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Full length article

Towards design strategies for circular medical products

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ABSTRACT

The framework of design for the circular economy is increasingly used in industry to improve product sustainability and decrease costs, and in academia various models have been developed to guide circular design. However, in the medical sector, although it generates a large amount of waste, application of circular design principles is difficult because of the clinical challenges of safety and sterility that reuse of products or materials entail. This paper categorizes and analyses existing instances of circular economy in the medical sector, using a literature review and examination of existing industry examples. This is used to identify challenges and unmet opportunities for circular design in the medical sector. The key factors affecting circular medical design are found to be device criticality in terms of sterilization requirements, device value and the organizational support structure around the device. A design heuristic and suggested strategies for circular design of medical products are proposed based on these findings.

1. Introduction

How can products be designed to be inherently good for the future of the planet, as well as good for the users they are made for? This is a question increasingly asked by product designers as more and more is understood about the environmental threats we face. Traditional “design for sustainability” has attempted to minimize the pollution and carbon footprint caused by products. Today, we also recognize the importance of the raw material value that is lost and the environmental damage that is imposed when products are manufactured from extracted materials, used and then disposed of in a single cycle. In response to this, the idea of the “circular economy” has developed. This is an idea which, starting from the 1970s, grew out of various schools of thought within economics, environmental science, engineering and design and has been developed further by academic researchers and industry organizations ever since (Ellen MacArthur Foundation, 2014). One of the core principles of the circular economy is that the value of products and the materials they are made of can be preserved by keeping them in the economic system, either by lengthening the life of the products formed from them, or “looping” them back in the system to be reused (Hollander et al., 2017). In the field of product design specifically, investigation into the circular economy has focused on establishing frameworks and guidelines for how products can be designed to be compatible with circular economy principles (Bocken et al., 2016). In particular, research has been performed on how to differentiate products according to which circular economy strategies would be best suited for them – for example, whether to retain a

product’s material value by lengthening its life or by recycling it (Bakker et al., 2014) based on its typical lifespan, function, energy consumption and perceived value by users. Though growing rapidly, research into circular product design is still in its nascent stages. As a result, little research has been done on the application of circular design principles to specific fields or industries, and how the particular needs of those industries might affect product circular design frameworks.

The purpose of this paper is to form an introduction to be used as a basis for further investigation in circular design applied to one such field: the healthcare industry. This field was chosen for investigation for two reasons: firstly because of the problems of material waste that exist within it, and secondly because of the potential difficulty of introducing circular design strategies to it. Worldwide, the amount of waste created per hospital patient per day ranges from 0.44 kg in Mauritius to 8.4 kg in the US, with EU countries tending to be between those two extremes (UK 3.3 kg, Germany 3.6 kg and France 3.3 kg) (Minoglou et al., 2017). In the US, an additional 50,000 tonnes per year is estimated to be generated from home healthcare (Kaiser et al., 2001). There are several reasons to be concerned about this. The first is that the global healthcare sector is growing rapidly due to emerging markets and ageing populations (Deloitte, 2016). The second is that general medical waste – the kind disposed of from hospitals and clinics – can present a huge health risk through re-infection. The UN estimated that over half the world’s population is at risk from illness caused by healthcare waste (Georgescu, 2011).

Introducing circular economy principles into design for healthcare is challenging. Product designers in this field must already comply with

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existing regulations on product safety. Design of medical products is a high-risk field, where any potential reduction in functionality or increase in risk could endanger patients' health or even lives. And whereas in consumer products 'disposability' is usually seen solely in financial and environmental terms, in the medical industry the introduction of disposable products has greatly reduced infection and thus improved health outcomes.

This paper intends to establish an introduction upon which can be based further studies, as well as practical work by designers and engineers, on incorporating circular economy design principles in the design of medical products. It does so by first defining what is currently meant in design literature by 'circularity' in product design. A literature search is performed to find out what principles of circularity are already in place in the medical sector. This approach is then used to identify the particular challenges of circular design in the medical sector and methods of differentiating different types of medical technology based on their potential for circular design. From this, a set of strategies is developed to help designers and engineers approach the design of a circular medical product.

2. Circular economy framework

There are many different definitions of what constitutes a 'circular economy'. The definition used in this paper is one arising from the field of industrial ecology, which defines a circular economy in terms of material flows (Ayres, 1994; Stahel, 1994; Stahel, 2010; Lifset and Graedel, 2002). In a linear economy, raw materials are extracted, are formed into products, then at some point reach the end of their functional lives in the economic system and are disposed of as 'waste', never to re-enter it. A circular economy aims to eliminate 'waste', by lengthening product life and/or 'looping' the product or its constituent materials back into the system to be reused. The mechanism by which products in the linear economy become 'waste' is 'obsolescence' – defined by den Hollander et al. (2017) as a loss of perceived value of the product which leads to it being discarded from the economic system. This can take the form of, for example, functional obsolescence (i.e. the product no longer performs its intended function), technological obsolescence (i.e. the product is outperformed by newer technology), economic obsolescence (i.e. the product's use is no longer profitable), regulatory obsolescence (i.e. the product is no longer legal) or aesthetic obsolescence (i.e. the product is outmoded or its aesthetic appeal is damaged). According to the principles of a circular economy, obsolescence should not lead to waste. Rather, an action of 'recovery' (Hollander et al., 2017) must be taken to remove the product/materials from their state of obsolescence, restore perceived value, and thus return them to the economic system. Different methods of recovery are defined in the literature. Repair, for instance, involves a reconfiguration or replacement of parts to restore a product from functional obsolescence caused by a specific fault. Products which are obsolete or near obsolescence (e.g. through wear-and-tear) can be retrieved by manufacturers at the end of their lifecycle and put back into service by the replacement of crucial parts, a process known as refurbishing or remanufacturing (Thierry et al., 1995). Recycling is employed when a product can no longer be recovered from obsolescence in its current form, but must be broken down into its constituent materials, which then regain value with a different function.

