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Circular economy for medical devices: Barriers, opportunities and best practices from a design perspective

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ABSTRACT

In an era of electronics-driven healthcare, the disposability of many medical devices raises environmental concerns. Transitioning these devices towards a circular economy, involving practices like reuse, remanufacturing, and recycling, holds promise. Our paper explores this transition through desk research, literature review, and expert interviews, examining the current state of circular design in electronic medical devices. We unveil barriers, opportunities, and design recommendations for circularization. First, we highlight the circularity potential of medical devices currently on the market, implementing e.g. refuse, reuse, recycle, etc. Second, we present barriers for circular medical device design, (e.g. (perceived) safety and infection risks, (perceived) regulatory difficulties, financial constraints, and difficulties in collection and separation) and opportunities to overcome these barriers. Finally, we present 29 design-specific recommendations for creating circular medical devices. Our insights into circular healthcare practices urge design engineers to integrate sustainable principles into medical device development without compromising safety, quality, or functionality.

1. Introduction

Circular economy principles hold the potential to transition the medical device industry towards a more sustainable future. This is important, as healthcare's current global climate footprint is greater than all aviation and shipping combined (Karliner et al., 2019). An increasing number of medical devices are designed for single use, a development that coincides with the rapid advancement of digitization in the field (Alkatout et al., 2021; Menvielle et al., 2017). While those technological advancements appear promising in improving clinical outcomes (Yan et al., 2020) and single-use devices may minimize cross-contamination risks and increase manufacturers' profits, e-waste is one of the fastest-growing types of waste and awareness about this in healthcare is low (Subhprada and K, 2017).

Our research focuses on mitigating the environmental impact linked to *active medical devices*, which are defined by the European medical device regulations (EU-MDR) (Regulation, 2024) as "any device, the operation of which depends on a source of energy other than that generated by the human body for that purpose, or by gravity, and which acts by changing the density of or converting that energy". In this paper we use the term to describe any electronics-based device that is intended by the manufacturer for specific medical purposes for human use. The

strong market growth of electronics-based medical devices underscores the timeliness of this research; when considering medical wearables, for example, 83 million new units were brought to the market in 2020 alone (Mück et al., 2019). At the same time, recycling of non-infected healthcare waste is still very limited, and infectious medical waste is routinely incinerated, owing to safety concerns and regulatory restrictions (Joseph et al., 2021). This leads to a considerable loss of valuable materials.

The healthcare industry is becoming increasingly mindful of the need for practices, procedures, and devices that fit in a circular economy and are environmentally sustainable. A circular economy is a restorative or regenerative system that aims to circle materials and products back into the economy for reuse and recycling, in an effort to 'design out waste' (Moreno et al., 2016). Circular designs are products designed to fit into a circular economy (Kane et al., 2018) using strategies like reuse, remanufacturing, and recycling. A comprehensive inventory and assessment of the current state of circularity in medical devices and manufacturer practices is currently lacking. Such an inventory and assessment could be used by the medical industry as a benchmark to improve the circularity of their current offering.

While some research has examined the barriers and opportunities to healthcare's circular transition (Kane et al., 2018; MacNeill et al., 2020;

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Alfina et al., 2022; Jafarzadeh Ghouschi et al., 2022), most of the identified barriers and opportunities are based on reviews of non-healthcare-related literature. Examples of barriers to circularity that may apply to active medical devices are: insufficient product traceability (Kandasamy et al., 2022), lack of data privacy and security (Kandasamy et al., 2022; Despeisse et al., 2017), and the lack of realistic business models (Kirchherr et al., 2018; Govindan and Hasanagic, 2018). Notably, although literature describes a lack of circular product design as a barrier to circularity (MacNeill et al., 2020; Bressanelli et al., 2019; Kumar et al., 2021), specific circular design guidelines for medical

devices are yet to be developed.

These research gaps need to be bridged to enable successful circular design of active medical devices. Our research aims to offer insights into the current state of circularity in medical device design, improve understanding of challenges and opportunities of making medical devices more circular, and provide design-specific recommendations. We do so by answering the following research questions:

- What circular medical devices are already on the market, and what can we learn from their strategies to drive future circularity?

Table 1
R-strategies definition and circularity scoring method.

Circular strategy (strategy type)	Definition	Max score	100 % score is given when ...	50 % score is given when ...
Refuse (Design)	Make device redundant by abandoning its function or by offering the same function in a radically different, more sustainable device. <i>Example: replacing a hearing aid device by a mobile application that amplifies sound, making the hearing aid device redundant in certain situations or scenarios.</i>	7	The device functionality could eliminate the use of one or more other devices and does so in a radically more environmentally sustainable way.	The device eliminates only parts of medical devices, or only for certain use scenarios, and does so in a radically more environmentally sustainable way
Rethink (Design)	Make device use more intensive (e.g. through sharing products, or by putting multi-functional products on the market). <i>Example: adapting the function of a wearable sensor by adding user profiles, making it shareable among multiple users instead of using one device per user.</i>	6	Device is made to be used more intensively than its counterparts by using multiple strategies, such as: Being used by multiple users at a time. Providing multiple functions. Being able to be used at locations that previously was not possible.	Device is made to be used more intensively than its counterparts by using only one of the strategies presented for the 100 % score.
Reduce (Design)	Increase efficiency in product manufacturing or use by consuming fewer natural resources and materials. <i>Example: Minimizing the amount of electronics used in laparoscopic devices, as some laparoscopic procedures can safely be performed with mechanic instruments.</i>	5	Device reduces its environmental impact, in comparison to equivalent devices, through both: Using less materials/resources in the manufacturing and/or use stage. Minimizing energy consumption during the manufacturing and/or use stage.	Device reduces its global warming potential in just one way of the strategies presented for the 100 % score.
Reuse (Technical)	Reuse 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) <i>Example: partly reuse a heart catheter after removing infectious parts, cleaning, disinfecting and sterilizing the reusable parts, and preparing them for the next use.</i>	4	Device is made with the purpose of being reused (which may include decontamination) for the same purpose without reduction of performance or quality of patient care. Maintenance/repair of the device is part of the service to extend the devices life even further.	Only one part of the device can be reused while the rest is single use, or the reusable device does not have maintenance/repair services.
Remanufacture (Technical)	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. <i>Example: perform high level disinfection and functionality tests on all components of a used pacemaker, and restore the device to a better than new condition for the next user.</i>	3	At least 50 % of the parts of the discarded device are brought back into manufacturing to develop a remanufactured device with the same function and a device quality that is similar or better than the original device.	Some, but less than half or the parts of the discarded devices are used in the remanufacturing cycle.
Repurpose (Technical)	Use discarded product or its parts in a new product with a different function <i>Example: updating the software of an ECG monitor to make it suitable to be used as a monitor or screen for any other type of device.</i>	2	The entire discarded device is being reused for a different purpose or function. This may be intended by design or initiated by the user at EoL.	Only part of the discarded device is being reused for a different purpose or function. This may be intended by design or initiated by the user at EoL.
Recycle (Technical)	Process materials to obtain the same (high grade) or lower (low grade) quality <i>Example: make disposable bags of a dialysis machine of safe but recyclable material and enable the process to create recycled granulate for production.</i>	1	The device is made to be easily recyclable. There is a recycling program in place.	The device is made for easy recycling. There is no recycling program, but recycling is encouraged with detailed instructions.
Renew (Bio-cycle)	Materials that can safely be returned to the biosphere are used in the production of the device, to enable processes that together help regenerate natural capital, such as composting and anaerobic digestion. <i>Example: make the lid of a smart pillbox of PLA, removing the electronics after use, and letting it biodegrade in days at a composting plant.</i>	1	At least 50 % of the parts are suitable for (tissue) regeneration, composting, or biodegradation and has a renew program in place.	Device parts are suitable for renew strategies, but this is only true for less than 50 % of all materials and/or there is no renew program in place.
Recover energy (Waste)	Incineration of materials with energy recovery <i>Example: in the incineration of a laparoscopic device, capture energy while burning non-infectious and non-hazardous parts (excluding batteries).</i>	0	Device is incinerated upon EoL.	Not applicable

- What barriers to the circular transition can be found, how likely do they occur, and what are potential opportunities to overcome them?
- What circular design guidelines can we identify based on the outcomes of these two research questions?

In this paper, we first describe a list of 346 active medical devices from all over the world that employ circular strategies (Hoveling et al., 2024). Thereafter, we share the most common barriers that make circularity challenging in the healthcare context, and opportunities to overcome them. Our final contribution is a list of design-specific recommendations that help medical device engineers and designers drive the medical circular transition through their expertise.

2. Method

The research was divided into three phases: the best practices inventory, the barriers and opportunities, and the consolidation of all findings into a list of design-specific recommendations.

2.1. Best practices inventory

We used desktop research (combining multiple data sources), field research, and expert interviews, with the goal to identify active medical devices that were on the market in 2023. We selected those devices that employed at least one circular strategy (as defined in Table 1: refuse, rethink, reduce, reuse, remanufacture, repurpose, recycle, or renew) and stored them in an Excel database (Hoveling et al., 2024).

