CIRCULÉIRE

Unpacking the Circular Innovation Opportunities for Ireland's MedTech Sector

A CIRCULÉIRE 2024 Circular Economy Guide developed by Irish Manufacturing Research

IRISH MANUFACTURING RESEARCH

Roinn Cumarsáide, Gníomhaithe ar son na hAeráide & Comhshaoil
Department of Communications, Climate Action & Environment

Guide authors: Paul McCormack Cooney, Marie Salova, Donal Healion.
Editors: Paul McCormack Cooney, Best Practice & Toolkists Lead, Circuléire. Dr. Geraldine Brennan, Head of Circular Economy, Circuléire.
Graphic design: Paul McCormack Cooney, Best Practice & Toolkits Lead, Circuléire.

About CIRCULÉIRE

CIRCULÉIRE, Ireland's National Platform for Circular Innovation seeks to accelerate Ireland's transition towards a net-zero carbon circular economy. A key objective of the programme is to demystify, de-risk and deliver circular business model innovation for Irish industry.

Want to learn more about CIRCULÉIRE?

Visit our website at www.circuleire.ie or contact circuleire@imr.ie.

Purpose of this Guide

This Sectoral Guide is intended for all stakeholders, potential project funders and policymakers involved in the Medical Technology (MedTech) sector in Ireland. It aims to provide industry stakeholders with a deeper understanding of what a Circular Economy (CE) is and why a CE in MedTech is necessary. It aims to give insight into what is driving the transition to a CE in Europe, enablers and barriers to its implementation and the value creation opportunities in adopting CE business strategies. The ultimate goal is to raise awareness and accelerate the transition to a CE in the MedTech sector in Ireland.

For policymakers, the Guide is intended to both draw attention to some of the key policy enablers which are supporting the advancement of a CE of MedTech in Europe and Ireland and to highlight the necessity for industry to participate in the policy process through sharing their insight, research results, and the challenges of implementing a CE in Medtech.

Guide Structure

This Guide is structured as follows:

- **Section 1** provides an overview of what a Circular Economy is and why it has been adopted as a core EU strategy in response to the triple planetary crises of climate change, biodiversity loss and pollution.
- **Section 2** presents a snapshot of the current MedTech sector in Ireland and high-level overview of the regulations that govern it.
- **Section 3** presents a selection of case studies representing circular MedTech best practice in action in Ireland and across the world.
- **Section 4** draws on the lessons learnt from the case studies and from other contexts that have made good progress in advancing a CE of Medtech. It highlights challenges for the implementation of a CE in Medtech and offers recommendations for what's needed to advance a CE of Medtech here in Ireland.

Methodology

The report is based on information gathered through desktop research on:

- The wider literature on a Circular Economy in MedTech across the world.
- Public-sector led policies in Europe and in Ireland aimed at supporting a Circular Economy in MedTech.
- A Cross-sectoral analysis of 22 case studies where R-Strategies for Circular Economy were applied in the MedTech sector;
  - The case studies were sourced from publicly available databases.
  - The companies profiled for the case studies were chosen based on the criteria of; maturity, innovation, applicability to Irish MedTech sector (transferable practices) and availability on web.

1. From the 22 case studies, 9 international case studies were written up for this report.
2. One additional case study, Tympany Medical, a CIRCULÉIRE member, was included as an example of a MedTech start-up with circularity at its core.
3. The case studies cover key themes—extending product lifecycles, design for circularity, material recovery and innovations, and sustainable packaging.
4. Each case study highlights the strategies adopted by companies worldwide to address challenges, leverage opportunities, and align their operations with CE principles.

