MEDTECH SPOTLIGHT REPORT: accelerating circular economy adoption

February 2024

Peter Hopkinson, Georgie Hopkins,
Fiona Charnley, Tom Dawson, Markus Zils,
Ananda Nidhi, Morin Akeredolu-Ale

CE-HUB
UKRI National Interdisciplinary Circular Economy Research

NICER PROGRAMME

CEctor
Accelerating CE Impact

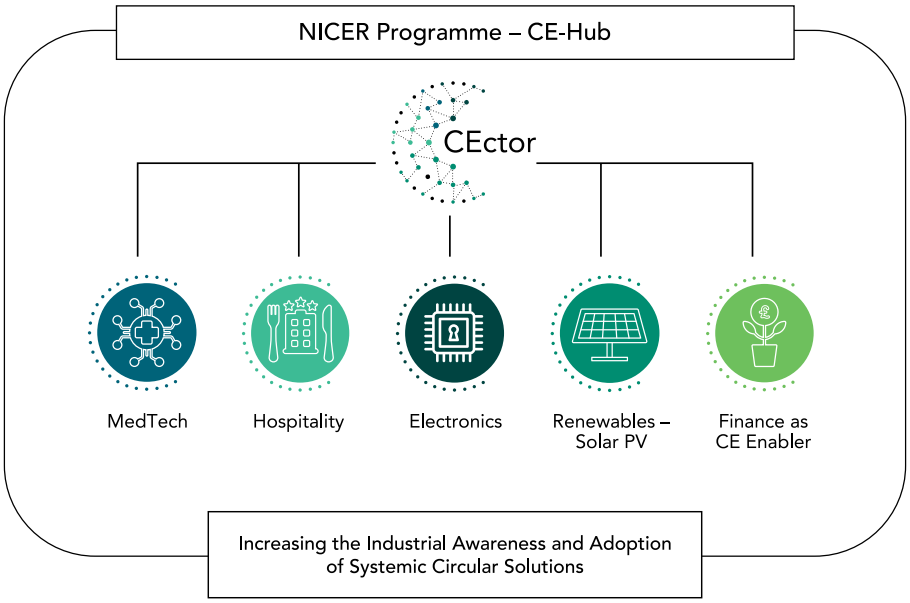
University of Exeter

UK Research and Innovation

Contents

Purpose of the report

As part of the National Interdisciplinary Circular Economy Research programme (NICER), the CEctor project is a dedicated workstream within the CE Hub. The project has the scope to identify and explore five different UK industrial sectors, where significant opportunity exists to accelerate Circular Economy (CE) adoption. The five sectors are: 1. MedTech 2. Hospitality 3. Electronics 4. Renewables-Solar PV and 5. Finance as enabler of the CE. The purpose of the project is to engage with stakeholders across each of the five sectors, building CE knowledge and understanding, and working collaboratively to identify key enabling mechanisms, then prioritising actions to deliver outcomes and impact, including research and innovation funding and scaling requirements. The ultimate goal is to assist in accelerating industrial awareness and the adoption of CE systemic circular solutions, including value creation opportunities. As an output of the CEctor project, this Spotlight Report draws together academic research and insight from a broad range of stakeholders, providing an evidence base for CE adoption within the Medical Technology (MedTech) sector.



Authors & Acknowledgements

Authors: Prof Peter Hopkinson, Georgie Hopkins MBA, Prof Fiona Charnley, Dr Tom Dawson, Prof Markus Zils, Ananda Nidhi MBA, Morin Akeredolu-Ale

Acknowledgements: The authors would like to express thanks to the Department for Health and Social Care (DHSC) and the Design for Life (DfL) Collaborative for their engagement and input into this report and are pleased to remain as academic partner of the DfL Collaborative. See Appendices A, B and C for an overview of the DfL Collaborative programme, details of engaged organisations who have input into the research of this report and an outline of the co-delivered workshops. Thanks also to NHS England and Vanguard for their support on the illustrative case example, and also Stefán F. Einarsson, University of Exeter, for case study analytics.

Methodology

This report is an output of the work undertaken by the CE Hub CEctor project team from March to December 2023. The research included:

- Comprehensive academic and grey literature review.
- Engagement with stakeholders from across the MedTech value chain, through DfL Working Groups, including the design and delivery of three workshops from June to September 2023. The outputs included initial recommendations from each Working Group which have been synthesised into the wider findings of this report.
- Selected stakeholder interviews for development of specific case examples.
- Deep dive use case modelling, through data collection and analysis by the CE Hub Data Observatory team, applying a value chain, data led modelling architecture.

This report can be referenced as follows: Hopkinson, P., Hopkins, G., Charnley, F., Dawson, T., Zils, M., Nidhi, A., & Akeredolu-Ale, M. (2024). MedTech Spotlight Report: Accelerating circular economy adoption.

Executive Summary

The MedTech sector, a cornerstone in the provision of health and social care to the UK population, has an annual turnover of £27.6 billion and a diverse array of 500,000 medical products. However, this innovative sector supports a health system in the UK facing a myriad of challenges, including global supply chain volatility, material scarcity, decarbonisation imperatives, tightening healthcare budgets, growing patient demands, healthcare disparities, and escalating waste production. The compounding effect of these challenges, coupled with the looming threat of climate change, necessitates a departure from the unsustainable 'business-as-usual' approach.

In response, this report advocates for a paradigm shift to a circular economy, rejecting the linear 'take-make-waste' model. The circular economy, rooted in principles of designing out waste, material circulation and cascades at highest value, and natural capital regeneration, presents a transformative opportunity for the MedTech sector. Beyond merely recycling, embracing circular approaches positions the sector for innovative solutions that address systemic health system challenges, offering benefits such as enhanced material security, resilient supply chains, job creation, reduced operational costs, and positive environmental and social impacts.

The report highlights some of the successful examples of circular activities within the UK MedTech sector impacting the inflow, use and outflow phases of product life cycles and their applications. It showcases proof of concept to proof of value, with positive business cases for both the supplier and the health service provider. Two more detailed cases illustrate the multi-million financial and carbon benefits of medical textile reuse and the remanufacture of harmonic shears, operating successfully at scale within the current regulatory and legislative landscape. Motivated clinicians, start-ups, and innovative suppliers have pioneered circular business models within existing regulatory frameworks. However, transitioning to a systemic circular economy demands collaborative efforts to overcome barriers related to clinical considerations, data gaps, economic obstacles, cultural shifts, regulatory frameworks, and technological advancements. Stakeholders, including healthcare providers, regulators, industry players, clinicians, patients, and academic partners, must unite in this endeavour.

Key systems level recommendations outline coordinated actions across four critical areas of circular economy enablers and capabilities: design, circular business models, reverse logistics, and system enablers. Clear leadership emerges as vital to navigate the transition, requiring a focus on the complex interplay between economic, environmental, and business continuity factors. Specific actions are delineated for five key stakeholder groups, acknowledging their pivotal roles in the circular transformation of the MedTech sector.

In conclusion, the report underscores that a circular economy offers a tangible solution to the systemic challenges faced by the UK MedTech sector. However, achieving a circular MedTech landscape demands collaborative and forward-looking actions from all stakeholders throughout the value chain. Serving as an initial diagnostic, the report identifies pain points and opportunities, presenting comprehensive recommendations to drive sustainable innovation and address the systemic challenges shaping the future of healthcare provision in the UK.

Introduction

The UK National Health Service (NHS) and its providers represents the largest supply chain in Europe. The NHS employs over one million people and contributes greater than 7% of GDP and 4% of UK domestic greenhouse gas emissions.[1]

In 2019, NHS Scotland became the first national health service to commit to becoming a Net Zero organisation[2] followed by NHS England in October 2020.[3] To meet the many demands placed on the health services while addressing net zero requirements is a significant challenge. Multiple connected factors need to be considered and balanced including intervention effectiveness, patient wellbeing, families, communities, workforce, the environment, wider society and resource limitations.

Tackling the above factors will require innovation across multiple domains and focal points, from addressing highly specific issues through to system and society wide considerations. The sector that applies and develops technologies for addressing medical challenges, Medical Technology (MedTech), is both highly innovative and effective with a UK turnover of £27.5 billion per year.[4]

There are approximately 500,000 medical product types in use across the NHS, from walking aids to advanced imaging equipment, many of which are used only once. Moving away from single use products and practices, through increasing utilisation, transparency and traceability can help address many of the NHS delivery challenges and factors described above.

A Circular Economy (CE) is an effective framework to address these various pressures. As a discipline, CE offers a proven, practical way to preserve product, material, energy and information resources through multiple use cycles, displacing single-use products and wasteful practices. There are established CE approaches to initiate, co-ordinate and implement the shift away from single use that will reduce material demand, increase product utilisation and preserve their economic and material value for repeat or alternative use.

To achieve this across the UK health service and make CE the new norm, many challenges need to be addressed. However, these are not insurmountable and there are many existing examples of innovative MedTech re-use and remanufacture initiatives to increase utilisation, and the tracking of assets across global health systems. These activities are currently prevalent in the USA, Canada, Germany and France.[5] Within the UK NHS, there are a small number of emerging, innovative CE case examples with high impact and scalability potential.

In this report we set out the scale and scope of the MedTech sector and demonstrate how and where CE can be effectively applied. We show that CE is already realising economic benefits, jobs, and carbon and waste reductions at scale across many devices and care pathways. Through extensive stakeholder consultation, we have defined and validated the challenges to be overcome along with the enablers to initiate, implement and scale up a Circular MedTech system fit for the future.

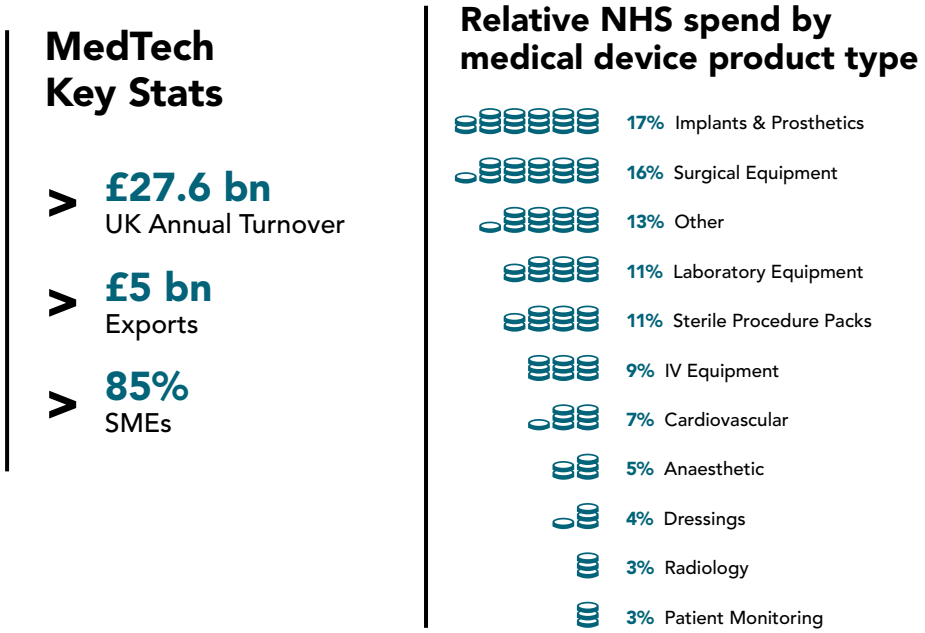
To make this a reality, we identify recommendations for five key stakeholders across the UK MedTech value chain: regulators and policymakers, industry and supply chain, clinicians and patients, healthcare providers and NHS, academics and research partners. We then outline the core programme components for a long term linear to circular transformation.

Image credit: Getty Images

The UK MedTech Sector: Understanding a medical device

Most readers will have experienced MedTech at some stage in their lives. However, they are likely to be unfamiliar with the diversity,[1] scale and forms of medical devices used in modern medical and health systems. Medical devices are used for the prevention, diagnosis and treatment of illness, disease and disability, from walking aids to advanced imaging equipment. These devices may contain a small number of materials and components (e.g. plastic blood bags) to complex combinations of metals, plastics, glass, electronics, critical materials, and textile fibres. Some of these are highly specialised and purchased in small numbers lasting many years, while others are consumed and disposed in large quantities on a weekly basis. The NHS currently spends around £10bn on medical devices.[6] More widely for the UK, the industry including service and supply chain represents an annual turnover of £27.6bn with more than £5bn in exports. Around 2 million MedTech devices are registered for use in the UK, with around 500,000 different product types being regularly used across the NHS, with each NHS Trust reported to use 30,000 devices on average. Figure 1 shows key statistics of the UK MedTech industry.[7] [8]

Figure 1: The UK MedTech industry: key statistics (adapted from DHSC and NHS)



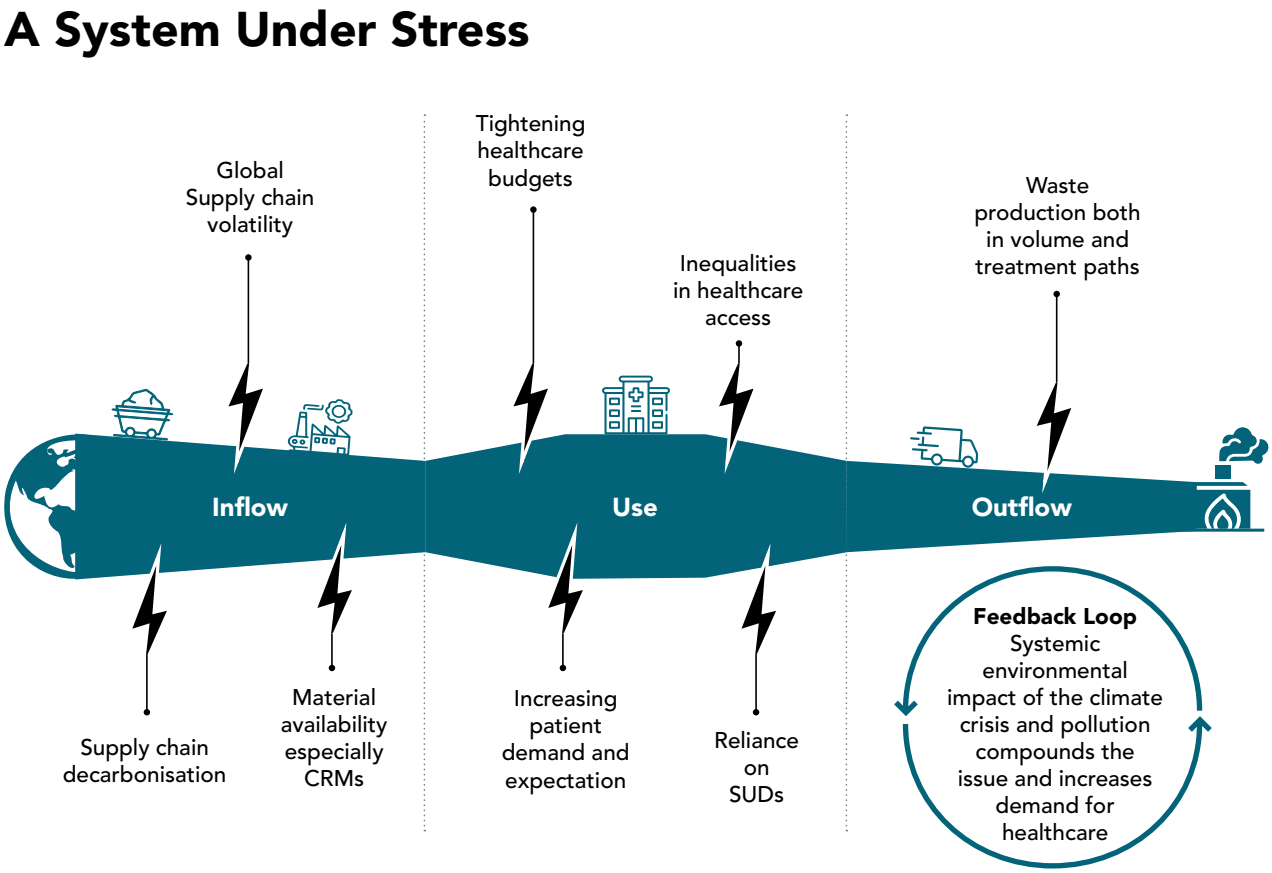
All medical devices must be registered with the Medicines and Healthcare Products Regulatory Agency (MHRA) before being offered into the UK market. The sector is highly regulated with a comprehensive system of device categorisation according to intended use and defined level of risk (see Appendix D). Additionally, the MedTech sector is recognised as a highly innovative field with a global R&D investment rate estimated to be around 8% of sales, with a typical product lifecycle being just 18-24 months before being improved.[9] MedTech supply chains are global and highly interconnected. The UK makes up around 3% of the global MedTech market demand, and alignment with worldwide markets, especially in terms of the regulatory landscape, is essential to ensure multinational suppliers both maintain existing products and bring their newest technologies to the UK.[10]

[1] In the UK, there are three main types of medical devices: General medical devices, such as syringes, dressings and ECG monitors; Active implantable medical devices, covering powered or partial implants including pacemakers and cochlear implants; In vitro diagnostic medical devices (IVDs), covering equipment or systems used to examine specimens, such as blood glucose tests and pregnancy tests.

MedTech and circular economy: Helping a health system under stress

Against this backdrop, the NHS and wider health care providers are facing multiple stresses and challenges (Figure 2), against which, proposals to adopt and implement CE must demonstrate the benefit to medical professionals, care providers, funders, patients and suppliers.[11] These stresses and challenges include, but are not limited to the following:

Figure 2: Systemic challenges presented across the value chain



Global supply chain volatility

In 2021, the UK imported over £7.5bn of medical devices.[12] Brought to the fore during the Covid-19 pandemic and war in Ukraine, the systemic risk of complex global supply chains in the provision of critical medical devices is significant, being vulnerable to disruption and demand variations.[13] This has become especially evident for single use devices (SUDs), where a lack of both technical ability and supporting infrastructure to reprocess or remanufacture devices exacerbates any shortage in supply.

Material availability

The MedTech sector is dependent on many critical materials (such as rare earths, yttrium, holmium, gallium), metals (including copper, steel, aluminium, tungsten) and components (batteries, semi-conductors) for diverse products and applications including medical imaging and scanners, monitoring and ultrasound, implants, drills and incision tools. Certain critical materials are classified as scarce or subject to commodity price volatility.[14] These are likely to become more pronounced in the future as

the same materials are in demand at unprecedented levels due to their fundamental importance to electrification technologies such as electric vehicles, solar PV and wind turbines. By way of example, research has highlighted the reliance of MRI scanners on permanent magnets that contain rare earth elements, which is dominated by Chinese supply chains, and therefore vulnerable to potential supply chain disruption.[15] Similarly, many MedTech devices rely on semi-conductors, hence any global shortages in the future will impact multiple data, control and analytical processes.

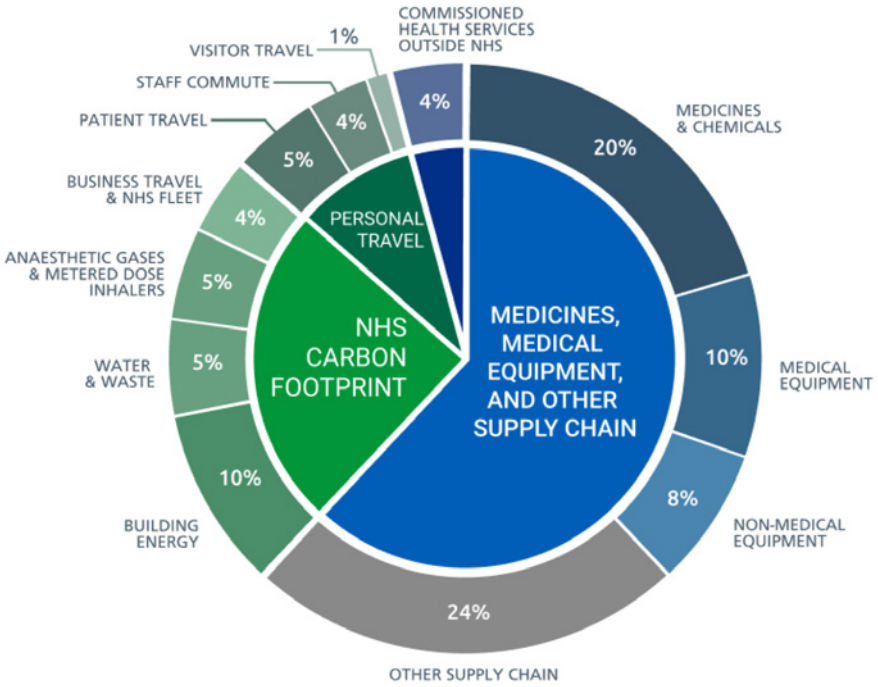
Supply chain decarbonisation

The NHS supply chain contributes to 62% of its carbon emissions, with medical equipment contributing 10% of the total (Figure 3).[16] Supporting the NHS in reaching Net Zero targets will require significant reduction in the emissions across the lifecycle of MedTech, employing innovative reduction, reuse and remanufacturing strategies that are, as yet, undefined.

Tightening healthcare budgets

While healthcare spending has increased every year in real terms by an average 3.6% since 1955/56, there has been significant variation over time with current health and social care budgets projecting spend to increase by just 0.1% in real terms from 2022/23 to 2024/25.[18] This is set against a backdrop of increasing demand. For instance, the number of people waiting for NHS treatment in England has grown dramatically, from 4.43 million at the start of the Covid-19 pandemic in February 2020, to 6.5 million as of September 2023.[19] This is despite £83 billion extra funding for the pandemic response between 2020-2022[20] including £5.9bn specifically to cut waiting lists.[21] As a direct impact of long-term funding challenges, staff shortages, real term pay reductions and insufficient workforce planning, NHS workforce morale is repeatedly reported as being at an all-time low.[22] Vacancies in March 2023 represented 9% of the nursing workforce and 6% of the medical doctors' workforce.[23]

Figure 3: Sources of carbon emissions by proportion of NHS Carbon Footprint Plus (Scope 3)[17]



Increasing patient demand and expectation

Around a fifth of the UK population was aged 65 or over in 2019. The number of people in this age group increased by 23% between 2009 and 2019, at a time when the whole UK population only increased by 7%.[24] At a population level, increasing age is associated with an increase in complicated health issues, social care needs and engagement with NHS services. An unwell 65-year-old patient is estimated to cost the NHS 2.5 times more than a 30-year-old[25] with older people at the highest risk of adverse outcomes or requiring long-term care. Similarly, healthcare demands are rising due to increasingly prevalent chronic, non-infectious degenerative diseases, such as obesity, diabetes, cardiovascular diseases, cancer, autoimmune diseases and Alzheimer's disease.[26]

Reliance on Single Use Devices (SUDs)

A key contributor to increasing clinical waste has been the shift away from reusable devices to SUDs, much of it a result of new, low-cost polymers that replaced previous glass, rubber or metal materials and on-site disinfection and sterilisation.[27] Reliance on single use increased through the 1990s, accelerated by heightened concern of the prevalence of Creutzfeldt–Jakob disease (CJD) being traced to the use of contaminated surgical instruments and blood products. However, as of January 2020, the National Institute of Clinical Excellence (NICE) guidance no longer supports the need for single use surgical instruments with regards to this perceived risk.[28] Nevertheless, the behavioural and system-wide procurement structure is embedded in linear activity, continuing to prioritise SUDs.

