A Methodology to Assess Sustainability in Medical Device Design

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Abstract

The medical device design and development process is highly interdisciplinary and complies with stringent regulatory requirements and safety standards to de-risk the product. Medical device designers generally give considerable attention to functional, performance, and safety requirements during development, while sustainability takes the backstage. In this thesis, we have developed a methodology to incorporate sustainability in medical device development. We offer a set of sustainability evaluation criteria to assess design concepts and develop mitigation strategies to improve the design. A case study on a surgical guide was carried out to demonstrate the usefulness of this methodology. A mini-Delphi study with eight design experts was conducted in Singapore to evaluate the methodology's benefit, effectiveness, interpretability, comprehensiveness, and usability. The results suggest that the methodology is comprehensive and beneficial to the designers in identifying and developing sustainability-impacting design elements and making informed design decisions in incorporating sustainability at the early stage of the medical device design process.

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Chapter

1

INTRODUCTION

The Healthcare sector's contribution to global net emissions is ~4.5% (Salas et al., 2020). The USA, EU, and China make up 56% of the total healthcare climate footprint(Liu et al., 2019). The United States leads the pack as the number one emitter in absolute and per capita measures. The carbon-intensive healthcare supply chain accounts for 71% of the total emission (Eckelman et al., 2018). Producing, transporting, and disposing of goods and services are part of the healthcare supply chain. Those goods and services may range from pharmaceutical chemicals, food products, medical devices, hospital equipment, and instruments. Medical device designers give significant attention to functional, performance, and safety requirements during the design phase due to the safety risk involved during product usage to all stakeholders, not just the end-users. It is to be noted that the medical device industry is one of the last technological frontiers to embrace sustainability.

1.1 Motivation

Considering do-no-harm (safety) is paramount, regulations have delayed the much-needed innovations to reach the bedside. Desperation for vaccines to control the spread of Coronavirus disease 2019 (COVID-19) and public and political pressure forced regulatory bodies worldwide to issue emergency authorizations for use even though innovations like Messenger Ribonucleic Acid (mRNA) have never been used for vaccine development and long-term safety or impact on health have not been studied. At the same time, it is undisputed that human necessity and safety have enabled the industry to design and manufacture single-use healthcare products in vast quantities with scant regard to their environmental implications (Hu et al., 2022).

These products include life-saving medical devices (for example, physiological signal monitoring devices, electroencephalogram (EEG) patches, and surgical guides), delivery systems (for example, syringes, needles, saline bags, and catheters), and instruments (for example, Ear, Nose, and Throat (ENT) scopes, safety devices, colonoscopy devices, and biopsy devices). Industry-wide consensus on the need for sterility, efficacy, and affordability of these medical devices has been used to justify this unsustainable design paradigm (Kleber & Cohen, 2020; Molero et al., 2021). Once used, these devices are discarded as biohazard waste and disposed of accordingly, without concern for the environment. While after-use management has cost and environmental implications, it is only one aspect of sustainability.

1.2 Challenge

The entire product lifecycle, from design, material selection, manufacturing, production, distribution, and disposal, offers opportunities to impact sustainability. The impact could be in many forms, including the ethical sourcing of materials, responsible manufacturing and production of products, and efficient supply chain management with minimal environmental and human rights harm. Decisions made at every stage of the design phase and lifecycle impact long-term sustainability (Fig. 1). 80% of the sustainability decisions are made during the design phase of medical devices (Piaggio et al., 2021). Considering earlier decisions significantly impact the device's sustainability, a holistic understanding of the design spaces is required to tackle this problem.

Technological advances in Computer-Aided Design (CAD), Design Simulation and Analysis, 3D-printing or additive manufacturing, Digitalization, Sensors, and Industry 4.0 offer significant space to experiment, prototype, and assess designs at the early stages of new product development in the virtual environment (Piaggio et al., 2021). Verification testing, assessment, and modification in the virtual environment are cost-effective. However, late-stage design modifications are costly due to the downstream changes in the tools and production lines, which also impact time to market. Design strategies, including design for manufacturing, have been shown to visualize and improve issues related to manufacturing at the early stages of the design process (Tan et al., 2017). In the engineering design industry, in addition to manufacturing, researchers have given attention to sustainability (design for sustainability). However, their focus on sustainability was aimed at energy savings, material waste (primary and secondary), and idle-time reduction during production in line with business and cost management objectives.

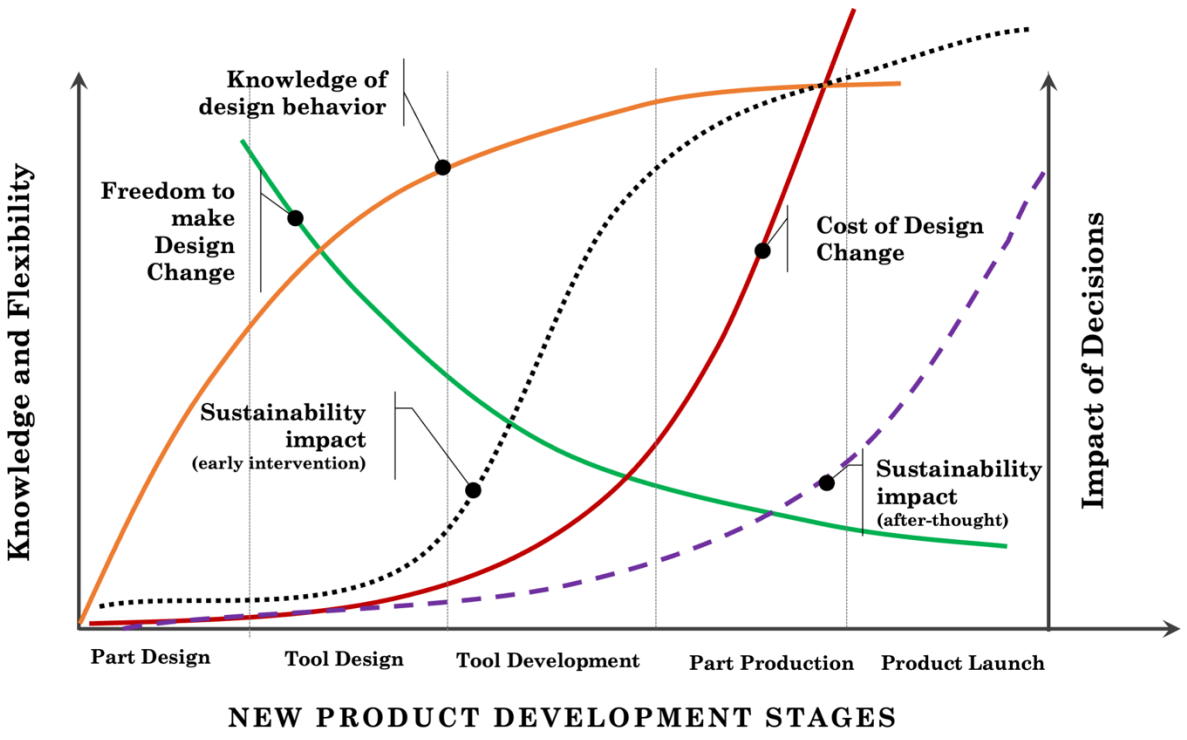

Fig. 1: *A schematic diagram representing design space for opportunities to assess designs and design decisions for their impact on sustainability and costs and develop design strategies to address them during different stages of the new product development.*

Each medical device is unique, so no one-size-fits-all strategy would be suitable for improving sustainability in this industry. Patients demand custom-designed solutions for better functional outcomes, especially in long-term use, performance-enhancing, mobility-related, and rehabilitative devices. Thus, there is a need for a systematic method to incorporate, assess, and quantify sustainability-impacting aspects of medical devices at the early stage of the design process without compromising their performance, safety, and usability and develop design mitigation strategies to make the most significant difference with the fewest possible trade-offs.

1.3 Aim and Objectives

The thesis aims to develop a series of sustainability evaluation criteria that enable designers of medical devices to assess their design concepts and develop mitigation strategies to improve the design in the early stage of the design process. The following study objectives have been derived from the stated aim of the thesis:

- Identify and derive the design elements, decisions, and attributes impacting the sustainability aspects of medical devices.
- Categorize and relate these attributes to enable them as actionable design assessment criteria (stimuli) during the concept evaluation phase of the design process and develop mitigation strategies based on identified and prioritized issues.
- Demonstrate the usefulness of the methodology in assessing and revising design concepts to improve sustainability by applying it to a case
- Evaluate the methodology to assess its benefits, effectiveness, comprehensiveness, and usability.

1.4 Thesis organization

Chapter 2 presents an overview of the research methodology of the thesis. It also discusses the study objectives and research approaches to achieve the study aim.

Chapter 3 critically evaluates prior work on sustainability in the medical device industry and metrics that capture and quantify factors affecting overall downstream sustainability. It also analyzes, identifies, and captures sustainability aspects related to product design in other sectors to derive inspiration for developing criteria suitable for medical device design.

Chapter 4 describes a methodology to incorporate and assess sustainability-related aspects of medical devices at the early phase of the design process to improve sustainable medical device design by developing design mitigation strategies based on the assessment.

Chapter 5 details a case study to demonstrate the effectiveness of the methodology in revising a design concept (surgical guide).

Chapter 6 describes the study conducted to evaluate the method by field experts. Then it presents the revision made to the methodology based on the assessment and feedback shared by the experts.

Chapter 7 presents a summary of the thesis and the limitations of the research work presented in the report and gives direction for further research in this domain.

Chapter

2

RESEARCH METHODOLOGY

This chapter discusses the research methodology followed to achieve the aim of the thesis. As discussed in the introduction chapter, afterthought sustainability analysis results in higher change cost, longer product development time, and low incentive to adopt sustainability-enhancing design elements to the product design. Early incorporation of sustainability assessment during the conceptual stage of the design process would improve the quality of the ideation process and generate innovative design concepts toward achieving pre-defined sustainability goals. A comprehensive evaluation would allow the designers to identify, assess, and quantify sustainability-impacting design aspects of medical devices and develop design mitigation strategies to make the most significant difference with the fewest possible trade-offs.

2.1 Overall Research Approach

The goal of the thesis is to develop a methodology to incorporate sustainability assessment in the early stage of the medical device process to enable the designers to assess their design concepts, identify sustainability-impacting design elements and design decisions, and develop design mitigation strategies to improve them in line with their sustainability goals. We have derived the following study objectives from the stated thesis goal.

- **Objective 1:** Identify and derive the design elements *(geometric, functional, and operational features*), design decisions *(choice of materials, manufacturing processes, number of uses, and disposal),* and attributes *(procurement, outsourcing, and pricing)* impacting sustainability aspects of medical devices from the literature review, case studies, and experience.

- **Objective 2:** Categorize and relate these attributes to different design decisions *(materials, design and manufacturing, usage, and after-use management*) to enable them as actionable design assessment criteria (stimuli) during the concept evaluation phase and develop mitigation strategies based on identified and prioritized issues.

- **Objective 3:** Conduct a real-life design case study by applying the methodology to demonstrate its usefulness in assessing and revising design concepts to improve sustainability in medical device design. We evaluate the design with the method, identify design elements and decisions that can be modified to improve the overall sustainability of the product, develop design mitigation strategies, revise the design, and redo the assessment.

- **Objective 4:** Conduct a mini-Delphi study with experts in medical device design, design for sustainability, green manufacturing, sustainable supply chain, and design methods to evaluate the methodology. We ask the experts to assess the methodology based on a set of criteria, including perceived benefits, effectiveness, interpretability, comprehensiveness, and usability, along with open-ended questions to gather their thoughts on the methodology on missing attributes and improvement.

Fig. 2 shows a schematic representation of the overall research approach taken to study these objectives and their relationship. In our research approach, we have employed 3 different research methods to study these defined objectives, including categorization (themes), case study method, and mini-Delphi method (structured consensus method).

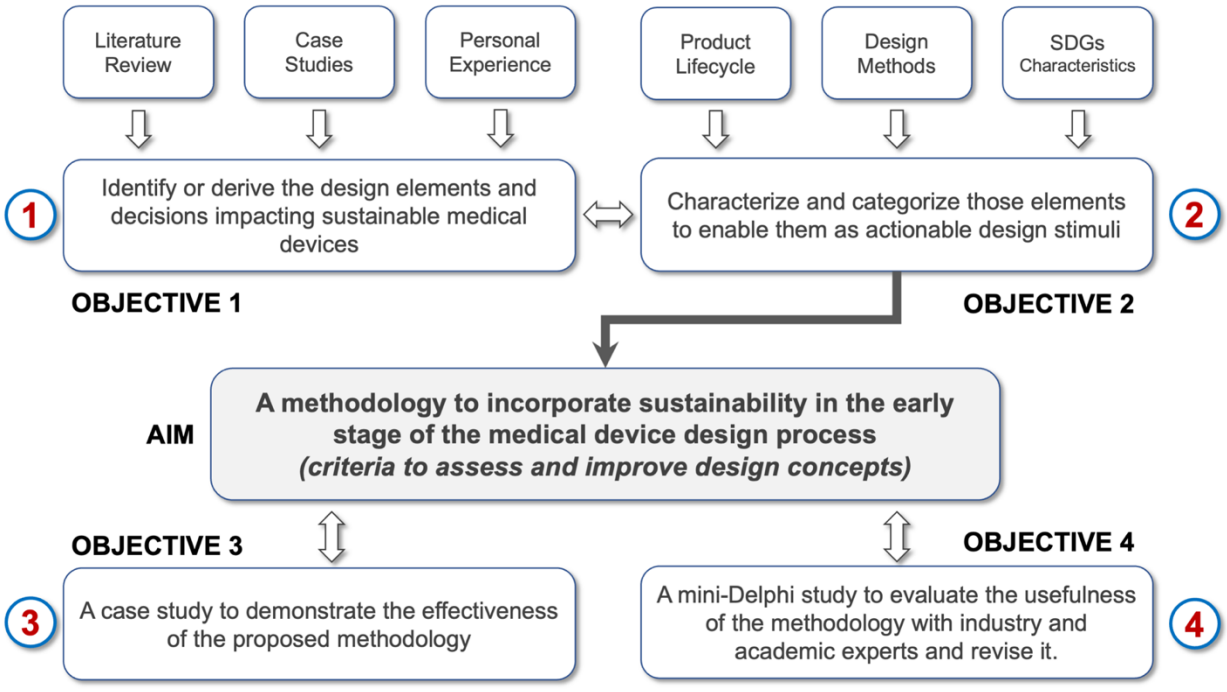

Fig. 2: *Overview of the research approach*

The case study method is one of the most used empirical research methods in academia to investigate a phenomenon or demonstrate a methodology by focusing on the dynamics of the case within its real-life context (Burkholder et al., 2019; Crowe et al., 2011). This method offers a high level of flexibility that is not readily offered by other qualitative methods, like grounded theory or phenomenology (Crowe et al., 2011). It can be exploratory, descriptive, or explanatory in nature, depending on the context and research question being analyzed. The tasks included in this case study are (1) case identification or design, (2) data collection, (3) data analysis, and (4) results reporting and presentation. The challenges (limitations) faced by this method are lack of generalization (single case), introduced bias due to pre-selection of the case, and subjective analysis within a context (Burkholder et al., 2019; Rashid et al., 2019). However, the strengths of this method include that case studies aim to attain analytic generalization, not a statistical one, and context-sensitive analysis of a methodology offers critical insights into practical implications that might not be observed in controlled experimental settings (Mills et al., 2010). In our case, we choose a descriptive case study method to derive an in-depth understanding of a single case of a new medical device (surgical guide for high tibial osteotomy). We have chosen the descriptive case study method as it allows us to offer a focused and detailed articulation of steps and questions about the effectiveness of the proposed methodology in a design setting. Also, this method enables us to understand the nuances associated with implementing the methodology in practice that can get lost in numbers (quantitative research).

