

Ophthalmic Medical Devices and Sustainability: a Dialogue for R & D

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0. Abstract

This paper describes the practice of research and design of ophthalmic medical devices and the confrontation with sustainability questions. The ophthalmic medical devices industry sector is far away from sustainability innovations currently. The confrontation is developed on the basis of a scientific dialogue between the two authors about their respectively daily R&D practices and sustainability research.

The strong regulation rules and the risk-elimination in safety policy determine a small playing field for changes on the basis of sustainability. The regulation is even different per country. That means that changes have to be tested in several regulatory situations and cultural settings. The strict requirements in the medical sector also mean that a starting sustainability dialogue needs to follow the theory about the introduction and dissemination of new concepts: information sharing, awareness raising, recognition, acknowledgement, commitment, education, assessment of opportunities, demonstration projects, evaluation, and continuous improvement. Such emerging sustainability dialogue in an industrial sector often meets reluctance from companies and resistance to start an assessment process. When there is a medical professional market, the demands and needs of medical staff are strongly determining the R&D space. Risk-elimination in the health treatment of patients is a major component of safety policy in the medical sector.

In general however, leading companies foresee growing environmental pressures and want to explore the opportunities of new sustainability business models. In such context, medical product R & D can consider aspects such as product waste prevention, energy use, cleaning, maintenance, recycling, reuse (in developing countries), and leasing.

The paper dialogues conceptual thinking about eco-design of ophthalmic medical devices on the basis of both practical R & D experience in the ophthalmic medical devices company D.O.R.C. International in the Netherlands as well as academic sustainability research.

Keywords: Eco-design, Medical devices, Stakeholder network, Sustainability innovation

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1. Introduction

The medical sector is a big provider of waste. For instance, the health sector is the second-largest contributor to landfills after the food industry in the United States (Kwakye et al., 2010). The United Kingdom National Health Service, the largest health organization in Europe, emits annually approximately 17 million tonnes of CO₂ above the future carbon cap for the sector (Thomas & Costorp, 2010). Although, already more than 25% of U.S. hospitals are reprocessing medical devices, the dissemination of green practices has continued to be slow because of a misunderstanding of the process and concerns about patient safety (Kwakye et al., 2011).

The ophthalmic medical devices industry sector is far away from sustainability innovations currently. The strong regulation rules and the risk-elimination in safety policy determine a small playing field for changes on the basis of sustainability. The direct relation with the health and safety issues of involved patients provides a vulnerable basis for changing handlings and equipment. Many stakeholders with different positions, wishes or requirements are involved in the trajectory from design to application of medical devices, such as:

- Patients: persons with a need for treatment and having a background with a variety in knowledge and skills,
- Users: professionals such as doctors and nurses
- Hospitals, medical centres: purchase, environmental management
- Suppliers: designers and producers
- Government: decision-making about costs and quality requirements
- Conditional organisations: Government health regulation department, health care insurance companies, patient organisations

We want to describe and analyze the organizations and actors that have a stake in the medical process around ophthalmic medical devices. That stake can have different dimensions, such as applying medical skills, information providing, profit making, marketing, hospital purchasing, designing and production of equipment. It means that such diverse relationship generates a complexity of different needs that are not exchanged between stakeholders at the same time. You can say that there is an unconstructed virtual network of stakeholders around a patient that is not a network in reality. It is a semi-structured construction with mostly bi-lateral connections, such as doctor – patient, nurse - patient, and purchasing department hospital – production company relations. That situation provides a structure that is not easy for the introduction of new issues like sustainability. Research questions in this paper are:

- Who are the stakeholders in the ophthalmic medical devices?
- What is their position with respect to sustainability change processes?
- How can sustainability dimensions be stimulated and disseminated as R & D tool in the ophthalmic medical devices industry?

The paper will introduce and discuss the questions about who are the different actors and organizations in the network of ophthalmic medical devices application and their position in section 2. A review of the relevant medical devices regulation is provided in section 3. An analysis of the current ophthalmic medical devices design process considerations at D.O.R.C. International in the Netherlands will be reflected upon in section 4. In section 5, a dialogue about how sustainability issues can become part of this design process and how such introduction and dissemination process can be managed will be analysed. Finally, conclusions about the challenges of eco-design of ophthalmic medical devices and the contours for the development of a sustainability business model innovation will finalize the paper.