Inequalities in healthcare access

Unequal access to healthcare can impact a person's opportunity to live a healthy life resulting in health inequalities. There are multiple factors that can result in individuals being disadvantaged, and the impacts tend to multiply for those with more than one type of disadvantage.[29] How to address health inequalities and access to healthcare most effectively continues to remain a significant challenge for the NHS.

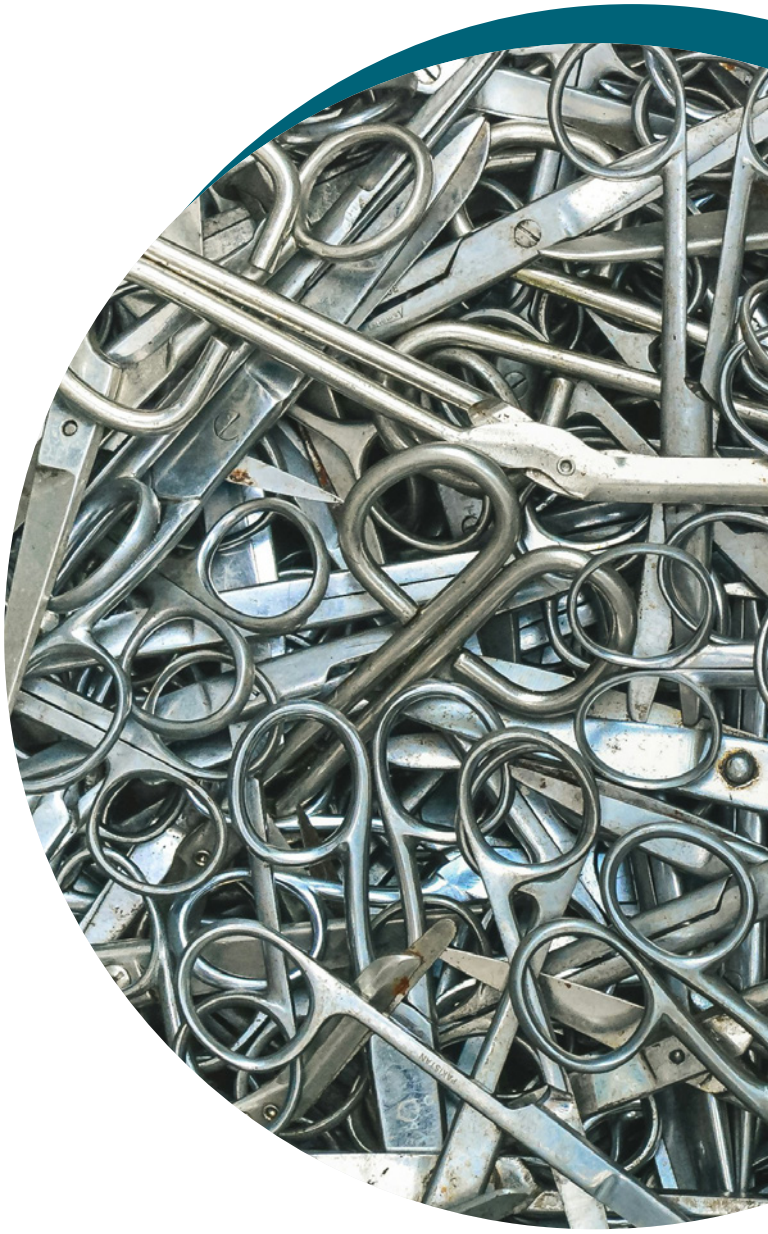


Image credit: Paul Felberbauer, Unsplash

Waste Production

As with other high-income nations, a take-make-waste 'linear' health system prevails in the UK, involving large volumes of waste, including that generated by SUDs and premature disposal of medical equipment.[30] As outlined in the NHS Clinical Waste Strategy (2023), NHS England produces over 156,000 tonnes of clinical waste each year. This is mainly disposed through high temperature incineration or alternative treatment, providing energy from waste (EfW) each presenting their own wider challenges.[31] Waste disposal generates a financial and environmental cost burden and due to minimal waste segregation at source, it is evident that a higher than necessary volume is treated through this clinical waste stream.[32] This may potentially increase as the NHS extends out of hospital care, through 'virtual wards' and similar.[33] The Medical Technology Strategy (2023) focuses on addressing these costs through eliminating unnecessary waste, developing options for reuse and ensuring safe and sustainable disposal. Projections suggest an opportunity for revenue savings of £11 million each year over the next 10 years, along with 30% carbon emissions reduction through following the Strategy.[34]

Image credit: Possessed Photography, Unsplash

The Feedback Loop

Recognising the negative impact of the worsening climate crisis on human health, the Lancet Commission declared that ***"tackling climate change could be the greatest global health opportunity of the 21st century"***.[35] Tightly coupled with increasing emissions from human activities, pollution is deemed to be the cause of approximately 9 million deaths globally per annum, with the greatest impact felt in low- and middle-income countries.[36] As a sector with significant economic, environmental and social impact, the very system that delivers these healthcare services exasperates the challenges through a negative feedback loop.[37]

In summary, it is evident that the systemic pressures on the health sector are significant and increasing, to a point where 'business-as-usual' is recognised as not being economically, environmentally and socially sustainable over the long term. MedTech already plays a crucial role in supporting the UK's collective health and wellbeing and the sector has the potential to be a driver of change to reduce system stresses through enabling CE to be embedded within health services.

The structural solution: A Circular MedTech system

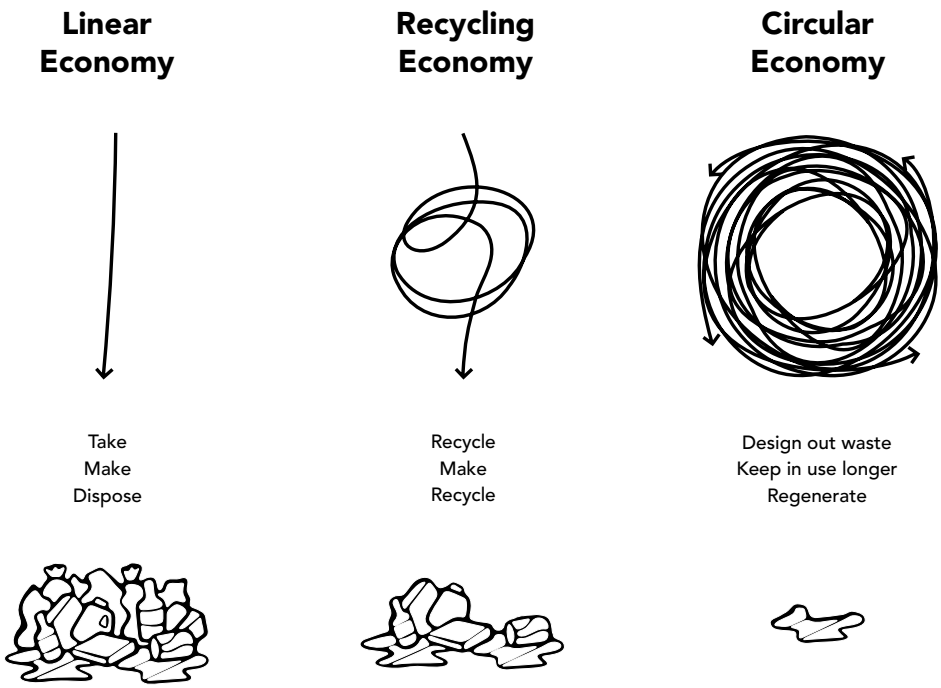
The foundation of a CE

While there are many definitions of CE, the majority are underpinned by a set of core principles, which originate from the work of the Ellen MacArthur Foundation (EMF). Four of the core guiding principles are:

- Eliminate waste and pollution (through design),
- Circulate materials and products at their highest value for as long as possible,
- Regenerate natural capital,
- An economy run on renewable energy.

The CE concept has been subject to many diverse debates and definitions by multiple authors and organisations, and sometimes interpreted as being a slightly enhanced form of recycling. As Figure 4 shows, a CE is more than just improved recycling, which only slows down the rate of resource consumption and should be a last resort. Rather a truly circular economy rebuilds and maintains capital, promoting higher quality stocks and flows of materials, components and products for repeated life cycles and cascades.

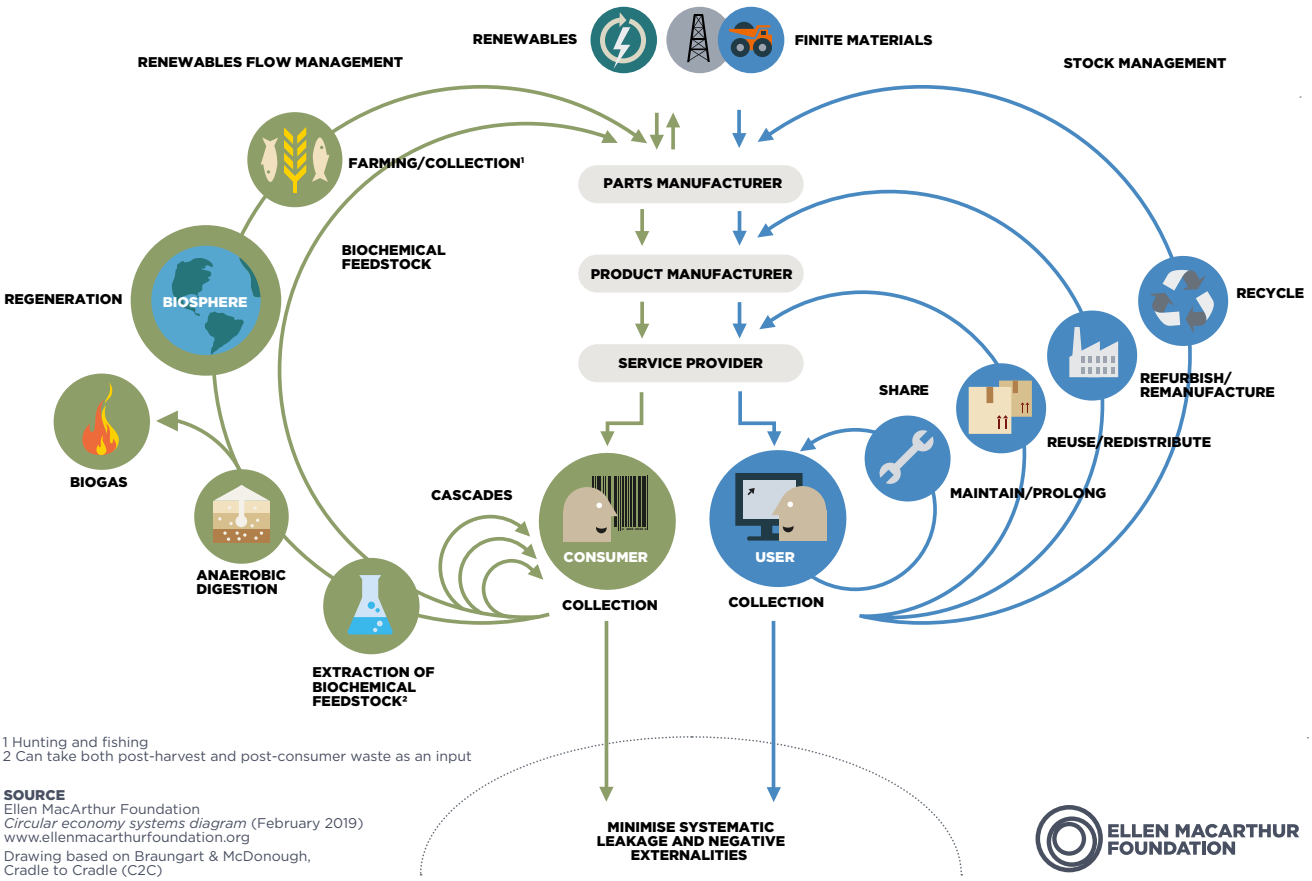
Figure 4: A linear, recycling and circular economy in 3 images (adapted from Circular Flanders[2])



[2] For the original infographic, see: https://vlaanderen-circulair.be/en/infographics.

Developing a CE is therefore a system challenge. The CE visual originally developed by the Ellen MacArthur Foundation, known as the 'butterfly diagram' is a useful heuristic that demonstrates the CE as a whole system framework (Figure 5). In this conception, the current linear take-make-dispose economic model is depicted as a vertical value chain, where materials and resources flow through the economy to disposal and externalities, often in a single use cycle. In contrast, in a circular economy, the aim is to preserve, circulate and cascade materials, and products productively back into the economy at various life cycle stages. The way this might be achieved differs depending on whether materials, components and products are designed for one of two spheres – the biosphere or the technosphere. The technical sphere encompasses materials and products (known as products of service) that are that are durable, including many MedTech devices comprising materials such as steel, titanium, copper, plastics. In the biological sphere, materials biodegrade, are consumed (known as products of consumption) and then metabolise, or compost and dissipate or can become stocks (e.g. soils). Many forms of pollution and harm to life occur when technical durable materials, such as plastics, end up in the biosphere (e.g. ocean plastic, air pollution), or biodegradable materials become mixed with technical materials, which are hard to separate and more costly to preserve the value of either.

Figure 5: Circular Economy System Diagram (Ellen MacArthur Foundation, 2013)

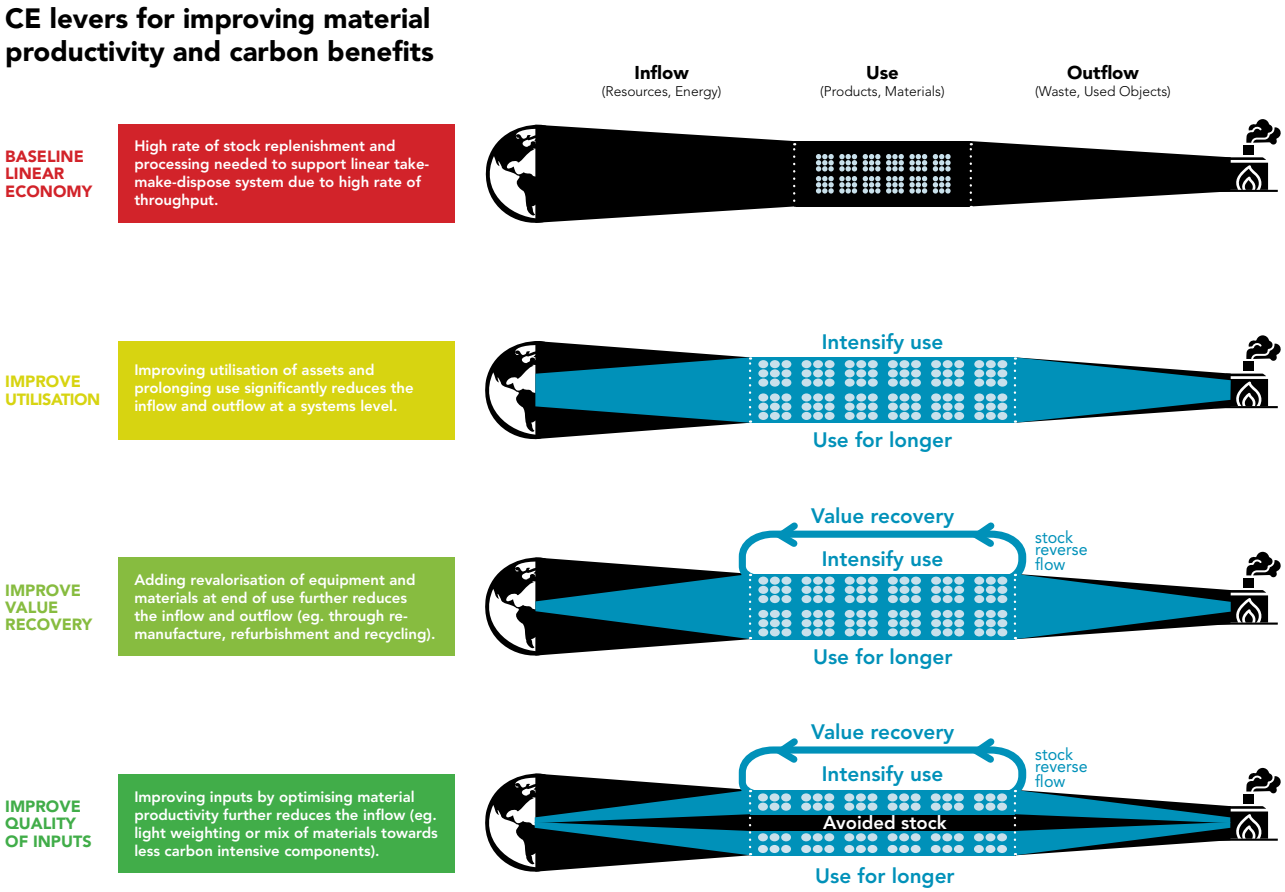


1 Hunting and fishing
2 Can take both post-harvest and post-consumer waste as an input

SOURCE
Ellen MacArthur Foundation
Circular economy systems diagram (February 2019)
www.ellenmacarthurfoundation.org
Drawing based on Braungart & McDonough, Cradle to Cradle (C2C)

The power of circular economy value creation is compounded by designing interventions and innovations as a system across the value chain (Error: Reference source not found). Prolonging and intensifying product life spans (without compromising patient safety or clinical need) drives up asset utilisation and overall resource productivity and drives down carbon emissions. These actions reduce the overall rate and size of the outflows from the system (reducing waste disposal costs), whilst designing and managing the reverse flow of products and assets on circular principles, drives value retention and reduces demand for new product or materials at the inflow stage. Designing products and components for circularity at the outset, reduces material complexity, toxicity and in some instances necessity, and forms a key value creation enabler in the use and outflow stages. By connecting each phase as a circular value system, this avoids the prevalent value leakage characteristics of the linear economy, compounds carbon and material productivity, reduces supply chain risk and reduces costs.

Figure 6: CE levers for improving material productivity and carbon benefits (adapted from Zils, 2021)[38]



To facilitate a shared understanding of CE among and between stakeholders, it is helpful to have an agreed taxonomy or classification of terms and entities relevant to the field of interest, including what constitutes eligibility criteria for activities to be labelled circular. This is an important first step to be able to concisely describe the current state of play in relation to a desired CE target state and chart the transformation steps required to get there. This report provides a foundation to describe the current state and limitations of the linear economy in MedTech, the potential application of CE interventions across the inflow, use and outflow stages of the MedTech value chain and begins to build a picture and outline the steps needed for a CE target state and its benefits.

Figure 7: Transformational steps to a CE target state (adapted from Zils et al, 2023)

Description of current state including limitations

- Describe current state including stakeholders and activities.
- Identify problems in areas such as materials, economy, society and external factors.
- Find opportunities to improve overall value process, at system and individual level.
- Define factors influencing value to enable prioritisation.

Application of CE interventions

- Describe CE interventions based on core principles, CE reverse loops and necessary foundations.
- Combine individual CE actions into a larger plan, starting from small-scale testing to implementation at scale.
- Explain how different stakeholder (especially policy and regulators) engage with and contribute to embedding CE interventions.

Description of CE target state and benefits

- Describe CE target state including activities and stakeholders.
- Document impact and benefits in various areas such as materials, economy, society and external factors.
- Summarise key learnings and insights that can be applied to comparable starting situations in scaling.

Image credit: Getty Images

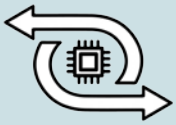
How the CE works in practice within MedTech

Given that the MedTech sector procures and manages a wealth of existing assets and devices, and critically, has well-articulated aspirations and appetite for change, it is ideally placed to innovate and utilise CE concepts. This could significantly improve asset and resource productivity, reduce costs and support the challenging targets for net zero.

In practice, companies and organisations who are already benefitting from the circular economy typically succeed by harnessing four core building blocks:

Design

For the MedTech sector this means working with the supply chain that design assets, products and services to reduce intake, reduce reliance on SUDs, promote maintenance, product life extension and eliminate toxic materials that prevent re-use or recircuIation.



Reverse Logistics

From the outset, design an adaptive through-life cycle with reverse loops back to the suppliers, third parties or adjacent value chains to ensure valuable products, components and materials can be recirculated profitably.

Business Models

This involves working towards business models that focus on the total cost of ownership and carbon impact, shift to performance-based models that incentivise greater utilisation with guaranteed performance and options to significantly extend product life, through upgrades, repair, refurbishment, remanufacture and cross value chain collaborations (e.g. industrial symbiosis).

System enablers

For the NHS and health service this means thinking in systems and identifying enablers that drive system wide and project specific systemic innovation including procurement, new forms of collaboration, core service design, digital and software tools, financial and accounting tools. In the longer-term legislation and policy, such as Extended Producer Responsibility (EPR), will influence cost profiles and impact system and project design, material selection and future carbon and financial costs and revenue streams.

What is the level of circular adoption in the MedTech sector to date?

There is already a large and growing CE market within the MedTech sector, including remanufacture, refurbishment, and recycling applications. Globally, the maturity of this varies across different regions[39] and within the $472bn MedTech market,[40] CE offers a significant economic opportunity. As a subsector example, the global medical equipment remanufacturing market was valued at £8.8bn, with projected compound annual growth rate (CAGR) in the range of 11.8% to 12.2% until 2027.[41] [42] This represents growth at broadly double the projected CAGR of the wider MedTech market at 5.26%.[43]

Currently, the largest market for remanufactured/ refurbished medical devices is the US, with the greatest growth predicted to come from Asia Pacific markets. The practice of remanufacturing has become more widely adopted, fueled by increasing demand from BRICS countries: Brazil, India, Russia, China and South Africa. In the US, hospitals utilise device reprocessing and sterilisation of reusable sharps as there is a strong economic case.[44] A recent European study assessing medical devices with electronic components found that more than 73% of devices were single use with the most common circular activity being reuse. Devices utilised in a clinical setting were found to be five times more likely to have a circular strategy employed than devices used at home.[45]

The following vignettes offer a snapshot of some initiatives and innovations signposted by clinicians, health and social care policy teams, industry stakeholders, and funders. These initiatives showcase different CE levers, outlining the strategies and key elements of success for specific MedTech devices and consumables, across the inflow, use and outflow phases, alongside further system enablers. Following this, two deeper dives present illustrative case examples to highlight in greater detail the economic and resource benefits of going circular, specifically in the contexts of reuse and remanufacture.