The methods of recovery can be ranked according to the 'inertia' principle of Walter Stahel, which states "Do not repair what is not broken, do not remanufacture something that can be repaired, do not recycle a product that can be remanufactured. Replace or treat only the smallest possible part in order to maintain the existing economic value of the technical system." (Stahel, 2010, p.195). In other words, value can be maximised and environmental losses minimized if a product is recovered by changing it as little as possible from its original manufactured state. In product design terms, this can be thought of as the maximization of 'product integrity'. The extent to which product

integrity can be maintained depends on both the product itself and the way in which it has become obsolete. The impact of product design on recovery is often described in terms of 'repairability', 'remanufacturability' or 'recyclability' (Prendeville et al., 2015; Mulder, 2012). The type and severity of a product's obsolescence also affects the way in which it is recovered – for instance, aesthetic obsolescence may be reversed by making minor changes to a product's appearance (i.e. repair), technological obsolescence may require refurbishing or upgrade, and severe functional obsolescence might leave recycling as the only option for material recovery. The integrity of a product can also be said to have increased if it becomes obsolete less frequently. For example, making a product more robust could increase its mean-time-to-repair (the time between necessary recovery by repair) or its overall lifespan (the time until which recovery actions of lesser integrity – such as recycling or refurbishing – are required). In both cases, product integrity is maximized over time since fewer of the materials required for recovery are expended overall.

3. Method & scope

Using the above terms, a 'circular' product could be defined as a product that is able to go through repeated cycles of obsolescence and recovery while maintaining the highest level of integrity possible. Therefore, when assessing how 'circularity' can be applied in the medical industry, it is important to understand the ways in which products within it become obsolete, and what methods – if any – are already being used for their recovery from obsolescence. This can be used as a starting point for analysing the constraints of and opportunities for circular recovery of medical products. This paper is therefore structured as a literature search, based on the following questions.

Research Question 1: What examples exist of product/material recovery in the medical industry?

Research Question 2: What are the causes of product obsolescence in the medical industry?

Research Question 3: What strategies can designers use to encourage recovery?

To answer RQ 1 and 2, a literature review was performed in accordance with the procedures described in Hagen-Zanker and Mallett (2013). Since circular economy in the medical sector is not a distinct field with its own terminology, and relates to many different disciplines, a broad number of search terms was defined so as to capture as many instances as possible of 'obsolescence' and 'recovery'. An initial list of search terms was assembled consisting of combinations of the a first group of terms relating to circularity, obsolescence, and recovery and a second group of terms relating to the medical industry (Table 1). An academic literature search was performed to create an initial body of literature. Literature searches were performed using Scopus, Google Scholar and Pubmed databases.

Given the relatively academically unexplored nature of circular economy in the medical sector, non-academic 'grey literature' was also searched. This included journalistic articles, policy documents and the website and brochures of medical equipment manufacturers. Grey literature was initially searched for in Google using the same initial search terms. Using snowballing, new keywords emerged from both academic and grey literature and were subsequently added to the set. The results of the searches were scan-read for evidence of either a cause of obsolescence or an instance of recovery; as defined earlier in this paper. Irrelevant papers were discarded.

It should be noted that articles were not spread broadly over different sub-topics, but tended to exist in "clusters", with high numbers of articles concentrated in specific areas where medical circularity happens to overlap with an existing field. For instance, many articles were found from medical journals on the proliferation and clinical consequences of the reuse of single-use devices (SUDs), since this is an important topic in clinical infection control. However, far fewer articles were found on the effect of SUD design on reuse, since the issue has not

Table 1
Keywords used in literature search.

Initial Keywords	Keywords obtained through snowballing
<i>Obsolescence and recovery</i>	<i>Obsolescence and recovery</i>
'circular economy'	'waste separation'
circularity	reprocessing
Reuse	resterilization
refurbishment	disinfection
equipment-sharing	'Infectious waste'
remanufacturing	'non-infectious waste'
refurbishing	
second-hand	
waste	
disposal	
recycling	
repair	
maintenance	
<i>Medical Industry</i>	<i>Medical Industry</i>
medical	high-criticality
healthcare	low-criticality
clinical	'single-use devices'
technology	biomedical
devices	hospital
products	clinic
equipment	

yet been fully examined from an engineering or design perspective. Similarly, most articles found on the issue of non-infectious hospital waste were written from the perspective of infection control or cost reduction, and thus offered little detail on the specific types of materials being wasted. Thus it was difficult from the existing literature to find a comprehensive overview of circular potential in the medical sector, and it is evident that this field could benefit from more studies taking a specifically circular economy-focused perspective.

To answer the third research question, "What strategies can designers use to encourage recovery?", the types of obsolescence and recovery found in the initial literature search were analyzed. A framework was developed to broadly categorize medical equipment according to its most preferable recovery strategy. Where there was similarity to existing strategies defined in circular economy literature, the relevant literature was quoted, otherwise new strategies were defined based on the information previously gathered.

4. Obsolescence and recovery of medical products

The findings of the literature review were grouped using the forms of recovery previously defined in this paper as a framework: repair, recycling and remanufacturing. 'Reprocessing', a form of recovery found during the literature search, was addressed as a separate type of recovery. Recovery was used as the primary organizing framework since recovery methods most directly affect the design requirements of products. The various forms of obsolescence associated with each recovery method are addressed within this framework.

