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.

➔ *space available for images / figures on next page*

introduction (continued): space for images

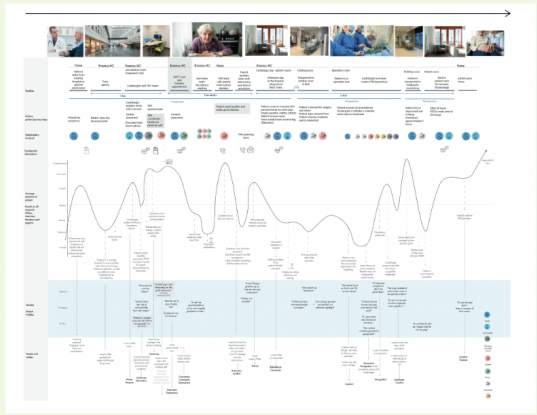
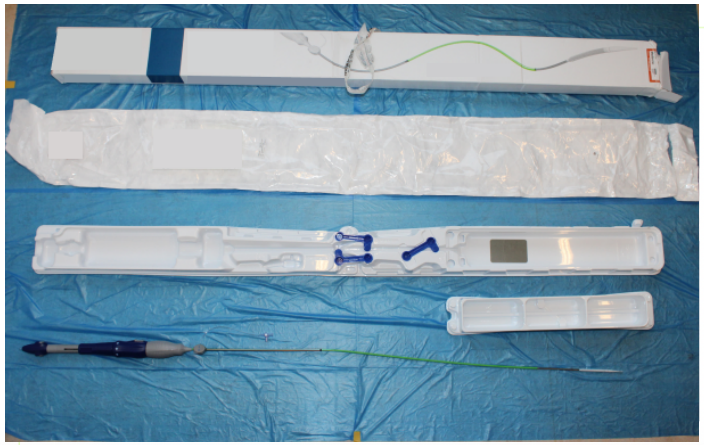


image / figure 1 TAVI patient journey (Bedaux, 2022)



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:

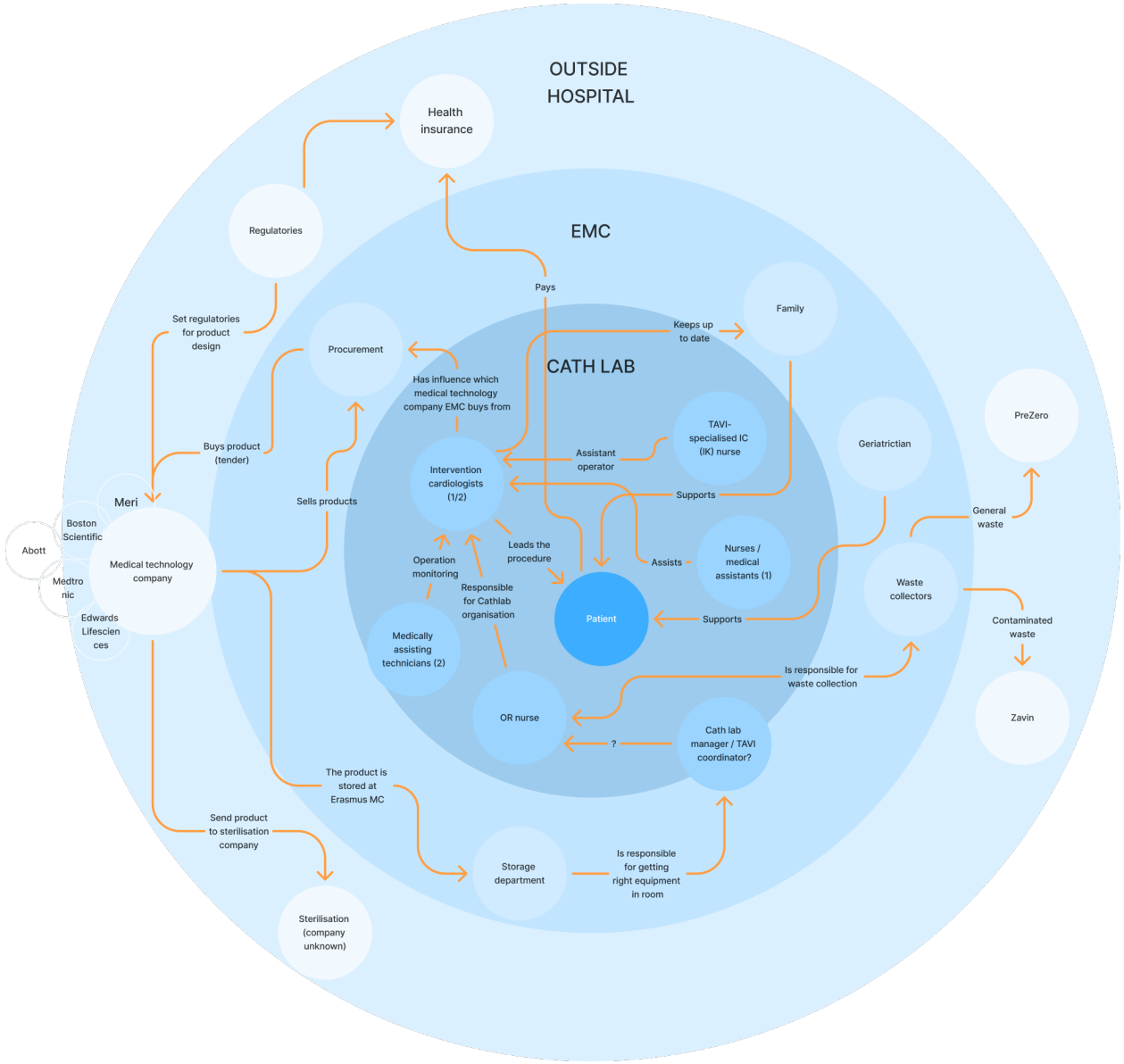
- Interventional cardiologists (2): primary users of the delivery system; responsible for procedural performance and patient outcome.
- Sterile TAVI nurse: prepares and hands over sterile materials; key for preparation steps and correct handling of components.
- TAVI/circulating nurse: supports the procedure, 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
Meri
Sells products
Supports
General waste
Boston Scientific
Abott
Medtronic
Edwards Lifesciences
Medical technology company
Operation monitoring
Leads the procedure
Assists
Nurses / medical assistants (1)
Waste collectors
Responsible for Cathlab organisation
Patient
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).