Contents

Acronyms

C3S - Copernicus Climate Change Service (C3S)

CBMs - Circular Business Models

CE - Circular Economy

CEAP - Circular Economy Action Plan

DETE - Department of Enterprise Trade and Employment

DPP - Digital Product Passport

EPA - Environmental Protection Agency

ESRS - European Sustainability Reporting Standards

ESOTC - European State of the Climate

EU - European Union

EU MDR - European Union Medical Device Regulation

ESG - Environmental, Social & Governance

ESPR - Ecodesign for Sustainable Products Regulation

GHG - Greenhouse Gas

HPRA - Health Products Regulatory Authority

IVDR - In Vitro Diagnostic Regulation

LCC - Life-Cycle Costing

MDR - Medical Devices Regulation

MedTech - Medical Technology

PaaS - Product-as-a-Service

SUD - Single Use Device

TWG – Thematic Working Group

WBCSD - World Business Council for Sustainable Development

WMO - World Meteorological Organization

Executive Summary

Irish Manufacturing Research and CIRCULÉIRE's Sectoral Guide to the Circular Economy in Medical Technology (MedTech) is intended for all stakeholders, potential project funders, and policymakers involved in the MedTech sector in Ireland. It aims to provide a deeper understanding of what a Circular Economy (CE) is and why its adoption in MedTech is necessary. It provides insight into the European drivers for this transition, the enablers and barriers to its implementation, and the value creation opportunities available. By showcasing industry-led circular innovations from Ireland and around the world, this guide highlights the clear opportunity to circularise the MedTech value chain.

This guide is part of a series of reports produced by CIRCULÉIRE, Ireland's National Platform for Circular Manufacturing, targeted at Irish industry players in sectors deemed strategically important to supporting Ireland's transition to a net-zero carbon, circular economy.

The Strategic Importance of a Circular Economy to Ireland's MedTech Sector

Humanity's linear consumption of resources is the primary driver of the triple planetary crises of climate change, biodiversity loss, and pollution. Global material use has more than tripled in the last 50 years and continues to grow unsustainably. The transition to a circular model is described by the European Commission as "a prerequisite to achieve the EU's 2050 climate neutrality target and to halt biodiversity loss" (European Commission, 2020). As a key instrument of the European Green Deal, the Circular Economy Action Plan (CEAP) signals a fundamental shift in economic strategy, moving away from the traditional 'take-make-waste' model.

For Ireland, a top-five global MedTech hub employing over 50,000 people and accounting for €14.9 billion in annual exports, this transition is both a critical challenge and a major opportunity. The sector's current environmental impact is significant, driven by a reliance on single-use devices (SUDs)—which constitute up to 90% of medical device waste—energy-intensive manufacturing, complex global supply chains, and the consumption of finite, critical raw materials. This linear dependency exposes the industry to resource scarcity, supply chain volatility, and increasing regulatory pressure under frameworks like the Corporate Sustainability Reporting Directive (CSRD). A Circular Economy offers a pathway to mitigate these risks, enhance competitiveness, and position Ireland as a global leader in sustainable healthcare innovation.

A Case Study-Led Approach to Developing the Justification for a Circular Economy in MedTech

A Circular Economy aims to eliminate waste by design and keep products and materials in use at their highest value for as long as possible. This is achieved through the adoption of strategies commonly referred to as the 10 R-Strategies (e.g., Refuse, Rethink, Redesign, Reuse, Repair, Remanufacture, Recycle). This guide bases its analysis on a cross-sectoral review of case studies where these R-Strategies were successfully applied. The companies profiled were chosen based on their maturity, innovation, and the transferability of their practices to the Irish MedTech sector.

The following table provides an overview of the selected case studies, which demonstrate that circularity is not only technically feasible but also commercially viable within the stringent regulatory environment of MedTech.

No.	Case Study	Location	Circular Economy R-Strategies Employed
1	Royal Philips' Refurbishment and Product-as-a-Service Models for Medical Imaging Systems	Netherlands	Refurbish (R6), Remanufacture (R7), Repair (R5)
2	Vanguard AG's Specialised Remanufacturing of Single-Use Medical Devices	Germany	Remanufacture (R7)
3	Stryker's 'Redesigned for Sustainability' Philosophy for Reprocessed Devices	USA	Redesign (R1), Remanufacture (R7)
4	Zsquare's Modular Endoscope with Reusable Core and Single-Use Shells	Israel	Redesign (R1), Reuse (R4)
5	Tympany Medical's Sustainable, Reusable Panoramic Endoscope	Ireland	Redesign (R1), Reuse (R4)
6	GE Healthcare's Industrial Symbiosis Turning PVC Waste into a Resource	USA/Mexico	Repurpose (R2)
7	Envetec's Clean Technology for On-site Treatment and Recycling of Biohazardous Waste	Ireland	Enables high-quality Recycling (R8)
8	Novo Nordisk's PenCycle Initiative for Take-Back and Recycling of Injection Pens	Denmark/UK	Product take-back scheme enabling Recycling (R8)
9	Klöckner Pentaplast's Medical Grade Packaging with Certified Recycled Content	Global	Reduce (R0) virgin material use
10	Plastic Ingenuity's Reusable Transport Packaging for Merit Medical	USA	Redesign (R1) for material reduction, packaging Reuse (R4)

