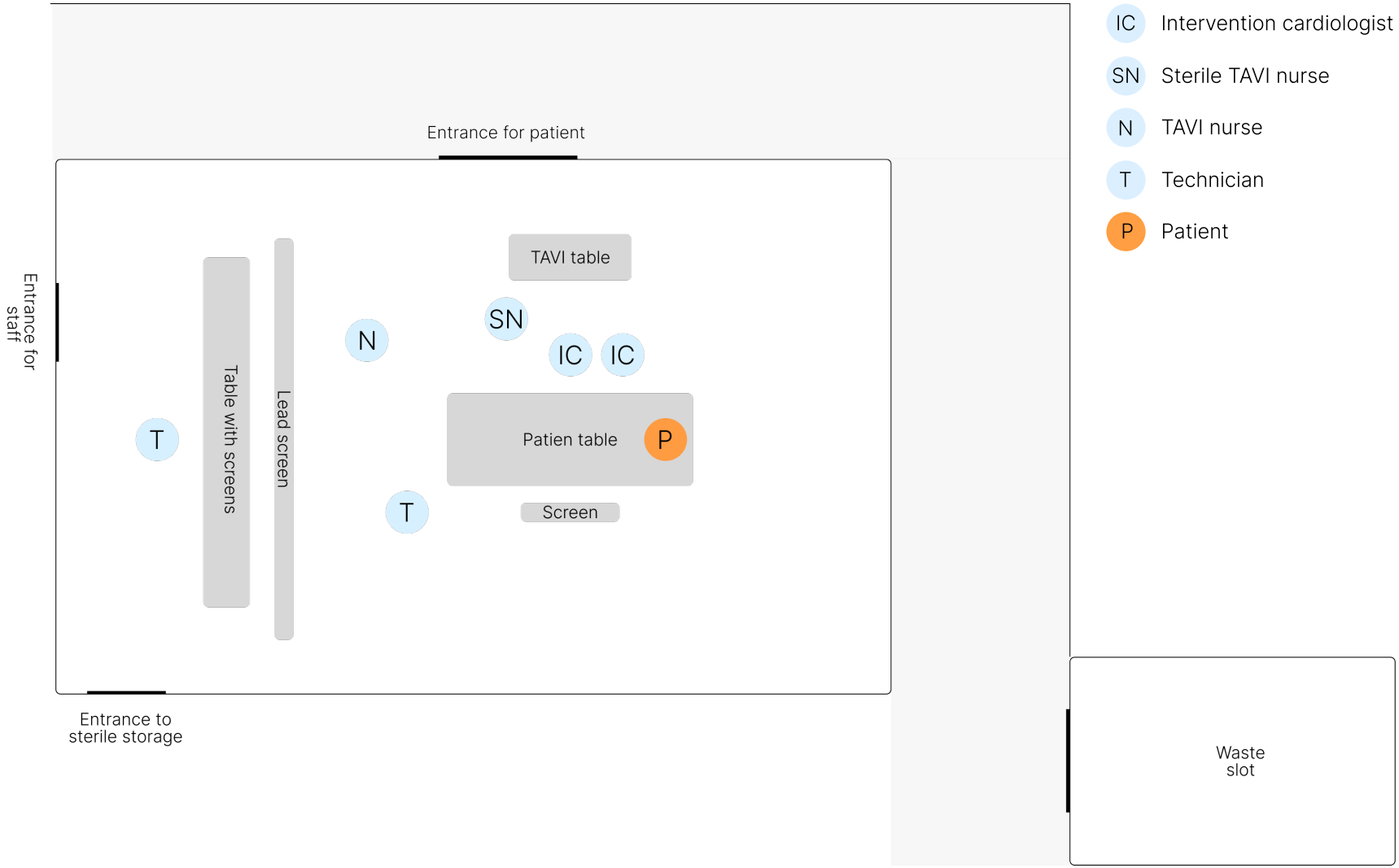


Figure 24: Map of one of the Cath labs at EMC

2.5 Conclusion

The TAVI delivery system is part of a broader product and care system in which the valve, loading system, packaging, clinical workflow, and hospital infrastructure are closely connected. Because the delivery system is a Class III medical device used in a time-critical Cath lab environment, any circular intervention must adhere to the strict safety, regulatory, and operational requirements. Circularity in this case therefore requires more than product redesign alone: it depends on solutions that also align with the realities of the procedure and its surrounding system.

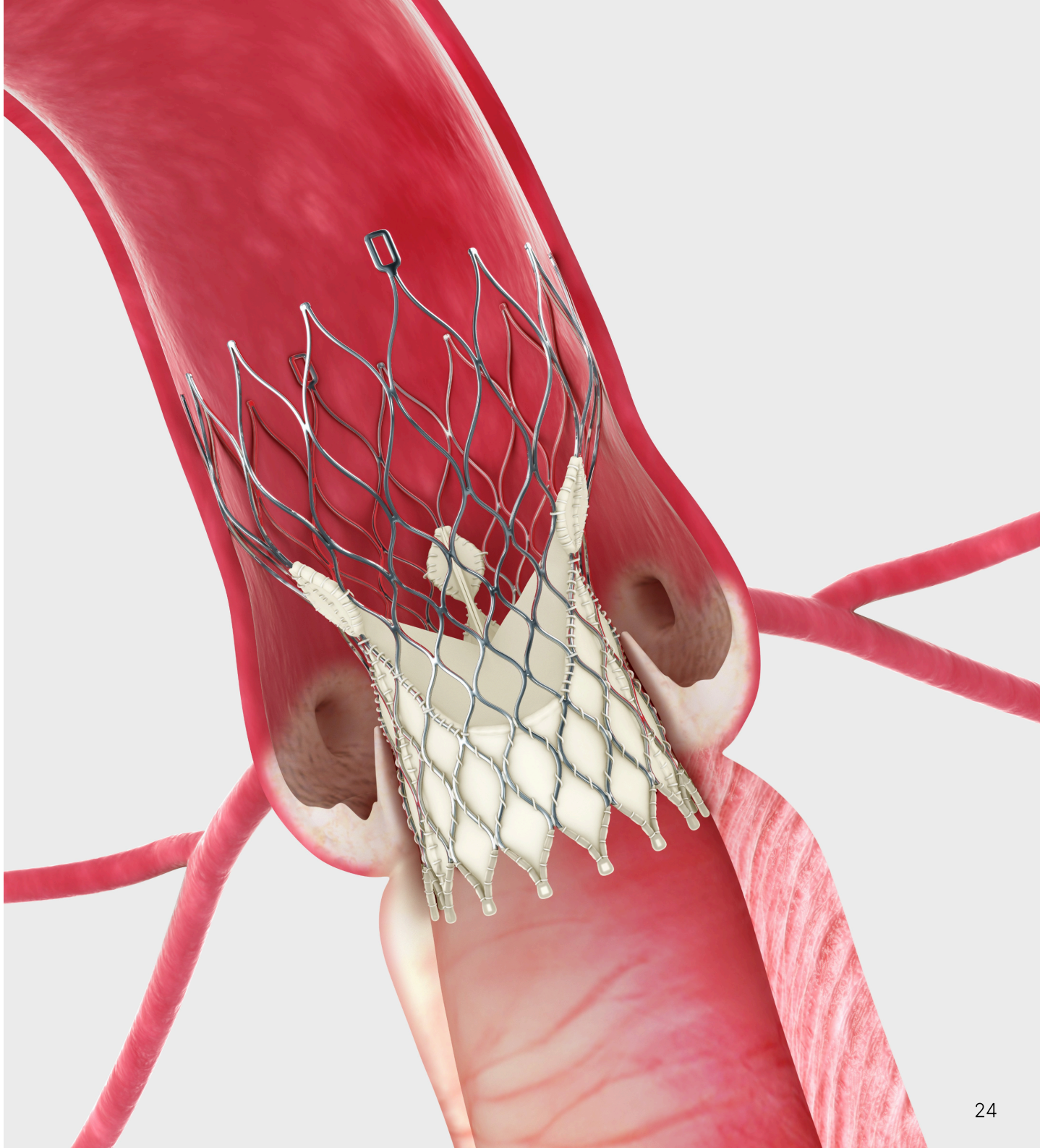


Figure 25: Valve in heart
Source (Uppal, A., 2022)

03

Circularity in healthcare: a system perspective

This chapter focuses on the top-down part of this project. It first introduces the theoretical perspectives used to understand sustainability in healthcare at system level. Then it applies these insights to the TAVI case through a stakeholder map and trend analysis.

Research question 2:
Which system-level characteristics create the main opportunities and barriers for more circular strategies for the TAVI products?



Figure 26: Handle delivery system

3.1 Socio-technical system

A useful way to understand sustainability challenges in healthcare is through the lens of a socio-technical system. A socio-technical system describes how outcomes are shaped not only by technology, but also by the people, routines, rules, and organisations around it (Carayon et al., 2011).

Geels (2004) defines a socio-technical system as the alignment of three constraints:

1. **Operational constraints:** what fits within daily clinical practice, including time, space, and workload.
2. **Institutional constraints:** rules, standards, and contracts that define what is allowed and who is responsible.
3. **Material and technical constraints:** what the product is made of and how it can be separated, cleaned or reprocessed.

For the TAVI products, these constraints interact. The product contains valuable materials, but they are also used in a safety-critical setting and handled within strict routines. The products end-of-life is therefore not the result of one single decision, but of how the wider system works in practice.

Viewing healthcare as a socio-technical system helps to identify where interventions can have leverage: not only in redesigning the product, but also in changing the practices and structures that determine how the product is handled and processed.

3.2 Multi-level perspective

The multi-level perspective (MLP) is a common way to describe how sustainability transitions happen in complex systems (Saad et al., 2023). It distinguishes three interacting levels: landscape, regime, and niche. The value of this model is that it explains why change is often slow, and why promising innovations can fail if they do not fit the dominant system.

Landscape level

The landscape level refers to broader external trends that organisations cannot easily influence in the short term. In healthcare, examples include climate targets and reporting requirements, demographic change and growing care demand, rising material and disposal costs, and increasing public expectations around sustainability (Guo et al., 2023). These trends create pressure for change, but they do not directly specify what should change.

Regime level

The regime level refers to the dominant way a system currently operates. In healthcare, the regime includes established clinical routines, procurement practices, waste handling, infrastructure, infection prevention norms, regulatory compliance processes, and supplier relationships (Khalil, 2024). These structures provide stability and safety, but they also make change difficult.

For example, single-use devices are embedded in routines that prioritise sterility, speed, and predictable performance, and waste is often placed into existing categories that favour risk avoidance.

Niche level

The niche level refers to protected spaces where new practices or technologies can be tested (Guo et al., 2023). They start small and are protected from the regime level. In hospital context, niches can take the form of pilots, research collaborations, or small-scale trials with selected departments and partners.

Implication for TAVI

Applying the MLP to the TAVI case suggests moving away from incineration requires more than a single design change. Landscape pressures (sustainability targets and resource constraints) create a reason to change, but the regime (workflow, contracts regulation, and waste infrastructure) determines what is feasible today. Circular interventions therefore need to be designed as niche steps that fit within regime constraints while gradually building evidence, routines, and stakeholder alignment.

This helps explain why implementation needs to be structured and risk-aware rather than treated as a one-off redesign exercise.

3.3 Healthcare system

The socio-technical system perspective and the multi-level perspective become more meaningful when they are applied to healthcare. The Dutch healthcare system is not a simple network of hospitals and products, but a large specialised system that has developed over time around the diagnosis and treatment of disease. Johansen (2023) explains that this development was shaped by medical science, technological progress, hospitals, medical specialisations, the welfare state, and the growth of a supporting healthcare industry for pharmaceuticals and medical devices. This has resulted in a system with many specialised organisations, healthcare works, institutions, and suppliers.

This development has made the healthcare strong in delivering specialised and reliable treatment but it has also created a system that is highly structured around existing roles, routines, and ways of organising care. Johansen (2023) describes the Dutch healthcare system as being built around constellations of healthcare professions, especially medical specialists, with hospitals as supporting structures and a healthcare industry that has developed around demand of treatment, including specialised medication and medical devices.

This means that environmental outcomes in healthcare are shaped by more than products alone. Products are part of a wider system of roles, routines, infrastructures, and rules (Essink, 2012).

3.4 Actors and roles in the healthcare system

Healthcare is a multi-actor system, in which decisions are shaped by different interests, responsibilities, and levels of influence (Kaplan & Babad, 2011). What is implemented in practice is therefore not only determined by clinical need or technical feasibility, but also by how incentives and decision power are distributed across actors. In literature, this is often described as misalignment between objectives of different actor groups and the structure that guide decision-making (Gray, 2006).

Pereno and Eriksson (2020) divided the multi-actor system in three main groups: **health industries, health providers and patients**. These groups are surrounded by many other actors such as authorities, NGOs, and waste management stakeholders.

They also show that communication across this system is often only partly structured, the decision-making power is unevenly distributed, and downstream actors such as waste handlers have little contact with upstream actors.

This also shows in the TAVI case. Different actors influence the life cycle of the products, but they do so from different roles, interests, and levels of decision-making. Clinical teams influence how a device is used and handled , but they usually do not control procurement, infection prevention, contracts, or external processing routes. Hospital departments such as infection prevention and procurement shape what is allowed and how change is approved, while manufacturers influence product design. At the same time, authorities and policy frameworks influence what is allowed. Because these stakeholders often work separately and have limited contact with each other, decisions are not easily aligned.

3.5 From system perspective to system analysis

The previous chapters show that circular change in healthcare cannot be explained or achieved by looking at one product or one actor alone. It requires understanding how the wider system is organised, where power and responsibilities are placed, and which external developments create pressure or opportunity for change.

Therefore, the next part of this chapter moves from theory to analysis. First, a stakeholder map is used to identify the main actors involved in the TAVI case and to understand their roles, interests, and influence. Second, a trend analysis is used to explore the broader developments that shape the context in which circular interventions may become possible.



Figure 27: Interventional cardiologists (Cleveland Clinic, 2024)

3.6 Stakeholder map

To understand who influences the use and end-of-life of the TAVI products, a stakeholder analysis was done. This was done to identify where responsibilities sit, where constraints are set, and where alignment is needed to make circular alternatives feasible.

Two complementary views were used. First a **stakeholder map** was created to group actors based on where they operate in the system: inside the Cath lab, within Erasmus MC but outside the Cath lab, or outside the hospital (Figure 28). The stakeholder map also highlights three dimensions (Grey, 2006) that are especially important for the feasibility of circular intervention:

- **Clinical safety:** actors responsible for sterility, infection risk, and patient outcomes. These define non-negotiable conditions or any circular option.
- **Operations and time:** actors who keep the Cath lab workflow running (set-up, staffing, logistics, and waste handling). They strongly shape adoption because added steps or delay could cause friction.
- **Money and contracts:** actors who define purchasing requirements and decide what is paid for, by whom, and under what terms (tenders, service contracts, waste contracts).

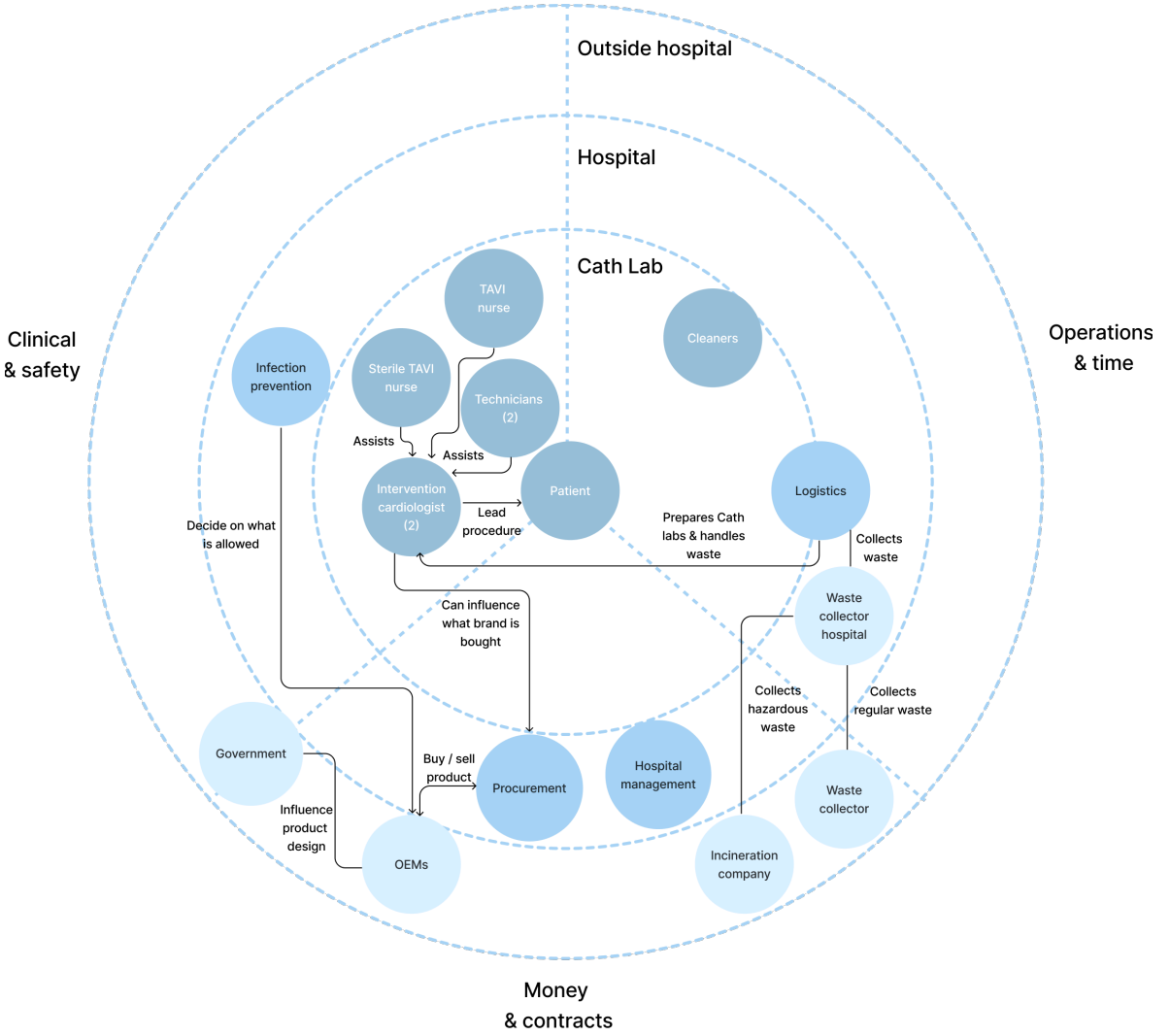


Figure 28: Stakeholder map

Secondly a **power-interest matrix** was used to assess which stakeholders have power to enable or block change, and which stakeholders are most directly affected by it (Nguyen, 2018) (Figure 29). The full stakeholder overview is included in Appendix 12.2.

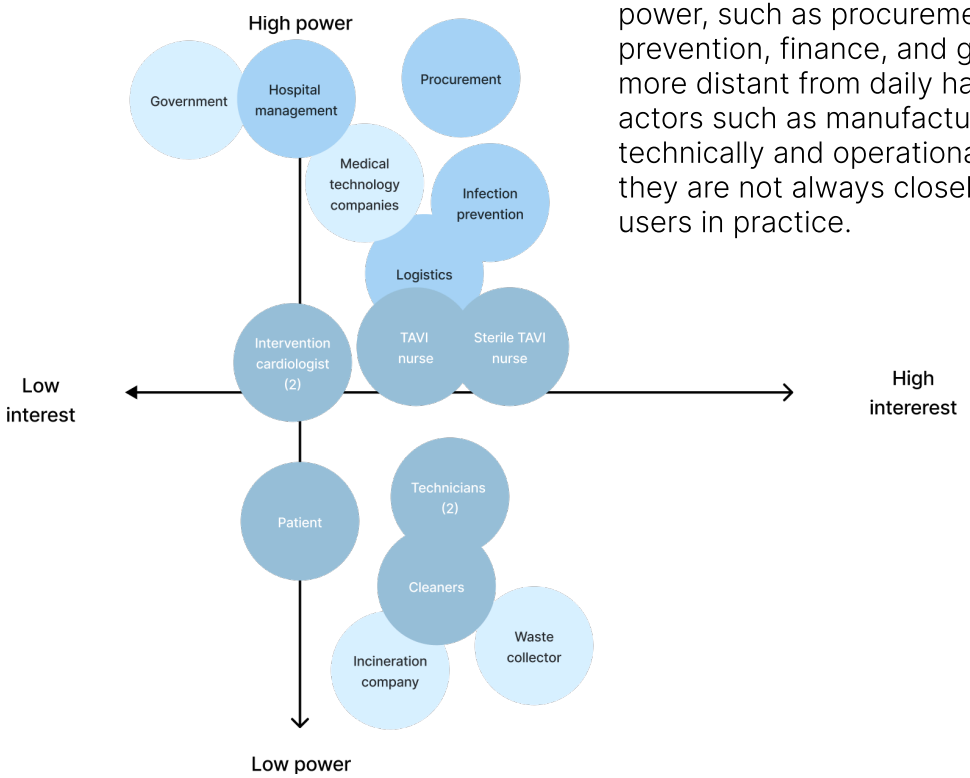


Figure 29: Power-interest matrix

The mapping shows that actors closest to daily product use, such as clinical staff, have a high interest in the practical consequences of change and strongly influence in which bins the products end up.

However, they usually have limited power to change procurement criteria, contracts, compliances, or processing routes. In contrast, actors with more decision-making power, such as procurement, infection prevention, finance, and government are more distant from daily handling. External actors such as manufacturers shape what is technically and operationally possible, but they are not always closely connected to users in practice.

This split in power, interests, and use matters: even a technically recyclable or reusable option is unlikely to work if it adds friction in the Cath lab, but it also cannot scale without procurement criteria, contractual structures, and compliance support that shape a new route.

At Erasmus MC, the green teams indicate that there is already internal motivation to support more circlar healthcare practices. These teams consist of small groupes of colleagues who initiate practical sustainability actions within their hospital context (Erasmus MC, n.d.). This suggests that, alongside formal decision-makers, there are also internal actors who are willing to help drive change from within daily practice.

Takeaways

- High-interest actors have limited power (nurses), while high-power actors (OEMs) have less interest.
- Infection prevention and government are important to involve early in any redesign process as they block innovations that threaten clinical safety.
- Actors with the power to make changes are often distant from the actual use of the product, which means they do not always fully understand how it is used in practice.
- Erasmus MC's green teams show that sustainability ambitions are also supported by staff within everyday hospital practice.

3.7 Trend analysis

To understand how the context around medical devices may change over time, a trend analysis was done using the STEEP framework (Society, Technology, Economy, Environment, and Politics / Regulation) (Fisher et al., 2020). This framework helps to identify external developments that influence which circular strategies are realistic today and which may become more feasible in longer term. Figure 20 summarises the main trends. The full analysis can be found in Appendix 12.3.

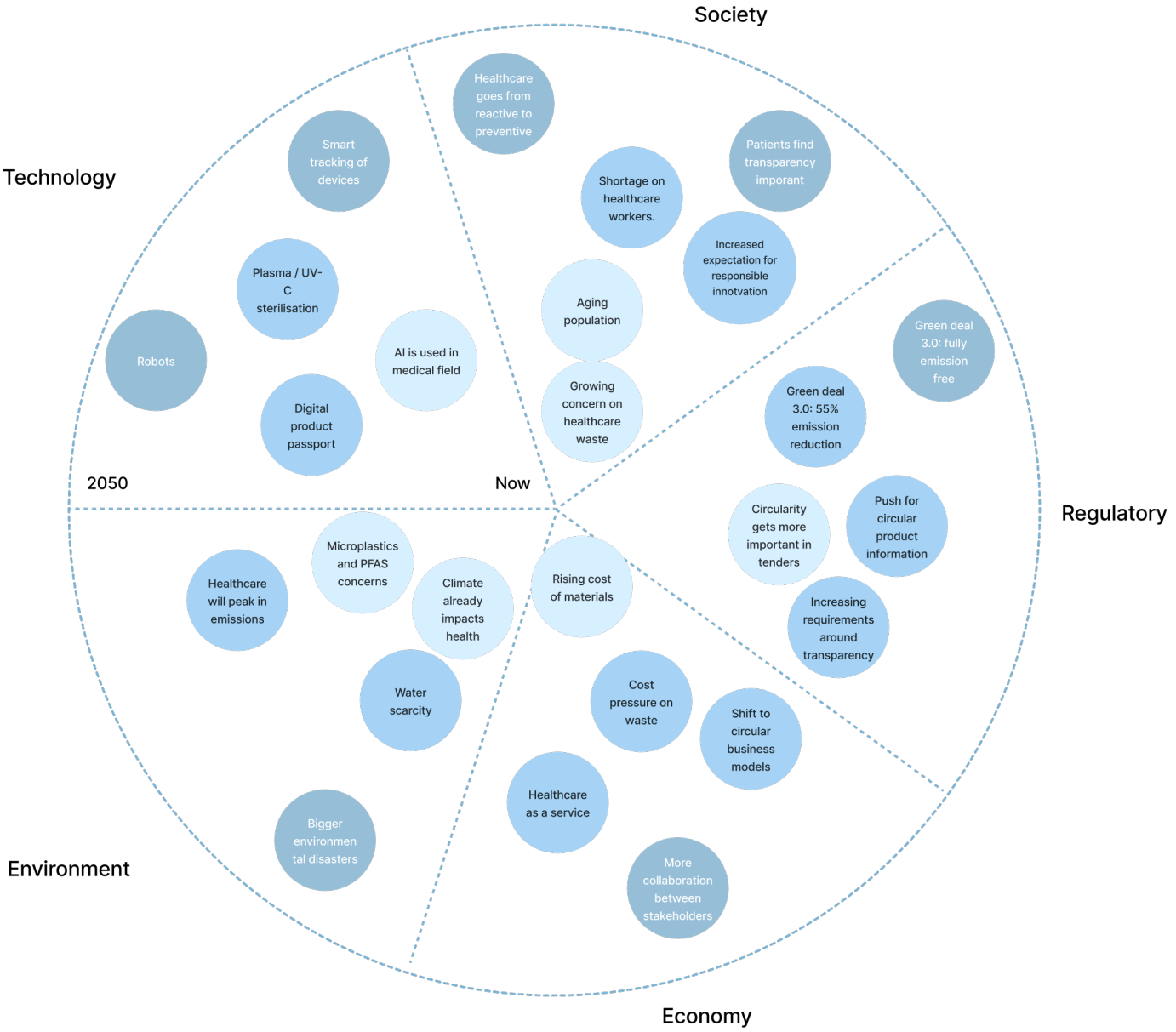


Figure 30: Trend analysis

The analysis shows that the overall direction is supportive of circularity, but the short-term constraints remain strong. In the current situation, strict safety requirements, time pressure in clinical practice, and unclear responsibilities limit what can be implemented. At the same time, broader developments suggest that the conditions for circularity may gradually improve.

From a **social perspective**, demand for healthcare is expected to grow, while also public and institutional expectations for sustainable healthcare increase. In the far future, healthcare will become preventive instead of active (Waldman & Terzic, 2018). From a **technical perspective**, developments in traceability, data systems, and sterilisation might make circular strategies easier to organise and control (Sim et al., 2022). From an **economic perspective**, rising disposal costs and increasing material costs may put more pressure on the current linear model (Sepetis et al., 2022). From an **environmental perspective**, climate targets, resource scarcity, and growing awareness of environmental health impacts strengthen the urgency for change (Sebire et al., 2025). Finally, from a **political and regulatory perspectiv**e, safety requirements will stay strict, but sustainability policy and clearer guidance may gradually create more room for circular alternatives (Weimann, 2025).

Together, these trends support a transition perspective in which early interventions should be designed to fit current clinical and governance constraints, while also building the conditions needed for more ambitious circular strategies.

Takeaways

- Traceability and technology, together with stronger climate targets and rising costs, are likely to make circular options more popular over time.
- Scarcity is an important driver for circular change.
- Transparency on sustainability will become more important. Not only on products, but also to patients.

3.8 Conclusion

This chapter showed that sustainability in healthcare needs to be understood from a system perspective. The socio-technical system perspective helps explain that outcomes are shaped not only by products, but also by routines, rules, infrastructure, and the actors involved. The multi-level perspective adds that change in healthcare is often slow, because new solutions should fit within an existing system that values safety, reliability, and stability. In addition, the healthcare system is made up of many actors with different roles, responsibilities, and levels of influence, which makes circular change difficult to organise through one stakeholder alone.

Applied to the TAVI, the stakeholder analysis shows a split between interest and formal power. Clinical staff are closest to the product and strongly influence daily practice, but they typically have limited authority to change contracts or external routes. In contrast, actors with formal decision power, such as procurement, infection prevention, and external processors, are more distant from daily use but determine what can be approved and scaled.

Moreover, the trend analysis suggests that the long-term direction supports circularity, but near-term feasibility depends on solutions that fit current safety requirements, workflow constraints, and responsibility allocation.



Figure 31: Disassembly

04

Circularity in healthcare: a product perspective

This chapter focuses on the bottom-up part of this project. It first introduces the theoretical perspective used to understand the circular economy at product level. It then applies these insights to the TAVI case through an analysis of the products set, its life cycle, and its product-level hotspots.

Research question 3:
Which product-level haracteristics create the main opportunities and barriers for more circular strategies for the TAVI products?

4.1 Circular economy

A circular economy aims to reduce waste and retain value by keeping products, components, and materials in use for as long as possible (Ellen MacArthur Foundation, 2021). In a linear system, value is lost quickly because products are manufactured, used, and disposed of. In a circular system, value is retained through strategies that extend product use and recover resources to the greatest extent possible.

To describe these strategies in a structured way, this report uses the “R-strategies” framework. The R-strategies represent a set of circular options that range from higher-value strategies (keeping products in use) to lower-value strategies (recovering materials) (Hoveling et al., 2024). The definitions of the R-strategies are shown in Figure 33.



Figure 32: Circular economy

0	REFUSE	Make device redundant by abandoning its function or by offering the same function in a radically different, more sustainable device.
1	RETHINK	Make device use more intensive (e.g. through sharing products, or by putting multiple functional products on the market).
2	REDUCE	Increase efficiency in product manufactring or use by consuming fewer natural resrouces and materials.
3	REUSE	Resue by another customer (or for another patient in healthcare) of discarded product which is still in good condition and fulfills its original function (in healthcare, often after cleaning processes).
4	REPAIR	Repair and maintenance of defective products so it can be used with its original function.
5	REFURBISH	Restore an old product and bring it up to date
6	REMANUFACTURE	Restore a discarded product and bring it up to date or use parts of a discarded product in a new product with the same function.
7	REPURPOSE	Use discarded product or its parts in a new product with a different function.
8	RECYCLE	Process materials to obtain the same (high grade) or lower (low grade) quality.
9	RECOVER	Incineration of materials with energy recovery.

Figure 33: R-strategies definitions (Hoveling et al., 2024)

4.2 Value hill

The value hill is a framework that describes how value is created, retained, and lost over a product's life cycle (Huijben et al., 2025). It is often used to explain why some circular strategies have a higher potential than others. The model shows that products gain value during design and production, maintain value during use, and lose value when they are discarded.

On the upward slope of the value hill (pre-use), value is added through activities such as material selection, manufacturing, assembly, and quality control. During the use phase, value can be retained when products continue to perform their intended functions. On the downward slope (post-use), value is typically lost when products are disposed of, because functional value is destroyed and materials are either downcycled or lost completely.

From a circularity perspective, the value hill highlights an important hierarchy. Strategies that maintain a product at its functional level, such as reuse, repair, and refurbishment, retain more of the value created during design and manufacturing. Recycling typically retains less value because it reduces products to raw materials and often yields lower-quality outputs, especially when products contain mixed materials or are contaminated by residues such as blood or bodily fluids.

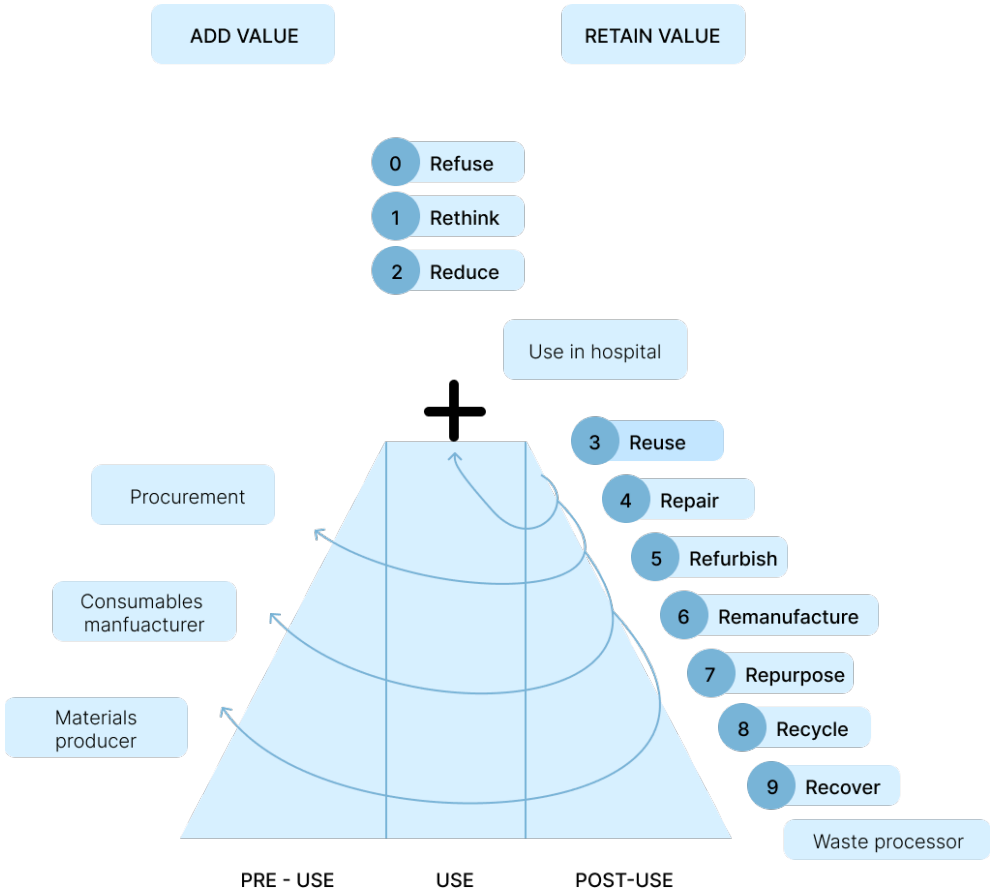


Figure 34: Value hill

4.3 Circular economy in healthcare

Applying circular economy principles in healthcare is challenging because safety, quality and reliability requirements are strict and non-negotiable. Many devices are designed for single-use to reduce infection risk and ensure predictable performance. As a result, circular strategies that might be straightforward in other industries often require additional conditions in healthcare.

A first constraint is **safety and sterility**. Items that come into contact with blood or bodily fluids cannot be reused unless cleaning, disinfection, and sterilisation are validated. Even when reuse is not considered, contamination affects material recovery because it changes how products are handled and whether high-processing partners can accept them.