For the field research we interviewed circular economy experts, medical device manufacturers and healthcare workers and we visited a major MedTech trade fair, looking for active medical device innovations that used circular strategies. Additionally, we queried LinkedIn to find additional device examples. For our desktop research, we reviewed relevant trade journals and catalogues of medical device manufacturers.

To ensure a good representation of worldwide medical device examples, we selected 13 countries (representing various income levels) from different continents for catalogue review: Norway, Australia, Mexico, USA, Germany, India, China, Japan, South Africa, Kenya, Brazil, Sweden, and the UK. These countries were chosen based on the location of major medical corporations and each country's export rate of active medical devices, obtained from OEC statistics (OEC, 2023) and through desk research.

For each country, we examined the medical device catalogues of several manufacturers. For feasibility reasons, we limited our search to a maximum of 10 manufacturers per country and 10 devices per manufacturer. However, due to the size of the USA, we doubled the manufacturer limit for this country. When more than 10 device examples were available for one manufacturer, our focus shifted to achieving a wider variety of device categories. Our country sample covered eight of the top 10 medical device companies in the world (Proclinical, 2023). Therefore, we analyzed the resulting two, Philips and Medtronic, separately.

All selected devices were stored in an Excel sheet mentioning the company name, country, device name, device description, URL, use location (in healthcare facility, at home, or both), medical criticality (based on the MDR-EU745 medical device regulations device classifications), device size, used circular strategies, number of strategies used, circularity rating, and explanation of circularity rating. We assumed (based on (Kane et al., 2018)) that the degree of circularity would be influenced by the economic value of a device; i.e., the more expensive a device, the more likely that circular strategies would be implemented because of value retention and cost savings. However, economic value (or sales price) was hard to determine through desktop research. We therefore categorized devices based on size, recognizing that size is not a direct proxy for economic value, as it does not consider factors such as, for instance, device complexity.

To determine which devices had the highest circularity potential, we developed a circularity scoring method based on the hierarchy and

original definitions of the R-strategies (Potting et al., 2017). The most important adaptations we made to the definitions of the circular strategies hierarchy:

- For refuse, we added the notion that the replacement device must not only be radically different, but also more environmentally sustainable.
- We introduced renew (regenerate, compost, biodegrade), akin to the bio cycle in the Butterfly Diagram (Ellen MacArthur Foundation, 2023), as an option for parts unsuitable for 'techno cycle' strategies.
- We merged refurbish and remanufacture despite distinct definitions, driven by identical processes due to the high-quality standards for medical devices.
- We merged reuse and repair. While recognizing repair as a distinct R-strategy, in our research we found repair and maintenance frequently mentioned together without further clarification. As we consider maintenance to be an intrinsic part of reuse, we categorized repair and maintenance under reuse, awarding bonus points for maintenance and repair to address this issue.

In the R-strategies hierarchy, *refuse* is considered the most and *recover energy* the least favorable strategy. The further up the hierarchy, the more points the device was given. Based on Table 1, the circularity score was calculated in the following way: $Circularity\ score = (sum\ of\ points\ from\ strategies) + (number\ of\ strategies - 1)$. Devices do not only score higher based on which strategies they address, but also on the number of strategies. The argumentation is that e.g. if device A can be *remanufactured*, *repurposed*, and *recycled*, it should have a higher circularity score than device B that only addresses *rethink* (even though *rethink* is further up the hierarchy). In this example, device A receives two bonus points for addressing more than one strategy (1 point for each strategy without counting the first strategy). Although we strive for as many circular strategies as possible, we are aware that not all strategies can be combined. For example, *recycle* and *renew* are often mutually exclusive and *repurpose* and *remanufacture* are often not easily combined.

2.2. Interviews and literature review to identify barriers and opportunities

To uncover barriers to the circular design of active medical devices and opportunities to overcome these barriers, we employed two methods: expert interviews and a systematic literature review. Prior to the expert interviews and systemic literature review, we performed an initial search of literature using Google Scholar to help identify key concepts to explore further (i.e. potential safety, financial, systemic, regulatory, technological, and social barriers and opportunities). This helped us develop our interview protocol and systemic literature review search string. In this initial search, we utilized various search keywords related to sustainability and healthcare, including terms such as 'barriers', 'challenges', and 'limitations'. Initially, our focus was on industrial design, but we broadened our search to include medical literature using keywords suggested by Kane et al. (2018). In this section, we further explain the approach taken for the expert interviews and systematic literature review.

2.2.1. Interviews approach

We conducted 21 expert interviews with participants from diverse backgrounds, selected based on their profession and expertise (Table 2). Interviews included 1–3 individuals, and no individuals were present in more than one interview. Semi-structured interview questionnaires (Appendix A) were used and adapted based on the expertise of the participant. The interviews were video or audio recorded, transcribed and proofread using Sonix.ai. Coding was done in ATLAS.ti. Interesting quotes were highlighted and labeled as 'barrier' or 'opportunity' and additionally labeled with a code describing the main topic of the quote. Examples of such codes are 'safety risks' and 'terminology confusion' for

Table 2
Interview participants.

#	Participant category	Expertise	Number of people in each interview
P1	Sterilization facilities	External sterilization	2
P2	Sterilization facilities	Internal sterilization	1
P3	Manufacturers	Engineering, supply chain, and <i>parts harvesting</i>	2
P4	Manufacturers	Design Engineering	2
P5	Manufacturers	Strategy and design engineering	3
P6	Manufacturers	Research and development	1
P7	Hospital procurement	Academic hospital procurement	1
P8	Hospital procurement	Non-academic hospital procurement	1
P9	Hospital procurement	Non-academic hospital procurement, and intensive care	2
P10	(International) foundations	Sustainable use of natural resources	3
P11	(International) foundations	E-waste responsibility	3
P12	(International) foundations & (hazardous) waste handling	E-waste handling, and recycling	2
P13	Collection systems developer	Circularity collection systems	1
P14	Collection systems developer & recycling facilities	Recycling & collection	1
P15	Recycling facilities	Metal and electronics recycling	1
P16	Recycling facilities & (hazardous) waste handling	Plastics recycling	1
P17	(Hazardous) waste handling	Waste handling policies & practices, and handling sharps	3
P18	Remanufacturing experts	Remanufacturing of construction machines, and circular business concepts	1
P19	Remanufacturing experts	Remanufacturing of devices and components, and relevant regulations	1
P20	Bio cycle / reduce experts	Design engineering, bio-design and biomaterials	1
P21	Bio cycle / reduce experts	Expert on bio cycle processes, and material choices	1

barriers and ‘traceability’ and ‘innovation investment’ for opportunities. All codes with similar meanings were merged into one overarching code (e.g. ‘device contamination’ and ‘patient infections’ were merged into one barrier: ‘safety, infection, and contamination risks’). To enhance the reliability of our coding process, we engaged two independent researchers who reviewed and checked the codes prior to merging them. Discrepancies identified during the review were discussed in iterative sessions until full consensus was reached. As the scientific articles of the literature review were being coded simultaneously (by two independent researchers), we took steps to align the interpretations of the interview codes with those derived from the literature review. This alignment further fortified the robustness and coherence of our coding framework.

2.2.2. Literature review approach

The literature review was done in PubMed and was limited to scientific articles published in or after 2018, as our initial search yielded limited relevant articles predating that timeframe. We employed the search string below.

((device AND (healthcare OR "health care" OR medical OR hospital OR surgical OR "intensive care" OR ic) AND (("sustainable design" OR

"circular economy" OR "circular design" OR recyc1* OR "environment* sustainab**" OR reuse OR "carbon footprint" OR resterilizat* OR repurpos* OR reproces* OR "eco design" OR "environment* friendly") AND (barriers OR obstacles OR hurdle* OR limit* OR boundar* OR hamper))) AND ("2018/01/01"[PDAT]: "2023/02/24"[PDAT]) AND (English [lang]) AND (Journal Article[ptyp]))

The search string focused on healthcare devices, circular economy, barriers, and (eco)design. To prevent the misinterpretation of "circularity" as e.g. circular RNA, drug delivery systems were excluded. Initially, 377 abstracts were screened, with 101 meeting inclusion criteria (articles related to both circular economy and healthcare devices/materials written in the English language). For 96 out of 101 articles, we were able to gain access to the full text PDFs. A systematic approach was applied, noting the paper’s topic, identified barriers and opportunities based on a full-text search using predefined synonyms of the words ‘barrier’ (e.g. challenge, limitation, obstacle) and ‘opportunity’ (e.g. advantage, benefit, alternative). The analysis involved detailed reading while evaluating whether the searched terms related to actual circularity barriers when viewed in-context and coding them accordingly. Synonyms that brought up no results (e.g. achieve, combine) or too many irrelevant results (e.g. increase and change) were excluded. The literature was coded in the same ATLAS.ti file and in the same way as the interview transcripts. As the analysis of two of the 96 papers did not reveal any relevant results, the final number of included articles was 94.