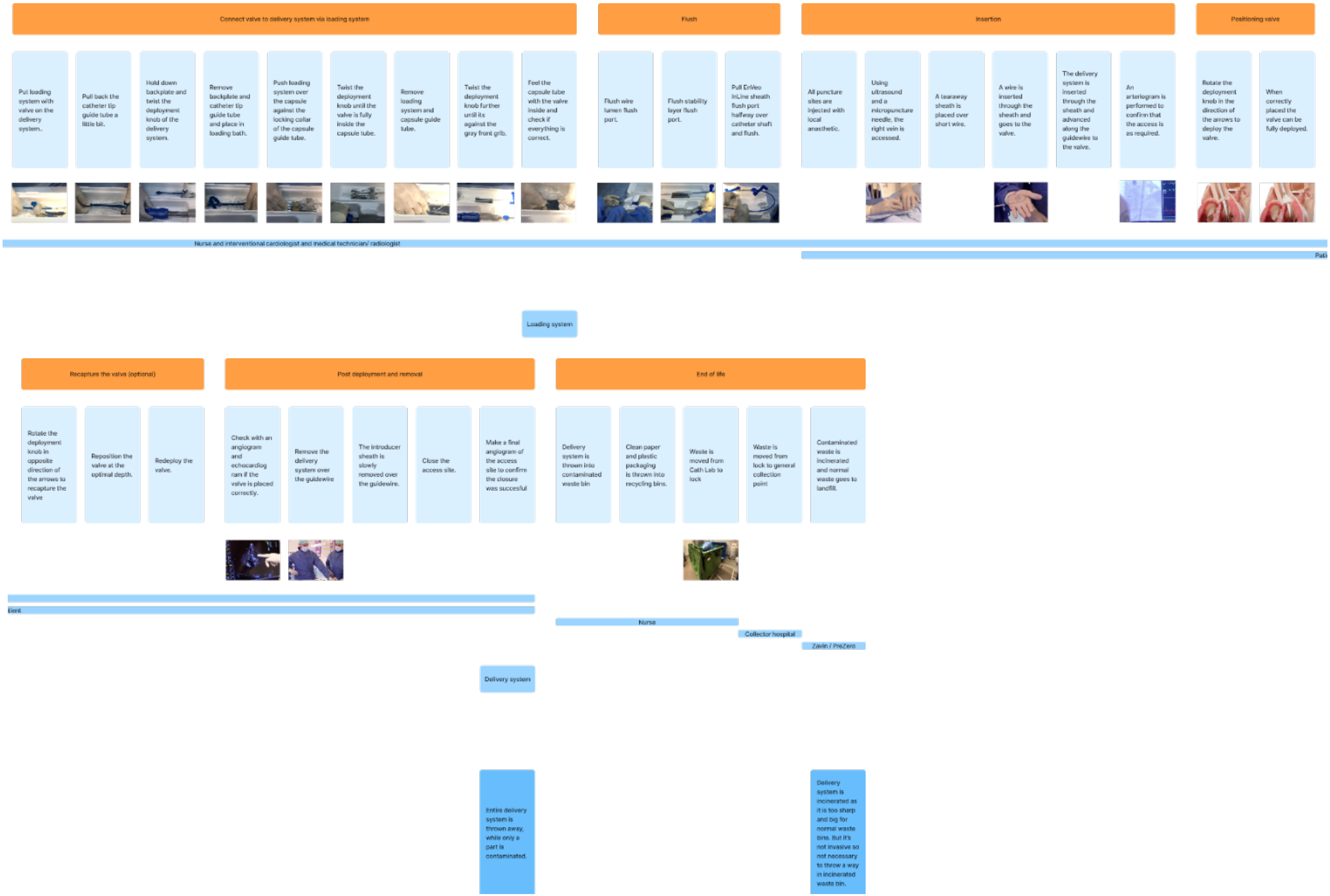
Regulatory
- EU and national policies align: devices without a credible circular pathway (recycle / reuse / remanufacture) are increasingly restricted or not reimbursed in high-income health systems (inference from tightening climate targets and circular-economy law).

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) che	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) che	1,662	10%				1,10	0,55
Packaging: integrated bowls	0,0880000	Thermoplastic	3,344	Idemat2023 PET (Polyethylene terephthalate) che	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 upclycl	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 upclycl	3,826	10%			Explanation Figma	0,02	0,02
All purple hidden in device	0,0130000	Thermoplastic	3,34420	Idemat2023 PC (Polycarbonate) chemical upclycl	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 lighgreen 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 :	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		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

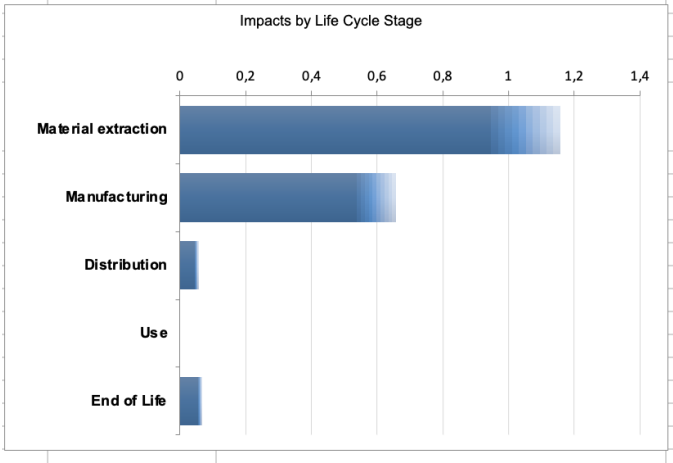
End-of-life process description	Weight per item	Process category	Category average Carbon Footprint	Actual end-of-life process	Actual material Carbon footprint	Uncertainty	Location	Source	Assumptions, doubts	Rough Carbon footprint	Actual material Carbon footprint
	(kg)		CO2 eq		CO2 eq	%				CO2 eq	CO2 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