2. Actors and organisations in the research field

It is assumed that the nature of the different actors and organizations need different approaches of awareness raising for initiating change processes. According to Kanter (2011), complex systems of multiple actors and interest groups rarely change by fiat. They are more likely to change because of the accumulation of many positive deviations from tradition that prove themselves and gain support. Each small innovation pushes at some aspect of the system and ends up triggering greater change.

For the description and analysis of the research field of the ophthalmic medical devices industry sector and sustainability the actors and organizations will be characterized first. Related to that analysis information processes and the type of incentives are designed. The process of information provision, recognition, acknowledgement, education and demonstration project (Baas, 2005) is tuned to separate stakeholder needs. During this process the installation and communication with focus groups functions both in awareness raising as well as feedback providing with respect to sustainability design of either the product or the change process.

With respect to constructed networks of stakeholders (Freeman, 1984) it is argued that three organisational culture characteristics – trust, open communication, and joint problem solving – are key elements for network embeddedness (Noorderhaven et al., 2002). When such conditions are present, problems are perceived as a joint responsibility of all network members (Baas, 2008). The findings of Simsek et al. (2003) that informal social networks effect entrepreneurial behaviour and on innovation strategies of large companies strongly is often not found back in the business practice. Historical developments and collective norms and values in guiding economic behaviour are the basis for routine approaches with limited space for change. In the decision-making process about purchasing MRI scanning equipment is recently found that the respondents find environmental and social sustainability dimensions personally relevant but professionally secondary to cost, performance, and ability to use the equipment in their organization's physical infrastructure (Lindgreen et al., 2008).

Another issue is that the perception of stakeholders can be significantly different from the real sustainability performance of a company. In a recent research about the biggest companies in ten industrial sectors in the United States it was found that the difference between perception and performance was in two directions: either the perception was positive, but the performance poor, or opposite (Map-Change, 2010). An illustration of the food sector shows that the perception of the sustainability performance of the Kellogg's brand is 81 out of 100, while the actual performance is 41. The authors see a big risk for the company when they do not speed up their sustainability innovation. They indicate that on the basis of a certain event consumers can drop the brand in a short time, such as was the case when Shell intended to store the Brent Spar oil separator at the end of its life-cycle at the bottom of the sea as a good environmental solution (Elkington & Trisoglio, 1996). Consumers started to boycott Shell until the decision for another solution was made. Shell could survive the boycott; smaller companies probably not when their brand is under pressure.

Of course the Map-Change is research that is performed on the consumer market. The professional purchase market is different. Nevertheless, the professional attitude has an underlying personal commitment to the environment (Lindgreen et al., 2008) that can pop up in a specific situation. As sustainability is increasingly embedded in society, this is an issue for reflection. We will assume the influence of the different stakeholders on initiating sustainability processes in the ophthalmic medical devices industry sector

Patients, needing medical care or treatment, cover all categories of society, levels of education, and interests in environmental issues. The presence and degree of distribution of those assets show a broad variety. The severity of the medical need will determine whether all attention is focused on that or that there is room for other aspects, although it is expected that the concern for environmental issues will hardly be expressed in the medical treatment situation.

The medical professionals mainly focus on treatment and care activities in their position. The healing perspective is dominant in treatment situations. The medical professionals are important actors in sustainability change processes as adaptors. We assume that they are not the initiators in such processes.

Hospitals and medical centres can be qualified as institutional frameworks for initiating change processes. These institutions are dealing with tonnes of disposable waste and increasing costs, mainly coming from Single-Use Devices (SUD). Waste reduction through reprocessing of medical devices is one of their possible strategies. That can be a major driver for sustainability processes in the medical devices industry.