A second constraint is **regulation and quality assurance.** Medical devices operate in a regulated environment, where responsibilities for performance and patient safety must be clearly defined. Changes in product design, intended use, or processing route can trigger evidence requirements and quality management obligations. This influences what can be implemented and how quickly it can be implemented.

A third constraint is **workflow and operational fit**. Clinical environments, such as Cath labs, operate under time pressure. New circular routes must be simple to follow at the point of use and must not rely on complex decision-making by clinical staff. Collection systems need to be practical in terms of space, safety, and workload; otherwise, compliance will be low, and outcomes will be inconsistent.

4.4 From product perspective to product analysis

The previous chapters introduced the main circular economy concepts used in this report. The R-strategies provide a shared vocabulary to describe circular options, while the value hill explains why strategies that retain product function generally preserve more value than strategies that recover materials only.

The next part of this chapter moves from theory to analysis. It applies the circular economy perspective to the TAVI case by examining the TAVI product set, its life cycle, and its product-level hotspots. This helps identify where value is currently lost, which parts of the product set create the main barriers, and where product-level circular opportunities may exist.

4.5 Life cycle overview

To understand where the main environmental and material losses occur, the life cycle was mapped for the current TAVI delivery system, loading system, and packaging (Figure 35). The map describes the steps from raw materials extraction and component production, through assembly, packaging and sterilisation, distribution and storage, to use in the Cath lab and end-of-life routing.

In the current situation, the life cycle is largely linear. The products are manufactured, used once, and then disposed of. For the delivery and loading systems, the dominant end route is incineration of hazardous waste streams. Packaging is separated into the existing recycling stream.

This linear life cycle is problematic for two reasons. First, each procedure requires a new delivery and loading system, which drives repeated demand for virgin materials and upstream emissions from material production and manufacturing. Second, it leads to a significant loss of material value after use. Incineration can recover energy, but it destroys high-quality plastics and prevents the recovery of embedded metals. A circular pathway would aim to retain value for longer by using higher-value strategies where feasible (such as reuse or refurbishment) and by recycling when functional retention is not realistic under current constraints.

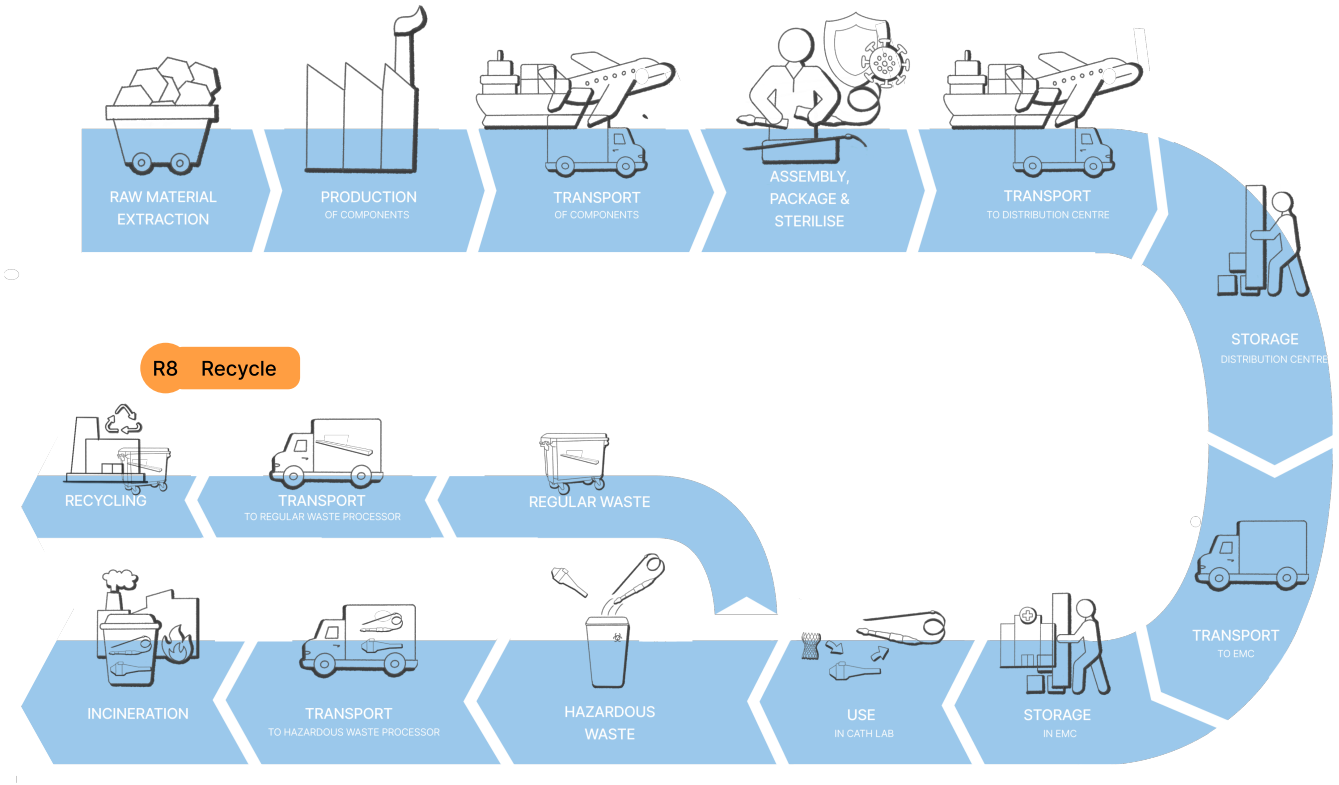


Figure 35: Life cycle overview

Takeaways

- The current life cycle of the delivery system and the loading is linear. They are incinerated after use.
- The packaging is recycled in an already existing recycling stream.

4.6 Product journey map

To identify opportunities for circular improvements, a product journey map was created for the TAVI products. The map follows the product set from the moment it arrives at the hospital until waste processing. The full step-by-step journey map is included in Appendix 12.4. Figure 36 shows a simplified version organised in ten steps.

Several observations point to a mismatch between the product design and clinical practice. Storage space near the Cath lab is limited, so the relatively large delivery systems are stored elsewhere on the floor. In addition, logistics prepares a standard TAVI table before the procedure, including products that are not always needed for every delivery system brand. During unboxing and preparation, staff also do not use the packaging fully as intended. The integrated bowls are used, but additional bowls are also used to cool the valve, so that the delivery system doesn't need to be unboxed yet. The blue clips that come with the packaging are used in an improvised way to support the delivery system during preparation. Together, these observations suggest that the current design does not fully fit the workflow in practice.

After use, the delivery and loading system is disposed of in the hazardous waste bin, mainly for safety reasons, while the packaging is discarded separately in the hospital's recycling stream. This shows that some material separation already occurs, but the product itself still follows a largely linear end-of-life.

Takeaways

- A lot of space is needed to remove the delivery system from its box. The design of the box should fit the space of the Cath lab.
- During preparation, staff already adapt the product set to make it work better in practice, for example, by using separate bowls and repurposing the blue clip.
- Any circular intervention should be based on real-world product use, rather than on intended use alone.
- The current disposal is shaped by safety concerns, especially the risk of puncturing waste bags. So, alternatives must be safe and practical
- Packaging already follows a separate route within the existing hospital system.
- The hospital already has a structured waste system with multiple categories, so circular interventions should, where possible, build on this existing infrastructure.

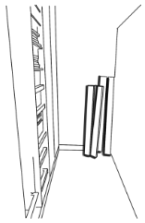
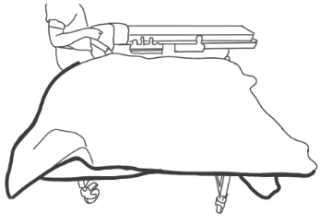
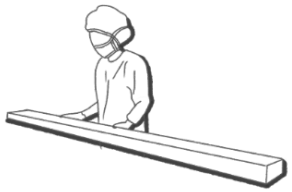
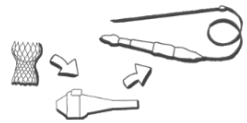
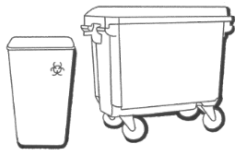
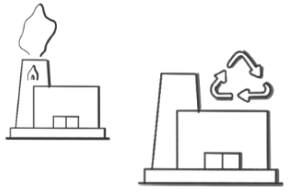
Steps	1 Delivery to hospital	2 Storage in hospital	3 Transport to Cath lab	4 Unboxing	5 Preparation of device
Description					
Stakeholders					
Logistics					
Nurse					
Sterile nurse					
Intervention Cardiologist					
Waste processors					
Hotspots		Current storage space is already full and the delivery systems are stored somewhere else.	Logistics prepare a TAVI table with all the products needed and a standardised package with products such as bowls and wipes.	Much space needed for unboxing, as the opening of the box is on the top.	Loading system is thrown away after 1 use, but not contaminated. Blue clip is squeezed between tray to hold the delivery system up when filling the loading bath with saline. Seperate bowls are used at Erasmus MC to cool the saline, as the delivery system is unboxed as late as possible

Figure 36: Product journey

Steps	6 Use during procedure	7 Disposal in Cath lab	8 Waste brought to slot	9 From slot to collection point	10 External processing
Description					
Stakeholders					
Logistics					
Nurse					
Sterile nurse					
Intervention Cardiologist					
Waste processors					
Hotspots		Delivery and loading system are discarded in hazardous waste bin.		The slots are small and have a lot of different bins in them (e.g. paper, plastics, hazardous waste, sharps, etc.)	Delivery and loading system are incinerated.
					Packaging is recycled.

4.7 Waste audit

A waste audit was conducted at Erasmus MC to map the products generated during a single TAVI procedure.

The analysis shows that approximately 80 product types are used in a single intervention. Some of these are standard consumables used multiple times during the procedure, such as sterile wipes, gauze, and syringes. When these repeated items are accounted for, a single TAVI procedure generates approximately 300 individual waste items.

Value - Volume

To identify which of these products are most relevant for circular intervention, the waste stream was assessed using two metrics:

- **Value**: This refers to the product's engineering complexity, material quality, and economic worth.
- **Volume**: In this context, volume refers to the number of individual items used during the procedure. It does not refer to the physical size.

Using these two metrics, the TAVI-specific products can be positioned as follows:

- **Delivery system:** high value, low volume
  - It is a highly complex, precision-engineered medical device made of multiple materials. Because one system is used per procedure, its unit volume is low.
- **Loading system:** high value, low volume
  - The loading system is used to load the valve on the delivery system. This is a highly complex, precise step, making it a relatively high-value product.
- **Packaging**: low value, low volume
  - The box that comes with the delivery system is not complex and is also only one product.

This shows that the delivery and loading systems are the most relevant products from a circularity perspective, as high-value products are currently discarded after a single use.

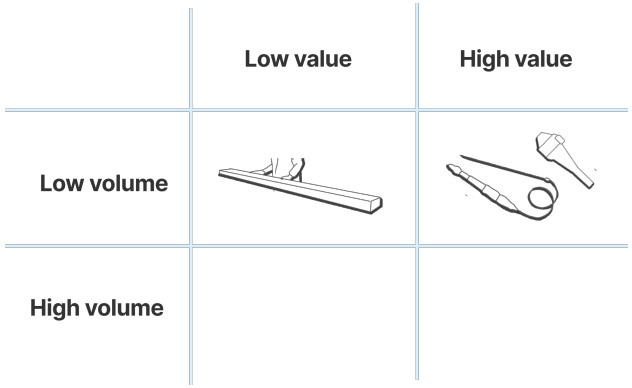


Figure 37: Value - Volume

Current disposal of the products

The total weight of all waste of the entire procedure is about 14 kg. The delivery system weighs 1.1 kg (including the tray and the box).

Around 9 kg (≈65%) of the total waste is disposed of in the hazardous waste bin. But only 5% (approximately 500 grams) of this amount should be in this bin: the glass pot containing the valve (internal data, n.d.).

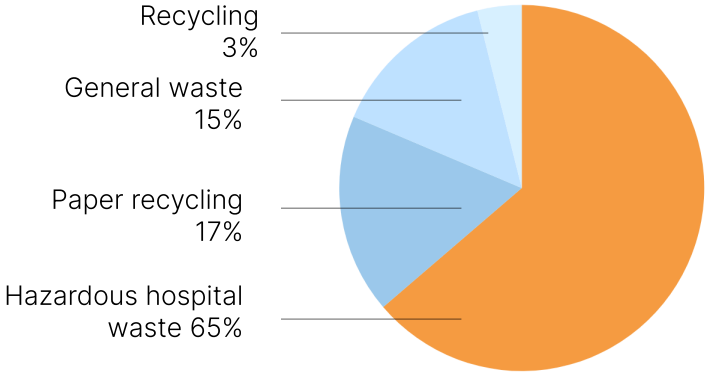


Figure 38: Current disposal



Figure 39: Waste audit

Misalignments of waste disposal

The first misaglignment is in the Dutch waste guidance. The dutch waste guidance distinguishes between hazardous and non-hazardous healthcare waste. Classification depends mainly on whether an item is sharp and whether it contains liquid blood or body fluids in more than negligible quantities. The “wel/niet-lijst specifiek afval” (LA3, Sectorplan 19) lists sharps and items contaminated with non-dried blood or bodily fluids under EWC 18 01 03* (hazardous). It also indicates that many disposable items can be classified as EWC 18 01 04 (non-hazardous) when they are leak-free and drip-free. For this category, no special infection-prevention requirements apply. Examples include infusion systems and catheters.

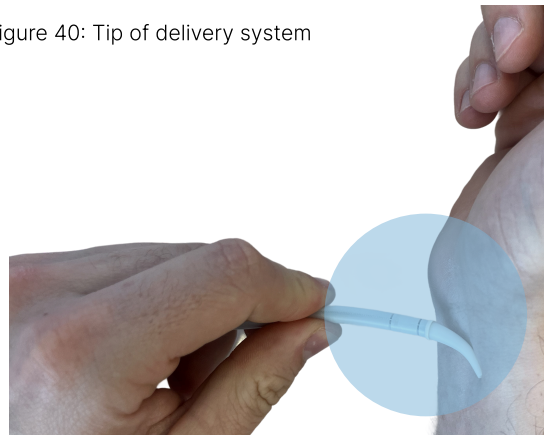
Under the waste rules, the product may be eligible for a non-hazardous route if it meets leak-free and drip-free conditions. In practice, however, it is still disposed of in the hazardous waste stream, largely due to contamination concerns.

A second misalignment concerns the Tyvek packaging in the wrap. In practice, this material is assumed to belong in the paper bin, while this is not the correct disposal route (Figure 41). This shows that even relatively simple packaging materials can be routed incorrectly when assumptions replace clear guidance.

A third misalignment concerns the assumption that the delivery system is sharp and therefore cannot safely enter normal waste bins. However, the distal tip is not actually sharp (Figure 40). The practical issue is instead the product’s long and rigid geometry, which makes it difficult to fit into existing waste bins and slots. This means that the barrier lies not only in formal classification but also in how the product's physical form interacts with existing hospital waste infrastructure.

Together, these examples show that current disposal practices are shaped not only by waste regulations themselves but also by assumptions, fears of contamination, and the practical realities of hospital handling. Circular intervention, therefore, requires not only compliance with the rules but also clearer guidance and better alignment between classification and practice.

Figure 40: Tip of delivery system



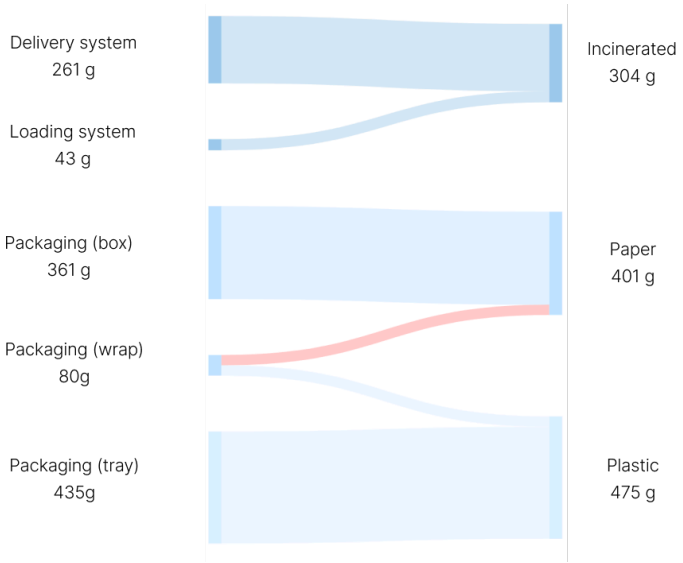


Figure 41: Waste flow

Takeaways

- The delivery and loading systems are important for circularity, as a high-value product goes to waste after 1 use.
- Packaging has low value and low volume, but is very large.
- Nothing except the valve pot is supposed to go in the hazardous waste bin, according to the Dutch waste classification.
- The grey area of the Dutch waste laws classification of what is and isn’t allowed in the hazardous waste bin leaves room for hospitals and OEMs to define this area.

4.8 Disassembly

To assess how the current delivery system construction influences circular strategies, a disassembly analysis was conducted using the disassembly approach from Flipsen, 2023. The disassembly map documents the sequence of separation steps and indicates where parts can be removed without damage, where force or tools are required, and where components are permanently joined. This provides insight into the practical feasibility of strategies such as repair, refurbishment, remanufacturing, and recycling.

The analysis focuses on the delivery system, as this is the most complex element of the product set and contains the highest material diversity. The resulting disassembly map is shown in Figure 42.

List of components:

1. Trigger
2. Deployment knob
3. a: tip retrieval mechanism with opening

3. b: tip retrieval mechanism without opening

4. Grey front grip
5. Size covers
6. Half rings
7. Small spring
8. Big spring
9. Purple flush ports wire lumen and capsule
10. Purple stick
11. Grey small part
12. Grey grip parts
13. Gray long stick with thread
14. Purple small tube end
15. Purple small parts
16. White small ring
17. White big ring
18. Grey big part
19. Purple syringe shaped part
20. Yellow clear plastic part
21. Purple part with dark green wire
22. Purple part with thread
23. Dark green wire
24. Light green wire
25. Grey tube with flush port
26. Pink tip
27. Grey tip
28. Purple flush port

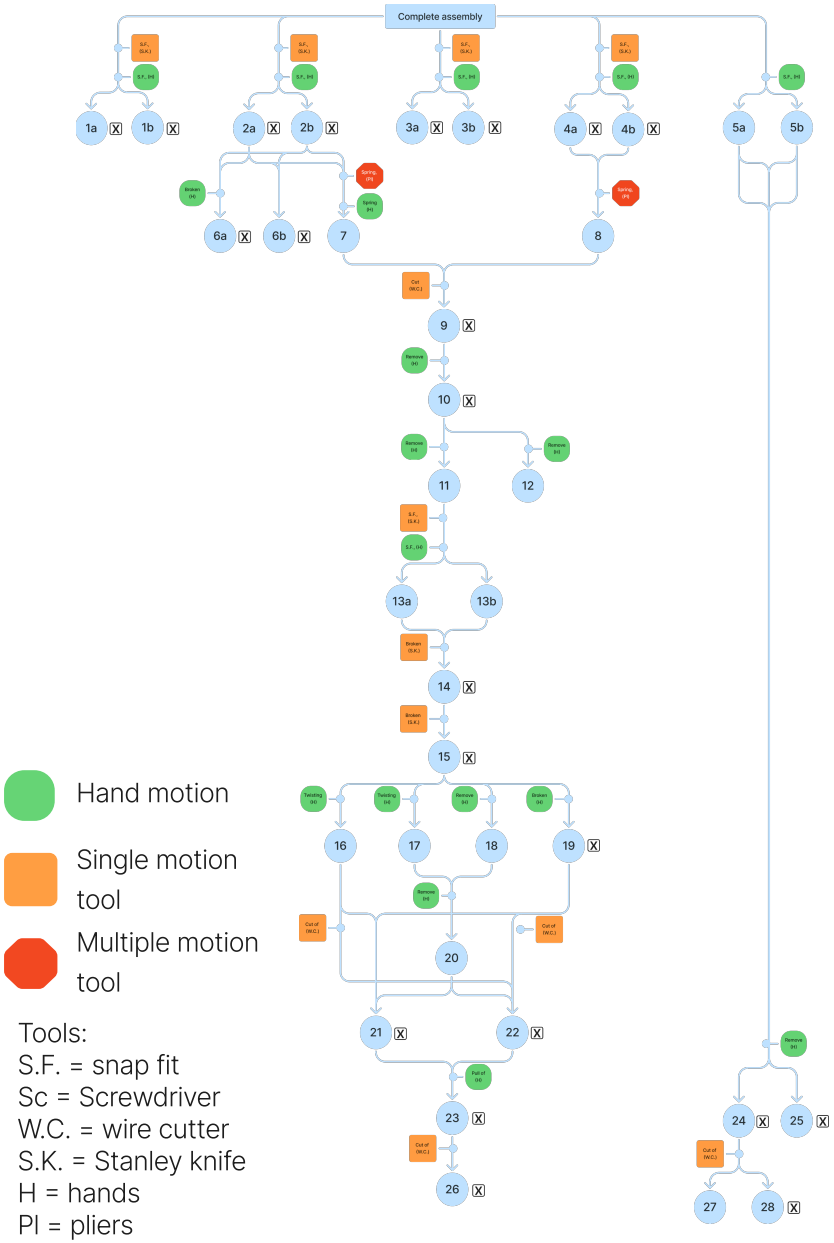


Figure 42: disassembly map

List of components:

1. Trigger
2. Deployment knob
3. a: tip retrieval mechanism with opening
3. b: tip retrieval mechanism without opening
4. Grey front grip
5. Size covers
6. Half rings
7. Small spring
8. Big spring
9. Purple flush ports wire lumen and capsule
10. Purple stick
11. Grey small part
12. Grey grip parts
13. Gray long stick with thread
14. Purple small tube end
15. Purple small parts
16. White small ring
17. White big ring
18. Grey big part
19. Purple syringe shaped part
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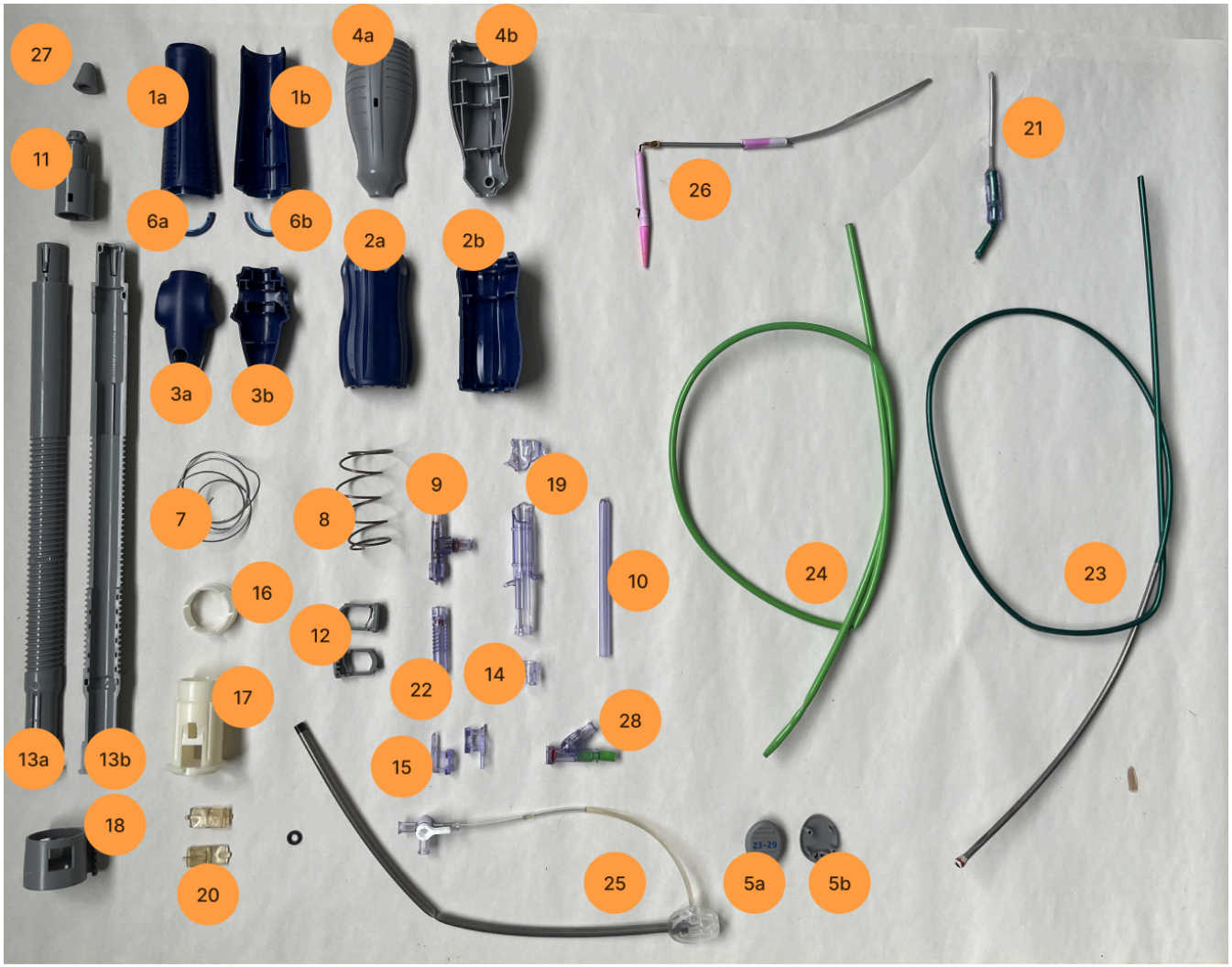


Figure 43: parts disassembly

Disassembly started at the handle. The outer shells (1, 2, 3, 4, 5, 6) were held together by irreversible snap-fits and could be opened with light prying. This exposed the internal mechanism. The mechanism components (7, 8, 11, 13, 16, 17) were also relatively easy to separate. They were mainly connected via snap fits, and a prying tool was sufficient (Figure 44).

Below the mechanism, several transparent purple components (10,14, 15, 19, 22) held the wiring in place. These components were stacked and glued to each other. They could not be separated cleanly, and freeing the wires required breaking parts of the structure (Figure 45).

The wire assembly itself consisted of multiple layers (23, 24, 25) that can slide over each other. Several attached components had to be cut off before the wires could be removed (9, 21, 26, 28) (Figure 46).

The disassembly results show a contrast within the product architecture. The handle section is accessible and separable with minimal effort, suggesting potential for higher-value strategies. In contrast, glued and stacked components around the wire assembly create irreversible connections that reduce disassembly efficiency and material purity. Without redesign, these features are likely to limit high-quality recycling and complicate any approach that relies on non-destructive separation.

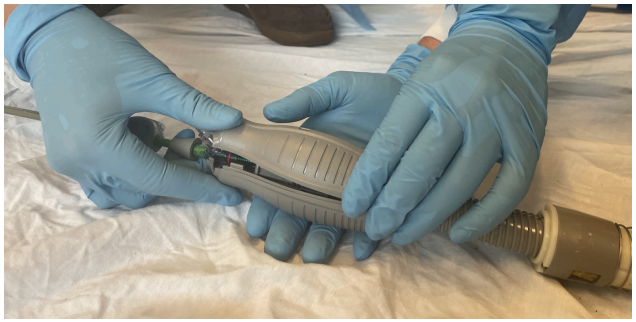


Figure 44: taking apart outer shells

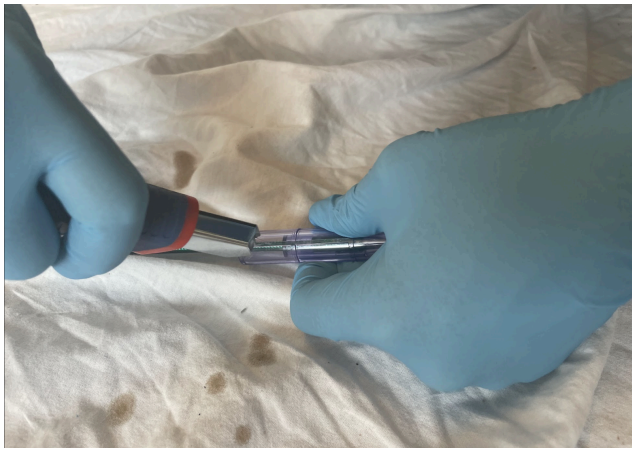


Figure 45: breaking the transparent purple parts

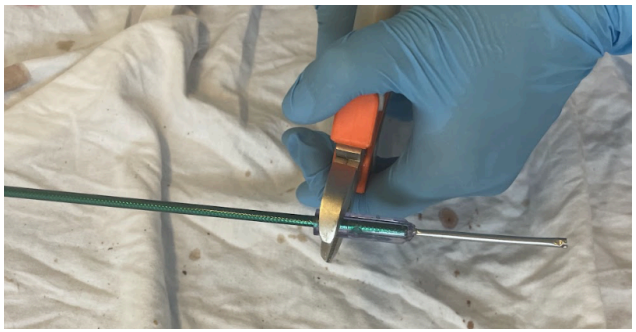


Figure 46: cutting parts of to free the wire

Takeaways

- The handle is easy to take apart due to the irreversible snap fits.
- The wires run through the entire device, and most of the surrounding parts are plastic for the mechanism.
- There are multiple types of plastics used in multiple colours.
- The device has low visibility: it is hard to see connections between parts, making it difficult to take apart without breaking it.
- The disassembly map is “vertical”. Many steps depend on removing a previous part to reveal the next. A more “horizontal” design would allow parts to come off in parallel, reducing dependencies.
- There are 28 parts in total.

4.9 LCA

To identify environmental hotspots in the current product set, a Life Cycle Assessment (LCA) was performed using the Idemat 2023 database. The assessment estimates the carbon footprint of the TAVI delivery system, loading system, and packaging across four life-cycle stages: material extraction, manufacturing, distribution, and end-of-life.

Assumptions

Several assumptions were required to model the products. A detailed overview is provided in Appendix 12.5. Key assumptions include:

- Wire elements: modelled as layered structures with an assumed construction of 50% outer polymer layer, 40% metal middle layer, and 10% inner polymer layer (Ojha et al., 2023).
- Handle components: modelled as ABS, based on visual analysis, typical medical device construction.
- Radiopaque marker band: modelled as a platinum-iridium alloy (90% platinum, 10% iridium) based on similar devices (Guide Extension Catheters: Review of Technology and Future Directions, 2023).
- Transport: manufacturing in the USA, distribution from Heerlen, and final transport to Erasmus MC

Total footprint and contribution per product

The LCA estimates a total footprint of 3.7 CO2e per procedure across the delivery, loading, and packaging. The contribution per product is:

- Packaging: 1.68 CO2e (54% of total)
- Delivery system: 1.46 CO2e (39% of total)
- Loading system: 0.25 CO2e (7% of total)

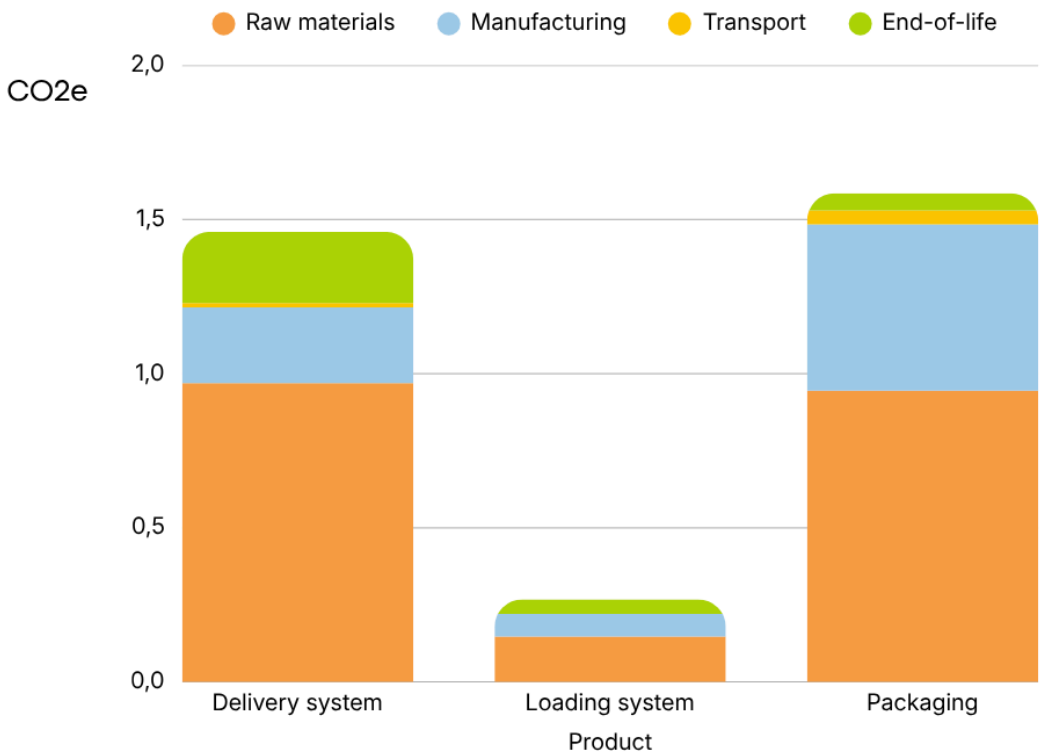


Figure 47: CO2e per product

Hotspots interpretation: delivery system

The delivery system footprint is dominated by the ABS handle, where ABS material production and injection moulding energy account for a large share of emissions. In addition, the platinum-iridium marker band contributes disproportionately to the footprint despite its very small mass, reflecting the high impact intensity of precious metals. End-of-life incineration also contributes, because carbon in plastics is released.