4.1. Refurbishment and remanufacturing

Refurbishing or remanufacturing refers to a process by which products – often high-complexity, long-life devices – are retrieved by manufacturers when at the end of or close to the end of their lifetime and put back into service (Thierry et al., 1995). Products which are refurbished or remanufactured are often by nature reusable and repairable, but still have a finite overall lifetime after which certain parts must be replaced or features upgraded. The difference between refurbishment and remanufacturing is that a remanufactured product must be brought up to the same or greater quality than an original product (Ijomah and Childe, A model of the operations concerned in remanufacture, 2007), whereas a refurbished product may have a

quality standard which is lower (e.g. a shorter warranty) than the original.

A review of literature and grey literature found that the practice of refurbishing and remanufacturing is relatively widespread in the medical industry. In 2015 it was estimated that the global market for refurbished medical devices was worth \$9.37 billion (compared to an overall global medical device market of \$381 billion the same year, approximately 2.5%), with the US and Europe as leading producers and consumers, with emerging "BRIC" markets increasingly purchasing refurbished equipment (Markets and Markets, 2015; Kalorama Information, 2016). Three of the largest manufacturers of medical equipment (Siemens, Philips and GE) have implemented take-back schemes for their medical equipment, built dedicated refurbishment facilities, and sell their refurbished equipment with full warranty under distinct brand names (Philips, 2014; GE Healthcare, 2012; Siemens, 2016). In the US in particular third-party refurbishers are very common. Medical device refurbishment is a mature and well-regulated practice in most of the world, and international guidelines exist on quality standards for refurbished medical equipment, which outline strategies for identifying suitable equipment for refurbishing, the refurbishment itself, and post-refurbishment testing and documentation (COCIR, 2009).

The types of equipment which are most commonly refurbished or remanufactured are high-complexity, high-cost equipment such as medical imaging equipment (X-rays, MRI machines), patient monitors and anesthesia machines, and "furnitures" such as tables, gurneys and surgery lights (Dremed, 2015). There are some cases noted where small, medium-complexity equipment is refurbished (by for example, replacing staples or sharpening blades), though these tend to be performed as part of a hygienic recovery process (detailed in a subsequent section of this paper) (SterilMed, 2014; Kruger, 2008).

There is no clear overview in the literature of what types of obsolescence cause equipment to be remanufactured. However, the presence of trade-in schemes in the refurbishment programs of manufacturers, in which an old machine is given back to offset the price of a new one, suggests that technological obsolescence is common (GE Healthcare, 2012; Philips, 2014; Siemens, 2016).

The driving reason for the refurbishment/remanufacture of medical equipment is reduced cost for the end-user. This form of circularity in the medical device sector has been a successful product strategy for several decades due largely to the high value of equipment, which results in both consumer demand for lower prices and a relatively small refurbishment cost in comparison with the overall cost of the product (Griese et al., 2004). Refurbished and remanufactured equipment can be sold for 60–70% of the original price (Agito Medical, 2015; Boorsma, 2016).

Keeping the refurbishment cost-effective is not without its challenges. Even companies experienced in remanufacturing and refurbishing face challenges in balancing the cost effectiveness of new equipment manufacturing with refurbishing/remanufacturing, since the design requirements for each are sometimes in conflict. For instance, making an outer product covering with an irreversible snap-fit design decreases time and costs on the new product assembly line, but greatly increases costs when that product is later refurbished (Boorsma, 2016). Another challenge to refurbished medical equipment which may decrease the rate of potential recovery regards the supply chain. New equipment is manufactured at a certain quantity in response to market demands; however refurbished equipment vendors are also dependent on the number of machines coming out of commission for their supply. Vendors therefore need to employ some unique strategies such as "bundling" selections of different refurbished products together and selling to hospitals as a package in order to keep inventory low (Ross and Jayaraman, 2009).

4.2. Repair and maintenance

Repair and maintenance refers to activities which are intended to either recover a product from temporary functional obsolescence (e.g. a breakdown or performance error) or to prevent that temporary functional obsolescence from happening. Since more repair tends to be performed on longer-lived devices, the types of devices mentioned in the prior refurbishment/remanufacturing section are likely to undergo repair at many points in their lives.

In most of the world, medical equipment maintenance is performed by specialised biomedical engineers who are trained in not only the practice of repairing the equipment but also in the risks surrounding it (Enderle, 2012). In low-income countries, a shortage of these trained biomedical engineers has been noted (Mullaly, 2003) and linked to the high portion of medical equipment (up to 40%) estimated not to be functioning in these regions (Perry and Malkin, 2011). The comparable figure for high-income countries is less than 1% (Imperial College/Lancet Commission, 2012).

In Europe, North America and increasingly in South America and Asia, service contracts in which the original equipment manufacturers or a third party perform all repair and maintenance, rather than in-house biomedical technicians, are becoming more common, representing a USD 1,034.2 Million industry in 2015 (Markets and Markets, 2016).

In some cases, repair and maintenance of devices is prohibited for customers or third-party manufacturers, due to both highly competitive levels of IP protection and the reliance of manufacturers on revenue from their own service contracts (Wang, 2016).

Since medicine is a high-risk field, repair (i.e. responding to restore the machine after it loses function) is highly costly and potentially dangerous. Maintenance, in which parts are changed and systems cleaned and checked at regular intervals, is preferred. It does, however, run the risk of replacing parts more often than necessary (Jamshidi et al., 2014). Borrowing from similar methods in aviation, statistical methods have been developed which use data to predict the optimal time interval for maintenance activities (Taghipour et al., 2011). In recent years, with the arrival of ‘big data’, this has been further improved in high-value, complex systems (such as MRI/CT scanners) by using networked sensors to predict exactly when a part will fail, allowing it to be repaired precisely before it breaks (Philips, 2013).