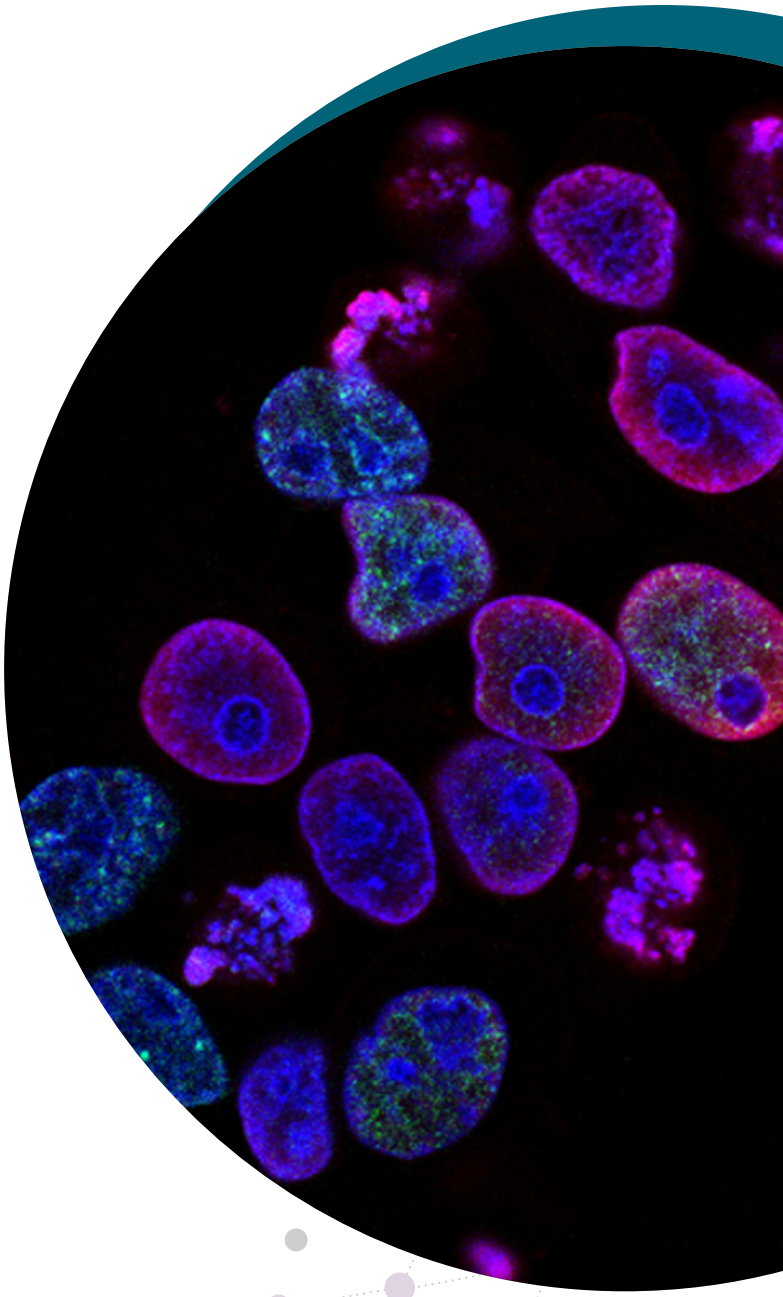


Image credit: National Cancer Institute, Unsplash

Inflow phase: Reduce inflow

At the heart of a CE lies the foundation of circular products, materials, and services meticulously crafted to optimize the utilization of materials and components. These innovations aim to eliminate substances of concern that could hinder the efficient recirculation or recycling of value within the system. Within this framework, numerous design and redesign solutions can be strategically employed to enhance the circularity of the overall system.

Surgical Tray Content Reduction

Questioning whether a product is needed in the first place is a fundamental approach to reducing impact and one which can easily be overlooked in system redesign. Surgical tray rationalisation is an area of focus following research highlighting that across four surgical services, over 75% of instruments included within standard trays remain unused,[46] adding to operating costs and increasing carbon impact, with up to 85% of the carbon footprint from reusable surgical instruments being attributed to the decontamination process.[47] One early pilot carried out by Leeds Teaching Hospitals Trust audited the surgical instrument trays for laparoscopic appendectomies as part of the Green Surgery Challenge, a collaborative effort led by the Centre for Sustainable Healthcare. The outcome was a reduction in instrument numbers from 119 to 49, with the subsequent creation of 'green trays' which are now routinely used, reducing both the demands on sterilisation services and the number of SUDs. This rationalised tray has been estimated to save £22.92 per procedure in sterilisation costs alone and approx. 1.77kg in waste generation, with an annual reduction of 740kg CO2e.[48] Based on an estimated 42,000 appendicectomies being carried out nationwide each year, the sterilisation cost saving alone would total almost £1m.

Further studies have since been completed and learnings having been drawn together in a recent Innovation Agency report by NHS England (2023), outlining the benefits and providing advice for other healthcare providers in replicating the process.

High Impact Anaesthetic Gas

Current anaesthetic and analgesic products and practices are estimated to contribute to 2% of NHS carbon footprint. Initially, through quantifying the carbon emissions connected to specific gases, it has been possible to switch to lower impact products. Desflurane, a common anaesthetic gas has a comparably high carbon footprint of 73 kg CO2e per MAC-hour (minimal alveolar concentration) compared to alternatives, such as Sevoflurane with a climate impact of 1.6 kg CO2e per MAC-hour. Over 40 NHS Trusts have switched to use lower carbon alternatives instead of Desflurane, with many more pledged to reduce or eliminate use in their sustainability roadmaps. Since 2018/19 use of the gas has dropped from 20% to approximately 3% in 2022/23.[49]

Hybrid Product: Design for CE

It is possible for medical devices to be defined by their component parts in terms of reprocessing opportunity. Hybrid design options have the potential for further innovation, where only a small component of a device makes contact with the body, allowing the rest of the device to be decontaminated in-house and the small component can be either disposed or recycled. A study by Rizan and Bhutta (2022) has proposed certain types of devices used in laparoscopic procedures, such as ports, scissors & clip appliers, have the potential to switch from single use to hybrid options. Based on analysis of laparoscopic cholecystectomy, the study projected the total financial cost of using a combination of hybrid laparoscopic instruments was less than half that of single-use equivalents (GBP £131 vs £282).[50] In addition, through using hybrid laparoscopic clip appliers, scissors, and ports for a laparoscopic cholecystectomy, the total plastic content was just 15% that of using single-use equivalents and generated around 15% of the waste. If translated across all laparoscopic cholecystectomies in England, this would save an estimated production and disposal of 30 tonnes of plastic per year. The carbon footprint per operation of a laparoscopic hybrid instrument compared to its single-use equivalent was 17% for a clip applier (445g vs 2559g CO2e), 33% for scissors (378g vs 1139g CO2e), and 27% for four ports (933g CO2e vs 3495g CO2e) per operation. In total, the carbon footprint of using hybrid scissors, ports, and clip appliers was 76% lower than using single-use equivalents, saving 5.4 kg CO2e per operation (equal to driving 16 miles in an average petrol car).

Use phase: Asset optimisation

An increase in the length of time an asset remains in use and the intensification of use during that time are both key drivers to a CE, reducing demand for new devices, increasing resource productivity and reducing costs, at no additional risk to patients or impact on clinicians. For example, with high cost, complex equipment a shift to service-based models can allow healthcare organisations to move from large capital expenditure to more predictable, operational expenditure.[51]

Increase utilisation – the role of software and prognostics

With the rise in digitalisation of devices, there is an increasing challenge of early obsolescence through software support withdrawal. Philip's SmartPath is a commercial offering which provides both hardware and software updates, alongside product and component replacement and upgrade to maintain device performance over the long term.[52] Mainly focused on high value, highly complex equipment such as MRI scanners and imaging devices, the programme also now includes ultrasound equipment and bedside monitors. Alongside this, the company offers a take-back service and refurbished medical equipment sale through the Diamond Select programme with savings of 20% or higher compared to new equipment with similar warranty terms.[53] Delivering these two programmes to healthcare providers, Philips has developed a market-leading circular business model which saves cost, reduces material consumption and maximises resource utilisation through managed services. As the manufacturer, Philips maintains control over the material assets and is able to responsibly manage end-of-use devices, which has contributed to the organisation reintroducing 7,000 tons of refurbished medical imaging equipment to the market over the last decade.[54] As part of a company-wide circular strategy, the organisation has a target of achieving 25% of revenue from circular business models by 2025, having secured 18% of its €17.8 billion revenue in 2022 from circular products and services.[55]

Remote diagnostic devices & digitally enabled care

When considering the pressured resources of healthcare providers, especially the NHS, optimising face to face appointments and in-hospital stays through remote care is a key route to maximise overall healthcare delivery from existing resources. The adoption of remote diagnostic devices and patient monitoring services are increasingly being used to both support faster recovery and manage demand for in-hospital care. In addition, providing hospital care in a home setting has been shown to reduce carbon impact with an evaluation of managing 310 covid-19 patients from Leicester NHS Trust through virtual ward care delivering estimated savings of 1,100 bed days, £530,000 and 138 tonnes CO2e[56] Importantly, further research studying the outcomes of patients over 65 years old receiving 'hospital at home' treatment concluded that health outcomes were equivalent to those of patients admitted to hospital at 6- and 12-month reviews.[57]

NHS @home uses technology to provide connected personalised care in homes or existing care settings, for those who may otherwise be admitted to hospital or as early supported discharge schemes. Similarly, NHS virtual wards (also known as hospital at home) provide patients with hospital level care safely in their home setting, while freeing hospital beds for those most at need. The service is delivered by a multi-disciplinary team, enabled by technology including a patient-facing app, medical devices (such as a wearable remote monitoring devices and blood pressure cuffs) connected through a digital platform for healthcare professionals. Initial analysis on the cost of this technology has shown a £872 saving per person compared to inpatient care, however this is an area of ongoing research to quantify the full cost saving opportunity.[58]

Outflow phase: Post use asset recovery

When products and materials reach the end of their first use or consumption phase, a CE system recovers the assets and components for repurposing, remanufacturing or recycling.

Loopcycle

A key enabler of CE is mechanisms to recapture of value at end-of-life (EoL). Loopcycle is a start-up technology company providing a digital platform that helps trace, manage, and recover physical products throughout their lifecycle. The organisation collects and shares asset information from different stakeholders in the supply chain including manufacturers and asset owners/operators, increasing supply chain transparency, resilience and circularity of products. This is achieved via a unique digital product passport ID called a Cyclecode which allows users to visualise information shared during the product lifecycle (e.g. point of manufacture/ownership/resale) by the stakeholders in the Loopcycle platform. Loopcycle's data dashboard also provides auditable calculation of the embodied carbon of any asset; insights to improve operational efficiency; an action monitoring function; and a EoL options impact calculator. Additionally, the company facilitates reuse and resale of equipment through its marketplace feature.

Actively managing assets and commercialising obsolete products will help achieve NHS' carbon objectives while reducing costs. To date, Loopcycle has helped large NHS estate holders maximise second life asset values of clinical laboratory refrigerators and freezers by providing recommendations through a carbon data-led methodology for decommissioning and procurement.

Remanufacturing Electrophysiology (EP) Catheters

An EP catheter is a device used to test the performance of heart's electrical system and to diagnose abnormal heartbeats (arrhythmia) for further treatment (Figure 8). These catheters are mostly marketed as single use.

NHS England conducts 7,744 ablation procedures amongst the prevalent population of 1.3 million having atrial fibrillation (AF) which is approximately 3% of the total adult population over 20 years in England.[59] The rate of procedure is increasing by 6% every year as a trend which is expected to continue.[60]

Leeds Teaching Hospitals Trust has been a pioneer of using remanufactured medical devices in the UK with physicians now using remanufactured EP catheters delivering financial cost savings of around 50% from the equivalent OEM purchase price. In addition, there is a 50% reduction in the Trust's carbon footprint for every remanufactured device used. In the year 2021, by using 604 remanufactured devices, Leeds Teaching Hospitals Trust reduced the carbon footprint by 525kg CO2e and saved an estimated £76,610. Additionally, the Trust was paid £22,923 for collection of 75.33kg of used devices, diverting them away from the waste stream and capturing further cost savings.[61]

Similarly, Norfolk and Norwich University Hospitals NHS Foundation Trust switched to use remanufactured EP catheters to treat cardiac arrythmias in patients, reducing its carbon footprint by 50%, diverting 28kgs of devices from landfill and realising cost savings of £57,000 in 2022.[62]

Figure 8: Electrophysiology Catheters in use (Adapted from Healthwise & McKesson Corporation)

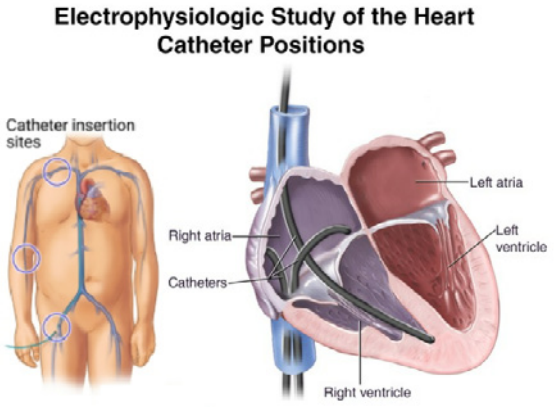


Fig. 4.2
Multipolar Ring (Lasso, *Left*) and Star-Shaped PentaRay *(Right)* Mapping Catheters. (Courtesy Biosense Webster, Inc., Diamond Bar, CA, United States.)

High value material recovery

Mapping the current position is the first requirement to enable a move to circularity, providing opportunity to identify value leakage and identify impactful interventions. NHS Scotland Waste Route Maps are the output of collaborative research focusing on both reducing virgin material use and material value capture.

A 6-week trial was developed to assess the potential opportunity of segregating high-value, non-clinical plastic waste across 18 theatres and recovery areas in NHS Tayside. Plastics entering non-clinical waste streams from clinical areas, such as single use containers and bottles, were collected and audited. The trial demonstrated the opportunity for reduction in both waste volumes and costs, along with carbon emissions. The greatest volume recovered by plastic type were films and large rigid plastics. Using this trial data and assuming similar results across all comparable NHS theatres would reduce 92 tonnes of plastic waste p.a. save £60k per annum and approximately 123 tonnes CO2e.[3]

The success of this trial has gathered wider industry interest along with providing key insight for the Plastics Charter, which aligns with both the NHSS and NSS sustainability strategies and provides greater understanding of the products being procured and their plastic content. Building on waste stream mapping, the Charter includes a plastics hierarchy supporting high quality recycling, which ranks 'preferred polymers' down to those which inhibit recycling and ideally need to be phased out. This insight will give procurement teams greater understanding of end of life (EoL) plastics treatment and enables proactive contract discussion with suppliers on product and material composition. A key output will be the inclusion of specific information and action for suppliers within National Procurement frameworks.

NHS Scotland have been working on plastics in the clinical waste stream, engaging with the key contractors and extended value chain over a 7-year period to recover and process plastics into quality-certified pellets, now being sold into the FMCG market. Assisted by the waste segregation process in Scotland, estimates suggest that one third of clinical waste passes through recovery, with a resulting 500 tonnes of accredited carbon credit being assigned to NHS Scotland. This is seen as a 'carbon inset' benefit with an ambition to increase the volume of waste recovery, alongside wider efforts to reduce overall consumption and increase product circularity.

Excess material recovery post use

Only 5% of anaesthetic gases are metabolised by the patient during surgery while the rest is exhaled unchanged as waste anaesthetic gas (WAG) causing significant environmental pollution.[63] Innovative organisations such as ZeoSys Medical Gmb (in partnership with Baxter) and UK-based Sagetech Medical have designed specialist cannisters which attach to the back of anaesthetic machines to capture the exhaled anaesthetic gas in its porous material (excluding N2O), thus preventing its release into the atmosphere. Once the canisters are full, they can be collected to extract, separate, and purify the captured gas, which is then used to manufacture new anaesthetic gas, allowing usable resources to be recirculated.

One of the main challenges is that under UK waste laws, only a licensed waste management company can collect, store and treat the so-called waste products, even if it is managed in a closed loop system to be reused as a new product.[64] Consequently, such providers must either become a licensed waste company or contract with third party waste companies to process the cannisters. Such hurdles can inflate the cost, regulatory burden and increase the complexity of reverse logistics ultimately disincentivising voluntary adoption by healthcare institutions. Positively, in October 2023, Sagetech Medical achieved a CE Mark for their anaesthetic capture device, the SID-Dock, taking this technology one-step closer to widespread commercial adoption.[65]

[3] Figures extrapolated from data provided by NHS Scotland, as of 21 December 2023 Source: Email communication with Wendy Raynor, Head of Circular Economy Programme, Scottish Government Health.

System enablers

System enablers catalyse system change through initiatives that support CE innovation and business model design.

Green Surgery Challenge

This programme was designed to provide grassroots engagement with clinicians and healthcare professionals to explore and enable adoption of sustainable surgical practices through engagement, awareness creation and knowledge sharing on best practices. It was developed by the Centre for Sustainable Healthcare (CSH) in partnership with the Royal Colleges of Surgeons of England & Edinburgh, Sustainable Healthcare Coalition and other healthcare organisations.

In the form of a competition, the Challenge encouraged healthcare institutions to reduce their carbon footprint through various clinician-led initiatives, such as energy conservation, waste reduction, and sustainable procurement and provided a framework for setting goals, measuring progress, and sharing best practices among participating institutions. Successful projects demonstrated review by surgical patient pathways, embracing holistic systems redesign and engaging broad stakeholder groups, identifying sustainability champions in the process. One example, led by a multi-disciplinary team at Wrexham Maelor and Ysbyty Gwynedd Hospitals, undertook a quality improvement project on carpal tunnel release surgery, auditing consumables used and waste created. This resulted in the replacement of single use devices with reusable equivalents, reduction in the size of instrument sets and moving the procedure from the operating theatre to the procedure room. This case example delivered multiple benefits including reduced hospital stays and surgical wait times, a lower number of staff required per procedure and over £12,000 financial savings, alongside 11.6 CO2e reduction per annum.[66] A key success factor of this challenge was the engagement of clinicians and healthcare professionals in the development of solutions, taking a holistic view of entire care pathways.

Healthcare LCA

Healthcare LCA is an open-access database which brings together research and environmental assessments from over 480 institutions and 245 data sources over 20 years, into one repository, including data on healthcare services, medical equipment and pharmaceuticals.[67] As a collaboration between CASCADES, Dalhousie University and Brighton and Sussex Medical School, the platform aims to accelerate the transition to sustainable health systems through providing access to global primary research, collated into one database with comprehensive visual outputs, showing results and trends into accessible formats. With data availability and interoperability a perennial challenge in the acceleration of a CE, the platform provides the first step towards assessing the environmental impacts through product-based life cycle assessment (LCA) and economic input-output analyses. Since launch, the database has been used by more than 6,000 individuals from almost 80 countries, with many returning users.

The role of Trade and sector bodies

Based in the US, the Association of Medical Device Reprocessors (AMDR) is the global trade association advocating for responsible reuse of medical devices through regulated SUD reprocessing. Originally born out of the cost saving opportunity for healthcare providers, the organisation has more latterly focused on reprocessing as a tool to reduce waste, lower emissions, enable supply chain resilience and increase healthcare equity. Advocating for the same levels of regulatory oversight to be applied to reprocessed devices, the organisation is committed to growing the scale and scope of reprocessed device adoption. It reported $412m savings achieved by hospitals and surgical centres in the US in 2021 through the sale of over 33m regulated, reprocessed devices to more than 10,000 healthcare centres.[68] This equates to 10 million tonnes of medical devices diverted from landfill, and an additional $6m in waste disposal costs, creating 1300 jobs.

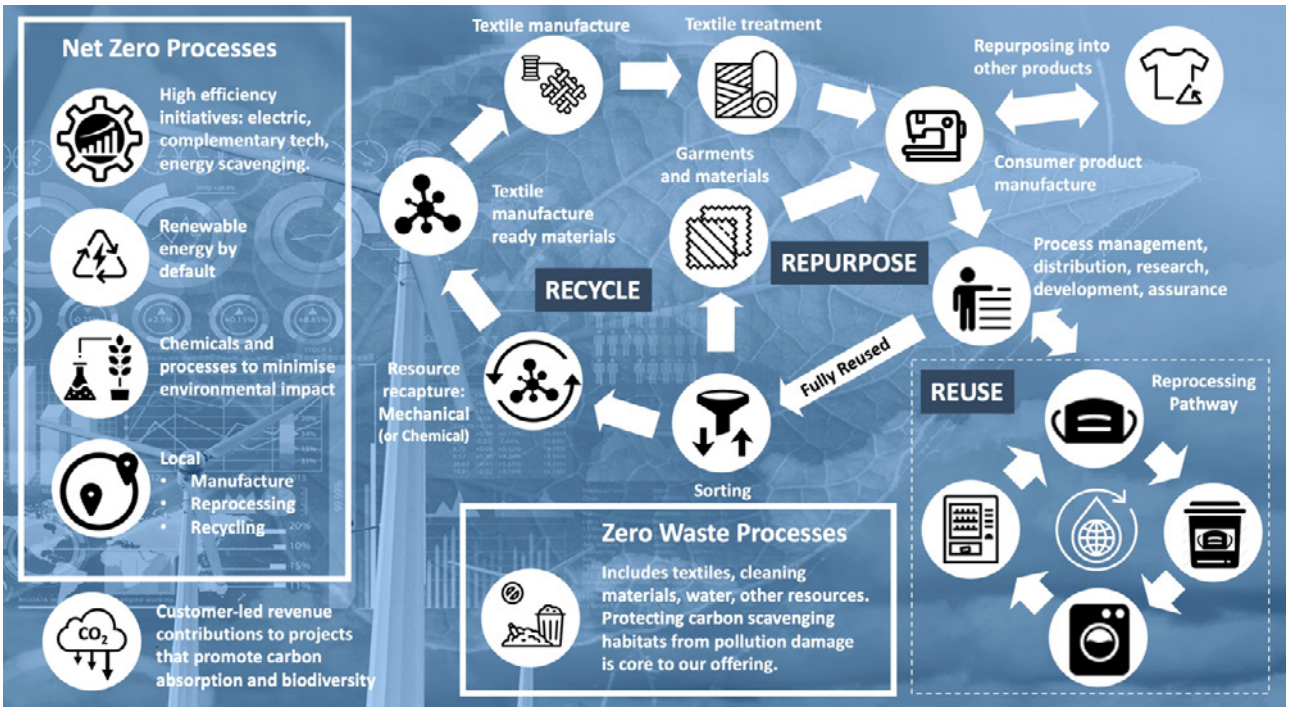
A further 49m devices were collected for remanufacture of which 33m were sold to hospitals and surgical centres worldwide, saving over $395m and preventing around 5m tonnes of medical waste going to landfill or incineration, a saving of $5m in waste disposal. In addition, the Food and Drug Administration (FDA) has issued clearance for more than 300[69] remanufactured SUDs for clinical use, ranging from non-invasive products such as infusion bags and tourniquets, to general surgical instruments, laparoscopic, cardiovascular and arthroscopic devices, which are utilised in the US and Canada. Nineteen countries worldwide use regulated remanufactured medical devices. Figures on the adoption of medical device reprocessing and remanufacture in the UK are not public but our interviews indicated they are less widely purchased than in the USA, Germany or Canada.