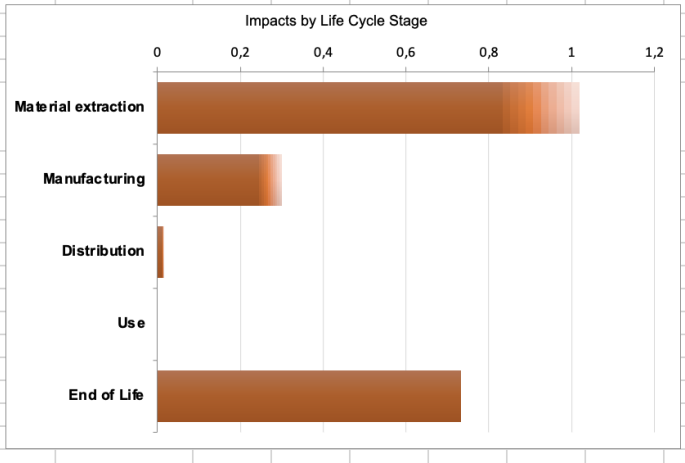
Scenario 1 Packaging

CO2 eq



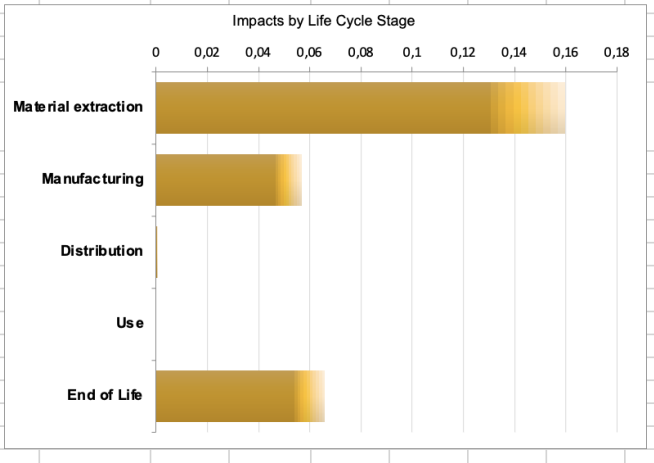
Scenario 2 Deivery system

CO2 eq



Scenario 3 Loading system

CO2 eq

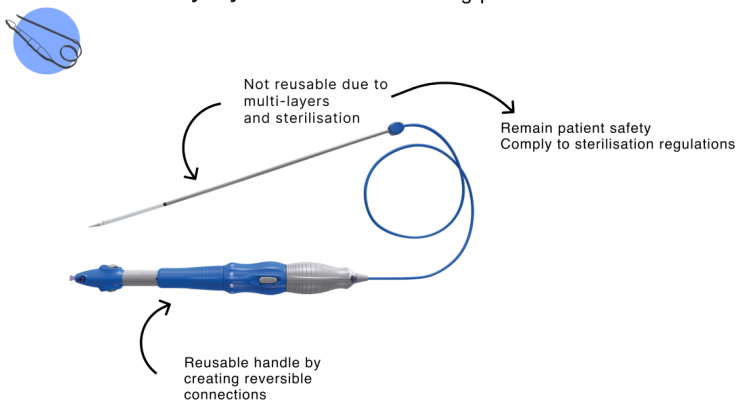


12.6 Co-creations

1 OEM & ESCH-R

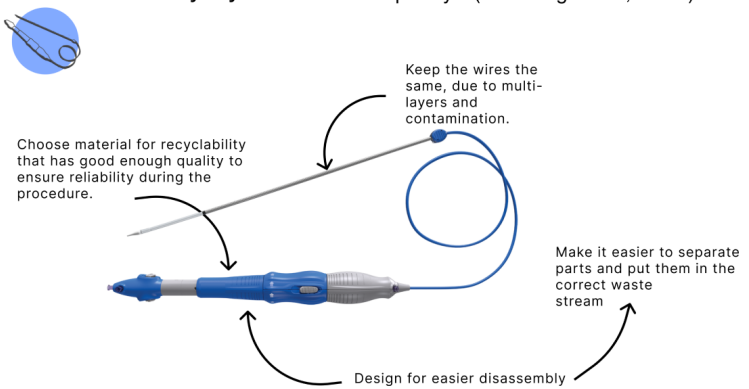
01 Reusable delivery system

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



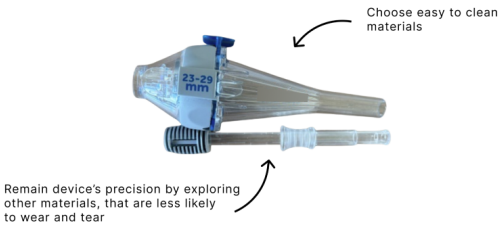
02 Recyclable delivery system

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



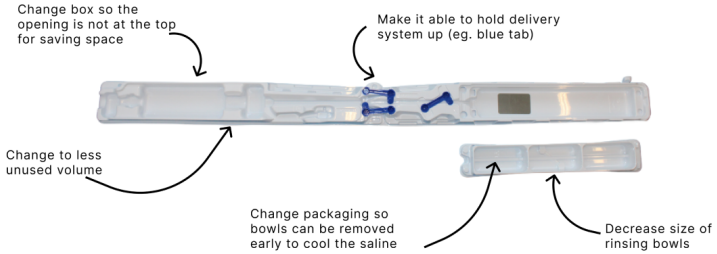
03 Reusable loading system

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