At the supply side is observed that the medical and regulatory requirements provide a small playing field for product design and related production of medical devices. Such small playing field generates hardly a culture for sustainability innovation. However, change that does not effect the core functions and safety issues, is a current challenge for R&D. Sensitivity for the conditions of involving radical sustainability aspects is the challenge for making it operational when the time is ripe.

Government policy with respect to quality and pricing of medical activities can indirectly influence sustainability development in the medical devices industry in several ways. Restricted pricing for medical treatment can have a negative impact on sustainability innovation. However, when conditions such as waste and carbon footprint reduction are formulated then incentives for sustainability issues are stimulated.

Government policy with respect to health regulation will be the basis for authorization of the results of medical equipment changes through sustainability aspects. We do not assume that they are health regulation departments are drivers in sustainability processes.

Both health care insurance organisations and patient organisations are focussing on their core activities that are different from sustainability questions. We assume that they support, but not initiate, sustainability issues.

Reflecting our assumptions about the position of the different stakeholders we do not see blocks for sustainability drivers for ophthalmic medical devices. We also do not see direct needs for that. However, seeing the societal needs with respect to waste management, carbon footprint reduction, energy saving and resource efficiency, this situation can change in an unpredictable time perspective. We see different stakeholder's positions with respect to influencing such sustainability change process in the ophthalmic medical devices industry. The positions can be qualified as primary influencing stakeholder when sustainability assets can be initiated, required, wished and/or strongly promoted. They can be characterised as indirectly influencing organisations when general policies are requiring or challenging the translation into specific sector sustainability assets. Sensitivity and openness for societal development and market signals can also be categorised in this characterisation. Following organisations, also called "third party", have no direct position in the core activities. They support or tolerate sustainability developments from other organisations. Along that line we design Table 1 as follows:

Table 1 Qualification of the influence of organisations on Sustainability change processes

Qualification of organisation	Type organisation
Primary influencing	Hospitals, medical centres, government
Indirectly influencing	Supplier, government, medical staff
Following/third party	Patient, patient organisation, Health care insurance

When we look how the three dimensions (ecological, economic and social) of the sustainability concept (United Nations General Assembly, 2005) can be the main driver(s) for sustainability development we construct Table 2 in the following way:

Table 2 Overview of stakeholders' main drivers on dimensions of sustainability

Stakeholder	Environmental dimensions	Economic dimensions	Social dimensions
Patients			√
Medical staff			√
Hospitals	√	√	√
Producers	√	√	√
Government	√		√
Health care insurance		√	√

With respect to the table 1 and 2 we see hospitals, producers of medical devices, and government as main players in the network. As there is a professional consumption market, producers of medical devices are more dependent on the expressed needs of medical professionals for product modifications in daily practice. In case of the developing new medical devices, producers can apply the optimal balance of sustainability dimensions in their product. In that position producers are qualified as primary influencing organisations.

The influence of governmental organisations comes in from different directions. The European Union directives might directly influence the composition of medical devices or indirectly with directives on certain aspects such as energy efficiency. National governmental policies modify those directives within their own context that directly influence producers. They will influence indirectly via environmental policies, the stimulation of renewable energy, resource efficiency requirements and so on.

Hospitals, including medical centres, are placed in the category of direct influencers. Their stake as organisational institution is strongly in economic incentives and developing environmental (sustainability) management.

3. Medical devices regulation

For the medical devices industry three mayor directives are leading in Europe, these are:

- The Council Directive 93/42/EEC on Medical Devices (MDD) (1993)
- The Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) (1990)
- The Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDMD) (1998)

These directives all have the main goal to assure the safety of the patients and minimize the risks for patients and users of the medical devices. One of the topics in this legislation is for example is the need for biocompatibility. Biocompatibility means that the devices entering the human body have little or no immune response to the human body, or is able to integrate with human tissue. For this specific subject in the regulation an ISO-standard (ISO 10993) is developed to provide a framework and standardize the definitions, the test methods, etc. Unfortunately, the perception of the definitions and tests is still different throughout the world, leading sometimes to double testing. These human safety studies use in vitro methods, thus using cells and tissues outside the body in an artificial environment. From a sustainability point of view the use of those tests should and could be as low as possible.