The examples above provide a short overview of some of the CE developments taking place within the MedTech sector. To build on these examples, we provide two longer cases to show in detail how circular re-use and remanufacture work in high volume, low price medical textiles and a medium complexity, high value surgical device, evidencing their economic and carbon reduction business case opportunity and scalability. Both cases work within current UK MHRA regulatory requirements and address many of the challenges that are frequently perceived to be barriers to the adoption and implementation of circular economy strategies in MedTech.

The business case for circular economy: Reuse of surgical PPE

Revolution-ZERO is a MedTech CE company founded in 2020 to address the supply chain resilience, quality, emissions and waste issues associated with the single-use medical textile industry, including surgeons' gowns and operating theatre drapes. These issues are considerable with the UK NHS generating at least 55,000 tonnes of waste from regulated medical textiles every year, not including the packaging. Prior to being incinerated for around £600/tonne these products cost in excess of £400 million per year not including logistics, storage and transportation.[4]

Figure 9: Revolution-ZERO Circular Economy model for medical textiles integrating reuse, repurposing and recycling cycles.



[4] Figures presented by Dr Tom Dawson, Revolution-ZERO, as of 30 September 2023.

Approach
With a mission to deliver medical textiles that were more effective, sustainable and economical Revolution-ZERO adopted a circular economy model (Figure 9) designed to minimise loss and enhance efficiencies at every use or processing point.

Challenges
Key challenges to the implementation of this model included requirements for: regulatory compliance; physical reprocessing infrastructure; and specialist expertise across healthcare, textiles, reprocessing, commercial, logistics, circular economy, chemistry, analytics and reporting.

Compliance and Digital Infrastructure
One of the main barriers to medical textiles re-use is decontamination and sterilisation to meet exacting clinical regulatory requirements. Compliance with process standards including but not limited to EN14065 (textile decontamination), ISO13485 (medical device quality management systems), ISO14971 (medical device risk management systems) and product performance standards including ISO13795 for gowns and drapes is required. Creating digital frameworks that encapsulate the requirements of these standards so they can be replicated across different sites, organisations and territories is key to effective, safe and efficient scaling. Furthermore, digital systems can also enable domain-expert knowledge capture and real-time reporting of assets, costs and environmental impact. In essence, this is the core to Revolution-ZERO's digital infrastructure and the preservation of data, information and knowledge that can otherwise be framed as a circular data economy.

Infrastructure
As stated earlier there is a general lack of processing infrastructure in the UK for enablement of CE models. Establishing traditional reprocessing infrastructure typically requires years of planning, permissions and builds creating sites that have extended periods of downtime. Revolution-ZERO has adopted a modular building approach where the reprocessing units can be built off site and installed in a matter of days (Figure 10) for an estimated 50% of the cost of a traditional build. This approach allows for reprocessing units to be rapidly scaled across multiple sites, extended or moved depending on demand requirements.

Figure 10: Installation of Revolution-ZERO reprocessing unit for Royal Cornwall NHS Hospitals Trust (Cornwall NHS)



Working in partnership
Key to CE implementation is breaking down traditional barriers in supplier-customer relationships. Revolution-ZERO and Cornwall NHS have been working in partnership since 2021 delivering several world-first CE initiatives together. In 2023, Revolution-ZERO built and operationalised an 80m2 state-of-the-art processing unit in Truro, Cornwall (Figure 10). This integrated with the Cornwall NHS sterile service services to supply sterile surgical textiles for orthopaedic operating theatres in St Michael's Hospital, Hayle. The initiative was enabled through support from private investment and the Small Business Research Initiative (SBRI) Healthcare programme, an Accelerated Access Collaborative programme funded by NHS England, together with Greener NHS.

Built for Compliance and CE
The processing unit combines internet connected barriers washers, heat-pump dryers and in unit sensors including real-time power reporting. The drying and packing side of the unit is in a ISO8 certified controlled Cleanroom environment to ensure particle control which is important to minimise particle contamination within sterile surgical environments that can increase surgical site infection risk. In addition, the unit is built to last with 25-year unit and 40-year material guarantees.

Quantifying Impact

Top level impact modelling, based on operational data, published LCA[70] and unpublished LCAs (performed by University College London) have modelled annual savings of £83,000, 20 tonnes of waste and 222 tonnes of CO2e emissions for a small to medium NHS Trust running 10 elective operating theatres 250 days a year. Linking to Radio Frequency Identification (RFIDs) within the items processed, Revolution-ZERO has also developed a real-time reporting system (Figure 11) to monitor processing efficiencies and environmental impact.

Figure 11: Revolution-ZERO real-time data reporting system September 2023 for St Michael's Hospital Service (Source: Revolution-Zero)

In theatre assessment

Revolution-ZERO solutions have now rolled out to 10 surgical teams at St Michael's hospital (Figure 12). The responses have been overwhelmingly positive with selected quotes from surgeons being: "Absolutely love the system"; "I trust them more than the single use"; and "If I never had to go back there would be no complaints from me". The impact on waste has been significant with waste audits showing around 3kg of waste savings per operation for total hip replacement or knee replacement operations.

Figure 12: Reusable surgical PPE in use (source: Revolution-Zero)

Enabling scaled adoption

Barriers remain to scaling-up the offer across the NHS including to non-operating theatre environments. Importantly, there is currently no fit for purpose procurement mechanism for a Revolution-ZERO type CE solution. There are also barriers regarding a hold on capital spending for most NHS Trusts. Revolution-ZERO are able to offer a product as a service model to mitigate this, however would need contracts upwards of three years to secure financing for the capital spend. The final barrier is consistent across healthcare settings which is cultural resistance to move away from the status quo. However, there is an increasingly willingness for change as key NHS stakeholders acknowledge it is needed to realise the net zero benefits, overall cost savings and resilience of supply chain benefits that the Revolution-ZERO and other CE solutions provide.

The business case for circular economy: Remanufactured Single Use Harmonic Shears

The advent of minimally invasive surgery has led to huge advances in abdominal surgery[5] over the last three decades, with advantages over open approaches including faster recovery, shortened hospital stay, reduced chance of wound infection, reduced postoperative pain, and scarring. A minimally invasive surgery enabling MedTech, the harmonic shear makes small incisions (usually 0.5–1.5 cm) via vibration/ultrasound (harmonic) or cutting (Figure 13) and can handle multiple surgical jobs such as dissecting, cauterising and sealing. There are many types of minimally invasive abdominal surgery. Laparoscopic cholecystectomy operations are just one example of these, albeit a key contributor, with 73,000 performed each year in England alone.

The case is based on two harmonic shear OEM Class IIb single use devices[6] (SUDs), the HARH36 and HARH233[7] which are used for minimally invasive abdominal surgery. Both of these can and have been successfully remanufactured meeting all of the requirements of the Medicines and Healthcare Products Regulatory Agency (MHRA) guidance on SUD remanufacturing.[8]

Figure 13: A harmonic shear (Source: Vanguard)

From linear to circular

In the UK the MHRA as the competent authority, or regulator, permits the remanufacture[9] of a range of SUDs. To meet the regulatory requirements the re-manufacturer must be able to ensure and validate 'a process carried out on a used device in order to allow its safe reuse including cleaning, disinfection, sterilisation and related procedures, as well as testing and restoring the technical and functional safety of the used device.[10]

Compliance with regulatory standards (EN ISO14971 and ISO13485) is assessed by a notified body (in this case study, British Standards Institute (BSI)) which is ultimately communicated via CE or UKCA marking.[11] [12] This requires a device classification for single use to clearly show it has been remanufactured and remains for single use only in its subsequent cycles.[13] Labelling of remanufactured devices therefore must show the number of times the product has been remanufactured, i.e. one out of two, two out of two.

[5] Including Removal of the gallbladder, e appendix.inguinal (groin), femoral (below the groin), and some abdominal hernias, spleen.freeing of scar tissue build up, also called Adhesions.part of the colon for treatment of a wide range of colorectal diseases such as colon cancer, diverticulitis, chronic ulcerative colitis, and Crohn's Disease. An estimated 14 million laparoscopic procedures were performed worldwide in 2020, at which point the global laparoscopic devices and accessories market was estimated at US $13.7 billion per annum.

[6] All current harmonic scalpels are imported.

[7] Manufactured by Ethicon, US.

[8] Note that as the device design changes over time (hardware or software) this needs validation by the notified body BSI, to ensure compliance with MHRA guidance.

[9] In the US and Germany the term reprocessing is more widely used to refer to remanufacturing.

[10] EU Medical Device Regulation (2017/745)

[11] "Single-use devices may be re-manufactured for use in the UK. However, the re- manufacturer, prior to placing their device on the UK market or to putting it into service, should meet all relevant criteria under the appropriate medical devices directive [1, 2] and place a CE mark on their product to declare conformity with that directive"https://assets.publishing.service.gov.uk/media/5a74c14240f0b619c865a2c1/Remanufacture_SUD_guidance.pdf

[12] S3.4: As part of ensuring good quality systems the re-manufacturing company should demonstrate that they comply with the standard EN ISO 14971 Medical devices: application of risk management to medical devices [3]. The notified body should assess compliance with the harmonised standard for risk management. This standard defines the requirements of risk management systems for medical devices, detailing best practices throughout the life cycle of the re-manufactured single-use device, including a risk analysis identifying all possible risks and associated mitigation strategies.

[13] A re-manufactured single-use device should only be used on an individual patient during a single procedure and after that use the SUD should be returned to the contracted re-manufacturer.

Understanding the stocks and flows of products and materials:
NHS procurement data shows cumulative sales from financial year 2019/20 of c.£30m. Data for the financial year to March 2023 reported £16.2m recorded sales of harmonic shears with 71% eligible for remanufacture and 27% non-eligible. With a median sales price of approximately 50% of the OEM sale price, remanufactured devices accounted for 1.7% of the total, though this increased by 350% to 6.9% to date in 2023/2024.

The remanufacturing process:
After use, the Ethicon harmonic shear is collected from NHS operating theatres for remanufacture by a German medical remanufacturing company, Vanguard. The organisation has over 25 years' experience in the remanufacture of a wide range of medical devices. The devices are currently transported to Germany where they undergo several remanufacturing stages including cleaning and disinfecting; labelling for traceability; and multiple component tests to guarantee safety and functionality.[14] Devices are then packaged and sterilised in line with industry standards and placed into supply stock.

From a standing start four years ago, Vanguard is supplying 35 sites in the UK, with the expansion being enabled by working closely with key stakeholders in each hospital location, supported by national endorsement. One example is the Leeds Teaching Hospitals Trust which uses around 700 Harmonic shears per annum. Working with Vanguard, the Trust introduced a remanufacturing programme to deliver savings and a reduction in waste and environmental impact of clinical procedures. In 2022, through collections of used devices the Trust diverted 70kg of devices from waste and earned £2,068 for those collections as Vanguard pay for accepted used devices. Through using remanufactured devices, the Trust saved an estimated £73,800 and reduced its scope 3 emissions by 285 kg CO2e.[71]

Vanguard recognises that key to the success of the remanufacturing programme is to have all the necessary clinical stakeholders' approval and buy in – this for both collections and usage. The organisation provides on-site training with end users to maximise the collection efficiency and yield. Each device collected is tallied and a payment is made to Trusts quarterly. The use of remanufactured devices is a decision made by the clinical leads based on all the regulatory requirements being met and supplemented by the provision of supporting user evidence for additional assurance. To support these decisions, Vanguard has several peer reviewed papers as does the trade association AMDR. This evidence is further supported by the growing use of remanufactured devices in the UK with stakeholders sharing their experience of remanufacture across NHS networks.

Carbon reduction opportunity
A recent USA LCA based product carbon footprint[15] calculation compared a single use harmonic shear (HARH36) to remanufacture of the same device, covering all production steps from raw materials through to final disposal,[16] including collection, transportation, energy, check[17] and replacement of damaged components, disinfection,[18] sterilisation[19] and repackaging.[20]

The results showed an overall 46% reduction in CO2e emissions, an actual saving of 1.74 kg CO2e comparing the remanufactured device to the original.[72]

Modelling potential impact
To quantify the potential benefits of applying CE strategies, three illustrative forward scenarios have been modelled on NHS England data from 2023/24 to 2030, on an estimated overall procurement spend on the specific harmonic shears of £100m over the period (2019/20 to 2030), holding median prices of new and remanufacture constant at 2022/23 levels.

[14] For details of the process: https://www.vanguard.de/en/devices/medical-remanufacturing/

[15] The sum of greenhouse gas (GHG) emissions and GHG removals in a product system, expressed as CO2 equivalents and based on a life cycle assessment (LCA) using the single impact category of climate change. Based on Ecoinvent data and US data

[16] Paper: 68% recycled, 26% landfilled, 6% incinerated based on US average statistics (EPA 2020); Plastics: 9% recycled, 75% landfilled, 16% incinerated based on US average statistics (EPA 2020); Metals: 100% landfilled as, when applying a cut-off approach, the disposal of metal will have very little contribution to the footprint, irrespective of the management type.

[17] Shaft rotation knob pin, jaw tissue pad, trigger return, spring, torque wrench, torque wrench spring

[18] Detergent, steel brush, plastic bag, cleaning swabs, zip tie, nylon brush, isopropanol, water Isopropanol, printed paper cup, plastic bag, cleaning wipes

[19] Ethylene oxide

[20] Tyvek lid, thermoformed tray, retainer, folding carton

- Low Circular, the current situation: The cumulative financial and carbon saving from 2023/24 by maintaining the number of eligible devices purchased per annum at current levels compared to zero remanufactured devices.
- Enhanced Circular: The additional cumulative financial and carbon savings by 2030 against the Low Circular scenario from increasing purchase of eligible remanufactured devices by 1,000 per annum from 2023/24 year on year until 2030.
- Circular Plus: The additional cumulative financial and carbon savings by 2030 against the Low Circular scenario from increasing the remanufacturing use cycles from 2 to 3, combined with increasing purchase of remanufactured devices by 1,000 per annum from 2023/24.

In the calculation, we assumed 20% loss rate of an original OEM SUD on each lifecycle, and these take place within the same financial year. For the Circular Plus scenario, we assumed a 25% failure rate on the third cycle. We assumed the same proportion of non-eligible devices are purchased year on year. New devices will always be required as devices fail, become too costly to remanufacture or repair or become obsolete through beneficial innovation rather than deliberate obsolescence strategies. However, there are currently more harmonic shears collected in the UK than demand, leaving them to be sold into other markets for remanufacture. We have not modelled any waste cost disposal savings or potential revenues from end-of-life material recycling, which is a preferred strategy for some OEMs. Table 1 summarises the financial saving in purchase cost and carbon savings for all three scenarios.

Table 1: Estimated outcome for modelled scenarios, 2023-2020

	Low Circular	Enhanced Circular	Circular Plus
Potential cumulative purchase saving by 2030	£2.5m	£5.9m	£9.7m
Reduction in new device demand (% of total eligible) per annum in 2030	7%	51%	75%
Carbon footprint reduction (cumulative)	2.3%	5.6%	9.2%

Our high-level analysis shows that the current purchase of remanufactured devices (Low Circular) will deliver £2.5m cumulative savings through to 2030 and a 2.3% carbon saving compared to purchasing new (non-remanufactured) eligible devices. Increased purchase of remanufactured harmonic shears will generate financial savings for the NHS and contribute to NZ targets, with the more remanufactured devices per annum the higher the cumulative financial savings and carbon reduction. This case demonstrates that reuse of SUDs is a practical reality in the UK and as seen in the USA and elsewhere. Given the cost and carbon savings that can be made now and the lack of a viable "designed for reuse" alternatives, there is a strong case for the rapid and widespread adoption of remanufactured harmonics shears across the UK NHS.

In addition, when considering NHS net zero targets, this modelling demonstrates that even in the Circular Plus scenario, remanufacture by itself will not achieve the level of carbon reduction required to meet targets. This highlights both the scale of the challenge but also why more profound systemic innovations in the MedTech sector is required.

Wider Policy, Industry and Research Initiatives

These case examples highlight successful examples of the implementation of CE in two clinical settings with demanding requirements for safety, infection control and clinician acceptance. There is now a groundswell of recent and new initiatives that are driving CE and NZ in other clinical arenas, and non-invasive or lower risk applications, described below:

- Recent funding calls such as the UKRI and NIHR call realising the health co-benefits of the transition to net zero or the Innovate UK Small Business Research Innovation (SBRI) Competition 24.
- Delivering a Net Zero NHS for a Healthier Future provide incentives for clinicians and SMEs to demonstrate a range of circular economy and NZ innovations.
- The DHSC MedTech strategy also acknowledges the need to prioritise clinically safe and effective products that are better for the environment through reuse and remanufacture.
- Sustainability, horizon scanning and innovation through NHS initiatives including the Accelerated Access Collaboration (AAC), along with NIHR and AHSN[73] and Green Hospital Programme.
- The ESRC funded ReMed programme demonstrates latest research and current industrial initiatives in support of the application of the Circular Economy in the healthcare sector.
- The Horizon Europe funded Digital Health in a Circular Economy (DiCE) project, a collaborative of twenty organisations across nine European countries, addressing the challenge around increasing digital health waste.
- The UKHACC Green Surgery Report and Green Theatre Checklist both provide examples for applying circular economy principles to reduce the environmental impact of surgical products.
- Accessible to NHS staff, the FutureNHS platform to "join or create workspaces and communities to connect with others, learn and share". This includes teams publishing short case examples to highlight projects closely aligned to CE and 'Green initiatives' across diverse areas such as reusable suture and 'green' sexual health.
- The NHS net zero supplier roadmap sets out the steps suppliers must take to align with its net zero ambition between now and 2030. From April 2024, a full Carbon Reduction Plan will be required for new suppliers of contracts over £5m and for all new frameworks, and a Net Zero Commitment being required for new lower value contracts.
- NHS Scotland has its own Sustainable Procurement, Waste and Circular Economy (SPWCE) strategy as part of the Scottish Government NHS circular economy programme.
- The General Medical Council (GMC) Good Medical Practice sets out the standards of patient care and professional behaviour expected of all doctors in the UK. This has been updated with the standards now reflecting the requirement for those on the GMC's register to manage resources effectively and sustainably.

Key Learnings

Of the successful circular initiatives outlined in the illustrative use cases, key learnings include:

- Adoption and implementation of circular economy MedTech is happening across the inflow, use and outflow stages of a circular economy value chain within existing regulatory and policy frameworks. These examples are being led by pioneering, motivated clinicians, start-ups, innovative suppliers and lead bodies and programmes (through NHS Innovation and AHSN, as examples).
- In many cases there is a clear and compelling economic, carbon and wider benefits from circular economy MedTech, which is already big business in the USA and other advanced health care systems. The UK is making progress but lagging behind.
- Circular economy can be accelerated through innovation funding, such as the Green Surgery Challenge, NHS Innovation Service and the Accelerated Access Collaborative.
- Technology, and digital infrastructure are key enablers for tracking and validation, particularly for reverse logistics, sterilisation and decontamination.
- Involvement of end users, including clinicians and patients, is critical to gain support and encourage the behaviour change required to make the shift from linear to circular.
- Data systems to build the evidence base and demonstrate outcomes are difficult to find and access, and lack interoperability, meaning there are many gaps in understanding and opportunities being missed.

Identifying the challenges to CE adoption

In this section we synthesise the many challenges that have been identified as potential barriers to making the shift from linear to circular. These challenges come from three different sources:

i) The DfL project and working groups described further in Appendices A, B and C.

ii) Practitioner and industry literature.

iii) Academic literature.

We have synthesised these into six areas as below:

Clinical Efficacy & Safety

Leadership & Behaviour Change

Regulatory & Policy

Economic & Value Creation

System & Product Innovation

Infrastructure & Facilities

Clinical Efficacy & Safety

Creating a circular MedTech requires overcoming sector specific challenges around clinical risk, infection control and patient safety. These challenges are prioritised by clinicians and users above all other factors[74] and can be amplified by secondary system challenges that also need addressing including:

- Embedded Behaviour
  There are perceptions of increased risk through device reuse, including greater opportunity for human error.[75] While Infection Prevention and Control (IPC) guidelines[76] do not specifically promote SUDs over reusable products on the basis of clinical safety, such devices have become embedded in clinical practices due in part to their perceived low cost and safety. Without appropriate guidance and risk stratification, this can lead to change avoidance especially for suppliers that have established and lucrative single-use business models.
- Lack of incentives
  Procurement functions have limited incentives to encourage re-use, remanufacture and other CE practices. Furthermore, there is personal risk to employees associated with changing the status quo which indirectly favour SUDs.
- Lack of Guidance
  There is a lack of clear guidance and risk stratification around activities such as device reuse and remanufacture.

  "The Infection prevention and control, and health and safety guidelines have created linear 'use and disposal' practices." [DfL narrative]
- Lack of modern decontamination and sterilisation infrastructure
  Decontamination and sterilisation infrastructure and the operations required to reprocess medical devices can be complex. While the RevolutionZERO and AMDR case examples show financially and environmentally sustainable solutions exist for the NHS and its suppliers, at present there is not sufficient capacity in existing national infrastructure.

- Proof of Value
  The benefits of reusable devices over SUDs vary on a case-by-case basis. In some examples, such as harmonic shears, the financial and carbon benefit is clear. In other cases, particularly for low complexity devices that are difficult to clean, such as wound dressings, single use design is presently the only viable option.[77] In other cases, the benefits of a 'reusable product' can be compounded when designed as a full CE full system, such as Revolution-ZERO, to capture system wide benefits including inventory control, tracking and tracing, supply chain resilience, reduced total cost of ownership, social value and a continuous cycle of innovation at local scale. Due to the siloed nature of typical healthcare procurement, these benefits are generally not captured in the sale price.
- Quality assurance
  To overcome clinician and patient concern about re-use, it is important, as it is for SUDs, that CE solutions are treated the same and are assessed and quality assured to the same Medical Device Quality Management Standards.[78]

Leadership & Behaviour Change

The success of any large-scale shift from linear to circular requires committed leadership and a clear understanding of the new behaviours and cultural changes required for effective adoption and implementation. The leadership characteristics required to enable the transition to CE that were either identified in the literature and/or shared by key stakeholders included:

- A clearly defined leadership capability that shares and coordinates the delivery of the overarching vision.
  This leadership also had to be seen as relatively neutral to optimise buy in across potentially competing organisations.

