

# Eco-Friendly Medical Devices: Bridging the Gap between Environmental Sustainability and Healthcare

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**Annotation:** The world is experiencing an aging population and chronic diseases deeply affecting the fundamental structure of healthcare systems. National and international organizations together with design communities are currently addressing new approaches to foster realistic tools, such as innovative, eco-friendly solutions. Healthcare design has recently been included into the Sustainable Design field to pursue strategies aimed at reducing energy consumption and hazardous substances in products. This paper discusses brief guidelines to develop a new sector of eco-friendly medical devices, with the aim to bridge the gap between environmental sustainability and healthcare by combining information and perspectives from diverse sectors and individuals, amongst corporate managers, healthcare employees, patients, students and scholars of diverse disciplines. The

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integration of different competences and roles is necessary to enhance corporate responsibility and to disclose socio-ecological exceedings due to healthcare products life cycle. Experiencing hospitals and specialistic universities, this discussion further broadens the debate on healthcare as a multi-layered open system connected to diverse and changing context. New research will be addressed to Analytical Design methods, focusing on the study of energy requirements and ethic consequences of medical devices related to the therapeutic phases. Finally, the role of R&D and the ongoing Industrial Design project will be discussed, aimed at the restitution of a sustainable, interdisciplinary modular system.

**Keywords:** Eco-friendly Medical Devices, Environmental Sustainability, Reusable Medical Devices, Biodegradable Materials, Energy Consumption and Carbon Footprint, Sustainable Procurement Strategy.

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## 1. Introduction

Earth population is increasing, and thus are the healthcare services consumption and the public health concern about environment. All over the world, population projections estimate an increase from 6.5 billion people in 2005 to 8.3 billion in 2030, particularly affecting European countries due to the aging population, with an estimation of 152 million people older than 65 by 2030, as predictions of a 40% increase over these 25 years. Nonetheless, these demographic changes can have an important impact on the environment, especially in healthcare services consumption. [1]

## 2. Environmental Impact of Medical Devices

Single-use medical devices are intended for just one use and are discarded afterward. Because of their high environmental cost, several approaches for improving the environmental footprint of single-use medical devices have been proposed. Reusables do not have any such constraints and are treated and tested before each use to ensure they meet specified standards. These tests and refurbish procedures avoid undesirable environmental and economic impacts that may be associated with the use of reusables. Dupont points to effective use, repairing, and biological impacts as making reusables better than disposables. The simplification of directives applicable to reusable packaging systems is expected, however the enabling conditions for this move has not been achieved so far. At least some approaches to reuse e.g. ultrasonically cleaning the equipment was unsafe. All this has left policies pursuing disposability free of clear benefits facing particularly-passionate opponents. The domestic dishwasher is wired and programmed to enable the use of excess capacity cost-effectively. Kits used in ESA have a surplus or reusable guard components for repetition that can be individually replaced if contaminated. This would be safe too if the risk factors were not accessible. A good kit manager will have spotlessly cleaned, reused equipment ready in the necessary quantities. Carelessness in this area risks running out of disposable kits mid-procedure. Patients can bring in their own kits of the right type and volume

to their procedure. The analysis of biocompatibility testing over the specified cleaning cycles of reusable vaginal specula was not provided. Technicians who have a financial incentive to assemble the largest number of kits in the shortest possible time using the most aggressive maintenance procedures may compromise the safety of the final output. Concerns about disinfection of reusable vaginal specula came from the non-profit corporation that sells disposable vaginal specula as an apparent threat to the reuse of their products. RE processed vaginal specula received less favorable response from the first-time users with a statistically significant  $p=0.00003$ . However the majority (57.6%) were neutral in attitude, possibly amenable to education on procedural risks. Single speculum use agrees with guidelines from [1].