Key Insights from the Case Studies and Wider Literature

1. Designing for circularity unlocks the greatest value

Case studies from Stryker, Zsquare, and Tympany Medical demonstrate that embedding circular principles at the design stage is one of the most effective strategies. By designing for modularity, durability, and repairability, companies can prevent waste from being created, which is far more impactful than managing it at the end-of-life.

2. Extending product lifecycles is a proven, viable business model

The success of industry leaders like Philips and specialist firms like Vanguard proves there is a strong market for refurbished and remanufactured medical devices. These models deliver significant cost savings to healthcare providers, reduce resource consumption, and build lasting customer relationships through service-based offerings, all while adhering to stringent safety standards.

3. Collaboration is essential for systemic change

Circular opportunities often require cross-sectoral partnerships. The GE Healthcare case, where medical-grade PVC waste was repurposed by a shoe manufacturer, illustrates that value chains for secondary materials often exist outside the original sector. Collaboration between device manufacturers, healthcare providers, reprocessing specialists, and recyclers is fundamental to creating closed-loop systems.

4. Regulatory navigation is complex but possible

While the regulatory landscape is a significant challenge, it is not an insurmountable barrier. Companies like Vanguard are successfully navigating the complexities of the EU Medical Device Regulation (MDR) to bring reprocessed devices to market. This requires deep regulatory expertise but demonstrates that pathways for circularity exist within the current frameworks.

5. Sustainable packaging is an impactful and accessible starting point

For companies whose core products cannot be easily circularised (e.g., implants), focusing on packaging offers a powerful way to reduce environmental impact. Innovations in recyclable materials, lightweighting, and reusable transport systems, as shown by Klöckner Pentaplast and Plastic Ingenuity, can deliver immediate and significant environmental and economic benefits.

Key Barriers to Transitioning to a Circular Economy for MedTech

1. **Regulatory Compliance & Guidance**

   The sector operates within stringent, complex, and often fragmented regulatory frameworks that were not designed for circular products. This creates uncertainty and complexity for companies attempting to implement reuse, repair, and remanufacturing models while ensuring patient safety.

2. **Supply Chain Complexities**

   The globalised nature of MedTech supply chains makes implementing effective reverse logistics for product take-back and material recovery exceptionally challenging. This is compounded by varying international regulations on waste and material transport.

3. **Technological & Material Limitations**

   There is a limited availability of recyclable or biodegradable materials that also meet the strict biocompatibility, sterility, and performance standards required for medical devices. Furthermore, cost-effective technologies for disassembling complex devices to recover high-value materials are not yet widely accessible.

4. **Economic and Financial Barriers**

   Transitioning to circular models demands significant upfront investment in R&D, new infrastructure, and process re-engineering. A lack of specific financial incentives, subsidies, or funding mechanisms for circular MedTech can make the business case difficult.

5. **Cultural Shift in Healthcare**

   The healthcare sector has a deep-seated cultural preference for single-use devices, driven by convenience and strong perceptions around infection control and patient safety. Overcoming this inertia requires robust clinical evidence, education, and building trust in the safety and efficacy of circular alternatives.

6. **"Waste" Classification and Management**

   Many used medical devices are classified as hazardous or biohazardous waste, mandating specialised and costly disposal methods like incineration. This classification, while essential for safety, often prevents the recovery of valuable, non-contaminated materials and components, locking them into a linear disposal pathway.