  "Without clear direction signaling it is difficult for the sector to justify investment in the necessary product, infrastructure or workforce development in the short and long term" [DfL narrative]
- Total System thinkers and communicators
  Different stakeholders in the MedTech value chain are experts in their domain or have specialist knowledge essential to enable system transformation. However, they lack time, incentives or opportunity to demonstrate integrative or recombinant capabilities, and boundary spanning innovations. Many people we consulted have a CE mindset and see the need for change but are often locked into tight focus on specific functions, devices or product categories, and therefore have to operate in isolation against short terms commercial pressures and knowledge deficits. The leadership function needs to be able to see at a whole system level to communicate and coordinate CE activities.
- Knowledge sharing
  A lack of mechanisms and processes for knowledge sharing across the MedTech value chain regarding (often local) best practices was identified. This limits the opportunity for staff with high workloads to consider, evaluate or embrace new circular options. Horizontal diffusion of innovations is a proven strategy within successful CE corporates, OEMs and value chains. Developments such as the EverGreen Sustainable Supplier Assessment and FutureNHS platform are important resources and stepping stones, to improve the evidence base and incentivise teams and suppliers to adopt CE.
- The need for standards and standard well-defined terminology.
  While a CE is simple concept with a small number of guiding principles, there are many variants of definition, proliferated by academic researchers working in isolation from industry.[79] [80] As reported above, terms such as reprocessing and remanufacturing are used differently in different countries. As a framework, CE also has the potential to be conflated with 'sustainability' and 'green' initiatives. During consultations, we were frequently informed of the need for a common, simple MedTech language, and short list of key value creation interventions relevant to a taxonomy of MedTech devices, to guide future practice.
- A grounded evidence-based approach to risk and safety
  Unwarranted concerns that are not backed by strong scientific evidence about the safety and efficacy of CE solutions compared to SUDs remains a deterrent to universal adoption.[81] It is critical that leadership functions have a strong understanding of the relevant scientific literature and can robustly examine and as necessary challenge risk and safety concerns.

Regulatory & Policy

Regulatory guidance, standards, governmental and institutional policies play a significant role in shaping user behaviours, commercial actors and wider stakeholders. MedTech is interconnected with global value chains,[82] hence different stages in a product or device lifecycle span multiple actors, shared responsibility and cross border regulatory oversight.[83]

Challenges include:

- Perception around safety and clinical efficacy
  Over time various concerns over liability, patient safety, infection control and clinical efficacy has tended to favour SUDs, over re-use or remanufacture, which carry with them increased complexity and cost.[84] OEMs therefore have tended to designate a device as SUD, regardless of its reuse potential.[85]
- Limited incentives for end of life recovery
  As with many sectors, there is currently no legal requirement for manufacturers of most SUDs to design for end-of-life pathways other than landfill or incineration. Currently, most MedTech is exempt from WEEE and waste disposal regulation due to their classification as infectious or hazardous waste (respectively). This position may change with the extension of EU Extended Producer Responsibility (EPR) regulation and increasing UK waste taxes, however as several of the case studies have shown, valuable products and materials which otherwise would be landfilled or incinerated, can be retained or reused within current regulations.
- Regulatory leadership
  In addition to institutional leadership many of those consulted reported that to drive circularity requires clarity relating to risk stratification and risk ownership. Two recurring topics were:

  - National guidance does, at times, preclude aspects of CE adoption. For example, dictating SUD only for clinical use in addition to having to meet international standards where CE/reusable options are available that do meet the standards.

  - Formal infection risk categorisation is at times drawn from OEM documentation, as opposed to independent guidance, which may overstate the risk and difficulty associated with reuse.[86]
- Public Procurement
  Demand signalling through public procurement frameworks is a recognised key enabler of circular economy. Many industry stakeholders considered the NHS framework is not sufficiently clear or weighted towards circular options, giving limited incentive for industry change or alignment with value-based procurement.

Economic & Value Creation

Overcoming legacy systems and prior investments in capital assets, together with the costs of transitioning towards circularity is often referred to as 'linear lock in', which can contribute to a significant barrier to change from the current system of economic value creation.[87]

Challenges were identified as follows:

- Where to start
  Many members of the DfL collaborative highlighted a lack of clarity of where to start and how to identify opportunities to make the value shift from linear to circular. In a market sector with a highly complex and diverse product portfolio, at different price points (pence to millions) with different CE opportunities there is a need for guidance, business case examples, and evidence of successful adoption and implementation.
- Reducing profitability
  The value creation opportunity from circular economy will vary depending on position in the value chain, with the potential for CE to impact the sale of new devices.
- Analysis, evidence and insight
  Finding, accessing and being able to use data to build system scale business case is notoriously difficult but is possible, as the Revolution-ZERO case study demonstrates. Where there is data uncertainty (such as the total sales volume in the harmonic shears case), this can be augmented with industry intelligence and insights. In the case of LCA, additional limitations are noted regarding the use of generic source databases with a lack of detailed manufacturing and location-specific data, addressing device-specific differences in performance,[88] as highlighted in the harmonic shears illustrative example earlier.

- First mover disadvantage
  OEMs and third-party remanufacturers highlighted the fast innovation cycles and long product development and regulatory approval timeline in MedTech, which can act against reuse and product life extension due to technical obsolescence. Companies such as Vanguard could remanufacture more devices and products but need assurance that these will still be in the market given the length of time and financial investment required to gain approval.

- Multiple dimensions of value
  Different stakeholders perceive value in different ways. Increasing the visibility, measurement and quantification of a range of dimensions of value is important, not only for circularity but for measuring the impact of the MedTech sector generally. For the majority of products there is a lack of environmental, carbon and social data across the product life cycle. Financial considerations are generally focused on point of sale, rather than the costs incurred during use or at the end of life. Often data that exists is not compliant with international standards such as ISO14040 (for Life Cycle Assessments) which presents a major challenge for meaningful comparisons of products or services on cost, circularity and quality across the full lifecycle, ultimately hindering decision makers.

  "(there is a need for) additional tools to understand metrics such as embodied carbon and the pathway carbon footprint through utilisation, processing and waste streams to enable informed purchasing decisions" [DfL narrative]

System & Product Innovation

As we have noted, there are examples of product and system innovation based on circularity taking place globally and in the UK, though these remain fragmented. Key enablers for CE include:

- Digital technology
  The measured use of digital technology, such as for linked asset tracking, can accelerate and scale circularity through feeding back operational and productivity data to allow continuous system refinement and increasing efficiencies.

- Infrastructure
  Facilities, equipment and specialist staff for processing required for CE, such as reprocessing for reuse or remanufacture, are lacking.

- Material recovery networks and innovation pipelines
  It was identified there is a need for investment to establish both material recovery networks and innovation pipelines.

Challenges to implementation include:

- Incremental versus programmatic innovations
  With a broad and diverse product base, there are many opportunities for circular innovations, but to avoid fragmentation and incrementalism requires major new, long term innovation programmes operating across multiple product categories otherwise *"existing innovations may remain incremental". [DfL narrative]*

- New materials
  With advances in material science, some with superior environmental performance and impact, medical approval at a material or product/material scale is time consuming and costly.

  "Even if incentivised for action, the pace of change can be challenging". [DfL narrative]

- Interoperability
  DfL consultations highlighted a broad challenge to product and system innovation due to a lack of interoperability and compatibility of devices and systems. While digital technology can be an enabler for standards adoption, it also creates its own complexity in implementation, both in investment and system redesign.

- Single life mind sets
  Overcoming single use requires a circular design mindset shift. This can involve technical challenges to address component material choice, design for disassembly and disclosure of bills of materials. Guidance on areas of greatest impact to focus change "to enable informed action" was frequently cited by the DfL working groups [DfL narrative].

Infrastructure & Facilities

Identified as an area ripe for innovation and competition, currently there is a lack of facilities, equipment, processes and specialised staff to be able to process the quanta of medical devices required as the UK shifts to a CE MedTech sector.

Specific challenges to address include:

- Infrastructure costs
  Reverse logistics are a common challenge in CE due to costs of collection and reverse logistics. Some stakeholders queried the cost-benefit of product re-use, given that sterilisation infrastructure had been cut back, and will require additional capital investment to support circular interventions. Considerable investment into CE infrastructure is now needed to enable the transition to a circular MedTech sector.

  "Capacity to clean, decontaminate, and harvest clinical products and clinical instruments remains a significant challenge." [DfL narrative]

- Infrastructure facilities
  Establishing the facilities for the segregation, return and reprocessing of multiple medical devices and materials is widely recognised as a key barrier for clinical teams and hospital facilities, as well as the wider infrastructure provision across the sector.[89]

- Cross-border material recovery
  The import and export characteristics of the current UK MedTech sector represents challenges both in terms of meeting more than one national regulatory barriers and the subsequent cost impact, both financially and environmentally.

- Workforce
  The required workforce with the appropriate skills to scale up and deliver critical decontamination, sterilisation, repair, reprocessing and remanufacturing tasks is not readily available.

Towards a Circular MedTech sector

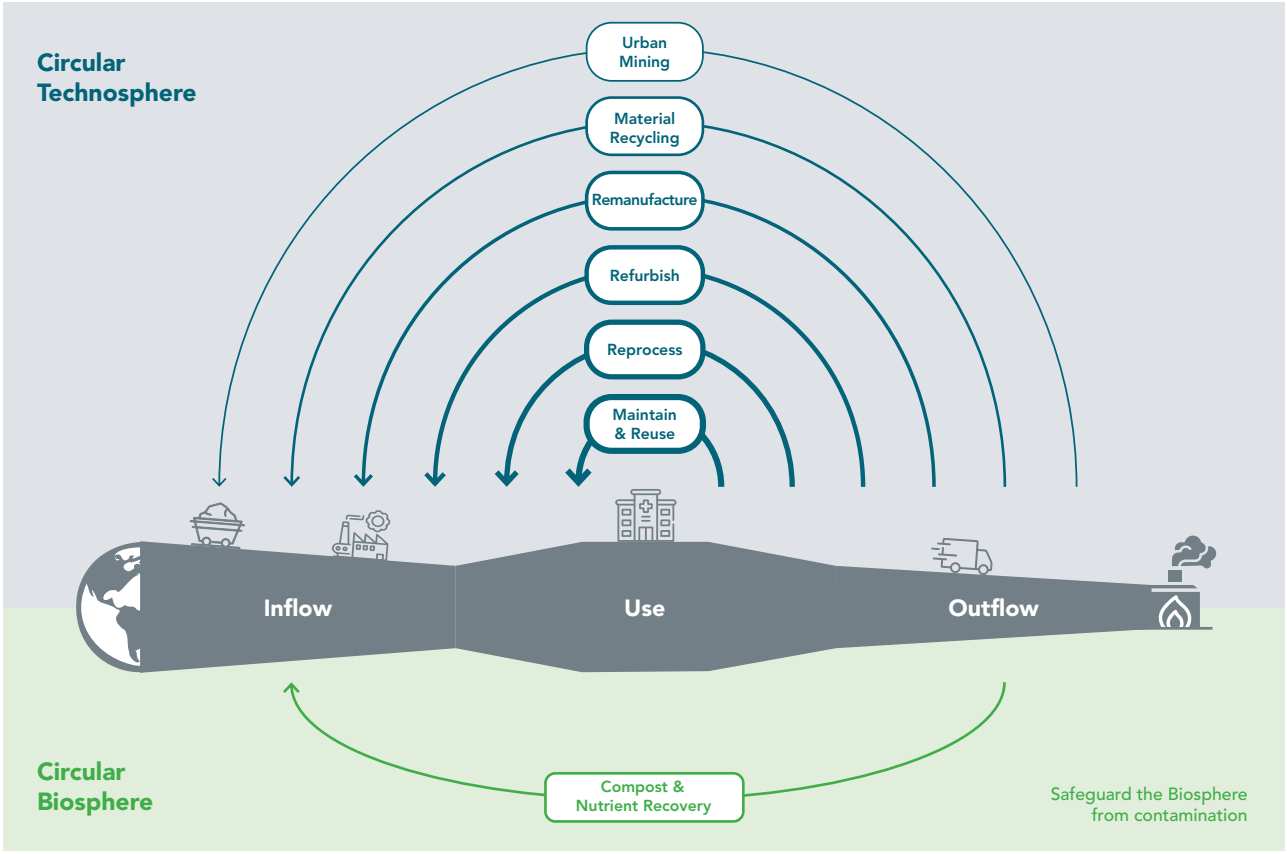
The CE framework provides an overarching conceptualisation of a new type of economy (Figure 14). However, making the value shift is not straightforward, and making the transition often comes up against many embedded features of the existing linear economic model, which continues to deliver many benefits.

The ability to scale up CE practices cannot be achieved instantly and involves the ability to identify, manage and trade off complex interactions between economic, environmental and linear business continuity factors.

This will create internal and external tensions and conflicts, meaning that circular practices are unlikely to be adopted or implemented without co-ordination.

Experience from other sectors shows key success factors to include the need for top level leadership, an overarching value proposition, visibility of stocks and flows of assets across the value chain, investment in digital technologies and tools, to manage complex value creation dynamics and anticipate rapidly changing business environmental and societal requirements.

Figure 14: A Circular MedTech sector



Key Capabilities

To make the shift from linear to circular value creation requires a wide range of capabilities which has implications for leaders, managers and followers. The first implication is the transition and scaling up of a circular model requires the continuous iteration of the four key CE building blocks previously described, with specific requirements and key capabilities in relation to each building block:

Design

From a design perspective, MedTech CE practitioners need to address design for circulation and cascading at the outset to enable repeat sales and design all product and material combinations to not only enhance, but also protect future revenues, rather than designing products and services with their eventual fate as an afterthought.

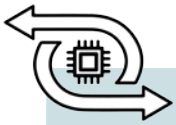
As the case examples have shown, fully integrated design for re-use and cascades requires attention to a variety of issues including material choices affecting disassembly and subsequent biological or technical pathways, durability of design, simplifying products via standardization or modularity of structures and future-proofing equipment, including upward compatibility of software. Without this, OEMs or third-party collaborators may not achieve the full value creation potential from remanufacturing, re-using or cascading assets (see reverse logistics below).

Business Model

From a business model perspective, MedTech is well positioned to make the shift from products to servitisation strategies offering differentiation and competitive advantage, both in terms of added value customer services (new delivery models, service contracts, and performance-based deals) but also ensuring product designs are easy to service and can be repaired or remanufactured at least cost.

The rapid diffusion and lowering costs of digital technology, machine-based learning, data analytics, and embedded intelligence are creating new opportunities for MedTech to create and capture circular opportunities and support the value shift. This can include new service offerings, tracking and managing assets and material flows, and new forms of collaboration to work with intermediaries to achieve economies of scale, scope and density.

In the case of carbon reduction, local economic multipliers, social value, adding positive externalities into the business case at system, organisational or even product level can dramatically affect the return on investment (ROI) and capture the potential 'lost' value, that is typically obscured or opaque in standard linear methods of accounting and business planning. Breaking through this barrier is a potential tipping point for a CE as demonstrated in the both the harmonic shears and surgical PPE case examples presented above.



Reverse Logistics

From a reverse logistics perspective, reaching scale has the potential for reducing costs and maximizing CE network profits. In MedTech, the value recovery from technical durable products, as featured in the case examples, can be enhanced by improving the level of automation of remanufacturing and by co-ordinating actors across all the CE loops rather than focusing solely on individual loops (e.g. remanufacturing or recycling alone). Companies such as Philips have successfully demonstrated such an approach.

From a CE systems perspective, individual or groups of firms can influence broader system enablers and conditions in support of scaling up circularity through developing new collaborations, partnerships and extending the scope of traditional value chains. As demonstrated in the surgical PPE case study, different businesses are working in new ways with upstream and downstream partners, promoting standards to influence client purchasing decisions and support regulation for remanufacture and reuse.

System enablers – Leadership

A key CE managerial capability is the need for constant iteration of the underlying circular proposition and ability to build capacity and leaders, as well as followers, within the business to innovate and be a catalyst for change. Successful leaders who have managed the value shift from linear to circular share four key capabilities:

Firstly, to compound the benefit of the building blocks, leadership and management teams throughout the organisation find strategic ways to resolve some of the fundamental challenges and tensions from CE in their organisations. By accepting these tensions as a potential source for innovation, successful leaders enable and empower teams to develop integrative and re-combinative capabilities to make the value shift which is often unpredictable, complex and dynamic. In MedTech, the volatility of commercial pressures, changing regulatory landscape and faster innovation cycles require dynamic capabilities to manage and realign the transition against competing demands. This requires commitment, structures and incentivisation from management teams.

Secondly, scaling up the circular model, can be anchored through a road map setting out targets and key performance indicators (KPIs) (e.g. a resource productivity or sales target, or net zero ambition) and strategic direction for many of the long-term decisions, such as upgrading technology and using natural discontinuities (such as times of disinvestment, merger, restructuring, recession, trade wars) to replace existing linear capabilities with more circular ones.

The third capability is the ability to recognise the many trade-offs and tensions in the short term. Macro-economic and competitive pressures are a constant, and CE propositions must demonstrate their positive business contribution. Business models are a potential source of growth, market share and profit for OEMs and suppliers, hence the need to develop capabilities in circular business modelling and to improve the existing management system and the day-to-day operations towards more circular practices over time.

Finally, there are many employees, customers, policy makers, stakeholders who have never heard of a CE. The ability to engage different audiences in meaningful ways raises important questions for practitioners across a wider range of business and industrial cases, for example, in how the concept is framed. MedTech and the health service need to develop capabilities in education, training and awareness raising to bring about the individual and collective actions and support for circular economy. Internal CE leadership training and awareness initiatives, such as adopted at Philips, or systems to spread CE innovation across large, complex organisations are needed to show what CE means, why it is important and how it can be applied in practice. External courses such as the Exeter Circular Economy Masterclass, in collaboration with the Ellen MacArthur Foundation, is one example of a course designed to support practitioners, many from MedTech and the health services sector, with tools and know how to initiate and implement the value shift.

Our experience of running the Exeter Circular Economy Masterclass since 2013 highlights that there is a typical CE journey that individuals and their organisations take in making the value shift (Figure 15). The many stakeholders we engaged in the development of this report are also at different stages of their CE journey. Many are in the initial stage, identifying opportunities and ready to move forward, whilst others are initiating or testing pilots and proof of concept. Organisations such as the NHS show characteristics between stages 1 and 2, whilst some OEMs such as Philips, and remanufacturers such as Vanguard, are implementing the higher value loops of CE at scale.

Figure 15: The typical CE journey for organisations (adapted from Zils et al, 2023)

Stage 1

Identify opportunities

- CE discussed in business context with a sense of potential contribution to parts of the agenda.
- Initial scan of internal CE activities and qualifying activities identified.
- Approximate idea of business potential developed but not systemised.
- Unclear direction and missing coordination at a systems level.

Stage 2

Initiate pilots and proof of concept

- Dedicated pilots with clear roles, responsibilities, budgets and success criteria.
- Senior management aware of ongoing initiatives, informed of progress and steering meetings.
- Clear perspective on potential scale up and 'linear' trade offs.
- Initial proof points to show feasibility, contribution and improved business performance.

Stage 3

Implement at scale

- Clear senior management commitment to pursue CE initiatives as core pillar for company performance.
- Clear, ambitious targets for dedicated transformation programme with sufficient funding and resources.
- Understanding and ideas to actively manage emerging trade offs between linear and circular activities.
- Explicit launch of dedicated CE products and services under own brand and vehicles.

Image credit: Getty Images

Key enabling actions by stakeholder group

To accelerate CE adoption at scale, stakeholders across the value chain will be required to adopt different behaviours, often engaging in new activities and decision-making processes, different from current business as usual. To address the complex stakeholder landscape, complete within inherent power imbalances, there is the need to identify key leadership and coordination roles as proposed here:

Regulators & policymakers

Catalysts

Industry & supply chain

Innovators

Clinicians & Patients

Pioneers

Healthcare providers & NHS

Accelerators

Academics & research partners

Investigators

Regulators & policymakers: Catalysts

There is an urgent need for a clear overarching vision, supported by an appropriately ambitious standards and regulation landscape, aligned to global markets, to set the direction of travel towards a circular MedTech economy.

Policymakers and regulators can catalyse change across the system by:

- Galvanising stakeholders in the co-creation of a common language and shared vision for Circular MedTech sector.
- Developing a well-structured, practical roadmap for change including delineated pathways for stakeholders, technological and infrastructure requirements.

This vision and roadmap will need to be supported by:

- Definition of standards to enable the implementation of circularity at different levels and scales (design, business model, reverse logistics and systems).
- Policy alignment and harmonisation across the value chain, integrating circularity into existing governance structures of regulatory bodies.
- International collaboration to develop global regulation, building on the UK's market leading position and regulatory alignment with global standards and trends.
- Development of circular and sustainability performance metrics, backed by a standardised methodology, enabling stakeholders to assess the environmental impact and supply resilience of MedTech devices more easily.
- Evidence based identification of product and service categories and care pathways that prioritise and balance resilient patient care and environmental impact, to realise the greatest transformational change.

Policy makers can also catalyse change across the funding landscape through:

- Developing targeted CE innovation investment funding, aimed at collaborative circular projects engaging clinicians and supply chain (with a focus on SMEs).
- Embedding funding mechanisms, incentives and tariffs to support CE interventions and long-term value-based procurement, defining critical measures of success and prioritised KPIs.
- Establishing cross-sector collaboration to develop an Infection Prevention and Control Circular Economy Framework, closing the gap between emerging evidence and existing guidelines.
- Commissioning behavioural insight work to provide evidence around the influence and decision making of clinicians and patients that impact circular adoption.

Furthermore, policy makers and regulators can play a key role in supporting other stakeholders to implement circular approaches to design and manufacture including:

- Accelerating a shift in MHRA guidelines to increase the range of remanufactured devices available in the UK. Opportunity exists to extend regulatory schemes from other healthcare nations (such as FDA) as well as to amend MHRA guidelines to allow remanufacture of Class I devices.
- Developing an expedited, risk-based post-approval process to support manufacturers transitioning existing devices to enable increased circularity.
- Supporting the expansion of current pilots and scaling of existing circular activity as part of product-category specific roadmaps, building the evidence base for change.
- Addressing challenges around waste regulations to enable reverse flow of materials.
- Establishing funding for feasibility studies to identify the need for reconfiguring operational infrastructure and new organisational systems to capture and valorise waste.
- Mapping existing sterilisation and decontamination services capacity (infrastructure and workforce), funding research to quantify requirement to meet demands of circular MedTech sector and most effective delivery.

Industry & supply chain: Innovators

Many OEMs, suppliers and innovators are already building CE MedTech business models. An overarching vision will increase the strength of signals to accelerate and amplify CE innovation and reduce investment risk.[90]

"The sentiment from industry was that they have the resources and capability to make the transition, what they need is clarity of what direction to invest in, and the flexibility to find the best way to deliver that." [DfL narrative]

Industry and supply chains can utilise the power of innovation to realise change themselves by:

- Engaging with value chain stakeholders, CE engineers and designers for user-centred circular product and service system co-creation.
- Collaboration with regulators and healthcare providers to develop, create and embed procurement and funding mechanisms, incentives & tariffs to accelerate CE adoption and identify commercial transition strategies to minimise first mover disadvantage and deliver shared risk.
- Collaboration with academics and research partners including provision of product and category specific data to develop feasibility models, particularly around device Bill of Materials (BoM).
- Accelerating investment in innovation cycles with a CE focus:

  - Critically challenging the clinical need for SUDs.