At the moment there are three European Union directives for enhancing Eco-design principles in the medical devices industry.

- Restriction of Hazardous Substances (RoHS), directive 2002/95/EC;
- Waste Electrical and Electronic Equipment Directive (WEEE), 2002/96/EC;
- Energy-using Products (EuP), as part of the Ecodesign Directive, 2009/125/EC.

Furthermore the International Electro-technical Commission (IEC) published the International Standard IEC 60601-1-9: Environmentally Conscious Design of Medical Electrical Equipment in July 2007. The standard provides a systematic approach for product designers to address all life cycle aspects when they design new medical devices. As this family of standard (IEC 60601-1) is used intensively in the medical equipment development it is expected that the acceptance and use of this standard will be high.

4. From general to specific design processes

The design process at D.O.R.C. is based upon the general process of product design as describes in the model of Roozenburg and Eekles (Roozenburg, 1995).

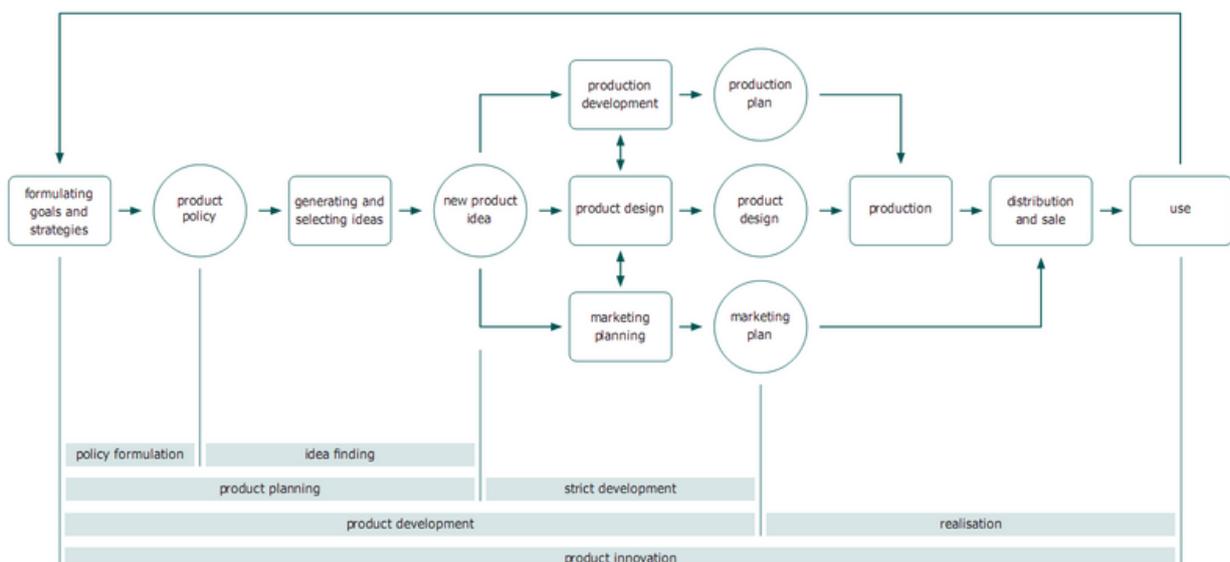


Figure 1: The phases of the product innovation process (Roozenburg and Eekels, 1995)

The development of new products start with a new product idea often brought to the attention by an user (surgeon) of the ophthalmic devices. At this moment sustainable goals or preconditions are not integrated into the design process. D.O.R.C. starts with the development of prototypes to obtain an understanding if the new product idea is a good solution for the experienced bottlenecks of the surgeons. Once the feedback is positive the strict development of a product begins, meaning developing better concepts of the first idea and engineering of the concept. In this phase the regulatory framework of the medical device industry plays a very important role; is the use of the device safe for the patient, are the material biocompatible, is the device really solving the problem of the patient (in other words does the device do what it is intended to do), etcetera.

One of the products that D.O.R.C. recently designed is a disposable forceps, see figure 2. In the development process of this instrument all kinds of requirements are taken into account like ergonomics, user requirements, production facilities, regulatory demands, etcetera.