3. Results

3.1. Current state of circularity in healthcare

Our search strategy allowed us to review more than 1400 active medical devices. Of these, 346 devices (about 25 %) used at least one circular strategy. The full dataset of 346 devices can be found in the online data repository of Dutch Universities of Technology (Hoveling et al., 2024). On average, the 346 devices had a circularity score of 4.5, ranging from 2 (minimum score) to 20.5 (maximum score). Two thirds (67 %) of the devices only implemented one strategy, while only 18 devices (5 %) had a circularity score ≥ 10 . Some devices implemented two strategies (25 %); but three (7 %) or four (1 %) strategies in one device seemed uncommon. However, all 8 circular strategies we searched for were found at least once. Strikingly, as displayed in Fig. 1, from all 346 active medical devices, 95 % was reusable for more than one product life cycle. (e.g. an active surgical instrument that can be reused for a next surgery on a different patient after going through decontamination processes (e.g. cleaning, decontamination, and sterilization)). For 49 % of these reusable devices, this also included maintenance/repair services. Other circular strategies were implemented to a much lesser extent, although rethink (13 %), remanufacture (12 %), reduce (10 %), refuse (7 %), and recycle (5 %) were more common than repurpose (0.2 %), and renew (0.2 %).

Based on the outcomes of our desktop research, we conclude that the following circular strategies are most common for the top 15 devices:

- Introducing devices that eliminate the use of other less environmentally sustainable devices (refuse).
- Enabling sharing among users or offering multiple functions in one device (rethink).
- Minimizing the use of material and energy consumption (reduce).
- Reusing devices (after decontamination) for multiple use cycles (reuse).
- Designing devices to be remanufacturing at the end of life (remanufacturing).

Our results also indicate that the use of circular strategies seems to depend on the size, use location, and medical criticality of the device. As can be seen in Fig. 2, most circular active medical devices we identified

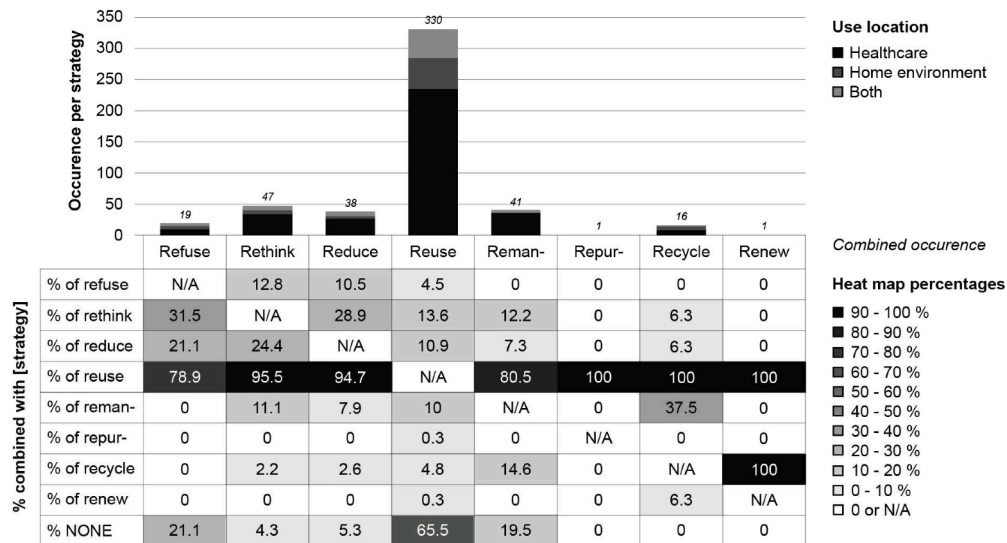


Fig. 1. Occurrence per strategy and use location and combined occurrence of multiple strategies.

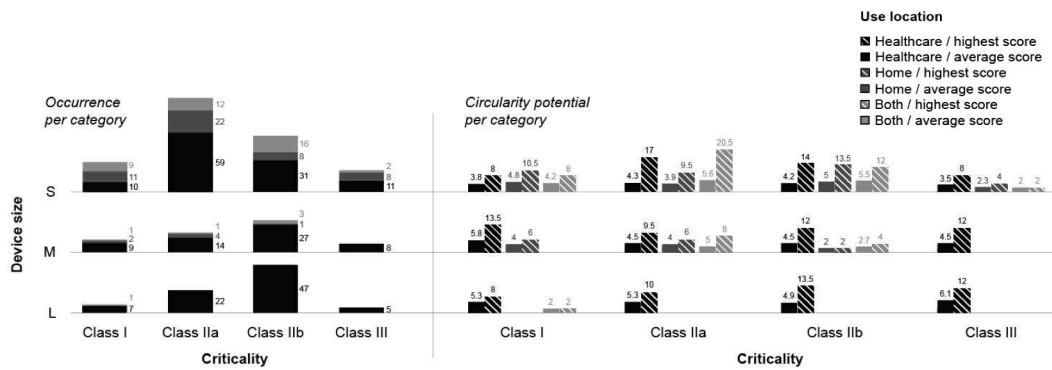


Fig. 2. Occurrence and circularity potential per category.

are small devices (60 %), most devices are used in a healthcare setting (71 %), and have a low/medium or medium/high medical criticality (IIa or IIb MDR classification, each 38 %). Overall, as also displayed in Fig. 2, based on our circularity rating, smaller devices with a low/medium medical criticality (class IIa) seems to score higher than devices from other categories.

3.2. Barriers to circular transition of medical devices

The set of 94 articles covered the following topics: reuse and decontamination (62 %), environmental impact and LCA (12 %, tech) innovation (6 %, reverse) logistics / strategies (6 %), repurpose (4 %), environment friendly material (3 %), engagement / attitudes (2 %), recycling (2 %), and circular design (2 %). This underlines the finding of Section 3.1 that currently healthcare has a large focus on the strategy of reuse. Additionally, 24.5 % of the work was related to the COVID-19 pandemic, discussing the difficulties of mitigating cross-contamination risks in a circular economy.

In total, we highlighted 1948 quotations from 21 interview transcripts and 94 articles, which were sorted under 102 unique codes related to barriers, opportunities, and/or design specific guidelines. Table 3 shows the 31 barriers to the circular transition of medical devices that resulted from the coding of the interviews and scientific articles. The barriers are divided in six categories, and numbered and sorted based on their occurrence.

Our results indicate that (perceived) safety risks, e.g. infection and decontamination concerns, emerge as the most common barrier to

circularity in medical devices. Other significant barriers are challenges with collecting and sorting devices, (perceived) regulatory constraints, financial limitations, unsuitable device characteristics, and lack of awareness about the circular economy. In general, overcoming ingrained linear norms and addressing stakeholder issues, such as social acceptance, collaboration, and terminology confusion, seems to be challenging. Implementing circularity introduces new barriers like scalability and maintaining device quality. Although some barriers are typical to circular economy transitions in general, barriers like (perceived) safety risks, (perceived) regulatory constraints, focus on clinical outcomes, and problems surrounding decontamination processes (e.g. careless decontamination adherence and unsuitable device characteristics for decontamination) are more specific to medical devices.

3.3. Opportunities for circularizing healthcare

We identified opportunities across the general healthcare ecosystem, social acceptance, manufacturer suggestions, and product development. However, it should be noted that the product development opportunities are not included in Table 4. In Table 4 opportunities within the first three categories are ranked based on their frequency in interviews and literature. Additionally, the product development opportunities were assessed separately by comparing them with findings from desktop research on the current state of circularity in medical devices market. These findings were then transformed into design-specific recommendations, detailed in Section 3.2.

Table 3
Overview of barriers.