  - Improving material selection and adopting circular design principles to facilitate cascading use cycles, including the ability to remanufacture and facilitate material recovery.

  - Exploring digital innovations such as sharing platforms, asset management systems and tools to optimise utilisation of resources.
- Prioritising CE training and awareness both internally and through establishing businesses that promote and market design for circularity as core training across healthcare professionals to increase awareness and engagement.

Clinicians & patients: Pioneers

It was observed that many existing circular interventions are driven by pioneering clinicians, professional bodies and third sector groups, such as the Sustainable Healthcare Coalition. These stakeholders are critical to successful circular business model innovation and adoption, holding essential insight on actual service and device design.

Culture and behaviour change is a focus for all actors across the value chain when shifting to a CE, and most specifically for clinicians and patients, who in circular systems will need to adapt to their role as custodians of products and partners in service delivery, rather than consumers of SUDs.

Clinicians and patients can lead the way through:

- Collaboration with NHS and industry to share behavioural insights and identify practical and deliverable circular value creation opportunities.
- Embracing CE leadership and knowledge development around the opportunity of circular strategies, encouraging culture change and adoption of an innovative mindset, especially around the perceived risk of reusable devices and recognising waste as a resource.
- Engaging with wider stakeholders to develop CE innovation investment opportunities, aimed at developing collaborative circular projects.

Healthcare providers & NHS: Accelerators

As the primary procurer of medical devices in the UK, the NHS has a position of influence over the value chain, exemplified by response to the ambitious net zero targets. Alongside other healthcare providers, the NHS is a lynchpin in accelerating a shift to circularity through:

- Adoption of a Circular MedTech Vision within the Integrated Care Systems (ICS) as a public commitment to change, embedding within the policy of each board.
- Leading a mechanism for collaboration and continuous exchange of information from across the MedTech value chain from which to accelerate understanding of material stocks and flows.
- Mapping economic barriers and enablers to circularity within existing NHS procurement frameworks and developing updated procurement models to support and incentivise circular products and services, taking a long term, systems level, value-based approach.
- Engaging with DHSC and research partners in the identification of priority areas with regards to supply vulnerability and environmental impact, developing product category specific roadmaps for greatest transformational change.
- Establishing a dedicated CE category embedded within NHS Innovation services and creating a more direct route for UK Innovation channels such as ESPRC, UKRI, SBRI and NIHR to feed into frameworks.

With a focus on facilities and workforce, the NHS and healthcare providers can accelerate change through:

- Collaboration with industry, clinicians, patients and resource managers to facilitate user-centred circular product & service design, especially to understand current practice and facilitate reverse logistics for material flows.
- Implementing feasibility studies to identify infrastructure needs and explore new organisational systems to enable CE processes utilising NHS Supply Chain.
- Developing a CE education and awareness programme, including circularity as core training across NHS and healthcare professionals to increase awareness and engagement.

Academic and research partners: Investigators

There is no 'silver bullet' for successful CE implementation but instead it is a continuous process of situational business model development, piloting, learning and iterating to reach scale.[91] With a focus on data and technology, academics and research partners have the role of delivering applicable, cross-sector insight, updated standards and frameworks for change, accelerating CE learning and knowledge sharing.

Key opportunities for academia and research partners include:

- Providing agnostic frameworks to demonstrate CE value creation, with a mechanism for pre-competitive data sharing to provide data aggregation and analysis, and scenario-modelling.
- Developing modelled case studies demonstrating the business case for CE adoption, identifying value creation opportunities and decision-making processes in the short, medium and long term.
- Collaborating with industry partners to define criteria and identifying prioritised key metrics which are relevant and reliable to demonstrate sustainability and circularity performance.
- Developing a standardised methodology, enabling stakeholders to assess the environmental impact and supply resilience of MedTech devices.

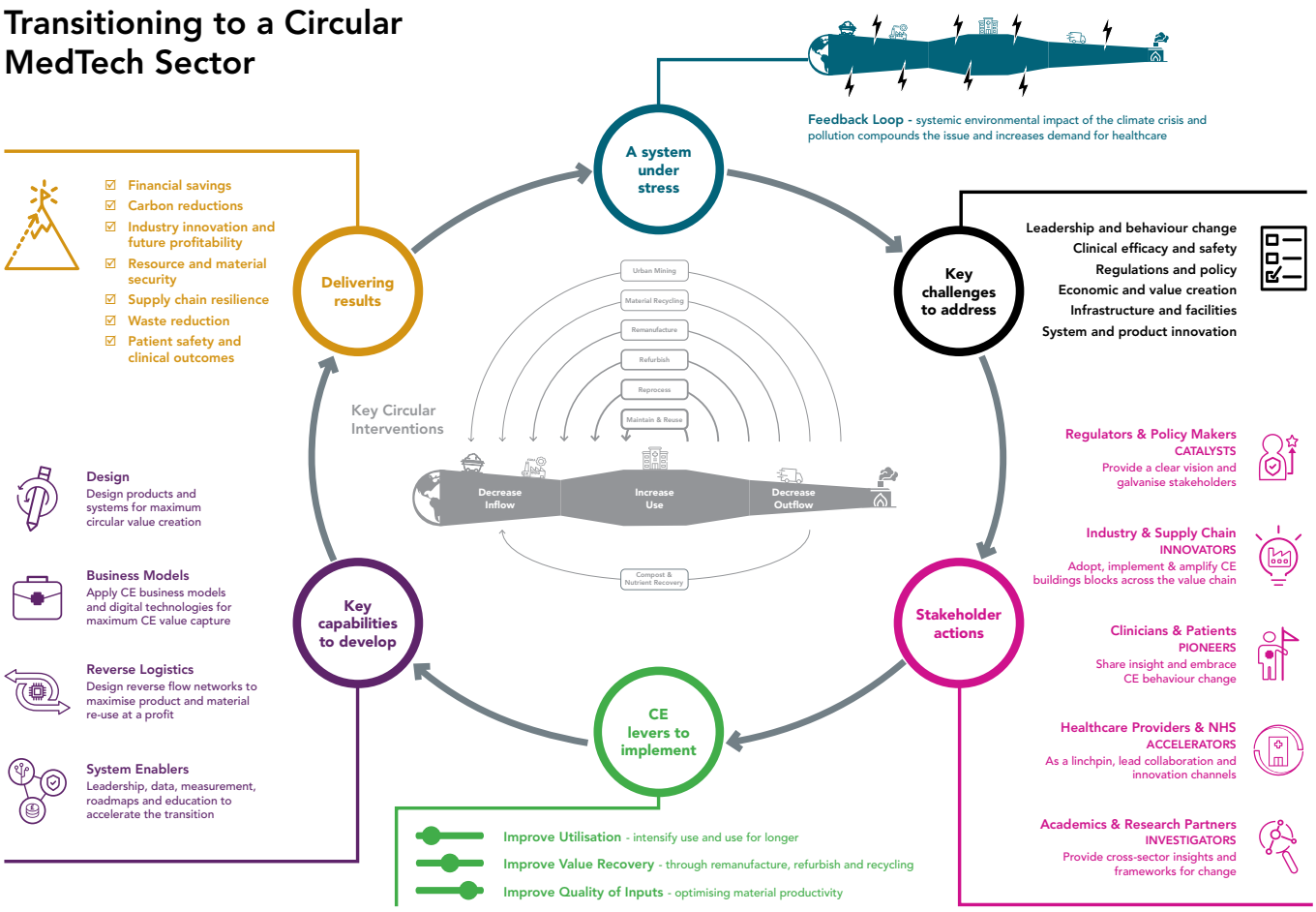
Through leading interdisciplinary research capabilities, academics can also advance circularity in MedTech through:

- Applying cross-industry insight to enhance the evidence base for change.
- Engaging advances in digital technologies and approaches to accelerate circular solutions at material, product and systems levels.
- Supporting the MedTech sector with knowledge sharing and education around CE innovation and implementation.

What next for UK MedTech?

This report underscores that a circular economy offers a tangible solution to the systemic challenges faced by the UK MedTech sector (Figure 16).

Figure 16: Transitioning to a Circular MedTech Sector



Illustrative examples presented indicate that a CE has a positive business case with the potential to save the health service hundreds of millions of pounds in the short term through procurement savings, deliver significant carbon savings, drive private sector innovation and future profitability, and fulfil government policy commitments for MedTech resource security, resilience and waste, while protecting patient safety and clinical outcomes.

However, despite a number of promising pilots and isolated case studies, USA and European comparators are further ahead in the adoption and implementation of a circular economy within the sector. Achieving a circular MedTech system of the future within the UK is a priority that requires clear leadership and collaborative forward-looking actions from all stakeholders throughout the value chain.

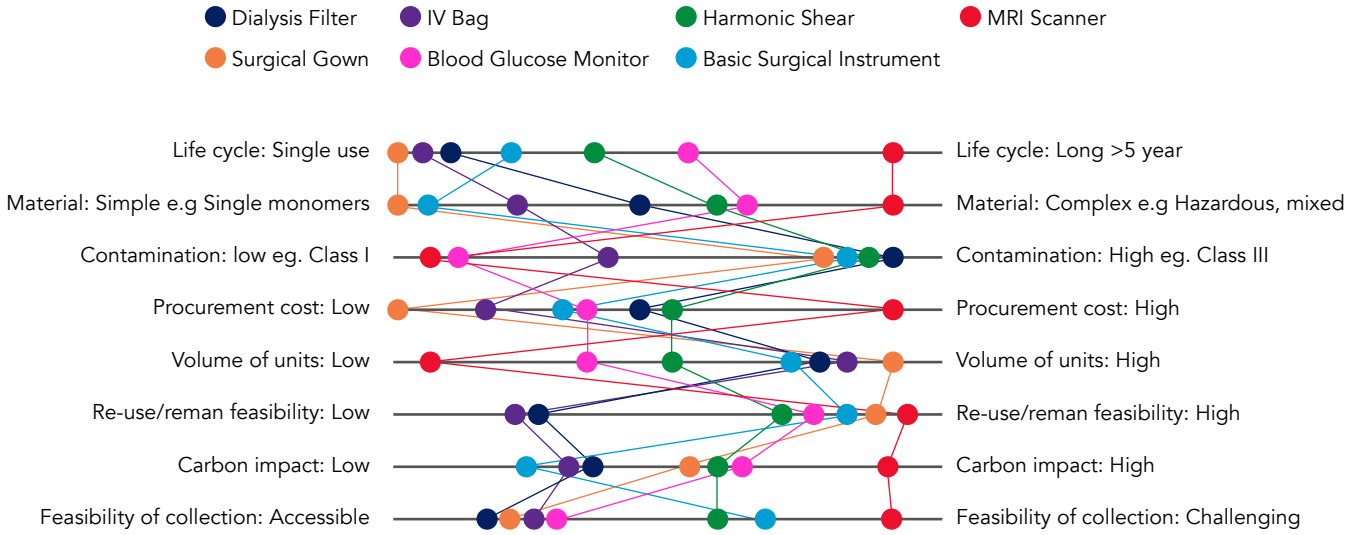
As Phase 1, this report provides a diagnostic of current CE systems level maturity to identify key pain points, potential opportunities for value creation and future pragmatic piloting and experimentation across a wider range of MedTech applications and cases, in the next phase (Figure 17).

Figure 17: Adopting a circular MedTech system

Phase 1	Phase 2	Phase 3
Identify opportunities and potential value	Initiate pilots to create proof of value	Implement at scale and systematically integrate
• **Diagnostics** of current systems-level maturity. • **Identification** of most important pain points and potential value creation. • **Outline opportunities** for pragmatic piloting and experimentation in Phase 2.	• **Build underlying systems** and data representation. • **Build consortium** of industry and government players to create proof of value. • **Synthesis required capabilities** and specifications for scaling in next phase.	• **Establish governance and IT structure** for scaling across value chains and signature products at scale. • **Enlarge sub-industry consortia** to drive data pools. • **Integrate capabilities systematically** into government decision making and industry collaboration.

Phase 2 requires the initiation of a dedicated and co-ordinated programme of pragmatic pilots to create further proof of value. To ensure consistency of approach, this requires building the underlying systems and data requirements through consortia of policymakers, industry and health service against an agreed taxonomy. Figure 18 provides an illustrative taxonomic approach against a short list of criteria and signature devices and products suggested by stakeholders (a longer list of potential case studies and criteria are shown in Appendix E.

Figure 18: Illustrative sample classification of MedTech use cases



Sample Classification of MedTech Use Cases (Illustrative example)

To implement CE at national scale requires systematic integration of a taxonomic approach, a common data framework and an IT infrastructure within an agreed governance structure, as is emerging in other sectors and approaches globally. Findings and successes from Phase 2, with learnings from across a signature set of devices and services, would provide the confidence and support to enlarge and set up further policy-industry-health service consortia to drive data pooling and the evidence for proof of value. Learnings and experience from this stage will identify and develop the dynamic capabilities required for total system integration into governmental, industry, and health service decision making and collaboration.

Image credit: Getty Images

Glossary

These terms are taken from a combination of institutional definitions, published literature or DfL Collaborative resources that have been collated through the course of the research.

Bill of Materials: An extensive list of raw materials, component and instructions needed to construct or manufacture a product or service.

British Standard Institute (BSI): The national standards body of the UK, producing technical standards on products and services, and providing certification.

Carbon Footprint: A calculated value which details the total amount of greenhouse gas emissions (GHG) that a product or activity add to the atmosphere, usually reported in tonnes of emissions (tonnes CO2e)

Carbon Intensity: A calculated value which details the amount of greenhouse gas emissions (GHG) per unit of activity or output.

CE Mark: A mark confirming that the manufacturer or importer verifies the goods' conformity with European health, safety and environmental protection standards.

Circular Economy: In contrast to a linear economy in which products and materials are made, used, and then thrown away, a Circular Economy focuses on regeneration, restoration, and re-use at all stages of a resource's life cycle. This allows products, materials, and components to remain in circulation at their highest value for the longest period, and the waste generated by a linear economy is designed out from the start.

Cleaning: A process that physically removes contamination but does not necessarily destroy micro-organisms.

Clinical Waste: Waste from a healthcare activity that contains viable micro-organisms or their toxins which are known or reliably believed to cause disease in humans or other living organisms; contains or is contaminated with a medicine that contains a biologically active pharmaceutical agent; or is a sharp; or a body fluid or other biological material containing or contaminated with a dangerous substance.

Clinician: A trained health care professional who works directly with patients, rather than in a laboratory or research setting.

Component: A constituent part of equipment that cannot be physically divided into smaller parts without losing its character and that combines with other parts to form a Product.

Compound Annual Growth Rate (CAGR): The mean annual growth rate of an investment or market sector over a specified period of time of more than one year.

Consumable: A product or component that is intended to be consumed or used, often singularly, quickly or for a short period of time.

Critical Materials: A substance, most commonly minerals and metals, used in technology that has a growing economic importance and high risk of supply shortage.

Decontamination: A process which removes or destroys contamination and thereby prevents micro-organisms or other contaminants reaching a susceptible site in sufficient quantities to initiate infection or any other harmful response. Three processes of decontamination are commonly used: cleaning, disinfection, sterilization.

Department of Health and Social Care (DHSC): The central government department with responsibility for policy, legislation, funding and delivery of health and care in England, working in coordination with the governments and health authorities across the devolved nations.

Disassembly: The process of taking apart of an assembled product into constituent components or materials.

Disinfection: A process used to reduce the number of viable micro-organisms but which may not necessarily inactivate some bacterial agents, such as certain viruses and bacterial spores.

Disposal: Any operation which is not recovery, even where the operation has, as a secondary consequence, the reclamation of substances or energy.

Food and Drug Administration (FDA): The organisation responsible for protecting human health in the United States by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, food supply, cosmetics, and products that emit radiation.

Greenhouse Gases (GHG): A collection of gases in the Earth's atmosphere which trap heat through absorbing infrared radiation and reflecting it back to the Earth's surface, most notably carbon dioxide and methane.

Health Service: A service provided to protect and improve health, prevent diseases, treat patients and deliver medical and social rehabilitation to provide quality and long life.

Interoperability: The ability of two or more devices, including software, from the same or different manufacturers, to work together as intended, including information exchange and communication where necessary.

Lifecycle: The consecutive and interlinked stages from raw material acquisition or generation from natural resources to final disposal.

Lifecycle Assessment (LCA): A method for assessing the environmental impact of a product or service, covering the entire lifecycle.

Maintenance: Activities carried out to keep a product in its original, useable state within the current life cycle.

Material: A physical substance or element that things can be made from.

Material intensity: A calculated measure of the materials needed for the production, processing and disposal of a unit of a good or service.

Material Recovery: The extraction and restoration of materials found in the waste stream for reuse and recycling.

Medical and Healthcare products Regulatory Agency (MHRA): The agency responsible for the regulation of medicines, medical devices and blood components for transfusion in the UK, operating in a statutory framework set by HM Government.

Medical Device: Any instrument (other than a medicine) that is used to diagnose, monitor, treat or manage a medical condition. The definition includes In vitro diagnostic and active implantable medicals devices, and covers a wide range of products including syringes, dressings, surgical tools, scanners, software, apparatus, machines and some medical apps.

Medical Equipment: Medical equipment are medical devices requiring calibration, maintenance, repair, user training and decommissioning, activities usually managed by clinical engineers.

Medical Technology (MedTech): A broad field of innovative or technology based products, services and solutions that are utilised within the healthcare sector, including Medical Devices.

National Health Service (NHS): The umbrella term for the publicly funded healthcare system in the UK, under government administration, comprising NHS England, NHS Scotland, NHS Wales and Health and Social Care (HSC) in Northern Ireland.

Net zero: The state when greenhouse gas emissions (GHG) are as close to zero as possible, with any remaining emissions re-absorbed from the atmosphere, by oceans and forests.

Original Equipment Manufacturer (OEM): The natural or legal person who manufactures a device or has a device designed, manufactured and markets that device under their name or trademark.

Product: An item or service (either physical or virtual) offered for sale, as reported annually to the UK Office of National Statistics, concerning manufactured products included in the EU ProdCom list.

Product life extension: Activity which lengthens the period of time a product can be used before a cascade or ultimate disposal.

Recycle: Turning a material which has previously been used into a new product or component. A downcycle occurs when the material is degraded from its original form, and cannot be returned to the same level of material health or functionality.

Refurbish: The industrial process which returns a used product, or component to a satisfactory performance level when made available on the market as a used product

Remanufacture: The industrial process which creates a new product, from used products or components, which can be placed on the market. In the global MedTech context, used interchangeably with the term reprocess.

Repair: Returning a faulty, worn or broken product or component back to a usable state.

Reprocess: A process carried out on a used device to allow its safe reuse, including cleaning, disinfection, sterilisation and related procedures, as well as testing and restoring the technical and functional safety of the used device. In the global MedTech context, used interchangeably with the term remanufacture.

Repurpose: To use a product or component in a role that it was not originally designed to perform, in some cases leading to substantial alteration. This action does not relate to materials which fall under recycling.

Reuse: To complete another episode of use, or repeated episodes of use, of a medical device which has undergone some form of reprocessing or has been fully refurbished between each episode.

Reusable Medical Device: A device intended for repeated use either on the same or different patients, with appropriate cleaning and other reprocessing between uses.

Risk Stratification: A process of predictive modelling which enables health risk levels to be categorised based on objective and subjective factors.

Scope 3: All indirect GHG emissions that occur in the value chain of the company, including both upstream and downstream emissions, not included in Scope 2 emissions (from the generation of purchased energy).

Single Use Medical Device (SUD): A single use medical device is intended to be used on an individual patient during a single procedure and then discarded.

Sterilisation: A process used to make an object free from all viable micro-organisms including viruses and bacterial spores.

Total Cost of Ownership: The costs incurred from the creation, fabrication, use, maintenance and final disposal and elimination of a product. Also referred to as whole-life cost.

UKCA Mark: A mark confirming that the manufacturer or importer verifies the goods' conformity with the UK Medical Device Regulation 2002.

Use intensification: Activity which enables a product or service to be used more within a defined period of time, increasing performance metrics.

Value chain: The full lifecycle of a product or process, including raw material extraction, sourcing, production, distribution, consumption and ultimate disposal or recycling.

Value creation: Actions within the steps of a value chain which create or add value. Traditionally reported in terms of financial gain to stakeholders, but more recently also recognised as environmental and societal value.

Appendices

Appendix A: DfL Collaborative overview

The Department of Health and Social Care (DHSC) published the UK Government's Medical Technology Strategy in February 2023. The Strategy focused on four priority pillars including improving resource security and efficiency and the Design for Life Collaborative was established to address this priority pillar. Six working groups were created to look at the challenges associated with shifting to a circular economy in MedTech.

These working groups focused on the following themes:

1. Product Design
2. Clinical Efficacy and Safety
3. UK Growth and Economic Opportunity
4. Commercial Models and Logistical Changes
5. Infrastructure and Workforce

Appendix B: Organisations engaged with the DfL Collaborative

Industry & Supply Chain	NHS & Healthcare providers	Policymakers & Regulators	Clinicians & Patients	Academics & Research Partners
ABHI	NHS England	AHSN	Black Country Alliance	CE Hub / University of Exeter Centre for Circular Economy
AXREM	NHS Scotland	BSI	East Suffolk and North Essex NHS Foundation Trust	ESPRC
Baxter	NHS Supply Chain	DBT	Great Western Hospitals NHS	High Value manufacturing catapault
BBraun	NHS Wales Shared Services	Defra	Leeds Teaching Hospital Trust	UK Critical Minerals Intelligence Centre
BD		DESNZ	Manchester University NHS Foundation	UKRI
BIVDA		DHSC	Queens Nursing Institute	University of Cambridge
Boston Scientific		Environment Agency	Royal College of Nursing	
British Plastics Association		MHRA		
Coloplast		Scottish Government		
Cook Medical				
Denroy Plastics				
Gambica				
Institute of Decontamination services				
Johnson & Johnson				
Kimal				
Medtronic				
Nutricia				
PD-M				
Pennine Healthcare				
Philips				
RevolutionZERO				
Surgical Holdings				
Roche				
Steris				
TFX Group				
Vanguard				

Appendix C: DfL Workshop Series

Following the DfL Discovery Day held in March 2023, a series of three workshops were co-delivered by the CE Hub team and the DfL Collaborative team to the DfL Working groups with an attendance of between 40-50 in total on each occasion. In addition to the workshops, the working groups were asked to progress independent research and information collation around their specific challenge area, culminating is a short narrative and series of recommended actions.