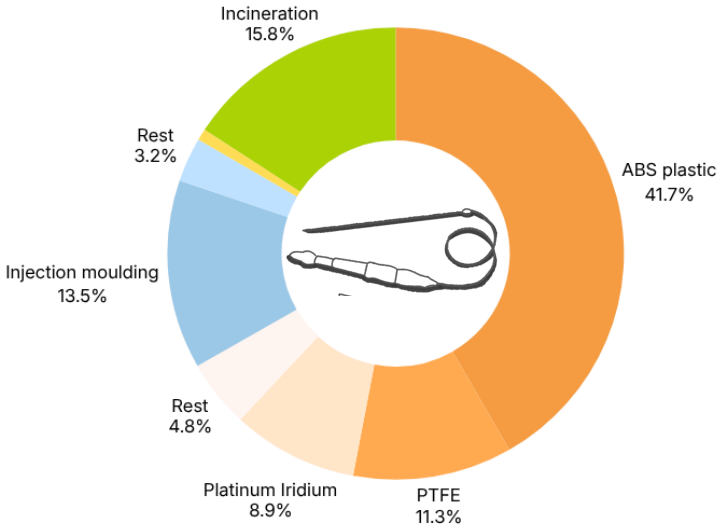


Figure 48: CO2e delivery system

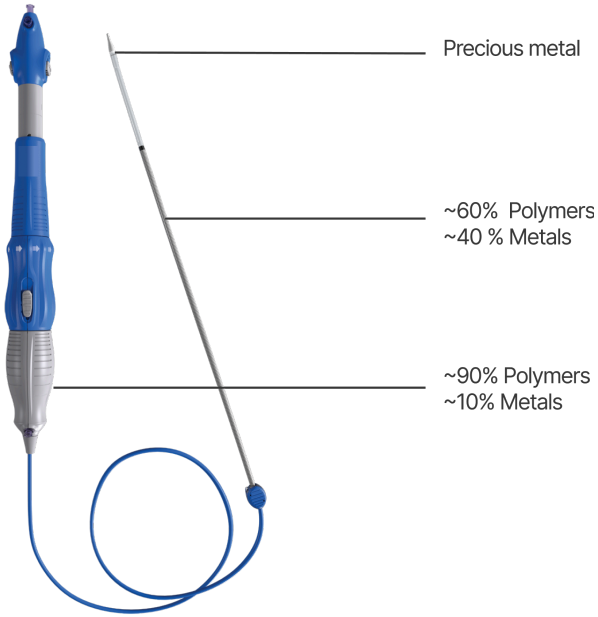


Figure 49: Materials delivery system

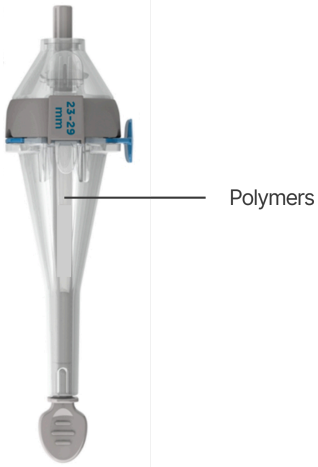


Figure 50: Materials loading system

Hotspots interpretation: loading system

The loading system has the smallest footprint. Material production is the dominant contributor, as the system is made of ABS, followed by manufacturing.

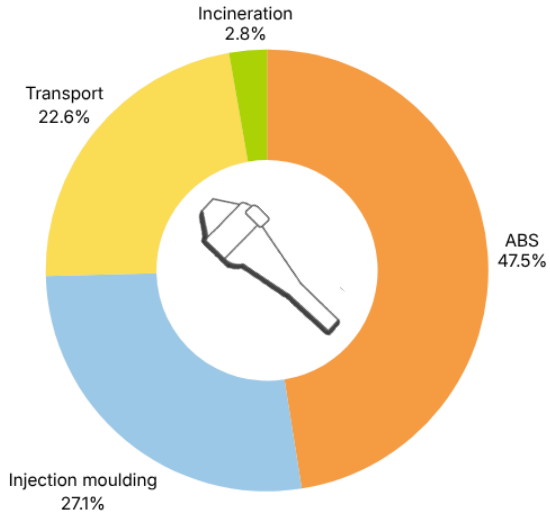


Figure 51: CO2e loading system

Hotspots interpretation: Packaging

Packaging is the largest contributor. Within packaging, the PET tray is the main hotspot, driven primarily by PET material extrusion and manufacturing.

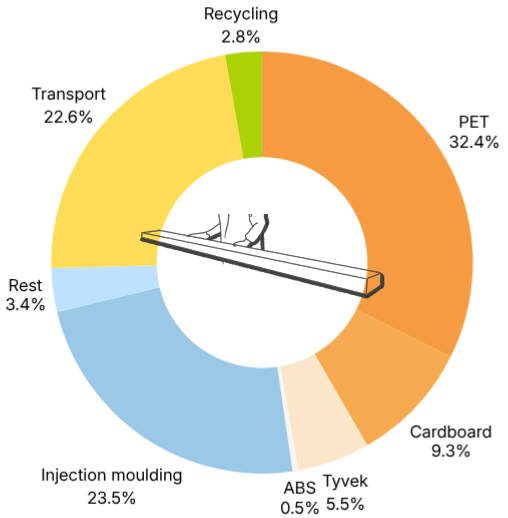


Figure 52: CO2e packaging

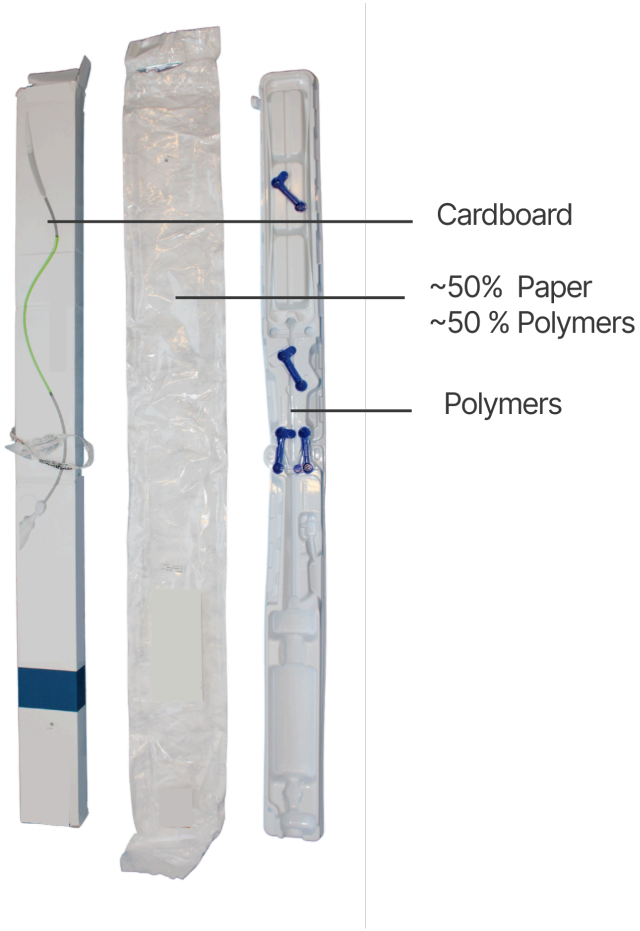


Figure 53: Materials packaging

Limitations

These results should be interpreted as indicative. The assessment relies on simplified material models, assumed logistics, and database averages. The purpose is therefore to identify relative hotspots and support later design requirements, rather than to provide a definitive carbon footprint.

Takeaways

- As the extraction and manufacturing of materials have the greatest impact across all products, the biggest environmental gains are likely to come from avoiding the production of new materials.
- In terms of packaging, the PET used for the tray has the greatest impact.
- Platinum-Iridium has, for its small weight, a relatively high impact. But this small fraction can still be strategically important, as it contains high-impact materials.
- The packaging results show that it's a lower-complexity product but still has the highest environmental impact.
- The impact of the loading system is small compared to the delivery system and packaging, making it a less interest...

4.10 Benchmark

To compare how different manufacturers design and package their TAVI delivery systems, a benchmark was done using brands available at Erasmus MC. The aim was to identify differences in material intensity and packaging, as these directly influence waste volumes and potential circular opportunities.

Five brands were included. For each brand, the following elements were documented and weighed (Figure 56):

- Delivery system
- Tray: the inner tray that holds the delivery system in place
- Box: the outer carton used for protection, storage, and labelling

A sterile wrap was visible for several brands. However, wraps were excluded from the comparison because they were not available for all products. It is assumed that a comparable sterile wrap is used for all brands. The benchmark includes both self-expandable and balloon-expandable systems. These mechanisms influence delivery system construction, as self-expendable systems have more complex mechanisms, and they can also affect packaging.

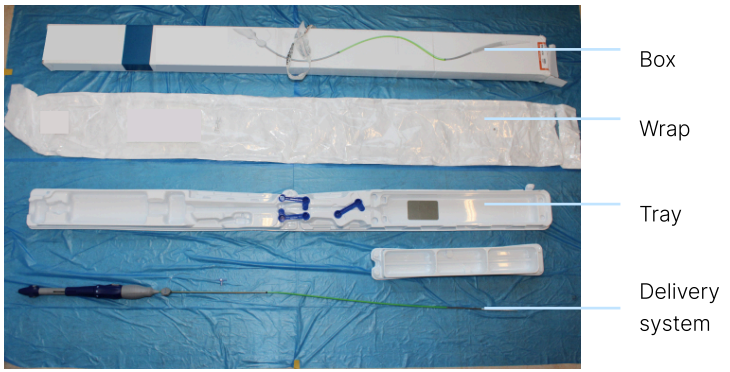


Figure 54: parts compared in bencmarking

The benchmark shows a large difference in packaging mass between brands. The box weight ranges from 330 g to 875 g, with brand 2 as a clear outlier due to a much heavier box. Tray weight ranges from 272g to 435 g, and in several cases, the tray is heavier than the device itself.

Delivery systems' weight ranges from 102g to 362 g. In general, self-expanding delivery systems are heavier than balloon-expandable systems. Visual comparison also suggests that self-expandable systems often have larger handles than balloon-expandable systems, which may contribute to this difference.

Overall, the benchmark indicates that packaging design is a major and controllable contributor to material use.

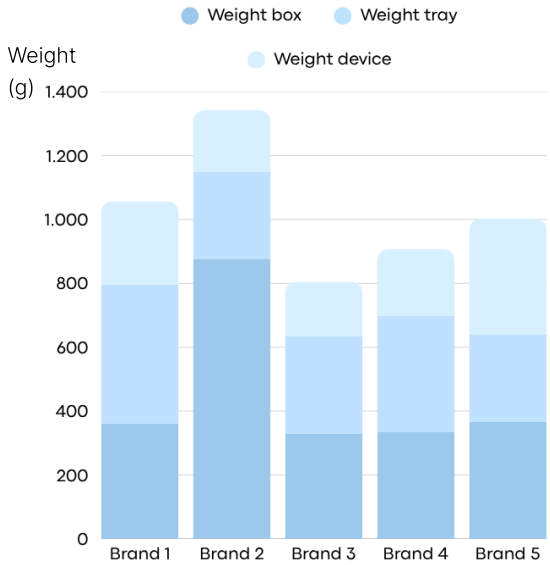
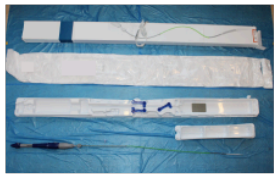


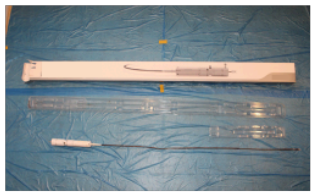
Figure 55: weight of parts per brand

Takeaways

- Self-expandable devices are heavier than balloon-expandable devices. The more complex mechanism of the self-expandable accounts for the higher mass.
- The trays of the self-expandable are, in general, bigger.
- The tray of brand 1 is much heavier than the others (including the bowls integrated in the packaging). This is because brand 1 is the only brand with a functional tray.
- Some of the packaging opens from the top, requiring less space. Others open from the side.







BRAND	Brand 1	Brand 2	Brand 3	Brand 4	Brand 5
MECHANISM	Self expandable	Balloon expendable	Balloon expendable	Self expandable	Self expandable
WEIGHT BOX (g)	361	875	330	335	367
WEIGHT TRAY (g)	435	275	305	362	272
WEIGHT DEVICE (g)	261	102	170	210	362

Figure 46: Benchmarking

4.11 Conclusion

The product-level analyses identify a small number of dominant hotspots and constraints relevant to circular intervention design.

First, packaging is a major contributor to the estimated carbon footprint. The LCA shows that packaging accounts for the largest share of emissions in the product set, with the PET tray as the main hotspot. The benchmarking results support this finding by showing that packaging mass varies widely across brands, suggesting that packaging is not fixed by clinical function and could be reduced through redesign.

Second, within the delivery system, the handle is a key point of focus. It represents a large share of product mass (75%), and in the LCA, ABS material production and injection moulding energy account for a substantial part of the delivery system footprint. In addition, the platinum-iridium marker band contributes disproportionately to emissions despite its very small pass, reflecting the high impact intensity of precious metals and the potential value of recovery.

Third, product design limits high-quality recovery. The disassembly analysis shows that parts of the handle can be opened and separated with minimal effort, while other sections contain stacked, glued components that require destructive separation.

These irreversible connections reduce disassembly efficiency and material purity, and they are likely to lead to downcycling or loss of value unless redesign improves separability.

Together, these findings suggest product-level priorities for circularity. The first is to reduce and simplify packaging. The second is to improve the delivery system architecture to enable safer, faster separation of key materials, especially high polymers in the handle and high-value metals in the marker band. These product-level priorities are further assessed against system-level constraints in the next chapter.



Figure 57: Delivery system

05

From insights to intervention

This chapter combines the top-down and bottom-up perspectives and translates the findings from the product-and system-level analyses into a set of design requirements and design directions.

Research question 3:
What transition pathway could enable the TAVI products to move from its current linear model towards feasible circular strategies in practice?

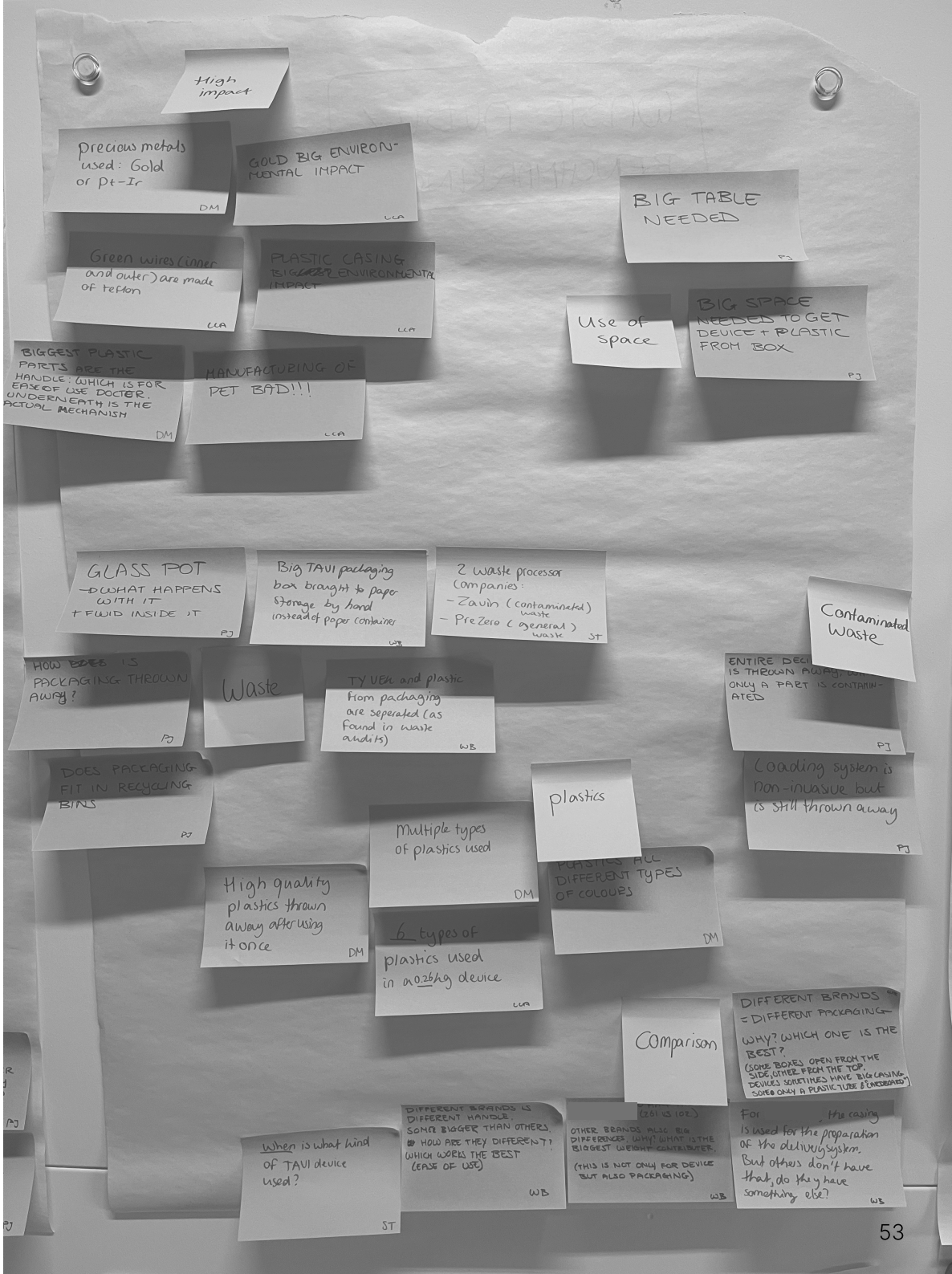


Figure 58: Clustering

5.1 Translating hotspots to requirements

Chapters 2 and 3 identified the product- and system-level hotspots that shape the current linear end-of-life route for the TAVI products. These hotspots were translated into a set of design requirements (the full process can be found in Appendix 12.7). Any proposed circular intervention must satisfy the following criteria across five topics:

System level:

R.1 Roles, responsibilities, and handovers are defined across hospital departments, the manufacturers, and external partners.
R.2 Ownership and liability boundaries are clear, including responsibility for contamination once the device is handed over.
R.3 Expected value retention and environmental benefit are meaningful relative to required effort and investment.

Information level:

R.4 Clear acceptance criteria exist for what can enter the circular route.
R.5 Material identification is available for key components to support reliable sorting and processing.
R.6 The intervention can be piloted and monitored with practical metrics (e.g. collection rate, mis-sorting incidents, recovered mass flows).

Operational level:

R.7 The intervention maintains sterility and does not increase infection risk.
R.8 Handling an internal transport after use are safe for staff, including control of puncture risk and exposure to fluids.
R.9 The point-of-use action is simple and fast (only small extra actions, that take max. a couple of minutes).
R.10 The intervention does not require clinical staff to perform complex sorting steps.
R.11 Collection and storage requirements are compatible with space constraints in the Cath lab and the slot.

Product level:

R.12 The product design supports separation where needed and avoids irreversible connections.
R.13 The intervention improves the likelihood of higher-quality recovery of polymers and metals.

Based on the hotspots and these requirements, four design directions were formulated (Appendix 12.8):

D1: reduce/redesign packaging
D2: design for reuse (loading system)
D3: design for recycling (delivery system)
D4: design for reuse (delivery system)

5.2 Idea selection

To determine the most strategic path forward, the four design directions were evaluated using two frameworks: the C-box to assess the practical implementation, and the Value Hill to assess circular ambition.

C-box

The C-box positions design directions on two dimensions: (1) how feasible they are to implement in the current context and (2) how novel the change is relative to current practice (Liu & Zhang, 2018). This method helps prevent the selection of ideas that are highly innovative but practically impossible, or highly feasible but insufficiently circular. The C-box is shown in Figure 59.

The C-box concludes the following:

- D1: Rethink or reduce packaging is very feasible, but not very novel.
- D2: Design for reuse (loading system) is highly feasible, but because the loading system is quite small, it has a lower environmental impact.
- D3: Design for recycling (delivery system) is less novel but more feasible. It can build on existing end-of-life handling practices if a controlled route and acceptance criteria are established.
- D4: Design for reuse (delivery system) sits high on novelty but low on feasibility. Reuse requires system conditions that are not yet in place (e.g., sterilisation, traceability, liability). It also introduces a larger workflow and logistics burden.

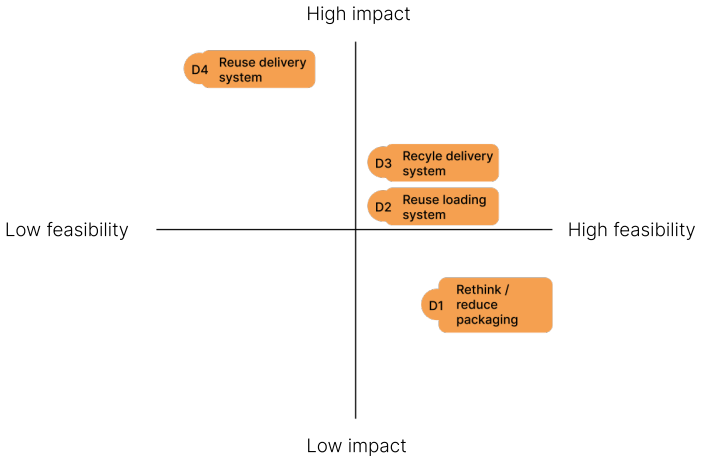


Figure 59: C-box

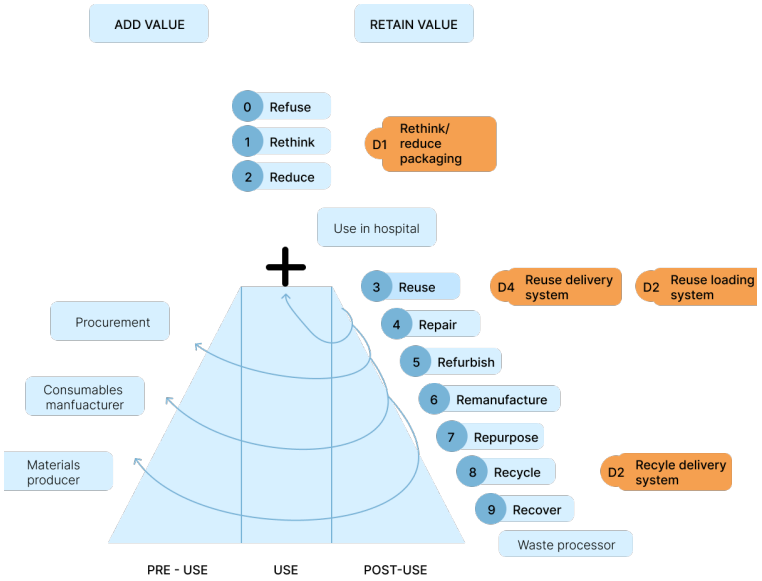


Figure 60: Design directions on value hill

Value hill

While the C-box evaluates implementation, the value hill is used to compare design directions by their ability to retain value. Within this framework, reuse strategies (D2 and D4) sit higher on the value hill than recycling or rethinking (D1 and D3) (Figure 60). Reuse retains the product's functional value, preserving the energy, labour, and emissions invested in manufacturing and assembly. In contrast, recycling retains value strictly at the material level. While recycling prevents the extraction of virgin resources, it still destroys the product's functional integrity and, without careful design for disassembly, risks downcycling.

5.3 Conclusion

The delivery system as main intervention point

When combining the results of the C-box and the Value-hill, it becomes evident that the loading system (D2) and the packaging (D1) represent “low-hanging fruit”. They are highly feasible to optimise and are easy to implement. However, while addressing them is beneficial, it does not fundamentally shift the procedure's linear paradigm.

To achieve a systemic transition, the intervention must target the delivery system (D3 and D4). The delivery system is the primary clinical tool and the core value-driver of the Cath lab. It contains the highest-value mix of materials, the most complex architecture, and the most irreversible connections. Resolving the end-of-life complexity of the delivery system yields the highest environmental return on investment and drives the necessary paradigm shift across stakeholder collaborations but may also require changes to the loading system and packaging. Therefore, the delivery system is selected as the primary focus for the transition design.

The evaluation of the delivery system gives a strategic paradox. The value hill shows that reuse (D4) is the ultimate circular goal, yet the C-box proves that the immediate implementation of a reusable delivery system is currently blocked by systemic, regulatory, and logistical infeasibility. Controversely, recycling (D3) is highly feasible in the short term, but relying solely on recycling falls short of long-term circular ambitions.

This reflects the logic of the socio-technical system and the multi-level perspective: higher-value circular strategies cannot be implemented in isolation, as they also depend on the wider system of routines, responsibilities, infrastructure, and regulation. As a result, the transition cannot jump directly to the most desirable end state but must proceed through intermediate steps.

For that reason, the most realistic conclusion is a phased socio-technical transition. To transform the TAVI procedure, the solution needs to be spread over time. The highly feasible recycling requirements will form a short-term intervention, serving as a logistical bridge to recover materials and build trust. Simultaneously, this bridge will prepare the medical ecosystem for a long-term intervention, in which the system conditions have matured sufficiently to support a reusable delivery system.



Figure 61: Co-creation OEM and ESCH-R

06

Collaborative creation with stakeholders

This chapter shows how stakeholder collaboration helped shape the transition pathway. Through co-creation, insights from practice were translated into opportunities for circular change.

6.1 The need for co-creations

Because this project combines product-level and system-level analysis, it was important to complement the research with real stakeholder input. The socio-technical system showed that circular change in healthcare depends not only on product design, but also on stakeholder alignment, responsibilities, routines, and system conditions.

For that reason, three co-creation sessions were organised. These sessions were used to test the research findings in practice and to understand how different actors viewed the proposed design directions and system changes. This was especially important because stakeholders within the same system, and even within the same organisation, do not always work closely together or share the same priorities.

The co-creations provided insights into which interventions were considered realistic, which barriers persisted, and what kind of alignment would be needed for circular change to become feasible.

6.2 Co-creation OEM and ESCH-R

6.1.1 Co-creation setup

To reflect on the four directions, a co-creation session was organised with participants from an OEM and the ESCH-R team.

The aim of this session was to gather their vision on the proposed design directions, understand which direction they considered most promising for further development, and identify where they saw the biggest potential and limitations.

The design directions

The following four design directions were used to discuss:

1. Reusable delivery system
2. Recyclable delivery system
3. Reusable loading system
4. Reduce/ rethink packaging

The participants were asked to reflect on two main questions:

- What works well in this design direction, and what does not?
- Which design directions seems most promising, and why?

The participants

The session included several participants from an OEM, including representatives from sales, research and development, and sustainability. In addition, several members of the ESCH-R team took part

Materials and setup

During the session, participants received printed sheets showing the four design directions and possible examples for each (Appendix 12.6). They used sticky notes to write down their reflections and discuss the strengths, weaknesses, and implementation challenges of the different scenarios.

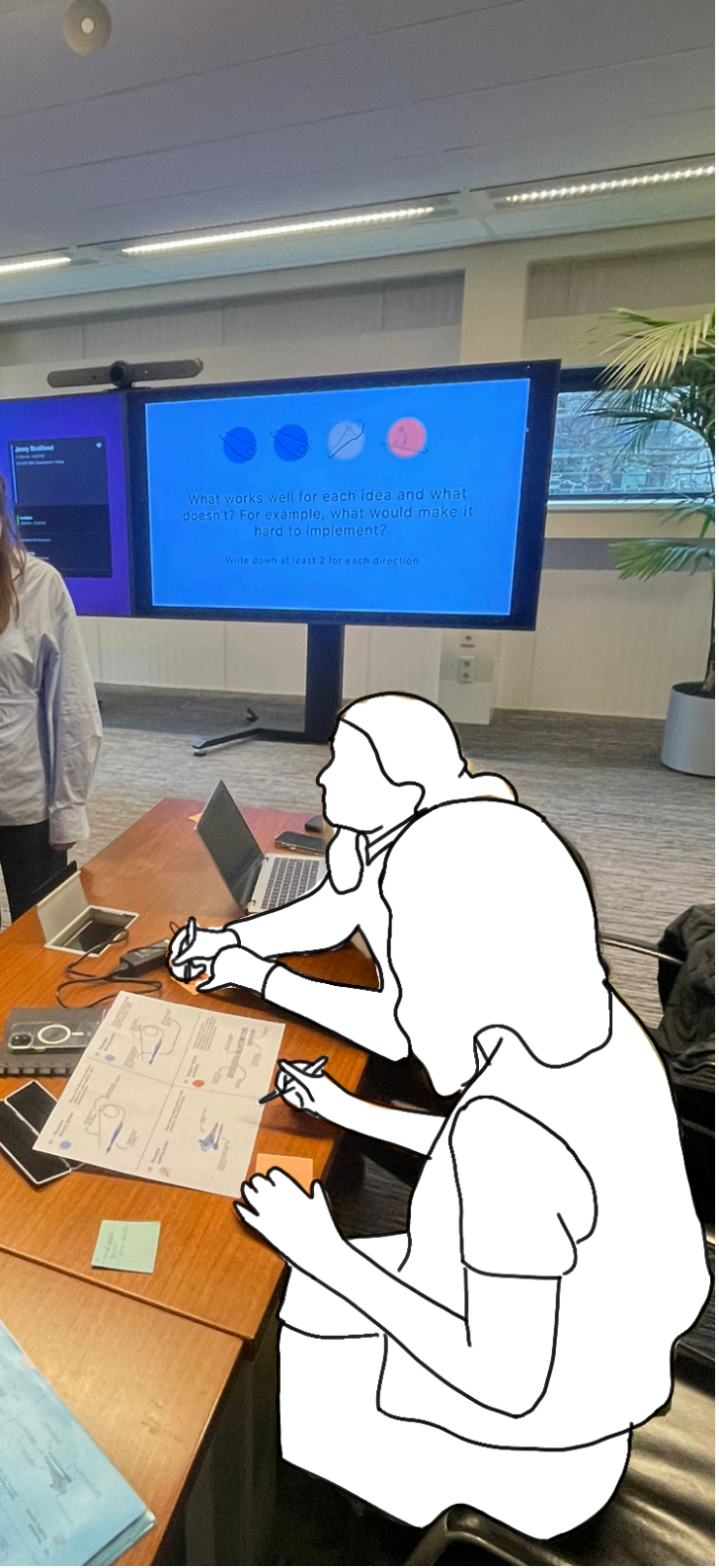


Figure 62: Discussing design directions

6.1.2 Co-creation findings

This session helped identify which design directions were considered most relevant and realistic from the perspectives of the OEM and ESCH-R. Overall, it showed that the different directions were not valued equally: some were seen as more promising, while others were considered easier to implement in the near future.

Design direction 1: reusable delivery system

The delivery systems were seen as the most complex direction, but also as one of the most promising. It was the direction the OEM would see as the most ideal, with the best long-term impact. At the same time, it was seen as the most difficult to realise due to the technical, regulatory, and organisational challenges involved.

Design direction 2: recyclable delivery system

The recyclable delivery system was also seen as a promising direction. Compared with reuse, it was considered more realistic in the short term, as it stays closer to the current product design and would require fewer changes to ownership, validation, and responsibility.

Design direction 3: reusable loading system

The reusable loading system was discussed as a relatively manageable intervention. Compared with the delivery system, it was seen as less complex and therefore potentially easier to change.

"There is no worth in the loading system, making this reusable wouldn't help". - Sales

At the same time, it was not considered the most impactful direction, as it is a very cheap product and does not contain any complexity.

Design direction 4: reduce/rethink packaging

The packaging was generally seen as the lowest hanging fruit:

"This is a quick and easy win". - Sustainability

Participants considered the packaging easier to improve than the product itself, especially because packaging does not face the same level of technical and regulatory complexity as the delivery system. However, the OEM mentioned they already have a team working on packaging improvements.

6.3 Co-creation hospital

6.2.1 Co-creation setup

A second co-creation was organised to understand what different stakeholders within the hospital would need, to implement environmental change in practice. The aim of the session was to collaboratively explore how circular scenarios for the TAVI delivery system would affect the hospital system, and what changes would be needed.

Scenarios

During the session, three possible circular scenarios were discussed, along with their steps.

1. Recycling the tip

In this scenario, only the tip of the delivery system would be cut off and collected separately for recycling. The following steps were discussed: (1) cutting the tip, (2) collection, (3) cleaning.

2. Recycling the entire delivery system

In this scenario, the full delivery system would be collected separately after use for recycling. The following steps were discussed: (1) cleaning, (2) collecting, (3) separating.

3. Reusing the delivery system.

In this scenario, the delivery system would be reprocessed and reused. The following steps were discussed: (1) assembly, (2) disassembly, (3) collection, (4) sterilisation, (5) storage, (6) transport.

The participants

The six participants represented different professions within the hospital: infection prevention, project optimisation advisor, strategic procurement, nurse, logistics coordinator, and logistics advisor. This session proved to be very valuable for gaining insights into the wishes, requirements and values of different stakeholders relating to each other, as many departments often work independently.

Materials and setup

The session was set up around one central template placed on the table (Appendix 12.6). Erasmus MC was positioned in the middle, with the surrounding stakeholders arranged around it. For each scenario, tokens were used to visualise the different process steps and actors involved.

After placing the tokens for each scenario, participants discussed what changes were needed within the hospital, including workflow, responsibilities, space, safety, and logistics. They then reflected on what would be required from the actors outside the hospital: OEMs, the government, sterilisation, and a recycler.

6.2.2 Co-creation findings

Overall, the session showed that stakeholders are willing to support environmental change, but only if it fits within clinical workflow and does not create additional safety risks or an unrealistic workload.

Scenario 1 - Recycling (Tip-Only)

Participants viewed cutting the tip as realistic. Similar practices are already carried out in other hospital departments, which makes the step familiar and achievable.

> "This is already done at another department and works well, so this is definitely possible." - Nurse

The collection was also deemed practical because it would require only a small, dedicated bin and minimal additional space.

System proposals:

- Simple disposal process
- Clear rules and brief training on what is permitted
- Internal collection route for logistics

Scenario 2 - recycling

Participants did not consider it realistic for nurses to disassemble the device for recycling.

They indicated that this would shift their role towards waste handling, which does not align with their responsibilities, and that it would also be unsafe due to the rigid construction and contamination risks. In addition, collecting whole devices would require an additional bin at the waste drop-off point, which is already crowded and space-limited.

"If every brand did this, then there would need to be lots of bins. There is no space for that." - Logistics

System proposals:

- Clear handling protocols
- Collaboration with recyclers on how to collect waste
- Standardised collection for all brands



Figure 63: Co-creation hospital

Scenario 3 - reuse
Participants described partial reuse as the ideal long-term direction, especially when supported by a product-as-a-service model.

"Product-as-a-service is the dream scenario." - Procurement

At the same time, they identified major barriers. Procurement indicated that sustainability is currently unlikely to outweigh cost and risk in tender requirements.

"We already pay OEMs a lot, and do we need to pay for their investments? It gives them a unique market position; we don't need to pay for that." - Procurement

Sterilisation was not considered feasible in-house due to limited capacity and the need for specialised training. This implies that reuse would require an external reprocessing partner and clear agreements on responsibilities, quality assurance, and liability.

System proposals:
- Handling protocols
- Sustainability in tender criteria
- Agreements on ownership
- Checklist to make sure the delivery system is safe to use
- Emergency stock



Figure 64: Discussing scenarios

6.4 Co-creation OEM

6.3.1 Co-creation setup

A third co-creation was organised with an OEM. The aim of this session was to reflect on the two proposed transition phases (Chapter 5) and to gather feedback on the suggested system and product changes for each phase. In particular, the session was used to understand how the OEM viewed the feasibility of the proposed changes, which elements they considered realistic, and where they saw alternative directions.

Scenarios

During the session, the two implementations of transition were presented separately:
1: partial recycling
2: partial reuse

During the session, the two implementations were shown to the OEM. For both, a list of suggested changes was shown. They had 5 minutes to write down their thoughts, and then they started discussing.

The participants

This session included participants from different parts of the OEM: research & development, engineers, sales, sustainability, and quality and regulatory. This helped bring together technical, strategic, and implementation-oriented perspectives.

Materials and setup

For each phase, participants were shown a list of suggested changes and two questions (Appendix 12.6):

- What do you think about these ideas?
- What could be alternatives?

They first had a short period to write down their thoughts individually, after which the group discussed the phase as a group. The same structure was then repeated for the second phase.