The Delphi technique is a well-known and industry-wide method for developing answers to research questions through consensus across experts (Barrett & Heale, 2020; Donohoe & Needham, 2009). The critical element of this approach is defining research questions that would allow the subject experts to use their knowledge and experience to develop responses

in a given context while avoiding the group-think phenomenon (Spranger et al., 2022). The mini-Delphi method is a simplified version of identifying critical issues in a new methodology or technique by subject experts in a single-stage process (Niederberger & Spranger, 2020; Pan et al., 1996). While the method has its limitations due to the lack of iteration (reflect and reconsider), the strength lies in a time-bound identification and rectification of critical issues and seeking feedback on potential adoption hurdles of the methodology in the early stage (Dalkey & Helmer, 1963; Essam Khamis, 2022). With a clear study design, the mini-Delphi technique taps into the most precious resource—the knowledge and experience of subject experts which the other methods, including observation of users, performance-related measurements, critical incident analysis, interviews, focus-group, model-based methods, and automated evaluation cannot rely on to offer perspectives and insights (Burck, 2005). In addition, we have opted for categorization or thematic analysis of the feedback received to identify issues commonly noted among the feedback given by the experts. The categorization or thematic analysis method is a systematic method of organizing and analyzing qualitative data acquired from questionnaires, interviews, surveys, and observations (Burck, 2005; Miller et al., 1986). The core assumption of this method is that specific themes or topics would emerge during data analysis when related findings or observations appear multiple times across participants (Braun & Clarke, 2022). The limitation of this method is that we might overlook a critical issue that would differentiate the product from the competition (latent needs) and allow us to offer a unique design solution to the need that the users themselves did not know they want it (Robinson, 2022). However, categorization enables us to focus on the issues that are salient to the research problem and important enough that the experts have attempted to highlight them.

Chapter

3

LITERATURE REVIEW

This chapter discusses reported works in the literature on sustainability in the medical device industry. A brief analysis of the metrics used to capture and quantify factors affecting overall downstream sustainability is also presented. It also analyzes sustainability aspects related to product design in other sectors to derive inspiration to develop the methodology.

3.1 Sustainability in Medical Device Design

From the perspective of the functional structure of the medical device design and development process, it is a resource-intensive endeavor in terms of materials, energy, human resources, and knowledge (field and technical expertise and skills). Globalization

(mass customization and production) has brought tremendous opportunities regarding access to a broader market, human resources, and expertise needed to develop medical devices suitable for the masses while offering significant cost-advantage (MacNeill et al., 2020; Tan et al., 2017). However, it also introduced an additional challenge to the process regarding supply chain management and quality control.

The detrimental impact of globalization on economic conditions, human rights, and the environment has made regulatory bodies and governments introduce legislation, regulations, and guidelines. Widespread awareness of various aspects of environmental sustainability and the socioeconomic welfare of any product applies pressure on business decisions and performance. The political, business, regulatory, and economic scenarios are highly dynamic and pose diversified challenges to MedTech companies, which affect their new product development, innovation, and business strategies. Thus, the social, economic, and ecological impact of medical devices is interlinked and should be treated as such when considering overall sustainability in the early stages of the design phase (Fig. 3) (Degavre et al., 2022; MacNeill et al., 2020; Piaggio et al., 2021).

Rising healthcare costs (affordability, accessibility, and profit margin) and ever-changing requirements from multiple stakeholders (patients, clinicians, insurance, regulatory bodies, and hospitals) are considered critical challenges faced by healthcare institutions and the MedTech industry (Degavre et al., 2022; Piaggio et al., 2021). In addition, a higher degree of uncertainty presents in the new healthcare product development due to an improved understanding of diseases, regulatory change in insurance and reimbursement, competitive negotiation with healthcare institutions, cost management objectives, and demand for higher patient satisfaction. Introducing sustainability-related measures and the aforementioned

challenges compels the industry to devise methodologies and business processes to identify the relevant gaps and shortcomings in developing mitigation strategies (Lennox et al., 2018). Issues about the stakeholders (end-users, clinicians, patients, regulatory bodies, human resources, suppliers, collaborators, manufacturers, distributors, shareholders, communities, healthcare institutions, governments, and insurance agencies) in the environment and socio-economic domains and business objectives would result in a sustainable approach to new product development in the industry (MacNeill et al., 2021).

Fig. 3: *Design considerations impacting sustainable medical device development*

Globally, no single design process for medical devices is adhered to and approved as the standard to follow. The food and Drugs Administration (FDA) recommends following their design control to identify relevant milestones in the design process for generating a design history file for regulatory approval submission(Design Control Guidance for Medical Device Manufacturers, 1997) . The process focuses on functional aspects of the design to minimize the risk of its use. The phases in the design control guidance include (1) user needs, (2) design inputs, (3) design process, (4) design outputs, and (5) medical devices (Fig. 4). These phases

are broad and follow the sequence of a version of the waterfall design process commonly used in engineering. Every firm interprets and applies this process to develop the design documentation needed for regulatory submission.

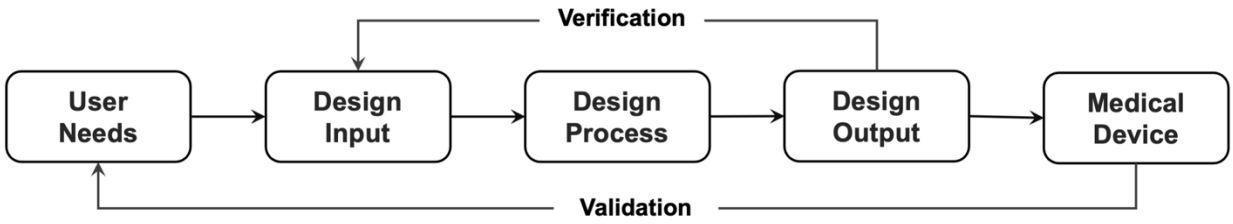

Fig. 4: *Different phases of the design process in the design control guidance document*

Academics and designers have developed various models and frameworks to represent the complex design process, from design discovery to post-market evaluation. Each framework or model considers various activities and factors during the early stages of the design process (Tan et al., 2017). However, they can be grouped into 3 primary phases: Identify, Ideate, and Implement (Fig. 5). Identify and ideate phases of the process that are shown in figure 5 comprise many activities, including needs gathering, need identification, need framing-reframing, user requirements gathering and documenting, converting them into engineering design specifications for verification and validation, developing design evaluation criteria to prune and select an innovative design, ideation, concepts development, concept evaluation, and concept selection.

The design evaluation criteria are generally derived from the user requirements related to expected functions, performance, aesthetics, usability, and cost. In the medical device design process, IP, regulations, and reimbursement are added to assess the challenges associated

with implementing the design solution concerning these aspects (Augustin et al., 2021; Dharmawan et al., 2020). However, a common absence among them is sustainability (social-economic and environmental dimensions) considerations.

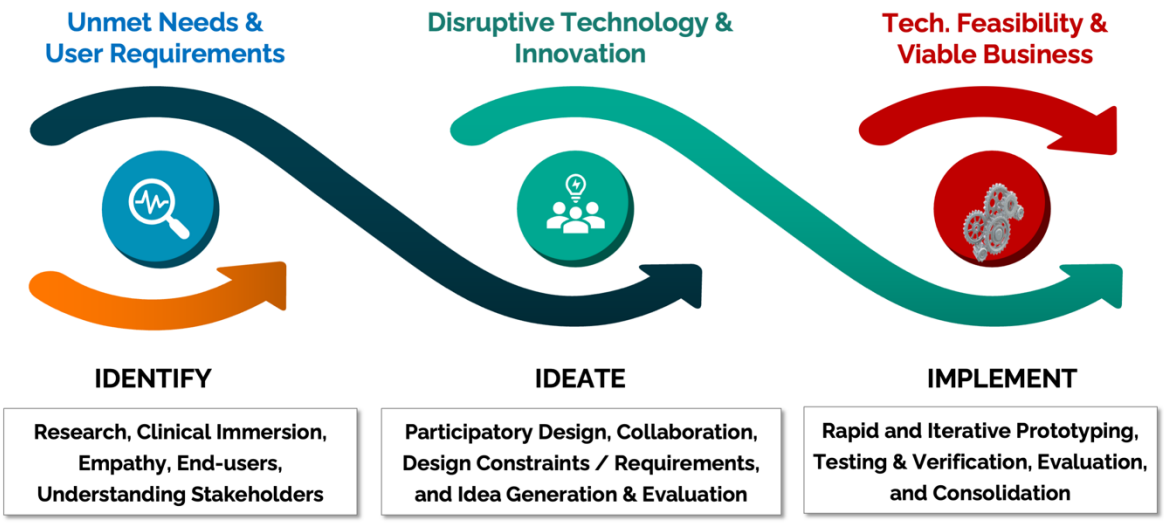

Fig. 5: *A schematic representation of a simplified design thinking process*

In this scenario, the following research questions could be asked.

- Whether any end-user or a stakeholder asks for sustainability as a requirement?
- If so, who is the stakeholder? How do we capture those requirements?
- How do we measure those requirements to be incorporated into the design evaluation?
- How do we verify at the design output stage of the process?

However, in this thesis, we focus on only one aspect. If sustainability is a requirement, how do we evaluate alternate design concepts against such a requirement? What are the design mitigation strategies that could be employed?

3.2 Sustainability Measures

Many methods have been used to assess the sustainability aspects of products, including the Life Cycle Impact Assessment (LCIA), Life Cycle Cost Assessment (LCCA), and Life Cycle Assessment (LCA) (Eckelman et al., 2018; Kumar et al., 2022; Onat et al., 2017; Stamford & Azapagic, 2012). These methods are interlinked and narrowly tailored to achieve the objectives set by the management. LCA is the most used framework in the tangible product design industry for assessing the environmental impact of a product along its life cycle. However, these methods are more suitable to implement during the late-stage design process as they require the designers to have a detailed design of their products and selected materials and manufacturing processes to realize their products.

Researchers have used Analytical Hierarchical Process (AHP) and Quality Function Deployment (QFD) tools to map the user requirements with environmental and economic sustainability aspects along with technical feasibility during the concept selection phase (Haber et al., 2020; Wu et al., 2018). QFD is particularly effective in assessing interconnectedness between design decisions, the voice of customers, and the process capabilities of the organization. However, the complexity associated with populating the matrix with subjective assessment has proven challenging. It introduces bias in using that quantitative information to make downstream design decisions (Azadi Parand, 2021; Bonci et al., 2020). If we investigate these models, their early stages consist of phases that can be broadly categorized as the 'input phase.' Coupled with the demand for patients, it would require identifying, developing, and maintaining methodologies to maintain the equilibrium among the social, economic, and environmental sustainability of the company itself (Marešová et al., 2020). Costs and time associated with rigorous evaluation of devices,

regulatory approval, and marketing and distribution result in increased time to market, delayed profits, and revenue losses.

In user-centric design approaches, design concepts are evaluated against functional and business requirements and novelty to take the product to the market, while sustainability-related requirements take the backstage (Moultrie et al., 2015a; Sousa et al., 2021a). Methods like the Pugh chart evaluate design concepts based on pre-defined criteria driven by user needs and business constraints. However, a limited number of methods prioritize and use sustainability requirements to evaluate design concepts, in addition to the functional and business-related criteria. Researchers have attempted to integrate life-cycle assessment (LCA), circularity assessment, socio-economic analysis, and eco-efficiency into product design development methods to incorporate sustainability in the design process (Mann et al., 2018; Marešová et al., 2020; Moultrie et al., 2015a; Sousa et al., 2021a)

Fig. 6 maps the significant categories of sustainability (economic, environmental, and social) that are affected by design decisions taken by different stakeholders. The sustainability assessment criteria relevant to a medical device should be derived as design constraints or specifications during the requirements engineering phase of the design process to allow the designers the develop design concepts satisfying those criteria during the conceptual engineering phase. Furthermore, during the concepts screening and evaluation phase of the design process, those criteria should be used to pinpoint design elements and decisions that significantly impact the sustainability-related outcomes and develop design mitigation strategies to improve those outcomes.

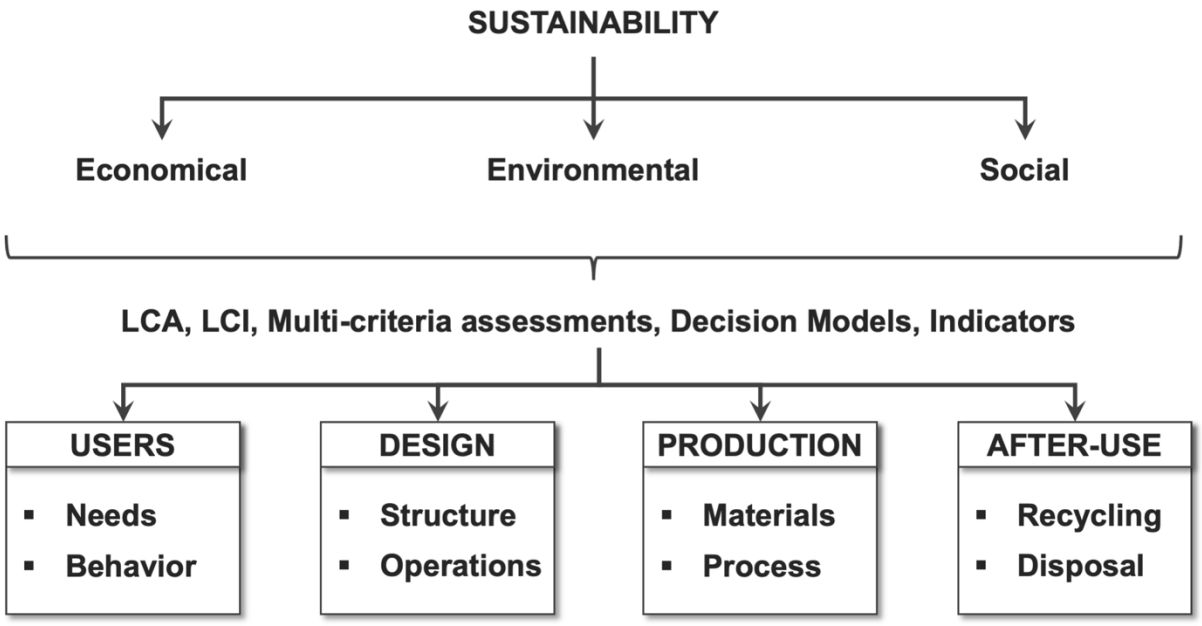

Fig. 6: *Sustainability-related attributes in different stages of the product life cycle*

Multi-criteria decision models have been used to incorporate sustainability by integrating LCA, engineering design, and multi-criteria assessment at the early stage of the design process. Decision models result in several design solutions, and their calculated impacts are used to input the multi-criteria evaluation. However, the level of information required at this stage is significant due to the dynamic nature of attributes.

Stamford and Azapagic introduced a list of 43 measures grouped into techno-economic, social, and environmental categories to assess a combination of energy sources (Stamford & Azapagic, 2012). Han et al. have developed a set of criteria for each stage of the product life cycle to assess design concepts early in the design process (Han et al., 2021). They have grouped these criteria under materials, production, use, and end-of-life to tackle sustainability from the perspective of environmental impact without economic and social

aspects. They have used a weighted approach to quantify the impact of design on ecological sustainability.

The stakeholders' behavior and attitude significantly influence the incorporation of sustainability into any medical device (Pereno & Eriksson, 2020). These stakeholders include regulatory bodies and healthcare institutions as well. Considerable resources have been allocated to improve sustainability in the system. However, these efforts have been primarily concentrated on waste efficiency and disposal (hazardous and non-hazardous), energy consumption, water consumption, packaging, and disposal.

The medical device industry has been left out to mend itself to introduce activities like the take-back program to introduce recycling into their activities (Kleovoulou et al., 2021; Lennox et al., 2017; Pereno & Eriksson, 2020; Sousa et al., 2021a). However, due to the safety and regulatory hurdles, medical devices were not targeted to reduce the downstream impact on environmental, social, and economic sustainability. Table 1 summarizes relevant measures reported in the literature applicable in different stages of the product life cycle to assess product design concepts. Many of these measures might not be applicable to the healthcare domain due to their unique risk profile and requirements.