#	Barrier	Finding based on analysis of ...	Interviews	Literature	Example quote
	<i>Category: Safety barriers</i>	<i>Times mentioned</i>			
1.1	Safety, infection, and contamination risks	171	P2, P3, P5, P7, P9, P11, 13, P14, and P16-P20	(MacNeill et al., 2020; Baboudjian et al., 2022; Robertson et al., 2021; Psaltikidis et al., 2021; Forrester et al., 2018; Jena and Sharan, 2021; Lopes et al., 2019; Yorio et al., 2020; Szirt et al., 2023; Washburn and Pietsch, 2018; Ditac et al., 2023; Singleton et al., 2022; Hennein et al., 2022; Parashar and Hait, 2021; Toomey et al., 2021; Parker, 2023; Goel et al., 2021; Santos et al., 2020)	“... it can be dangerous ... if you come into contact with certain pharmaceutical substances, sharps, lots of types of things, they can be contaminated with viruses from other persons” (P13).
1.2	Focus on use and clinical outcomes, opposing circularity	36	P3, P4, P7-P10, and P14	(MacNeill et al., 2020; Jena and Sharan, 2021; Lopes et al., 2019; Washburn and Pietsch, 2018; Singleton et al., 2022; Hennein et al., 2022; Parker, 2023; Farrell and Smyth, 2021; Jinia et al., 2020; Wilson et al., 2020; McAvoy et al., 2021)	“Regulators, accreditors, and professional societies focus almost exclusively on individual patient risk. Thus, they have tended toward the default position that patient safety is optimized by eliminating reuse of medical devices” (MacNeill et al., 2020).
1.3	Dangers of hazardous components such as batteries and toxins	23	P3, P6, P8, P9, P12-P17, P19, and P21	(Jinia et al., 2020; Corsaro et al., 2021)	“Some chemicals may be toxic and may also leave stain or odor on the equipment post sterilization, ...” (Jinia et al., 2020).
1.4	Careless adherence to decontamination method (human factor)	23	n.a.	(MacNeill et al., 2020; Forrester et al., 2018; Agarwal et al., 2018; Allescher et al., 2022; Ventimiglia et al., 2020; Grantcharov et al., 2019; Lee et al., 2021; Link, 2019; Chang et al., 2018)	“insufficient drying before storage was identified as a possible reason for contamination” (Allescher et al., 2022).
	<i>Category: Systemic barriers</i>	<i>Times mentioned</i>	<i>Interviews</i>	<i>Literature</i>	<i>example quote</i>
2.1	Practical difficulties related to collection and separation logistics	145	P1-P4, P6, P8-P16, P19, and P21	(Lopes et al., 2019; Szirt et al., 2023; Washburn and Pietsch, 2018; Singleton et al., 2022; Toomey et al., 2021; Al-Balushi et al., 2019; Naito et al., 2022)	“There are unlimited logistic issues. There is no return flow in place” (P5).
2.2	Difficulty to move away from linear norms	60	P2-P5, P7-P13, P17, P19, P20, and P21	(MacNeill et al., 2020; Robertson et al., 2021; Hennein et al., 2022; Toomey et al., 2021; Naito et al., 2022; Murphy et al., 2023)	“A linear supply chain minimizes liability and complexity for hospitals” (MacNeill et al., 2020).
2.3	Scalability problems and scarcity of materials, devices, equipment, and resources	40	P9, P14-P18, P20, and P21	(Robertson et al., 2021; Forrester et al., 2018; Hennein et al., 2022; Lima et al., 2023; Grantcharov et al., 2019; Hines et al., 2019; Murphy et al., 2023; Petre et al., 2019; Ventimiglia et al., 2020; P, 2023; Rodríguez et al., 2021; Zorko et al., 2020)	“None of the hospitals had dedicated tools and equipment or reprocessing surgical instruments” (Robertson et al., Jul. 2021).
2.4	Global market boundaries	32	P7, P10, P11, P13, P14, and P17	(Forrester et al., 2018; Rowan and Laffey, 2021; Cheng et al., 2021; Williams et al., 2022)	“When it comes to battery-based device, it is also essential to take into consideration the limitations of local contexts, such as the extreme environmental conditions” (Williams et al., 2022).
2.5	Time constraints of all stakeholders	29	P9, P14, P17-P21	(Robertson et al., 2021; Singleton et al., 2022; Al-Balushi et al., 2019; Ventimiglia et al., 2020)	“it takes ten years to change the cap, even though it doesn't really need to have that quality requirement” (P14).
2.6	Specialization / different norms and practices medical/recovery facilities	20	P1, P2, and P14-P16	(Baboudjian et al., 2022; De Wolfe et al., 2019; Williams et al., 2022)	“The basic surgery set of hospital A is not necessarily the same as the basic set for hospital B” (P1).
	<i>Category: Regulatory barriers</i>	<i>Times mentioned</i>	<i>Interviews</i>	<i>Literature</i>	<i>Example quote</i>
3.1	Regulations that complicate the process	125	P1-P6, P8, P9, and P11-P21	(MacNeill et al., 2020; Psaltikidis et al., 2021; Forrester et al., 2018; Jena and Sharan, 2021; Ditac et al., 2023; Singleton et al., 2022; Hennein et al., 2022; Parashar and Hait, 2021; Lima et al., 2023; Mallick et al., 2022; Thamyongkit et al., 2018a; Nacharaju et al., 2020; Khairy et al., 2020; Cassorla, 2021)	“Brazilian legislation prohibits the reuse and reprocessing of CIED, such as pacemakers, defibrillators, and CRT devices” (Lima et al., 2023).
3.2	Limited device knowledge of external parties	6	P6, P12, P18, P19, and P21	n.a.	“Our engineering team needs to reverse engineer devices to understand key requirements and specifications, and make sure we are testing to those specifications” (P6).
3.3	Concerns surrounding data and privacy	6	P3 and P13	(Hennein et al., 2022; Petre and Malherbe, 2020)	“LCAs may rely on estimates of proprietary manufacturing processes that companies may not readily share with researchers” (Hennein et al., 2022).
3.4	Loss of warranty	1	n.a.	(Thamyongkit et al., 2018a)	“Another concern is the loss of coverage under the original manufacturer's warranty when using third-party reprocessing” (Thamyongkit et al., 2018a).

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Table 3 (continued)

#	Barrier	Finding based on analysis of			
	<i>Category: Safety barriers</i>	... Times mentioned	Interviews	Literature	Example quote
	Category: Financial barriers	Times mentioned	Interviews	Literature	Example quote
4.1	Financial constraints of different stakeholders	108	P2-P11, and P13-P21	(Robertson et al., 2021; Psaltikidis et al., 2021; Szirt et al., 2023; Ditac et al., 2023; Singleton et al., 2022; Hennein et al., 2022; Parashar and Hait, 2021; Al-Balushi et al., 2019; Corsaro et al., 2021; Ventimiglia et al., 2020; Hines et al., 2019; De Wolfe et al., 2019; Naito et al., 2022; Ventimiglia et al., 2020; Scalvenzi et al., 2021; P, 2023; Wilson et al., 2020; Legemate et al., 2019) (Yorio et al., 2020; Parashar and Hait, 2021)	“You need economies of scale to be economically successful in something” (P17).
4.2	Differences in device value (high value gets circular priority)	22	P3, P6, P7, P10, P11, P13, P15, and P16		“You need lots of the very small devices to make recycling profitable” (P11).
4.3	Circular economy competition	6	P6, P14, and P16	n.a.	“The cost and complexity of collection needed for circularity creates a barrier to somebody new that’s entering the market” (P6).
	Category: Technological barriers	Times mentioned	Interviews	Literature	Example quote
5.1	Unsuitable device/material characteristics for circular strategies	81	P1-P4, P8, P10-P12, P14-P18, P20, and P21	(Robertson et al., 2021; Lopes et al., 2019; Yorio et al., 2020; Ditac et al., 2023; Hennein et al., 2022; Parashar and Hait, 2021; Lima et al., 2023; Jinia et al., 2020; Link, 2019; Mallick et al., 2022; De Wolfe et al., 2019; Dulal et al., 2022; Steinberg et al., 2020; McEvoy and Eveland, 2020; Wilson et al., 2020; Legemate et al., 2019; Bowdle et al., 2021; Rodríguez et al., 2021; Zorko et al., 2020; McAvoy et al., 2021; Grinshpun et al., 2020; Levine et al., 2021; Whyte et al., 2022) (Ditac et al., 2023; Hennein et al., 2022; Al-Balushi et al., 2019; Lima et al., 2023; Hines et al., 2019; Ventimiglia et al., 2020)	“The design team strictly adhered to the glued solution, as that was the only way to create a completely water tight devices that are still hygienic” (P3).
5.2	Focus on and need for high quality and function of the device	65	P3-P9, P11, P12, and P14-P21	(Ditac et al., 2023; Hennein et al., 2022; Al-Balushi et al., 2019; Lima et al., 2023; Hines et al., 2019; Ventimiglia et al., 2020)	“We are really stressing the material strength envelope to make it lightweight. It ends up bending, creating deformation that is really hard to take from one patient to the next” (P4).
5.3	(Outdated) designs not intended for circular strategies (+ forced obsolescence)	18	P3, P4, P6, P14, P18, and P21	(MacNeill et al., 2020; Lopes et al., 2019; Hennein et al., 2022; Grantcharov et al., 2019)	“We need to design these circular systems for current linear products because they will be here for a long, long time” (P14).
5.4	Inability to perform device updates in circular devices	3	P3	n.a.	“Normally in a life cycle you also see engineering changes. In circularity this must be discontinued, unless you offer a repaired part for the change” (P3).
5.5	Unmanageable device sizes	2	P16	n.a.	“The smallest materials we don’t recycle, we don’t have the technology for that yet, and also the bigger items are returned . . .” (P16).
	Category: Social barriers	Times mentioned	Interviews	Literature	Example quote
6.1	Unawareness about and complexity of the circular economy	78	P2-P11, P13-P15, P17-P19, and 21	(Robertson et al., 2021; Forrester et al., 2018; Singleton et al., 2022; Hines et al., 2019; Ventimiglia et al., 2020; Lee et al., 2021; Peters et al., 2021; P, 2023)	“People are often not aware of the impact of everything we use. Locally, but also in the supply chain” (P8).
6.2	Unclearities in or lack of taking responsibility	65	P1-P5, P7-P11, and P13-P19	(MacNeill et al., 2020; Robertson et al., 2021; Singleton et al., 2022; Hennein et al., 2022; Al-Balushi et al., 2019; Grantcharov et al., 2019; Lee et al., 2021; Hines et al., 2020; Petre et al., 2019; P, 2023)	“Regulation and oversight of the medical device industry occurs via a complex network of organizations, within which roles and responsibilities are sometimes ill defined” (MacNeill et al., 2020).
6.3	Terminology confusion	50	P1-P3, P5-P9, P11, P14, P15, and P17-P20	(Chang et al., 2018; Peters et al., 2021)	“Nobody seems to think about whether someone has the same interpretations. . . this [is] very problematic, since we often think we are talking to each other, while we are not really having a conversation” (P7).
6.4	Lack of trust/social acceptance that leads to favorable behaviors (partly due to greenwashing)	48	P7-P9, P11, P11-15, and P18-P21	(Baboudjian et al., 2022; Robertson et al., 2021; Singleton et al., 2022; Hennein et al., 2022; Parker, 2023; Farrell and Smyth, 2021; Ventimiglia et al., 2020; Grantcharov et al., 2019; Mallick et al., 2022; Hines et al., 2019; Naito et al., 2022)	“A large percentage, about 24 %, said they didn’t trust remanufacturers. They just didn’t think they were the sort of people they wanted to do business with” (P19).
6.5	Lack of or problems with stakeholder interactions	42	P1-P3, P5, P7, P8, P10, P12, P13, P18, and P19	(Washburn and Pietsch, 2018; Petre and Malherbe, 2020; Petre et al., 2019)	“It is a question to collaborate in a different way for lower environmental impact, . . . but we just don’t have those kinds of conversations” (P7).

