Project proposal: Sustainability of Medical Devices

Methodological Evaluation and Incorporation of Environmental, Social, Clinical, and Economic Sustainability Throughout the Design Process

Goals of the research

Our aim is to develop a methodological quantification tool to holistically incorporate sustainability (i.e., environmental, social, clinical, and economic sustainability) in the design process of medical devices (MDs).

With this research, we want to address the following research questions:

- 1. How to identify and arbitrate the trade-offs between the different dimensions of sustainability specific to the development of MDs?
- **2.** How to quantify and model sustainability throughout the design process of MDs without burdening the designer, and how to effectively handle the related uncertainty?
- **3.** Does the methodological integration of sustainability in the design process of MDs lead to preferable environmental, social, clinical, and economic outcomes?

Context

The medical sector plays a crucial role in the current environmental crisis, accounting for 5.2% of global greenhouse gas (GHG) emissions¹, with 20% linked directly to MD production and consumption². Beyond GHG emissions, MDs can impact social equality by e.g., incorporating discriminatory biases³. These unsustainable practices consequently negatively impact human health^{4–6}, creating a self-reinforcing feedback loop.

Biomedical designers have a significant influence and responsibility on this given that 80% of a MD's footprint is locked in during the design phase⁷. Therefore, they should incorporate additional risk management strategies based on holistic sustainability practices, as most risks in medical device design relate to sustainability issues^{8,9}, such as pollution, resource depletion, and social discrimination. However, integrating sustainability into medical device design is not yet standard practice¹⁰. This while, compared to general design processes, MDs are designed in a highly controlled and standardized manner to ensure compliance with regulatory frameworks. When looking at incorporating sustainability in design methodologies for MDs, there are two obstacles to consider:

- Incorporating sustainability into product design can be intricate, especially during the initial stages of the design process where the uncertainty surrounding design decisions is the highest¹¹. A methodological integration of sustainability requirements is needed to achieve favorable outcomes¹². Yet, most sustainable design tools do not focus on this alignment of knowledge and complexity¹³⁻¹⁵.
- 2. Despite studies indicating that single-use devices have a higher environmental footprint than reusable ones¹⁶, the market is shifting towards single-use MDs due to bacteriological safety concerns of reusable solutions^{17,18}. Striking a balance between sustainability and clinical requirements, such as infection prevention, becomes increasingly essential and illustrates the multi-dimensionality of trade-offs in the MD design process.

Our research aims to bridge the gap between design for sustainability (D4S), medical device design, and their associated methodologies and tools. We aspire to enhance multi-criteria decision-making for holistic sustainability in MD development, by acknowledging the complexity and uncertainty of the early design stages. The proposed methodological quantification tool will facilitate:

- The identification and balancing of trade-offs between the different dimensions of sustainability (environmental, social, clinical, economic) related to MD design.
- The quantification of these impact categories throughout the design process dealing with the uncertainty in the early design phases.

Through this approach, we seek to advance sustainable practices in medical device design, ultimately leading to more responsible and effective healthcare solutions.



Project proposal: Sustainability of Medical Devices

References

1 Romanello, M. et al. The Lancet 400, 1619–1654 (2022) 2 The Shift Project. (2023) 3 Kadambi, A. Science (1979) 372, 30-31 (2021) 4 Romanello, M. et al. The Lancet 398, 1619–1662 (2021) 5 Murray, C. J. L. et al. The lancet 396, 1223–1249 (2020) 6 Bressler, R. D. Nat Commun 12, (2021) 7 European Commission. (2022) 8 Bartoo, G. IEEE Engineering in medicine and biology magazine 22, 166–172 (2003) 9 Schulte, J. et al. in 21st International Conference on Engineering Design, ICED, Vancouver, Canada, 21 August 2017 through 25 August 2017 327-336 (The Design Society, 2017) 10 Faludi, J. et al. Sustainability (Switzerland) 12, (2020) 11 Fernández, M. G. et al. in 9th AIAA/ISSMO Symposium on Multidisciplinary Analysis and Optimization (American Institute of Aeronautics and Astronautics Inc., 2002) 12 Du Preez, N. D. et al. in PICMET: Portland International Center for Management of Engineering and Technology, Proceedings 546–558 (2008)13 Baumann, H. et al. J Clean Prod 10, 409-425 (2002) 14 Boks, C. J Clean Prod 14, 1346-1356 (2006) 15 Dekoninck, E. A. et al. J Clean Prod 135, 410-425 (2016) 16 Sousa, A. C. et al. Environment, Development and Sustainability 23, 9641–9666 (2021) 17 FDA. (2015) 18 Macneill, A. J. et al. Health Aff 39, 2088–2097 (2020)