An overview of the workshop series is as follows:

- **Workshop 1: 30 June 2023, 9am – 1pm**
  Presentation on an introduction to CE, Discovery Day findings, working group terms of reference and objectives, CE value creation opportunities and presentation of illustrative case example, working group discussion and feedback on individual challenge and key areas of exploration.
- **Workshop 2: 20 July 2023, 9am – 1pm**
  Working group updates, exercise exploring product selection criteria, presentation on roadmap strategy development, working group discussion and feedback on action plan recommendations, including prioritization, timeframes and noting co-dependencies.
- **Workshop 3: 22 Sept 2023, 9am – 1pm**
  Working group presentation of recommended actions for each challenge area, presentation on behaviour change and CE systems design, presentation on CE value chain data modelling, recap of workshop series, working group discussion around commonalities and prioritisation of recommended actions.

Appendix D: Medical device categorisation and regulation

All medical devices must be registered with the MHRA before being offered into the UK market. For Great Britain (covering England, Wales & Scotland) medical devices are regulated through conformity assessment by Medical Devices Regulations 2002 (SI 2002 No 618, as amended; UK MDR 2002). In Northern Ireland, they are regulated through the EU Medical Devices Regulation (2017/745) and the In vitro Diagnostic Medical Device Regulation (2017/746), since 2021 and 2022 respectively.[92]

Upon registration, each medical device is assigned a category (according to the intended use) and a class (according to the inherent risk) as detailed below.[93]

Categories of medical devices

Category	Definition	Examples
1. Non-invasive	Devices which do not enter the body	Plasters, walking sticks, wheelchairs, artificial kidneys (external dialysis)
2. Invasive	Devices inserted into the body's orifices	Contact lenses, enemas, examination gloves
3. Surgically invasive	Devices used or inserted in surgery	Needles, scalpels, cardiovascular catheters
4. Active	Devices requiring an external source of power	X-ray equipment, ultrasound, TENS devices
5. Implantable	Devices implanted into the body	Breast implants, orthopaedic implants, intraocular lenses

Categories of medical devices

Class	Level of risk	Examples
Class I	Low risk	Wheelchairs, spectacles, stethoscopes, tongue depressors
Class IIa	Medium risk	Dental fillings, surgical clamps, tracheotomy tubes
Class IIb	Medium risk	Condoms, lung ventilators, bone fixation plates
Class III	High risk	Pacemakers, heart valves, implanted cerebral stimulators

An additional, and globally recognised, method of classifying medical devices is according to the decontamination required using the Spaulding system, originally proposed in 1957. A summary is detailed below.

Spaulding classification of medical device decontamination[94]

Classification	Definition	Level of (re)processing	Examples
Critical	Items penetrating body tissues allowing for direct contact with the bloodstream or another sterile area of the body	Cleaning followed by sterilization after every use, between clients and if item becomes contaminated	Surgical and dental instruments, biopsy equipment, dental equipment, foot and nail equipment
Semi-critical	Items that come into contact with non-intact skin or intact mucous membranes, but do not penetrate body surfaces	Cleaning followed by high level disinfection (at minimum), sterilization preferred. After every use, between clients and if item becomes contaminated.	Reusable ear syringe nozzles, trans-rectal probes, vaginal, nasal and rectal specula
Non-critical	Items that do not touch the client or touch only intact skin, but no mucous membranes	Cleaning followed by low level disinfection. In some cases, cleaning alone is acceptable.	Stethoscopes, shared wheelchairs, treatment surfaces, blood pressure cuffs, stethoscopes, shared walking aids

Appendix E: Summary of potential assessment criteria and products

Life cycle: short/ single use/ consumable	Life cycle: long >5 year/ durable
Material composition: simple e.g. single monomers	Material composition: complex e.g. hazardous, mixed
Level of contamination: low e.g. Class I	Level of contamination: high e.g. Class III
Procurement cost: low	Procurement cost: high
Volume of units: low	Volume of units: high
Re-use/reman feasibility: low	Re-use/reman feasibility: high
Waste disposal cost: low	Waste disposal cost: high
Carbon impact: low	Carbon impact: high
Projected future demand: decreasing	Projected future demand: increasing
Feasibility/ease of collection: accessible	Feasibility/ease of collection: challenging
Residual material value: low	Residual material value: high
Digitally enabled: no/low	Digitally enabled: yes/high
Interplay products: standalone	Interplay products: larger service pack
Critical material content: low	Critical material content: high
Legislative requirements: low	Legislative requirements: high
Supply chain vulnerability: on/near shore, simple	Supply chain vulnerability: off/far shore, complex

Products

IV bag and tubing
Harmonic shears
Basic surgical instruments
MRI scanner
Pulsed vac/lavage systems
Surgical gowns and drapes
Blood glucose monitors
Dialysis filters
Ultrasound machine
Kidney tray
Syringes
Blood tubes
Tracheostomy tubes
Orthopaedic implants

References

Association of Medical Device Reprocessors (2021) 'Reprocessing by the numbers', AMDR.org. Available at: https://amdr.org/newsroom/reprocessing-by-the-numbers/ (Accessed: 30 January 2024).

Association of Medical Device Reprocessors (2022) 'Global regulatory standards for single-use device reprocessing/remanufacturing'. Available at: https://amdr.org/wp-content/uploads/2022/06/AMDR-Standards-05312022_FINAL_OUT-1.pdf (Accessed on 2 February 2024).

Benedettini, O. (2022) 'Green servitization in the single-use medical device industry: How device OEMs create supply chain circularity through reprocessing'. Sustainability, 14, 12670. doi: 10.3390/su141912670.

Boag, K., Ho, T., Culmer, P., Pike, T., Jayne, D. G., Peckham-Cooper, A., and Quyn, A. J. (2022) 'Introducing green innovation into clinical practice'. The Bulletin of the Royal College of Surgeons of England, 104(3), pp. 140–144. https://doi.org/10.1308/rcsbull.2022.47.

Brighton & Sussex Medical School, Centre for Sustainable Healthcare, & UK Health Alliance on Climate Change (2023) Green surgery: Reducing the environmental impact of surgical care. London: UKHACC. Available at: https://ukhealthalliance.org/sustainable-healthcare/green-surgery-report/ (Accessed on 2 February 2024).

British Medical Association (2023) 'Health Funding Data Analysis'. Available at: https://www.bma.org.uk/advice-and-support/nhs-delivery-and-workforce/funding/health-funding-data-analysis (Accessed: 30 January 2024).

British Medical Association (2024) 'NHS Backlog data analysis'. Available at: https://www.bma.org.uk/advice-and-support/nhs-delivery-and-workforce/pressures/nhs-backlog-data-analysis (Accessed: 30 January 2024).

Centre for Sustainable Healthcare (no date) 'NHS Scotland sustainability strategy resources and support'. Available at: https://sustainablehealthcare.org.uk/green-plan/nhs-scotland-sustainability-resources (Accessed on 1 February 2024).

Crawford T. C., Eagle K. A. (2018) 'Reuse of catheters and devices labelled for single use: evidence, recommendations and oversight', Heart Asia, 0(2): e011033. doi: 10.1136/heartasia-2018-011033

Department of Health and Social Care (2022) Health and Social Care Act 2008: Code of practice on the prevention and control of infections and related guidance. GOV.UK. Available at: https://www.gov.uk/government/publications/the-health-and-social-care-act-2008-code-of-practice-on-the-prevention-and-control-of-infections-and-related-guidance/health-and-social-care-act-2008-code-of-practice-on-the-prevention-and-control-of-infections-and-related-guidance (Accessed on 2 February 2024).

Department of Health and Social Care (2021) 'Factsheet: Medical Devices Overview'. GOV.UK. Available at: https://www.gov.uk/government/publications/medicines-and-medical-devices-bill-overarching-documents/factsheet-medical-devices-overview (Accessed on 2 February 2024).

Department of Health & Social Care (2023) 'Medical technology strategy', Policy paper. GOV.UK. Available at: https://www.gov.uk/government/publications/medical-technology-strategy/medical-technology-strategy (Accessed: 30 January 2024).

Ellen MacArthur Foundation (2021) 'Pioneering circularity in the healthcare industry: Royal Philips'. Available at: https://www.ellenmacarthurfoundation.org/circular-examples/pioneering-circularity-in-the-healthcare-industry-royal-philips (Accessed on 2 February 2024).

Ellen MacArthur Foundation (2023) 'Locked in: What is linear lock-in and how can we break free?'. Available at: https://www.ellenmacarthurfoundation.org/articles/locked-in-what-is-linear-lock-in-and-how-can-we-break-free (Accessed on 2 February 2024).

Fuller, R., Landrigan, P. J., Balakrishnan, K., Bathan, G., Bose-O'Reilly, S., Brauer, M., Caravanos, J., Chiles, T., Cohen, A., Corra, L., Cropper, M., Ferraro, G., Hanna, J., Hanrahan, D., Hu, H., Hunter, D., Janata, G., Kupka, R., Lanphear, B., Lichtveld, M., Martin, K., Mustapha, A., Sanchez-Triana, E., Sandilya, K., Schaefli, L., Shaw, J., Seddon, J., Suk, W., Téllez-Rojo, M. M., and Yan, C. (2022) 'Pollution and health: a progress update'. The Lancet Planetary Health, 6, e535–e547. https://doi.org/10.1016/S2542-5196(22)00090-0

Garratt, K., Kirk-Wade, E., Harker, R., Mirza-Davies, J. (2023) 'The NHS Workforce in England', Research Briefing, House of Commons Library. Available at: https://commonslibrary.parliament.uk/research-briefings/cbp-9731/ (Accessed: 30 January 2024).

Gillett, F., Bowden, G. (2021) 'Budget 2021: NHS in England to receive £5.9bn to cut waiting lists', BBC News. Available at: https://www.bbc.co.uk/news/uk-59030945 (Accessed: 30 January 2024).

Guzzo, D., Carvalho, M. M., Balkenende, R., and Mascarenhas, J. (2020) 'Circular business models in the medical device industry: paths towards sustainable healthcare'. Resources, Conservation and Recycling, 160, 104904.

Healthcare LCA (no date) 'A database of environmental assessments within healthcare'. Available at: https://healthcarelca.com/ (Accessed on 2 February 2024).

Hopkinson, P., MacInnes, N., Cunningham, N., Lysaght, O., Charnley, F., Nolan, R., & Zils, M. (2023) 'Is the circular economy illegal? UKRI Circular Economy Hub Discussion Paper (CE-Hub DP 2023-1). Available at: https://ce-hub.org/knowledge-hub/is-the-circular-economy-illegal/ (Accessed on 2 February 2024).

Hoveling, T., Svindland Nijdam, A., Monincx, M., Faludi, J., and Bakker, C. (2023, unpublished) 'Barriers and opportunities to circularizing digital health devices and an inventory of best practices'. Digital Health in a Circular Economy (DiCE).

Kane, G. M., Bakker, C. A., and Balkenende, A. R. (2018) 'Towards design strategies for circular medical products'. Resources, Conservation and Recycling, 135, pp. 38–47.

Keil, M., Viere, T., Helms, K., and Rogowski, W. (2023) 'The impact of switching from single-use to reusable healthcare products: A transparency checklist and systematic review of life-cycle assessments'. European Journal of Public Health, 33(1), pp. 56–63. doi: 10.1093/eurpub/ckac174.

Khan, Z. (2023) 'The emerging challenges and strengths of the national health services: A physician perspective', Cureus, 15(5), e38617. doi: 10.7759/cureus.38617.

Kopp, W. (2019) 'How western diet and lifestyle drive the pandemic of obesity and civilization diseases', Diabetes Metab Syndr Obes, 12, 2221-2236. doi: 10.2147/DMSO.S216791.

MacNeill, A. J., Hopf, H., Khanuja, A., Alizamir, S., Bilec, M., Eckelman, M. J., Hernandez, L., McGain, F., Simonsen, K., Thiel, C., Young, S., Lagasse, R., & Sherman, J. D. (2020) 'Transforming the medical device industry: Road map to a circular economy', Health Affairs, 39(12), pp. 2088–2097.

Mahjoob, A., Alfadhli, Y., and Omachonu, V. (2023) 'Healthcare waste and sustainability: Implications for a circular economy'. Sustainability, 15(10), 7788. https://doi.org/10.3390/su15107788

McGeoch, L., Hardie, T., Coxon, C., and Cameron, G. (2023) 'Net zero care: What will it take?'. Available at: https://www.health.org.uk/publications/long-reads/net-zero-care-what-will-it-take (Accessed 5 February 2024).

MedGadget (2020) 'Refurbished medical equipment market – Global industry analysis, size, growth, share, trends, segmentation, opportunity and forecast 2020 to 2025'. Available at: https://www.medgadget.com/2020/07/refurbished-medical-equipment-market-global-industry-analysis-size-growth-share-trends-segmentation-opportunity-and-forecast-2020-to-2025.html (Accessed on 1 February 2024).

Medicines and Healthcare Products Regulatory Agency (2020) 'Regulating medical devices in the UK'. GOV.UK. Available at: https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk#legislation-that-applies-in-great-britain (Accessed on 2 February 2024).

MedTech Europe (2022) 'The European Medical Technology Industry in Figures 2022'. Available at: https://www.medtecheurope.org/wp-content/uploads/2022/09/the-european-medical-technology-industry-in-figures-2022.pdf (Accessed: 30 January 2024).

Moore Jr, J., Kutlu, Y. (2023) 'Sectoral systems of innovation and the UK's competitiveness: The UK MedTech sector', Imperial College London. Available at: https://www.imperial.ac.uk/media/imperial-college/research-and-innovation/the-forum/public/348-IMP-Public-Affairs-3-reports_Medtech_AW_DIGITAL_SINGLES_Sept23.pdf (Accessed: 30 January 2024).

Mordor Intelligence Industry Reports (2023) 'Refurbished medical devices market size'. Available at: https://www.mordorintelligence.com/industry-reports/global-refurbished-medical-devices-market-industry/market-size (Accessed on 1 February 2024).

National Institute for Health and Care Excellence (2020) 'Reducing the risk of transmission of Creutzfeldt–Jakob disease (CJD) from surgical instruments used for interventional procedures on high-risk tissues', Interventional Procedures Guidance [IPG666]. Available at: https://www.nice.org.uk/guidance/ipg666/chapter/1-Recommendations (Accessed: 30 January 2024).

National Institute for Health and Care Excellence (2023) 'Technologies offering monitoring from home in virtual wards recommended for people with an acute respiratory infection'. Available at: https://www.nice.org.uk/news/article/technologies-offering-monitoring-from-home-in-virtual-wards-recommended (Accessed on 2 February 2024).

NHS England (no date) 'National ambition'. Available at: https://www.england.nhs.uk/greenernhs/national-ambition/ (Accessed on 1 February 2024).

NHS England (no date) 'NHS organisations cut desflurane in drive for greener surgery'. Available at: https://www.england.nhs.uk/greenernhs/whats-already-happening/nhs-organisations-cut-desflurane-in-drive-for-greener-surgery/ (Accessed on 1 February 2024).

NHS England (2019) 'The NHS long term plan'. Available at: https://www.longtermplan.nhs.uk/wp-content/uploads/2019/08/nhs-long-term-plan-version-1.2.pdf (Accessed on 1 February 2024).

NHS England (2020) 'Delivering a 'Net Zero' national health service'. Available at: https://www.england.nhs.uk/greenernhs/wp-content/uploads/sites/51/2020/10/delivering-a-net-zero-national-health-service.pdf (Accessed on 1 February 2024).

NHS England (2020) 'Clinical commissioning policy proposition catheter ablation for paroxysmal and persistent atrial fibrillation 1903'. Available at: https://www.engage.england.nhs.uk/consultation/catheter-ablation/user_uploads/1903-policy-proposition.pdf (Accessed on 2 February 2024).

NHS England (2023) 'NHS clinical waste strategy'. Available at: https://www.england.nhs.uk/estates/nhs-clinical-waste-strategy/ (Accessed on 1 February 2024).

Norfolk and Norwich University Hospitals NHS Foundation Trust (no date)'The clinicians cutting carbon and catheter costs'. Available at: https://www.nnuh.nhs.uk/news/the-clinicians-cutting-carbon-and-catheter-costs/ (Accessed on 2 February 2024).

Philips (no date) 'SmartPath upgrades & trade-ins'. Available at: https://www.philips.co.uk/healthcare/services/upgrading-services/smartpath-upgrades (Accessed on 2 February 2024).

Pieroni, M. P. P., McAloone, T. C., Borgianni, Y., Maccioni, L., and Pigosso, D. C. A. (2021) 'An expert system for circular economy business modelling: advising manufacturing companies in decoupling value creation from resource consumption'. Sustainable Production and Consumption, 27, pp. 534–550.

Platform for Accelerating the Circular Economy (2020) 'Circular insights on design, procurement and sales & marketing'. Available at: https://pacecircular.org/sites/default/files/2020-01/20200120%20-%20CEC%20Report%20web%20-%20single%20page%20-%20297x210%20%281%29_0.pdf (Accessed on 2 February 2024).

Platform for Accelerating the Circular Economy (2021) 'Capital equipment'. Circular Economy Action Agenda Working Paper. Available at: https://pacecircular.org/sites/default/files/2021-02/circular-economy-action-agenda-capital-equipment.pdf (Accessed on 2 February 2024).

Rammelkamp, Z., Dirnberger, J., Johnson, G., and Waisbren, S. (2021) 'An audit of all waste leaving the operating room: Can the surgical suite be more environmentally sustainable?'. World Medical and Health Policy, 13(1), pp. 126–136. https://doi.org/10.1002/wmh3.397

Rizan, C., Lillywhite, R., Reed, M., and Bhutta, M. F. (2022) 'Minimising carbon and financial costs of steam sterilisation and packaging of reusable surgical instruments'. British Journal of Surgery, 109(2), pp. 200–210. https://doi.org/10.1093/bjs/znab406

Rizan, C., and Bhutta, M.F. (2022) 'Environmental impact and life cycle financial cost of hybrid (reusable/single-use) instruments versus single-use equivalents in laparoscopic cholecystectomy'. Surgical Endoscopy, 36(6), pp. 4067–4078. https://doi.org/10.1007/s00464-021-08728-z

Rowan, N.J., Kremer, T., and McDonnell, G. (2023) 'A review of Spaulding's classification system for effective cleaning, disinfection and sterilization of reusable medical devices: Viewed through a modern-day lens that will inform and enable future sustainability'. Science of The Total Environment, 878, 162976.

SageTech Medical (2023) 'SageTech Medical receives CE Mark for its innovative waste volatile anaesthetic agent capture and recycling solution'. Available at: https://www.sagetechmedical.com/news/sagetech-medical-receives-ce-mark-for-its-innovative-waste-volatile-anaesthetic-agent-capture-and-recycling-solution/ (Accessed on 2 February 2024).

Sebastian, S., Dhar, A., Baddeley, R., Donnelly, L., Haddock, R., Arasaradnam, R., Coulter, A., Disney, B. R., Griffiths, H., Healey, C., Hillson, R., Steinbach, I., Marshall, S., Rajendran, A., Rochford, A., Thomas-Gibson, S., Siddhi, S., Stableforth, W., Wesley, E., Brett, B., Morris, A. J., Douds, A., Coleman, M. G., Veitch, A. M., and Hayee, B. (2023) 'Green endoscopy: British Society of Gastroenterology (BSG), Joint Accreditation Group (JAG) and Centre for Sustainable Health (CSH) joint consensus on practical measures for environmental sustainability in endoscopy'. Gut, 72(1), pp. 12–26. doi: 10.1136/gutjnl-2022-328460.

Shepperd, S., Cradduck-Bamford, A., Butler, C., Ellis, G., Godfrey, M., Gray, A., et al. (2022). 'Hospital at Home admission avoidance with comprehensive geriatric assessment to maintain living at home for people aged 65 years and over: a RCT'. Health and Social Care Delivery Research, 10(2). Available at: https://www.journalslibrary.nihr.ac.uk/hsdr/HTAF1569#/full-report

Statista (no date) 'Medical devices – worldwide'. Available at: https://www.statista.com/outlook/hmo/medical-technology/medical-devices/worldwide (Accessed on 1 February 2024).

Stockert, E. W., Langerman, A. (2014) 'Assessing the magnitude and costs of intraoperative inefficiencies attributable to surgical instrument trays'. Journal of the American College of Surgeons, 219(4), pp. 646–655.

Task & Finish Group (2023) 'Report on industry resilience for critical minerals: An analysis of sector risks and recommendations for the UK's supply chain resilience 2023', GOV.UK. Available at: https://assets.publishing.service.gov.uk/media/6585b37aed3c34000d3bfe0d/the-task-_-finish-group-report-on-industry-resilience-for-critical-minerals.pdf (Accessed: 30 January 2024).

Tennison, I., Roschnik, S., Ashby, B., Boyd, R., Hamilton, I., Oreszczyn, T., Owen, A., Romanello, M., Ruyssevelt, P., Sherman, J. D., Smith, A. Z. P., Steele, K., Watts, N., and Eckelman, M. J. (2021) 'Health care's response to climate change: a carbon footprint assessment of the NHS in England'. The Lancet Planetary Health, 5, e84–e92.

The King's Fund (2021) 'Health inequalities in a nutshell'. Available at: https://www.kingsfund.org.uk/insight-and-analysis/data-and-charts/health-inequalities-nutshell (Accessed on 1 February 2024).

The King's Fund (2023) 'The NHS budget and how it has changed'. Available at: https://www.kingsfund.org.uk/projects/nhs-in-a-nutshell/nhs-budget (Accessed: 30 January 2024).

The Leeds Teaching Hospitals NHS Trust (2022) 'Reducing waste in clinical procedures'. Unpublished report.

Thompson, C. (2015) 'Meeting the challenges of an ageing population', NHS England. Available at: https://www.england.nhs.uk/blog/catherine-thompson/ (Accessed: 30 January 2024).

Varughese, S., and Ahmed, R. (2021) 'Environmental and occupational considerations of anesthesia: A narrative review and update'. Anesthesia and Analgesia, 133(4), pp. 826–835. doi: 10.1213/ANE.0000000000005504.

Vozzola, E., Overcash, M., and Griffing, E. (2018) 'Environmental considerations in the selection of isolation gowns: A life cycle assessment of reusable and disposable alternatives'. American Journal of Infection Control, 46(8), pp. 881–886. doi: 10.1016/j.ajic.2018.02.002.

Vozzola, E., Overcash, M., and Griffing, E. (2020) 'An environmental analysis of reusable and disposable surgical gowns'. AORN Journal, 111(3), pp. 315–325. doi: 10.1002/aorn.12885.

Wallbank, S. (2023) 'NHS Staff Survey 2022: What do the results tell us?', The King's Fund. Available at: https://www.kingsfund.org.uk/blog/2023/04/nhs-staff-survey-2022-what-do-results-tell-us (Accessed: 30 January 2024).

Zils, M., Hopkinson, P., Charnley, F., Pencheon, D., Dawson, T., Eatherley, D., Burton, K., Gopfert, A. (2021) 'Accelerating the transition towards a net zero NHS'. University of Exeter Centre for Circular Economy, in association with Philips UKI. Available at: https://images.philips.com/is/content/PhilipsConsumer/Campaigns/CA20220315_DA_002_DP/6543_bcd_dl_thought_leadership_report_circular_econ_final.pdf (Accessed: 4 February 2024).