4.3. Recycling

Recycling consists of recovery by breaking down the product to the material level and reconstituting it into a useful form. A product's suitability for this type of recovery is dependent largely on its constituent materials – some are more conducive to effective breakdown and reformation than others. Up to 20–25% of medical waste is estimated to be composed of recyclable plastics (Byeong Kyu et al., 2002).

However, a major barrier to recycling of this plastic is the presence of infectious waste. Most countries have strict regulations on medical waste disposal, which demand that waste potentially contaminated with biological materials must be disposed of in a way that destroys the biohazard (UK Government Department for Environment, Food and Rural Affairs, 2013; US Environmental Protection Agency, 2016). In circular economy terms this can be thought of as a specific form of functional obsolescence, “hygienic obsolescence”, where a product is rendered obsolete by no longer meeting the hygienic standards required for its recovery.

Technologies have been developed which can sterilize infectious waste by grinding the material to small pieces and treating it with high temperature steam, microwaves, or chemical treatment. This process which could potentially allow the remaining materials to be separated and recycled (Chartier, 2014). However, it is expensive and often cannot be performed on-site, meaning infectious waste would risk being leaked during transport. The cheapest and thus most commonly used

method is incineration (World Health Organization, 2005). Since a considerable part of medical plastics are made from PVC – which can be toxic when burnt – this is a potentially hazardous method (Byeong Kyu et al., 2002), which also results in the irrecoverable loss of the material.

Though the cost barriers to recycling infectious waste are difficult to surmount, there is also evidence that existing potential for recycling is being lost because material that is not actually “biohazard” waste is being unnecessarily included in the infectious waste stream (Byeong Kyu et al., 2002; Hutchins and White, 2009; Stall et al., 2013). Waste management experts state that infectious waste makes up typically no more than 10–25% of hospital waste, but in many hospitals a far greater percentage is treated as such (Cheng et al., 2009; White, 2009; Mühlich et al., 2003). Often all waste from surgical operating rooms is treated as infectious, though it contains non-infectious waste items such as packaging and “overage”, meaning disposable items such as bandages or syringes which are taken out for the surgery and then not used (Lee and Mears, 2012; Rosenblatt et al., 1997). This is attributed to a “safety-first” culture in medical environments, where items are disposed of as infectious waste as default. This form of obsolescence can be thought of as a ‘societal’ or ‘emotional’ obsolescence. The products have not in themselves become irreversibly obsolete, but they are erroneously perceived as dangerous and so wasted even though they have the potential to be recovered.

There is some evidence to suggest that this “safety-first” attitude has also made its way into hospital purchasing practices, where typically reusable products such as surgical drapes and gowns are being replaced by disposable ones (Smithers Apex, 2014), though a literature review found that the use of reusable items which pose a low hygienic risk offers far greater environmental benefits and is comparable in terms of comfort and safety (Overcash, 2012). A US study of a Maryland hospital found that 65% of operating room waste could be avoided by replacing disposable items such as gowns and basins with reusable ones, which were also preferred by OR staff (Conrardy et al., 2010). Unnecessary waste is also caused by the increased purchase of “custom packs”, sterile bundles of all the materials required for a particular medical procedure. This is designed to save time, but often results in the unnecessary disposal of items which are not actually used in the procedure (Campion et al., 2015).

There is evidence of some success in increasing recycling of non-infectious waste by encouraging behavioural change in the way that products are disposed of. Opole General Hospital in Poland implemented a program of color-coded bins and trained its staff to use them to separate infectious from non-infectious waste more accurately, resulting in a 50% reduction in waste and 79% reduction in waste disposal costs (Gluszynski, 2005). Non-infectious waste was then recovered by recycling through existing waste streams. Similar programs in NHS Cornwall and Spain reduced non-recyclable waste by 15.7% and 6.2% respectively (Tudora et al., 2008; Mosquera, 2014).

4.4. Sterilization/“reprocessing”

A category of medical device recovery was found in the literature research which did not fit into the existing categories of product recovery. ‘Hygienic obsolescence’ was defined in the previous section as obsolescence caused when a product becomes unhygienic after clinical use. Any artefact used in a medical setting has the potential to spread pathogens to a patient from the environment or other patients if biological material is not sufficiently removed from it before disposal or between uses. Thus a medical product is effectively rendered ‘obsolete’ after each use on a single patient, and can only be recovered when sterilization or disinfection processes are applied to render it hygienic once again (Malchesky et al., 1995).

The type of sterilization or disinfection required to render a product hygienic depends on its clinical function, determined using the “Spaulding Scale”. This guideline categorises products according to ‘hygiene criticality’, which describes how important it is for biological

material to be removed from a product after its use on a patient. “Critical items” are those which enter tissue or the vascular system (e.g. a surgical instrument), and must be sterilized (all organic material removed) by high-pressure steam or, if the devices are heat-sensitive, a gas plasma. “Semi-critical items” contact a mucus membrane (e.g. an endoscope), and require high-level chemical disinfection (for example, full immersion in hydrogen peroxide). “Non-critical items” which do not enter the body (e.g. a blood-pressure cuff) may be lightly disinfected with alcohol (Rutala and Weber, 2008).

Whether a device is recovered from hygienic obsolescence or discarded depends partly on how well it is able to survive the process of sterilization or disinfection. A plastic syringe, for instance, would be unlikely to retain its integrity after high-pressure steam treatment, whereas a surgical scalpel would likely remain undamaged. Between these two extremes, however, there are devices whose potential for hygienic recovery is less easily discernable. In these cases, whether to label a device as ‘reusable’ or ‘single use’ is down to the decision of the manufacturer (Rutala and Weber, 2008).