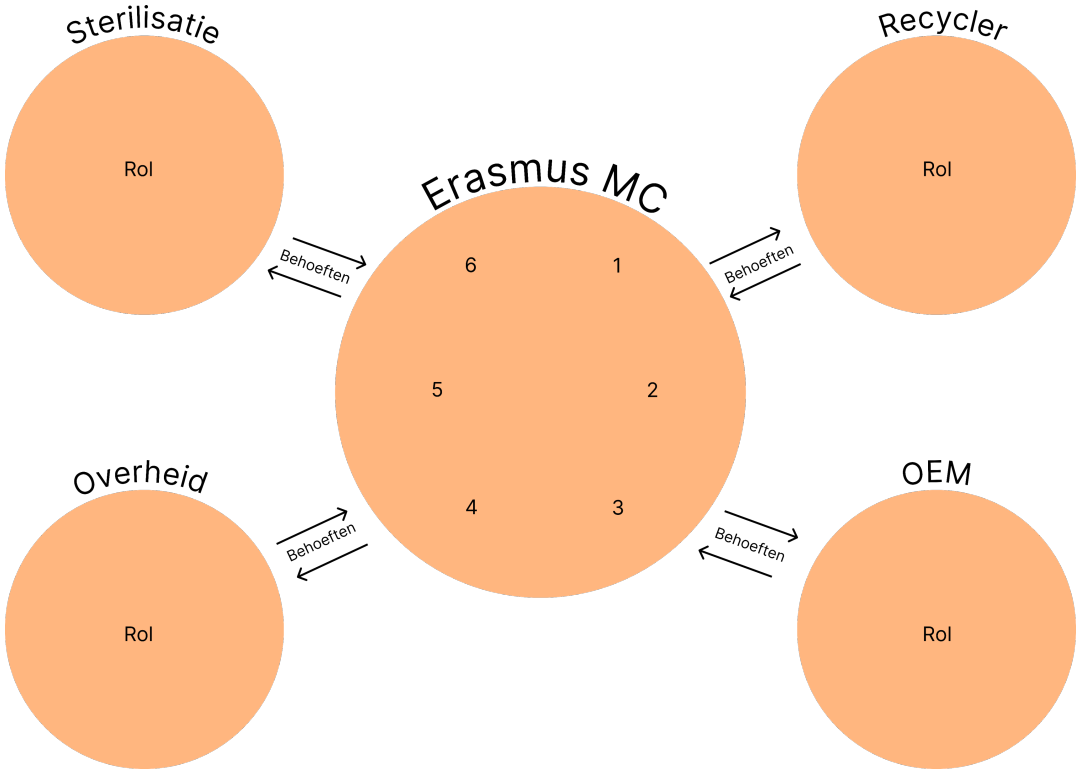


04 Reduce / rethink packaging

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

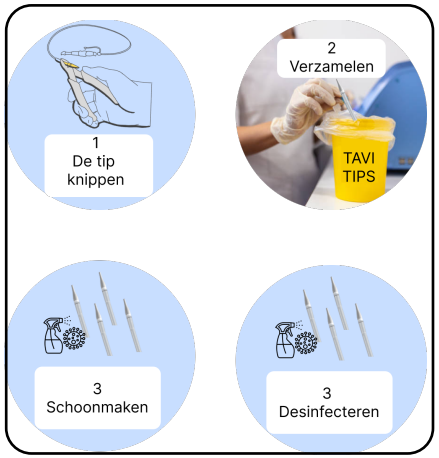


2 Hospital



Scenario 1

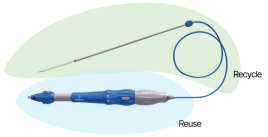
Scenario 2



Scenario 3

3 OEM

Partly reuse

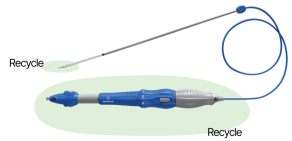


100 % **incineration** | 75% **recycle** 25% incineration | 75% **reuse** 25% recycle | 100% **reuse**

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

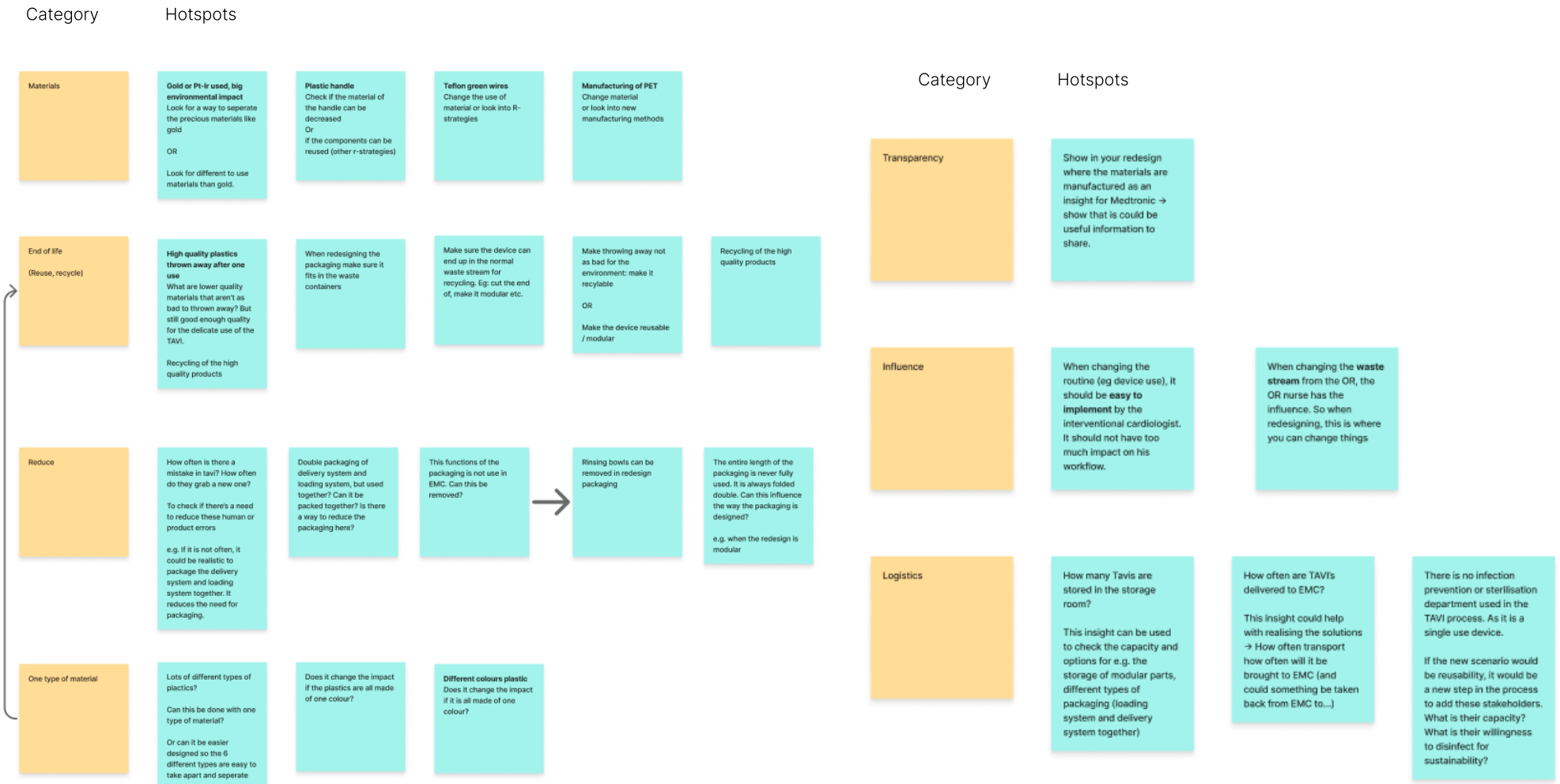


100 % **incineration** | 75% **recycle** 25% incineration | 75% **reuse** 25% recycle | 100% **reuse**