Zils, M., Howard, M., and Hopkinson, P. (2023) 'Circular economy implementation in operations & supply chain management: Building a pathway to business transformation'. Production Planning & Control. doi: 10.1080/09537287.2023.2280907. https://universityofexeteruk.sharepoint.com/:b:/r/sites/CECentreandHUB/Shared Documents/CEctor/5.0 Sector Projects 1 - 5/5.1 Sector - Health and Social Care/0. Sector Specific Resource and Evidence Gathering/Industry Reports/DiCE_Report(D2.1)_FINAL VERSION.pdf?csf=1&web=1&e=KqLoME

Endnotes

[1] NHS England (no date) 'National ambition'. Available at: https://www.england.nhs.uk/greenernhs/national-ambition/ (Accessed on 1 February 2024).

[2] Centre for Sustainable Healthcare (no date) 'NHS Scotland sustainability strategy resources and support'. Available at: https://sustainablehealthcare.org.uk/green-plan/nhs-scotland-sustainability-resources (Accessed on 1 February 2024).

[3] NHS England (2020) 'Delivering a 'Net Zero' national health service'. Available at: https://www.england.nhs.uk/greenernhs/wp-content/uploads/sites/51/2020/10/delivering-a-net-zero-national-health- service.pdf (Accessed on 1 February 2024).

[4] Department of Health & Social Care (2023) 'Medical technology strategy'. GOV.UK. Available at: https://www.gov.uk/government/publications/medical-technology-strategy/medical-technology-strategy (Accessed: 30 January 2024).

[5] Association of Medical Device Reprocessors (2021) 'Reprocessing by the numbers', AMDR.org. Available at: https://amdr.org/newsroom/reprocessing-by-the-numbers/ (Accessed: 30 January 2024).

[6] DHSC, 'Medical technology strategy'.

[7] DHSC, 'Medical technology strategy'.

[8] DHSC, 'Medical technology strategy'.

[9] MedTech Europe (2022) 'The European Medical Technology Industry in Figures 2022'. Available at: https://www.medtecheurope.org/wp-content/uploads/2022/09/the-european-medical-technology-industry-in-figures-2022.pdf (Accessed: 30 January 2024).

[10] Moore Jr, J., Kutlu, Y. (2023) 'Sectoral systems of innovation and the UK's competitiveness: The UK MedTech sector', Imperial College London. Available at: https://www.imperial.ac.uk/media/imperial-college/research-and- innovation/the-forum/public/348-IMP-Public-Affairs-3-reports_Medtech_AW_ DIGITAL_SINGLES_Sept23.pdf (Accessed: 30 January 2024).

[11] DHSC, 'Medical technology strategy'.

[12] DHSC, 'Medical technology strategy'.

[13] MacNeill, A. J., Hopf, H., Khanuja, A., Alizamir, S., Bilec, M., Eckelman, M. J., Hernandez, L., McGain, F., Simonsen, K., Thiel, C., Young, S., Lagasse, R., & Sherman, J. D. (2020) 'Transforming the medical device industry: Road map to a circular economy', Health Affairs, 39(12), pp. 2088–2097.

[14] Task & Finish Group (2023) 'Report on industry resilience for critical minerals: An analysis of sector risks and recommendations for the UK's supply chain resilience 2023', GOV.UK. Available at: https://assets.publishing.service.gov.uk/media/6585b37aed3c34000d3bfe0d/the-task-_-finish-group-report-on-industry- resilience-for- critical-minerals.pdf (Accessed: 30 January 2024).

[15] Zils, M., Hopkinson, P., Charnley, F., Pencheon, D., Dawson, T., Eatherley, D., Burton, K., Gopfert, A. (2021) 'Accelerating the transition towards a net zero NHS'. University of Exeter Centre for Circular Economy, in association with Philips UKI. Available at: https://images.philips.com/is/content/PhilipsConsumer/Campaigns/ CA20220315_DA_002_DP/ 6543_bcd_dl_thought_leadership_report_circular_econ_final.pdf (Accessed: 4 February 2024)

[16] NHS England, 'Delivering a 'Net Zero' national health service'.

[17] NHS England, 'Delivering a 'Net Zero' national health service'.

[18] The King's Fund (2023) 'The NHS budget and how it has changed'. Available at: https://www.kingsfund.org.uk/projects/nhs-in-a-nutshell/nhs-budget (Accessed: 30 January 2024).

[19] British Medical Association (2024) 'NHS Backlog data analysis'. Available at: https://www.bma.org.uk/advice-and- support/nhs-delivery-and-workforce/pressures/nhs- backlog-data-analysis (Accessed: 30 January 2024).

[20] British Medical Association (2023) 'Health Funding Data Analysis'. Available at: https://www.bma.org.uk/advice- and-support/nhs-delivery-and-workforce/funding/ health-funding-data-analysis (Accessed: 30 January 2024).

[21] Gillett, F., Bowden, G. (2021) 'Budget 2021: NHS in England to receive £5.9bn to cut waiting lists', BBC News. Available at: https://www.bbc.co.uk/news/uk- 59030945 (Accessed: 30 January 2024).

[22] Wallbank, S. (2023) 'NHS Staff Survey 2022: What do the results tell us?', The King's Fund. Available at: https://www.kingsfund.org.uk/blog/2023/04/nhs-staff-survey- 2022-what-do-results-tell-us (Accessed: 30 January 2024).

[23] Garratt, K., Kirk-Wade, E., Harker, R., Mirza-Davies, J. (2023) 'The NHS Workforce in England', Research Briefing, House of Commons Library. Available at: https:// commonslibrary.parliament.uk/research-briefings/cbp-9731/ (Accessed: 30 January 2024).

[24] Thompson, C. (2015) 'Meeting the challenges of an ageing population', NHS England. Available at: https://www.england.nhs.uk/blog/catherine-thompson/ (Accessed: 30 January 2024).

[25] Khan, Z. (2023) 'The emerging challenges and strengths of the national health services: A physician perspective', Cureus, 15(5), e38617. doi: 10.7759/cureus.38617. 26 Kopp, W. (2019) 'How western diet and lifestyle drive the pandemic of obesity and civilization diseases', Diabetes Metab Syndr Obes, 12, 2221-2236. doi: 10.2147/ DMSO.S216791.

[27] Crawford T. C., Eagle K. A. (2018) 'Reuse of catheters and devices labelled for single use: evidence, recommendations and oversight', Heart Asia, 0(2): e011033. doi: 10.1136/heartasia-2018-011033.

[28] National Institute for Health and Care Excellence (2020) 'Reducing the risk of transmission of Creutzfeldt–Jakob disease (CJD) from surgical instruments used for interventional procedures on high-risk tissues', Interventional Procedures Guidance [IPG666]. Available at: https://www.nice.org.uk/guidance/ipg666/chapter/1- Recommendations (Accessed: 30 January 2024).

[29] The King's Fund (2021) 'Health inequalities in a nutshell'. Available at: https://www.kingsfund.org.uk/insight-and- analysis/data-and-charts/health-inequalities-nutshell (Accessed on 1 February 2024).

[30] MacNeill et al. (2020), 'Transforming the medical device industry'.

[31] Mahjoob, A., Alfadhli, Y., and Omachonu, V. (2023) 'Healthcare waste and sustainability: Implications for a circular economy'. Sustainability, 15(10), 7788. https://doi.org/10.3390/su15107788

[32] Kane, G. M., Bakker, C. A., and Balkenende, A. R. (2018) 'Towards design strategies for circular medical products'.
Resources, Conservation and Recycling, 135, pp. 38–47.

[33] NHS England (2019) 'The NHS long term plan'. Available at: https://www.longtermplan.nhs.uk/wp-content/uploads/2019/08/nhs-long-term-plan- version-1.2.pdf (Accessed on 1 February 2024).

[34] NHS England (2023) 'NHS clinical waste strategy'. Available at: https://www.england.nhs.uk/estates/nhs-clinical- waste-strategy/ (Accessed on 1 February 2024).

[35] Rammelkamp, Z., Dirnberger, J., Johnson, G., and Waisbren, S. (2021) 'An audit of all waste leaving the operating room: Can the surgical suite be more environmentally sustainable?'. World Medical and Health Policy, 13(1), pp. 126– 136. https://doi.org/10.1002/wmh3.397

[36] Fuller, R., Landrigan, P. J., Balakrishnan, K., Bathan, G., Bose-O'Reilly, S., Brauer, M., Caravanos, J., Chiles, T., Cohen, A., Corra, L., Cropper, M., Ferraro, G., Hanna, J., Hanrahan, D., Hu, H., Hunter, D., Janata, G., Kupka, R., Lanphear, B., Lichtveld, M., Martin, K., Mustapha, A., Sanchez-Triana, E., Sandilya, K., Schaefli, L., Shaw, J., Seddon, J., Suk, W., Téllez-Rojo, M. M., and Yan, C. (2022) 'Pollution and health: a progress update'. The Lancet Planetary Health, 6, e535–e547. https://doi.org/10.1016/S2542-5196(22)00090-0

[37] Tennison, I., Roschnik, S., Ashby, B., Boyd, R., Hamilton, I., Oreszczyn, T., Owen, A., Romanello, M., Ruyssevelt, P., Sherman, J. D., Smith, A. Z. P., Steele, K., Watts, N., and Eckelman, M. J. (2021) 'Health care's response to climate change: a carbon footprint assessment of the NHS in England'. The Lancet Planetary Health, 5, e84–e92.

[38] Zils, M., Hopkinson, P., Charnley, F., Pencheon, D., Dawson, T., Eatherley, D., Burton, K., Gopfert, A. (2021) 'Accelerating the transition towards a
net zero NHS'. University of Exeter Centre for Circular Economy, in association with Philips UKI. Available at: https://images.philips.com/is/content/ PhilipsConsumer/Campaigns/CA20220315_DA_002_DP/ 6543_bcd_dl_thought_leadership_report_circular_econ_final.pdf (Accessed: 4 February 2024)

[39] Kane, et al. (2018), 'Towards design strategies for circular medical products'.

[40] Statista (no date) 'Medical devices – worldwide'. Available at: https://www.statista.com/outlook/hmo/medical- technology/medical-devices/worldwide (Accessed on 1 February 2024).

[41] Mordor Intelligence Industry Reports (2023) 'Refurbished medical devices market size'. Available at: https://www.mordorintelligence.com/industry- reports/global-refurbished-medical-devices-market-industry/market-size (Accessed on 1 February 2024).

[42] MedGadget (2020) 'Refurbished medical equipment market – Global industry analysis, size, growth, share, trends, segmentation, opportunity and forecast 2020 to 2025'. Available at: https://www.medgadget.com/2020/07/refurbished- medical-equipment-market-global-industry-analysis-size-growth- share-trends-segmentation-opportunity-and-forecast- 2020-to-2025.html (Accessed on 1 February 2024).

[43] Statista, 'Medical devices – worldwide'.

[44] Guzzo, D., Carvalho, M. M., Balkenende, R., and Mascarenhas, J. (2020) 'Circular business models in the medical device industry: paths towards sustainable healthcare'. Resources, Conservation and Recycling, 160, 104904.

[45] Hoveling, T., Svindland Nijdam, A., Monincx, M., Faludi, J., and Bakker, C. (2023) 'Barriers and opportunities to circularizing digital health devices and an inventory of best practices'. Digital Health in a Circular Economy (DiCE). Unpublished report.

[46] Stockert, E. W., Langerman, A. (2014) 'Assessing the magnitude and costs of intraoperative inefficiencies attributable to surgical instrument trays'. Journal of the American College of Surgeons, 219(4), pp. 646–655.

[47] Rizan, C., Lillywhite, R., Reed, M., and Bhutta, M. F. (2022) 'Minimising carbon and financial costs of steam sterilisation and packaging of reusable surgical instruments'. British Journal of Surgery, 109(2), pp. 200–210. https://doi.org/10.1093/bjs/znab406.

[48] Boag, K., Ho, T., Culmer, P., Pike, T., Jayne, D. G., Peckham-Cooper, A., and Quyn, A. J. (2022) 'Introducing green innovation into clinical practice'. The Bulletin of the Royal College of Surgeons of England, 104(3), pp. 140–144. https://doi.org/10.1308/rcsbull.2022.47.

[49] NHS England (no date) 'NHS organisations cut desflurane in drive for greener surgery'. Available at: https://www.england.nhs.uk/greenernhs/whats-already-happening/ nhs-organisations-cut-desflurane-in-drive-for-greener-surgery/ (Accessed on 1 February 2024).

[50] Rizan, C., and Bhutta, M.F. (2022) 'Environmental impact and life cycle financial cost of hybrid (reusable/single-use) instruments versus single-use equivalents in laparoscopic cholecystectomy'. Surgical Endoscopy, 36(6), pp. 4067–4078. https://doi.org/10.1007/s00464-021-08728-z.

[51] Guzzo et al. (2020), 'Circular business models in the medical device industry'.

[52] Philips (no date) 'SmartPath upgrades & trade-ins'. Available at: https://www.philips.co.uk/healthcare/services/upgrading-services/smartpath-upgrades (Accessed on 2 February 2024).

[53] Platform for Accelerating the Circular Economy (2021) 'Capital equipment'. Circular Economy Action Agenda Working Paper. Available at: https://pacecircular. org/sites/default/files/2021-02/circular-economy-action-agenda-capital-equipment.pdf (Accessed on 2 February 2024).

[54] https://pacecircular.org/sites/default/files/2020-01/20200120%20-%20CEC%20Report %20web%20-%20single%20page%20-%20297x210%20%281%29_0.pdf 55 Ellen MacArthur Foundation (2021) 'Pioneering circularity in the healthcare industry: Royal Philips'. Available at: https://www.ellenmacarthurfoundation.org/ circular-examples/pioneering-circularity-in-the-healthcare-industry-royal- philips (Accessed on 2 February 2024).

[55] Ellen MacArthur Foundation (2021) 'Pioneering circularity in the healthcare industry: Royal Philips'. Available at: https://www.ellenmacarthurfoundation.org/circular-examples/pioneering-circularity-in-the-healthcare-industry-royal-philips (Accessed on 2 February 2024).

[56] McGeoch, L., Hardie, T., Coxon, C., and Cameron, G. (2023) 'Net zero care: What will it take?'. Available at: https://www.health.org.uk/publications/long-reads/ net-zero-care-what-will-it-take (Accessed 5 February 2024).

[57] Shepperd, S., Cradduck-Bamford, A., Butler, C., Ellis, G., Godfrey, M., Gray, A., et al. (2022). 'Hospital at Home admission avoidance with comprehensive geriatric assessment to maintain living at home for people aged 65 years and over: a RCT'. Health and Social Care Delivery Research, 10(2). Available at: https://www. journalslibrary.nihr.ac.uk/hsdr/HTAF1569#/full-report

[58] National Institute for Health and Care Excellence (2023) 'Technologies offering monitoring from home in virtual wards recommended for people with an acute respiratory infection'. Available at: https://www.nice.org.uk/news/article/technologies-offering-monitoring-from-home-in-virtual-wards-recommended (Accessed on 2 February 2024).

[59] NHS England (2022) 'Clinical Commissioning Policy: Catheter ablation for paroxysmal and persistent atrial fibrillation (adults)'. Available at https://www. england.nhs.uk/publication/catheter-ablation-for-paroxysmal-and-persistent-atrial-fibrillation-adults/ (Accessed on 3 February 2024).

[60] NHS England (2020) 'Clinical commissioning policy proposition catheter ablation for paroxysmal and persistent atrial fibrillation 1903'. Available at: https://www.engage.england.nhs.uk/consultation/catheter-ablation/user_uploads/1903-policy-proposition.pdf (Accessed on 2 February 2024).

[61] The Leeds Teaching Hospitals NHS Trust (2022) 'Reducing waste in clinical procedures'. Unpublished report. NHS England (2020)

[62] Norfolk and Norwich University Hospitals NHS Foundation Trust (no date)'The clinicians cutting carbon and catheter costs'. Available at: https://www. nnuh.nhs.uk/news/the-clinicians-cutting-carbon-and-catheter-costs/ (Accessed on 2 February 2024).

[63] Varughese, S., and Ahmed, R. (2021) 'Environmental and occupational considerations of anesthesia: A narrative review and update'. Anesthesia and Analgesia, 133(4), pp. 826–835. doi: 10.1213/ANE.0000000000005504.

[64] Hopkinson, P., MacInnes, N., Cunningham, N., Lysaght, O., Charnley, F., Nolan, R., & Zils, M. (2023) 'Is the circular economy illegal? UKRI Circular Economy Hub Discussion Paper (CE-Hub DP 2023-1). Available at: https://ce-hub.org/knowledge-hub/is-the-circular-economy-illegal/ (Accessed on 2 February 2024).

[65] SageTech Medical (2023) 'SageTech Medical receives CE Mark for its innovative waste volatile anaesthetic agent capture and recycling solution'. Available at: https://www.sagetechmedical.com/news/sagetech-medical-receives-ce- mark-for-its-innovative-waste-volatile-anaesthetic-agent-capture-and- recycling-solution/ (Accessed on 2 February 2024).

[66] Brighton & Sussex Medical School, Centre for Sustainable Healthcare, & UK Health Alliance on Climate Change (2023) Green surgery: Reducing the environmental impact of surgical care. London: UKHACC. Available at: https://ukhealthalliance.org/sustainable-healthcare/green-surgery-report/ (Accessed on 2 February 2024).

[67] Healthcare LCA (no date) 'A database of environmental assessments within healthcare'. Available at: https://healthcarelca.com/ (Accessed on 2 February 2024).

[68] Association of Medical Device Reprocessors,'Reprocessing by the numbers'.

[69] Association of Medical Device Reprocessors (2022) 'Global regulatory standards for single-use device reprocessing/remanufacturing'. Available at: https://amdr.org/wp-content/uploads/2022/06/AMDR-Standards-05312022_FINAL_OUT-1.pdf (Accessed on 2 February 2024).

[70] Vozzola, E., Overcash, M., and Griffing, E. (2020) 'An environmental analysis of reusable and disposable surgical gowns'. AORN Journal, 111(3), pp. 315–325. doi: 10.1002/aorn.12885; Vozzola, E., Overcash, M., and Griffing, E. (2018) 'Environmental considerations in the selection of isolation gowns: A life cycle assessment of reusable and disposable alternatives'. American Journal of Infection Control, 46(8), pp. 881–886. doi: 10.1016/j.ajic.2018.02.002.

[71] Leeds Teaching Hospitals Trust (2022), 'Reducing waste in clinical procedures'.

[72] Anthesis (2023), 'Comparative Carbon Footprint of Reprocessed Single Use Medical Devices' (unpublished report)

[73] 73 DHSC, 'Medical technology strategy'

[74] Benedettini, O. (2022) 'Green servitization in the single-use medical device industry: How device OEMs create supply chain circularity through reprocessing'. Sustainability, 14, 12670. doi: 10.3390/su141912670.

[75] MacNeill et al. (2020), 'Transforming the medical device industry'.

[76] Department of Health and Social Care (2022) Health and Social Care Act 2008: Code of practice on the prevention and control of infections and related guidance. GOV.UK. Available at: https://www.gov.uk/government/publications/the-health-and-social-care-act-2008-code-of-practice-on-the-prevention-and-control-of-infections-and-related-guidance/health-and-social-care-act-2008-code-of-practice-on-the-prevention- and-control-of-infections-and-related- guidance (Accessed on 2 February 2024).

[77] MacNeill et al. (2020), 'Transforming the medical device industry'.

[78] MacNeill et al. (2020), 'Transforming the medical device industry'.

[79] DHSC, 'Medical technology strategy'.

[80] Guzzo et al. (2020), 'Circular business models in the medical device industry'.

[81] Sebastian, S., Dhar, A., Baddeley, R., Donnelly, L., Haddock, R., Arasaradnam, R., Coulter, A., Disney, B. R., Griffiths, H., Healey, C., Hillson, R., Steinbach, I., Marshall, S., Rajendran, A., Rochford, A., Thomas-Gibson, S., Siddhi, S., Stableforth, W., Wesley, E., Brett, B., Morris, A. J., Douds, A., Coleman, M. G., Veitch, A. M., and Hayee, B. (2023) 'Green endoscopy: British Society of Gastroenterology (BSG), Joint Accreditation Group (JAG) and Centre for Sustainable Health (CSH) joint consensus on practical measures for environmental sustainability in endoscopy'. Gut, 72(1), pp. 12–26. doi: 10.1136/gutjnl-2022-328460.

[82] Hoveling et al. (2023), 'Inventory of best practices'.

[83] Guzzo et al. (2020), 'Circular business models in the medical device industry'.

[84] Hoveling et al. (2023), 'Inventory of best practices'.

[85] Crawford et al. (2018), 'Reuse of catheters and devices labelled for single use: evidence, recommendations and oversight'.

[86] MacNeill et al. (2020), 'Transforming the medical device industry'.

[87] Ellen MacArthur Foundation (2023) 'Locked in: What is linear lock-in and how can we break free?'. Available at: https://www.ellenmacarthurfoundation.org/ articles/locked-in-what-is-linear-lock-in-and-how-can-we-break-free (Accessed on 2 February 2024).

[88] Keil, M., Viere, T., Helms, K., and Rogowski, W. (2023) 'The impact of switching from single-use to reusable healthcare products: A transparency checklist and systematic review of life-cycle assessments'. European Journal of Public Health, 33(1), pp. 56–63. doi: 10.1093/eurpub/ckac174.

[89] Hoveling et al. (2023), 'Inventory of best practices'.

[90] Pieroni, M. P. P., McAloone, T. C., Borgianni, Y., Maccioni, L., and Pigosso, D. C. A. (2021) 'An expert system for circular economy business modelling: advising manufacturing companies in decoupling value creation from resource consumption'. Sustainable Production and Consumption, 27, pp. 534–550.

[91] Zils, M., Howard, M., and Hopkinson, P. (2023) 'Circular economy implementation in operations & supply chain management: Building a pathway to business transformation'. Production Planning & Control. doi: 10.1080/09537287.2023.2280907

[92] Medicines and Healthcare Products Regulatory Agency (2020) 'Regulating medical devices in the UK'. GOV.UK. Available at: https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk#legislation-that-applies-in-great-britain (Accessed on 2 February 2024).

[93] Department of Health and Social Care (2021) 'Factsheet: Medical Devices Overview'. GOV.UK. Available at: https://www.gov.uk/government/publications/medicines-and-medical-devices-bill-overarching-documents/factsheet-medical-devices-overview (Accessed on 2 February 2024).

[94] Rowan, N.J., Kremer, T., and McDonnell, G. (2023) 'A review of Spaulding's classification system for effective cleaning, disinfection and sterilization of reusable medical devices: Viewed through a modern-day lens that will inform and enable future sustainability'. Science of The Total Environment, 878, 162976.

CE-HUB

UKRI National Interdisciplinary Circular Economy Research

NICER PROGRAMME

CEctor

Accelerating CE Impact

University of Exeter

UK Research and Innovation

2023IIB092