Figure 65: Co-creation OEM



6.3.2 Co-creation findings

Overall, the session showed that OEM recognised the relevance of the phased strategy and engaged with both phases from a practical and strategic point of view. The discussion also confirmed that the main barriers differ between the two phases. In the recycling phase, participants focused more on current product requirements and the limits they impose on circularity. In the reuse phase, the discussion shifted more towards implementation, training, and collaboration.

Partial recycling

In the discussion on partial recycling, participants emphasised that the current product is primarily designed around safety and procedural effectiveness, rather than circularity.

"The product is designed for the requirements of safety and procedure effectiveness, not circularity. It would be interesting to look at those requirements." - R&D

For the proposals, this meant that the most important changes were those that could support recycling without compromising the device's current functional and safety requirements. Proposals that improve material transparency, clarify recycling, and support safe separation were seen as more fundamental than broader redesign ambitions.

Partial reuse

In this discussion, participants did not see product design itself as the main problem. Instead, they focused more on the implementation side of the proposal.

"The design change is not a problem, but we need to train the clinical staff well." - R&D

This suggests that, from the OEM's perspective, the larger challenge of reuse lies not only in the product itself but in adopting new routines and in the support needed for safe use in practice.

Participants also highlighted possible wider benefits of reuse.

"We are saving a lot on transport with this." - Sales

For the proposals, this meant that training and safety assurance were seen as more critical than the product redesign itself. Product changes remained necessary but was seen as less of a challenge compared to the whole system around the product.

Figure 66: Discussing suggestions

07

Designing the transition pathway

This chapter translates the findings of the analysis into a transition strategy for the TAVI delivery system. It shows how the current linear system could gradually develop towards more circular alternatives through a future vision, backcasting, a phased pathway, and the changing roles of stakeholders.



Figure 67: Cath lab

7.1 The transition goal

Based on the combined system and product analysis, the following design goal was formulated:

Designing a gradual transition pathway for the TAVI delivery system towards reuse by combining system and product perspectives across stakeholders within the existing healthcare system.

7.2 Shaping the transition

To work towards this goal, the transition needs to be shaped in a way that connects product development to wider system change.

The OEM has a strategic role in the transition towards a more circular TAVI delivery system because it is one of the few actors able to connect product development to wider system change. Decisions about materials, product architecture, traceability, and information sharing strongly influence whether recycling or reuse can become feasible in practice. At the same time, this is not an individual responsibility. Healthcare is a multi-actor system in which implementation depends on collaboration between hospitals, external processing partners, and the government. The OEM does not implement the transition on its own; instead, it helps create the conditions that enable other actors to participate.

There is also a clear incentive for the OEM to take this role. In a linear model, value is lost once the product leaves the hospital after use, whereas developments in other medical device markets show that the post-use stage can still retain economic value.

This is particularly visible in the United States with companies such as Stryker Sustainable Solutions (Reimagining Healthcare Efficiency: How SSS Leads the Way in Medical Device Reprocessing, 2024), which collect single-use devices from hospitals, reprocess them, and return them to the market at a reduced price. If OEMs do not actively help shape circular infrastructures themselves, part of this value may increasingly be captured by external actors. By engaging early, the OEM can shape the market's direction. Early movers can influence how the transition is shaped, which gives them a unique market position as leader; the rest will have to follow.

The OEM's strategic role can therefore be understood as one of system enablement: not as the sole driver of circularity, but as a key actor in making it possible and meaningful within a broader collaborative transition.

7.3 Future vision

The long-term vision is a fully reusable TAVI delivery system. In this future state, the worn components are replaced when needed, and materials only leave the system when they have reached their true end-of-life. At that point, the remaining material value is recovered through recycling. The vision functions as a long-term reference point. It does not describe what can be implemented immediately, but it helps define where the transition should lead over time.

Based on system analysis, product analysis, and co-creation sessions, several conditions must be achieved for this vision to become a reality. First, the delivery system needs to be **redesigned for reuse**, allowing components to be safely disassembled, inspected, repaired or replaced, and reassembled. Secondly, successful implementation requires **clear collaboration and responsibilities** amongst involved parties, as reuse depends on coordination between the OEM and the hospital. Thirdly, a **specialised reprocessing partner** is essential for cleaning, inspecting, testing, and preparing the system for another use cycle. Lastly, full **traceability** of parts is crucial to monitor how often components have been used, whether repairs or replacements have occurred, and when parts are no longer fit for continued use.

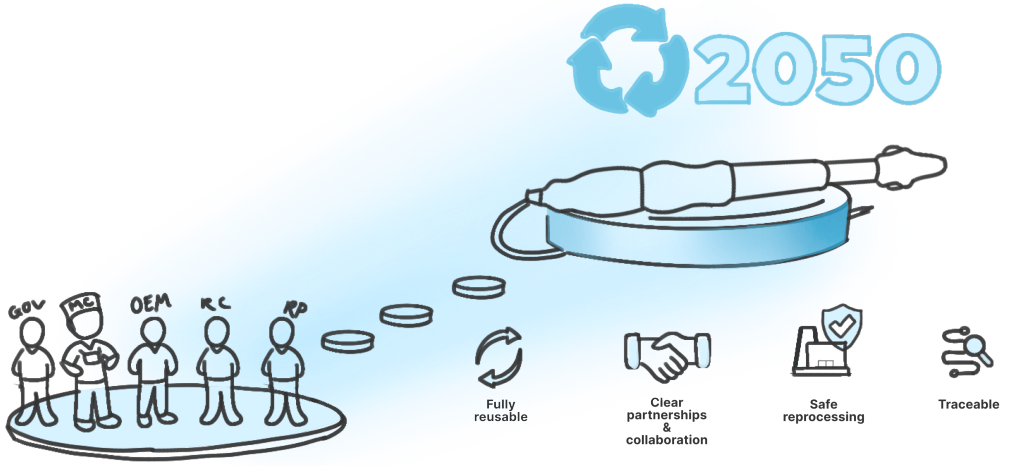


Figure 68: Future vision

7.4 Backcasting

The future vision of a fully circular TAVI delivery system was used as the starting point for backcasting. Rather than asking what can be changed immediately, backcasting asks what conditions must be in place for the desired end state to work in practice. This helps identify which gaps still exist between the current linear system and the long-term circular vision.

At the top of the pathway, **Product-as-a-Service (Paas)** represents a circular business model that can support reusable medical devices by shifting the focus from one-off sales to lifecycle-based sales. To make such a model possible, **safe sterilisation and reprocessing** must be in place so that products or components can be cleaned, checked, and prepared for reuse. This, in turn, depends on **traceability**, which is needed to monitor parts, usage cycles, replacements, and responsibilities throughout the system. Before that, **waste collection** and source segregation must ensure that products and components are routed into the correct stream rather than automatically entering the current hazardous waste stream. These flows become more feasible when the product itself supports **modular design,** allowing parts to be separated, replaced, or recovered more easily.

Underlying all these conditions is **collaboration** between the government, the hospital, OEM, and external partners, as circularity depends on shared responsibilities, aligned agreements, and an organised reverse logistics chain.

This backcasting vision is used as a guiding framework for the following sections, where these conditions are translated into a transition pathway and intermediate actions towards implementation.

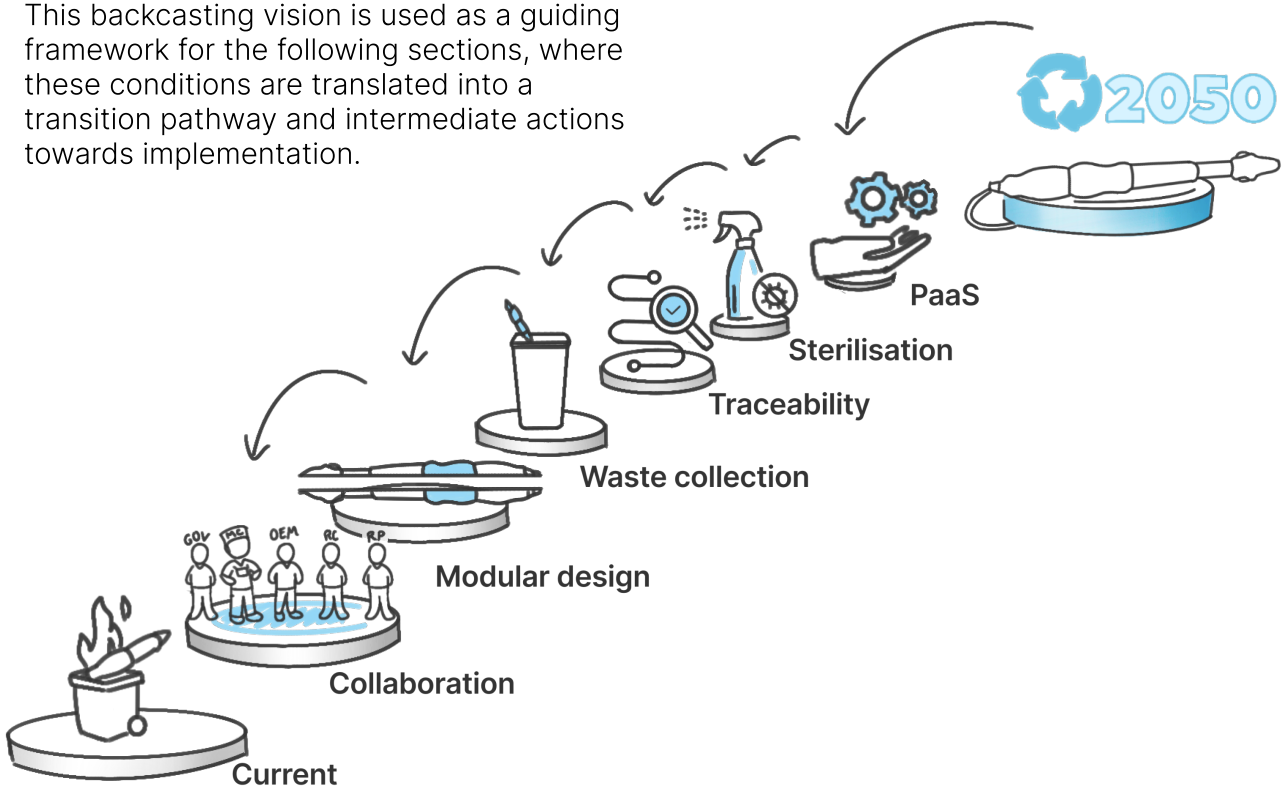


Figure 69: Backcasting

7.5 Key challenges in the transition

By studying the product and the system and doing co-creations and observations, several challenges were identified. These apply both for recycling and reuse, although they may play out differently across the transition.

Space limitations

Both the Cath lab and the waste slot operate within limited physical space. Existing waste streams, equipment, and work surfaces already compete for room, leaving little space for additional bins, collection systems, or temporary storage.

"If every OEM needed a bin for collection, there would not be enough space!" - Logistics



Figure 70: Space limitations

Clinical safety culture

The Cath lab is organised around patient safety, speed and routines. Staff work in an environment where standardisation and risk reduction are essential, so new actions are only likely to be adopted when they integrate smoothly into existing practice.

"We have a maximum of 5 extra minutes for an extra step" - Nurse

Circular interventions that introduce extra handling, additional time, or uncertainty are, therefore, difficult to embed. Also, the medical paradigm dictates that "new equals safe" and "used equals risky". Surgeons and nurses inherently trust a factory-sealed device. Asking clinicians to perform a critical heart valve replacement with a "second-hand" handle introduces massive friction regarding patient safety.

"There is a reason why we shifted to single-use devices" - Nurse



Figure 71: Clinical safety culture

Operational complexity

A circular route requires the product to be collected, separated, handled correctly, stored, and routed to the next appropriate actor. This adds new routines, extra coordination, and practical demands to a system that is already busy and tightly organised. The challenge is not only to define a circular route, but also to make it workable in daily practice.

"You can't ask nurses to also function as waste handlers, that is not their job, they did not sign up for that" - Logistics

If circular handling does not fit clearly within existing workflows, it becomes difficult to sustain.



Figure 72: Operational complexity

Financial pressure

The transition towards circularity requires investment, while the benefits are often distributed unevenly across the chain. Costs may arise from redesign, collection systems, reverse logistics, training, additional coordination, and external processing. At the same time, the actors involved do not necessarily have the same incentives or the same willingness to take on financial risk. This raises the question of who will pay for the transition and under what conditions. Financial pressure, therefore, slows down implementation, even when the broader ambition is shared.

"It is a big investment, but also a big risk. How are we going to pay for that?" - OEM



Figure 73: Financial pressure

Regulatory constraints

The delivery system is a class III medical device, placing it in the highest-risk category under the medical device framework. This means that changes to the product or its route require careful validation, strong evidence, and a time-consuming approval process. Circular interventions, therefore, move within a highly regulated environment in which safety and compliance are paramount.

"It takes forever to change such a device, which is not motivating if we need to wait that long to see a change." - Nurse

Especially for reuse, this significantly increases the time and effort needed for redesign before implementation becomes realistic.



Figure 74: Regulatory constraints

Responsibilities and liability

A circular system depends on multiple actors, but their roles are currently fragmented and not self-evident. Questions arise around who is responsible for collection, return, sorting, inspection, approval, and decision-making throughout the chain. In addition, reuse introduces questions of liability: if something goes wrong, it must be clear where responsibility sits. Without clear agreements on responsibilities and liability, actors are more likely to fall back on the certainty of the current linear route.

"Who is responsible when something goes wrong?" - Infection prevention



Figure 75: Responsibilities and liability

7.6 Multi-level transition

The future vision and barriers described in the previous chapters show that the transition is not blocked by one single issue, but by a set of interrelated challenges spread across the whole system. For that reason, the transition is structured across four interrelated levels: (1) system, (2) information, (3) operational, and (4) product.

This layered structure is inspired by socio-technical transition thinking, particularly the MLP (Geels, 2004) and work on Design for Sustainability Transitions (Ceschin & Gaziulusoy, 2016). The four levels are used as a structure that moves from macro-level, with less tangible conditions, to micro-level, with more tangible forms of intervention.

System level creates the conditions for change. These include regulation, procurement, partnerships, and agreements. They define what is allowed, who is responsible, and how stakeholders commit to the transition. Without this level, the actions below have no stable foundation.

Information level makes products, routes and outcomes visible across the chain. Transparency, traceability, and reporting help stakeholders understand what they are working with, what should happen next, and whether the intended impact is actually being achieved. Without this level, actors cannot coordinate effectively.

Operational level actions focus on how circularity can fit into daily practice. This level addresses barriers such as space limitations, clinical safety culture, and operational complexity.

Product level actions determine whether the delivery system is technically fit for circularity. These actions shape whether the product can be disassembled, recycled, or reused in practice. Without this level, the circular ambition cannot be translated into a feasible product pathway.

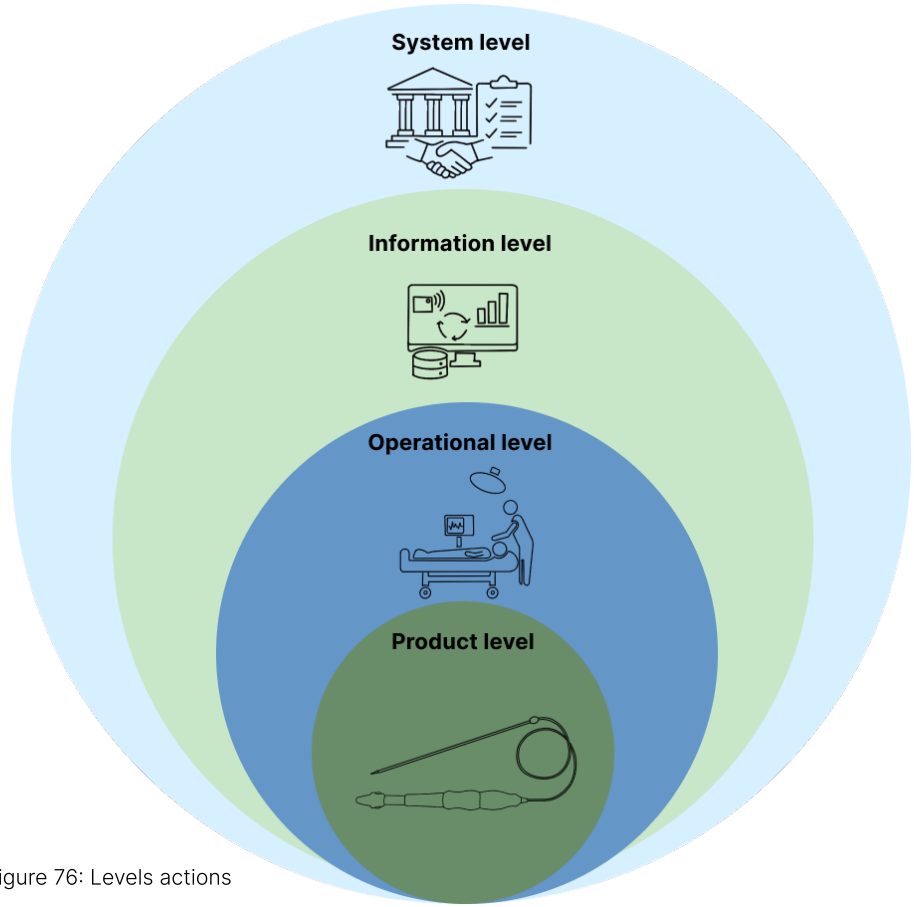


Figure 76: Levels actions

Although the levels are described separately, enabling recycling depends on their interaction. Product redesign has limited value if staff do not know how to separate and return the right components. Training alone is insufficient if there is no agreed route and no downstream actor ready to receive the product. Traceability cannot support coordination if the product has not been designed to allow different parts to be routed along different paths. Similarly, operational routines remain unstable if procurement, agreements, and responsibilities are not formally embedded at the system level.

The dependencies between the four levels are even stronger in reuse. Product redesign is of limited value without validated reprocessing procedures and actors capable of carrying them out. Traceability cannot support safe decision-making if clear wear-and-tear criteria have not been defined. Operational routines cannot function if ownership and liability remain unclear. Similarly, no business model for reuse can succeed if the product itself is not technically fit for repeated cycles.

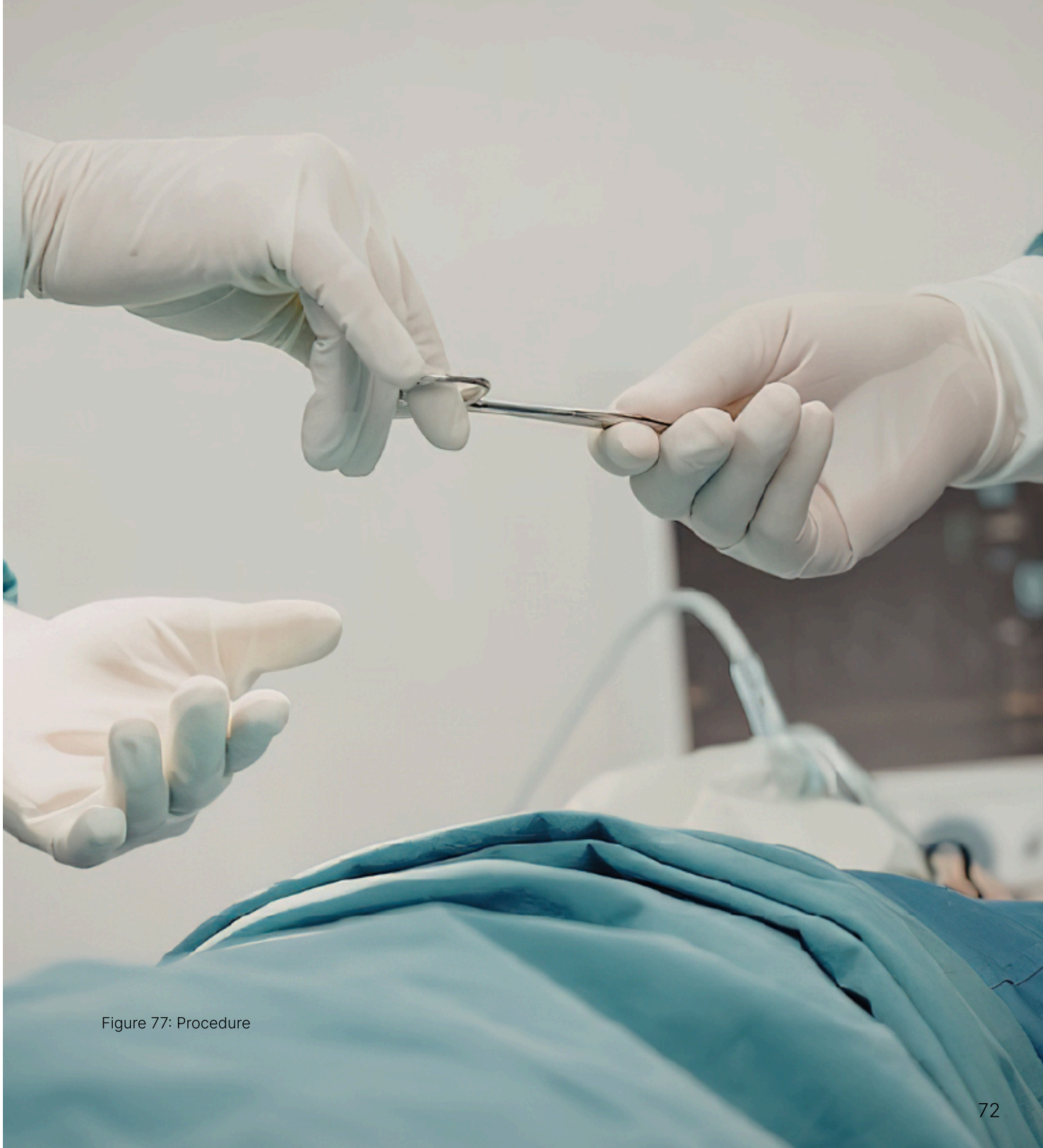


Figure 77: Procedure

7.7 Transition timeline

To consider when actions become relevant in the transition, a timeline is shaped.

Healthcare sustainability targets create clear long-term directions for change. In the Dutch context, the Green Deal Duurzame Zorg 3.0 sets 2050 as the horizon for climate-neutral and more circular care.

At the same time, this transition cannot happen in one step. Change in healthcare generally needs to happen gradually, because healthcare organisations function as complex systems in which new practices must be introduced, adapted, and embedded across multiple actors and routines rather than implemented as a simple linear change (Braithwaite et al., 2018).

In the TAVI case, this is particularly important because the delivery system is classified as a Class III medical device.

Design changes to these types of products cannot be introduced quickly: a redesign typically takes around 8-10 years, as it must undergo verification and validation, clinical testing, and approval under the EU Medical Device Regulation (MDR) (Nitzany, 2025). This means that if an OEM were to start redesigning today, it would not be on the market before roughly 2035.

This makes a phased transition pathway necessary. Rather than moving directly from the current linear model to a fully reusable system, the transition needs to be developed step by step.

The first phase focuses on recycling, as this is the most realistic near-term intervention and can be introduced with relatively limited disruption to current practice. The goal of the first phase is to enable recycling and lay the foundation for further circular steps.

This includes design changes that support recovery, shared agreements between stakeholders, collection and return routes, daily routines, training, and traceability of both the product and its route after use.

The second phase focuses on reuse, which enables higher value retention but also requires a Its goal is to retain more value by keeping products and components in circulation for longer. Its goal is to retain more value by keeping products and components longer in circulation. This requires redesign for repeated use, readiness for reprocessing, a product passport, contractual changes between actors, and a circular business model that supports multiple use cycles.

The transition pathway, therefore follows a stepwise timeline:
2035: implement partial recycle
2045: implement partial reuse
2050: future vision, fully reusable system.

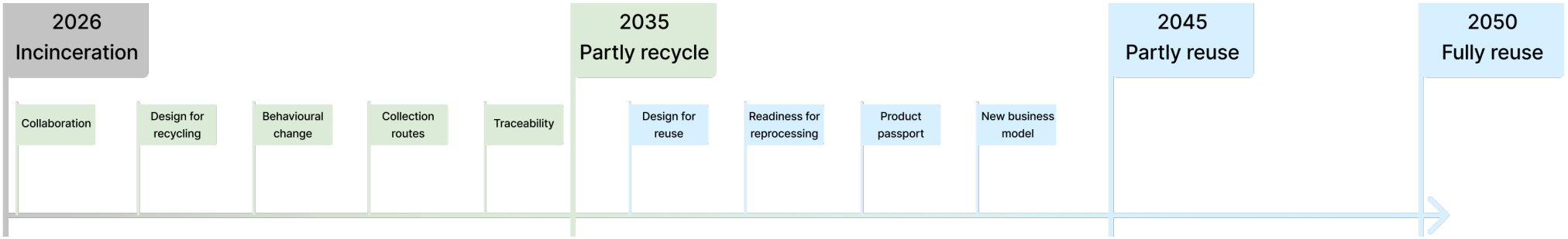


Figure 78: Timeline and goals

7.8 Parts for recycling and reuse

The choice of what to recycle, reuse, or discard in the healthcare context is based on a combination of material value, environmental impact, contamination risk, technical separability, and processing feasibility.

Handle

The handle is the most important component in both phases of the transition. It accounts for approximately 75% of the delivery system's mass and is made of high-quality medical-grade plastics.

In phase 1, the handle is recycled. Because the handle does not enter the patient, it can be safely recycled without extreme biohazard risks.

In phase 2, the handle shifts from recycling to reuse. By replacing the main polymer used in the handle, ABS, with high-performance medical-grade polymers (such as PPSU or PEI), the handle can withstand repeated sterilisation cycles without mechanical or material degradation. This material upgrade enables the handle to be safely reprocessed and returned to the hospital for reuse.

Tip

The tip is relevant in both phases because it is made of a precious metal alloy: platinum-iridium. Although this fraction is small in mass, it has high environmental and economic value. The production of these metals requires intensive mining and refining, which gives them a relatively high environmental footprint. For that reason, the distal tip is recycled in both phases.

Wire

The wire accounts for about 25% of the total weight. In phase 1, the entire delivery system is collected and disinfected by the recycler before disassembly. Due to the difficult layered composite structure, it cannot be recycled and is discarded.

In phase 2, the wires are considered potentially recyclable, but only under future conditions. This is based on the expectation that by around 2045, advances in decontamination and recycling may make it feasible to recover value from this part.

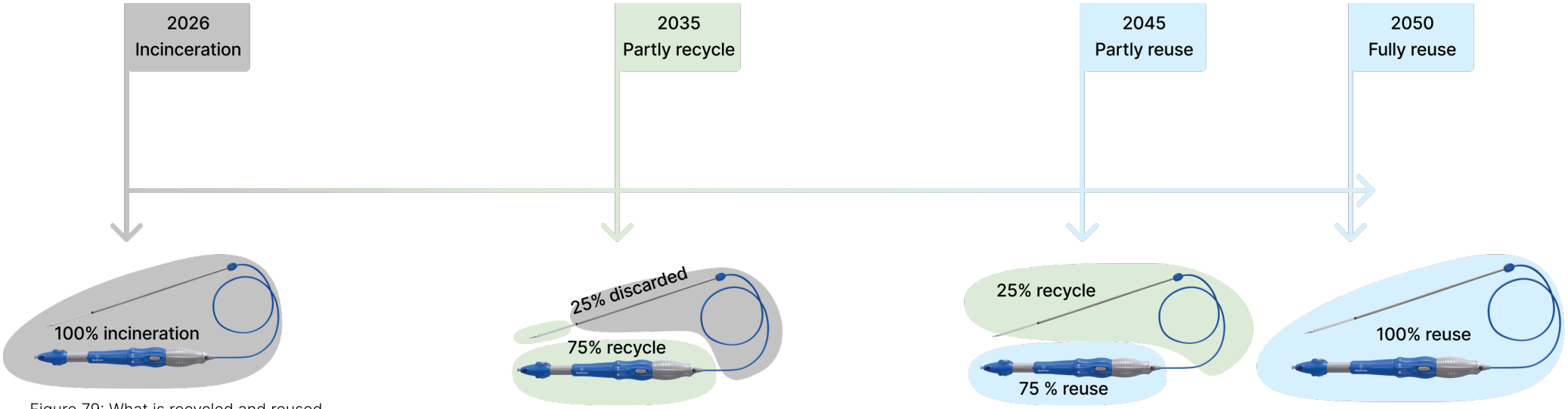


Figure 79: What is recycled and reused

7.9 Stakeholders in the transition

To decide who is responsible for what, their roles are shaped

The core stakeholders

The **OEM** has a central role throughout the transition. In phase 1, its main responsibility is to enable recycling by supporting product understanding, safe disposal and recycling steps, and the organisation of reverse logistics. In phase 2, the OEM becomes responsible for a circular service system in which traceability, product durability, quality assurance, and lifecycle responsibility are much more important.

Cath lab nurses remain the main actors. In both phases, their role includes simple and clearly defined handling actions. In phase 1, this means disposing of the delivery system in the correct recycling route. In phase 2, their role becomes slightly more complex, as they need to separate the reusable and recyclable part.

Logistics staff become responsible for managing additional internal flows alongside the existing hospital streams. In phase 1, this mainly means transporting and routing the new recycling stream safely. In phase 2, logistics become more complex, because separate routes for recycling and reuse need to be managed at the same time.

Hospital procurement and management have an enabling role across both phases. In phase 1, they are needed to assess economic feasibility, approve changes, and create the contractual conditions for recycling. In phase 2, their role becomes even more important, because reuse requires different purchasing logic, stronger partner agreements, and possibly a shift from buying single units towards service-based models.

Government remains important throughout the whole pathway. In phase 1 their role is mainly to provide clarity on classification, handling, and the conditions under which materials can safely leave the hospital for recycling. In phase 2, they also need to support the legal and regulatory framework for reuse, including clarity on responsibilities, liability, and quality requirements for reprocessed medical devices.

New external stakeholders

In phase 1, this is the **third-party recycler**. This actor is needed because the OEM does not have a recycling infrastructure. The recycler is an operational partner within the circular ecosystem. They provide the technical capacity to process the recycled parts.

In phase 2, the new partner is the **third-party reprocessor**. While Erasmus MC is currently expanding the capacity of its internal Central Sterilisation Department (CSA) to handle more reusable equipment, there is a strict operational limit to this internal capability. The hospital's CSA is optimised for high-volume, standardised surgical equipment (e.g., steel scalpels and clamps).

The TAVI delivery system, however, falls into a significantly more difficult category. It is a high-complexity, multi-material cardiovascular device that requires highly specific, device-dependent disassembly, cleaning, and validation protocols. Expecting generalised hospital staff to master and legally validate this intricate process for every specific OEM brand is neither practical nor safe.

By treating the reprocessor as a supply chain partner rather than a competitor, the OEM leverages its existing regulatory certifications and industrial capacity to accelerate the transition, while preventing the recycler from approaching the hospital directly. This effectively neutralises the competitive threat by absorbing it into the OEM’s own circular ecosystem.

7.10 Actions across the four levels

The following chapter discusses the actions needed to support the transition pathway on the four levels based on co-creations, research, wishes and needs of stakeholders.

System level

At the system level, the main change is a shift from a linear disposal structure towards a coordinated circular network. In the current situation, responsibilities for the delivery system after use are fragmented and largely organised around incineration. For phase 1, actors need to establish a collaboration structure that makes separate collection, handover, transport and recycling possible. This mainly requires agreement between the hospital, the OEM and recycling partners on responsibilities, logistics and safe handling.

In phase 2, the required change becomes more extensive. Once reuse is introduced as an additional strategy, the system can no longer be organised only around a return flow for recycling. Instead it needs to function as a more structured circular value chain in which responsibilities for traceability, quality control, inspection, reprocessing and redistribution are clearly assigned.

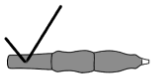
Action	 Partnerships & agreements	 Approval criteria	 Circularity in tender	 Regulatory clarity	 Product-as-a-service model
Stakeholder	OEM, hospital, reprocessor, recycler	Infection prevention	Procurement	Government	OEM
Explanation	Shared agreements on recycling / reusing, handover, quality.	Clear criteria for safe use.	Circular requirements in purchasing.	Rules on classification, traceability and liability.	OEM ownership and take-back through a circular business model.
Phase	Recycle Reuse	Recycle Reuse	Recycle Reuse	Recycle Reuse	Reuse

Figure 80: System level actions

Information level

At the information level, the required change develops from basic transparency towards detailed traceability. In phase 1, the main need is to support safe and reliable routing of the used product into a recycling stream. This requires clear acceptance criteria, practical instructions for hospital staff, and basic information on material composition and downstream processing requirements. The information system at this stage mainly supports sorting, handover and monitoring of the new return flow.

In phase 2, information requirements become significantly more demanding. Reuse requires more than knowing where a product goes; it also requires information on whether a part is still suitable for another cycle. This means that traceability needs to become more precise and more detailed, for example regarding handling history, use cycles, inspection results and processing steps. The role of information thus changes over time: in phase 1 it mainly supports control of the recycling route, whereas in phase 2 it becomes a condition for safe and accountable reuse.

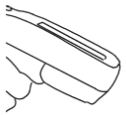
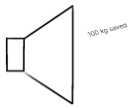
Action	 Transparency	 Traceability	 Traceability	 Reporting	 Product passport
Stakeholder involved	OEM, hospital, reprocessor, recycler	OEM	Hospital, reprocessor, recycler	OEM, hospital, reprocessor, recycler	OEM
Explanation	Clear information on materials, routing, responsibilities and condions for recycling and reuse.	Add a product or component identifier for tracking across products life cycle.	Use scanning to register handover, movement and reprocessing status.	Report collection rates, sorting quality, recovery results and incidents.	Digital product passport with material, handling and lifecycle information.
Phase	Recycle Reuse	Recycle Reuse	Recycle Reuse	Recycle Reuse	Reuse

Figure 81: Information level actions

Operational level

At the operational level, the required change develops from a simple adaptation in disposal practice to a more differentiated handling process. In phase 1, the aim is to keep the intervention as close as possible to the current workflow. For clinical staff, this means that the delivery system should be placed in a separate collection route instead of the existing waste route, with only minimal additional actions. For hospital logistics, it means organising a safe internal transport and storage flow that remains compatible with existing routines, space constraints and infection prevention requirements.

In phase 2, the operational implications become more complex. If reuse is introduced for selected parts, the workflow may require separation of components or more specific handling at the point of use or shortly afterwards. This creates additional demands on protocols, internal routing and coordination between nurses, logistics and infection prevention. The operational change therefore develops from a single, simple disposal adjustment in phase 1 to a more controlled and differentiated process in phase 2.

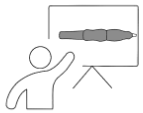
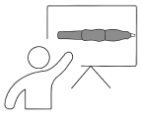
Icon	 Internal collection route	 Training for recycling	 Safe handling protocol	 Disassembly guide	 Use training	 Training for reuse	 Reprocessing guide	 Emergency stock
Stakeholder involved	Logistics	Nurses	Recycler and reprocessor	OEM	OEM	Nurses	OEM	Logistics
Explanation	Internal routing, designated bins and clear pickup points for used delivery systems.	Training on correct use, disposal and handover.	Protocols for safe transport, contamination control and exposure prevention.	Step-by-step guide for safe and correct separation of parts.	Visual role-specific training to support correct handling in practice.	Training on separating and returning the reusable part correctly.	Guidance for cleaning, inspection, sterilisation and release.	Backup stock to prevent disruption.
Phase	Recycle Reuse	Recycle	Recycle Reuse	Recycle	Recycle Reuse	Reuse	Reuse	Reuse

Figure 82: Operational level actions

Product level

At the product level, the required change develops from improving recyclability to enabling multiple circular strategies. In phase 1, product-related changes mainly aim to improve the quality of material recovery. This includes, for example, better material identification, easier separation of components where needed, and reduction of design features that hinder downstream processing. At this stage, the product does not yet need to support reuse, but it should become more compatible with safe and effective recycling.