Table 1: *Measures reported in the literature related to sustainability in different stages of the product life cycle. Some of these measures might not apply to the healthcare domain due to its unique risk profile and requirements.*

STAGES	ATTRIBUTES
DESIGN	▪ Modular design ▪ Design for X (*Assembly, disassembly, manufacturing, maintenance, repair, packing, transporting, refurbishability, and upgradability*) ▪ Reduce the size, weight, and number of components
MANUFACTURING	▪ Efficient manufacturing processes ▪ Use waste as fuel to make it efficient ▪ Use renewable energy sources
LABELLING	▪ Fairtrade and origin ▪ Eco-certifications ▪ Local production
USAGE	▪ Energy efficiency ▪ Carbon emission ▪ Infrastructure ▪ Human resources required
TRANSPORT	▪ Low-emission transport ▪ Local sourcing and procurement ▪ Compact packaging for ease of transport
WASTE	▪ Reuse / recycle ▪ Eliminate / reduce waste ▪ Reduce hazardous waste ▪ Reduce electronic waste
MATERIALS	▪ No to non-renewable materials ▪ Efficient use of materials ▪ Use natural materials ▪ Use responsibly sourced/recycled materials ▪ Biodegradable ▪ Extended useful lifetime / reusability

3.3 Summary

Sustainability has been recently introduced into the medical device industry, especially in life-saving products. The accessories product industry is increasingly caught with sustainability initiatives due to the limited contact with human tissues and body fluids. They introduced proven sustainability measures from the product design domain to push themselves ahead of the curve. However, the medical device industry has not caught up due to their products' safety and regulatory burden. Consumer behaviors, including price sensitivity, perceived quality, sustainability, and satisfaction, could force the industry. Regulatory bodies like EMA have been upfront about setting sustainability goals for marketing medical devices in those regions. So, regulations and consumer behaviors are forcing the industry to adopt measures to have sustainable medical devices. Some methods, including LCA, LCI, decision models, and multi-criteria assessments that have been proven valuable in introducing sustainability in the product design domain, can be repurposed to take on the medical device industry. Among them, the multi-criteria assessment method has shown potential at the early stage of the design process, where the cost and time could be effectively utilized.

Chapter

4

A METHODOLOGY TO INCORPORATE AND ASSESS SUSTAINABILITY IN MEDICAL DEVICE DESIGN

The medical device industry is highly regulated due to public safety concerns and issues with operating, using, and implanting devices in delivering healthcare services. Any malfunction or defective part can significantly raise the risk of malfunction and performance, potentially putting patients' lives at considerable risk. For medical device manufacturers, design issues, manufacturing defects, and device recall cost millions, if not billions, of dollars annually. So, the industry has focused heavily on assessing functionality, technical feasibility, and cost considerations of the device during the design phase of the cycle.

Due to the rising concerns about the healthcare industry's environmental, economic, and social impact, it is attempting to incorporate additional assessment criteria, including responsible sourcing, high-quality, affordable, environmentally friendly after-use management, and sustainable supply in the design phase of medical devices to reduce those

impacts in downstream. This chapter describes a methodology to incorporate and assess sustainability aspects into the medical device design and development process at the early stage by dissecting the design decisions. It also discusses different assessment criteria developed to evaluate design concepts during the selection process. Finally, a brief list of design mitigation strategies to maximize the impact on overall sustainability using TRIZ principles is given at the end of the chapter to aid the designers when reviewing the assessment and revising their design.

4.1 Sustainability Attributes

Incorporating an exhaustive list of sustainability goals into the methodology would be challenging for any medical device designer to conduct the assessment and might dilute the intended outcomes that this work aimed to have. So, we have targeted three significant aspects that are highly relevant in aiding the designers in developing medical devices that have reduced impact on the environment while giving attention to economic and social sustainability (Fig. 7). Each of them was further subdivided into various attributes to capture factors influencing the overall sustainability of the device.

The attributes were derived for environmental sustainability based on asking which activity, materials, processes, and design decisions in various phases of the life cycle of the product would result in environmental harm (Table 2). Similarly, the costs associated with designing functional and performance design features of the products, including associated costs (regulatory, sterilization, and usage), were considered when defining attributes to capture the economic sustainability of the product (Table 3). Finally, the activities and factors influencing society, including design complexity (high cost of production), use of rare

materials, sourcing inexpensively from conflict-ridden parts of the world, and reasonable workers' rights and safety precautions, were considered for defining attributes to capture social sustainability aspects of the product (Table 4).

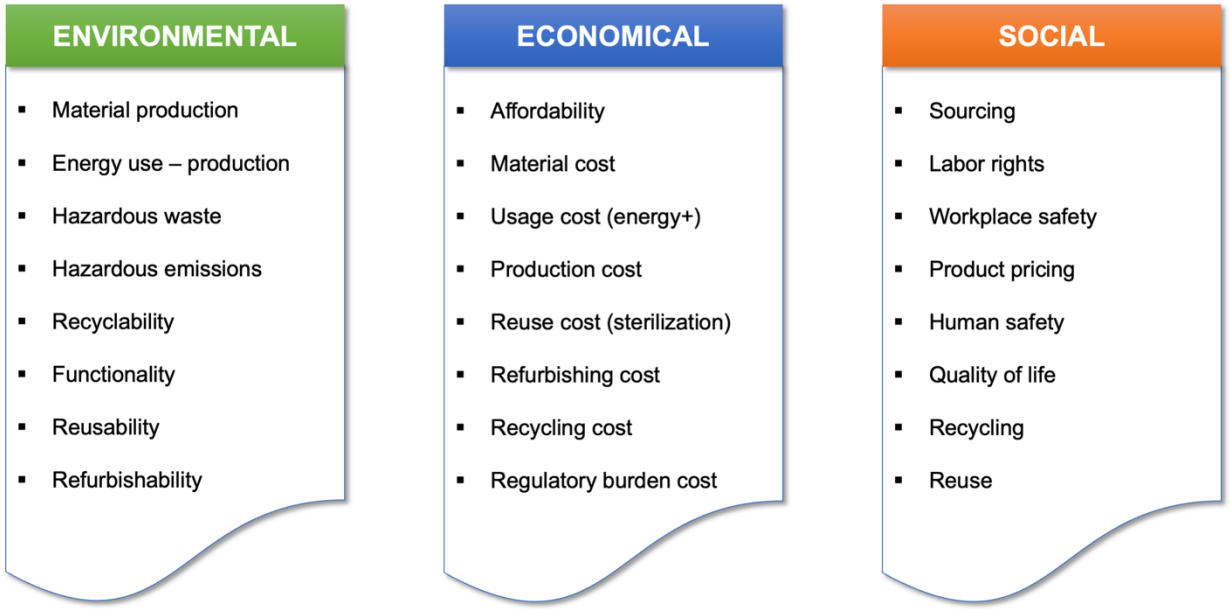

Fig. 7: Different categories of sustainability and contributing attributes

During the assessment in each sub-section, an effort was also made to add some notes to each attribute on their scope. Some of these attributes are purposefully repeated to aid the designers in identifying design opportunities and taking a different perspective in assessing them at that moment (Mann et al., 2018; Pereno & Eriksson, 2020; Sousa et al., 2021a). Sustainability assessment in the healthcare domain is a vast field of research, and incorporating all of them would dilute the purpose. Therefore, in this work, we have limited the scope to sustainability aspects relevant to medical device design (hardware – mechanical, and electronics).

Table 2: *Attributes relevant to the environmental sustainability aspects*

ENVIRONMENTAL SUSTAINABILITY		
Attributes	**Description**	**Motivation**
Material production	Responsible mining, sourcing, producing, and recycling	Materials that are responsible for environmental harm, especially single-use products (Volland et al., 2017)
Energy Use – Production	Types of energy sources used in producing the materials (renewable and non-renewable sources) and their impact	Economically effective but environmentally harmful energy sources (e.g., coal refuse)
Hazardous Waste	Generated waste during the production and processing of materials	During the mining and processing stages of production, harmful wastes are released into the environment and water bodies. (Arun Kumar, 2021)
Hazardous emissions	Carbon and other hazardous emissions during the production, processing, and transporting of materials to the destination.	Economically effective to release unprocessed emissions into the air.
Recyclability	Percentage of the material that could be recycled after processing it for industrial use.	A higher proportion of materials used in the device are meant for single-use and disposal. (Sousa et al., 2021b)

Attributes	Description	Motivation
Functionality	The amount of material that can be traded off without compromising the functionality with the intent to reduce wastage	The use of advanced generative design or 3D-printing methods could reduce excessive use of materials and generated waste.
Reusability	Disinfection or sterlizability (potential number of reuses of the material in a healthcare setting without compromising safety, functionality, and performance.	Different material characteristics demand different sterilization and disinfection methods before reuse. Each sterilization process has its impact on the environment and carbon emission from the material during the process.
Refurbishability	After-use use of material for other purposes (upcycling) - the cost of recycling and remanufacturing	Recycling process to convert the material (used) to useable raw material or a product have an impact of environment and emissions. (Moultrie et al., 2015b)

Table 3: *Attributes relevant to the economic sustainability aspects*

ECONOMIC SUSTAINABILITY		
Attributes	**Description**	**Motivation**
Affordability	The associated cost of fulfilling sustainability objectives must be balanced with business objectives to deliver affordable and innovative medical devices while ensuring functional and safety aspects of them are fulfilled.	Affordable by people in low-medium-income countries (LMICs) is ensures equality in health
Material Cost	The cost of acquiring raw and responsibly sourced (recycled or renewable origin) should be taken into consideration	Functionally necessary materials result in high costs, which could affect the pricing and make the product beyond reach to many deserving patients. (Sousa et al., 2021b)
Energy Cost	The cost of the energy required to produce the material, transform it into the final form (manufacturing), and transport them to the destination.	Green manufacturing including the use of cleaner energy sources and efficient use of waste products.
Production Cost	The cost associated with manufacturing, idle time, and workforce training due to the complexity in design or unique material choice	The complex design could become a bottleneck in a production line, time to market, reduced throughput, and need for expensive infrastructure. (Gabriel et al., 2018)

Attributes	Description	Motivation
Reuse Cost (sterilization)	The cost associated with disinfection, sterilization, components that need to be replaced before reuse, and consumables	Economies of scale and material choice to make the device affordable and suitable for mass production might result in a high reuse cost resulting from associated processes.
Refurbishing Cost	The cost associated with disinfection, sterilization, components that need to be replaced or repaired, testing, certification, and other consumables	Refurbishing requires an added cost on top of sterilization. The cost associated with replacing components and safety assessment.
Recycling Cost	The cost associated with separating the recyclable design elements from others and the efforts required to disassemble, disinfect, clean, and convert them to raw material and dispose of the unrecyclable components.	Low recovery to volume ratio and high cost of recycling would deter the manufacturer and healthcare providers to avoid recycling. (Sørensen et al., 2022)
Regulatory Burden Cost	Due to regulations at every stage of the design cycle, there is an undue administrative, testing, and financial burden.	Regulatory burden in reuse, recycle, and refurbish a product could result in moving the manufacturer to single-use products. (Arun Kumar, 2021)

Table 4: *Attributes relevant to the social sustainability aspects*

SOCIAL SUSTAINABILITY		
Attributes	**Description**	**Motivation**
Sourcing	The origin of the material, whether it is responsibly sourced, conflict-free, and verifiable.	Collective avoidance of material purchase from conflict regions results in significant social change.
Labour Rights	Efforts to ensure during various stages (material sourcing, manufacturing, recycling, re-manufacturing, and disposal) of the life cycle of the product no labor rights are violated.	Where, when, and who makes the difference in terms of cost of the product but at what cost to the labor rights and working conditions.
Workplace Safety	Safety of the workers during various stages (material sourcing, manufacturing, recycling, re-manufacturing, and disposal).	Handling materials at various stages of their journey requires workers to protect themselves (accidents, exposure, etc.)
Product Pricing	Affordable to % of the deserving population. The associated cost of fulfilling sustainability objectives must be balanced with business objectives to deliver affordable and innovative medical devices while ensuring functionality and safety aspects of them are fulfilled.	Choice of material, manufacturing process, design complexity, and sustainability goals would have a significant impact on product pricing, which could result in making the product not affordable by the deserving population in LMICs. (Pereno & Eriksson, 2020)

Attributes	Description	Motivation
Human Safety	Safety and functional performance of the device in use in different ethnicity and use or service environment.	The requirement for trained personnel and protective equipment to safely operate the device might deter adopting the device in practice. (Branaghan, 2018; Miclăuş et al., 2020)
Quality of Life	Potential for exploitation of workers in production, manufacturing, and distribution facilities	Cost-of-living, workers pay and rights, and quality life have been impacted by purchasing and contracting decisions.
Recycling	Including take-back, biodegradable, easy-to-dispose, and safe after-use management	The choice of processing of materials and combinations have impact on the recycling processes and workers involved in them due to associated safety (shipped to developing countries).
Reuse	Sterilize, disinfect, and the number of times reusable without compromising safety and functional performance.	Public health safety vs. cost vs. sustainability. (Kleber & Cohen, 2020)

4.2. Critical Assessment of Factors

We have mapped the factors relevant to overall sustainability goals (environmental, economic, and social) to the design decisions taken at the early stage of the product development cycle. The key design decisions taken at this stage are the choice of material, manufacturing, design elements, and after-use management of the device (Howard A. Kuhn, 1997). For example, even though packaging and distribution significantly impact the carbon footprint and sustainability aspects, they are either designed after the detailed design of the device or not a dependent variable. Also, we have assumed that the criteria to fulfill the functional aspects of the devices have been developed and incorporated into the assessment criteria.

- **Materials:** Can we use recyclable or reusable materials instead of single-use materials? Can we use an alternate material instead of fossil-fuel-based material? Can we increase the recyclability of the device by reducing the number of different materials used? Can we source a verifiable conflict-free material instead of materials of unknown origin? Can we source from eco-certified suppliers for pollution control, environmental impact, and carbon emissions? Can we source from a local supplier to reduce the transportation-related carbon footprint? What kind of undue regulatory burden to use new material to fulfill sustainability objectives? Would the procurement division participate in early design decisions to offer feedback on sourcing materials and suppliers to meet overall goals?

- **Design**: Can we minimize materials use-related carbon emissions by reducing the size and weight of the device? Could the device be redesigned to make it reusable instead of

single-use? Can we make it manual to avoid using customized electronic components and their disposal impact? Can we standardize the components across design varieties to exploit economies of scale? Can we modularize the design to explore sustainable ways (eco-manufacturing, reuse, refurbishing, and recycling) to address each design element instead of a lump sum? Can we use standard Original Equipment Manufacturer (OEM) components to reduce customization and its impact on extended use? Can we simplify the design to minimize the use of special machines and processes? How do we incorporate design for manufacturing, design for assembly and disassembly, and design for maintenance and repair while fulfilling functional, business, and sustainability objectives? When incorporating sustainability goals, what is the expected increased regulatory burden (administrative, time and effort, and financial)?

- **Manufacturing**: Can we use standard manufacturing processes to produce the design to make locally? Can 3D-printing processes reduce the lead time, material waste, and the need for special machines? Can the procurement division assist designers in identifying manufacturers who could be viable partners? How do we ensure our manufacturers follow GMP guidelines and best environmental practices (BEP) to reduce environmental impact? Is it economically feasible to opt for a process to adopt sustainability objectives? Would the manufacturers participate in early design decisions to mitigate late-stage manufacturing and production-related issues? How would a streamlined co-design process impact overall sustainability objectives?

- **After-use**: What are the challenges and risk factors associated with opting for a reusable alternative? How to increase the number of components and sub-systems that can be recycled or scavenged? Could the original manufacturer refurbish the device to extend its

usable life? Can responsible disposal methods be explored to reduce the environmental and economic impact? What critical infrastructure requirement or expertise is needed, and what are its financial implications? Do regulatory issues need to be considered when opting for a suitable after-use management protocol?