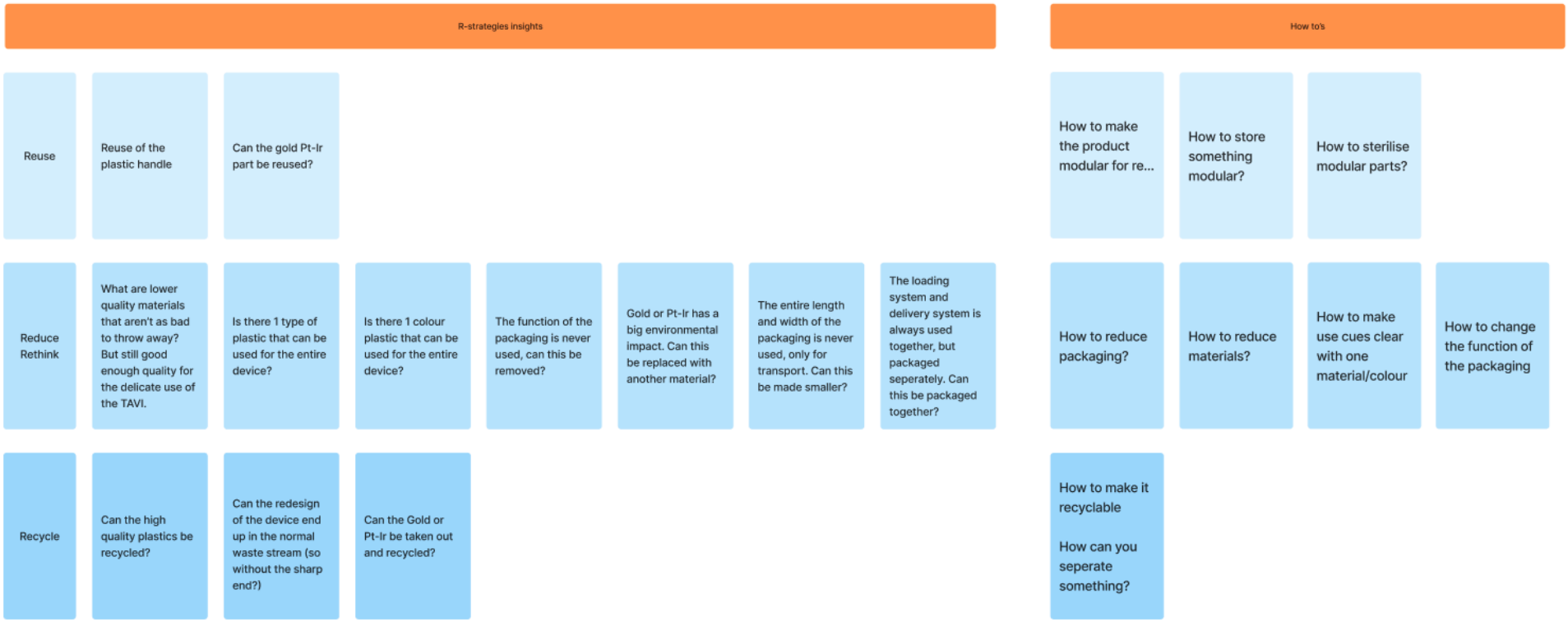
Phase 0 2026 | Phase 1 2035 | Phase 2 2045 | Future

	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

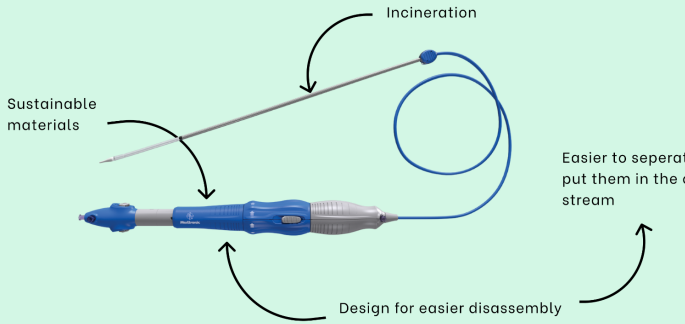


12.8 Design directions

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)

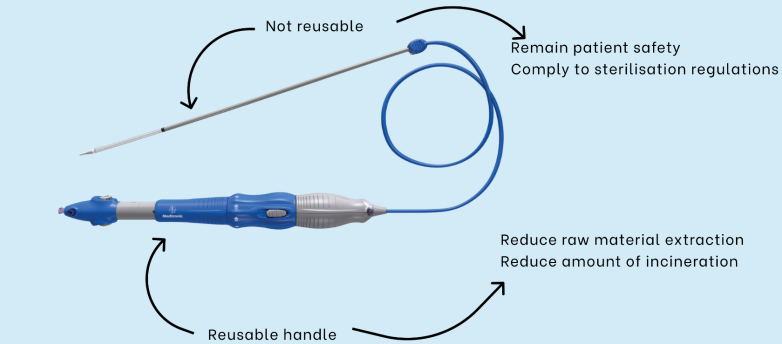


02 PMI

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.

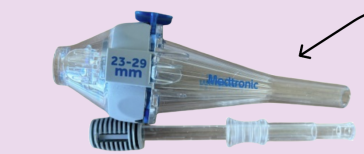


01 PMI

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

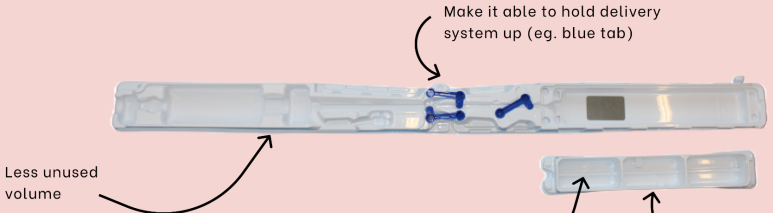
Other material that iss less likely to wear and tear