## **2.1. Materials Used in Medical Devices**

Research and development are major drivers for innovative products. In medicine and biotechnology, sophisticated medical devices are nowadays used in nearly all fields such as implants, orthotics, patient monitoring, disposables, therapeutics, etc. The materials used in medical devices are in the focus of this text. Similar to the definition of biomaterials, it proceeds from materials intended to interface with biological systems and covers all materials used in medical devices, from the very traditional metals, synthetic and natural polymers, ceramics to the very recent nanocomposites and intelligent materials, soft-matter and self-assembling systems.

On average, spending for healthcare systems consumes approximately 10% of the GDP of industrial countries. Pressure to reduce the overall healthcare costs has led to an increased interest in identifying the role of medical device materials in optimizing the performance of healthcare and improving overall living standards in the elderly. Today, with the approaching shortage in resources predicted for the 21st century and the awareness of sustainability, the use of materials for engineering has to change. Regarding the use of materials in the health sector, the new challenge is to ensure that the products (materials, technologies, energy, and services) that give rise to improve health are produced and used in a way that is risk-free to the health of the people, in environments that conserve the natural resources and the climate, and at a cost that guarantees the ability of all countries to provide basic health services to all constituents. On the other hand, the stipulation for new highly specialised devices (such as implant materials, drug-delivery and wound-dressing systems, diagnostics and disposable systems) is growing. In this context a vision of the type of research to be conducted is proposed. [2][3]

## **2.2. Energy Consumption and Carbon Footprint**

The energy resource consumption and global CO<sub>2</sub> emissions have increased substantially during the last decades. The residuum and emissions of bio organic matters generated after the consumption and conversion of biomass fuel are recognized as the greatest factors of interference and threat to the world climate and society. Thus, it is urgent to timely reveal and account the contribution of various emissions intakes to the carbon footprint effect owing to different global scales in the presence of the urgent need to decrease the carbon release pressure that some countries exert on the world environment. AMP is a convenient software that efficiently analyzes the extraction of energy for the construction of infrastructures, upstream operations, and end executions attributable to all the activities and production processes performed by companies, sectors, or institutions. The software distinguishes between the requirement of useful and loss energies and permits to appreciate the carbon content of the energy consumed according to the country and year for which the analysis is performed. From a standard database structured in accordance employed to compile the emission intakes at the national level, such as the sum of local emissions, the foreign emission release owing the requisite of imported commodities, the international tide of local emissions due to the demand derived by the export of final commodities and the demand of goods and services to satisfy the internal consumption of infrastructures and end users like institutions and households [1]. All this information is processed and disaggregated by products and industries, and through the input-output tables, it is feasible to achieve the carbon EFFECT of each 1 US\$ for a broad set of

CO<sub>2</sub>, CH<sub>4</sub>, N<sub>2</sub>O GHG and different years of the knowledge base.

### 3. Regulatory Frameworks and Standards

Medical devices, like any other appliance, may lead to significant environmental impact, if not properly managed after their end-of-life. Efforts are being taken by the European Union (EU) to foster eco-design of medical devices throughout the entire life cycle; unfortunately, only a few indications are yet available as amended by the most recent EU-Medical Devices Regulation 2017/745. A significant research gap is evident between concepts linked to environmental risk related to medical devices and their actual technical solutions. Efforts are being taken by the European Union (EU) to foster eco-design of medical devices [4]. Some physical constraints of medical devices make it difficult to be disposed of together with conventional waste; other risks are linked to its inherent functionalities, enriched by electronic or software components. Unfortunately, only a few indications are yet available as amended by the most recent EU-Medical Devices Regulation 2017/745. A significant research gap is evident between concepts linked to environmental risk related to medical devices and their actual technical solutions. At the same time, many innovative systems are technically evaluated in their first development step, when they are well remote from full commercialization and sometimes before the medical device definition is fixed. To bridge this gap, the state of the art procedures for handling end-of-life medical devices are thoroughly reviewed, and some indications are given to the developers of new medical devices, which will help to manage them in an environmentally friendly manner.