Key Recommendations for Advancing Ireland's Circular Economy of MedTech

1. **Adopt Circular Design Principles Early in Product Development**

   Embed eco-design into the core of the product development process to minimise resource use, design for disassembly, extend lifecycles, and enhance recyclability from the outset.

2. **Advocate for Policy Support and Clear Standards**

   Proactively engage with policymakers and regulatory bodies to co-develop clear, supportive, and harmonised standards for material recovery, device reprocessing, and reverse logistics to simplify compliance and de-risk innovation.

3. **Strengthen Financial Incentives and Access to Funding**

   Promote and pursue green funding opportunities, such as EU Horizon Europe, and advocate for tax incentives or credits for companies investing in circular economy-related R&D and infrastructure in the MedTech sector.

4. **Foster Leadership**

   Encourage executive-level commitment to embed CE into core business strategy, supported by measurable sustainability KPIs and the appointment of CE champions to drive initiatives internally.

5. **Enhance Collaboration**

   Strengthen public-private partnerships between industry, academia, government, and the healthcare sector to share knowledge, co-develop solutions, and build the integrated ecosystems necessary for circularity to thrive.

6. **Encourage Circularity in Education (Training and skills development)**

   Collaborate with academic institutions to embed CE concepts into MedTech, engineering, and healthcare curricula. This will build a future-ready workforce with the skills needed to design, implement, and manage circular systems, as highlighted in the *Future Skills Report for Ireland's Medtech Sector, 2024 - 2028*.

7. **Implement and Scale Up Circular Business Models**

   Pilot and scale innovative business models, such as Product-as-a-Service (PaaS), which shift the focus from selling units to providing a service. This retains company ownership of the device, incentivising durability and facilitating efficient material recovery.

8. **Establish Metrics and Monitoring Systems**

   Define, track, and report on circularity Key Performance Indicators (KPIs), such as the percentage of recycled materials used or the volume of remanufactured products sold. This is crucial for evaluating strategy effectiveness and preparing for mandatory reporting under frameworks like the CSRD.

Where Next for a Circular Economy of MedTech in Ireland?

The transition to a Circular Economy is an imperative for the Irish MedTech sector. While challenges remain, the technological and commercial viability of circular approaches is already being demonstrated by pioneers in the field. The journey requires a concerted effort to overcome the cultural preference for single-use products, navigate regulatory hurdles, and foster deep collaboration across the value chain. By embracing the recommendations in this guide, Ireland's MedTech sector can not only meet its environmental obligations but also unlock significant economic value, strengthen its resilience, and cement its position as a world leader in sustainable healthcare.

Section 1: What is the Circular Economy and why do we need it?

IN THIS SECTION:

- **We define what a Circular Economy is versus a Linear Economy,**
- **We look at some of the key issues driving a Circular Economy,**
- **We explain how a Circular Economy addresses those issues,**
- **We show how the transition is a prerequisite for the EU's 2050 Climate Neutrality Targets, and**
- **We highlight some of the core benefits to business from embracing the circular opportunity.**

1.1 What Is a Circular Economy vs a Linear Economy?

1.1.1
What is a Linear Economy?

The linear economy is the traditional economic model where resources are extracted from the earth, made into products and are thrown away as waste at the end of their life. This is sometimes referred to as the 'take-make-waste' approach. A linear economy relies on a constant stream of new, or 'virgin' resources to make products.

This one-way system, from raw material extraction through to waste disposal, results in significant environmental damage and resource depletion.

1.1.2
What is a Circular Economy?

In contrast to a linear economy, a Circular Economy (CE) is an economic model which focuses on **eliminating waste by design**. In its perfect state, resources are used repeatedly and no further virgin resources are needed (Figge et al., 2017).

The most cited core principles of a CE come from the Ellen MacArthur Foundation (EMF). They are:

- **Eliminate waste and pollution**
- **Circulate products and materials (at their highest value)**
- **Regenerate nature**

All of the above are underpinned by a transition to renewable energy and materials (Ellen MacArthur Foundation, 2017).

Fig. 1 below is a useful visual representation of the differences between the linear, recycling and circular economies. Where recycling aims to convert waste into reusable materials, a circular economy considers the entire system and designs it so that waste is significantly reduced or eliminated entirely.