In phase 2, the product needs to support a broader circular logic. Selected parts must then not only be recoverable, but also inspectable, separable, and suitable for reprocessing and reassembly. This requires additional design considerations such as durability, interface design, and compatibility with sterilisation and quality control procedures. The product-level change thus develops from design for recycling towards design for combined reuse and recycling.

The recycler and reprocessor need the technical capacity to process the delivery system. They need to have the right products, tools and machines.

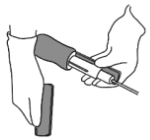
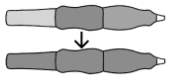
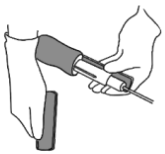
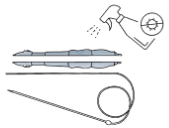
Icon	 Design for disassembly	 Design for simplification	 Design for reassembly	 Design for sterilisation	 Define wear-and-tear criteria	 Technical capacity
Stakeholder involved	OEM	OEM	OEM	OEM	OEM	Recycler and reprocessor
Explanation	Design parts so that they can be separated without damage.	Reduce material mix and unnecessary product complexity.	Design interfaces so reusable parts can be reassembled reliably.	Choose materials and interfaces that can withstand sterilisation.	Set limits for reuse based on damage, wear and performance.	Technical capacity to clean, inspect, sterilise, test, and prepare selected components after use.
Phase	Recycle Reuse	Recycle Reuse	Reuse	Reuse	Reuse	Recycle Reuse

Figure 83: Product level actions

7.11 The transition map

The transition map brings together the insights from the previous chapters. It shows how circular change depends on coordinated actios between multiple stakeholders over time. In this way, the map makes visible what needs to happen, who needs to act, when actions become relevant, and how progress in one part of the system enables progress in another.

The map is read from left to right, following the timeline of the transition. On the left side, the stakeholders are listed. Each horizontal line shows the actions of one stakeholder over time. At the top, the broader transition goals are shown. These goals indicate the main ambitions that the actions contribute to and help connect individual steps back to the overall vision.

Within each stakeholder lane, actions are placed at the moment in time they become relevant. Connections and numbers between actions show where stakeholders depend on one another, where coordination is needed, and how progress in one lane enables progress in another.

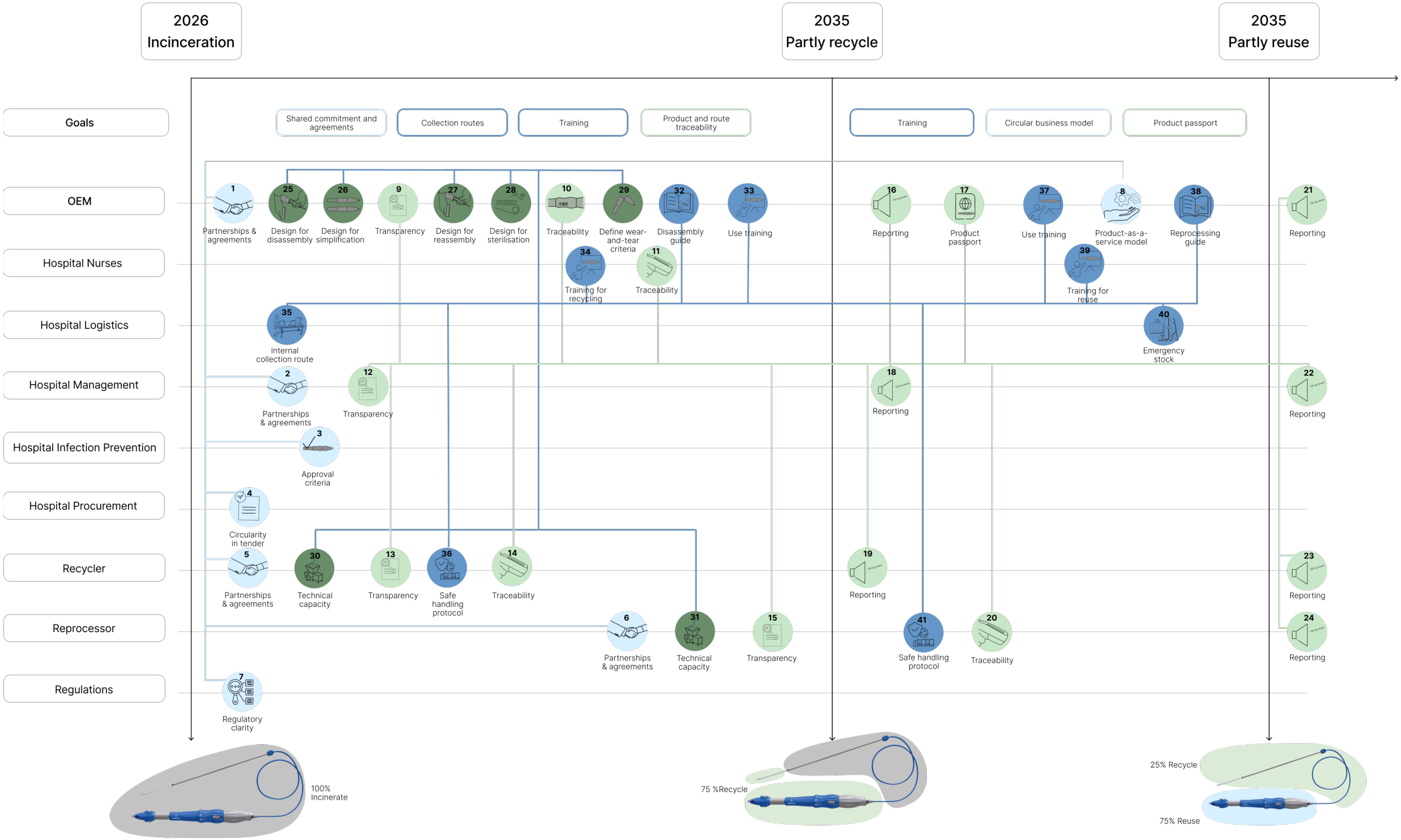


Figure 84: Transition map

7.12 Life cycle

Figure 85 shows how the TAVI delivery system moves from its current linear lifecycle towards future circular pathways.

The dark blue route represents the current lifecycle that still exists after the transition. The grey route shows the part of the current end-of-life that does not exist anymore after the transition.

The green and blue routes show the proposed recycling and reuse phases.

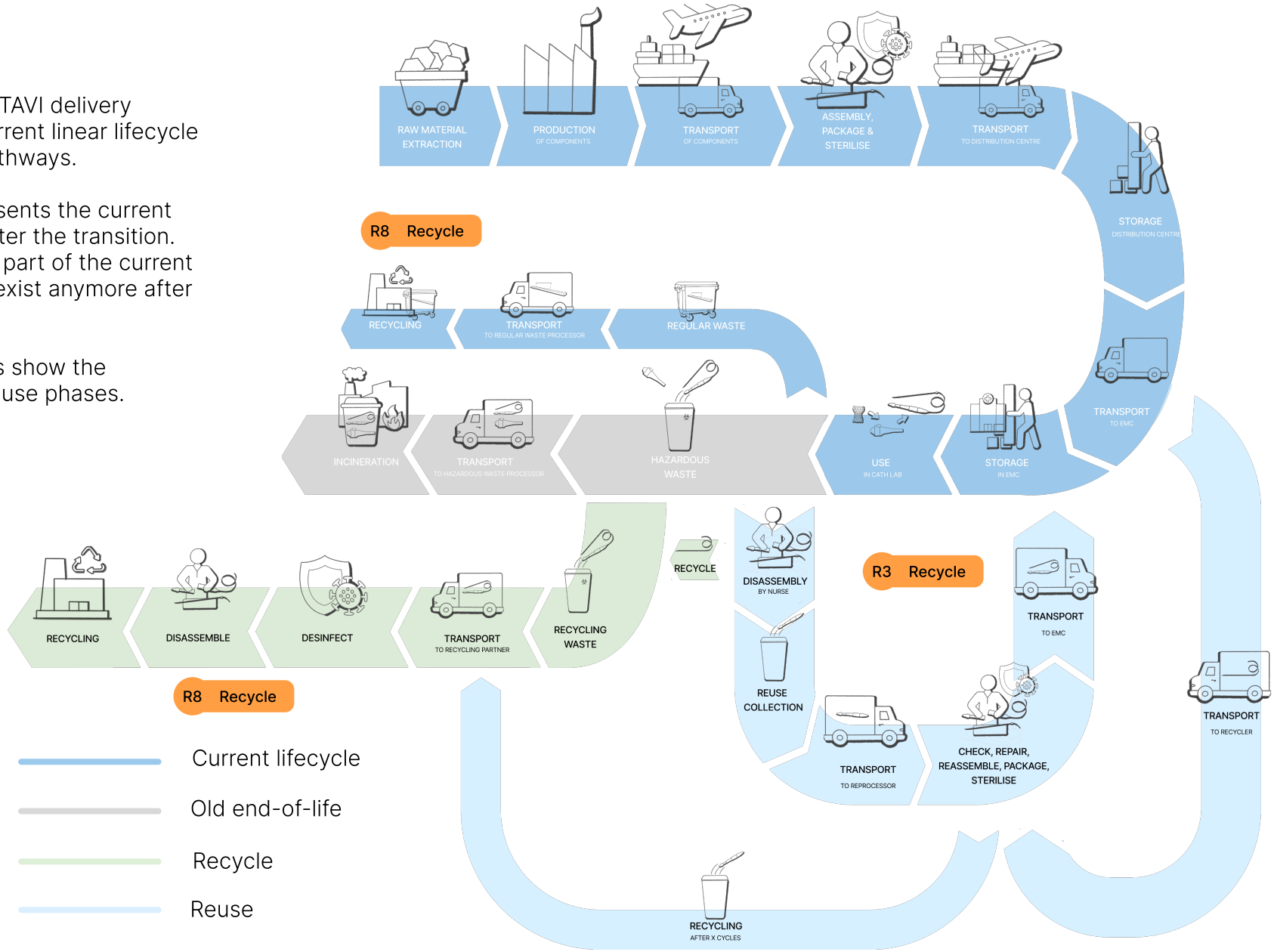


Figure 85: Levels actions

7.14 Product interventions

The delivery system needs different product changes in each phase. Also, different methods for recycling and sterilising need to be researched.

Methods to recycle

In the recycling phase, the goal is to recover value from selected parts of the delivery system through material processing. Two recycling routes are most relevant for polymers used in medical devices:

(1) Mechanical or chemical recycling

Mechanical recycling keeps the polymer as a polymer (How Does Recycling Work? - Plastics Recyclers Europe, 2025). Components are typically sorted, cleaned, shredded, and reprocessed into a new material stream. The main advantages are that it is relatively mature and usually has a lower environmental burden than chemical routes. The key limitation is sensitivity to quality: mixed polymers, coatings, fillers, adhesives, or embedded metals can quickly degrade quality and push the stream towards downcycling.

Chemical recycling breaks polymers down into smaller molecules that can be used again as feedstock (Heijnen & Vaessen, 2021). The primary advantage is its ability to process more complex or hazardous streams and potentially provide "virgin-like" feedstock. However, this usually comes with higher energy consumption and the need for industrial-scale facilities along with a stable feedstock supply.

In the short term, mechanical recycling is the most realistic route for the recoverable plastics, because it is relatively mature and generally has a lower environmental burden than chemical recycling. However, for the wires, chemical recycling is more relevant as a longer-term option. Although it is currently more energy-intensive and less accessible, future developments in chemical recycling may enable recovery of value from fractions that are not currently recyclable.

(2) Non-destructive or manual disassembly

In addition to industrial recycling methods, manual or non-destructive disassembly is also important. For most single-use medical devices, separation for recycling is destructive: the product is shredded, and separation happens afterwards. This is efficient at scale but only works well if the product has been designed to avoid material mixtures that cannot be separated.

Non-destructive or manual disassembly can achieve cleaner material streams, but it is only realistic under specific conditions: when the product has a high-value component, when there is a large, predictable volume, and when disassembly can be performed safely and quickly. In the context of a delivery system, this is especially relevant for the tip, which contains precious metals, and for the handle, which contains a larger share of high-quality plastics.

Methods to sterilise

As a class III medical device, the delivery system is categorised as “critical” under the Spaulding Classification (Nowan, N., 2023). These types of devices require sterilisation: the complete elimination of all microbial life, including highly resistant bacterial spores.

Three primary sterilisation methodologies were evaluated for compatibility with the delivery system.

Figure 86: Spaulding scale

Patient contact	Device classification	Minimum desinfection level
Intact skin	Non-critical	Low level or intermediate level desinfection
Murcous Membranes or non-intact skin	Semi-critical	High level desinfection
Sterile areas of the body, vascular system	Critical	Sterilisation

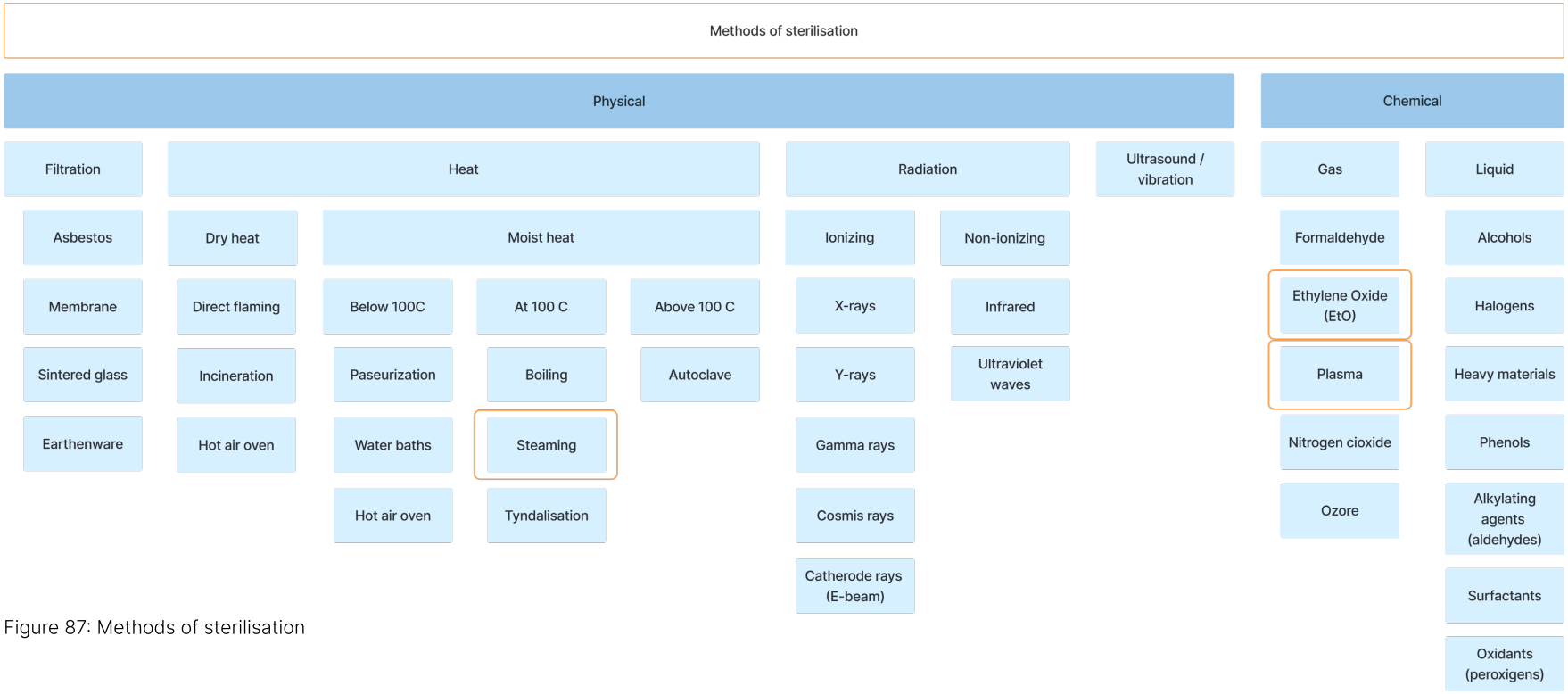


Figure 87: Methods of sterilisation

(1) Steam sterilisation (autoclave)
Steam sterilisation uses saturated steam under high pressure to destroy microorganisms. It is the global standard for hospital sterilisation due to its speed, effectiveness and safety. The design for reuse of the delivery system must change its material to allow this type of sterilisation, as only metals can withstand steam sterilisation.

(2) Ethylene Oxide (EtO)
EtO is a gas diffusion process used primarily for heat-sensitive devices. It kills microorganisms by disrupting their DNA. It is the industry standard for sterilising single-use devices during manufacturing. However, it is toxic, and due to safety regulations, most hospitals do not have EtO sterilisation on-site.

(3) Hydrogen Peroxide Glass Plasma (HGPG)
Hydrogen peroxide gas plasma is a low-temperature sterilisation method that uses hydrogen peroxide vapour to destroy microorganisms. An important advantage is that it can be used for suitable polymers and leaves non-toxic byproducts. Compared with steam sterilisation, it places less thermal stress on the product, and compared with EtO, it is more practical and safer for repeated reprocessing.

For these reasons, HPGP was selected as the most suitable sterilisation method for the redesign of the reusable handle.

Non-destructive or manual disassembly can achieve cleaner material streams, but it is only realistic under specific conditions: when the product has a high-value component, when there is a large, predictable volume, and when disassembly can be performed safely and quickly. In the context of a delivery system, this is especially relevant for the tip, which contains precious metals, and for the handle, which contains a larger share of high-quality plastics.



Figure 88: Tray with sterile wrap

Material suggestions

Transitioning to a reusable handle with HGPG sterilisation requires new materials for the handle. The current material, ABS, is chemically incompatible with this sterilisation method. It causes the material to suffer from environmental stress cracking and degradation over time.

To achieve the durability for reuse, the handle must be made of other high-performance medical-grade polymers. Three industry-standard materials were selected for evaluation.

- Polyphenylsulfone (PPSU): Widely considered the gold standard for reusable medical devices. The material is tough, highly resistant to chemical oxidation by glass plasma, and can withstand severe physical impacts.
- Polyetheretherketone (PEEK): This is an ultra-high-performance polymer often used as a replacement for metal. It is highly chemically inert and offers high precision for internal mechanical parts.
- Polyetherimide (PEI): Like PPSU, PEI offers massive strength and excellent resistance to the HPGP environment. It is widely used in reusable surgical instruments and sterilisation trays.

To determine which material has the lowest environmental impact, a comparative LCA was done. An important variable in this LCA is the environmental impact of HGPG sterilisation. A recent life cycle assessment (Pan et al., 2025) evaluated the environmental impacts of reusable medical devices and modelled the exact footprint of low-temperature plasma sterilisation: 0.70 kg CO_2e per individual sterilisation cycle.

The LCA results (Figure 89) map the environmental impact of handle reuse from 1 to 100 cycles.

For single use, the carbon footprint of PEEK is very high (36 kg CO_2e). This is because PEEL is produced through a highly complex chemical synthesis that requires extreme temperatures and aggressive solvents. PPSU and PEI have a much lower footprint (2.5 - 3.0 kg CO_2e). As the handle is reused, the environmental impact will be lower relatively.

To conclude, selecting PPSU or PEU for the redesign is advised, as these materials have a lower environmental impact than PEEK.

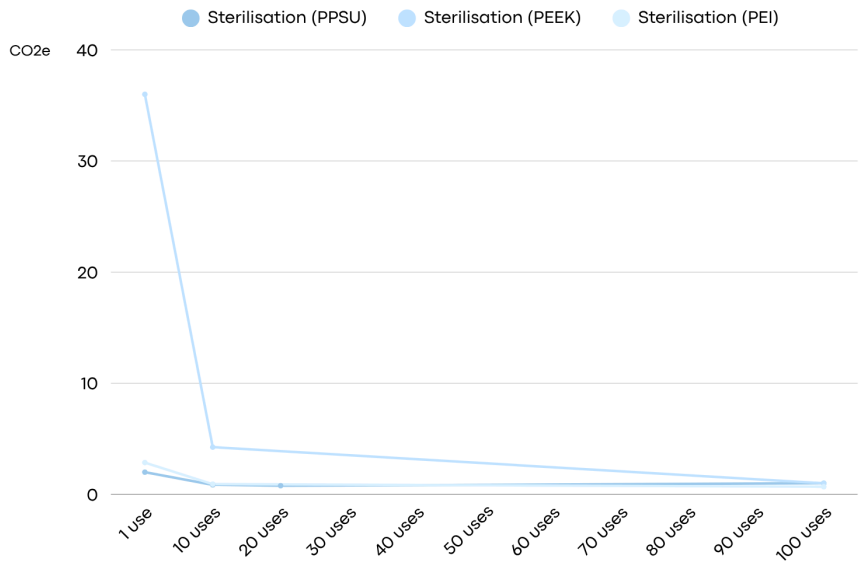


Figure 89: Materials LCA

Product redesign suggestions

The framework by Van den Berg & Bakker (2016) identifies design strategies that support recycling and reuse. This framework serves as a checklist to identify the product changes the OEM would need to make.

Disassembly Allow to service, remake and recycle	Connections	Quick and easy disconnect Limit use and diversity of fasteners Limit use and diversity tools
	Product architecture	Simplify product architecture Allow ease of acces to components Clarity of disassembly sequence
Maintenance Reuse of products	Maintenance	Ease of cleaning Ease of repair / upgrade Allow onsite repair and upgrade
	Lifetime prognotics	Online monitoring for quality, testing, maintenance and billing
Remake Reuse of parts	Modularity	Use modular components Standardize interfaces Back - & Forwards compatability
	Reliability assessment	Allow for easy read out of components
	(Reverse) Logistics	Product can easily be returned Spare part harvesting Local production
Recycle Reuse of materials	Materials	Avoid the use of (non-compliant) coatings Limit the number of different materials Only use materials that can be recycled Use preferred / pure materials
	Connections	Avoid fixed connections Break down by (shredding / disassembly) to Pieces of uniform composition Pieces of relatively large size (> 1 cm)

Figure 90: Product redesign suggestions

08

Evaluation

To assess if the transition is worth pursuing, it is reflected across three dimensions: viability, feasibility and desirability.

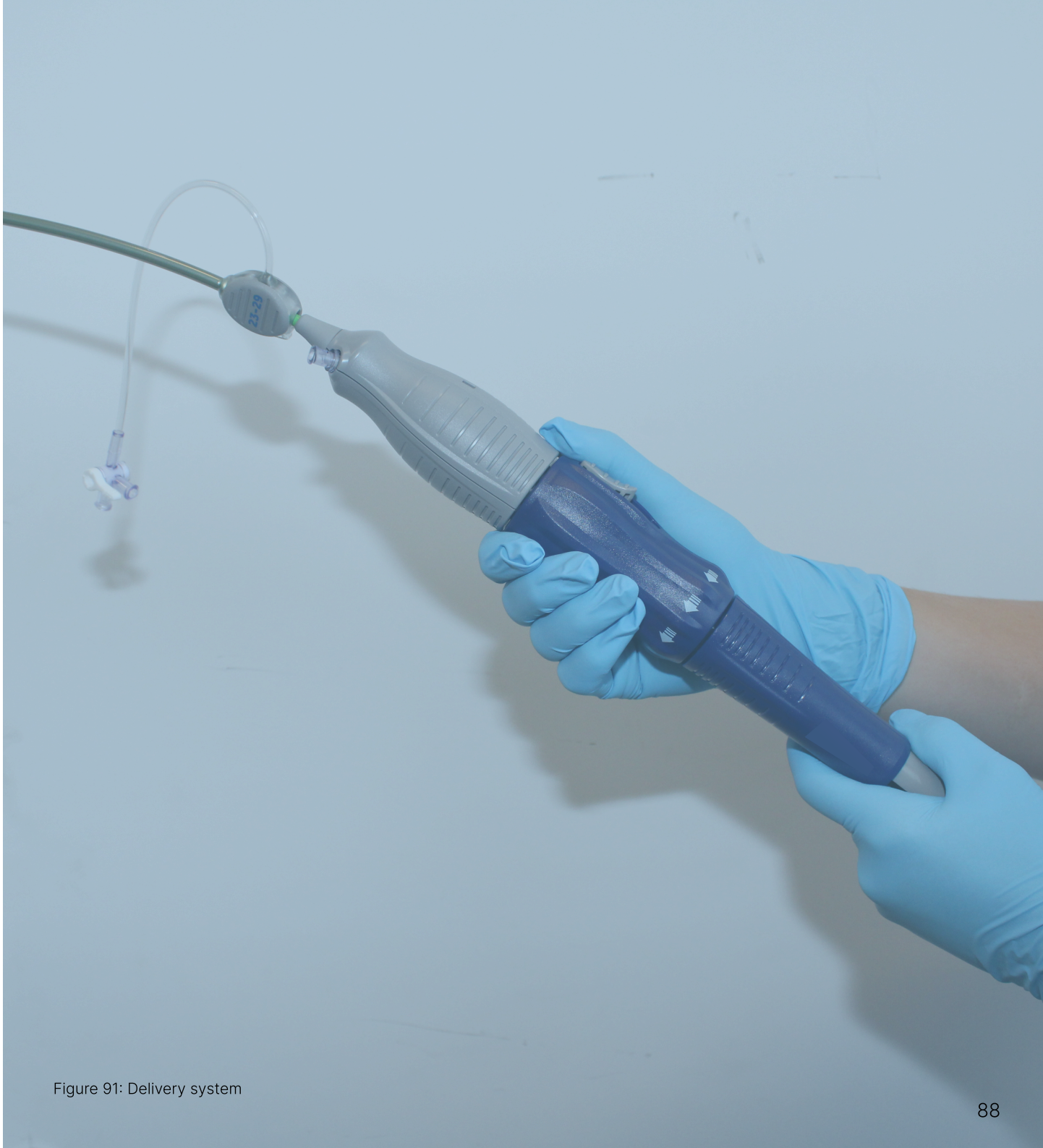


Figure 91: Delivery system

8.1 Desirability

The transition towards a more circular TAVI delivery system is desirable from both social and environmental perspectives.

From a social perspective, the phased pathway is desirable because it introduces change gradually rather than all at once. In phase 1, the main change for clinical staff is that the delivery system is disposed of via a recycling route rather than the hazardous waste stream. Because this step stays relatively close to the current Cath lab workflow, it is more likely to be accepted in practice. This is valuable not only because it supports recycling but also because it allows staff to experience that a sustainability-related change can still be safe, controlled, and workable in a clinical setting, and, with that, create the basis for the second phase.

From an environmental perspective, the transition is also desirable because both recycling and reuse reduce value loss. To assess this, two LCAs were conducted: one comparing recycling with the current incineration of the single-use delivery system, and another comparing reuse with the current single-use situation.

According to Immè et al. (2017), the CO_2e impact of hospital incineration of contaminated products is approximately 1 kg CO_2e per kg of waste. In the current system, incineration accounts for about 16% of the delivery system's total environmental impact. When the handle is recycled instead, this contribution decreases to approximately 8%. This indicates that partial recycling already reduces environmental impact compared with the current route.

For reuse, the comparison focused on the handle and compared the sterilisation of new reusable materials with repeated incineration of the current ABS handle. As shown in Figure 89, the cumulative impact of incineration exceeds that of the reusable alternative after approximately 10 use cycles. This indicates that reuse has the potential to retain even more value and further reduce environmental impact, provided that sufficient cycles can be achieved in practice.

The combination of these findings show that the transition is desirable because it can reduce waste, lower environmental impact, and support a gradual shift.

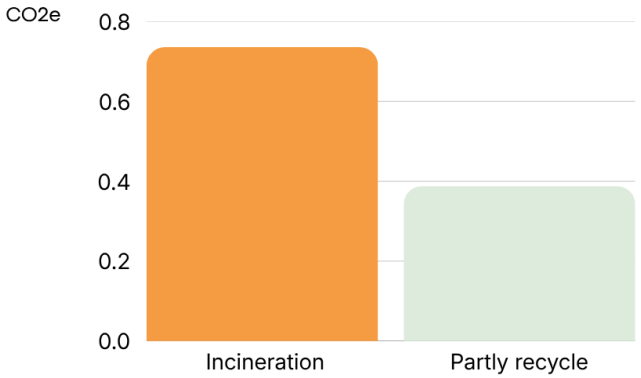


Figure 92: CO2e incineration and recycle

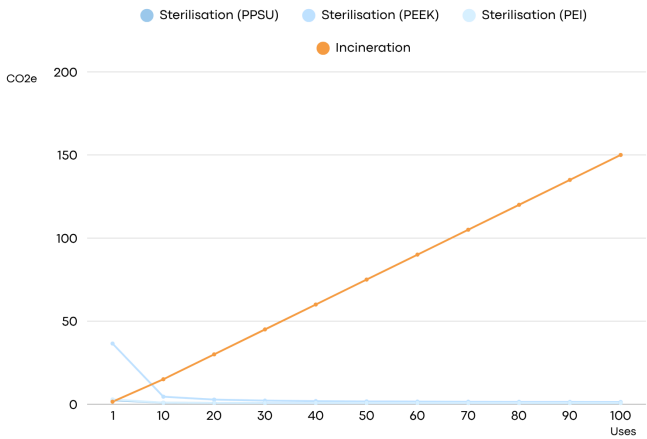


Figure 93: Comparison reuse and incineration

8.2 Feasibility

The transition is not immediately feasible in full, but the phased structure makes it significantly more workable in practice.

Phase 1 is relatively feasible because it remains close to the current Cath lab routine and is something they are already familiar with, since medical device collection for recycling is already done. The main practical change is that the delivery system is discarded in a recycling bin instead of the hazardous waste bin.

Phase 2 is more demanding. Reuse introduces a greater socio-technical shift because it requires additional handling steps, stronger behaviour change, and higher levels of trust. In many clinical environments, single-use is strongly associated with safety, whereas reuse is associated with risk. This means that even when reuse is technically validated, implementation still depends on whether clinicians trust that sterility, quality, and responsibility are fully guaranteed.

Reuse also places greater demands on workflow and training. The reusable component must be separated correctly after use and directed into the appropriate stream. Clinicians must also be trained in how to safely prepare and use the partly reusable delivery system, including checks to ensure the device is complete and intact. These activities require time and attention in a setting that is already highly time-sensitive.

In addition, reuse is subject to stricter technical and regulatory requirements. It depends on redesign for durability and reprocessing, validated cleaning and sterilisation procedures, wear-and-tear criteria, traceability across use cycles, and clear agreements on responsibilities and liability. This makes reuse less feasible in the short term, but completely infeasible.

The phased structure is therefore important. Because stakeholders first gain experience with a simpler recycling route, the move towards reuse becomes less abrupt. Overall, the findings suggest that the transition is feasible when approached gradually, with phase 1 building the practical and organisational foundation for phase 2.

8.3 Viability

The viability of the transition depends on both short-term value recovery and long-term business model alignment.

In phase 1, the economic case is driven mainly by two elements: material value recovery and waste disposal cost reduction. These figures are indicative and depend on factors such as market prices and operational conditions.

The tip of the delivery system contains a radiopaque marker band, often composed of 90% platinum and 10% iridium (Trento, 2025). Because these are precious metals that can be recycled repeatedly, their recovery is estimated at approximately €4.00 per delivery system.

The handle, which is largely made of ABS, also contains recoverable value. Recycled high-quality medical-grade ABS granulate typically trades around €1.00 per kg. This would correspond to approximately €0.20 of recovered value per delivery system.

Taken together, this indicates a material recovery value of around €4.20 per delivery system.

Although this recovery value is limited at the level of a single delivery system, it becomes more meaningful when scaled across larger volumes. In that sense, phase 1 is unlikely to be economically attractive through material recovery alone at small scale, but it may become more relevant when combined with waste disposal savings and broader implementation across many procedures and hospitals.

In addition to material recovery, it also reduces disposal costs. In the current situation, the hazardous waste bin used during a TAVI procedure weighs approximately 9 kg, resulting in an estimated disposal cost of €10 per procedure, including incineration, transport, and bin costs.

For phase 2, the economic picture becomes more complex. Reuse retains more value than recycling, but it also requires greater investment. For the OEM, partial reuse would require R&D for redesign, durability, and reprocessing compatibility. It may also reduce unit sales under a traditional sell-per-device model. In addition, reuse shifts more responsibility towards the OEM.

A service-based model may help to address this. Under a per-procedure fee, the hospital pays for performance and availability rather than for a single physical unit, while the OEM retains responsibility for lifecycle quality and system governance. Such a model could make reuse economically viable, but it would also shift risk towards the OEM, who would need to manage reprocessing costs, logistics reliability, and quality deviations within the service agreement.

Overall, phase 1 appears viable as a first step because it combines modest material recovery with potential savings in disposal costs. At the same time, according to the OEM, recycling only becomes profitable for the OEM when around 100,000 delivery systems are returned. This means that the route cannot rely on a single hospital but requires participation from a much wider network of hospitals. Viability, therefore, depends not only on the value of the recovered materials but also on the ability to build a sufficiently large and stable return system.

Phase 2 has the potential to retain more value in the long term, but its viability depends on whether the additional system costs and risks can be managed through an appropriate business model and stable operational performance.

09

Booklet

In addition to the report, the outcomes of this project were translated into a booklet. It serves as a communication tool to support discussion on the circular transition of the TAVI delivery system for stakeholders.



Figure 94: Booklet

9.1 The booklet as communication tool

To communicate the outcomes of this project in a way that is accessible to different stakeholders, a booklet was developed alongside the report.

The booklet was designed to guide stakeholders from problem to action. It aims to help stakeholders see where the transition is heading, what is needed to get there, and how different actions can contribute over time. In that way, it offers both a direction to the future and a starting point for action in the present.



Figure 95: Few pages of the booklet



Figure 96: Waste audit

10

Conclusion

This chapter concludes the thesis by reflecting on the main findings and their implications. It discusses the most important insights and limitations of the project, answers the research questions, and translates the results into recommendations for future action.

10.1 Discussion

An important finding of this project is that **recycling is not the highest-value circular strategy,** but it can serve as a realistic intermediate step. From a value-retention perspective, reuse is preferable because it preserves more of the value embedded in the product during design, manufacturing, and assembly. However, under current hospital conditions, a direct shift to reuse is not yet realistic. Recycling is therefore relevant not because it is the most ambitious solution, but because it offers a feasible first move away from the current linear model. At the same time, it is important that the transition does not stop there. If recycling becomes the final endpoint, much of the delivery system's higher circular potential remains unaddressed. Its value lies partly in recovery and partly in its role as a stepping stone towards more advanced circular strategies later on.