### 4. Innovations in Eco-friendly Medical Device Design

A “triple bottom line” approach which enhances environmental, economic, and social performance involves taking various strategies that target the prevention and re-use of waste, the creation of new eco-models or services, and/or the enabling of new eco-consumption patterns. This focuses on the Italian context and the argument that a renewed and stronger collaboration between product service designers and health industry stakeholders has the potential to drastically improve the environmental and social performance of newly designed medical technologies. Within developed economies, healthcare systems are a major consumer of resources and a significant source of pollution. Practice regarding environmentally sustainable procurement strategy for medical devices varies widely. In the light of the growing emphasis on sustainable development, this study takes a closer look at the procurement process with the aim of assessing the explicit inclusion of environmental requirements in tender documents when procuring certain high-risk medical devices, e.g., imaging equipment. The methodology developed yielded negative results for the case study of Poland. [5][6][7]

The healthcare sector is the cornerstone of the economy in all industrialised countries consuming 9–11% of GDP and employing around 10% of the workforce. However, it lags behind in terms of the sustainable development paradigm. Healthcare facilities are huge consumers of resources and the production of waste is five times higher than in any other sector. The traditional linear model of take-make-consume-dispose is not simply applicable to healthcare. Goods have transitioned to waste or are lost at every process in healthcare and the quality of service has a wide influence on the environment. Taking into account the development in healthcare sector, new challenges are required to be faced with respect to foresight and active enforcement, in order to develop ecological design solutions, cleaner technologies, innovative medical devices, and to conduct producer responsibility. [8]

#### 4.1. Biodegradable Materials

Medical devices that are used throughout the world are mainly composed of metal, polymer, and ceramic. Although these materials help to maintain the efficacy and functionality of devices, most are non-biodegradable materials, leading to the potential existence of device materials for a long period [9]. The global medical device cleaning market is expected to reach \$1.8 billion by the end of 2022. In addition to the high cost of material requirements, the cleaning market is a

huge market. It has been reported that 50% of medical waste is disposable medical devices. As a result, the biomedical industry has come to the proposal stage of selecting biodegradable materials for the safety of patients and cost reduction. On the other hand, environmental concerns can mine this proposal. A biodegradable device can be used and resorbed in the body without the need for a second surgery to remove the device. This is to eliminate the risk of infection and hospital cost returning to the hospital. Also, biodegradable electronics have an alternative to global issues in the electronic waste by providing an effective way for secure hardware. Biodegradable electronics can reduce the risk of electronic waste by resorption, and avoiding electronic waste associated with complex disposal and security issues from patient information. These electronics are seen as the next generation of medical device implants. Over time, they will resorb in the body without any irritation and long-term fibrosis for the body. Soft electronics are needed for causal media with soft biological tissues. A new research paradigm for the development of soft materials and system-level design in soft biomedical devices is being proposed. This page introduces a research trend on soft materials, devices, and design of soft biomedical devices. Recent advances in materials, fabrication techniques, and layout designs have introduced biodegradable and soft electronic devices, allowing the device to wrap intimately with biological tissues or resorb within the body following a predetermined period. Such newly designed materials, devices, and systems can provide unique opportunities for diagnostic and therapeutic functions. There is great potential for such electronics as innovative medical devices over the next decade. [10][11]

#### **4.2. Reusable Devices**

To reduce the environmental impact of the production, use, and disposal of a product, it is important to consider the entire product life cycle. Rather than relying on single-use devices, which are disposed of after a single use and have been associated with high healthcare waste profiles in both high- and low-income settings, consideration should be given to devices that can be reused several times. Using durable devices that can be resterilized and packaged between cases, or devices that create less waste due to the nature of the procedure would help in reducing the carbon footprint. This would help in managing hospital waste in a better manner, as lack of proper waste segregation is a major problem observed across different healthcare setups in the country [12]. Therefore, reusable devices should be preferred over the use of disposable devices. The potential of reusable devices in lowering the carbon footprint of a healthcare setup is immense, especially in resource-poor settings. However, adequate number of reusable devices should be made available in such setups.