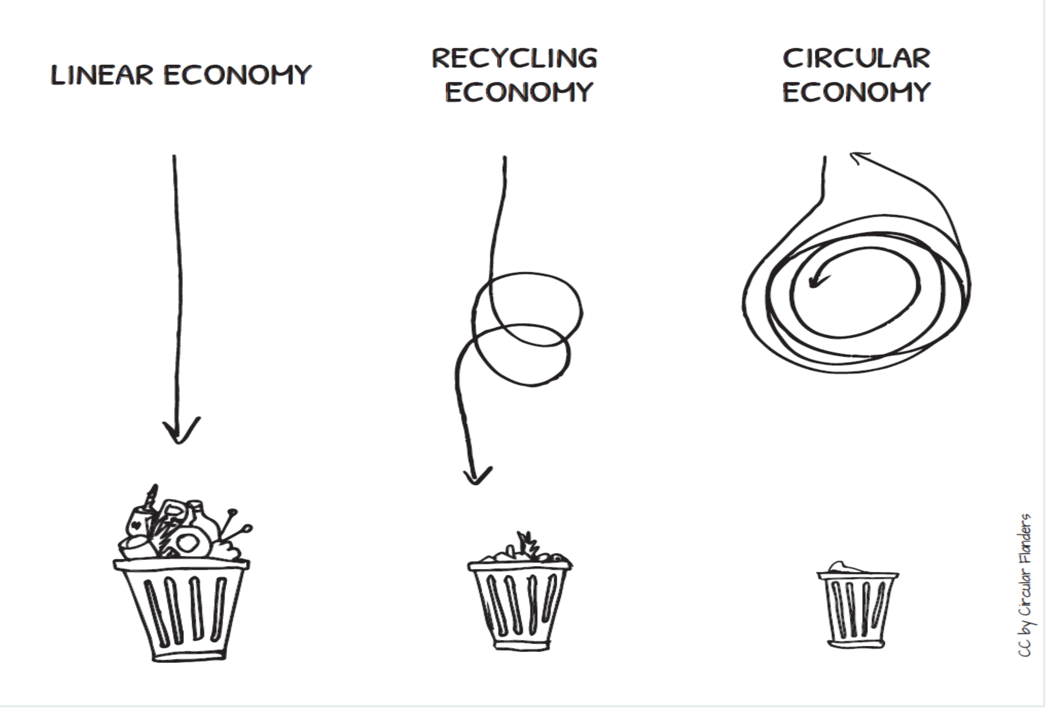


Figure 1: From Linear to Circular (Circular Flanders, 2017).

1.1.3
The Circular Economy as defined by the European Commission

For companies operating and reporting within the European Union (EU), the European Sustainability Reporting Standards (ESRS) define a CE as:

An economic system whereby the value of products, materials and other resources in the economy is maintained for as long as possible, enhancing their efficient use in production and consumption, thereby reducing the environmental impact of their use, minimising waste and the release of hazardous substances at all stages of their life cycle, including through the application of the waste hierarchy.
(EFRAG, 2022).

With the adoption of the European Union's Circular Economy Action Plan (CEAP) in March 2020, as one of the main building blocks of the EU Green Deal (European Commission, 2020) the transition to a CE within the EU is already under way.

1.3 Why do we need a circular economy?

1.2.1
Humanity’s linear consumption of resources in unsustainable

In the 2024 Global Resources Outlook 20024, the International Resources Panel found that humanity's increasing use of resources is the main driver of the three interlinked global environmental crises, referred to as the triple planetary crises: climate change, biodiversity loss and pollution (United Nations Environment Programme, 2024).

Material use has more than tripled in the last 50 years and continues to grow by an average of more than 2.3 per cent per year (United Nations Environment Programme, 2024).

Dangerous climate and biodiversity impacts from extraction and processing of materials greatly exceed targets based on staying within 1.5 degrees of climate change and avoiding biodiversity loss (United Nations Environment Programme, 2024).

With the human population increasing at approximately 200,000 per day (Ripple et al., 2024), it is necessary to urgently decouple both human well-being from resource use, and resource use from environmental impacts (United Nations Environment Programme, 2024).