A second discussion point concerns the organisation of infrastructure. From the hospital perspective, **shared infrastructure across OEMs** is likely to be more realistic than separate, brand-specific systems. Hospitals already face limitations in bin space, storage, and internal logistics, making it difficult to accommodate parallel return routes for each manufacturer. A shared system would therefore fit daily practice more closely. However, this creates tension with OEM interests in competition, control, traceability, and liability.

Manufacturers may be reluctant to lose oversight of their own products and materials once these enter a shared collection or processing system. This suggests that a future circular model may need to combine shared operational infrastructure with brand-specific accountability and traceability. In the longer term, this could even point towards greater standardisation, for example, a shared handle architecture with OEM-specific wire systems or valve types. Although this remains speculative, it highlights that circularity may eventually require not only product redesign, but also a different way of organising ownership and responsibility across the chain.

A third point is that the proposed **reuse phase remains conditional on future developments**. The pathway outlined in this project indicates that reuse may be possible for selected components, but only when key enabling conditions have matured. These include clearer regulation, sterilisation methods, stronger traceability systems, and the practical availability of reprocessing capacity. This means that the reuse phase should be understood as a future-oriented direction rather than an immediately implementable solution. Its inclusion in the pathway is important because it provides a long-term design and system development.

Finally, the findings should be interpreted in light of the **scope of the project**. This study is based on a single case and a single hospital context and, therefore, does not provide a universal blueprint for all single-use medical devices. The TAVI delivery system has specific characteristics regarding product design, contamination profile, clinical use, and stakeholder context. At the same time, the case does offer broader insight into how circularity in healthcare may need to be approached: not as a single technical fix, but as a gradual transition in which product, system, and stakeholder conditions must develop together.

10.2 Conclusion

This thesis set out to develop a transition pathway to move the TAVI delivery system from a linear model towards a more circular one, while maintaining clinical safety and compatibility with hospital practice.

The main conclusion is that such a transition is possible, but not through a direct shift to reuse. Under current conditions, reuse is not yet realistic. Instead, the most feasible pathway is a phased transition that starts with partial recycling and gradually moves towards partial reuse once the required system conditions are in place.

This answers the main research question: **How can the single-use TAVI products be transitioned towards more circular end-of-life strategies while maintaining clinical safety and compatibility with the hospital environment?**

Sub question 1: How is the TAVI delivery system currently used, handled, and disposed of within the hospital context of Erasmus MC?
The study showed that the delivery system is used in a highly specialised, safety-critical, and time-sensitive Cath lab environment. Within this context, the current end-of-life route is largely linear and shaped by workflow pressure, contamination concerns, and existing waste routines. Circular alternatives are therefore only viable when they fit smoothly into hospital practice.

Sub question 2: Which system-level characteristics create the main opportunities and barriers for more circular strategies for the TAVI products?
The system analysis identified several barriers to circularity, including time pressure, limited space, dominant waste routines, fragmented responsibilities, and procurement and contract structures that are not yet aligned with circular ambitions. These findings show that circularity is constrained by the interaction of multiple organisational and systemic conditions.

Sub question 3: Which product-level characteristics create the main opportunities and barriers for more circular strategies for the TAVI products?
Regarding the third sub-question, the product analysis showed that the delivery system is the primary focus of the circular intervention. The handle is most relevant because it accounts for the largest share of the material mass and is made primarily of high-quality medical-grade plastics.

The tip is important because it contains platinum-iridium, while the wire is less suitable for near-term circular strategies due to its complex construction.

Sub question 4: What transition pathway could enable the TAVI products to move from its current linear model towards feasible circular strategies in practice?
Regarding the fourth sub-question, the study showed that the most realistic transition pathway is gradual. In the short term, this begins with partial recycling of the handle and other valuable fractions, as this requires relatively little change and aligns more closely with current hospital practice. In the longer term, this pathway can develop towards partial reuse of selected components, but only once redesign for reprocessing, clear responsibilities, traceability, partner agreements, and validated operational procedures are in place.

Taken together, these findings show that the most realistic outcome is a phased transition pathway. In phase 1, partial recycling creates a first step away from the current linear model. In phase 2, partial reuse of selected components becomes possible once stronger system maturity has been achieved. The strength of this pathway lies in its realism: rather than aiming for full circularity at once, it proposes a route that fits current healthcare constraints while still building towards a more ambitious circular future.

10.3 Recommendations

Based on the findings of this thesis, several recommendations can be made for moving the TAVI delivery system from a linear model towards more feasible circular strategies in practice.

A first recommendation is to **start with a pilot** for partial recycling in the hospital context. Rather than aiming for a broad circular system immediately, the first step should be to test a limited and feasible intervention in practice. Such a pilot can help evaluate whether separate collection, handling, and return can be embedded in the Cath lab workflow without compromising safety or creating excessive operational burden.

A second recommendation is to **develop the supporting system around phase 1 before attempting to scale it**. Partial recycling will only become stable when supporting conditions are in place, such as clear responsibilities, practical collection routes, agreements with partners, and monitoring of outcomes. This means that phase 1 should be seen not only as a waste intervention but also as a system-building phase in which the foundations for future circularity are laid.

In addition, it is recommended to **explore service-based models** for the longer term. A more circular system may require the OEM to take greater lifecycle responsibility through take-back systems, product tracking, and possibly service-based agreements, rather than relying on one-time product sales alone. Although such models are unlikely to be implemented immediately, they are worth exploring because they may better align value retention with responsibility across the chain.

Stakeholders must also **jointly determine which actions are most urgent, which should happen first, and which require the most attention** in the next stage of the transition. Although the roadmap shows how actions connect across the system and over time, prioritisation is needed to decide where limited time, resources, and coordination effort should be focused first. Such prioritisation should be done collectively, since different stakeholders will value urgency and feasibility differently.

Finally, **stakeholders should begin by coming together in small, cross-functional teams to discuss the transition and its implications for practice.** Because the transition depends on interconnected changes across multiple levels, it is important that actors do not pursue isolated actions. Early conversations in small teams can help clarify priorities, surface concerns, identify dependencies, and build a shared understanding of what needs to be done first. This can serve as a practical starting point for translating the transition pathway into coordinated action.The booklet which was developed during this thesis helps translating transitions amongst stakeholders

10.4 Personal reflection

This graduation project introduced me to a new way of working. As a product designer, I was used to focusing mainly on the product itself, while in this project I also learned to analyse the wider system around it. Looking at stakeholders, regulations, workflows, and organisational structures was both challenging and interesting. It pushed me to move beyond the product and understand how design decisions are shaped by the larger context in which a product is used.

Through this, I learned a lot about collaborating with stakeholders, communicating with different types of actors and organising co-creations. I found that each stakeholder views the transition from a different perspective, with their own priorities, concerns, and language. This meant I had to adapt how I asked questions, presented ideas, and translated insights. I learned that designing for change is not only about creating a good solution, but also about building understanding and alignment between the people involved.

Overall, this project helped me grow from a more product-focused designer to one who is better able to connect product thinking with systems thinking. It showed me that meaningful design, especially in complex contexts such as healthcare, requires both technical understanding and the ability to work across disciplines and stakeholder perspectives.



Figure 93: Delivery system

11

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12

Appendix

1. Project brief
2. Stakeholder analysis
3. Trend analysis
4. Detailed product journey
5. LCA
6. Co-creation
7. Clustering
8. Design directions
9. Shaping the transition
10. MoSCoW
11. Comparative LCA

12.1 Project brief

Project title Redesigning the Evolut device used in the TAVI procedure for a circular hospital.

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)

In the Netherlands, the healthcare sector is responsible for approximately 7% of national CO2 emissions (Steenmeijer et al., 2022), as well as 4% of all waste and 13% of raw material usage including metals and minerals (Krens, 2024). This paradox: where the sector dedicated to health also impacts the health, underscores the urgency of sustainable interventions. At Erasmus MC, sustainability is a priority. They signed the Green Deal Duurzame Zorg 3.0 in 2022. It's a collaboration facilitated by the Dutch Ministry of Health, Welfare and Sport and supported by over 200 partners. The Green Deal wants to be climate neutral and 100% circular in 2050 (Green Deal Duurzame Zorg 3.0, n.d.).

Transcatheter Aortic Valve Implantation (TAVI) is a minimally invasive procedure used to replace the aortic valve with an organic alternative, offering patients a less disruptive treatment option. Over the last 5 years there have been 14000 procedures in the Netherlands (Versteeg et al., 2024).

This graduation project will be executed as part of the ESCH-R consortium. The focus lies on the TAVI procedures' single-use-plastic tools with a main focus on the Evolut device. The Evolut device is a delivery system used in the TAVI procedure to position and implant the replacement aortic valve inside the heart (Steblovnik & Bunc, 2022). Due to the size and the sharpness of the Evolut, it cannot go through standard recycling streams. Instead it ends up in the contaminated waste bins and is incinerated at high temperatures. This method is costly for hospitals and harmful for the environment (Janik-Karpinska et al., 2023).
The main stakeholders in this project include hospitals, patients, medical device manufacturers such as Medtronic, medical waste collectors such as Zavin, nurses, and interventional cardiologists.

This project will trace the lifecycle of the Evolut within Erasmus MC, identifying opportunities for a circular redesign.

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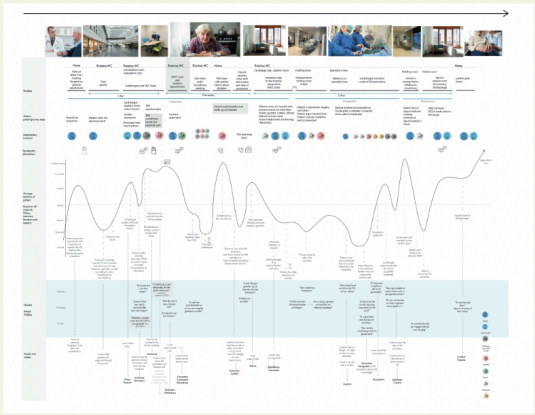
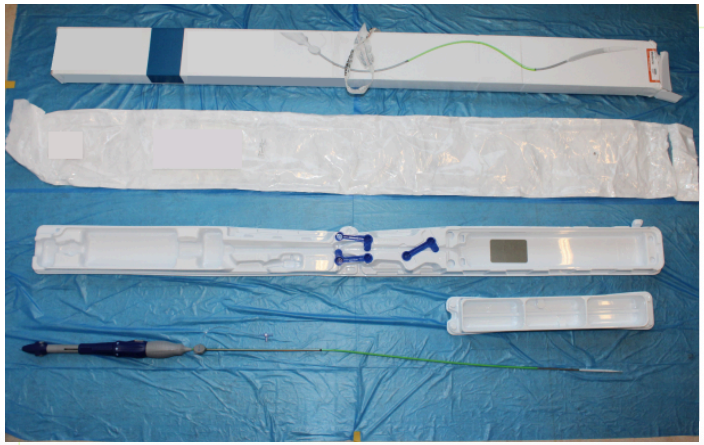


image / figure 1 TAVI patient journey (Bedaux, 2022)



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)

While the TAVI procedure is clinically effective, the product is not circular. It is made from good quality plastic, but only used once as it cannot be recycled due to its sharpness and size.

There is limited information of the material flows and environmental impact of the Evolut device. A patient journey has already been made of the TAVI procedure (Bedaux, 2022), but the detailed process steps of the TAVI procedure and the material composition of the Evolut is not yet mapped. This lack of knowledge can prevent good sustainable interventions of the device.

The graduation project will address this gap by mapping the TAVI procedure in detail and dismantling the Evolut to analyse its materials and mechanisms. These methods will help identify environmental hotspots and opportunities for new interventions.

Making the device circular will lower the hospital's environmental impact and may help as an example for redesigning other single-use devices into reusable solutions.

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:

Identify hotspots in the TAVI procedure through a product journey map, material flow, and disassembly map, and redesigning the Evolut to adress one hotspot for circularity at Erasmus MC.

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)

This project will follow the Triple Diamond approach. In the first diamond, the focus is on research to get a good understanding of the TAVI procedure and its clinical context. The Evolut device will be benchmarked against the same device from other brands, and dismantling will be done to examine the materials and mechanisms. In addition, a product journey map will be developed to visualize the step-by-step process. These methods will highlight environmental hotspots, after which one priority hotspot will be defined to improve during the rest of the project.

The second diamond involves ideation and concept generation based on the selected hotspot. Multiple ideas will be developed and tested in low-fidelity prototypes. The diamond closes with the selection of the most promising scenario.

The third diamond focuses on improving the selected concept and developing it into a prototype. Evaluating will be done in colaboration with stakeholders while also assessing the potential environmental benefits.

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)

The idea that design can contribute to a meaningful change has always been an important driver in my work. Combined with a childhood dream of working in a hospital environment, makes this project the ideal graduation challenge for me.

The importance of sustainability is ever-growing, and the healthsector is a key contributor to global emissions and waste. I am motivated to explore how sustainable interventions can be integrated into highly regulated medical contexts without compromising safety or quality of care.

During my master's studies, I have followed several electives related to medical design, sich as Designing for Emerging Markets, Biomechanics, and E-Health for Design. These courses have strengthened my knowledge of designing within medical contexts and prepared me to take on this challenge.

Through this graduation project, I want to further develop my skills in prototyping, visualising and doing accurate research.

12.2 Stakeholder analysis

Stakeholder groups
Inside the Cath lab
These stakeholders interact most directly with the delivery system during the procedure and therefore strongly influence day-to-day handling and disposal behaviour:

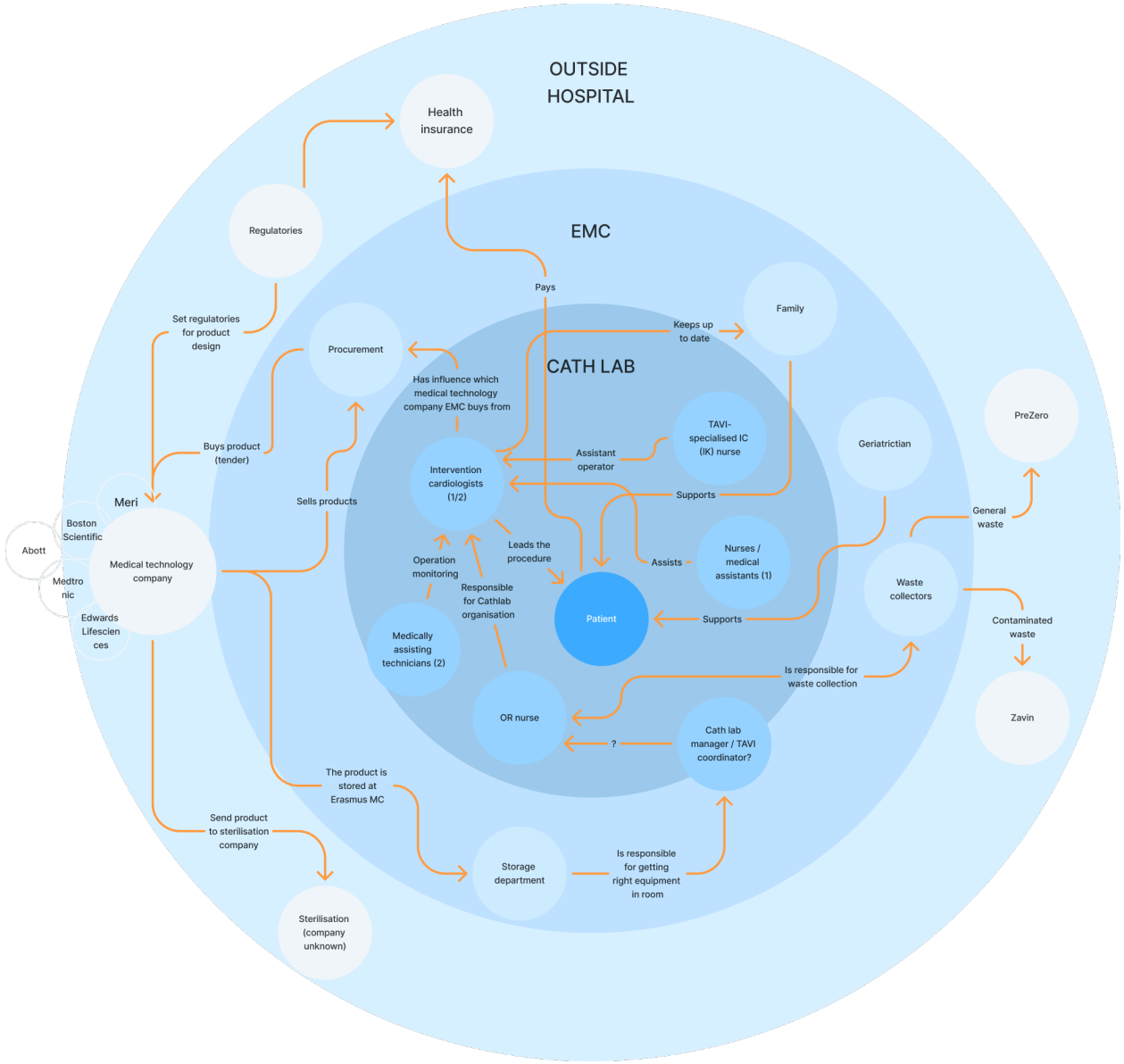
- Interventional cardiologists (2): primary users of the delivery system; responsible for procedural performance and patient outcome.
- Sterile TAVI nurse: prepares and hands over sterile materials; key for preparation steps and correct handling of components.
- TAVI/circulating nurse: supports the procedure, retrieves additional supplies, and often plays a role in post-procedure disposal steps.
- Technicians (2): support imaging/ measurements and equipment; influence workflow constraints in the room.
- Patient: indirectly represented in the system, but central from an ethical and safety perspective.
- Cleaners: interact with waste streams and room reset; affected by waste separation and safety protocols.

Within Erasmus MC (outside the Cath lab)
These stakeholders typically do not use the product, but they enable the procedure and determine how materials, waste, and responsibilities flow through the hospital:

- Cath lab managers: responsible for departmental operations, staffing, and implementation of new routines.
- Storage department: manages ordering, storage, and distribution of sterile supplies; relevant for stock levels and packaging handling.
- Logistics: transports materials and waste internally and manages collection points; crucial for any separate collection stream.
- Infection prevention: defines infection-control requirements and evaluates proposed changes that may affect contamination risk.
- Procurement: sets tender criteria, evaluates suppliers, and can formalise sustainability requirements in purchasing decisions.
- Hospital finance: influences business cases, budgeting, and the feasibility of investments (e.g., bins, storage capacity, sterilisation capacity, service models).

Outside Erasmus MC
These stakeholders determine external constraints and enabling conditions, such as legal waste classification, processing capacity, and market structures:

- Government: shape what is permitted in terms of waste handling, recycling/reuse of medical device components, and compliance requirements.
- OEMS: design and manufacture the device and packaging, define material choices, and can enable transparency and design-for-disassembly.
- Central Sterile Services Department (CSSD/CSA): relevant for any reuse scenario requiring validated cleaning and sterilisation workflows.
- Waste collector (e.g., PreZero): manages collection and transport of specific waste fractions; key partner for separate streams.
- Incineration facility (e.g., Zavin): current end-of-life route for hazardous waste; relevant as the “default” path that circular options must compete with.


OUTSIDE HOSPITAL
Health insurance
Regulatories
EMC
Pays
Set regulatories for product design
Procurement
Keeps up to date
Family
CATH LAB
Has influence which medical technology company EMC buys from
Buys product (tender)
Intervention cardiologists (1/2)
Assistant operator
TAVI-specialised IC (IK) nurse
Geriatrician
PreZero
Supports
Meri
Sells products
Boston Scientific
Abott
Medtronic
Edwards Lifesciences
Medical technology company
Operation monitoring
Leads the procedure
Assists
Nurses / medical assistants (1)
General waste
Responsible for Cathlab organisation
Patient
Waste collectors
Supports
Contaminated waste
Medically assisting technicians (2)
Is responsible for waste collection
OR nurse
Zavin
?
Cath lab manager / TAVI coordinator?
The product is stored at Erasmus MC
Send product to sterilisation company
Storage department
Is responsible for getting right equipment in room
Sterilisation (company unknown)

12.3 Trend analysis

2026 - 2035

Society

- Climate & health awareness grows: patient and staff know that healthcare itself causes 4-7% of national emissions and demand greener care options (Or & Seppänen, 2024)
- Dutch Green Deal Sustainable Care 3.0 makes sustainability part of professional responsibility and hospital culture (Green Deal Duurzame Zorg 3.0, n.d.)

Economy

- Rising costs of energy and raw materials increase pressure to reduce material use and waste in healthcare (Sepetis et al., 2022).
- Dutch/European hospitals face tighter sustainability targets and start including total cost of ownership and CO_2 impact in tenders, not just purchase price (Green Deal Duurzame Zorg 3.0, n.d.) .

Regulatory

- New EU Packaging Regulation applies, tightening rules on packaging waste and recyclability for medical devices (Beghetto et al., 2023)..

Technology

- Standardisation for products om healthcare (GE Healthcare, 2022)
- New low-temperature sterilisation and disinfection technologies (e.g. advanced H_2O_2/plasma, UV-C systems) are adopted more widely, enabling reuse of sensitive plastics and electronics (Sim et al., 2022).
- Smart inventory and tracking systems (RFID/IoT) monitor device flows and can track cycles of reusable components. (Tan & Sidhu, 2022)

Environment

- Climate crisis already impacts health: more heatwaves, air-pollution-related disease, and climate-sensitive infections; healthcare systems see both higher demand and pressure to decarbonise (Schaeffer et al., 2025).
- Dutch healthcare sector emits ~7% of national greenhouse gases; national and hospital strategies target reduced emissions, less waste and more circularity (Green Deal Duurzame Zorg 3.0).

2035 - 2045

Society

- Sustainability becomes a quality dimension: hospitals publish environmental performance alongside safety and waiting times (Dolcini et al., 2025)
- Younger clinicians are trained with circular care as “normal practice”, increasing openness to reusable devices. (Green Deal Duurzame Zorg 3.0, n.d.)

Economy

- Carbon pricing and waste taxes make high-temperature incineration significantly more expensive than recycling / reuse, improving business cases for circular delivery systems (Voss et al., 2021).
- Service and subscription models (product-as-a-service) for devices are widespread in MedTech, shifting value from selling units to selling performance (Royer, 2019).
- Companies who are more focussed on sustainability have competative advantage (Huang, 2021)

12.3 Trend analysis

Regulatory
- Product-specific ESPR measures and Digital Product Passports are extended to more medical device categories, requiring detailed material and repair/ reuse information for each device (Royer, 2019). .
- EU Waste Framework rules and end-of-waste criteria clarify when recycled plastics from medical streams are again “materials”, enabling cross-border trade in recyclate (European Comission, 2024) .

Technology
- Digital Product Passports store detailed material, repair and sterilisation data for each device; recyclers and hospitals can scan a handle to see how to disassemble and how many cycles it has left (WHO, 2024).
- Automation and robotics assist in disassembling complex devices and sorting medical plastics, making high-quality recycling of delivery-system components more feasible (projection from current automation trends in waste management) (Wah, 2025).

Environment
- More frequent climate-related disruptions (floods, heat, supply chain shocks) make resilient, resource-efficient systems crucial (Banholzer et al., 2014)

2050

Society
- Society expects high-risk procedures to be circular by default; single-use without circular plan is seen as outdated and ethically problematic (Royer, 2019).
- Healthcare shifts from reactive to preventive treatment (Waldman & Terzic, 2018)

Economy
- Mature markets for high-quality recycled plastics and metals, supported by EU-wide end-of-waste criteria for plastics, stabilise revenue from recovered materials (Beghetto et al., 2023).

Regulatory
- EU and national policies align: devices without a credible circular pathway (recycle / reuse / remanufacture) are increasingly restricted or not reimbursed in high-income health systems (inference from tightening climate targets and circular-economy law).

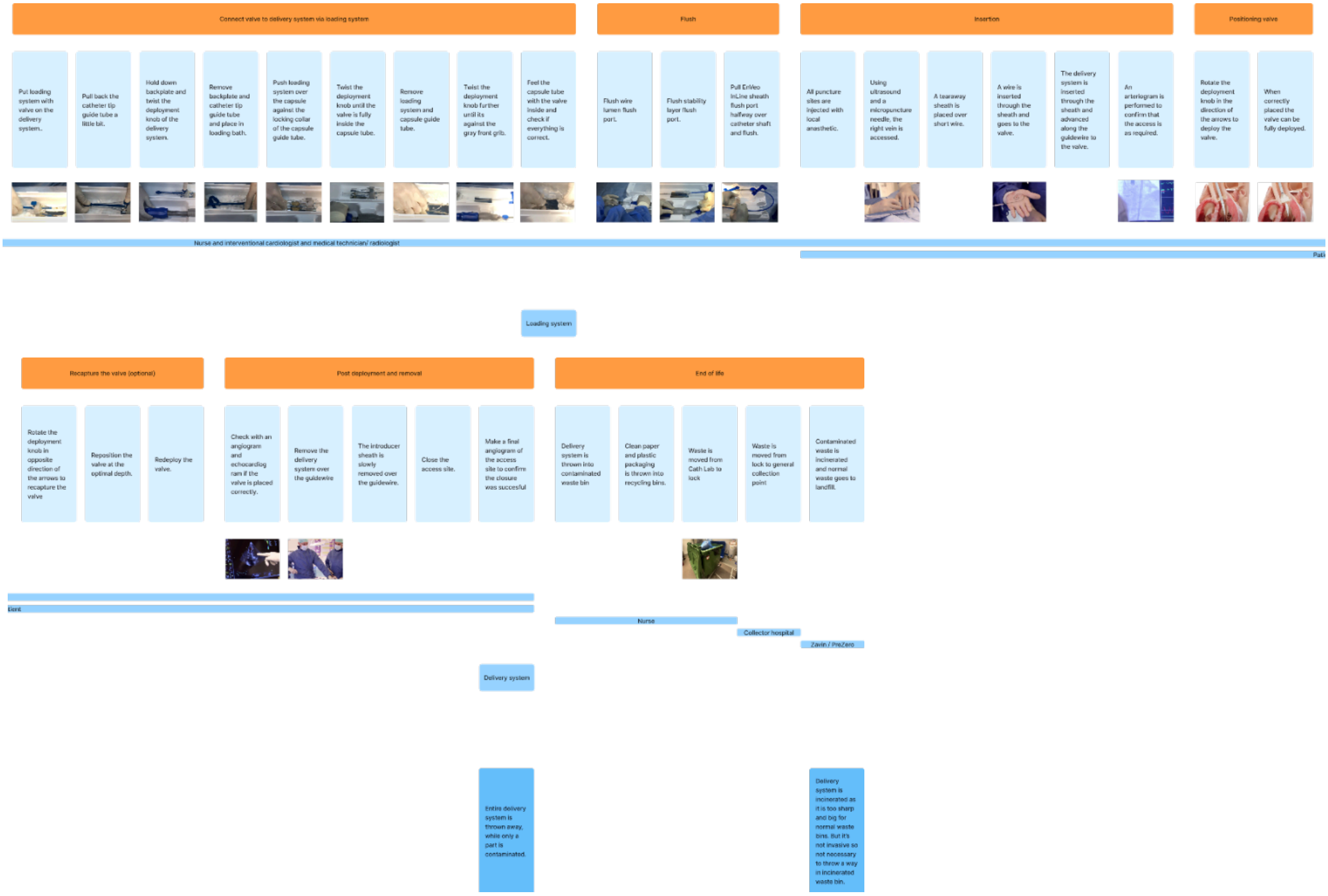
Technology
- Highly automated reprocessing hubs for high-risk devices combine cleaning, functional testing and material recovery, feeding recycled medical-grade polymers back into new device production (MDR)

Environment
- Healthcare must operate close to net-zero emissions; (Green Deal Duurzame Zorg 3.0).

12.4 Detailed product journey

12.1.3 Detailed product journey




Connect valve to delivery system via loading system
Flush
Insertion
Positioning valve
Put loading system with valve on the delivery system..
Pull back the catheter tip guide tube a little bit.
Hold down backplate and twist the deployment knob of the delivery system.
Remove backplate and catheter tip guide tube and place in loading bath.
Push loading system over the capsule against the locking collar of the capsule guide tube.
Twist the deployment knob until the valve is fully inside the capsule tube.
Remove loading system and capsule guide tube.
Twist the deployment knob further until its against the gray front grib.
Feel the capsule tube with the valve inside and check if everything is correct.
Flush wire lumen flush port.
Flush stability layer flush port.
Pull EnVeo InLine sheath flush port halfway over catheter shaft and flush.
All puncture sites are injected with local anasthetic.
Using ultrasound and a micropuncture needle, the right vein is accessed.
A tearaway sheath is placed over short wire.
A wire is inserted through the sheath and goes to the valve.
The delivery system is inserted through the sheath and advanced along the guidewire to the valve.
An arteriogram is performed to confirm that the access is as required.
Rotate the deployment knob in the direction of the arrows to deploy the valve.
When correctly placed the valve can be fully deployed.
Nurse and interventional cardiologist and medical technician/ radiologist
Pati
Loading system
Recapture the valve (optional)
Post deployment and removal
End of life
Rotate the deployment knob in opposite direction of the arrows to recapture the valve
Reposition the valve at the optimal depth.
Redeploy the valve.
Check with an angiogram and echocardiog ram if the valve is placed correctly.
Remove the delivery system over the guidewire
The introducer sheath is slowly removed over the guidewire.
Close the access site.
Make a final angiogram of the access site to confirm the closure was succesful
Delivery system is thrown into contaminated waste bin
Clean paper and plastic packaging is thrown into recycling bins.
Waste is moved from Cath Lab to lock
Waste is moved from lock to general collection point
Contaminated waste is incinerated and normal waste goes to landfill.
Client
Nurse
Collector hospital
Zavin / PreZero
Delivery system
Entire delivery system is thrown away, while only a part is contaminated.
Delivery system is incinerated as it is too sharp and big for normal waste bins. But it's not invasive so not necessary to throw a way in incinerated waste bin.

12.5 LCA

Packaging

Materials A2

Component/description	Weight per component (kg)	Material category	Category average Carbon Footprint CO2 eq	Actual material	Actual material Carbon footprint CO2 eq	Uncertainty %	Location	Source	Assumptions, doubts	Rough Carbon footprint CO2 eq	Actual material Carbon footprint CO2 eq
Packaging: box	0,3610000	Paper	0,436	Idemat2023 Board (solid) and recycled paper (tes	0,570	10%				0,16	0,21
Pakcaging: wrap plastic part	0,0140000	Thermoplastic	3,344	Idemat2023 PET (Polyethylene terephthalate) cher	1,662	10%				0,05	0,02
Packaging: wrap Tyvek paper	0,0670000	Paper	0,436	Idemat2023 PE (HDPE, High density Polyethylene)	1,800	10%				0,03	0,12
Packaging: plastic without bowls	0,3290000	Thermoplastic	3,344	Idemat2023 PET (Polyethylene terephthalate) cher	1,662	10%				1,10	0,55
Packaging: integrated bowls	0,0880000	Thermoplastic	3,344	Idemat2023 PET (Polyethylene terephthalate) cher	1,662	10%				0,29	0,15
Packaging: blue tabs	0,0030000	Thermoplastic	3,344	Idemat2023 ABS (Acrylonitrile butadiene styrene) (	3,377	10%				0,01	0,01
			0,000		0,000	10%				0,00	0,00
			0,000		0,000	10%				0,00	0,00
			0,000		0,000	10%				0,00	0,00
			0,000		0,000	10%				0,00	0,00

Manufacturing A2

Manufacturing process description	Weight per component (kg)	Process category	Category average Carbon Footprint CO2 eq	Actual manufacturing process	Actual material Carbon footprint CO2 eq	Uncertainty %	Location	Source	Assumptions, doubts	Rough Carbon footprint CO2 eq	Actual material Carbon footprint CO2 eq
Paper	0,3610000	Wood processing(per kg)	0,000	Idemat2023 Corrugated board box making, (excl	0,127	10%				0,00	0,05
Tyvek	0,07	Plastic forming(per kg)	0,000	Idemat2023 thermo forming, incl production :	0,457	10%				0,00	0,03
PET	0,43	Plastic injection molding (per kg)	0,838	Idemat2023 injection moulding, incl productio	1,203	10%				0,36	0,52
ABS	0,00	Plastic injection molding (per kg)	0,838	Idemat2023 injection moulding, incl productio	1,203	10%				0,00	0,00
			0,000		0,000	10%				0,00	0,00
			0,000		0,000	10%				0,00	0,00
			0,000		0,000	10%				0,00	0,00
			0,000		0,000	10%				0,00	0,00
			0,000		0,000	10%				0,00	0,00
			0,000		0,000	10%				0,00	0,00

Distribution A2

Distribution process description	Weight per component (ton)	Distance per component (km)	Process category	Category average Carbon Footprint CO2 eq	Actual transport process	Actual material Carbon footprint CO2 eq	Uncertainty %	Location	Source	Assumptions, doubts	Rough Carbon footprint CO2 eq	Actual material Carbon footprint CO2 eq
From Manufacturing to Ireland (assembl	0,0009	4935	Ocean cargo	0,005	Idemat2023 Container ship (max weight/volume ra	0,002	10%				0,02	0,01
From Ireland to Heerlen	0,0009	1246,00	Truck EU	0,001	Idemat2023 Truck+container, 28 tons net(max we	0,032	10%				0,00	0,03
From Heerlen to Erasmus MC	0,0009	205	Truck EU	0,001	Idemat2023 Truck+container, 28 tons net(max we	0,032	10%				0,00	0,01
From Erasmus MC to Zavin	0,0009	28,40	Truck EU	0,001	Idemat2023 Truck+container, 28 tons net(max we	0,032	10%				0,00	0,00
From Erasmus MC to landfill	0,0009	30,00	Truck EU	0,001	Idemat2023 Truck+container, 28 tons net(max we	0,032	10%				0,00	0,00
				0,000		0,000	10%				0,00	0,00
				0,000		0,000	10%				0,00	0,00
				0,000		0,000	10%				0,00	0,00

Use phase A2

Use process description	Amount for the total timespan Unit	Process category	Category average Carbon Footprint CO2 eq	Actual use process	Actual material Carbon footprint CO2 eq	Uncertainty %	Location	Source	Assumptions, doubts	Rough Carbon footprint CO2 eq	Actual material Carbon footprint CO2 eq
			0,000		0,000	10%				0,00	0,00
			0,000		0,000	10%				0,00	0,00
			0,000		0,000	10%				0,00	0,00
			0,000		0,000	10%				0,00	0,00
			0,000		0,000	10%				0,00	0,00
			0,000		0,000	10%				0,00	0,00
			0,000		0,000	10%				0,00	0,00
			0,000		0,000	10%				0,00	0,00

End of Life A2

End-of-life process description	Weight per item (kg)	Process category	Category average Carbon Footprint CO2 eq	Actual end-of-life process	Actual material Carbon footprint CO2 eq	Uncertainty %	Location	Source	Assumptions, doubts	Rough Carbon footprint CO2 eq	Actual material Carbon footprint CO2 eq
Recycling paper packaging	0,36	Incineration paper and wood (municipa	-0,300	Idemat2023, film HDPE 50 mu in mun waste inc	0,052	10%				-0,11	0,02
Recycling plastic packaging	0,50	Incineration thermoplastics (municipal	0,405	Idemat2023, film PET 50 mu in mun waste inc	0,084	10%				0,20	0,04