4.3 Sustainable Materials

We have derived attributes from the critical sustainability assessment during the design phase (refer to section 4.2). Overall sustainability objectives (refer to tables 1-3) for assessing the choice of materials (Fig. 8). Material selection during the design process directly impacts the medical device's functional, structural, performance, environmental, financial, and social aspects (Onat et al., 2017; Salas et al., 2020). Given that the device's safety during its use is paramount, characteristics like biocompatibility, cytotoxicity, and other properties that have implications for tissue-device interaction play an essential role in the design decision. However, concerning sustainability, we consider assessing its reusability, sterilizability, recyclability, and responsible disposal of the material during and after use.

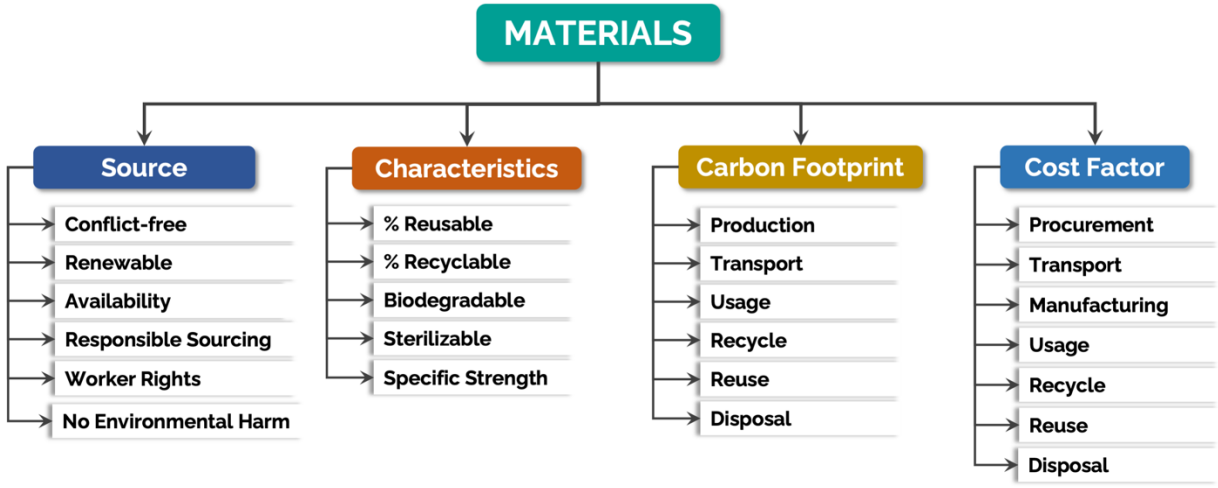

Fig. 8: *Sustainability criteria related to materials used in medical devices*

The environmental and social impact of the material from the origin includes responsibly sourced and conflict-free (verifiable) (Table 5). The carbon footprint generated during production, transportation, manufacturing, operating, reusing, recycling, and disposing of needs to be accounted for when developing mitigation strategies to reduce their impact (Tables 6 and 7). However, the functional and performance aspects of the product cannot be traded off to the level that it would compromise the safety of the stakeholders. Above all, the cost associated with these factors must be assessed for the financial sustainability of the product and to ensure they meet the business objectives.

Sustainability assessment metrics relevant to the materials focus on replacing fossil fuel-based materials with renewable materials like plant-based ones (Gaspar et al., 2020; Kumar et al., 2022). However, the impact of these suggestions on material selection for healthcare products is minimum since every new material must undergo rigorous in vitro and in-vivo tests to ensure no serious adverse events in human subjects. Also, the associated cost and time implications of introducing a new material force the designers to select a material from a portfolio of existing materials that have been approved for various medical uses to its impact on time to market and cost (Table 8). The choice of materials available with respect to functional and structural constraints is limited, which offers opportunities and challenges to the designers to innovate in terms of new design concepts, mechanisms, and operations. Some of the materials are rare and have been shown prone to be from conflict-ridden locations, or exploitation of labor is prominent and cannot be verified. The alternate mechanism would be for the designers to search for materials that offer similar functional performance, are locally sourced, renewable, and have plenty of suppliers to increase the robustness of the supply chain while reducing the impact on environmental and social sustainability issues.

***Table 5**: Sustainability aspects related to the source and production of the chosen material*

	Attributes	Low (Score 0)	Medium (Score 5)	High (Score 10)	Notes
SOURCING	**Conflict-free (S_1)**	High possibility of being a conflict mineral	Fair possibility of being a conflict-free material, but not verifiable	Certified conflict-free material	*Ethical and social sustainability*
	Renewable (S_2)	Non-renewable	Hybrid	Renewable	*Impact on environment*
	Availability (S_3)	Rare-earth material	Not rare but with high demand	Commonly used Industrial Material with good availability	*Reduce dependency*
	Sourcing (S_4)	Sourced and imported from another continent	Hybrid (imported from the same continent and/or locally sourced)	Locally sourced and supplied	*Transport*
	Labor Rights (S_5)	High possibility of using child labour and poor working conditions to produce the material	Fair possibility of having good labor rights at the material production facility – but not verifiable	Verifiable working conditions and child labor-free material production	*Social sustainability, human rights*
	$M_1 = M_{Source} = \sum_{i=1}^{n} x_i S_i$, *where* $0 \leq x_i \leq 1.0$ *while* $\sum_{i=1}^{n} x_i = 1$; *n represents the number of attributes (5) and* x_i *represents the assigned weightage to the* i^{th} *attribute.*				

Table 6: *Characteristics of the material that have a significant impact on sustainability*

	Attributes	Low (Score 0)	Medium (Score 5)	High (Score 10)	Notes
CHARACTERISTICS	**% Reusable (C_1)**	100% not reusable, strictly for single use and discard	Fair possibility of reusing but with reduced performance and added cost	100% reusable with a fair amount of added cost	*Not indefinitely but fair reuse with no safety and performance issues*
	% Recyclable (C_2)	100% not recyclable once formed into a part	Fair possibility of reusing but with a significant cost	100% recyclable	*Recycling the material for the same or similar purpose*
	Sterilizable (C_3)	It cannot be sterilized with a standard process and requires special procedures to avoid damage to the material	With effort, the material can be sterilized with a standard process, but a limited number of times.	It can be sterilized with the standard process without affecting functional, performance, and safety aspects.	*Potential for reuse and recycle*
	Biodegradable (C_4)	Not biodegradable and alternate disposal method required	Biodegradable with time, added processing, and effort	100% biodegradable in a reasonable amount of time and effort without added cost	*Disposal (environmental sustainability)*
	Specific Strength (C_5)	Low possibility of reducing weight and volume of the material used to achieve the required functional characteristics	Fair possibility of reducing the weight and volume of the material used to fulfill the required functional characteristics	High possibility to reduce the weight and volume without compromising the required functional characteristics	*Transport + storage + handling (environmental sustainability)*
	$M_2 = M_{Ch} = \sum_{i=1}^{n} x_i C_i$, *where* $0 \le x_i \le 1.0$ *while* $\sum_{i=1}^{n} x_i = 1$; *n represents the number of attributes (5) and* x_i *represent the assigned weightage to the* i^{th} *attribute.*				

Table 7: *Carbon footprint at different stages of the processing of the material*

	Attributes	Low (Score 0)	Medium (Score 5)	High (Score 10)	Notes
CARBON FOOTPRINT	**Production (C_1)**	Heavy carbon footprint (mining, pollution, energy usage, and toxic waste) and long-lasting environmental impact	A fair level of control over the carbon footprint (waste, energy usage, and pollution), but can be improved without economic cost.	Well-managed pollution, waste, and energy use during production to reduce environmental impact	*Environmental impact of production*
	Transport (C_2)	Long-distance transporting of the material to the destination and no potential to reduce the transporting distance	Potential to manage transportation-related emissions but interlinked to other issues like labor rights, cost, and time.	High potential to reduce transportation-related emissions without significant added cost (local sourcing, production near the source, etc..)	*Recycling the material for the same or similar purpose*
	Usage (C_3)	High carbon emission and energy consumption during the use of the device	A fair amount of carbon emission and energy consumption during the use of the device	No or below the recommended or standard amount of carbon emission and energy consumption during the use of the device	*carbon emissions may be present during the usage or consumption of the product.*
	Recycle (C_4)	No possibility of recycling	A fair possibility of recycling the material	100% recyclable after use	*Recover*
	Reuse (C_5)	Low possibility to sterilize without damage to the material or infrastructure cost	Alternate avenues of sterilizing the material exist within acceptable level of cost	Sterilizable without affecting inherent properties and safety (reasonable times)	*Sterilization / Disinfect*
	Disposal (C_6)	Low potential to safely dispose of without added strain on the environment and cost.	A fair possibility to safely dispose of within the industry standard and added cost	High potential to safely dispose of without significant strain on the environment and cost.	*Disposal (environmental sustainability)*
	$M_3 = M_{CF} = \sum_{i=1}^{n} x_i C_i$, *where* $0 \leq x_i \leq 1.0$ *while* $\sum_{i=1}^{n} x_i = 1$; *n represents the number of attributes (6) and* x_i *represents the assigned weightage to the* i^{th} *attribute.*				

Table 8: *The costs associated with different stages of the material's life cycle along with the product*

	Attributes	Low (Score 0)	Medium (Score 5)	High (Score 10)	Notes
COST FACTOR	**Procurement (C_1)**	Very limited choices in sourcing environmentally friendly and responsibly sourced materials and suppliers	Fair number of alternatives in sourcing environmentally friendly and responsibly sourced materials and suppliers	Plenty of choices in sourcing environmentally friendly and responsibly sourced materials and suppliers	*Antitrust and competitive pricing*
	Transport (C_2)	No or not-so-reliable domestic or local source (increased transportation cost)	A fair number of local suppliers with trade-offs in time, cost, and reliability.	A significant number of reliable local sources and suppliers within reasonable time and cost.	*Distance*
	Manufacturing (C_3)	Highly specialized manufacturing processes, machines and trained workforce are required	Except for some of the design features or parts, rest can be manufactured with standard machines and processes	Can be manufactured with routine manufacturing processes (no special machines or processes required)	*Complexity*
	Usage (C_4)	High cost of energy, carbon emission, and operating during its use	A considerable but fair cost consideration in terms of carbon emission, energy consumption, and operating during its use	No or below the standard cost of carbon emission, energy consumption, and operating during its use	*Cost to use the product.*
	Reuse (C_5)	High cost of sterilization due to sophisticated infrastructure and excessive operational and device maintenance cost	No excessive but fair amount of infrastructure, workforce, and operational costs and device maintenance cost	Can be sterilized with a standard sterilization protocol and low maintenance/repair cost	*Contamination Reuse – recycle*
	Recycle (C_6)	Not recyclable	Partially recyclable at significant cost	100% recyclable within reasonable cost	
	Disposal (C_7)	High economic and environmental cost to dispose	Fair amount of economic cost and environmental impact to dispose	Easy to dispose with reasonable cost and no environmental impact	*After-use managing cost*
	$M_4 = M_{Cost} = \sum_{i=1}^{n} x_i C_i$, *where* $0 \le x_i \le 1.0$ *while* $\sum_{i=1}^{n} x_i = 1$; *n represents the number of attributes (7) and* x_i *represents the assigned weightage to the* i^{th} *attribute.*				

4.4 Design, Manufacturing, and Operations

Design for manufacturing (DFM), assembly (DFA), and maintenance and repair are critical concurrent engineering design methods migrated from academic interests into industrial practices to allow designers to assess the downstream impacts of design decisions (Binedell & Subburaj, 2022). Design for manufacturing and assembly principles are exhaustive and aim to reduce the number of iterations between design and production teams, associated cost, and time-to-market. Some of these principles include modularization, standardization of components across products, exploiting the use of standard Original Equipment Manufacturer (OEM) parts, and reducing the complexity with respect to the manufacturing process that will be used to manufacture those components. Over-customizing a device would increase tooling costs, manufacturing time, and production costs. The financial and environmental burden due to manufacturing and assembling complex components should be targeted with the established and emerging design principles without compromising the safety, functional, and performance aspects of the device (Mann et al., 2018; Marešová et al., 2020; Miclăuş et al., 2020). The complex, integrated, and custom product design would result in expensive and waste-ridden manufacturing steps and have long-term implications for production and use costs. So, we have extracted attributes to assess their influence on downstream sustainability (Fig. 9).

Also, the required energy, maintenance, and effort to use the device during its lifecycle are affected by the design decisions. Quantifying them alongside the design complexity and product structure would offer a better understanding instead of assessing them as "during use" separately. The primary drivers of the product structure are the functional requirements and user experience of the device. The design decisions on the customization,

standardization, and design varieties would significantly influence the medical device class and regulatory pathway. The regulations are one of the primary design drivers that differentiate medical devices from consumer products. A simple design change from a battery-driven motor to a hand-operated mechanism or electrical pulses to vibration to simulate muscles would take the device to a lower class due to risk reduction. Designers must be aware of the regulatory burden (administrative, time, testing, and financial) of their design decisions. These decisions would allow the medical device manufacturers to make the device more easily accessible to deserving patients at an affordable and earlier (time to market) due to reduced regulatory burden and increased safety profile. Considering design, manufacturing, and functional testing (verification) phases of the design process are highly interlinked and designers iterate between them, we have opted to combine them for a comprehensive assessment. They are primarily driven by design complexity (Table 9), product architecture (Table 10), and product operations (Table 11).

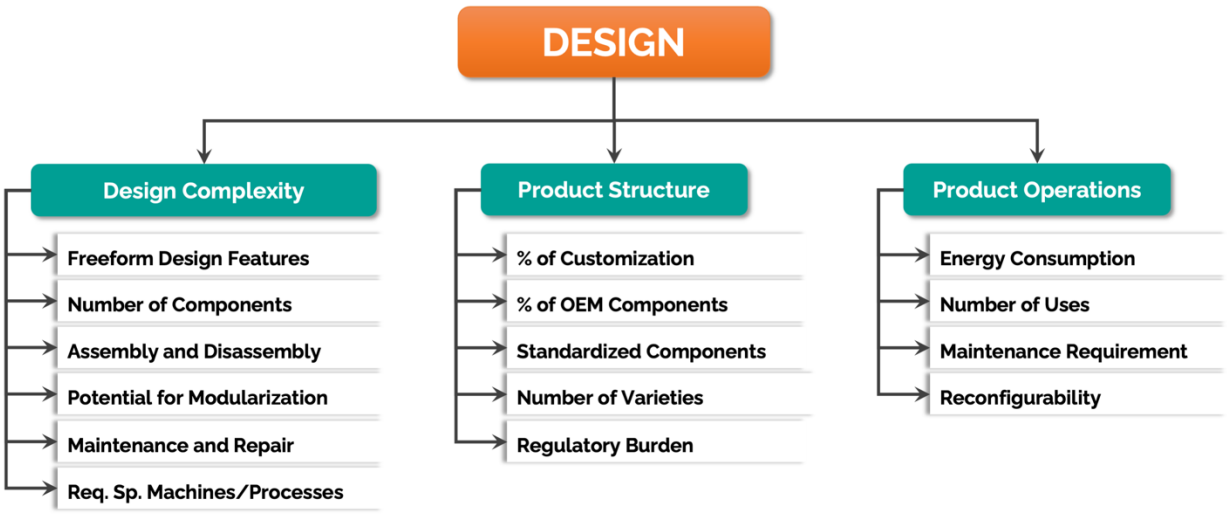

Fig. 9: *Attributes related to the design, manufacturing, and operations of the product*

Table 9: *Complexity of the design in terms of manufacturing, assembly, suppliers, maintenance, and repair*