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

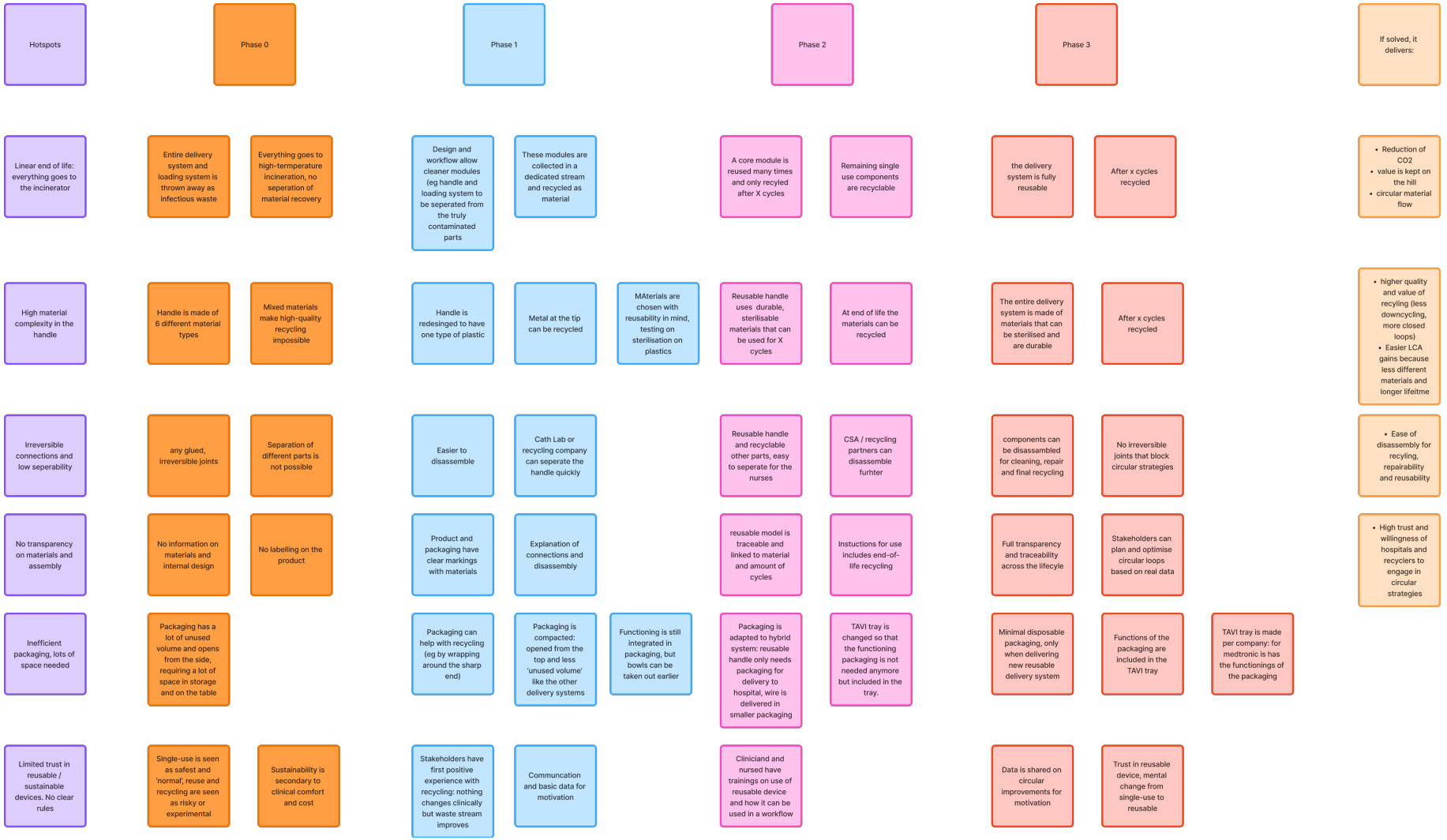
Smaller rinsing bowls.

04 PMI

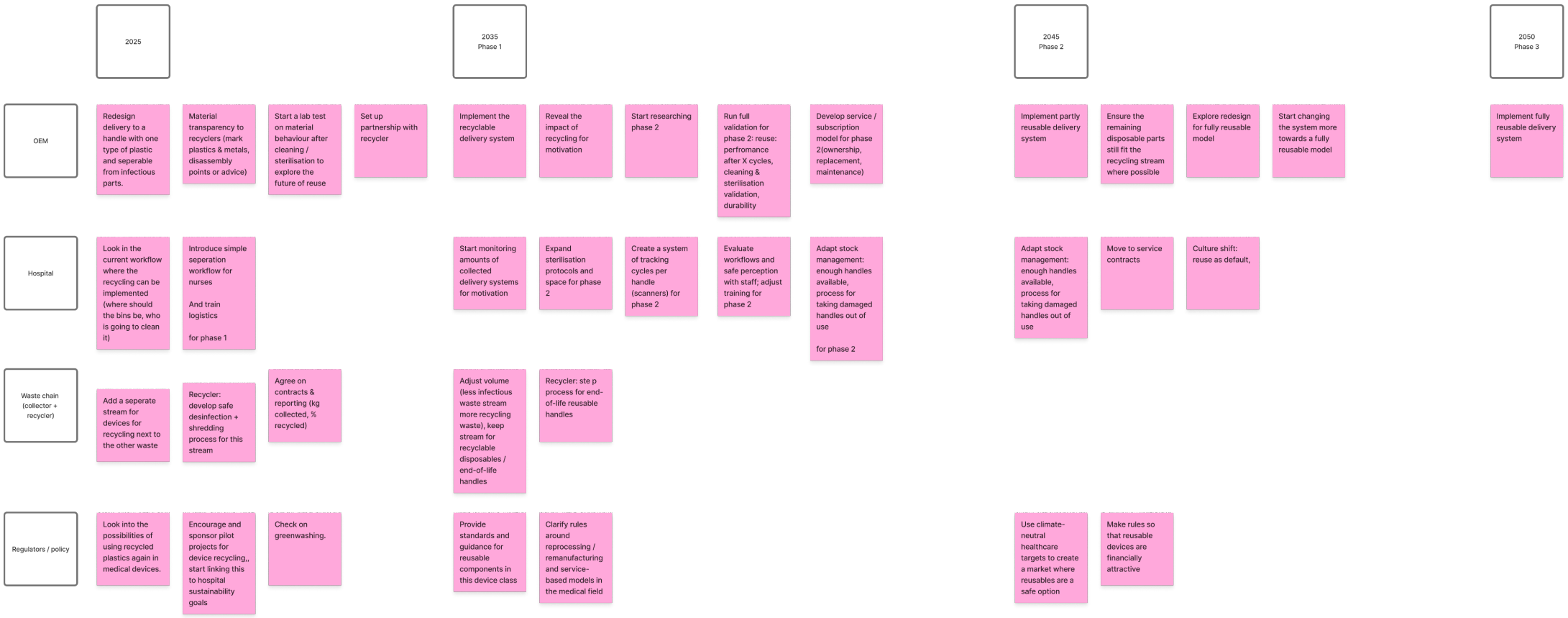
PLUS	MIN	INTERESTING
• **Low hanging fruit**, it's a quick win • Relatively **easy to implement** • **People from Medtronic are already working on this.** Could help with collecting information. • Less unused space means **lower transport and storage space**	• The **packaging will stil be necessary and 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