12.5 LCA

Delivery system

Materials A2

Component/description	Weight per component	Material category	Category average Carbon Footprint	Actual material	Actual material Carbon footprint	Uncertainty	Location	Source	Assumptions, doubts	Rough Carbon footprint	Actual material Carbon footprint
	(kg)		CO2 eq		CO2 eq	%				CO2 eq	CO2 eq
Trigger	0,0200000	Thermoplastic	3,34420	Idemat2023 ABS (Acrylonitrile butadiene styrene) (	3,377	10%			Explanation Figma	0,07	0,07
Deployment knob	0,0300000	Thermoplastic	3,34420	Idemat2023 ABS (Acrylonitrile butadiene styrene) (	3,377	10%			Explanation Figma	0,10	0,10
Tip retrieval with opening	0,0060000	Thermoplastic	3,34420	Idemat2023 ABS (Acrylonitrile butadiene styrene) (	3,377	10%			Explanation Figma	0,02	0,02
Tip retrieval without opening	0,0070000	Thermoplastic	3,34420	Idemat2023 ABS (Acrylonitrile butadiene styrene) (	3,377	10%			Explanation Figma	0,02	0,02
Gray front grip	0,0320000	Thermoplastic	3,34420	Idemat2023 ABS (Acrylonitrile butadiene styrene) (	3,377	10%			Explanation Figma	0,11	0,11
Grey long stick with thread	0,0560000	Thermoplastic	3,34420	Idemat2023 ABS (Acrylonitrile butadiene styrene) (	3,377	10%			Explanation Figma	0,19	0,19
White big ring	0,0120000	Thermoplastic	3,34420	Idemat2023 ABS (Acrylonitrile butadiene styrene) (	3,377	10%			Explanation Figma	0,04	0,04
Whites small ring	0,0020000	Thermoplastic	3,34420	Idemat2023 ABS (Acrylonitrile butadiene styrene) (	3,377	10%			Explanation Figma	0,01	0,01
Yellow clear plastic	0,0020000	Thermoplastic	3,34420	Idemat2023 PC (Polycarbonate) chemical upcycl	3,826	10%			Explanation Figma	0,01	0,01
Grey small part	0,0060000	Thermoplastic	3,34420	Idemat2023 ABS (Acrylonitrile butadiene styrene) (	3,377	10%			Explanation Figma	0,02	0,02
Grey big part	0,0080000	Thermoplastic	3,34420	Idemat2023 ABS (Acrylonitrile butadiene styrene) (	3,377	10%			Explanation Figma	0,03	0,03
Grey tip	0,0010000	Rubber	3,76712	Idemat2023 Silicone rubber (PDMS)	7,334	10%			Explanation Figma	0,00	0,01
Grey grip parts	0,0030000	Thermoplastic	3,34420	Idemat2023 ABS (Acrylonitrile butadiene styrene) (	3,377	10%			Explanation Figma	0,01	0,01
Big spring	0,0060000	Stainless Steel	4,80466	Idemat2023 Stainless Steel (secondary), average	1,965	10%			Explanation Figma	0,03	0,01
Small spring	0,0040000	Stainless Steel	4,80466	Idemat2023 Stainless Steel (secondary), average	1,965	10%			Explanation Figma	0,02	0,01
Size covers	0,0020000	Thermoplastic	3,34420	Idemat2023 ABS (Acrylonitrile butadiene styrene) (	3,377	10%			Explanation Figma	0,01	0,01
Purple stick + Flush ports wire lumend and capsule	0,0060000	Thermoplastic	3,34420	Idemat2023 PC (Polycarbonate) chemical upcycl	3,826	10%			Explanation Figma	0,02	0,02
All purple hidden in device	0,0130000	Thermoplastic	3,34420	Idemat2023 PC (Polycarbonate) chemical upcycl	3,826	10%			Explanation Figma	0,04	0,05
Lightgreen wire outer jacket	0,0048000	Thermoplastic	3,34420	Idemat2023 PTFE (Teflon, Polytetrafluoroethylene)	9,622	10%			Explanation Figma	0,02	0,05
Metal braid inside lightgreen wire	0,0020000	Stainless Steel	4,80466	Idemat2023 Stainless Steel (secondary), average	1,965	10%			Explanation Figma	0,01	0,00
Inner liner inside lightgreen wire	0,0012000	Thermoplastic	3,34420	Idemat2023 PE (Polyethylene) chemical upcycled	2,023	10%			Explanation Figma	0,00	0,00
Darkgreen wire outer jacket	0,0125000	Thermoplastic	3,34420	Idemat2023 PTFE (Teflon, Polytetrafluoroethylene)	9,622	10%			Explanation Figma	0,04	0,12
Metal braid inside darkgreen wire	0,0100000	Stainless Steel	4,80466	Idemat2023 Stainless Steel (secondary), average	1,965	10%			Explanation Figma	0,05	0,02
Inner liner inside darkgreen wire	0,0025000	Thermoplastic	3,34420	Idemat2023 PE (HDPE, High density Polyethylene)	1,800	10%			Explanation Figma	0,01	0,00
Pink tip	0,0000670	Thermoplastic	3,34420	Idemat2023 PE (Polyethylene) chemical upcycled	2,023	10%			Explanation Figma	0,00	0,00
Support hypotube	0,0000360	Stainless Steel	4,80466	Idemat2023 Stainless Steel (secondary), average	1,965	10%			Explanation Figma	0,00	0,00
Adhesive / primer at bonds	0,0000100	Thermoset	2,32351	Idemat2023 Epoxy resin	2,241	10%			Explanation Figma	0,00	0,00
Gold radiopaque marker band	0,0000068	High-end metals	41,50000	Platinum Iridium (90% / 10%)	20280,000	10%			Explanation Figma	0,00	0,14

Manufacturing A2

Manufacturing process description	Weight per component	Process category	Category average Carbon Footprint	Actual manufacturing process	Actual material Carbon footprint	Uncertainty	Location	Source	Assumptions, doubts	Rough Carbon footprint	Actual material Carbon footprint
	(kg)		CO2 eq		CO2 eq	%				CO2 eq	CO2 eq
Plastic (ABS)	0,18400	Plastic injection molding (per kg)	0,838	Idemat2023 injection moulding, incl productio	1,203	10%				0,15	0,22
Rubber	0,00100	Plastic injection molding (per kg)	0,838	Idemat2023 injection moulding, incl productio	1,203	10%				0,00	0,00
Plastic (PC)	0,02100	Plastic injection molding (per kg)	0,838	Idemat2023 injection moulding, incl productio	1,203	10%				0,02	0,03
Plastic (PE)	0,00400	Plastic extrusion(per kg)	0,236	Idemat2023 extrusion, incl production site	0,345	10%				0,00	0,00
Gold marker band	0,00001	Metal drawing and rolling(per kg)	0,708	Idemat2023 Rolling steel	0,898	10%				0,00	0,00
Stainless steel	0,02620	Metal drawing and rolling(per kg)	0,708	Idemat2023 Rolling steel	0,898	10%				0,02	0,02
epoxy	0,00001	Plastic forming(per kg)	0,340	Idemat2023 thermo forming, incl production s	0,457	10%				0,00	0,00
0	0,00	0	0,000	0	0,000	10%	0	0	0	0,00	0,00
0	0,00	0	0,000	0	0,000	10%	0	0	0	0,00	0,00
0	0,00	0	0,000	0	0,000	10%	0	0	0	0,00	0,00

Distribution A2

Distribution process description	Weight per component	Distance per component	Process category	Category average Carbon Footprint	Actual transport process	Actual material Carbon footprint	Uncertainty	Location	Source	Assumptions, doubts	Rough Carbon footprint	Actual material Carbon footprint
	(ton)	(km)		CO2 eq		CO2 eq	%				CO2 eq	CO2 eq
From Manufacturing to Ireland (assembl	0,00	4935	Ocean cargo	0,005	Idemat2023 Container ship (max weight/volume	0,002	10%	0	0	0	0,01	0,00
From Ireland to Heerlen	0,00	1246,00	Truck EU	0,001	Idemat2023 Truck+container, 28 tons net (max	0,032	10%	0	0	0	0,00	0,01
From Heerlen to Erasmus MC	0,00	205	Truck EU	0,001	Idemat2023 Truck+container, 28 tons net (max	0,032	10%	0	0	0	0,00	0,00
From Erasmus MC to Zavin	0,00	28,40	Truck EU	0,001	Idemat2023 Truck+container, 28 tons net (max	0,032	10%	0	0	0	0,00	0,00
From Erasmus MC to landfill	0,00	30,00	Truck EU	0,001	Idemat2023 Truck+container, 28 tons net (max	0,000	10%	0	0	0	0,00	0,00

Distribution A2

Distribution process description	Weight per component	Distance per component	Process category	Category average Carbon Footprint	Actual transport process	Actual material Carbon footprint	Uncertainty	Location	Source	Assumptions, doubts	Rough Carbon footprint	Actual material Carbon footprint
	(ton)	(km)		CO2 eq		CO2 eq	%				CO2 eq	CO2 eq
From Manufacturing to Ireland (assembl	0,00	4935	Ocean cargo	0,005	Idemat2023 Container ship (max weight/volume	0,002	10%	0	0	0	0,01	0,00
From Ireland to Heerlen	0,00	1246,00	Truck EU	0,001	Idemat2023 Truck+container, 28 tons net (max	0,032	10%	0	0	0	0,00	0,01
From Heerlen to Erasmus MC	0,00	205	Truck EU	0,001	Idemat2023 Truck+container, 28 tons net (max	0,032	10%	0	0	0	0,00	0,00
From Erasmus MC to Zavin	0,00	28,40	Truck EU	0,001	Idemat2023 Truck+container, 28 tons net (max	0,032	10%	0	0	0	0,00	0,00
From Erasmus MC to landfill	0,00	30,00	Truck EU	0,001	Idemat2023 Truck+container, 28 tons net (max	0,000	10%	0	0	0	0,00	0,00

Use phase A2

Use process description	Amount for the total timespan		Process category	Category average Carbon Footprint	Actual use process	Actual material Carbon footprint	Uncertainty	Location	Source	Assumptions, doubts	Rough Carbon footprint	Actual material Carbon footprint
	MJ or other			CO2 eq		CO2 eq	%				CO2 eq	CO2 eq
0	0,00	0,00	0	0,000	0	0,000	10%	0	0	0	0,00	0,00
0	0,00	0,00	0	0,000	0	0,000	10%	0	0	0	0,00	0,00
0	0,00	0,00	0	0,000	0	0,000	10%	0	0	0	0,00	0,00
0	0,00	0,00	0	0,000	0	0,000	10%	0	0	0	0,00	0,00
0	0,00	0,00	0	0,000	0	0,000	10%	0	0	0	0,00	0,00
0	0,00	0,00	0	0,000	0	0,000	10%	0	0	0	0,00	0,00
0	0,00	0,00	0	0,000	0	0,000	10%	0	0	0	0,00	0,00
0	0,00	0,00	0	0,000	0	0,000	10%	0	0	0	0,00	0,00

End of Life A2

End-of-life process description	Weight per item	Process category	Category average Carbon Footprint	Actual end-of-life process	Actual material Carbon footprint	Uncertainty	Location	Source	Assumptions, doubts	Rough Carbon footprint	Actual material Carbon footprint
	(kg)		CO2 eq		CO2 eq	%				CO2 eq	CO2 eq
Incineration entire delivery system	0,24			Waste incineration contaminated products hospita	0,990	10%				0,00	0,23
		Incineration thermoplastics (municipal	0,405		0,000	10%				0,00	0,00
										0,00	0,00
										0,00	0,00
										0,00	0,00
										0,00	0,00
									Total impacts	0,41	0,73

12.5 LCA

Loading system

Component/ description		Weight per component	Material category	Carbon Footprint	Actual material	Carbon footprint	Uncertainty	Location	Source	Assumptions, doubts	Rough Carbon footprint	Actual material Carbon footprint
		(kg)		CO2 eq		CO2 eq	%				CO2 eq	CO2 eq
Outflow cone		0,0080	Thermoplastic	3,344	Idemat2023 ABS (Acrylonitrile butadiene styrene)	3,377	10%				0,03	0,03
Inflow cone		0,0330	Thermoplastic	3,344	Idemat2023 ABS (Acrylonitrile butadiene styrene)	3,377	10%				0,11	0,11
Backplate		0,0020	Thermoplastic	3,344	Idemat2023 ABS (Acrylonitrile butadiene styrene)	3,377	10%				0,01	0,01
											0,00	0,00
											0,00	0,00
											0,00	0,00
											0,00	0,00
											0,00	0,00
											0,00	0,00
											0,00	0,00

Manufacturing A2

Manufacturing process description		Weight per component	Process category	Category average Carbon Footprint	Actual manufacturing process	Actual material Carbon footprint	Uncertainty	Location	Source	Assumptions, doubts	Rough Carbon footprint	Actual material Carbon footprint
		(kg)		CO2 eq		CO2 eq	%				CO2 eq	CO2 eq
ABS		0,04	Plastic injection molding (per kg)	0,838	Idemat2023 injection moulding, incl productio	1,203	10%				0,04	0,05
											0,00	0,00
											0,00	0,00
											0,00	0,00
											0,00	0,00
											0,00	0,00
											0,00	0,00
											0,00	0,00
											0,00	0,00
											0,00	0,00

Distribution A2

Distribution process description		Weight per component	Distance per component	Process category	Category average Carbon Footprint	Actual transport process	Actual material Carbon footprint	Uncertainty	Location	Source	Assumptions, doubts	Rough Carbon footprint	Actual material Carbon footprint
		(ton)	(km)		CO2 eq		CO2 eq	%				CO2 eq	CO2 eq
From Manufacturing to Ireland (assembl		0,0000	4935	Ocean cargo	0,005	Idemat2023 Container ship (max weight/volume ra	0,002	10%				0,00	0,00
From Ireland to Heerlen		0,0000	1246,00	Truck EU	0,001	Idemat2023 Truck+container, 28 tons net(max we	0,032	10%				0,00	0,00
From Heerlen to Erasmus MC		0,0000	205	Truck EU	0,001	Idemat2023 Truck+container, 28 tons net(max we	0,032	10%				0,00	0,00
From Erasmus MC to Zavin		0,0000	28,40	Truck EU	0,001	Idemat2023 Truck+container, 28 tons net(max we	0,032	10%				0,00	0,00
From Erasmus MC to landfill		0,0000	30,00	Truck EU	0,001	Idemat2023 Truck+container, 28 tons net(max we	0,032	10%				0,00	0,00
												0,00	0,00
												0,00	0,00
												0,00	0,00

Use phase A2

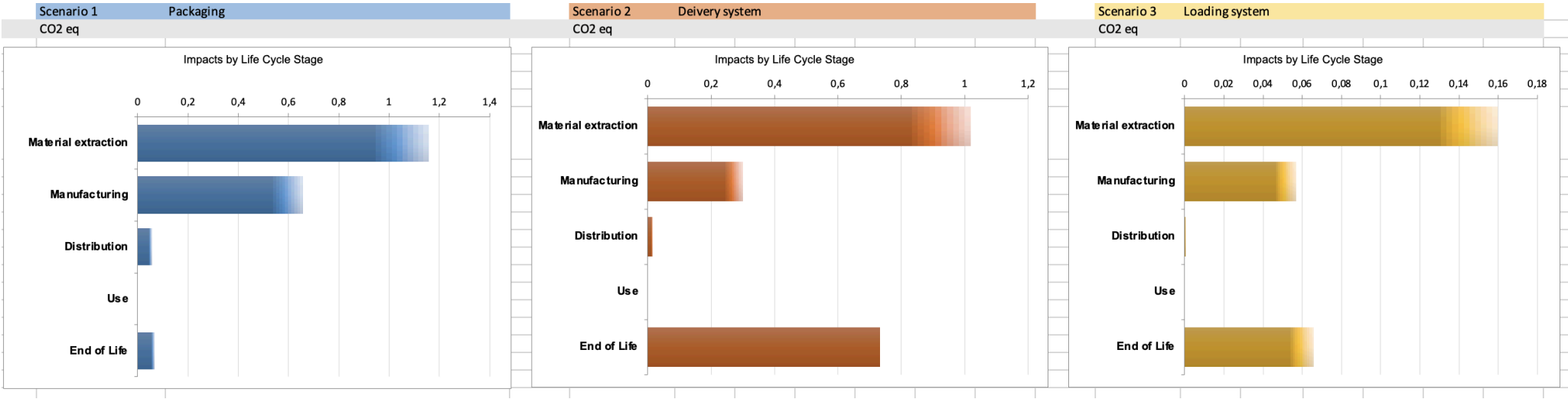
Use process description		Amount for the total timespan	Process category	Category average Carbon Footprint	Actual use process	Actual material Carbon footprint	Uncertainty	Location	Source	Assumptions, doubts	Rough Carbon footprint	Actual material Carbon footprint
		Unit		CO2 eq		CO2 eq	%				CO2 eq	CO2 eq
											0,00	0,00
											0,00	0,00
											0,00	0,00
											0,00	0,00
											0,00	0,00
											0,00	0,00
											0,00	0,00
											0,00	0,00

End of Life A2

End-of-life process description		Weight per item	Process category	Category average Carbon Footprint	Actual end-of-life process	Actual material Carbon footprint	Uncertainty	Location	Source	Assumptions, doubts	Rough Carbon footprint	Actual material Carbon footprint
		(kg)		CO2 eq		CO2 eq	%				CO2 eq	CO2 eq
Recycling plastic packaging		0,04	Incineration thermoplastics (municipal	0,405	Idemat2023 ABS (Acrylonitrile butadiene styrene)	1,393	10%	0	0	0	0,02	0,06
											0,00	0,00
											0,00	0,00
											0,00	0,00
											0,00	0,00
											0,00	0,00

12.5 LCA

Results

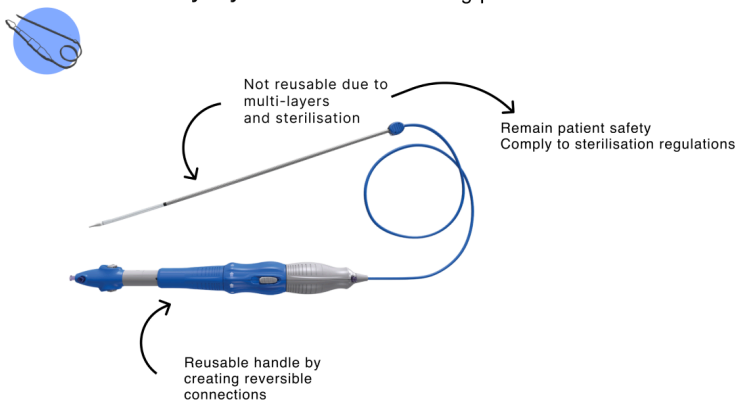


12.6 Co-creations

1 OEM & ESCH-R

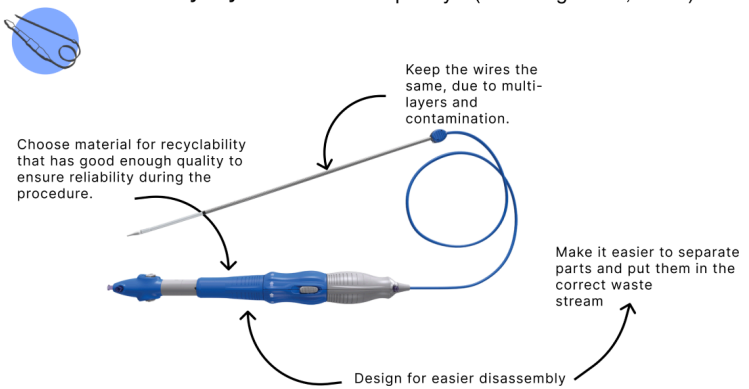
01 Reusable delivery system

Reuse of the handle of the delivery system for a new procedure, after cleaning process.



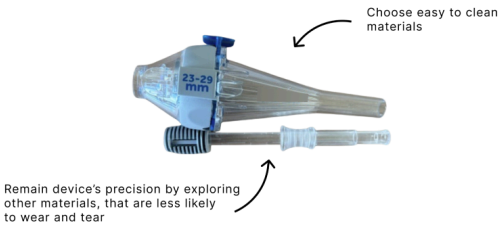
02 Recyclable delivery system

"Process materials to obtain the same (high grade) or lower (low grade) quality." (Hoveling et al., 2024)



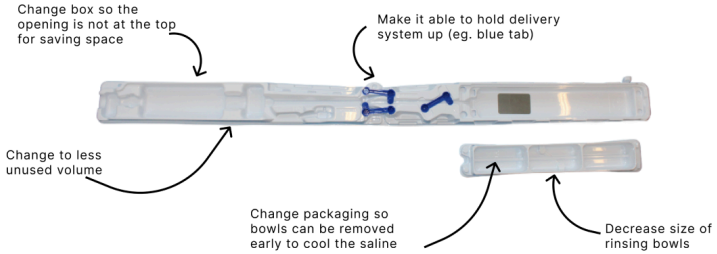
03 Reusable loading system

Reuse of the loading system for a new procedure, after cleaning process.

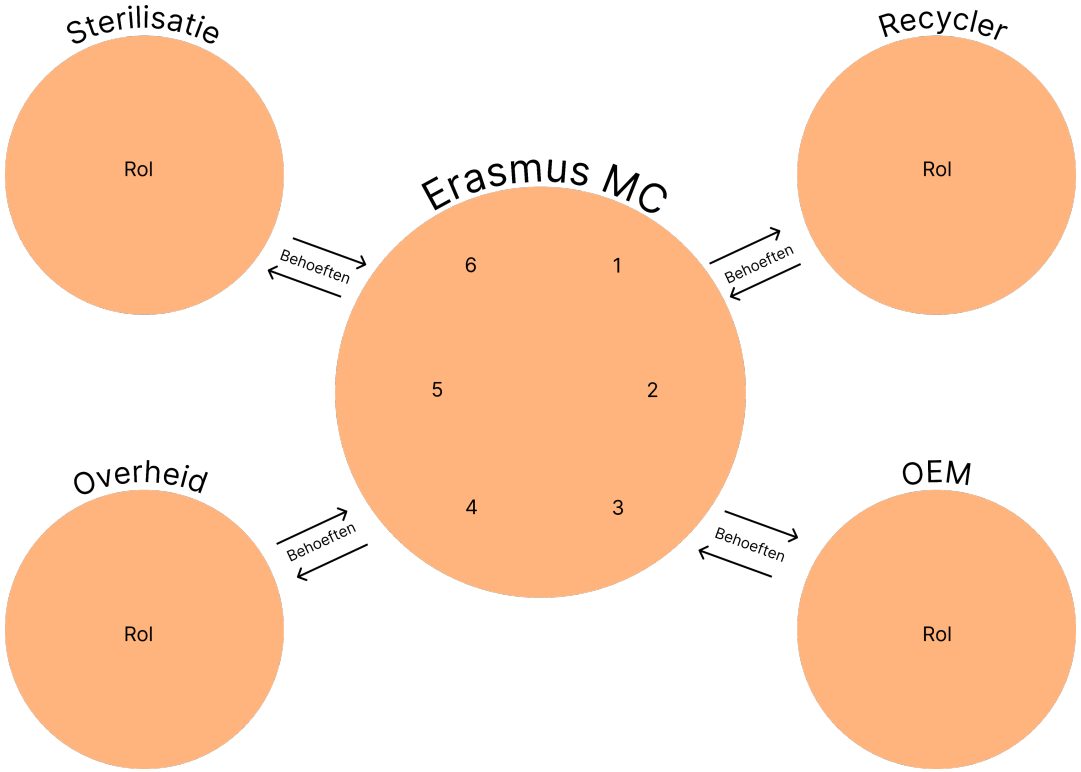


04 Reduce / rethink packaging

Increase efficiency in product manufacturing or use by consuming fewer resources in the packaging and make the device more interesting by increasing the functionality.



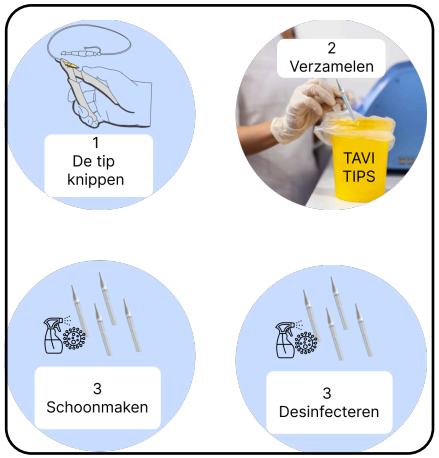
2 Hospital



Scenario 1



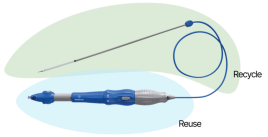
Scenario 2





Scenario 3

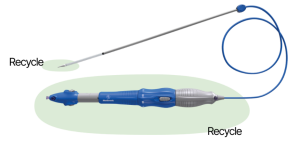
Partly reuse



100 % **incineration**	75% **recycle** 25% incineration	75% **reuse** 25% recycle	100% **reuse**
Phase 0 2026	Phase 1 2035	Phase 2 2045	Future

	Proposals	What do you think about this idea?	What could be alternatives?
Product design	**1. Design for dis- and reassembly** Redesign interfaces so the reusable part can be separated and reassembled consistently without damage.		
	2. Design for sterilisation Ensure the reusable part can be reliably cleaned and sterilised		
	3. Wear and tear indicators Add visible indicators (or simple checks) that show when a part is no longer safe to reuse.		
	4. Device passport Track use cycles and processing steps using a unique ID.		
Communication	**5. Transparency** Provide information needed for safe processing and end-of-life routing		
	6. Product-as-a-service Shift from one-off sale to a model where Medtronic retains responsibility for performance over multiple cycles.		
	7. Collaboration Define roles across hospital, reprocessor, logistics, and Medtronic (incl. quality release and liability).		
	8. Reporting Measure and report reuse cycles achieved, rejects, and environmental effect to motivate.		

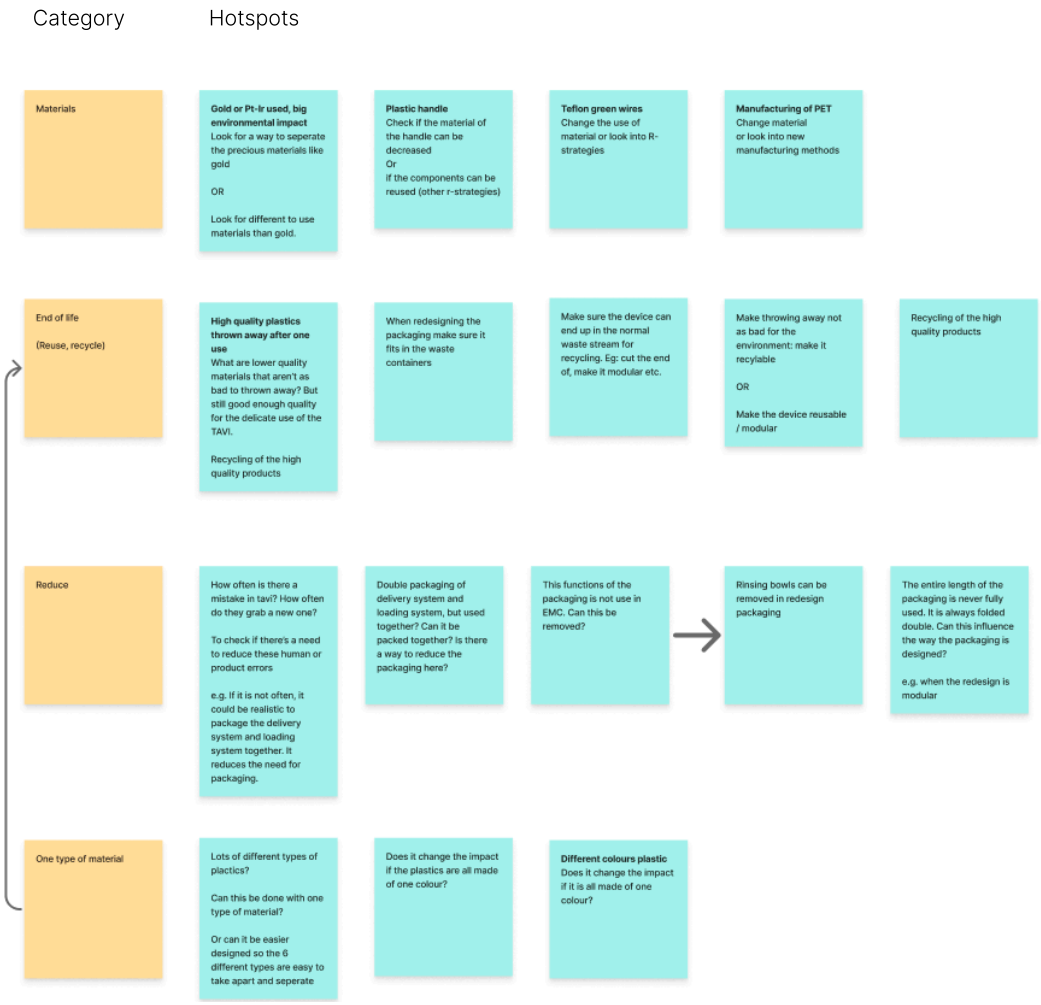
Partly recycle



100 % **incineration**	75% **recycle** 25% incineration	75% **reuse** 25% recycle	100% **reuse**
Phase 0 2026	Phase 1 2035	Phase 2 2045	Future

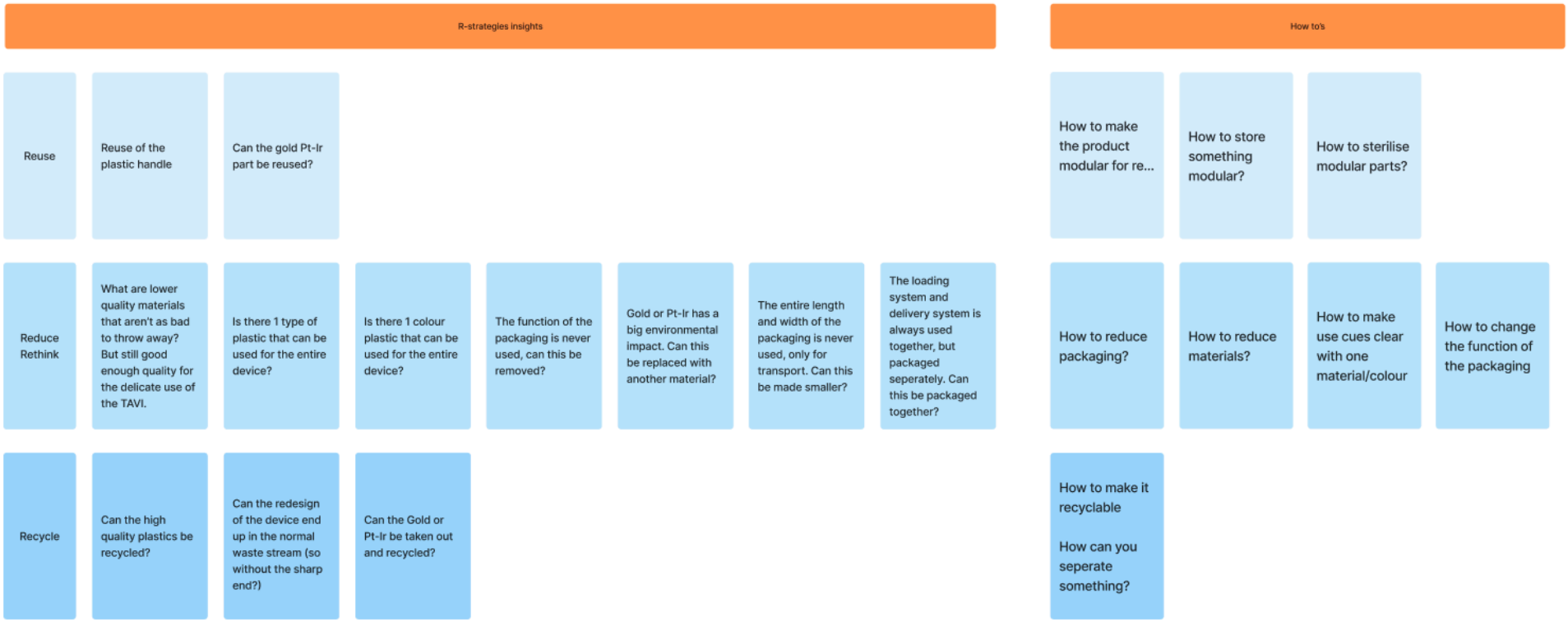
	Proposals	What do you think about this idea?	What could be alternatives?
Product design	**1. Mono-materials** Replace mixed plastics with one polymer to improve recycling quality		
	2. Ease of disassembly Reduce glue/permanent joints so the device can be taken apart quickly and safely.		
Instructions	**3. Safe disposal** Clear instruction at point-of-use: where to place the device, how to seal it, and what not to do.		
	4. Disassembly guide A short guide describing how to open and separate key components safely.		
Communication	**5. Transparency** Provide material information and clear markings to improve sorting and compliance.		
	6. Collaboration Define roles/responsibilities across hospital–Medtronic–recycler (including contamination responsibility).		
	7. Reporting Track and communicate recovered mass and avoided incineration to support continuation and scaling.		

12.7 Clustering





Translating hotspots into R-strategies

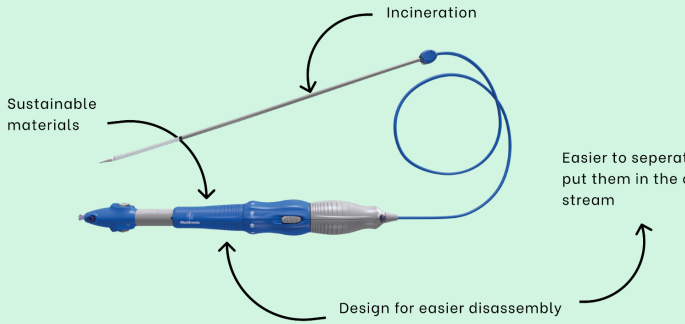


12.8 Design directions

Weighing the R-strategies based on the PMI method

02 Recyclable delivery system

"Process materials to obtain the same (high grade) or lower (low grade) quality." (Hoveling et al., X)

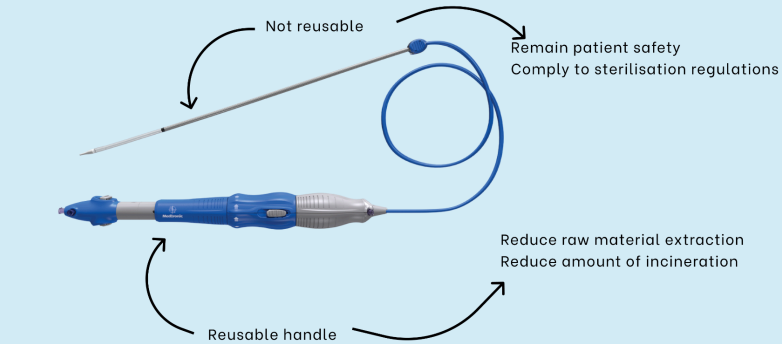


02 PMI

PLUS	MIN	INTERESTING
• **Fits in the current TAVI system** as the steps of the procedure don't change • **No higher costs or workload** for infection prevention • **Less incineration needed**, so **less costs for erasmus MC** as they have to pay per kg of incineration.	• **Higher production costs** for OEMS • **Higher workload for nurses or waste collectors** to seperate • **Complexity** of recycling • **Not all materials might be accepted** in the waste streams or need special processing	• **Easier to implement** than a reusable delivery system. • Can **keep the original design** and change the material and connections. • Can keep the **entire mechanism underneath the same**. • Chosen material for recyclablity, should have **good enough quality to ensure reliability during the procedure**.