Indeed, by far the largest category of articles found in the literature search on reuse of medical devices were those related to the recovery through sterilization of devices labelled ‘single-use’ by their manufacturers, a process referred to as ‘reprocessing’. In the US 45% of 250+ bed hospitals reuse at least some single-use devices (SUDs) (Kerber, 2005), and in Japan a 2003 survey found that 80–90% of surgeries reuse SUDs (Koh and Kawahara, 2005). Some hospitals use third party reprocessing firms to sterilize, refurbish and repack these devices – an industry which is estimated to be worth \$125million in the US alone (Kerber, 2005). In Australia, a survey found that 15% of hospitals (and up to 50% of 300+ bed hospitals) reused SUDs in-house (Collignon et al., 2003).

The bulk of SUDs which are routinely recovered are medium-complexity, high- or medium-criticality devices such as catheters, endoscopes and surgical staplers (Rutala and Weber, 2008). The labelling of these sorts of devices as ‘single use’ became widespread in the 1970s, after advances in materials science meant that more complex medical devices could be made using lower-cost plastics. The rise in minimally invasive surgery also resulted in a proliferation of these complex, high-criticality devices. Prior to this, most medical devices were designed to be sterilized and reused (Rutala and Weber, 2008). Under FDA regulation, which many countries other than the US use as a guideline, single-use devices are certified as sterile before packaging, and considered non-sterile as soon as that package is broken (US Food & Drug Administration, 2016) – see the example of a single-use surgical stapler in Fig. 1.

All aforementioned studies on reprocessing cited cost-savings as the primary motivation for the reuse of devices (Kerber, 2005; Koh and Kawahara, 2005; Collignon et al., 1996). Reuse does also benefit the environment; in the US, medical reprocessing companies save 4.6 million devices, approximately 935 tons of medical waste, annually from landfill or incineration (Klein, 2005).

There are, however, risks posed by recovering devices which are not intended to be recovered. Few clinical studies have been carried out on

the safety of reprocessed devices, and those that have been carried out sometimes find risk (Ishino et al., 2005) and sometimes do not (Colak et al., 2004). There have however been several high-profile emergencies blamed on reprocessed equipment, such as a 2015 “superbug” outbreak in two US hospitals due to contaminated reprocessed endoscopes, which killed two people (Drues, 2015) and a fatality in 1999 in which a one-use catheter which had been used six times broke, killing a patient (Neergaard, 1999). This has resulted in a lack of trust in reprocessed equipment in the public and among medical professionals, and calls for updated regulations on reprocessing (Drues, 2015).

Experimental studies undertaken into the reesterilization of SUDs found two main areas of risk – mechanical or chemical damage to the product through repeated sterilization, and inadequate sterilization. A study of sterilized catheters found that the electrical and mechanical properties of the catheters degraded after each cycle of sterilization, with the electrode tip beginning to dislodge after approximately 5 cycles due to thermal fatiguing of adhesive (Avitall et al., 1993). Similar studies found mechanical damage in reprocessed arthroscopic shaver blades (Kobayashi et al., 2009) and manual ventilation valves (Hartung et al., 2013). Numerous studies have discovered significant degradation to polymers during sterilization. This includes degradation by non-thermal chemical sterilization on nylon, polyethylene, and latex (Brown et al., 2002), steam sterilization on PCs, electron beam sterilization on PLA, gamma-ray sterilization on PTFE (Modjarrad and Ebnesajjad, 2014) and plasma-based sterilization on PVC (Lerouge et al., 2002).

The success of sterilization from a clinical safety perspective depends on removing all biological material from the device (Alfa, 2013). An investigation into design aspects affecting sterilization found that SUDs which contain moving parts, sharp edges or pockets make this process more risky (Collignon et al., 1996), and guidelines on cleaning effectiveness state the importance of being able to dismantle the device and remove biological material from crevices and joints (Dunn, 2002). Commonly reused SUDs are instruments used in minimally invasive surgery, which often require complex mechanisms to transmit action through small openings in the body, and are coated with insulating or low-friction material. All of these features make these devices difficult to sterilize (Malchesky et al., 1995). This is a potential reason why endoscopes – which contain complex inner structures and specialized polymers and coatings which are unsuitable for many forms of sterilization – are the largest contributor to infections caused by SUD reuse (Rutala and Weber, 2016; Barnden, 2016).

Despite the widespread practice and apparent risks of SUD recovery, regulation and policy on reprocessed single-use devices are scarce. Germany and the US are the only countries globally which have binding regulation on reprocessing – EU regulation is in progress (Hamberger, 2015). These US and German regulations only require that the reprocessed devices meet the same sterile standard as a new device, and that reproducers take on the same responsibility as an original equipment manufacturer (OEM). They do not require companies to track or display the number of times a device has been used. Given the evidence of fatigue degradation cited previously, this means devices are at risk of being continually reesterilized until a point of failure.

This policy stance suggests that though in practice recovery of SUDs is indeed widespread, there is no legal motivation for an OEM to design a device for easier sterilization, unless they want to incur the extra costs required to label it ‘reusable’, which include performing their own in-house sterilization validation, detailed sterilization instructions and taking on responsibility for the success of sterilization (US Center for Devices and Radiological Health, 2015). Indeed, since most reprocessing is performed by third-parties and in theory reduces sales of new equipment, it may be in the business interests of most OEMs to discourage devices from being reused. Information exists showing that recovery is sometimes actively discouraged through design, with several patents in existence for SUDs that “self-destruct” after a single use (Moduga, 2010; Burnside, 2003; OuYang et al., 2011; Ross and Zemlok, 2011).