There is a lack of transparency regarding the assessment of the environmental consequences of healthcare products. It is currently difficult or impossible to ascertain whether and how such an assessment has been conducted. Single-use supplementary feeding systems for infants (SFS, N = 4) were exchanged for reusable SFS in a large hospital in southeast Asia, and life-cycle assessments (LCAs) were conducted from a cradle-to-grave perspective. Observational and modeling-based comparisons with published LCA results for single-use and reusable SFS (N = 4) were also performed. The hospital-initiated substitution of all SFS types led to reduced cradle-to-gate global warming potential for SFS with the reusability factor considered in the reuse setting (Hospital: median -52%; range -44% to -61%) compared with the single-use scenario [13].

#### **5. Case Studies of Eco-friendly Medical Devices**

Today the penetration of environmental sustainability issues into the medical field is at the rise, promoting the optimization of resources and energy consumption at every stage of the lifecycle of medical products. Medical devices sustainability concerns are usually restricted to technical performances, reliability, and safety issues. Such features result as far the primary objectives pursued during the development process of new medical devices, whereas the economic, social and environmental aspects are nowadays gaining interest from scientific community [14]. In the



medical devices manufacturing field, great effort on energy consumption is usually posed, and promoted by international standards and technical norms. Furthermore the materials recovery at the end-of-life (EoL) of medical devices still suffer from the need of the disposable devices sterilization and final disposal. The most dedicated recycling procedures are usually applied to metal materials, and are usually restricted to collection policies and end-of-life treatments promoted by the devices manufacturing company. Instead the recovery of plastic materials and electronic equipment is usually carried out by external partners, or promoted by specialized companies dealing with recycling treatments, employing mechanical shredding and subsequent chemical depuration processes.

Case studies are presented in the field in which those products usually available as single package are sterilized and packed in the same production site intended for their use in operating rooms. The sterilization treatment is provided by a biphasic ethylene oxide (EtO) process, and is immediately followed by the automatic packaging of medical devices. During the first part, the design specifications will be faced that will allow the achievement of the sought KPIs. In the second part, the focus is moved on the packaging and monitoring equipment. The packaging machine has been developed by Mega s.r.l. and it is currently installed in some hospitals units in Italy. In the final part of the paper the data analysis carried out for the packaging equipment during its acceptance and reassembling procedures are presented. [15][16][17]

## **6. Challenges and Barriers to Adoption**

Globally, the healthcare sector is one of the major contributors to greenhouse gas emissions, accountable for an estimated 4.4% of overall carbon footprint emission. Despite this, many medical facilities and healthcare professionals have been slow to transition to eco-friendly products and business practices. Such products have been steadily gaining traction with consumers in the private sector, where energy-efficient household items are marketed with energy cost savings. The healthcare industry finds itself in a unique position, acting as a bridge between the growing need for medical devices in an aging population and the push for environmentalism both legislatively and from the public. The complex technical nature, long procurement process, and stringent infection control standards of medical equipment contribute to a higher upfront cost, while the effectiveness of renewable, reusable, and/or energy-efficient devices and their overall environmental impact can be difficult for procurement professionals to assess, compared to the standard, single-use alternative. The medical industry is highly regulated. Regulatory approval, sterilization procedures, and active management will be needed for eco-friendly devices due to the relative novelty of such technology in the scope of medicine.

## **7. Economic and Social Benefits of Eco-friendly Medical Devices**

Since both consumers and public authorities are becoming increasingly focused on environmental protection, the mere application of European and national laws is no longer sufficient, making necessary new measures able to conjugate the pursuit of bioethical aims with consideration of environmental friendliness. Eco-friendly medical devices have a smaller carbon footprint, have a lower impact on water resources and soil, are either degradable or more easily recyclable, make use of vegetable or animal origin renewable raw materials, or of recycled or regenerated materials. Furthermore, eco-friendly medical or surgical devices are characterized in that their intended use has an environmental sustainability in its objectives. The success of eco-friendly medical or surgical devices depends on the cooperation of all concerned social actors involved. More specifically, a first task is for the regulatory authority to implement the above mentioned definition. On the economic side, there exist various existing and new financial or fiscal measures that promote eco-friendly medical or surgical technology. Accordingly, a number of additional measures are taken to promote the diffusion of eco-friendly technology in the healthcare field. Eco-friendly dialysis with the Systemic Design methodology: an eco-friendly dialysis may start [18]. A crucial role is also played by the formulation of CC guidelines for the eco-design of future tender specifications. On the other hand, the effectiveness of the eco-