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Table 3 (continued)

#	Barrier	Finding based on analysis of			Example quote
		... Times mentioned	Interviews	Literature	
	<i>Category: Safety barriers</i>				
6.6	Attitudes, preferences (or differences between), and lack of support	39	P18-P20	(MacNeill et al., 2020; Robertson et al., 2021; Forrester et al., 2018; Lopes et al., 2019; Singleton et al., 2022; Hennein et al., 2022; Farrell and Smyth, 2021; Ventimiglia et al., 2020; Grantcharov et al., 2019; Mallick et al., 2022; Hines et al., 2019; Naito et al., 2022; Peters et al., 2021; P, 2023; Wilson et al., 2020; McAvoy et al., 2021; Grinshpun et al., 2020)	"That [use of biological materials] is something people are not willing to accept" (P20).
6.7	(Expected) limited environmental benefits of actions	20	P7, P8, P10, P18, P20, and P21	(Singleton et al., 2022; Hennein et al., 2022; De Wolfe et al., 2019)	"We're driving trucks all over the state and interstate to get these [circular] devices to us. I think it would be interesting to understand what the carbon footprint of that is [transporting circular devices]" (Hennein et al., 2022).
6.8	Interpretation of regulations	3	P17	(MacNeill et al., 2020)	"Lack of clear and consistent guidelines has resulted in confusion around standards for reusable device reprocessing. In this environment, many device consumers have resorted to single-use disposables to avoid the potential for error, citation, and liability" (MacNeill et al., 2020).
6.9	Approaching customers	1	P18	n.a.	"How to reach customers [that would purchase remanufactured items]; that is probably also a barrier" (P18).

Our list of opportunities indicate that the circular transition of medical devices could be realized through policies, human factors, and (technological) innovations (such as enabling systems, e.g. related to efficient collection and circular procedures). Circularity can be stimulated through different regulations, guidelines, and standards that manufacturers and users should adhere to. Additional motivation could be driven through creating circularity-related financial benefits, enabling practices, ensuring transparency about environmental benefits, highlighting material scarcity, stimulating normalization, and offering education and training. To make the circular economy work, we also need to establish better stakeholder collaborations, implement system thinking, and improve (circular) design practices. Apart from all this, we need to find a way to ensure successful collection and separation of devices, for example, by sorting devices per type, implementing collection point communication systems, and making use of already existing and centralized collection methods. However, our research also presents an alternative approach: avoiding the need for complicated collection systems by providing circular strategies locally, close to the use site.¹

3.4. Design-specific recommendations

Based on the identified best practices, the barriers and opportunities, and on the results of our interviews and literature review, we developed a set of design-specific recommendations that may help drive medical device design towards a more circular future (Table 5). Some recommendations were directly mentioned in interviews or literature, while others were interpreted based on a combination of the other results (e.g. the notion that mixed plastics cannot easily be recycled, which falls under barrier 5.1, was interpreted as a need to avoid the use of mixed plastics for recycling, which falls under design recommendation 28). Table 5 also indicates which circular strategies the design recommendations apply to. They are ordered based on their relevance in line with

¹ Donating used devices to low-income settings is a potential opportunity to explore. However, it is important to take ethical considerations and additional environmental impacts that may come with this strategy into account.

the hierarchy of the R-strategies and the number of R-strategies they apply to.

Firstly, we recommend engineers to look beyond the circular strategy of reuse: in terms of circularity it may be worthwhile to look into refuse, rethink, and reduce, or to determine whether a device could be made suitable for repurpose or remanufacture once it has reached its maximum number of reuse cycles (as is illustrated by guidelines 2, 18, 21, 22, 23, 24, 25, and 26). Our findings indicate that to develop a circular active medical device, at least 29 different recommendations need to be considered. This underlines a need for further design guidance to help designers and engineers take into account so many guidelines and account for contradictions and exceptions. The most important guidelines are numbers 1–5, as they apply to all circular strategies we investigated. These five guidelines stress that circular medical devices should not be inferior to their (non-circular) predecessors in terms of quality, function, and usability. Another recommendation is to combine as many circular strategies as possible, while prioritizing strategies higher in the hierarchy. Implementation of circular strategies may in some cases lead to increased safety risks (e.g. because of access to batteries or functionality risks after sterilization). It is important to take all possible hazards and risks into account and make sure to mitigate those risks for the intended use of the device, material, or system. Successful circular designs should ideally be supplied with sustainability certificates. It is therefore important to already start thinking about circular strategies and EoL scenarios in the early stages of the design process, as this allows designers to embed circular principles into the product's foundation, optimizing resource use, durability, and EoL recovery. This proactive approach minimizes the need for costly retrofits, fosters sustainable design practices, and aligns with broader environmental goals.²

² Although the need to reduce transport emissions was mentioned in the interviews, the relevance of this guideline is to be discussed, as transportation impacts are generally low or even negligible in this context. However, based on opportunity 1.8, we believe that localization of circular practices has additional benefits that still make this guideline worth looking into in future research.

Table 4
Circularity opportunities.

#	Opportunity <i>Category: General (circular) healthcare ecosystem</i>	Times mentioned	Finding based on analysis of ...		Example quote
			Interviews	Literature	
1.1	Develop circularity-enabling and -stimulating regulations, guidelines, and standardizations.	67	P2, P3, P5, P7, P9, P11, 13, P14, and P16-P20	(MacNeill et al., 2020; Baboudjian et al., 2022; Robertson et al., 2021; Psaltikidis et al., 2021; Forrester et al., 2018; Jena and Sharan, 2021; Lopes et al., 2019; Yorio et al., 2020; Szirt et al., 2023; Washburn and Pietsch, 2018; Ditac et al., 2023; Singleton et al., 2022; Hennein et al., 2022; Parashar and Hait, 2021; Toomey et al., 2021; Parker, 2023; Goel et al., 2021; Santos et al., 2020)	“If right-to-repair were applied to original equipment manufacturers, it could be considered illegal to design devices that preclude reprocessing” (MacNeill et al., 2020).
1.2	Increase and improve reuse and decontamination (cleaning, disinfection and sterilization) of devices and their electronics.	35	P1, P2, P4, P6, P15, P16, and P17	(Baboudjian et al., 2022; Forrester et al., 2018; Jena and Sharan, 2021; Ditac et al., 2023; Parashar and Hait, 2021; Agarwal et al., 2018; Allescher et al., 2022; Ventimiglia et al., 2020; Mallick et al., 2022; Petre and Malherbe, 2020; Petre et al., 2019; Khairy et al., 2020; Wilson et al., 2020; O’Hearn et al., 2020; Rizan et al., 2020; Zulauf et al., 2020; Okano et al., 2022; Kenney et al., 2022; Zha et al., 2022; Thiel et al., 2018; Riditid et al., 2020)	“If such items [like syringes] could be reused and not just thrown away, it would be good” (P16).
1.3	Develop a large variety of new return solutions (e.g. collection point communication systems, smart drop-off points, easy and clear return infrastructure, and centralized collection and separation).	15	P5, P6, P12-P14, and P17	(MacNeill et al., 2020; Psaltikidis et al., 2021; Hennein et al., 2022; Mallick et al., 2022; Peters et al., 2021; Parashar and Hait, 2021)	“There will not be one solution that fits all here. . . . you would probably need to have a large variety of collection solutions” (P14).
1.4	Make use of existing collection infrastructure.	12	P6, P12, P14, and P17	(Ditac et al., 2023; Singleton et al., 2022; Corsaro et al., 2021; Murphy et al., 2023)	“There are synergies to make use of the existing collection methods for waste from hospitals” (P12).
1.5	Categorize and sort devices per type to enable efficient collection and transport.	10	P10, P13, P15	(Petre and Malherbe, 2020)	“There is a need to find these different categories of devices and how you can process them” (P13).
1.6	Take inspiration from other/existing waste streams or methods.	5	P12, and P13	(Murphy et al., 2023; Parashar and Hait, 2021)	“Expertise and learnings from existing and previous recycling schemes can be used to develop and to enhance any future initiatives” (Murphy et al., 2023).
1.7	Consider chemical recycling as an option for polymers that are not suitable for mechanical recycling.	4	P16, P21	(Kleber, 2022)	“A lot of plastic that we cannot recycle in our plants you could, in theory, recycle chemically” (P16).
1.8	Enable the execution of circular strategies close to the use site for efficiency (e.g. in-hospital decontamination, repair, and remanufacturing).	3	P20	n.a	“You could use it and clean it, and already sort of reuse it at the same time. You could have a super local loop because a lot of the materials are already in that environment” (P20).
	<i>Category: Social acceptance</i>	<i>Times mentioned</i>	<i>Interviews</i>	<i>Literature</i>	<i>Example quote</i>
2.1	Increase stakeholder motivation by enabling circularity and creating commitment.	64	P1- P3, P5, P7-P14, and P16-P20	(MacNeill et al., 2020; Baboudjian et al., 2022; Robertson et al., 2021; Forrester et al., 2018; Szirt et al., 2023; Singleton et al., 2022; Hennein et al., 2022; Parker, 2023; Goel et al., 2021; Farrell and Smyth, 2021; Allescher et al., 2022; Mallick et al., 2022; Petre and Malherbe, 2020; Hines et al., 2020; Petre et al., 2019; Parashar and Hait, 2021; Esmaeili et al., 2018)	“We can also come up with a sustainability challenge and have manufacturers come up with solutions; that is called creative procurement” (P7).
2.2	Circularity-related education or training.	62	P9	(Robertson et al., 2021; Forrester et al., 2018; Lopes et al., 2019; Yorio et al., 2020; Szirt et al., 2023; Washburn and Pietsch, 2018; Ditac et al., 2023; Singleton et al., 2022; Hennein et al., 2022; Goel et al., 2021; Agarwal et al., 2018; Allescher et al., 2022; Grantcharov et al., 2019; Thamyongkit et al., 2018a; De Wolfe et al., 2019; Petre and Malherbe, 2020; Murphy et al., 2023; Hines et al., 2020; Petre et al., 2019; Cheng et al., 2021; Scalvenzi et al., 2021; Parashar and Hait, 2021)	“Surgical instrument reprocessing is a complicated procedure and requires training, infrastructure, supplies, and strong organizational principles to be successful”[28].