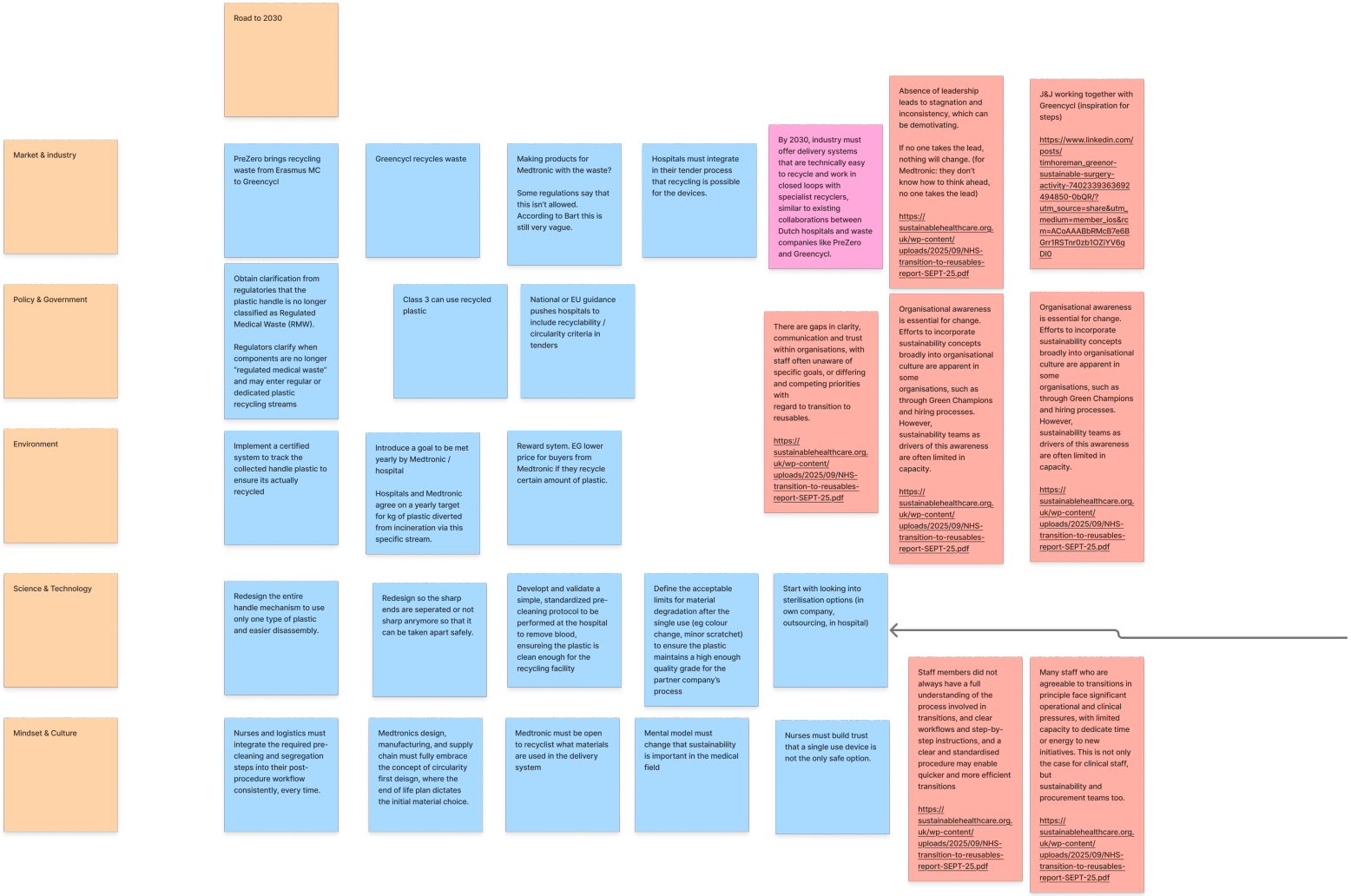
1. Translating the hotspots to design opportunities per phase