	Attributes	Low (Score 0)	Medium (Score 5)	High (Score 10)	Notes
COMPLEXITY	**Design Features (C_1)**	Complex freeform design features	A mix of complex and standard design features	Standard design features	*Mfg. Complexity*
	Number of Components (C_2)	Too many components with respect to the expected functions	Fair number of components to fulfill the required functions	As few components it can be to fulfil the required functions	*No. of elements*
	Assembly (C_3)	Multiple assembly directions and lack of possibility to improve the ease of assembly and create sub-assemblies	More than a fair share of assembly directions and has potential to create subassemblies and improve the ease of assembly	High potential to have top-down assembly and develop sub-assemblies	*Design for assembly*
	Modularization (C_4)	No or low potential to modularize the design	Fair potential to modularize the design	High potential to modularize the design	*Time to market*
	Maintenance and Repair (C_5)	Low potential to incorporate design for disassembly, maintenance, and repair	Fair potential incorporate design for disassembly, maintenance, and repair	High potential to incorporate design for disassembly, maintenance, and repair	*Reduce downtime*
	Requirements for Special Machines / Processes (C_6)	More than a fair share of special manufacturing processes and set-ups with respect to expected functionalities of the design	A fair share of special manufacturing processes and setups with respect to expected functionalities of the design	Standard manufacturing processes are sufficient to get the design manufactured	*Resource constraints*
	$D_1 = D_{complex} = \sum_{i=1}^{n} x_i C_i$, $where\ \ 0 \le x_i \le 1.0\ while\ \sum_{i=1}^{n} x_i = 1$; *n represents the number of attributes (6) and* x_i *represents the assigned weightage to the* i^{th} *attribute.*				

Table 10: *Product architecture aspects of the design that contributes to the sustainability*

	Attributes	Low (Score 0)	Medium (Score 5)	High (Score 10)	Notes
PRODUCT ARCHITECTURE	**% Customization (P_1)**	More than 2/3rd are customized design elements (Z > 2/3)	Less than 2/3rd but more than 1/3rd are customized design elements (1/3 < Z <2/3)	Less than 1/3rd are customized design elements (Z < 1/3)	*Time and efforts*
	% OEM Components (P2)	Less than 1/3rd are OEM components (Z < 1/3)	More than 1/3rd but less than 2/3rd are OEM Components (1/3 < Z < 2/3)	More than 2/3rd are OEM components (Z > 2/3)	*OEM (off the shelf)*
	Standardization (P_3)	Low potential to use the standardized components	Fair potential to use standardized components	High potential to use standardized components	*Economics of Scale*
	Design Varieties (P_4)	Many design varieties are required to cater to a larger cohort of patients.	A fair set of design varieties are required to cater to a larger cohort of patients.	Less number of design varieties are required to cater to a larger cohort of patients.	*Inclusive*
	Standards and Regulatory Burden (P_5)	High level of burden due to design conceptualization, customization, non-std. materials, and manufacturing processes against the business objectives.	A higher burden than expected due to design conceptualization, customization, non-std. materials, and manufacturing processes against the business objectives	Significantly lower than expected level of burden due to innovativeness of the design, technologies used in the design, standardization, and exploiting existing systems	*Regulatory Burden, time, and cost*
	$D_2 = D_{product} = \sum_{i=1}^{n} x_i P_i$, *where* $0 \le x_i \le 1.0$ *while* $\sum_{i=1}^{n} x_i = 1$; *n represents the number of attributes (5) and* x_i *represents the assigned weightage to the* i^{th} *attribute.*				

Table 11: *Operational aspects of the design that contributes to the sustainability*

	Attributes	Low (Score 0)	Medium (Score 5)	High (Score 10)	Notes
PRODUCT OPERATIONS	**Energy Consumption (O_1)**	Low potential to reduce the high energy consumption with alternatives	Good potential to reduce the energy conception to an acceptable level with design modifications	High potential to reduce the energy consumption and improve energy efficiency of the device with design changes	*Energy consumption during use*
	Number of Uses (O_2)	Significantly a smaller number of uses than expected of a similar product and low potential to increase it with design changes	Below average number of uses than the expected and offers some potential to improve it with design changes at cost.	Larger number of uses than the expected and offer high potential to optimize without compromising safety and performance.	*Number of uses*
	Maintenance Requirement (O_3)	Frequent and resource-intensive maintenance and service are required to operate the device safely.	Regular interval maintenance is required with above-average resource intensiveness to operate the device safely	Low-level maintenance is required with standard resources than a similar device to operate the device safely	*Maintenance and service*
	Reconfigurability (O_4)	Complex and time-consuming steps are needed to reconfigure the device to meet patients' needs	A fair level of Complex and time-consuming steps is needed to reconfigure the device to meet patients' needs	Easy and less time-consuming steps are needed to reconfigure the device to meet patients' needs	*Adjustability*
	$D3 = D_{Operationt} = \sum_{i=1}^{n} x_i O_i$, *where* $0 \leq x_i \leq 1.0$ *while* $\sum_{i=1}^{n} x_i = 1$; *n represents the number of attributes (4) and* x_i *represents the assigned weightage to the* i^{th} *attribute.*				

4.5 After-use Management of Medical Devices

According to the theory of the 5Rs, the designers should consider viable alternate options before considering recycling or disposing of the device at the end of the described life cycle. There are four fundamental options: refuse, reuse, reduce, and repurpose. Refusing and reducing opportunities are critical for designers during the early stage of the design cycle when making the material choice decision to ensure they are fairtrade and renewable. The designers can remove the materials from the consideration ("refuse") that could harm the environment and the safety of the users during or after-use stage of the device's life cycle. In addition to the discussion on specific in the materials section, the designers should consider reducing the material used to fulfill the functional requirements of the device ("reduce") without compromising the operational integrity and safety aspect of the device during its use.

The other two options (reuse and repurpose) have different implications in the after-use management of the device due to safety, performance, and regulatory burden. The risk associated with the device-specific public health safety aspects for the end-users and stakeholders. It must be considered when analyzing the device for potential reuse and repurpose. The design decision related to reusing the device comes with the unique challenge of satisfying sterilization requirements, infection control, reduced functional performance, and additional regulatory issues. The healthcare industry takes the err side of caution to avoid the hassle of going through regulatory hurdles for various reasons, including time to market, additional testing, associated costs, revenue, and opting for single use. Repurposing (recycling) the device after use can be carried out in different forms, including finding a purpose to reuse the device for other purposes or taking it apart to salvage as many

components as possible before taking the rest to either the raw material stage (melt, pulverize, and other processes.) or disposing of it responsibly (landfill or incinerate).

In this work, we have considered the refuse and reduce at the material evaluation stage and reuse, recycle, and disposal at this stage of the methodology to follow the natural flow of the design thinking process (Fig. 10). In addition, we have considered sterlizability, refurbishability, associated risk profiles for health and safety (disease, contact, and performance), and regulatory burden in the reuse option (Table 12). In the recyclability option, we have considered the salvageability of the device for scavenging parts and materials that could be recycled, avenues to recycle the device without added harm to the environment responsibly, the safety of the workers, and the cost to do so, how safely the device could be recycled considering its use in a healthcare setting, and ability to disassemble and separate components that could be recycled and not contaminated (Table 13). Finally, we have considered carbon emissions, generated hazardous waste, the cost and energy consumed during the safe disposal of the device, and associated health and safety aspects (Table 14).

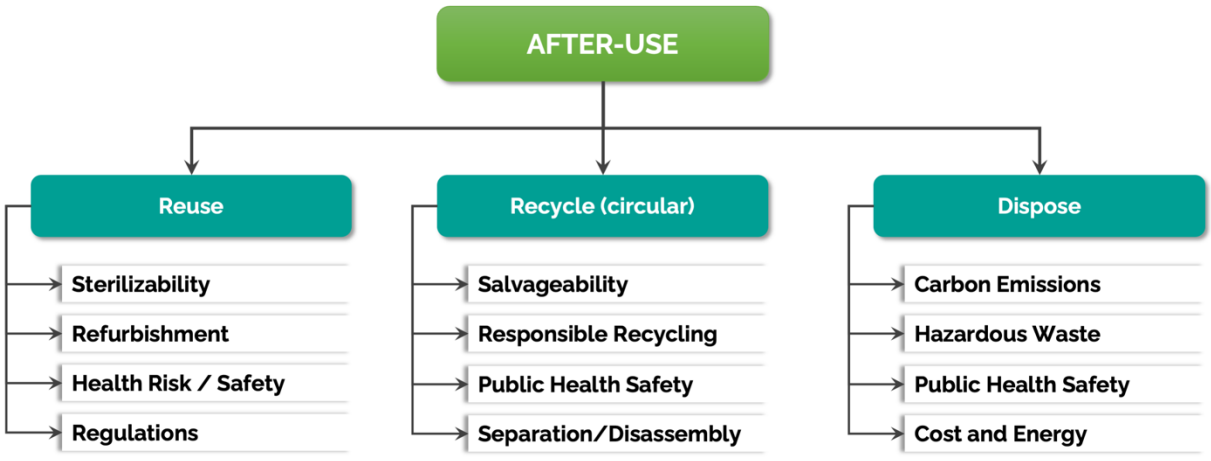

Fig. 10: *Sustainability attributes related to after-use management of medical devices*

Table 12: *Critical aspects of reusing the device in healthcare settings that impact overall sustainability*

	Attributes	Low (Score 0)	Medium (Score 5)	High (Score 10)	Notes
REUSABILITY	**Sterilizability (R_1)**	Low potential to sterilize the device without affecting its performance and safety during subsequent use and adding significant cost	A fair potential to sterilize the device at cost without affecting its performance and safety during subsequent use	High potential to sterilize the device at reasonable cost without affecting its performance and safety during subsequent use	*Cost, performance, and safety of the sterilizing the product for reuse*
	Refurbishment / Remanufacturing (R_2)	More than 2/3rd of the components must be replaced to refurbish the device and the associated cost is significant	More than 1/3rd but less than 2/3rd of the components must be replaced to refurbish the device at a reasonable level of cost	Less than 1/3rd of the components must be replaced to refurbish the device at an acceptable level of cost	*2nd hand use*
	Health Risk / Safety (R_3)	High-risk use and potential for the spread of infection	A fair potential for spreading the infection but can be controllable with precaution and cost	Negligible risk of infection spread and controllable	*Public safety due to reuse*
	Standards and Regulatory Burden (R_4)	High level of burden with respect to the business objectives.	A fair level of a burden than expected with respect to the business objectives	Significantly lower than expected level of burden with respect to the business objectives	*Regulatory Burden, time, and cost*
	$A_1 = A_{Reuse} = \sum_{i=1}^{n} x_i R_i$, *where* $0 \le x_i \le 1.0$ *while* $\sum_{i=1}^{n} x_i = 1$; *n represents the number of attributes (4) and* x_i *represents the assigned weightage to the* i^{th} *attribute.*				

Table 13: *Critical aspects of recycling the device in healthcare settings that impact overall sustainability*

	Attributes	Low (Score 0)	Medium (Score 5)	High (Score 10)	Notes
RECYCLABILITY	**Salvageability (R_1)**	Offers the low potential to salvage components for recycling without compromising public health and environmental safety	Offers a fair potential to salvage several components for recycling without compromising public and environmental safety	High potential to salvage a significant portion of the device for recycling without compromising pubic and environmental safety	*How much of the device can be recycled without safety hazards?*
	Responsible Recycling (R_2)	Low-value addition to the sustainability objectives with respect to the added carbon footprint and cost during the recycling step.	Good value addition to the sustainability objectives with respect to the added carbon footprint and cost during the recycling step.	High-value addition to the sustainability objectives with respect to the added carbon footprint and cost during the recycling step.	*Balance*
	Public Health Safety (R_3)	High risk to public health safety due to biohazards, emissions, waste generation, etc.	A reasonable risk to public health safety is due to biohazards, emissions, waste generation, etc.	Low risk to public health safety due to biohazards, emissions, waste generation, etc.	*Safety*
	Disassembly / Separation (R_4)	Low potential to separate and disassemble recyclable elements from the rest of the device without compromising the safety	Fair potential to separate and disassemble recyclable elements from the rest of the device without compromising safety	High potential to separate and disassemble recyclable elements from the rest of the device without compromising safety	*Design for disassembly and separation*
	$A_2 = A_{Recycle} = \sum_{i=1}^{n} x_i R_i$, $where\ \ 0 \le x_i \le 1.0\ while\ \sum_{i=1}^{n} x_i = 1$; *n represents the number of attributes (4) and x_i represents the assigned weightage to the i^{th} attribute.*				

Table 14: *Aspects of disposing of the device after use relevant to the overall sustainability*

	Attributes	Low (Score 0)	Medium (Score 5)	High (Score 10)	Notes
DISPOSAL	**Carbon Emissions / Carbon Footprint (D_1)**	High carbon footprint and emissions during the disposal	Reasonable carbon footprint and emissions during the disposal	Low carbon footprint and emissions during the disposal	*Impact (environmental)*
	Hazard Waste (D_2)	High levels of hazardous waste are generated during the disposal and add high costs to the process	Reasonable levels of hazardous waste are generated but manageable at a cost.	No hazardous waste is generated during the disposal	*Hazardous to the environment and associated cost*
	Publish Health Safety (D_3)	High risk to public health safety due to biohazard, emissions, waste generation, etc.	A reasonable risk to public health safety is due to biohazard, emissions, waste generation, etc.	Low risk to public health safety due to biohazard, emissions, waste generation, etc.	*Safety*
	Cost and Energy (D_4)	Significant cost and energy required to dispose of the device with respect to the sustainability objectives	Reasonable cost and energy required to dispose of the device with respect to the sustainability objectives	Acceptable cost and energy required to dispose of the device with respect to the sustainability objectives	*Energy waste*
	$A_3 = A_{Disposal} = \sum_{i=1}^{N} x_i D_i$, $where\ \ 0 \le x_i \le 1.0\ while\ \sum_{i=1}^{N} x_i = 1$; *n represents the number of attributes (4) and* x_i *represents the assigned weightage to the* i^{th} *attribute.*				

Attributes are design-problem dependent variables, so they cannot be weighted equally toward design decisions. Instead, the designer and the domain experts must step in to assign weightage based on the functionalities of the design, business objectives, and sustainability goals. Thus, the scores can be calculated using the following equations (1-10 scale).

Materials = $\sum_{i=1}^{m} x_i M_i$, *where* $0 \leq x_i \leq 1$ *while* $\sum_{i=1}^{m} x_i = 1$; *m represents the number of categories in the assessment of the choice of material, and* x_i *represents the weightage of the* i^{th} *category (assigned by the designer)*

Design = $\sum_{i=1}^{d} x_i D_i$, *where* $0 \leq x_i \leq 1$ *while* $\sum_{i=1}^{d} x_i = 1$; *d represents the number of categories in the assessment of the design characteristics, and* x_i *represents the weightage of the* i^{th} *category (assigned by the designer)*

After-use = $\sum_{i=1}^{a} x_i A_i$, *where* $0 \leq x_i \leq 1$ *while* $\sum_{i=1}^{a} x_i = 1$; *a represents the number of categories in the assessment of the design choices related to after-use of the device, and* x_i *represents the weightage of the* i^{th} *category (assigned by the designer)*

Overall sustainability score = (Materials + Design + After-use)/3.

The weightage values (x_i) assigned to each category and attribute vary as they are dependent on the type of medical device (implantable, supportive, non-critical accessories, critical life-saving device, mechanically operated, electromechanical systems, and other types), the scale and organizational culture of the organization (sustainability goals), the structure and culture of the design team (capabilities and collaboration), and work experience of the

designer. Even though we calculate the overall sustainability assessment score, one must be cautioned when using it to portray that the product meets the sustainability requirements. The scores of individual attributes offer a better insight into developing design mitigation strategies.

4.6 Design Mitigation Strategies

Based on the Teoriya Resheniya Izobretatelskikh Zadatch (TRIZ) principles (*lit. "theory of inventive problem solving"*), we have listed simple design mitigation strategies that could be employed when assessing individual attributes (Table 15). Considering there are 40 known TRIZ principles and an infinite number of combinations, it offers designers an avenue to explore design mitigation strategies as demanded in the context (Gao et al., 2015; Russo & Spreafico, 2020).