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Table 4 (continued)

#	Opportunity	Times mentioned	Finding based on analysis of ...		Example quote
			Interviews	Literature	
<i>Category: General (circular) healthcare ecosystem</i>					
2.3	Creating transparency about environmental and safety impacts of (circular) medical devices by means of benchmarking.	34	P7, P9, P12, P19, and P21	(MacNeill et al., 2020; Baboudjian et al., 2022; Psaltikidis et al., 2021; Szirt et al., 2023; Ditac et al., 2023; Singleton et al., 2022; Hennein et al., 2022; Goel et al., 2021; Grantcharov et al., 2019; Petre and Malherbe, 2020; Peters et al., 2021; Petre et al., 2019; Vozzola et al., 2018)	“As hospitals and healthcare providers move toward more sustainable or ‘green’ practices, publicly available, transparent environmental information is needed to support product decisions” (Vozzola et al., 2018).
2.4	Use environmental benefits as a motivator for change.	20	P1, P6, P9, P17-P20	(MacNeill et al., 2020; Szirt et al., 2023; Ditac et al., 2023; Petre and Malherbe, 2020; Petre et al., 2019; Vozzola et al., 2018)	“You can remanufacture to reduce waste, which is a visible moral aspect” (P18).
2.5	Normalize the use of environment-friendly and/or recovery-suitable materials	8	P14, and P20	(Ditac et al., 2023; Parker, 2023; Petre and Malherbe, 2020; Dulal et al., 2022; Rodríguez et al., 2021)	“Reducing material quality, in favor of recyclable and ecofriendly materials, could be a way to save energy while ensuring patient safety” (Ditac et al., 2023).
<i>Category: Manufacturer suggestions</i>					
3.1	Enable financial benefits for customers or for manufacturers through good circular business models.	54	P1-P3, P5-P8, P10, P13, P14, and P17-P20	(MacNeill et al., 2020; Robertson et al., 2021; Psaltikidis et al., 2021; Hennein et al., 2022; Parker, 2023; Thamyongkit et al., 2018a; De Wolfe et al., 2019; Petre and Malherbe, 2020; Petre et al., 2019; Wilson et al., 2020; Rizan et al., 2020; Thiel et al., 2018; Vozzola et al., 2018)	“For high end equipment circularity as already been planned for a long time . . . that is because there circularity and business models go together quite well” (P3).
3.2	Improve and intensify collaboration among stakeholders.	41	P3, P7-P9, P15, P17, P19, and P21	(Lopes et al., 2019; Szirt et al., 2023; Ditac et al., 2023; Hennein et al., 2022; Goel et al., 2021; Agarwal et al., 2018; Link, 2019; Mallick et al., 2022; Petre and Malherbe, 2020; Murphy et al., 2023; Peters et al., 2021; Thamyongkit et al., 2018b; Petre et al., 2019)	“It is not only about product level. It is about daring to design a completely different collaboration” (P7).
3.3	Invest in innovation (for all stakeholders).	35	P3, P7, P9, P13, P14, P16, P17, P20, and P21	(Moreno et al., Sep. 2016; Bressanelli et al., 2019; Lopes et al., 2019; Washburn and Pietsch, 2018; Washburn and Pietsch, 2018; Hines et al., 2019; Grantcharov et al., 2019; Thamyongkit et al., 2018a; Petre and Malherbe, 2020; Rowan and Laffey, 2021; Rohit et al., 2021; Petre et al., 2019; Nacharaju et al., 2020; McEvoy and Eveland, 2020)	“If [company] develops a circular concept . . . then you must also be daring to invest in this as a hospital” (P7).
3.4	Let producers take responsibility and ownership over their wastes.	29	P2-P4, P6, P8, P11, P14-P16, P18, P19, P21	(MacNeill et al., 2020; Ditac et al., 2023; Hennein et al., 2022; Farrell and Smyth, 2021; Thamyongkit et al., 2018a)	“If they would return to the manufacturer, they would have a larger chance of being recycled because they will know what to do with it” (P16).
3.5	Improve circular design and engineering practices.	24	P3, P19, P20, and P21	(MacNeill et al., 2020; Robertson et al., 2021; Ditac et al., 2023; Allescher et al., 2022; Petre and Malherbe, 2020; Dulal et al., 2022; Petre et al., 2019; Legemate et al., 2019; Rodríguez et al., 2021; Rizan et al., 2020; Parashar and Hait, 2021)	“To make sure this effort continues to extend the life of products, design them better” (P19).
3.6	Introduce system thinking and service concepts.	12	P3, P7, P18, and P20	(MacNeill et al., 2020; Szirt et al., 2023; Goel et al., 2021; Vozzola et al., 2018)	“Adding the life cycle of other textile and non-textile items found in healthcare facilities, such as gloves, wipes, or masks, would further strengthen the environmental benefits of reusable systems” (Vozzola et al., 2018).
3.7	Use scarcity of materials (or the prevention thereof) as a motivator to perform circular practices.	8	P3, P5, P18, and P21	(Hennein et al., 2022)	“Remanufacturing is . . . something that comes from the aim to deal smartly with scarce resources” (P18).
3.8	Break the linear pattern and utilize first mover advantage.	7	P7, P17, P20, and P21	(Szirt et al., 2023; Farrell and Smyth, 2021; Lima et al., 2023; Thamyongkit et al., 2018a; Cassorla, 2021; Thiel et al., 2018; Kleber, 2022)	“It definitely provides you with a first mover advantage, if you’re the first in the market. So that is definitely a reason to do it” (P17).
3.9	Make use of contracted recovery facilities.	6	P3, and P19-P21	(Psaltikidis et al., 2021)	“The second business model is when the OEM appoints a third party . . . [The third party] is licensed to operate by the OEM” (P19).
3.10	Donate devices to low-income countries or charity.	3	P2, P3	(Petre et al., 2019)	“Other sustainability efforts in Canadian ORs included donating unused medical equipment and supplies to medical missions” (Petre et al., 2019).

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Table 4 (continued)

#	Opportunity	Times mentioned	Finding based on analysis of ...		Example quote
			Interviews	Literature	
	Category: General (circular) healthcare ecosystem				
3.11	Create circularity-related employment opportunities.	1	P1	n.a.	"There's a huge benefit to having more reusable devices: it ensures employment opportunities for this work field" (P1).

4. Discussion

Our inventory of best practices revealed that out of at least 1400 medical devices, only 346 implemented at least one circular strategy. Of these 346 devices, only 33 % implemented more than one circular strategy. Most circular devices we found were reusable medium-criticality devices used in a healthcare setting. This underscores the need to improve circularity in active medical devices, particularly for low and high-criticality devices used in patients' homes.

While our interviews and literature review indicated that reusability and decontamination practices could still be increased and improved (also e.g. in terms of environmental impact (Baboudjian et al., 2022)), looking beyond reuse is advisable, as in our best practices search all other circular strategies were found to a much lesser extent. Especially *repurpose*, *recycle* and *renew* were uncommon. It is particularly noteworthy but not unexpected that the fundamental *recycle* strategy is scarcely found in medical device design: this finding was confirmed by the interviewed recyclers, who are not allowed by law to recycle potentially contaminated devices (i.e. all devices falling under the medical device directive).