Figure 2: Disposable forceps/scissors

Products like these scissors or forceps are non-active. D.O.R.C. also develops and produces active devices like an ophthalmic surgical system, the Associate, see figure 3.



Figure 3: Associate - Phaco & Vitrectomy Surgical System

The Surgical Systems as the Associate use energy during its whole lifetime.

Possibilities seen by D.O.R.C for their own sustainability influences in the design process:

- Waste reduction: packaging reduction, reduction of waste in the production processes
- Design with less material: minimize use of raw materials, less energy intensive material
- Reduce weight of the products for better transportation (less energy needed during transportation), reduce volume of the packaging of the products
- Use of less energy of the surgical units during their lifetime
- To enlarge the lifetime of the products, to have good reliable products, easy to upgrade and repair, upgrade of software
- Leasing equipment as the associate (for a longer lifetime and energy consumption correction during lifetime)
- Different business model approaches for developing countries: how to make eye-surgery available for people in a feasible way?

Difficulties seen by D.O.R.C for their own sustainability influences in the design process are:

- Use of new materials: due to the biocompatibility issues it is hard to use new materials like bioplastics, recycled plastics
- The growing market for disposable devices (versus re-usable devices), D.O.R.C. has a need for life cycle analysis to have a good understanding of the environmental impact compared to disposables: the effect of cleaning and sterilizing energy and consumables

5. How can sustainability be introduced in a new area?

The concept of sustainability, formulated in the Brundtland Report in 1987 is more than two decades old nowadays. Sustainability was defined as “the ability to meet the financial, environmental, and social needs of the present generation without compromising the ability of future generations to meet their financial, environmental, and social needs.” However, the concept is not applied in the same way over time, or not at all in different sectors of society. The ongoing dialogue about sustainability can be qualified as a weak exposure of the concept. On the other hand can the concept be qualified as strong because the conceptual framework of sustainability is nowadays connected to the integration of ecological, economic and social developments (United Nations General Assembly, 2005).

The application of the concept in new areas meets the traditional resistance such as: it is not applicable in our sector, it is economically not feasible, it is something for the future. In case of the introduction of the concept of cleaner production, Gunningham and Burritt (1997) found many barriers to cleaner production dissemination in empirical research in Australia that is also illustrative for world-wide implementation. We make an overview of *internal and external barriers* for the dissemination of new concepts in organisations in Table 3 (Gunningham and Burritt, 1997, Baas, 2005):

Table 3 Overview of *internal and external barriers* for the dissemination of new concepts

Internal barrier	External barrier
Lack of information and expertise	Failure of existing regulatory approaches
Low awareness of environmental issues	Difficulty in accessing cleaner technology
Competing business priorities, in particular the pressure for short-term profits	Difficulty in accessing external finance
Bounded rationality in decision-making processes	Perverse economic incentives
Financial obstacles	Absence of markets for recycled goods
Lack of communication in firms	Economic cycles
Middle management inertia, labour force obstacles	
Difficulty in implementing cleaner technology	

In overcoming these barriers and in order to change corporate culture, they drew attention to identifying the roles of information strategies, economic instruments, third parties, industry and regulation.

Sustainability issues are strongly related to actual issues such as the greenhouse effect caused by burning fossil fuels, waste management, the transition to renewable energy, and resource efficient recovery. Solutions are more and more seen in keeping materials in closed loop systems. Concepts such as circular economy (Yuan et al., 2006) that came into force as the Law on Circular Economy in China at 1 January 2009 and the Cradle-to-Cradle concept (McDonough and Braungart, 2002) are illustrative for that development.

Along that line reflection on both corporate culture as well as on actual sustainability issues shows us that the environmental and economic context is changing. Illustrations are among

others that resources are becoming scarce and increasingly expensive. In the U.S. reprocessing of SUDs in hospitals is strongly growing. Kwakye et al. (2010) describe a remarkable process that in the past most medical devices were manufactured for multiple uses and were reused after cleaning and sterilization in hospitals. With increasing concerns regarding safety and rising costs of sterilizing multiple-use devices, health care migrated to SUDs. But as these also became increasingly sophisticated, their costs drove them to explore other options such as reprocessing. A difference with the past is that because of staffing shortages, third-party reprocessing companies came into the market for performing the cleaning and sterilization task.