Fig. 1. Sterile packaged single-use surgical stapler.

There is evidence, however, for at least one product that breaks this pattern. Instead of a product certified as disposable (one use) or reusable (infinite uses), German manufacturer Pioneer Medical Devices AG have created a surgical shaver (MasterCut I.S.S) which is the first product to be CE-certified for a fixed number of cycles (ten). Whereas most surgical devices are designed as one-use or for infinite uses, Pioneer's surgical shaver consists of a non-critical control unit and a critical shaver head. This shaver head is sold by Pioneer on a pay-per-use model – they take it back after each use, reprocess it, and then resell it to the customer when needed (Pioneer Medical Devices AG, 2014, 2011).

5. Main factors determining opportunities for recovery

The body of literature was examined to determine what factors are most influential to the required recovery strategy for a piece of medical equipment. These factors will be analysed in this section. In the subsequent section strategies for circular product design will be related to specific combinations of these factors.

A clearly influential factor in all the cases of recovery identified in the literature was the financial considerations of recovery. That is, whether it is more financially viable to recover the product or to discard and replace it. This trade-off is recognised in existing literature of the circular economy strategy (Cong et al., 2017), however, Sloane (2007) points out that in the medical world a cost-benefit analysis of recovery must also take into account the costs potentially inherent in the clinical risks of device reuse. In the case of refurbishment or remanufacture of high-value, high-complexity devices, this balance already seems to tip in favour of recovery, considering the large and growing refurbishment/remanufacturing industry. Both customer and manufacturer stand to benefit from the refurbishment, resulting in its widespread practice today. The literature on the reesterilization of SUDs shows a case in which design and policy are not aligned with the reality of this cost-benefit balance. Though these devices are by and large not designed to be reused, and policy does not require them to be so, their high cost of production compared to cost of recovery leads many hospitals to regard recovery as the most financially viable option. The cost-benefit model created by Sloane (2007) suggests that there are some items which will always remain disposable, since the cost of their recovery will always be greater than the cost of the device itself. For these products, recovery at the level of material (recycling) may be the only viable option, and thus should be the strategy which designers should optimise for.

A second factor seen to widely affect the recovery of medical devices is their hygienic criticality, as defined by the Spaulding Scale. High-criticality devices must be hygienically recovered using more aggressive means than low-or -medium criticality devices, and thus in order to be recovered must be designed using materials and forms which can withstand this sterilization and allow it to proceed effectively. There are many links between criticality and product value – a general rule of thumb (though by no means universally applicable) is that more expensive materials (metals, silicone polymers) more easily withstand high-criticality sterilization than cheaper ones (e.g. polyethylene, nylon) (Brown et al., 2002; Gautriaud et al., 2010). A product's place on the Spaulding scale also directly affects the cost-benefit analysis of recovery, since more aggressive sterilization methods are also more expensive (Rutala and Weber, 2008). Lower-cost products for which recycling is a likely recovery options are also affected by criticality. High criticality low-cost products (i.e. 'infectious waste') must be rendered sterile before being transported and recycled, a requirement which severely limits their rates of recovery and could be improved by better methods of on-site recycling. Low-criticality, low-value products can also erroneously meet the same fate as infectious waste due to a culture of disposal caused by safety concerns around high-criticality products.

Another factor affecting the recovery of medical devices is the device's location, or more broadly the infrastructure and support structure which surrounds it. As identified in the literature on repair, a device

which is repairable in the context of service support may be far less so without it. Devices in larger hospitals may have greater access to facilities for hygienic recovery or sterile recycling than those in small clinics. Additionally, the growing prevalence of home healthcare distributes medical products outside from hospitals and thus potentially away from a centralized reverse supply-chain.

The factor of location and support structures was considered important and a crucial area to investigate further. However, due to relevance to systems and policy as opposed to products, it was considered outside the scope of this paper, which is primarily targeted at product designers.

Therefore it was decided to base the analysis of recovery strategy in this paper around the two other factors identified from this analysis – criticality and product value. A product's value is a likely determinant of whether it will be refurbished/remanufactured or recycled, and its criticality determines the design constraints it needs to meet in order to be hygienically recovered during its lifetime. By mapping different types of medical product along the axes of product value and criticality, one can make a judgement about what types of recovery are most suitable for a particular product, and thus what tactics designers should take in order to optimize its recoverability. The diagram below shows various types of medical equipment mapped along these axes.

The next section discusses the design examples and strategies that are most useful for particular combinations of criticality and product value. A variety of medical products has been ranked according to these categories in Fig. 2.

6. Design strategies for recovery

From Fig. 2 four categories of medical devices emerge, based on their criticality as described in the Spaulding Scale, and their product value. Each has distinct design challenges and opportunities for circularity. Important design aspects of the categories will be illustrated with examples and suitable design strategies will be discussed.