The difficulty of finding good circular examples was not very surprising, considering the extensive list of barriers to the circularity of active medical devices we provided. Barriers were divided into six categories: safety, systemic, regulatory, financial, technological, and social barriers. Although safety concerns made it to the top of our list, interview participants indicated that in practice this sometimes leads to an unhelpful overemphasis on infection prevention. For example, some devices are thrown into the medical waste bin 'just to be safe' even though they are not contaminated. This is unfortunate because both our best practices inventory and existing literature (Leung et al., 2019; Qi et al., 2019) have shown that well-performed circular practices can result in efficient, reliable and safe medical devices. A similar situation is true for regulations; they are often interpreted extra strictly to prevent possible business risks. A potential way to equate perception with reality was presented as the most-mentioned opportunity: circularity-enabling regulations, guidelines and standardizations could minimize safety risks while further clarifying needed regulatory adherence.

Despite identified barriers and somewhat disappointing results in the best practices inventory, we showed that circular design of active medical devices is feasible. Notable circular practices included eliminating the need for unsustainable devices (*refuse*), reducing energy consumption (*reduce*), offering multiple functions in one device (*rethink*), and eliminating electronic components without compromising functionality (*reduce*). Surprisingly, *rethink* emerged as the second most prevalent strategy, following reuse. However, our definition of *rethink* encompassed sharing devices among users or patients, and portable devices that can be used in various locations. Therefore, developments in this direction could be motivated by considerations such as enhanced adaptability, improved user experience, and increased accessibility, rather than circularity. This in itself underlines the opportunity to connect circular practices to e.g. functionality, scarcity, business or regulation-related incentives, as was also proposed in our list of opportunities.

Our research resulted in a unique set of specific circular design recommendations for active medical devices, presented in Table 5. This represents a novel, pioneering representation of design guidelines that builds on the previously unexplored topic of design strategies for

medical devices.

4.1. Limitations

In our research, we ranked barriers and opportunities based on their frequency of occurrence in the literature review and interviews. However, it is important to note that the order of importance of barriers may vary per device. Participants highlighted for instance that for devices storing patient data, privacy concerns in *reuse*, *repurpose*, and *remanufacture*, influenced by recent developments in European privacy regulation, was a major barrier that could significantly hinder the circular transition.

The best practices were ranked by means of our circularity rating method. We made use of the hierarchy of circular strategies based on two assumptions: that certain strategies are always superior to other strategies and that the more strategies a device uses, the higher the circularity score of a device is (based on (Blomsma et al., 2018)). This was necessary to make our circularity rating easy to apply to a large number of devices. However, the reality is somewhat more nuanced. While certain strategies may be prioritized from an environmental perspective, strategies like refuse or reduce may seem counterintuitive from an economics point of view, as they can lead to economic challenges such as cannibalization issues (Zanjirani Farahani et al., 2022).

Also from a sustainability perspective, strict adherence to the hierarchy must be avoided, as demonstrated by the example of reusing an old device with hazardous substances, which may be worse than remanufacturing it and replacing those unsafe components. Although our assumption that more circular strategies in one device is better was endorsed by our interview participants, it is crucial to consider that circularity depends not only on the number of strategies but also on their quality of execution (e.g., maximizing reuse cycles, minimizing sterilization impact, and recycling into similar or higher-quality materials). Furthermore, it is unlikely for one device to employ all strategies, as some are mutually exclusive (e.g., *recycle* and *renew*).

The circularity scores were based on manufacturer-provided claims, with efforts made to verify reliability through expert input. The subjective nature of these assessments may introduce some degree of uncertainty and may have posed some limitations, e.g. in capturing devices *repurposed* in developing world markets after use (as manufacturers often lack knowledge of such practices), or the inability to analyse the use of the *repair* strategy separately due to limited data availability. Additionally, we were unable to verify sustainability claims made by the company due to time constraints. This may lead to unintended consequences like burden shifting, as seen when transitioning a device like a hearing aid to an app format, potentially reducing smartphone lifespan or encouraging more frequent upgrades. Despite the assumptions made in our circularity rating method, we are confident that our final list provides accurate findings that can help understand the current state of circularity in medical devices.

We identified some common themes in high scoring devices, such as remanufacturing after reuse, replacing devices with more sustainable alternatives and reducing energy consumption. However, we identified another interesting strategy that is worth mentioning: the elimination or minimization of the need to use infection prevention materials such as disposable alcohol wipes or sterile sleeves (*refuse*), which is for example applied in device 22 and 270 of the full list of best practices. The reason this strategy is found in devices with a lower circularity score, is because

Table 5
Design-specific recommendations.

#	DESIGN RECOMMENDATION	CONCLUDED FROM ANALYSIS OF ...		CIRCULAR STRATEGIES								
		Best practices	Barriers and opportunities		Refuse	Rethink	Reduce	Reuse	Remanufacture	Repurpose	Recycle	Renew
			Interviews	Literature								
1	Maintain (or improve) quality, function & usability of the original device when introducing circular strategies.	n.a.	P2, P3, P5-P8, P10, and P14-P21	Ventimiglia et al., 2020	X	X	X	X	X	X	X	X
2	Aim to combine different circular strategies as much as possible (while prioritizing the strategy higher in the hierarchy).	We had already assumed this to be true in our circularity rating method	P1-P5, and P10-P12	n.a.	X	X	X	X	X	X	X	X
3	When integrating circular strategies, make sure to mitigate safety risks for intended use of the device/material/system.	n.a.	P8, P10, P15, and P21	n.a.	X	X	X	X	X	X	X	X
4	Make sure the device has sustainability certificates.	n.a.	P9, and P21	n.a.	X	X	X	X	X	X	X	X
5	Consider the device EoL from the start of the design process.	10% of reusable devices we found are designed for remanufacturing upon EoL	n.a.	n.a.	X	X	X	X	X	X	X	X
6	Be careful not to unjustly prioritize the selection of biomaterials when other options are more sustainable.	n.a.	P21	n.a.	X	X	X	X	X	X	X	X
7	Design devices for local manufacturing and distribution to minimize transportation emissions. ¹	n.a.	Based on findings from opportunity 1.8, e.g. P20	n.a.			X	X	X	X	X	X
8	Enable both extensive testing and simplified assessment of device and/or material quality and circularity.	n.a.	P6, P8, P18, and P21	(MacNeill et al., 2020; Psaltikidis et al., 2021; Forrester et al., 2018; Szirt et al., 2023; Hennein et al., 2022; Farrell and Smyth, 2021; De Wolfe et al., 2019; Rowan and Laffey, 2021; Rizan et al., 2020)				X	X	X	X	X
9	Ensure quick, efficient procedures needed for the different circular strategies (such as collection, decontamination, etc.) that fit within the current workflow (where this is possible).	n.a.	P1, P3-P5, P8-P10, P12, P14, P15, and P17	(Robertson et al., 2021; Psaltikidis et al., 2021; Agarwal et al., 2018; De Wolfe et al., 2019; Petre and Malherbe, 2020)				X	X	X	X	X
10	If needed, make device good and easy to clean, (suitable for various decontamination methods – water/heat/chemicals resistant).	n.a.	P1, P2, P8, P9, P17, P18, and P20	(Jinia et al., 2020)				X	X	X	X	X
11	Minimalize the needed (and performed) decontamination processes.	Some circular devices improve sustainability by avoiding sterilization in their reuse cycle.	P4, P5, and P20	n.a.				X	X	X	X	X
12	Provide clear and easy-to-understand instructions on the execution of the steps in the different circular strategies.	n.a.	P1, P10-P12, and P14	n.a.				X	X	X	X	X
13	Enable easy disassembly (for cleaning, removing hazardous materials, and sorting materials).	Most reusable and remanufacturable devices are easy to disassemble	P1, P3-P6, P8-P10, P12, P15-P18, and P20	(Rodríguez et al., 2021)				X	X	X	X	X

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Table 5 (continued)