01 Reusable delivery system

Reuse of the handle of the delivery system for a new procedure, after cleaning process.



01 PMI

PLUS	MIN	INTERESTING
• Will have a **big impact in the future** • **Keeping a high value** device in the system • **Reuses uncontaminated parts** as they don't enter the body • **Less incineration** needed, so **less costs for erasmus MC** as they have to pay per kg of incineration. • **Cheaper** over longer period of time • **Reduces the need for new materials** after each use • Less packaging waste	• Takes **long to implement**. • **High clinical expectations** from device. Reusable design shouldn't lose this expectation after reuse. No wear and tear • **Higher production costs** for OEMS • **Higher sterilisation and infection prevention costs** for hospitals • **Higher workload and labour costs** for preparation of device • **Complex cleaning**	• Makes the medical staff **aware** of sustainability initiatives • Can **keep the entire mechanism underneath the same**, and only change the parts of the handle around it. • **New business model**: lease or buying

03 Reusable loading system

Reuse of the loading system for a new procedure, after cleaning process.



Easy to clean materials

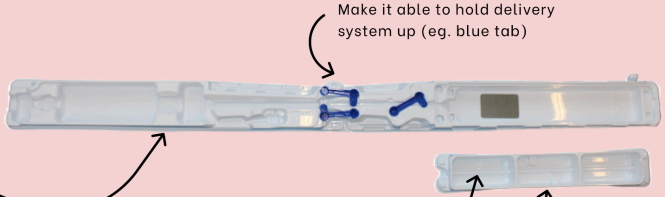
Other material that iss less likely to wear and tear

03 PMI

PLUS	MIN	INTERESTING
• **Longer term solution** • **Cheaper** over longer period of time • **Non-invasive**, doesn't come in touch with the patient • Strong impact on **waste reduction**	• **High investment costs** • Loading system functions is very precise. It can **loose this precision** after multiple uses / sterilisation cycles. • **Reprocessing complexity** (sterilisation) • Needs **workflow change**	• Doesn't go in the body. So **reuse might already be possible**. • **New business model**: lease or buying

04 Reduce / rethink packaging

Hotspots



Make it able to hold delivery system up (eg. blue tab)

Less unused volume

Change packaging so bowls can be removed early to cool the saline

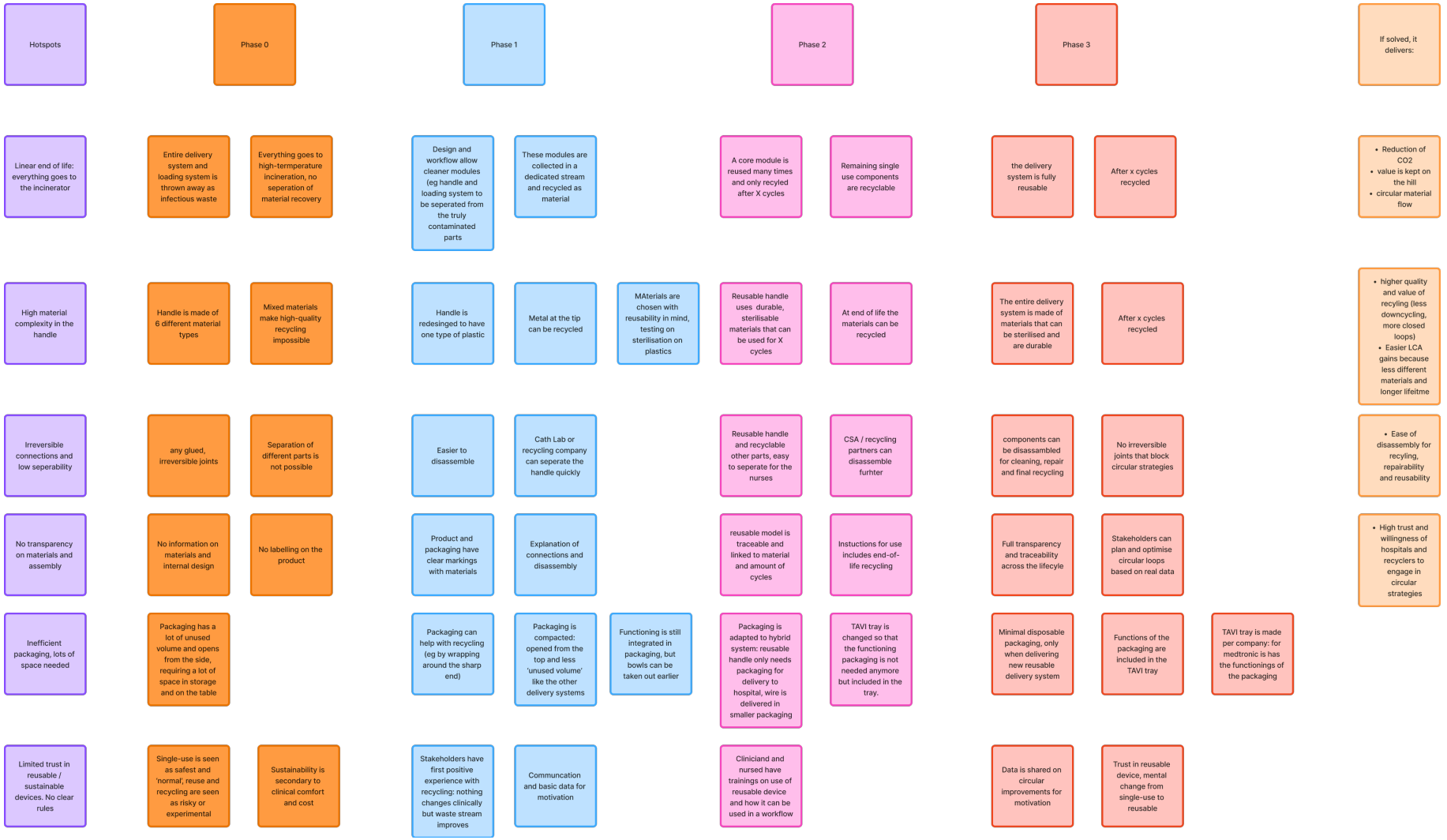
Smaller rinsing bowls.

04 PMI

PLUS	MIN	INTERESTING
• **Low hanging fruit**, it's a quick win • Relatively **easy to implement** • **People from Medtronic are already working on this.** Could help with collecting information. • Less unused space means **lower transport and storage space**	• The **packaging will stil be necessary and needed to protect the devices**, so the amount of impact would be limited • **Higher risk of damage** when reducing volume. • **Change workflow** • **Different wishes and needs** from different hospitals for functions of packaging	• Can be **redesigned to work with a reusable delivery system** • Could take **more components** into account, like the loading system

12.9 Shaping the transition

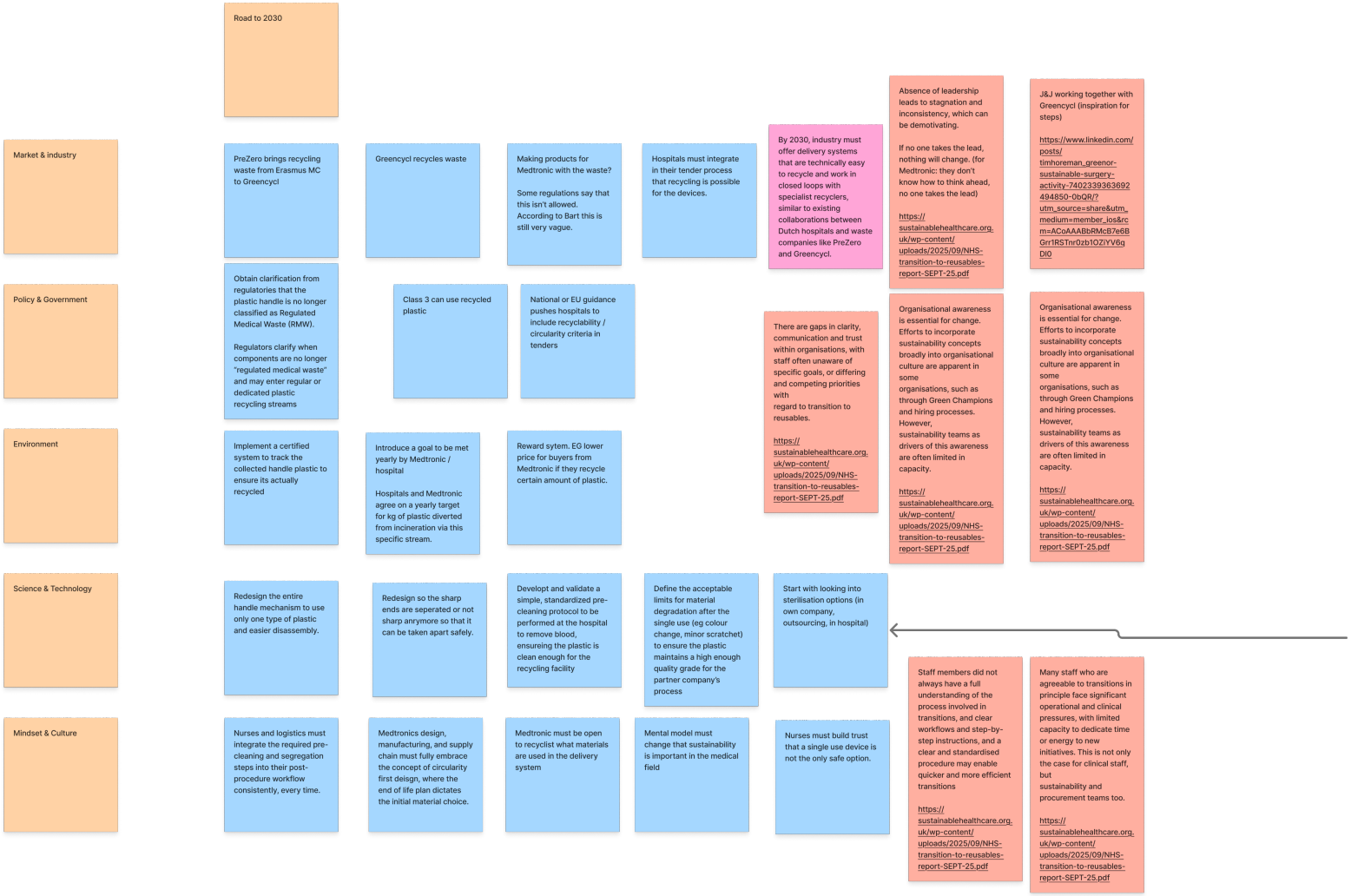
1. Translating the hotspots to design opportunities per phase



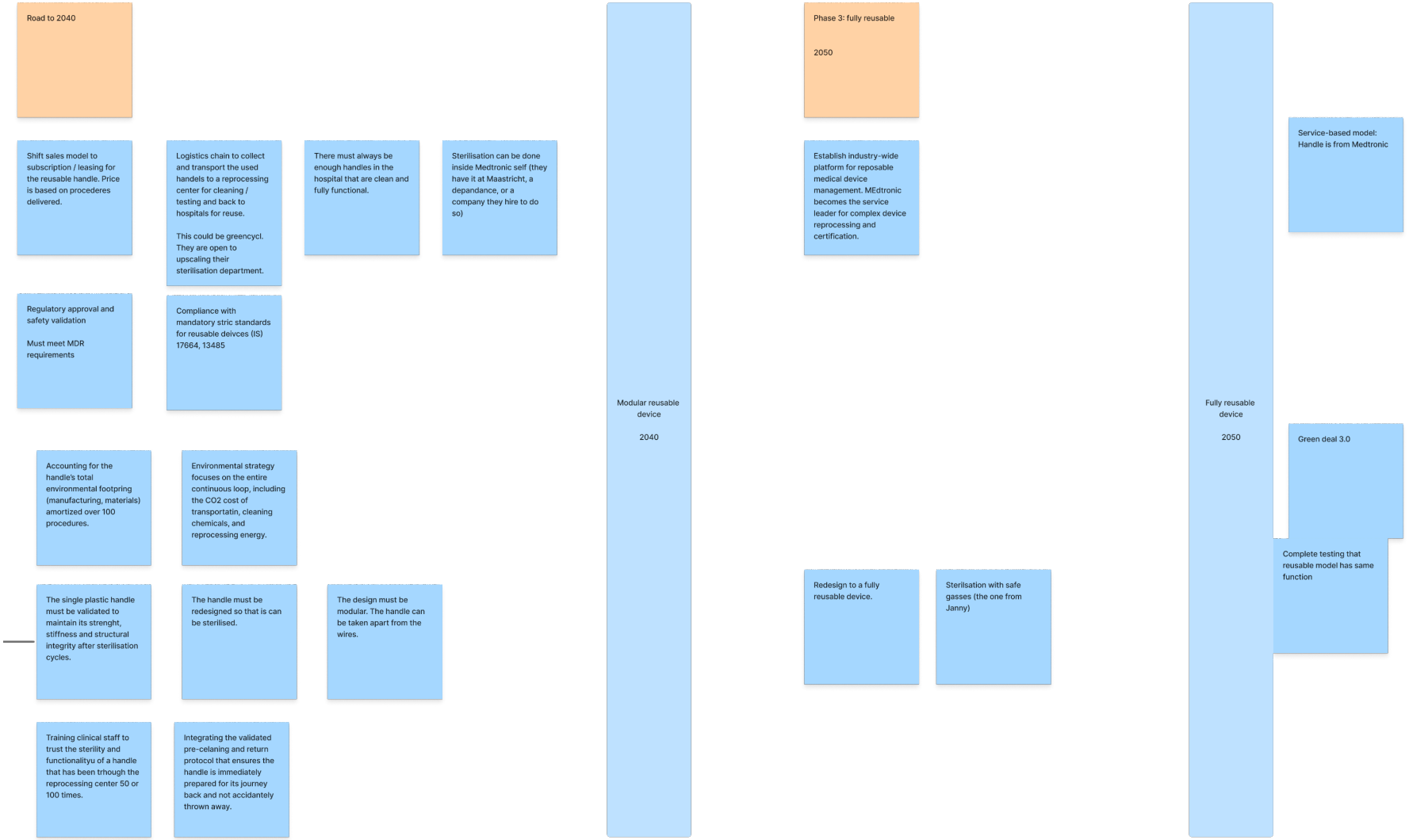
2. Using stakeholder perspectives for actions per phase

	2025				2035 Phase 1					2045 Phase 2				2050 Phase 3
OEM	Redesign delivery to a handle with one type of plastic and seperable from infectious parts.	Material transparency to recyclers (mark plastics & metals, disassembly points or advice)	Start a lab test on material behaviour after cleaning / sterilisation to explore the future of reuse	Set up partnership with recycler	Implement the recyclable delivery system	Reveal the impact of recycling for motivation	Start researching phase 2	Run full validation for phase 2: reuse: perfromance after X cycles, cleaning & sterilisation validation, durability	Develop service / subscription model for phase 2(ownership, replacement, maintenance)	Implement partly reusable delivery system	Ensure the remaining disposable parts still fit the recycling stream where possible	Explore redesign for fully reusable model	Start changing the system more towards a fully reusable model	Implement fully reusable delivery system
Hospital	Look in the current workflow where the recycling can be implemented (where should the bins be, who is going to clean it)	Introduce simple seperation workflow for nurses And train logistics for phase 1			Start monitoring amounts of collected delivery systems for motivation	Expand sterilisation protocols and space for phase 2	Create a system of tracking cycles per handle (scanners) for phase 2	Evaluate workflows and safe perception with staff; adjust training for phase 2	Adapt stock management: enough handles available, process for taking damaged handles out of use for phase 2	Adapt stock management: enough handles available, process for taking damaged handles out of use	Move to service contracts	Culture shift: reuse as default,		
Waste chain (collector + recycler)	Add a seperate stream for devices for recycling next to the other waste	Recycler: develop safe desinfection + shredding process for this stream	Agree on contracts & reporting (kg collected, % recycled)		Adjust volume (less infectious waste stream more recycling waste), keep stream for recyclable disposables / end-of-life handles	Recycler: ste p process for end-of-life reusable handles								
Regulators / policy	Look into the possibilities of using recycled plastics again in medical devices.	Encourage and sponsor pilot projects for device recycling,, start linking this to hospital sustainability goals	Check on greenwashing.		Provide standards and guidance for reusable components in this device class	Clarify rules around reprocessing / remanufacturing and service-based models in the medical field				Use climate-neutral healthcare targets to create a market where reusables are a safe option	Make rules so that reusable devices are financially attractive			

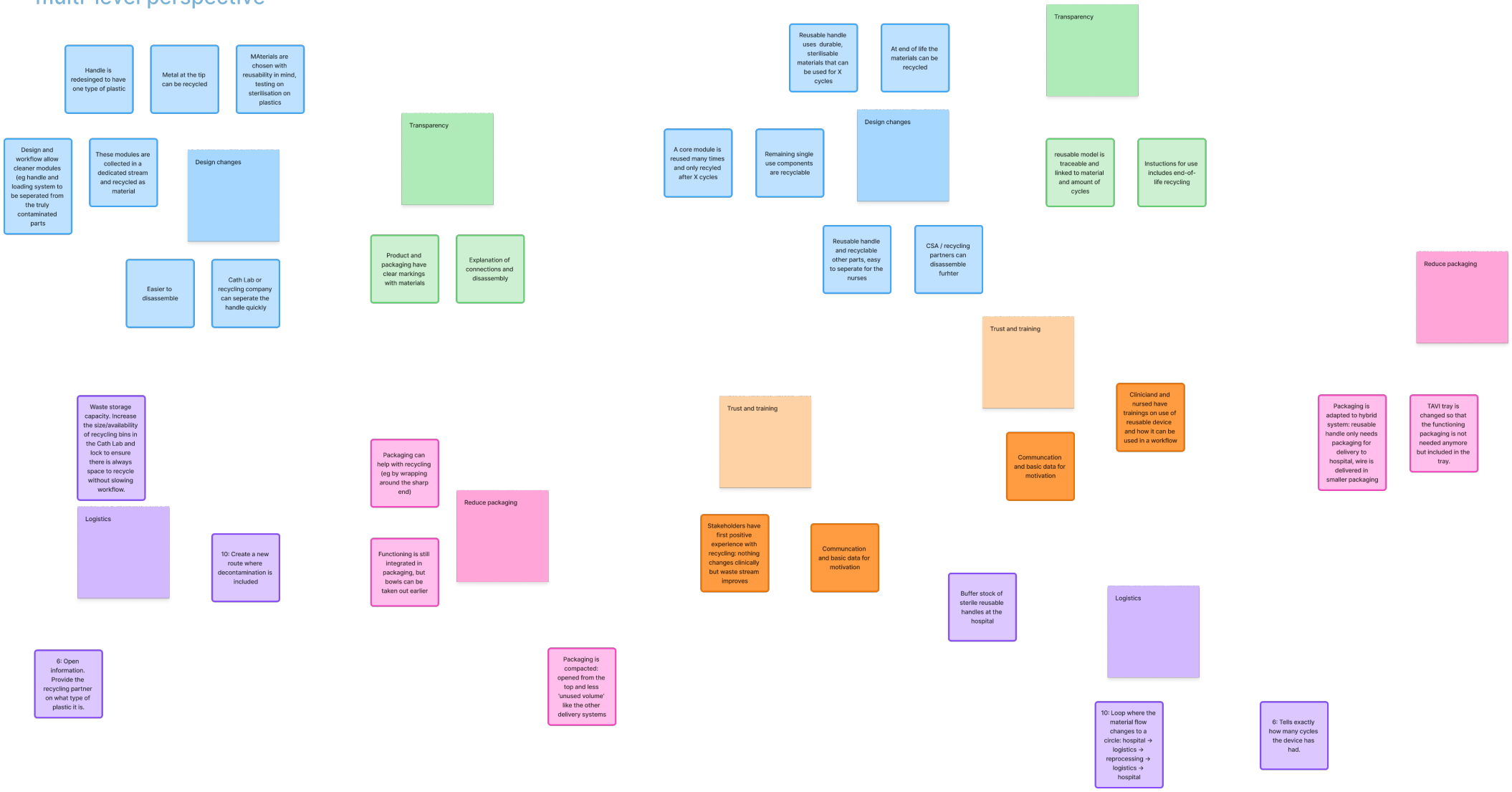
3. Using the multi-level perspective for actions per phase



3. Using the multi-level perspective for actions per phase



4. Clustering all the insights from the stakeholder perspectives, hotspots and multi-level perspective



5. Stakeholder needs and wishes

OEM

Values	Patient safety, product performance, market position
Needs	Feasible circular model, regulatory clarity, predictable return flows
Conflict	Liability, cost, limited control after use

HOSPITAL

MANAGEMENT

Values	Quality of care, organisational feasibility, strategic direction
Needs	Clear responsibilities, internal alignment, manageable implementation
Conflict	Circularity competes with time, budget, and operational priorities

NURSES

Values	Patient safety, workflow efficiency, wanting to do good
Needs	Simple and fast handling, clear instructions, no extra risk.
Conflict	Circular handling adds time and can feel less safe

LOGISTICS

Values	Safe and efficient flows, hygiene, practical organisation
Needs	Clear routing, storage space, workable collection system
Conflict	Extra waste streams and limited space.

PROCUREMENT

Values	Cost control, reliable supply, fair contracts
Needs	Clear business case, measurable impact, reliable supplier agreements
Conflict	Circular options may increase short-term cost and complexity

GOVERNMENT

Values	Public health, patient safety, environmental protection
Needs	Compliace, evidence, accountability
Conflict	Approval processes are slow and not tailored to circular devices

EXTERNAL PARTIES

REPROCESSOR

Values	Safety, reliability, viable operation
Needs	Validated procedures, traceability, predictable quality and volume
Conflict	High validation burden and unclear liability

RECYCLER

Values	Safe recovery, material quality, efficient processing
Needs	Clean separated streams, material information, sufficient volume
Conflict	Contamination risk and complex mixed materials

6. Mapping the barriers per phase: recycling

Phase 1	Phase 0: current role & beliefs	Gap: what is the missing (knowledge, tools, incentices)	Phase 1: desired role & believes
OEM	• Role / actions: designs, assembles, packages and sterilises a fully single-use delivery system; supplies it to hospitals; has limited involvement in what happens after use. • Beliefs / assumptions: primary responsibility is product safety and performance; assumes used devices end up as infectious waste and that waste handling is mainly the hospitals job.	• Limited insights into actual hospital waste flows and how design choices affect recyclability in practice. • No internal design guidelines for recyclable device modules.	• Role / actions: designs a clearly defined recyclable module, provides material data to recyclers, and works together with recycling company. • Beliefs / assumptions: sees recyclability and reduced incineration as part of product quality and brand value, not a “nice to have”; accepts shared responsibility for end-of-life.
Erasmus MC	• Role / actions: orders and uses single-use system; after procedure the entire device goes into the infectious waste stream; focuses on safety, sterility and efficient workflow. • Beliefs / assumptions: end-of-life of devices is largely fixed by refulation; circularity is mostly about energy, buildings and maybe packaging, not devices.	• Limited clarity on which parts could be considered “clean enough” for a seperate recyclable stream. • No simple protocol, bins or training for seperating recyclable device parts. • Little feedback on environmental impact or cost savings from better material flows.	• Role / actions: implements a simple, standardised workflow for seperating the recyclable handle from infectious parts; uses dedicated containers; includes recyclability requirement in procurement. • Beliefs / assumptions: trusts that safe, compliant recycling of certain components is possible and sees it as part of delivering responsible care.
Waste collector (hospital)	• Role / actions: collects all hospital device waste as mostly regulated medical waste and transports it to incineration facilities. • Beliefs / assumptions: it is safer to treat all used devices as infectious; no material recovery.	• No experience with a seperate, “recyclable medical device” stream form this hospital • Contracts and pricing structures do not reward seperate collection for recycling.	• Role / actions: Operates two clear flows: infectious waste to incineration and dedicated containers with seperated recyclable handes for a recycler • Beliefs / assumptions: sees that a pre-sorted, low risk stream can be handled safely and can be part of their service offering
Recycling company (either OEM or other company)	• Role / actions: REcycles standard, well-known plastic and metal streams; usually not involved in semi-infectiuous medical devices. • Beliefs / assumptions: Medical devices are too contaminated, too complex (mixed materials) and too low-volume to be an attractive recycling stream.	• Detailed information about the devices material composition and contaimination level • Proven decontamination / pre-treatment process that makes the stream acceptable with regulations • A clear business case (volume, quality of recyclate, contracts with OEM/hospitals).	• Role / actions: Runs a dedicated line (or process step) to disinfect, shred and separate the selected device modules; provides recyclate to Medtronic or other markets. • Beliefs / assumptions: Recognises this as a promising niche stream for high-quality plastic/metal recovery and as a pilot for broader medical-device recycling.
Dutch / EU regulators	• Role / actions: Set MDR and waste regulations; current guidance effectively pushes most used medical devices into the medical-waste → incineration route. • Beliefs / assumptions: Patient safety and infection control dominate; recycling of used devices is seen as high-risk and is not specifically facilitated.	• Clear criteria for when and how components can safely leave the medical-waste stream. • Evidence and guidelines on risk-managed recycling pathways for selected device parts. • Policy instruments that explicitly encourage circular strategies in medical devices (beyond high-level Green Deal ambitions). • Recycled plastics are not allowed in medical devices	• Role / actions: Provides clarified guidance for partial recycling (e.g. classification of “cleanable” components); allows and supports pilot projects for device recycling in collaboration with OEMs and hospitals. • Beliefs / assumptions: Sees circular strategies (recycling/ reuse) as compatible with patient safety when properly controlled, and as necessary to meet healthcare climate targets.

7. Mapping the barriers per phase: reuse

Phase 2	Phase 1: current role & beliefs	Gap: what is the missing (knowledge, tools, incentices)	Phase 2: desired role & believes
OEM	• Role / actions: Designs a clearly defined recyclable module (e.g. handle), provides material data to recyclers, and is involved in the recycling program. • Beliefs / assumptions: Sees recyclability and reduced incineration as part of product quality and brand value; accepts shared responsibility for end-of-life.	• Proven design and validation of a reusable, sterilizable handle that maintains performance over many cycles. • Business model for providing the handle as a service / asset (tracking units, maintenance, replacements).	• Role / actions: Supplies a modular system with reusable handle and disposable/recyclable distal components; provides validated reprocessing instructions; supports tracking of handle life cycles; offers a service / subscription model. • Beliefs / assumptions: Regards reuse (when validated) as a safe, normal part of product strategy, and sees long-lived devices as a competitive advantage and key to meeting sustainability targets.
Erasmus MC	• Role / actions: Implements a simple workflow for separating recyclable modules from infectious parts; uses dedicated containers. • Beliefs / assumptions: Trusts that safe, compliant recycling of certain components is possible and part of responsible care.	• Sterilisation capacity and validated processes to reprocess reusable handles alongside other instruments. • Clear responsibilities between cath lab and CSSD for handling, counting and checking reusable handles. • Systems for tracking number of cycles per handle (to avoid over-use or premature discard). • Cultural shift: clinicians and nurses must be comfortable using reprocessed handles in high-risk cardiology procedures.	• Role / actions: Uses reusable handles as standard; sends them to CSSD after each procedure; ensures correct separation of disposable/recyclable parts; keeps sufficient stock of reprocessed handles available. • Beliefs / assumptions: Sees reuse of validated handles as safe and routine; views circular device management (reuse + recycling) as integral to quality of care and hospital sustainability policy.
Waste collector (hospital)	• Role / actions: Operates two flows: infectious waste to incineration and dedicated containers with separated recyclable modules to a recycler. • Beliefs / assumptions: Sees that a pre-sorted, low-risk stream can be handled safely and included in their service offering.	• Adjusted volumes and compositions of waste streams when reusable handles replace some disposables. • New contracts that reflect reduced infectious waste volume and possibly lower transport frequency.	• Role / actions: Mainly handles infectious waste from disposable distal parts and residuals; continues to route recyclable components to recyclers. • Beliefs / assumptions: Recognises that successful reuse programs will gradually shrink certain waste streams and is prepared to adapt their business model accordingly.
Recycling company / reprocessor(either OEM or other company)	• Role / actions: Disinfects, shreds and separates selected device modules; provides recycled plastics to Medtronic or other markets. • Beliefs / assumptions: Sees this as a promising niche stream for high-quality material recovery and as a pilot for broader medical-device recycling.	• Clarity on which parts of the hybrid system remain recyclable (e.g. parts of the distal module, end-of-life handles). • Processes to handle end-of-life reusable handles after many cycles. • Long-term contracts securing enough volume.	• Role / actions: recycles both: selected disposable plastic parts and reusable handles at the end-of-life. • Beliefs / assumptions: Considers hybrid devices as a stable, long-term stream and invests in technology to maximise recovery of metals and high-grade plastics from them.
Dutch / EU regulators	• Role / actions: Provide clarified guidance for partial recycling; allow and support pilot projects for device recycling in collaboration with OEMs and hospitals. • Beliefs / assumptions: See circular strategies (recycling / limited reuse) as compatible with patient safety when properly controlled.	• Detailed standards and guidance for reusable components in high-risk interventional devices (performance over many cycles, cleaning validation, tracking). •	• Role / actions: Provide and enforce clear standards for reusable components in these devices (e.g. performance after X cycles, cleaning validation, labelling and traceability); recognise and regulate hybrid device architectures (reusable + disposable modules). • Beliefs / assumptions: Treat safe reuse of device components as an important lever to decarbonise healthcare, and as a direction that regulation should actively enable rather than passively tolerate.

12.10 MoSCoW

Stakeholder (phase 1)	Urgency	Proposal	Action	
OEM	Must have	Material transparency	Provide material disclosure for key components relevant to recycling and safe handling	Information
		Disassembly guide for recycler	Provide a safe, step-by-step disassembly guide	Information
		Partner agreements	Set up agreements with hospital and recycler on responsibilities, acceptance criteria, and data sharing	Information
	Should have	Design-for-recycling: ease of disassembly	Improvements that reduce irreversible connections and support ease of separation	Product
		Early collaboration with recycler	Align product features with recycler capability (sorting, shredding, output quality)	Information / product
		Digital product passport	Register what is recycled when, and the outcomes	Information / product
	Could have	Mono-materials	Reduce amount of polymers in handle to improve recyclate quality	Product
		Reporting	Sharing recycling data	Information

Stakeholder(phase 1)	Urgency	Proposal	Action	
Hospital (nurses)	Must have	One-step disposal action	A clear, simple disposal route (dedicated bin / container at point of use)	Clinical / material
		Training on clear rules	Staff must know what is allowed in the recycling stream	Clinical
	Should have	Behaviour reassurance	Short training and communication that explains why this does not compromise safety and what to do in exceptions.	Clinical / information

Stakeholder(phase 1)	Urgency	Proposal	Action	
Hospital (logistics)	Must have	Internal collection and routing	Defined process to collect full containers and transport them to a designated internal point	Clinical
		Safe handling protocol	Training + labelling so the stream stays closed and correctly routed	Clinical

Stakeholder(phase 1)	Urgency	Proposal	Action	
Hospital (management)	Must have	Approval of handing protocol	Confirmation that the proposed route is authorised under infection-prevention and waste practices	Clinical
	Should have	Tender criteria	Integrate requirements such as material transparency, take-back partnerships, and circular criteria into procurement	Clinical
	Could have	Incentives and feedback loops	Simple dashboards (kg diverted, CO_2 estimate, operational issues) to motivate teams	Information

Stakeholder(phase 1)	Urgency	Proposal	Action	
Recycler	Must have	Capability to accept contaminated waste	Safe handling procedures + ability to disinfect at least to the level needed for processing	Product
		Documented process route	Clear description of how devices are processed and what outputs are produced	Clinical / information
	Should have	Traceability	Tracing the delivery systems to track data	Clinical /information
	Could have	Reporting	Share amount of kg recycled, quality of recycled materials,	Information

Stakeholder(phase 1)	Urgency	Proposal	Action	
(OEM)	Must have	Design for sterilisation and durability	Materials and geometries must withstand repeated reprocessing without degradation.	Product
		Design for separation and reassembly	Handle can be separated from non-reusable parts, and reassembly is consistent and error-resistant.	Product
		Wear-and-tear / end-of-life criteria	Clear pass/fail indicators or limits that define when a handle must be removed from being used.	Product / information
		Traceability (unique ID)	Each reusable handle has a unique identifier and cycle tracking.	Product
	Should have	Digital product passport	Register cycles, maintenance, inspection outcomes, and end-of-life decisions	Product / information
		Training package for clinicians	Instructions on use of the partly reusable system.	Clinical / information
		Product-as-a-service model	Per-procedure fee or service model to align incentives with reduced unit sales.	Clinical
	Could have	Reporting	Sharing recycling data	Information

Stakeholder	Urgency	Proposal	Action	
Hospital (nurses)	Must have	Simple handling steps	Disassembly and routing of reusable handle must fit Cath lab pace (minimal steps, clear behaviour)	Clinical / information
		Safety reassurance	Staff must have clear guidance that the route is approved and safe (training + authorised protocol)	Clinical / information
		Safety training	Training on how to use the new delivery system and how to use it safely	Clinical / information

Stakeholder	Urgency	Proposal	Action	
Hospital (logistics)	Must have	Two-stream routing	Separate, clearly labelled routes for reuse and recycling.	Clinical
		Contamination control	Containers remain closed, labelled, and routed correctly to the right direction	Clinical
	Should have	Emergency stock	Emergency stock of assembled delivery systems.	Clinical

Stakeholder	Urgency	Proposal	Action	
Hospital (management)	Must have	Approval of handing protocol	Confirmation that the proposed route is authorised under infection-prevention and waste practices	Clinical
	Should have	Tender criteria for reuse	Requirements for traceability, validated reuse, lifecycle responsibility, and reporting.	Clinical
		Incentives and reporting	Targets of feedback loops to maintain compliance and monumentum.	Information

Stakeholder	Urgency	Proposal	Action	
Reprocessor	Must have	Validated processing route	Defined and validated cleaning + sterilisation process for the handle, including packaging for return.	Clinical
		Inspection + checklist	Documented checks and a release decision before the handle is retuned to use.	Clinical
		Capability to sterilise	Safe sterilisation + safe handling procedures	Product
	Should have	Traceability	Scan delivery systems to see the life cycle.	Clinical
	Could have	Reporting	Report quantities collected and reprocessed	Information

Stakeholder	Urgency	Proposal	Action	
Government	Must have	Responsibilities and liability defined, clarity on classification	Ownership, liability, and quality release responsibilities are explicitly agreed.	Clinical

12.11 Comparison LCA