6.1. Medium-to-high value, high-criticality devices

This category refers to products whose cost-benefit analysis points towards more product-integral forms of recovery, because of the high

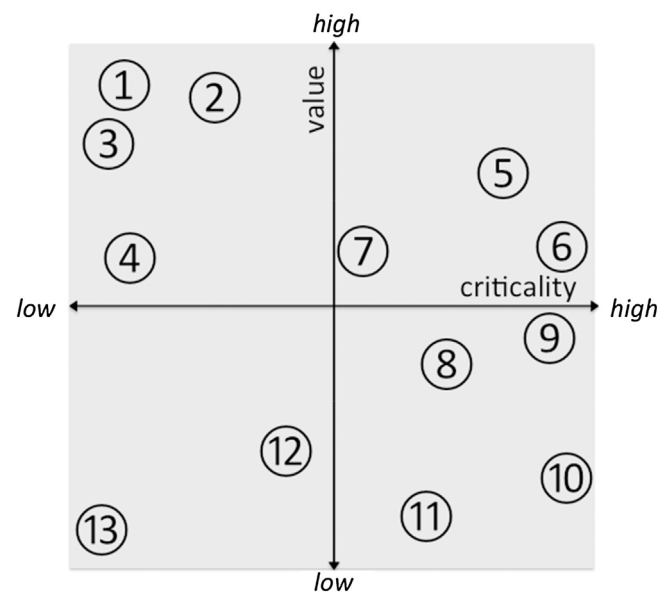


Fig. 2. Design framework for circular medical products; 1: imaging equipment, 2: anesthesia machines, 3: patient monitors, 4: furnitures, 5: surgical shaver, 6: surgical stapler, 7: hearing aids, 8: catheter, 9: endoscope, 10: syringe, 11: bandages, 12: single use compression sleeves, 13: packaging materials.

value of the device, but for which recovery remains a challenge because of the high criticality of the device's use.

Though the Spaulding scale states what is required for the recovery of a medical device based on its use case, there are no comparable guidelines on whether a particular device is designed suitably for a certain type of recovery. This is important in the case of critical devices, because both sterilization and high-grade disinfection processes have the potential either to be unsuccessful (endangering the patient) or to damage the device itself. The latter case is a particular danger for mechanically complex devices or those made from polymers.

One design strategy for such devices is to optimise them as much as possible for hygienic recovery to be performed effectively and safely, making use of existing literature on the subject.

Silicone elastomers, for example, were minimally affected by chemical sterilization (Gautriaud et al., 2010). Other studies and guidelines suggest that the inclusion of smooth surfaces and the minimization of corners, sharp edges and moving parts greatly increases the safe sterilizability of a device (Collignon et al., 1996; Dunn, 2002).

There is a danger, however, that optimising a device for repeated sterilization may make it prohibitively expensive for customers. Thus a complimentary strategy is to design a device for neither a single use nor an infinite number of cycles, but for a fixed, pre-determined number of cycles, as shown in the example from Pioneer Medical. In this design strategy, instead of trying to avoid damage entirely by choosing the most resistant materials, devices could be lowered in cost by choosing materials which can last a known number of cycles before losing a certain quality standard. The manufacturer can then specify that the number of device reuses be tracked and decommissioned well before the designed 'cycle lifetime' of the product. This may also require the design of a service system around the device which allows retrieval by the manufacturers after each use, re-delivery to the customer, and adequate labelling and documentation to insure sterilization is being performed correctly and within the certified number of cycles.

Another tactic exemplified in the Pioneer Medical surgical shaver is the development of a hybrid device. Many products are not wholly "critical" or "non-critical", but a hybrid of some parts which enter a patients' body and others which do not. If these pieces are designed to be detachable, they can be hygienically recovered using different methods. Not only this, but the 'fixed cycles' strategy described previously could be applied differently to components of a device depending on the fatigue damage resistance of each, thus minimizing the materials replaced.

A key point noted in several of the sources on equipment reuse is that the issue of trust was a potential barrier in the reuse of medical devices. Doctors and patients resisted reused SUDs even when statistical evidence proved they were not dangerous (Drues, 2015). This attitude may be improved by the aforementioned design strategy of making products certified for a fixed number of cycles. However, trust may still prove to be a barrier. Users may want to be assured that the sterilization of a fixed-cycle product has been performed correctly, or that the product is indeed well within its designed number of cycles.

This could be insured by embedding cues in the device that would assure medics and patients that even though a device is reused it is still safe. One suggested – though by no means the only – tactic for building trust in reprocessed devices is lifespan labelling, i.e. to embed markers in the devices to convey explicitly to the medic the number of cycles it has left in its lifetime. Another strategy in design for trust is to design warnings into products to alert the user to possible faults. This could consist, for instance, of a material which changes colour when overstressed, a colour-change mark similar to autoclave tape which shows whether a certain temperature or chemical process has been carried out. More design research needs to be conducted into what factors make doctors, patients or hospital managers trust a piece of reprocessed or refurbished equipment

6.2. High value, non-critical products

This grouping refers to high-value products which can be reused without the necessity for hygienic recovery through aggressive sterilization. Since these products are generally complex, long-life pieces of equipment, such as imaging equipment or large surgical equipment, well-established principles for the design of long-life equipment and its refurbishment and maintenance can be followed (Ijomah et al., 2007; Mulder, 2012) along with the additional rules and regulations for refurbished medical devices (COCIR, 2009). This means that products should be designed to facilitate the remanufacturing process, including component durability, disassembly and reassembly, accessibility, cleaning, reverse logistics and marketing (Shu and Flowers, 1999; Nasr and Thurston, 2006). Hatcher et al. (2014) compiled an overview of design concepts that are useful in design for remanufacturing: modularization, platform design, active disassembly, failure mode analysis and quality function deployment (QFD). Design for refurbishment involves decisions related to standardization of parts, and selection of durable materials and reversible fasteners.

6.3. Low-value, high-criticality products

These products are perhaps the most difficult subset for which to develop a circular design strategy, since they combine a high cost of recovery with a low cost of disposal and replacement. Design innovations for this grouping of products may be best targeted not at the products themselves but at the equipment and infrastructure required for their recovery.