1.2.2
The Triple Planetary Crises

CLIMATE CHANGE

The 2024 State of the Climate Report begins with a stark warning: 'We are on the brink of an irreversible climate disaster. This is a global emergency beyond any doubt. Much of the very fabric of life on Earth is imperilled.' (Ripple et al., 2024).

Concentrations of CO2 in our atmosphere are at the highest levels they have been in 15 million years and as a result global mean temperatures are higher than at any point since human civilisation emerged (Caesar and Sakschewski, 2024). In July 2024 the three hottest days on record were recorded (Guterres, 2024).

The extraction and processing of fossil fuels, minerals, non-metallic minerals and biomass account for more than 55 per cent of greenhouse gas (GHG) emissions.

When land use change, primarily from forestry and agriculture are factored in, climate impacts grow to more than 60%.

(United Nations Environment Programme, 2024).

BIODIVERSITY LOSS

Since 1970 the average size of monitored wildlife populations has shrunk by 73% (WWF, 2024).

Of the world's estimated 8 million species of plants and animals more than 1 million are threatened with extinction (IPBES, 2019) and as of 2024, more than one in three tree species worldwide faces extinction (IUCN, 2024).

Extraction and processing of agricultural crops and forestry account for 90 per cent of the total land use related biodiversity loss and water stress
(United Nations Environment Programme, 2024).

AIR POLLUTION

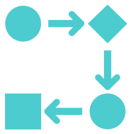
Air pollution is the greatest environmental threat to public health globally and accounts for more than 8 million premature deaths every year causing one in nine deaths worldwide (UNEP, 2021).

Stroke, heart disease, lung disease, lower respiratory diseases (such as pneumonia), and cancer are the deadliest illnesses linked to fine particle air pollution. High levels of fine particles also contribute to other illnesses, like diabetes, can hinder cognitive development in children and also cause mental health problems (UNEP 2021).

Extraction and processing of material resources account for 40 per cent of particulate matter health related impacts.
(United Nations Environment Programme, 2024).

1.2.3
Supply and Availability of Materials

SUPPLY CHAIN VOLATILITY



The issue of supply chain vulnerabilities from manufacturing shortages, interrupted transportation systems, international trade dynamics, and price shocks have become particularly visible since the Covid 19 pandemic (MacNeil et al., 2020) and more recently due to the war in Ukraine.

According to the State of European Supply Chains 2024 report, geopolitical instability is by far the top disruption in the minds of supply chain professionals
(Hardwick, 2024).

In the MedTech sector the threat of supply chain shocks became particularly evident during the Covid 19 pandemic, especially in relation to single use devices (SUDs), where the lack of technical ability and reprocessing or remanufacturing infrastructure exacerbated a shortage in supply (Hopkinson et al., 2024).

MATERIAL AVAILABILITY

As the world population grows the demand for raw materials grows with it, as does the competition for limited supplies.

The EU currently imports a lot of its raw materials from outside of its borders. Europeans consumed 14.9 tonnes of raw materials per capita in 2022 (European Parliament, 2023). The total value of trade between the EU and the rest of the world in 2023 was €165 billion. Exports were lower than imports leaving a trade deficit of €29 billion (European Parliament, 2023).

The world's top aluminium producers are China, Russia, and India. Titanium is sourced from Japan, Ukraine, Russia and elsewhere. Cobalt is sourced from Democratic Republic of Congo, Russia, and Australia. Plastics are made from materials such as natural gas and crude oil which can be impacted by geopolitical events like the Russia-Ukraine war. (Barbella, 2023).

The MedTech sector is dependent on supplies of many critical materials, metals and components for a wide range of products and applications such as medical imaging and scanners, monitoring and ultrasound, implants, drills and incision tools (Hopkinson et al., 2024).

As the environmental crises worsens the chance of geopolitical instability increases. Recovering and reusing raw materials, already in the value chain can help mitigate the risks associated with supply, such as price volatility, availability and import dependency. This is especially true for critical raw materials needed for the production of batteries for example (European Parliament, 2023). Critical raw materials are the raw materials that are most important economically and have a high supply risk (European Commission, 2020).