#	DESIGN RECOMMENDATION	CONCLUDED FROM ANALYSIS OF ...		CIRCULAR STRATEGIES								
		Best practices	Barriers and opportunities		Refuse	Rethink	Reduce	Reuse	Remanufacture	Repurpose	Recycle	Renew
			Interviews	Literature								
14	Enable traceability of devices and materials during their circular life cycles, for example through a digital device passport	Many reusable devices have limited allow use cycles, which needs registration.	P1, P3, P6, P9, P13, P14, and P17-P21	(Psaltikidis et al., 2021; Hennein et al., 2022)				X	X	X	X	
15	Aim to increase device value and lifetime where possible.	n.a.	P4, P16, and P20	(MacNeill et al., 2020; Forrester et al., 2018; Szirt et al., 2023; Hennein et al., 2022; Lima et al., 2023; Petre and Malherbe, 2020; Williams et al., 2022; Kleber, 2022)				X	X	X		
16	Provide clear information about circular principles and proper maintenance to enhance longevity of devices.	n.a.	Based on findings from barrier 6.1, e.g. P10				X	X		X		
17	Assure a simplification of shapes and parts to enable disassembly, decontamination, and separation.	n.a.	P2, P8, P14, and P16	n.a.			X	X		X		
18	Try to refuse (prevent the use of the device or materials where possible).	A small number of circular devices applies this strategy successfully.	n.a.	(Szirt et al., 2023; Parker, 2023; Petre and Malherbe, 2020; Rizan et al., 2020; Kleber, 2022)	X							
19	Save spare parts from partly reuse devices that cannot be reused in whole to use them in other circular processes, such as remanufacturing.	In some circular devices, some parts have more use cycles than others.	P3-P5, P12, P17, and P21	(MacNeill et al., 2020; Williams et al., 2022)				X	X			
20	Align the battery life (and point of assembly thereof) with the device life.	Long-lasting circular devices tend to have longer battery life.	P4, and P12	(Hennein et al., 2022; Lima et al., 2023)				X	X			
21	Aim to design a modular device with standardized connections compatible with different parts and systems.	Some circular devices have “add-ons” that fit on different systems.	n.a.	Based on findings from opportunity 3.5, e.g. [34], [60]		X						
22	Aim to design a (portable) device that can be used in different locations, such as the home and healthcare setting.	This is an example of “rethink”, which may make a device more circular.	n.a.	n.a.		X						
23	Aim to design a device that can be used by multiple users (at the same time) to minimize the need for individual ownership.	This is an example of “rethink”, which may make a device more circular.	n.a.	n.a.		X						
24	Aim to design a multifunctional device, able to be used for multiple purposes (at a time).	This is an example of “rethink”, which may make a device more circular.	n.a.	n.a.		X						
25	Minimize material use in both device and packaging while maintaining device quality, longevity, and functionality (design for dematerialization).	This is an example of “reduce”, which makes devices more circular.	P8, and P9	(Szirt et al., 2023; Petre and Malherbe, 2020; Rizan et al., 2020; Thiel et al., 2018)				X				
26	Minimize energy consumption (refuse/reduce) electronics, increase efficiency, or introduce energy saving features.	This is an example of “reduce”, which makes devices more circular.	n.a.	Petre and Malherbe, 2020; (Rowan and Laffey, 2021; Petre et al., 2019; Rizan et al., 2020; MacNeill et al., 2020)				X				
27	If possible and useful, consider repurposing the device for different functions upon EoL.	“Repurpose” is underrepresented in the best practices.	P6, and P18	(MacNeill et al., 2020; Szirt et al., 2023; Ditac et al., 2023; Santos et al., 2020; Petre and Malherbe, 2020; Kleber, 2022)					X			

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Table 5 (continued)

#	DESIGN RECOMMENDATION	CONCLUDED FROM ANALYSIS OF ...		CIRCULAR STRATEGIES											
		Best practices	Barriers and opportunities	Refuse	Rethink	Reduce	Reuse	Remanufacture	Repurpose	Recycle	Renew				
28	Make materials easy to separate, by avoiding combining different materials and mixed materials such as fancy plastics.	Recyclable devices typically have minimal material variance and complexity.	Interviews P3, P10, P12, and P14-P17												X
29	Consider biobased, bioactive, and/or biodegradable materials where possible (but always check whether those options actually increase sustainability).	n.a.	P6, P12, P20, and P21												X

we scored the devices specifically on the circularity of the device itself, while this strategy addresses the overall sustainability of the full care pathway.

Apart from the scoring of the devices, we also aimed to categorize them based on their use location, economic value, and criticality. As data about economic value was unavailable, size was used as a value indicator. This size-based evaluation yielded conflicting findings: while the best practices inventory included numerous smaller devices, the interviews indicated a greater likelihood for high-value devices to implement circular strategies. We expect this to be the case due to our search and selection method: there being more small devices in our best practices inventory likely means that more small devices exist, rather than low value devices being more circular.

Lastly, although we present opportunities that apply to different parts of the supply chain, it is important to keep in mind that we have conducted this research from a design point of view. For this reason, different perspectives related to e.g. circular business models, supply chain logistics and regulatory constraints may be underexposed in our analysis. We acknowledge that for a successful circular transition, effort is needed from all supply chain stakeholders.

4.2. Future research

Future research on circularity in medical devices should include users’ needs, the care pathway, and the entire product life cycle. Adopting a systemic approach during the development of circular design guidelines will help ensure that circular practices do not compromise the functionality, usability, and safety of the devices. Additionally, integrating circularity recommendations in successful business models and evaluating their compatibility with existing regulations (or suggesting regulatory adaptations) is essential for practical implementation. Further research is also needed to assess the applicability of the recommendations in real-life contexts, considering existing medical device design practices through testing by experienced medical device engineers across a range of design cases.

5. Conclusion

The aim of our research was to investigate the extent to which circular design principles are currently employed in the development of active medical devices, to create a concise overview of the barriers and opportunities to the transition towards circularity, and to create a set of circular design-specific recommendations tailored to active medical devices.

The analysis of the current state of circularity in healthcare revealed limited circularity of active medical devices. However, reusing devices is relatively common, as is minimizing material and energy consumption. The identified barriers to circular design encompass safety concerns, challenges in device collection and separation, regulatory constraints, financial limitations, and a lack of awareness. Opportunities for promoting circularity in healthcare include policy interventions, technological innovations, financial incentives, stakeholder collaboration, and system thinking. Design-specific recommendations, derived from the analysis of the best practices and interviews and literature review used to identify the barriers and opportunities, emphasize the importance of maintaining device quality, function and safety when implementing circular strategies. Additionally, we recommend early consideration of circular potential, prioritizing reuse, and addressing potential safety risks. The recommendations encompass 29 guidelines, reinforcing the need for comprehensive design guidance to navigate the complexities of circular medical device development. The findings of this study offer valuable insights for design engineers, providing actionable recommendations to navigate the complexities of circular medical device development, ultimately contributing to sustainable and innovative healthcare solutions.

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CRedit authorship contribution statement

Tamara Hoveling: Writing – original draft, Methodology, Investigation, Conceptualization. **Anne Svindland Nijdam:** Writing – review & editing, Methodology. **Marlou Moninx:** Writing – review & editing, Investigation. **Jeremy Faludi:** Writing – review & editing, Conceptualization. **Conny Bakker:** Writing – review & editing.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Tamara Hoveling reports financial support was provided by Horizon Europe. If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

Confidential data cannot be shared. Non-confidential data can be found in <https://data.4tu.nl/datasets/2f58f936-045b-4aa9-9644-456ed160eebe>

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Appendix A Example interview questions

General questions

Question 1: Could you first explain a bit about what you / your company works on exactly?

Question 1.1: What are the sustainability goals of your company and how do you make sure to reach those goals (and by what time)?

Question 2: What types of devices / materials does your company focus on more specifically?

Question 3: Do you also have specific expertise in the area of sustainability of health devices / medical devices? Can you explain?

Question 3.1: How do you believe circularity to be different for medical devices, compared to non-medical devices?

Question 4: How do you define the terms [insert relevant R-strategies and other relevant terms such as reprocessing]? Do you believe we have used the terms correctly?

Question 5: Is there any recovery flow that you think is best for the environment, in the context of medical devices, and why?

Question 6: Are there specific things you do differently when working with devices that are intended to go through multiple loops?

Barriers, risks, and opportunities

We would like to know what the advantages, risks/barriers and opportunities are for each circular strategy [for each mentioned barrier, we asked participants to also come up with possible solutions].

Question 7: What do you think are the most important reasons to choose or not choose for your each of these circular strategies?

Question 7.1: Can you mention any specific advantages, barriers, and risks? [if participants could not come up with many answers, we mentioned for following possible categories as examples: financial, regulatory, social, safety, and practicality]

Question 7.2: Why do you think many circular strategies are currently not (yet) implemented within the healthcare sector?

Question 7.2: Of all barriers that you have previously mentioned, which one do you think is the most important one?

[The questions below are examples of questions that could be asked to get more information about the barriers that are mentioned by the participants]

Question 8: How do you think should be dealt with the dangers of electronics? And of medical waste that is potentially contaminated?

Question 9: How do devices or components reach the right facilities?

Question 10: Are there any logistic issues that often occur in these processes?

Question 11: Do you believe circular flows are generally ‘accepted’ in Europe (and beyond)? How is this for medical devices?

Question 12: We assume you also know quite a lot about the [fill-in depending on the participant] barriers to circularity in this context. Can you tell us a bit more about these barriers and potential opportunities of overcome them?

Design recommendations

Question 13: If we were to design a new medical device or redesign an existing medical device that contains electronic components, and we want it to be suitable for [circular strategies of their expertise], what requirements should this device ideally have, for as far as you know?

Question 13.1: Are there particular design requirements you think are already adhered to for this purpose?

[The questions below are examples of questions that could be asked to get more information about the recommendations that are mentioned by the participants]

Question 14: What specific recommendations are most important to help overcome the barriers that we have discussed earlier?

Question 15: What specific design aspects are to be considered to make a device [e.g. easy to clean, easy to disassemble, suitable for recycling, etc., based on what the participants have mentioned].

Question 16: Are there certain materials that are considered a ‘no-go’ for most flows?

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