Table 15: *A list of Design Mitigation Strategies*

(Design strategies are context-sensitive and can be derived using TRIZ governing principles)

ATTRIBUTES		DESCRIPTION
SUBSTITUTE	**Materials**	▪ Substitute the chosen material with an alternate material that can withstand reuse or has the potential to recycle or remanufacture the same or a similar product in line with the safety and regulatory standards. ▪ If the chosen material is a rare commodity and there is potential for it to be a conflict material, then select an alternate material that satisfies the functional requirements of the product. ▪ Suitable material with high specific strength (low mass) can lead to a compact design and easy to transport to reduce the environmental and economic impact associated with packaging, transporting, storing, and disposing of.
	Energy Source	▪ Replace the power-operated function with manual operation, if technically feasible, without significant compromise in useability ▪ Maximize the use of mechanical energy storage systems, including springs and coils, to reduce the non-renewable power use ▪ Source for efficient and less impacting alternate power sources ▪ opt for a renewable power source when feasible

	Suppliers	▪ Work with the procurement department to find and develop a domestic supplier ▪ Contract local manufacturing firms to convert raw materials into final form before transporting them to the destination of the end-users. ▪ Even though Good Manufacturing Practices (GMP) certifications are not mandatory (eco-certifications are still in the early stage), encourage suppliers to acquire them to add value to the supply chain. ▪ Develop alternate suppliers to have a robust supply chain
O P T I M I Z E	Product Structure	▪ Optimize the product structure to minimize material use, waste, and volume with innovative design features. ▪ Explore alternate methods to modularize the product ▪ Develop standardized components across the products to reap the benefits of economies of scale. ▪ Explore ways to exploit standardized and certified Original Equipment Manufacturer (OEM) components, especially for low-value-added items to have robust maintenance and repair options, especially for reuse and refurbishment. ▪ Reduce the number of different materials used in a device to improve the reusability and recyclability of the device ▪ Follow the design for manufacturing, assembly, and maintenance and repair principles to avoid downstream challenges and reduce time to market.

		▪ Co-design with various downstream departments that would be affected by design. ▪ Exploit CAX tools to design, develop, and assess design varieties before developing physical prototypes to reduce waste generation and time.
EXPLOIT	User Experience	▪ Focus on user experience (ergonomics, dimensional limits, cognitive load requirement, and context and environment in which the device be used by the end-users and other stakeholders) as the first design goal before targeting functional outcome
	Modularity	▪ Design the components to ensure it is adjustable or adaptable to reduce the number of varieties to cater to a wider range of the population. ▪ Combine components to reduce the number of articulating components or components that need to be secured. ▪ Segment the product into sub-assemblies and components that can be independently manufactured. ▪ Use modularity to standardize the components across different products and use Original Equipment Manufacturer (OEM) components ▪ Reduce ad-hoc or custom components to reduce the complexity in manufacturing ▪ Avoid or eliminate components that require the use of special machines or high-skilled operations that add infrastructure cost and high operating cost.

4.7 Summary

In this chapter, we have presented a methodology to incorporate and assess sustainability aspects of medical device design and a set of design mitigation strategies to improve them. The myriad opportunities and challenges in integrating sustainable design in the medical device industry are significant. The key to unlocking the potential is to develop methods that focus not on the product alone; it should be the entire product life cycle from conception to disposal. Also, early-stage design decisions significantly influence the sustainability aspects of product development down the line. While we focus on sustainable medical device design, we must also aim to meet the financial objectives of the product to reach the bedside and thrive. The products must be evaluated for their impact on the use of materials and energy, environment, usability, and cost at every stage of the design process. An integrated product design process for functional and sustainability requirements across the entire life cycle would lead to efficient use of energy and materials, increased regulatory and safety compliance, shortened time to market, and reduced transportation costs while impacting society. The presented methodology must be evaluated by experts in the field and demonstrated with a case to show its potential and shortcomings. Chapter 4 presents the evaluation of the method.

Chapter

5

CASE STUDY – SURGICAL GUIDE

Due to technological advances, computing power, materials design, and manufacturing technologies, medical device designers spend considerable time balancing many factors, including functional and safety requirements, human factors, and robustness. Increasingly, regulators (FDA/EU) and manufacturers are forcing designers to consider sustainability (Marešová et al., 2020; Pelayo et al., 2021; Privitera et al., 2017). This chapter describes a case study on surgical guide design to demonstrate the usefulness of the methodology and how it could be used to improve the overall sustainability of the device. We report the assessment of the original design, the design mitigation strategies developed based on the assessment, the revised design of the device, and the assessment of the revised design.

5.1 Surgical Guide Design

The case aims to design a patient-specific surgical guide that reduces intra- and postoperative complications during high-tibial osteotomy procedures. The primary functions of the device were derived from the user requirements. They are:

1. Shall guide the cutting saw blade along a pre-defined path and depth
2. Shall protect the neurovascular bundle (posterior) during the surgery
3. Shall protect the hinge point with a safe margin to prevent hinge fracture

Based on these primary functions of the surgical guide, we have developed detailed engineering specifications that could be testable and verifiable later. At the first ideation stage, only functional and user experience were prioritized to create design concepts. We have derived a set of concept evaluation criteria from the user requirements and design discovery interviews to prune and select the best among the developed ideas. Then we carried out a C-sketch session and morphological matrix with clinicians (end-users) and designers to generate multiple design concepts. Using the concept evaluation criteria, we selected one concept that fulfills the primary functional requirements that we had set at the start of the concept engineering phase of the design process.

The selected design was a single-piece design with a slit for the blade to slide through and cut the bone. We used the 3D anatomical model of the tibia bone generated from the pre-operative Computed Tomography (CT) image data. The model allows us to extract the bone surface that meets the surgical guide and design it accordingly. The long shank was added to guide the blade during the surgical procedure to avoid damaging the vascular bundle. Fig.

11 shows the annotated design concept and a 3D printed version of the design to conduct functional testing before subjecting it to a detailed design and analysis. The design was conceived to have the highest level of customization to suit the surgical needs of the patient, so it was decided to make the device using a 3D-printing process with certified medical-grade plastics. Furthermore, to reap the benefits of the process capabilities of additive manufacturing, reduce the issues with assembly, and increase the useability, it was decided to make the device a single piece (no assembly).

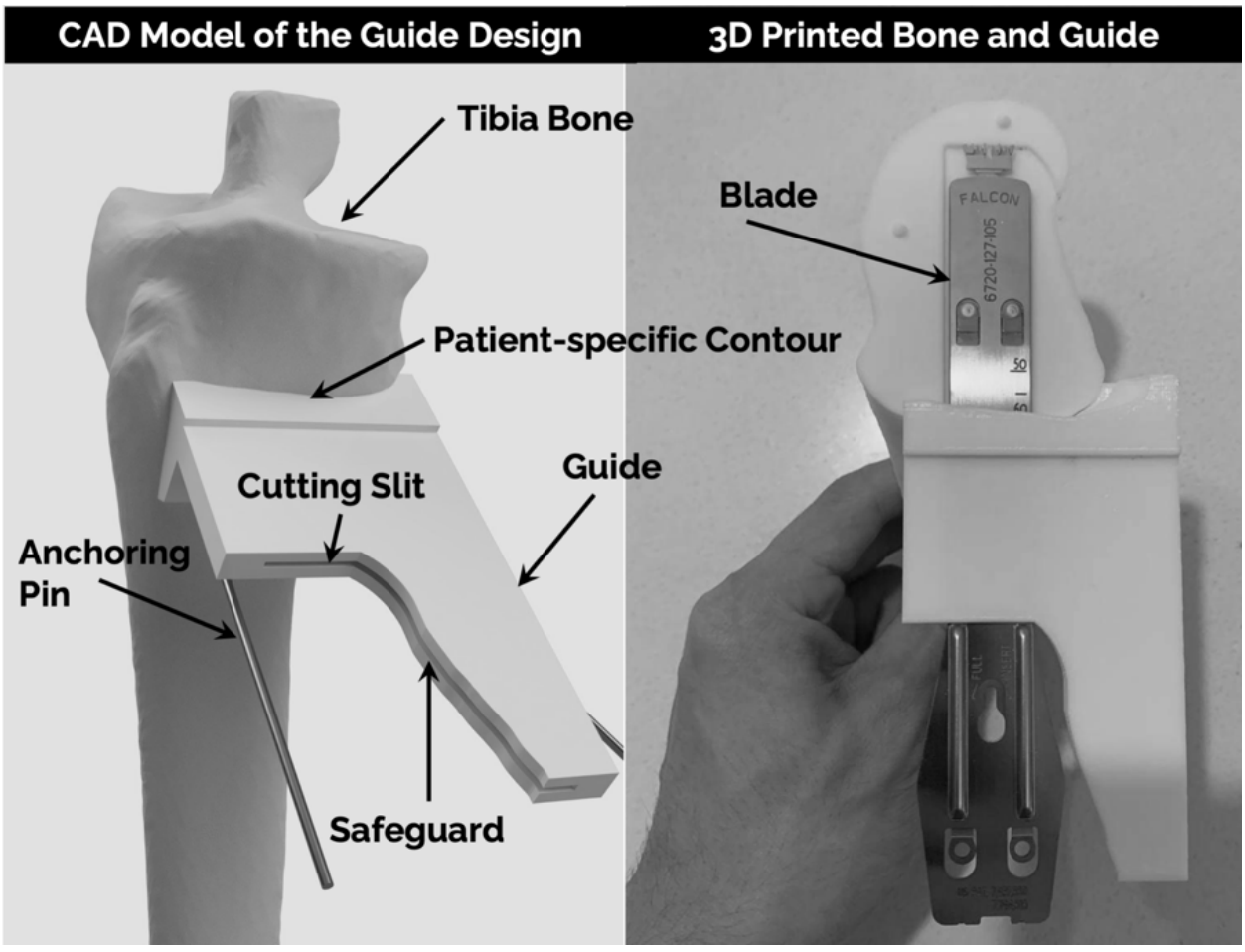

Fig. 11: *A cutting jig (before applying the evaluation criteria)*

5.2 Sustainability Assessment

We have applied our methodology to study the initial design of the surgical guide and develop design mitigation strategies to have value-added design features to improve the overall sustainability of the device (Table 16). The weightage for each attribute was assigned based on the practical design experience in developing surgical guides and medical devices with significant mechanical design components. Before starting the assessment, clinicians, manufacturing technicians, and designers were involved in finalizing these weights (conflict was resolved through discussion). Every attribute was evaluated based on the choice of material, manufacturing process, sterilization, and after-user management of the device during the concept generation and evaluation phase of the design process and assigned score accordingly. Descriptions in the concept sheet were used to infer additional details which are not explicit. For example, 3D printing and nylon have been chosen as the final manufacturing process and material. However, which printer should be used to manufacture the device was not defined or prescribed at this stage—considering that Nylon-based 3D printers required to manufacture the device to the described precision (for blade entry and matching bone contour) are expensive and in limited availability in Singapore. Also, these printers use only proprietary Nylon material filaments or powders (depending upon the process mechanism). It was also assumed that the device would be manufactured in Singapore (transport, production, and procurement-related costs and emissions). So, during the assessment, this inferred information was used to assign scores to identify design elements that could be revised to improve the sustainability aspects of the device.

Table 16: *Assessment matrix of the original design concept of the surgical guide*

	SCORE			NOTES
MATERIALS				
Source			**4.3**	
Conflict-Free	10%	10		Factory Generated
Renewable	30%	0		Synthetic
Availability	30%	5		Readily availabile, proprietary material
Location	25%	5		Imported
Labour Rights	5%	10		High-tech factories
Characteristics			**3**	
% Reusable	25%	0		Single-use custom device
% Recyclable	25%	5		With effort and changes to properties
Biodegradable	20%	0		Plastics
Sterlizable	25%	5		Alchocol wipe / ETO
Specific Strength	5%	10		Geometry matters for this design
Carbon footprint			**2**	
Production	20%	5		Fossil fuel-based polymerization
Transport	20%	0		Imported
Reuse	20%	0		Customized
Recycle	20%	5		After disinfection, sterlization
Disposal	20%	0		Incinerate and disposed to landfill
Cost Factor			**5**	
Procurement	10%	0		Limited number of suppliers
Transport	20%	0		Imported
Manufacturing	15%	10		Controlled process, no significant waste
Recycle	20%	10		Standard process after sterlization
Reuse	20%	0		Req. for infrastructure and safety
Disposal	15%	10		Incinerate and dispose of for landfill (std.)

		SCORE		NOTES
DESIGN, MANUFACTURING, AND OPERATIONS				
Design Complexity			**5.8**	
Freeform Design Features	15%	5		2.5D complex shapes.
Number of Components	20%	10		Only one component
Assembly and Disassembly	20%	10		No assembly
Modularization	15%	0		Custom Device
Maintenance and Repair	10%	10		Single Use
Req. Special Machines	20%	0		Yes, made for 3D printing
Product Structure			**1**	
% of Customization	25%	0		Fully customized
% of OEM Components	25%	0		No OEM components
Standardized Components	20%	0		No component to standardize
Number of Varieties	20%	0		Custom device
Regulatory Burden	10%	10		Custom device exemption
Product Operations (use)			**4.5**	
Energy Consumption	25%	10		Manual
Number of Uses	25%	0		Single use
Maintenance Requirement	20%	10		Single use
Reconfigurability	30%	0		Custom device

	SCORE			NOTES
AFTER-USE DEVICE MANAGEMENT				
Reusability			**1.3**	
Sterilizability	25%	5		Alcohol or ETO or UV
Refurbishment	10%	0		Single component
Financial Cost	15%	0		Req. for sp. Infrastructure
Health Risk / Safety	30%	0		High due to the material choice
Regulatory Burden	20%	0		No rule for reusing 3D-printed one
Recyclability			**9**	
Salvagability	20%	10		0 or 100%
Responsible Recycling	20%	5		Recyclable with property change
Health Risk / Safety	20%	10		Process is safe
Separation / Disassembly	20%	10		Single component
Regulatory Burden	20%	10		Plastic recycling is a standard
Disposability			**5**	
Carbon Footprint	20%	0		Time to degrade and incinerate
Hazardous Waste	20%	5		Not to humans but to environment
Health Risk / Safety	20%	5		Incinerate gas and particles
Regulatory Burden	20%	10		Well established procedures
Cost and Energy	20%	5		Required to incinerate and dump

5.3 Design Revision

Based on the assessment (Table 16), there is a need to change the design to increase these values to improve the sustainability aspects of the device. Attributes related to overall sustainability, including usability, product structure, carbon footprint, and material

characteristics, have suffered due to the design decisions related to single-use, customized, and additively manufactured end-product. Based on this understanding, the design mitigation strategies could be formulated to revisit those design decisions and develop alternate design concepts. These strategies could be considered for reusing the product by incorporating modularization and sterilizability. However, they would also affect the product structure and operations.

The standard steam-based sterilization process should be used to balance existing infrastructure and economies of scale (with respect to existing surgical instruments) to reuse the device potentially. The steam-based sterilization happens at 121^0C for 30 mins. So the material should withstand the thermal shock resistance at the maximum surface temperature. The surgical guide would experience vibrations from the oscillating saw blade, which could result in structural damage or dislodgment from the anchored position and orientation during the surgical procedure. In addition to choosing a suitable material, a design change with respect to the direction of the anchoring pin can be incorporated to limit the effect of vibration on the device's performance and surgical outcome. Stainless steel and Ti-6Al-4V are suitable candidates with the necessary specific strength and biocompatibility to fulfill the functional requirements of the device.

In terms of modularizing the device, the surface of the device that comes in contact with the bone geometry should be customized, not the entire device. This could be only achieved when we integrate the retractor to avoid the risk of injuring the neurovascular bundle. The safeguard with the posterior anatomy matching curve in the original design fully utilizes the customization design decision. However, since we are customizing only a part of the device

to improve the sustainability characteristics of the device, we could revisit the design decision to cater to a broader population. Even when we customize only a component of the device, which could have severe implications on time between the order and delivery, we opt for 3D printing as a potential manufacturing process for that design element, and the rest are manufactured in stainless steel (cost-effective).