Competition for critical raw materials, classified as scarce, is likely to become more pronounced as the demand increases for electrification technologies such as electric vehicles, solar PV and wind turbines (Hopkinson et al., 2024).

1.3 How Does a Circular Economy Tackle These Issues?

1.3.1 Decoupling Economic Growth from Environmental Impacts and Resource Use

The 2024 edition of the Global Resources Outlook demonstrates that it is both possible and profitable to decouple economic growth from environmental impacts and resource use (United Nations Environment Programme, 2024).

The European Parliament (2023) cites numerous benefits which would result from a CE including:

- a reduction in the use of natural resources;
- a reduction in biodiversity loss;
- a reduction in total annual GHGs; a reduction in energy consumption;
- a reduction in waste;
- less requirement for imported raw materials which would mitigate risks of supply chain disruption and price volatility;
- an estimated 700,000 jobs created in the EU by 2030.

By designing products from the outset so that their lifecycle is extended, and so that materials are more easily kept in use at their highest value for multiple lifecycles, a CE reduces the need for extraction of virgin raw materials and reduces the amount of waste and pollution entering the environment.

Efforts to tackle excessive amounts of planet heating GHGs entering the atmosphere have tended to focus mainly on renewable energy and energy-efficiency measures. However, such efforts only address 55% of the problem (See Fig. 2) (Ellen MacArthur Foundation, 2021). A circular economy offers a systemic and cost-effective approach to addressing the remaining 45% of emissions associated with making products (Ellen MacArthur Foundation, 2021).

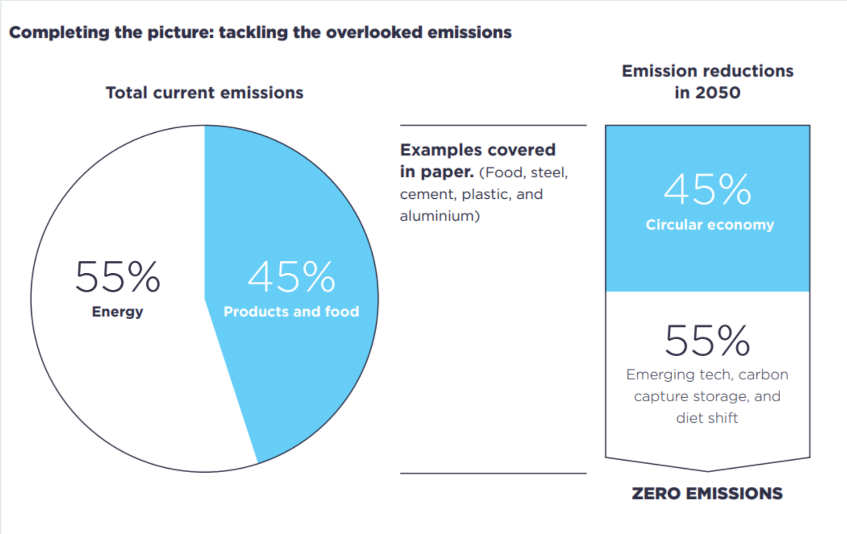


Figure 2: Completing the picture: How the circular economy tackles climate change (Ellen MacArthur Foundation, 2021).

1.3.2
The R-Strategies

A CE aims to achieve this by the adoption of a number of strategies, commonly referred to as the **10 R Strategies** (Potting et al., 2016). Numbered 0 to 9 they describe strategies for the treatment and use of resources over the various stages of a products lifecycle (Fig. 3).