innovation effort depends on the degree of commitment to environmental policies of the parties involved. For the competitive industry, vis-à-vis the industry, the work is emergent from the business community and the industry by being part of eco-silicify of the group, and by doing the FT R & D on the eco-industry. For the efficient implementation of CD procedures, ecological criteria need to consider the empirical constraints. For the particular case of packaging design, a natural method is Syst Exam has been applied to design disposable cartridges of medical devices. [19][20]

## 8. Future Trends and Technologies

Designing sustainable medical devices, their components, and their production processes is an emerging area of research [14]. The potential for recovery and recycling, reuse, remanufacture, or extended product life, also known as sustainability/end-of-life options, are considered at the outset of the design phase rather than as an afterthought. Potential routes for component recovery are identified and weighed against the reusability of existing parts; devices are designed more legibly and to include their design datasheets in a control zone where they can be examined without needing disassembly, providing potential for safer and more complete recovery of parts; this technique has been prototyped in plastic and IR transparent materials and is being developed in line with recent knowledge in recycling and end-of-life options. New developments in healthcare put new demands on the technical characteristics, e.g. chemical purity, precision, inexpensiveness, correctness, usability, and life span of medical devices. In the case of disposables, low prices should correspond with a short exploitation. Hundreds of tons of medical plastics are used in European countries and many thousands of tons worldwide. The residual amount after therapeutic usage is disposed of in various ways. Fixing a standard schedule for disposable products or changing product specification means adjusting the value of time use, and functional characteristics of medical devices disposed. Researchers propose a method of examination of medical materials that serves for the short-term exploitation of medical devices and their safe disposal after that time has expired. It is based on laboratory tests which involve an aggressive medium, i.e. a liquid simulating physiological saline solution. There is a statistical description of the time of transition between dis- and malfunctions. A several-stage verification of device reliability can be done at a laboratory level. At the final market stage, it is necessary to confirm testing the time to malfunction at the level of  $p = 0.95$ . Also, a market estimation of the parameters regulating product time of functionality is presented for products with a low retail price. The realization of these proposals assures both an appropriate application of these disposable products and safe disposal. Relaxation of stringent restrictions for products whose application is not associated with life and death cases is possible. Potentially harmful materials can be replaced with bio-degradable and safe materials. [21][22][23]

## 9. Conclusion

Thanks to the growing interest towards environmental sustainability in every field of industry, packaging of medical disposable products has been recently reconsidered under many points of view. The present paper focuses on packaging design of medical devices in the healthcare field. Environmentally eco-compatible packaging solutions are conceived to be used for generating guidelines for product design and also production. By analysing a specific case the possibility of designing sustainable medical devices is explored by setting a direct bridge between materials science and product design techniques [14]. This approach enables one to consider the environmental impact of a product since the very first steps of the initial idea and it guides the developing procedure by suggesting the most suitable solutions for both materials and production process. Considering all ecological aspects related to the proposed solution, the final packaging design analysis depends on the efficiency of packaging both as a vehicle for unimpaired use and as presentation for different kinds of medical devices. Moreover, packaging is meant to contain disposable products dealt with hazardous materials, and so it should guarantee to the patient a first-level food product [18]. On each individual sterile disposable is specified, when appropriate, the International Standard for the packaging material to ensure its

biocompatibility. It is also worth taking into account the sterilization method used for the different medical disposables: a complete rejection of the single usage implies the probable lapse of the sterilization term, with high risk for the patient. The study of the potential replacement of traditional materials with environmentally friendly plastics on the basis of the available home collection for recyclable materials is still in progress.

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