A more ambitious strategy for the designer is to design out of existence a low-value, high-criticality product by replacing its function with other products. An example of this is the jet-injector, a reusable vaccination tool designed to replace disposable hypodermic syringes. However, concerns have been raised about the jet injector's safety (Kelly et al., 2008; International Organization of Standardization, 2006). As with all high-criticality devices, extreme care must be taken when following this design strategy to ensure that patient safety is paramount.

6.4. Low-value, low-criticality products

These are products for which recycling is the most viable recovery option, and which is not hampered by the need for infectious waste control. However, as discussed in the previous analysis, the greatest barrier to the recovery of low-value, low-criticality products is that they are not effectively separated from high-criticality waste. Thus there are opportunities for designers to design affordances or prompts into products that guide users to dispose of them correctly. Standard recycling bins guide disposal by shaped openings that encourage users to put a particular type of waste in a particular bin – an approach that has been proven to increase recycling by 34% (Duffy and Verges, 2009). There are also more unusual approaches, like design group The Fun Theory's World's Deepest Bin, which encourages users to throw away trash using fun audio feedback (The Fun Theory, 2009). Waste management could also be encouraged by looking at medical user's workflows and the way they use physical space to position waste disposal in the right place. The Royal College of Art used this method for the design of a cardiac trolley, which positioned equipment to make it easiest to reach at the appropriate point of treatment: an equivalent design could be made which positions disposal points in the same way (Coleman et al., 2009).

Assuming recycling of these products is achieved, guidelines exist for designers on how to optimize recycling of non-critical medical waste, advising uniformity of plastic types, easy cleaning of residual fluid, minimization of paper labels and water-soluble adhesives (Healthcare Plastics Recycling Council, 2016).

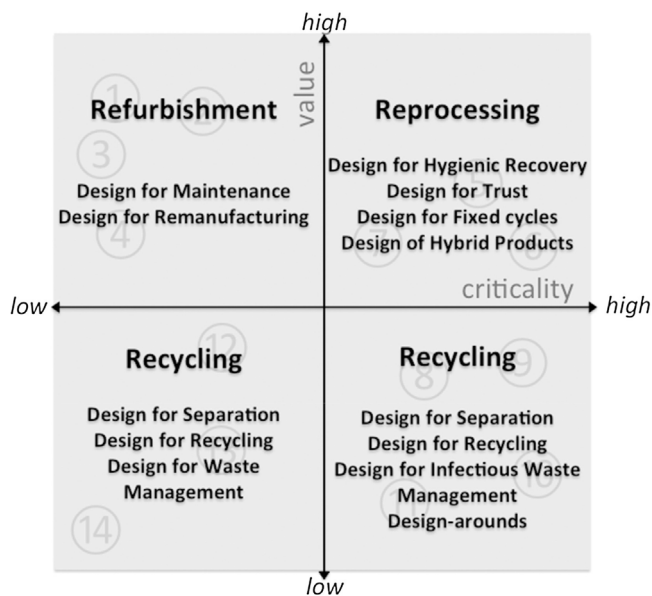


Fig. 3. Design strategies for recovery of circular medical products in relation to product criticality and product value.

6.5. Summarizing

The design strategies identified in this paper for recovery of medical products in relation to product criticality and value are depicted in Fig. 3. The third identified factor, the local support structure, does not directly affect the design guidelines for products as such, but opens opportunities towards product service design (Bocken et al., 2016), as does the increase of remanufacturing and fixed-cycle equipment. With an accompanying shift in responsibility for maintenance and recovery to the manufacturer, incentives to maximize the product integrity following Stahel's Inertia Principle (Stahel, 2010, p.195) become much stronger.

7. Conclusions

Review of current circular economy practices in the medical sector showed that some circulation of products and materials does already exist in the sector, in various different forms and levels of maturity. Refurbishment of complex equipment is already performed in practice to some extent, with well-documented design guidelines. By contrast, hygienic recovery of high-criticality, medium-to-high-value devices, though a widespread practice, is often performed poorly and is usually unaccounted for in equipment design, with many of these devices being sold unnecessarily as 'single-use'. Separation of recyclable waste and circularity of home healthcare devices are new fields which are still being explored. The unexplored opportunities observed in this sector show the need for design strategies in order to expand circularity of medical equipment. Recovery opportunities in the medical sector have been shown to primarily depend on hygienic criticality, product value and the environmental support structure, which affect infection control requirements on the one hand and resources for repair, refurbishment and recycling on the other.

This led to the following design strategies: in the case of high-value, high-criticality devices design for hygienic recovery, design for fixed cycles, design for trust, and design of hybrid products. For low-value, low-criticality items, design for separation, design for waste management and design for recycling, and for high-value, high-criticality items, design for infectious waste management, or 'design-arounds' which design out the need for such a product. High-value, low-criticality devices were identified as being aligned with existing circular strategies for complex long-lived equipment.

The design directions outlined are derived from the challenges discovered, and are intended to be used as inspiration and guidance for designers looking to make healthcare more sustainable. Thus they are chosen to include a wide range of products and situations. Designers or engineers using this framework can either start from one of these strategies, or begin a project by going back to the design framework and seeing which strategy is most relevant based on the product's value and sterilization requirements. This paper intends to provide a starting point for defining a heuristic framework for circular medical products – however, there is undoubtedly much more to be learned as the field progresses and more projects are completed with this focus.

It is therefore expected that future design research will add case studies, find new design directions and modify the strategies as they develop the field. Areas for further research identified in this paper include the further investigation of product materials and forms which are suitable for repeated sterilization, factors contributing to user trust in reused equipment, and the most effective ways of encouraging waste-segregation in medical contexts.

Relevance to design practice

Design strategies are provided for a relatively unexplored area of product design (circular medical products). These can be directly used by designers or for development of more comprehensive frameworks.

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