The revised design consists of six components (Fig. 12). We decided to go for standard OEM anchoring pins used in surgical settings instead of custom-designed ones as in the original design. Reusable guide attachments are made of stainless steel to improve the reusability, sterlizability, and recyclability of the device. Also, stainless steel is a standard engineering material. It is available from various suppliers, enhancing the supply chain's robustness and increasing the possibility of using responsibly sourced material. Those attachments were designed in three different pieces to aid the surgeons in progressively cutting the one as performed currently without surgical guide not to affect the workflow (reduce adoption hurdle) while reducing the risk of hinge fracture and injury to the neurovascular bundle. Standard dovetail joints were opted to attach the guide attachments to the custom guide. The direction was chosen anterior to posterior to avoid impeding the retractor attachment. The retractor attachment is also integrated with the custom 3D-printed guide, as the angle of the retractor is customized to prevent overstretching the bundle during the surgical procedure.

Once we have the 3D model of the bone, the surface is extracted and performed boolean with the standard component that we have to generate a custom component that is fabricated with a 3D-printing process (Nylon material, Stratasys J750. After air blasting for particle removal, we have selected ETO gas to sterilize it before use). The rest of the devices are sterilized with the standard steam-based sterilization protocol before and after use. The custom-designed

guide element is disposed of (incinerated) after use due to the cost associated with disinfecting and recycling and changes to the material characteristics after processing.

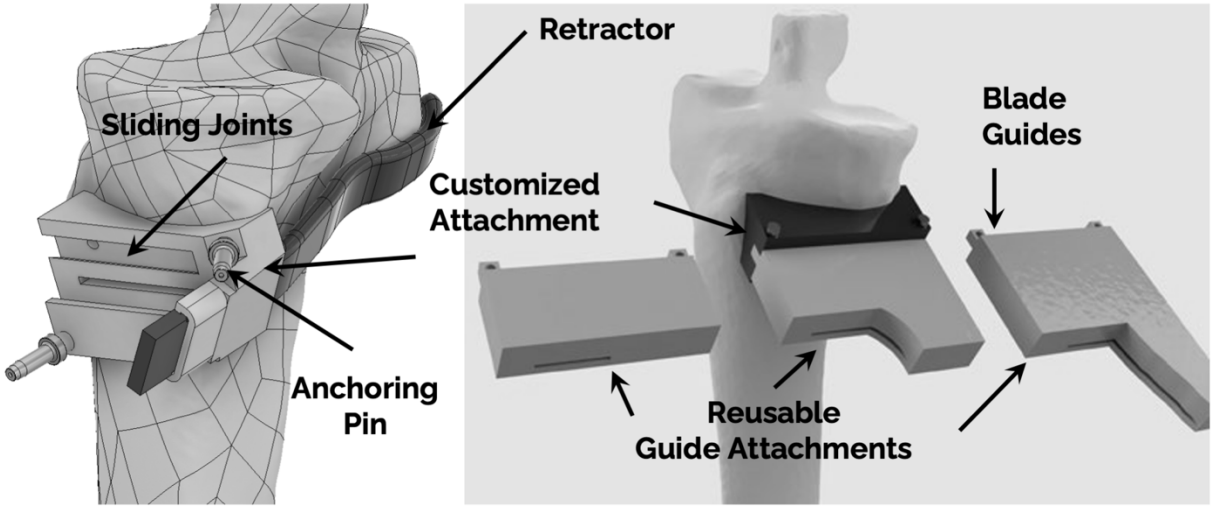

Fig. 12: *Pragmatically modularized and personalizable surgical guide optimized after applying the sustainability-based metrics as evaluation criteria*

5.4 Re-Assessment

We have performed the sustainability assessment with the revised design to analyze it against the criteria in the methodology (Table 17). Even though we tried to balance the functional requirements of the device along with the overall sustainability, challenges with some attributes could not be overcome due to the conflicting design requirements. On the other hand, some attributes scored high due to the realistic or practical nature of the semi-quantitative scoring system (<25% of damage has been considered acceptable concerning safety and regulatory burden).

Table 17: *Assessment matrix of the revised design of the surgical guide*

	SCORE		NOTES
MATERIALS			
Source		**6.3**	
Conflict-Free	10%	5	Good potential for being responsibly sourced
Renewable	30%	0	Mined
Availability	30%	10	Excellent availability
Location	25%	10	Local suppliers
Labour Rights	5%	5	Fair potential but need to be verified
Characteristics		**9**	
% Reusable	25%	10	> 75% of components are reusable
% Recyclable	25%	10	> 75% of components are reusable
Biodegradable	20%	5	Except the plastic, rest are in time
Sterlizable	25%	10	Std. sterilization process could be used
Sp. Strength	5%	10	Geometry matters for this design
Carbon footprint		**8**	
Production	20%	5	Ore to useable material
Transport	20%	5	Plenty of local suppliers
Reuse	20%	10	>75% reusable
Recycle	20%	10	>75% after disinfection and sterilization
Disposal	20%	10	<25% Incinerated and disposed to landfill
Cost Factor		**9**	
Procurement	10%	10	Excellent source of suppliers
Transport	20%	5	High potential to have a local suppliers
Manufacturing	15%	10	Controlled process, no significant waste
Recycle	20%	10	Standard process after sterlization
Reuse	20%	10	Regular infrastructure and low risk
Disposal	15%	10	Incinerate and dispose of for landfill (std.)

		SCORE	NOTES
DESIGN, MANUFACTURING, AND OPERATIONS			
Design Complexity		**10**	
Freeform Design Features	15%	**10**	2.5D complex shapes.
Number of Components	20%	**10**	Relative to functions, reasonable
Assembly and Disassembly	20%	**10**	Dove-tail assembly
Modularization	15%	**10**	Modularized
Maintenance and Repair	10%	**10**	Easy to disassemble and replace
Req. Special Machines	20%	**10**	No. Std. machining process, <25%
Product Structure		**10**	
% of Customization	25%	**10**	<25% customized
% of OEM Components	25%	**10**	Yes, anchoring pins
Standardized Components	20%	**10**	Standardized guide attachments
Number of Varieties	20%	**10**	Only one, but multiple steps
Regulatory Burden	10%	**10**	Custom device exemption
Product Operations (use)		**10**	
Energy Consumption	25%	**10**	Manual
Number of Uses	25%	**10**	<25% components are single use
Maintenance Requirement	20%	**10**	Deformation, damage
Reconfigurability	30%	**10**	Yes, with the custom attachment

	SCORE		NOTES
AFTER-USE DEVICE MANAGEMENT			
Reusability		**7.5**	
Sterilizability	25%	**10**	Std. process
Refurbishment	10%	**10**	Yes, easy to replace
Financial Cost	15%	**10**	Std. Infrastructure
Health Risk / Safety	30%	**5**	Medium due to 3D-printed / reuse
Regulatory Burden	20%	**5**	Reuse and 3D-printed component
Recyclability		**10**	
Salvagability	20%	**10**	>75% salvagable
Responsible Recycling	20%	**10**	>75% recyclable
Health Risk / Safety	20%	**10**	Process is safe
Separation / Disassembly	20%	**10**	Easy to disassembly
Regulatory Burden	20%	**10**	Recycling is a standard process
Disposability		**10**	
Carbon Footprint	20%	**10**	Reuse is high for other low-value
Hazardous Waste	20%	**10**	<25% is the waste
Health Risk / Safety	20%	**10**	<25% generate plastic waste
Regulatory Burden	20%	**10**	Surgical tool not a device
Cost and Energy	20%	**10**	25% incinerate and dump

5.5 Summary

The case study demonstrates the usefulness of the methodology and its importance in generating alternate design mitigation strategies based on TRIZ principles. The original design suffered from over-customization, a restricted manufacturing process, and material choices. Once those constraints were removed to improve the reusability, recyclability, and standardization of the device, we were able to develop multiple design alternates, which resulted in an improved sustainable design of the device. The reassessment of the design after revision resulted in a higher scoring in almost all aspects except in the materials section due to the use of 3D-printing material availability and robustness of the local supply chain. The scores were higher (almost perfect) than pre-revised design but there are ways to improve the sustainability because some of our metrics have considered less then 25% of waste or greater 75% of potential as good enough. They could be changed in the future version of the methodology.

Chapter

6

EVALUATION OF THE METHODOLOGY

This chapter describes a mini-Delphi study that we have conducted to gather opinions from the experts in the domain to evaluate the ease of use, comprehensiveness, and the perceived benefits of the methodology from their perspective and experience.

6.1 Mini-Delphi Study

We have conducted a mini-Delphi study (one stage) to seek opinions from practicing experts in the field of medical device design, design methods, and sustainability in healthcare to assess the usefulness of the methodology. Based on the literature, a minimum of eight experts are needed when seeking opinions about the usefulness of a framework using the Delphi method (Niederberger & Spranger, 2020; van Vliet et al., 2016). The experts participated in a workshop on advanced design methods for medical device development in Singapore in early October 2022. They were introduced to the framework as a part of the program. Our institutional review board approved the study. The participation was entirely voluntary. The

experts are in the field of design thinking, engineering design, medical device design, design education, assistive devices, and clinical science, with interests in devices with research and practice experience ranging from 6 – 14 years (refer to Table 18 for detailed information). Four of them have Ph.D., one has M.D., and the rest have master's degrees in design. No personally identifiable information or opinion or thoughts on themselves has been collected or stored.

At the end of the session, their opinions were recorded in five different attributes, including the perceived benefits, comprehensiveness, interpretability of the attributes and scoring system, ease of use, and the efficiency of the methodology (Table 19). We opted to use the Likert scale (1-5) to quantify their opinion on those aspects of the method, considering their subjective nature and potential bias. The methodology was briefed to the experts and clarified raised queries before starting the assessment. The criteria were provided to the experts in a flip-card format for them to go through along with the case study. Experts have reviewed the methodology individually and asked for clarifications (if any) during their assessment. No group discussion or analysis was conducted after the briefing session. Instead, they have keyed in their response via a google form.

In addition, the following questions focusing on the methodology were posed to the experts:

- What other attributes can be added to improve the methodology?
- How can the methodology be improved regarding its ability to assess sustainability in design decisions and design elements at the early stage of the design process?
- Can the methodology benefit from further refinement in terms of ease of use?

Table 18: *Professional background and research expertise and interests of the experts*

	Profession, Degree	Exp. (Yrs)	Area of Expertise or Research Interests
1	BioDesign Fellow, M.Eng.	7	Medical Device Design, Surgical Guides, Surgical Tools, and Healthcare Innovation
2	Research Fellow, PhD	9	Design Methods, Design for X, and Design-based Education and Research
3	Research Scientist, PhD	14	Personalized implantable medical devices, Tissue Engineering, and Bioprinting
4	Prosthetic Designer, MS	12	Customized prosthesis design and development, Digitalization, and 3D printing
5	Clinician Scientist, MD, PhD	12	Biomechanics, Implants, and Surgical Tools
6	Senior Designer, M.Des.	8	Data-driven Design, Sustainable Design, and Technology Entrepreneurship
7	Product Designer, M.S.	6	Medical Device Design, Biomechanics, and Clinical Trials
8	Senior Research Fellow, PhD	7	Product Architecture, Design Methods, Creativity Stimuli, Usability in Medical Devices, and Digitalization

Table 19: *Criteria for evaluating the methodology*

Criteria	Definition	Likert Scale (5-1)
Perceived Benefit	Does the methodology have the potential to have a logically justifiable effect on sustainability?	Excellent to Poor
Comprehensiveness	Does the methodology capture relevant sustainability-impacting elements during the design process to develop mitigation strategies?	To a Great Extent to Not at All
Interpretability	How easy are the overall methodology, attributes, and consequences on sustainability to interpret?	Very Easy to Very Difficult
Ease of use	How easy is it to use the methodology?	Very Easy to Very Difficult
Efficiency	What is the perceived capability of the methodology?	Excellent to Poor

6.2 Assessment

The summary of the semi-quantitative assessment of the methodology by the experts is presented in Fig. 13. We have collated their inputs and averaged them out to give the overview. The overall minimum rating received was 3. Due to the comprehensive nature of the methodology, the ease of scoring has taken a hit, especially from industry experts. Considering some attributes were repeated in different sub-sections, it contributed to confusion on what to focus on in each instance. The perceived benefit and efficiency of the methodology have been rated good but suffered due to the comprehensive nature of the methodology.

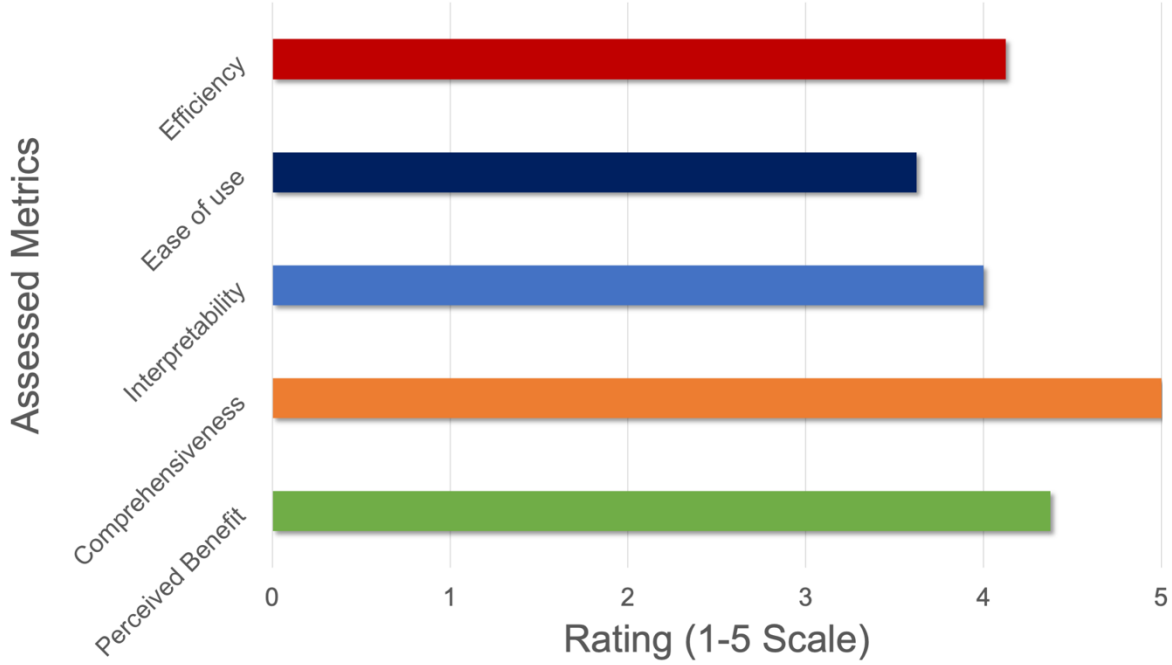

Fig. 13: *Summary of the semi-quantitative evaluation of the methodology*

6.3 Aggregated Responses on the Methodology

We have used ATLAS.ti (ver. 22.0; ATLAS.ti GmbH, Berlin, Germany) to categorize the open comments shared by the experts based on the triggering questions into six major sub-sections to improve the methodology.

References and Database

Due to the comprehensiveness of the methodology, experts have highlighted the need for a reference database for assigning importance to each criterion, technical information (sterilizability and recyclability of different materials used in medical device design), and the origin of the material and associated certifications. Also, it was suggested to include the standards database related to the carbon footprint of each manufacturing process, material production, and transportation modes from different continents as an add-on to the methodology.

Traceability Issues

One of the key issues that the experts brought up was having reliable sources to trace materials' origin and their sustainability aspects. This issue came to light because supply chain traceability for standard engineering materials has yet to be attained as it did for rare, precious, and high-value minerals.

Assessment Metrics

As mentioned earlier, one suggestion was the repeated use of some attributes in various sections that need to be associated with notes to define their scope concerning the area. Also, it was suggested that reconfigurability should be moved to product architecture instead of operations, as reconfigurability is a design feature that should have been triggered by a user need, a functional requirement of simplicity in design, or reduced design variations and inventory.

Applicability of the Metrics in the Industry

One critical suggestion shared was co-designing with various departments, including sourcing, procurement, design, manufacturing, and production, which would eventually be affected by every design decision. These co-design methods or integrated design reviews are becoming a standard in the design industry due to their impact on time to market and associated costs.