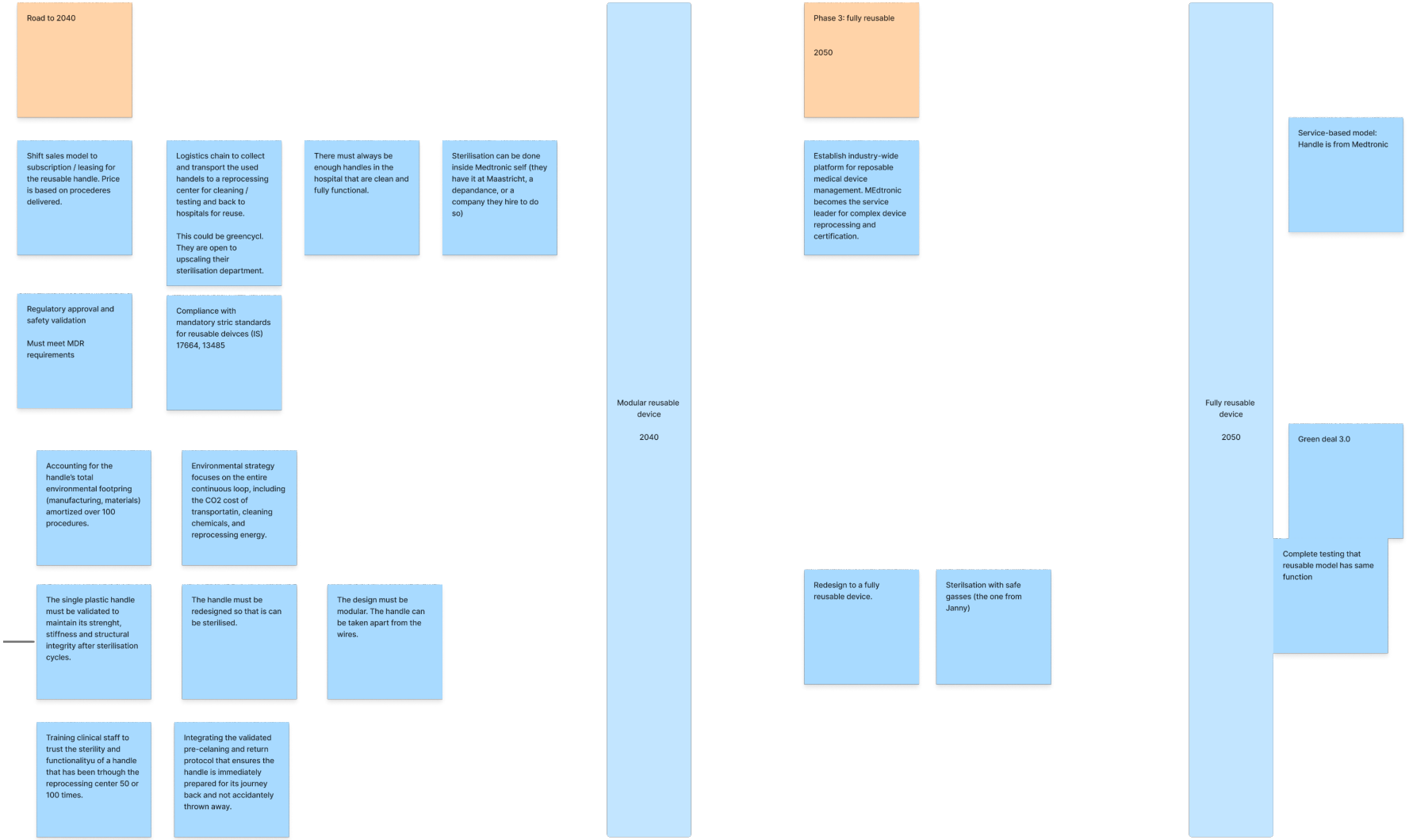
2. Using stakeholder perspectives for actions per phase



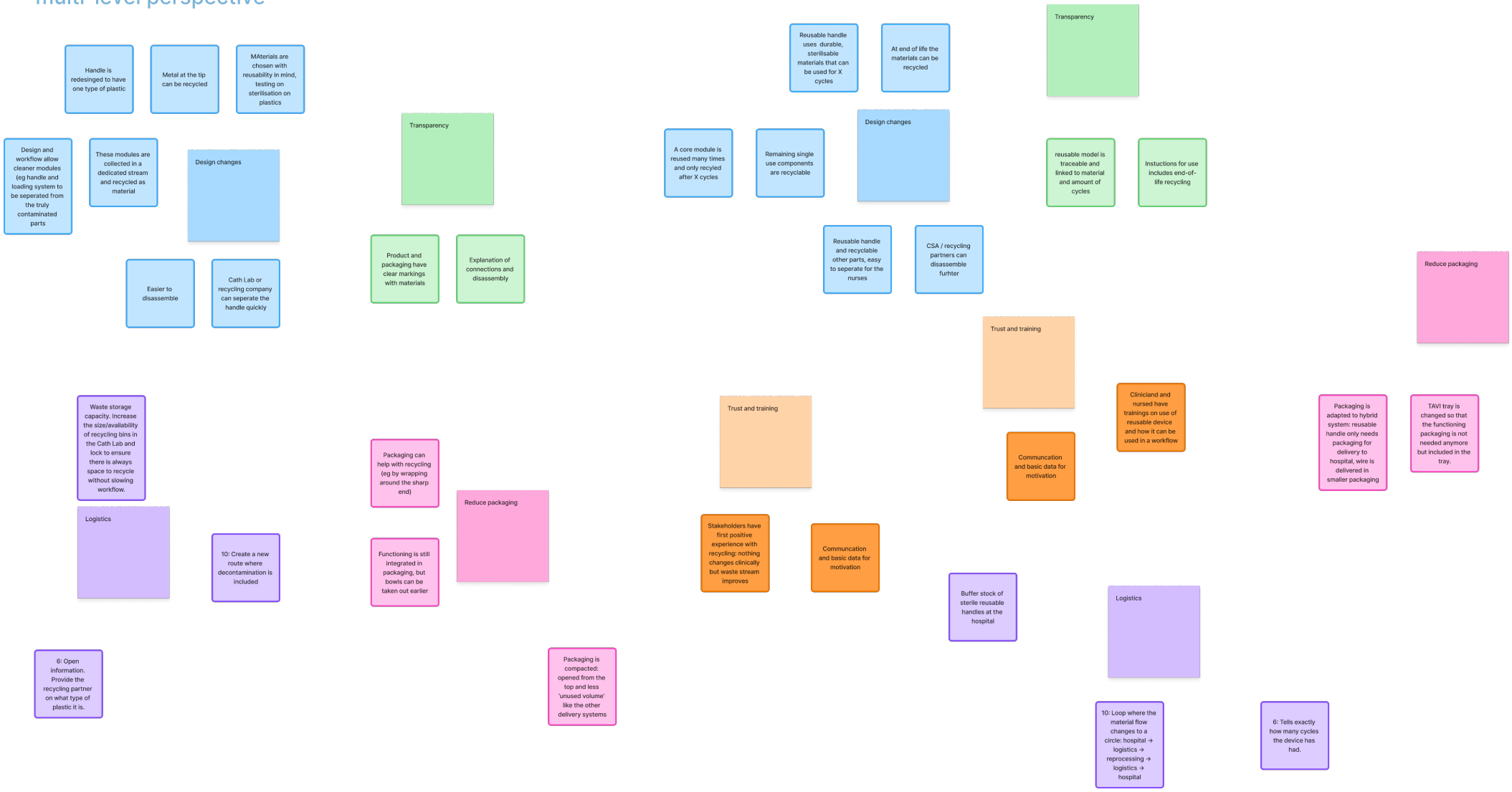
3. Using the multi-level perspective for actions per phase



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