Energy on the basis of fossil fuel is moving in the same direction. Fossil fuels are becoming increasingly scarce and expensive. One of the strategies for “controlling the energy bills” is energy reduction. So energy issues, waste reduction and reuse of resources can be optional targets for R&D in the medical devices industry. From a business perspective leasing can be considered as a business model that includes sustainability issues such as longer endurance and less material use; furthermore it stabilizes the economics of a company. Of course, attention to barriers to change has to be taken into account. As we observed that the different stakeholders are not meeting in joined networks, the installation of sustainability focus groups can be considered. For optimal functioning of such focus groups the influencing organisations have to start awareness raising processes within their own organization. Waste management, toxic use reduction, energy reduction and resource management are focal points for hospitals and the medical devices industry in this area.

6. The challenge of eco-design of ophthalmic medical devices

We stated that the strong regulation rules and the risk-elimination in safety policy determine a small playing field for changes on the basis of sustainability. Furthermore, that the regulations and cultural interpretations are different per country, even in the European Union. For instance, reuse of materials, also from medical devices, is very common in Germany. In France and the U.K. in contrary, the perception of the “mad cow disease” blocks reuse of medical devices indefinitely. That means that radical changes have to be tested in both different regulatory situations and in a different cultural context. However, radical changes need a critical mass that is sensitive for that. That is why first activities in sustainability issues are usually not of a core-business nature.

We see that at the level of organisations that sustainability sensitivity stimulation can be promoted by information processes related to daily practice. The always returning discussion question at the work floor: “What is better for the environment? To use a single-use or a multi-use cup for your coffee?” has been the basis for many company environmental management programmes.

The type of environmental management programmes in hospitals can be modified into sustainability benefit approaches by reducing resource use and waste activities. Information and education processes are the basis for learning processes in all departments in hospitals. Those activities can be foreseen of data collection of the type of material use, the environmental and energy performance and costs. As further step in the process, equipment and material managers in hospitals can develop sustainability criteria for the purchase department in case of buying new medical devices. As specification, material managers of surgical units can support sustainable preferable purchasing by obtaining supplies from vendors who use environmentally friendly raw materials or products. For instance, Flynn and Knishinsky published in 2005 their findings that reprocessing of ophthalmic medical devices provided 18% savings.

Such sustainability developments have been or are starting in several hospitals (Kwakye et al., 2010). As we see hospitals as primary influencer of sustainability in the medical sector these developments are relevant for all stakeholders and the medical devices industry in particular.

In the contours of developing a sustainability business model, a dialogue network or focus group of stakeholders can be established for awareness raising and providing feedback about sustainability design of either the product or the change process. As the stakeholder awareness is at different levels, the process of information provision, recognition, acknowledgement, education and demonstration projects (Baas, 2005) can be tuned to separate stakeholder needs. For D.O.R.C. as a medical devices supplier R&D on waste and packaging reduction is an incremental option. Design with less or less energy intensive material is a bigger challenge, especially when new materials with a limited sustainability profile are considered. In non-material R&D leasing is an emerging concept in the medical devices industry. Durability and energy consumption are the leading aspects in this R&D process. Furthermore, sensitivity development for sustainability issues can contribute to a challenging company culture, customer and employee loyalty, positive stakeholder perception and lead to an improved brand image. Finally, we see corporate social responsibility as a concern for D.O.R.C. According to McMichael (2009) we often fail to recognize that, over time, the health profile of a population is the real *bottom line* indicator of the prevailing environmental and social conditions: food yields, freshwater supplies, climatic stability, social relations, and the within-population distribution of access to these environmental assets. Besides such fundamental living conditions we also see a question such as: "How to make eye-surgery available and affordable in a feasible way for people in developing countries?" as a societal mission for the ophthalmic medical devices industry.

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