Reframing the Methodology

The experts have opinionated that regulations could have been a separate section instead of repeating in each section, even though they agreed that the focused regulatory standards of each section are different. Another main suggestion was to combine standardization, modularization, and the use of OEM components into one metric.

6.4 Discussion and Revision

One common point that the experts raised is to supplement the methodology with links to databases that could aid the designers to reference when they conduct the assessment. As a result, we have compiled a list of sources that have collected different data sources to provide carbon footprint with respect to manufacturing, transportation, sterilization, recycling, and disposal of medical devices.

- Carbon footprint and financial costs of sterilization of the reusable surgical instruments, https://doi.org/10.1093/bjs/znab406
- The Carbon Catalogue comprises of Carbon footprints of 866 commercial products from 8 industry sectors and five continents (https://doi.org/10.6084/m9.figshare.c.5408100.v1)
- A list of available third-party databases that collect data for product life cycle and corporate value chain https://ghgprotocol.org/life-cycle-databases
- Carbon Footprint – a Searchable Carbon emission database, https://www.carbonfootprint.com/factors.aspx
- Embodied Carbon - The ICE Database (the energy consumed to extract, refine, process, transport, and fabricate material or a product, https://circularecology.com/embodied-carbon-footprint-database.html
- Carbon footprint related to the operating theatre, https://doi.org/10.1016/S2542-5196(17)30162-6
- The carbon footprint from disposable surgical devices, https://journals.lww.com/aosopen/toc/2021/09000

- Transportation-related carbon emissions, https://storage.googleapis.com/scsc/Green%20Freight/EDF-Green-Freight-Handbook.pdf

We also revised the design section of the assessment as per the feedback (Tables 20-22). Modularization, standardization, and OEM components were brought under one section; however, they were assessed independently to develop mitigation strategies.

Also, the reconfigurability has been removed from the operations and replaced with human factors and the effort required (Branaghan, 2018). Studies have shown that the effort needed to assemble, reconfigure, and operate the device successfully without trial and error significantly improves the device's usability and reduces cognitive load and resultant medical errors (Pelayo et al., 2021; Privitera et al., 2017). However, it was captured in design varieties to cater to a broader range of populations due to variations in anatomical, physiological, social, and psychological factors.

For the common comment on the repeated use of some aspects, we have taken steps to have detailed notes in the last column of the assessment matrix to allow the designers to understand the scope of those attributes in the section. Also, as highlighted by the experts that regulatory standards are field-specific, so we have decided to leave them in each section but added additional notes to distinguish them clearly. This is to ensure that the regulatory and standards attributes reflect the effect of innovations in materials, design, and manufacturing processes and vice versa unless the product is custom designed.

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Table 20: *Revised complexity of the design in terms of manufacturing, assembly, suppliers, maintenance, and repair*

	Attributes	Low (Score 0)	Medium (Score 5)	High (Score 10)	Notes
DESIGN COMPLEXITY	**Design Features (C_1)**	Complex freeform design features	A mix of complex and standard design features	Standard design features	*Mfg. Complexity*
	Number of Components (C_2)	Too many components with respect to the expected functions	Fair number of components to fulfill the required functions	As few components it can be to fulfil the required functions	*Reliability*
	Assembly and Disassembly (C_3)	Multiple assembly directions and lack of possibility to improve the ease of assembly and create sub-assemblies	More than a fair share of assembly directions and has potential to create subassemblies and improve the ease of assembly	High potential to have top-down assembly and develop sub-assemblies	*Design for assembly and disassembly for reuse/ repair / time*
	Maintenance and Repair (C_4)	Low potential to incorporate design for disassembly, maintenance, and repair	Fair potential incorporate design for disassembly, maintenance, and repair	High potential to incorporate design for disassembly, maintenance, and repair	*Reduce downtime during the use*
	Requirement for Sp. Machines / processes (C5)	More than a fair share of special manufacturing processes and set-ups with respect to expected functionalities of the design	A fair share of special manufacturing processes and setups with respect to expected functionalities of the design	Standard manufacturing processes are sufficient to get the design manufactured	*Infrastructure cost, time, and cost (skilled labour)*
	$D_1 = D_{complex} = \sum_{i=1}^{N} x_i C_i \, , where \;\; 0 \leq x_i \leq 1.0 \; while \; \sum_{i=1}^{N} x_i = 1 \, ; N = 5$				

Table 21: *Revised product architecture aspects of the design that contributes to the sustainability*

	Attributes	Low (Score 0)	Medium (Score 5)	High (Score 10)	Notes
PRODUCT ARCHITECTURE	**% Customization (P_1)**	More than 2/3rd are customized designed elements (N > 2/3)	More than 1/3rd but less than 2/3rd are customized designs (1/3 < N <2/3)	Less than 1/3rd are customized design elements (N < 1/3)	*Time and effort after the order*
	% OEM Components (P2)	Less than 1/3rd are OEM components (N < 1/3)	Less than 2/3rd but more than 1/3rd are OEM Components (1/3 < X < 2/3)	More than 2/3rd are OEM components (N > 2/3)	*OEM (off the shelf parts)*
	Standardization (P_3)	Low potential to use the standardized components	Fair potential to use standardized components	High potential to use standardized components	*Economics of Scale across products*
	Design Varieties (P_4)	Many design varieties are required to cater to a larger cohort of patients.	A fair set of design varieties are required to cater to a larger cohort of patients.	Less number of design varieties are required to cater to a larger cohort of patients.	*Cater to a wider cohort of patients*
	Modularization (P_5)	No or low potential to modularize the design	Fair potential to modularize the design	High potential to modularize the design	*Parallelize and standardize*
	Standards and Regulatory burden (P_6)	High level of burden due to non-std. design, materials, and manufacturing against the business objectives.	A higher burden than expected due to non-std. design, materials, and manufacturing against the business objectives	Low burden due to innovativeness of the design, technologies used in the design, standardization, and exploiting existing systems	*Regulatory Burden, time, and cost (time to market and financial burden)*
	$D_2 = D_{product} = \sum_{i=1}^{N} x_i P_i \, , where \;\; 0 \leq x_i \leq 1.0 \; while \; \sum_{i=1}^{N} x_i = 1 \, ; N = 6$				

Table 22: *Revised operational aspects of the design that contributes to the sustainability*

	Attributes	Low (Score 0)	Medium (Score 5)	High (Score 10)	Notes
OPERATIONS (USE)	**Energy Consumption (O_1)**	Low potential to reduce the high energy consumption with alternatives	Good potential to reduce the energy conception to an acceptable level with design modifications	High potential to reduce the energy consumption and improve energy efficiency of the device with design changes	*Energy required to use the product*
	Number of Uses (O_2)	Significantly a smaller number of uses than expected of a similar product and low potential to increase it with design changes	Below average number of uses than the expected and offers some potential to improve it with design changes at cost.	Larger number of uses than the expected and offer high potential to optimize without compromising safety and performance.	*Max. No. of uses with sterilization before disposing*
	Maintenance Requirement (O_3)	Frequent and resource-intensive maintenance and service are required to operate the device safely.	Regular interval maintenance is required with above-average resource intensiveness to operate the device safely	Low-level maintenance is required with standard resources than a similar device to operate the device safely	*How frequent - maintenance and service*
	Effort Required (O_4)	Complex and time-consuming steps are needed to reconfigure the device to meet patients' needs	A fair level of Complex and time-consuming steps is needed to reconfigure the device to meet patients' needs	Easy and less time-consuming steps are needed to reconfigure the device to meet patients' needs	*Human factors and effort required*
	$D3 = D_{Operationt} = \sum_{i=1}^{N} x_i O_i \, , where \;\; 0 \leq x_i \leq 1.0 \; while \; \sum_{i=1}^{N} x_i = 1 \, ; N = 4$				

6.5 Summary

We have evaluated the usefulness, ease of use, comprehensiveness, and perceived benefit of the methodology with a mini-Delphi study. The results from the study are promising, and the experts have agreed and disagreed on many aspects. They have also offered many suggestions and comments to improve the methodology. The comprehensiveness of the method resonated well with all the experts, but some have raised concerns about its ease of use. Another common point was the repeated use of some attributes that have been supplemented by added notes to describe their scope with respect to the section to aid the designers in assessing them accordingly. Other minor but multiple references were the design's reconfigurability, modularization, and standardization aspects and their interlinks. So, we have reframed the section to bring them together and incorporate reconfigurability with the design variations to improve the accessibility of the design.

Chapter

7

SUMMARY OF THE THESIS

7.1. Summary

In this thesis, we aimed to develop and evaluate a methodology to assess sustainability in the medical design process. To achieve this aim, we have developed sustainability-related criteria for evaluating design concepts during the concept engineering phase of the design process from the overarching theme of sustainability without compromising the functional, performance, safety, and business requirements. These criteria were mapped against design decisions during various product life cycle phases, including materials, design, manufacturing, operations, and after-user management. We have also developed a list of design mitigation strategies for each attribute group based on TRIZ principles. A surgical guide was taken as a case study to demonstrate the usefulness of this methodology in assessing the sustainability of the design and developing alternate design concepts to improve the sustainability of the device. We have conducted a mini-Delphi study with experts in the medical device design field to gather their feedback on the perceived benefit,

effectiveness, interpretability, comprehensiveness, and ease of use of the methodology. Comprehensiveness, perceived usefulness, and efficiency were rated very good to excellent. Also, they have agreed on the trade-off between comprehensiveness and ease of use of the methodology due to fatigue and repeated assessment of some attributes with different perspectives. Based on their feedback, we have added a list of references to databases that can aid the designers in understanding the environmental, economic, and social implications of their design decisions. We have also revised the design, manufacturing, and operations section of the methodology based on their feedback on interpretability.

7.2 Limitations

Limitations of this work must be acknowledged. First, technological advances, computing power, sensing devices, materials, and manufacturing processes have provided significant new opportunities to innovate medical devices. However, the associated understanding of their impact on sustainability is not comprehensive for designers to get hold of while assessing and developing alternate designs. Second, we have only briefly covered the supply chain side of the evaluation; it should be well-integrated into the methodology to offer the full benefits of sustainability. Third, the dynamic nature of regulatory pathways for many of the advanced technologies (e.g., finite element analysis-based design verification) and materials that would positively impact sustainability has affected the abilities of designers to appreciate them in their design (Lottes et al., 2022). Fourth, the weightage assigned to each attribute to quantify the sustainability aspects of the design is not the same for different healthcare products (Bonci et al., 2020). To capture this variability, we have attempted to assign relative scores rather than absolute ones. Even though we have taken steps to ensure the listed attributes are shared among different medical devices, it is possible that some

attributes might not even be relevant to some devices. This dilemma has the potential to introduce bias and variability in the assessment. While we have opted to conduct the expert evaluation and questionnaires to assess the methodology (mini-Delphi study), there are other methods, including observation of users, performance-related measurements, critical incident analysis, interviews, focus-group, model-based methods, and automated evaluation that could be explored to offer alternate perspectives and insights.

7.3 Further Research Directions

This study highlights that the sustainability of a medical device could be improved with an early-stage design assessment. The consumers' behavior should improve the industry's appetite for sustainability (healthcare institutions, regulatory bodies, and manufacturing industries). No or little attention has been devoted to understanding the pulse of the industry for incorporating sustainability in the design. Design for Sustainable Behaviour would allow researchers to understand consumers' play in developing holistic design solutions to satisfy user needs without compromising safety standards and regulations (Bhamra et al., 2011; Miclăuş et al., 2020). As mentioned in the limitation section, the supply chain should be resilient. The medical device supply chain faces pressures from the local market, technological, cost factors, and economic-political factors. We have incorporated some measures in our methodology to capture these aspects by opting to procure locally sourced and supplied materials and manufacturers (Webber et al., 2020). However, the economic realities might not view those design decisions favorably (access to skilled labor, affordable suppliers, and taxes). So, a multi-objective scenario-based methodology could be developed to capture these conflicting requirements from the general dimensions of sustainability (environmental, economic, and social).

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Annex 01: Participant Information Sheet

SINGAPORE UNIVERSITY OF TECHNOLOGY AND DESIGN

Participant Information Sheet

You are invited to participate in a research study. This information sheet provides you with information about the research. The Principal Investigator (the person in charge of this research) or his representative will also describe this research to you and answer all your questions. Read the information below and ask questions about anything you don't understand before deciding whether to participate.

Project title
Design Stimuli for Medical Device Innovation – Interviews and ethnographic research

1. **Principal Investigator and co-investigator(s), if any, with the contact number and organization.**

Prof	Subburaj Karupppasamy	PI	Singapore University of Technology and Design, Email: subburaj@sutd.edu.sg Tel: +65 6303 6600

2. **What is the purpose of this research?**
   We aim to extract design drivers from the perspectives of the experts on the factors affecting design thinking and the evaluation process through semi-structured interviews. These factors could be in the form of sustainability objectives, bio-inspiration, and existing coded knowledge bases (patents, design repositories). We aim to determine the impact of these design stimuli on creativity-inducing design drivers or factors (outcomes basis).

3. **Who can participate in the research? What is the expected duration of my participation? What is the duration of this research?**
   Persons with the technical expertise in design methods, design process, and medical device design. You should be over 21 years of age. Your participation will be on two occasions each for approximately 1 hour. The first session will be the interview and the second session will in the form of workshop to share and verify the results.

4. **What is the approximate number of participants involved?**
   We aim to recruit a total of 15 subjects for this study.

5. **What will be done if I take part in this research?**
   Suppose you agree to take part in this research. In that case, you will be only required to attend two zoom sessions for approximately 1 hour each, firstly for the discussion on medical device design and the above-described influencing factors and a follow up session 2 weeks later to verify the answers.

6. **How will my privacy and the confidentiality of my research records be protected?**
   Identifiable information will never be used in a publication or presentation. All your identifiable information and research data will be coded (i.e., only identified with a code number) at the earliest possible stage of the research. Only the Principal Investigator will have access to your data. No one else will. The delinked extracted data from the App will be presented only in an aggregated form, so no identification from the given data could

be possible. The collected information will be stored in an encrypted format and kept per the regulations.

7. **What are the possible discomforts and risks for participants?**
   There are no associated risks with this research as we only discuss your perspectives and understanding of the medical device design and development and factors that affect the innovation. In any case, you may discontinue should you feel uncomfortable at any time by informing the Principal Investigator.

8. **What is the compensation for any injury?**
   We do not expect any injury or compensation for this research.

9. **Will there be reimbursement for participation?**
   There will not be any reimbursement for your participation.

10. **What are the possible benefits to me and others?**
    The direct benefit to the subject by participating in this research could include a deeper understanding of the medical device design process, which the experts share in the field. The knowledge gained will benefit the designers in the future by developing innovative medical devices based on the guidelines.

11. **Can I refuse to participate in this research?**
    Yes, you can. Your decision to participate in this research is voluntary and entirely up to you. You can also withdraw from the research without giving any reasons by informing the principal investigator, and all your collected data will be discarded.

12. **Whom should I call if I have any questions or problems?**

    Please contact the Principal Investigator, Prof. Subburaj Karupppasamy, at **telephone** 6306 6600 and **email** Subburaj [at] sutd.edu.sg for all research-related matters and in the event of research-related injuries.

    For an independent opinion regarding the research and the rights of research participants, you may contact the SUTD Institutional Review Board at telephone 6499 4985 or email at irb [at] sutd.edu.sg.

Online Consent Page

I hereby acknowledge that:

1. I have read the above information sheet that explains the use of my data in this research.
2. I understand its contents and agree to attend two-zoom sessions for approximately 1 hour each, firstly for the discussion on medical device design and a follow-up session 2 weeks later to verify the extracted information from the first session.
3. My participation in this study is entirely voluntary. I can withdraw from the research without giving any reasons by informing the principal investigator, and all my data collected will be discarded.
4. Any personal information (i.e., my name and contact information) collected in this study that can be associated directly with me will remain confidential. My unique identifiers will be coded to protect my privacy.
5. Only the research team members have access to the data collected in this research. The data will be password protected and stored in a secure server in SUTD.

☐ By ticking this box, I agree to participate in this study. (Start the online Interview)

☐ I do not wish to participate in this study. (Exit)