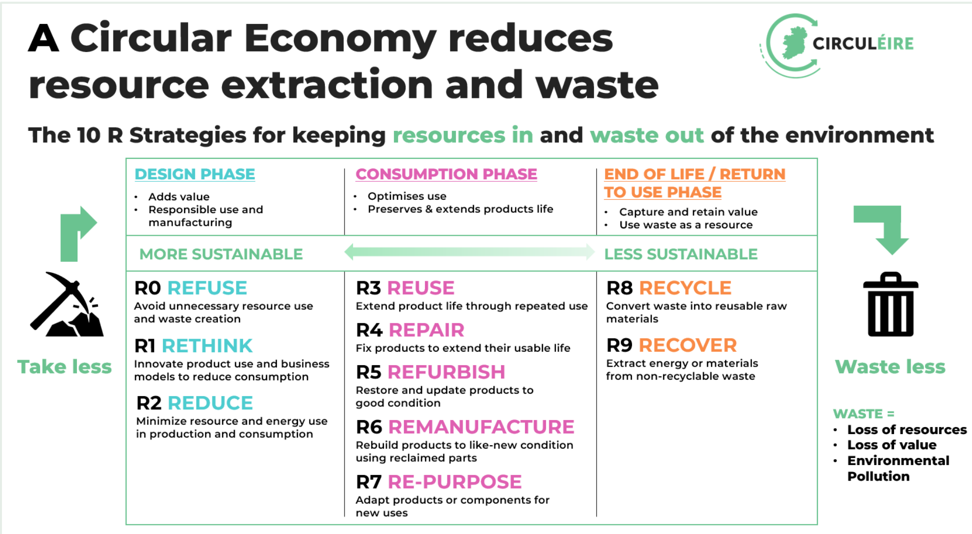


Figure 3: The 10 R Strategies for keeping resources in and waste out of the environment (Based of Potting et al., 2016)

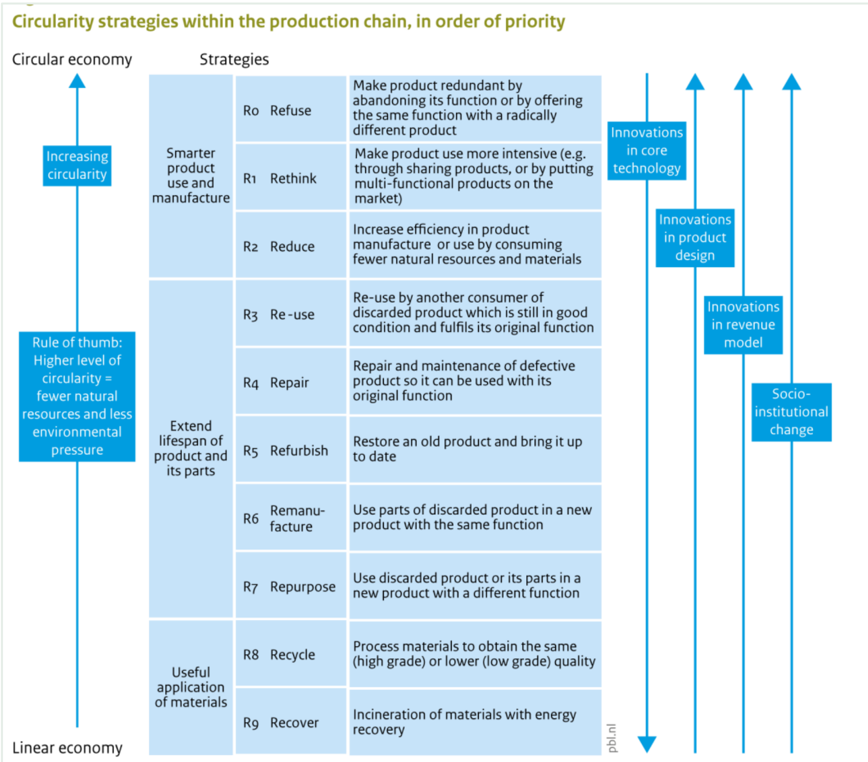


Figure 4: Circularity strategies within the production chain, in order of priority (Potting et al., 2016).

As can be seen in Fig. 4, the R Strategies exist within a hierarchy. Recycling (R8) and Energy Recovery (R9) are rated lower in terms of sustainability as they only slow down the use of resources. By adopting strategies higher up fewer natural resources are required. It is possible to adopt multiple cascading strategies to extend the life and use of products and materials in as many ways as possible.

1.3.3
Biological and technical cycles

When designing products and materials in a circular economy it is important to distinguish between biological and technical cycles as illustrated in 'The Butterfly Diagram' developed by the Ellen McArthur Foundation and depicted in Fig. 5 (Ellen Macarthur Foundation, 2019).

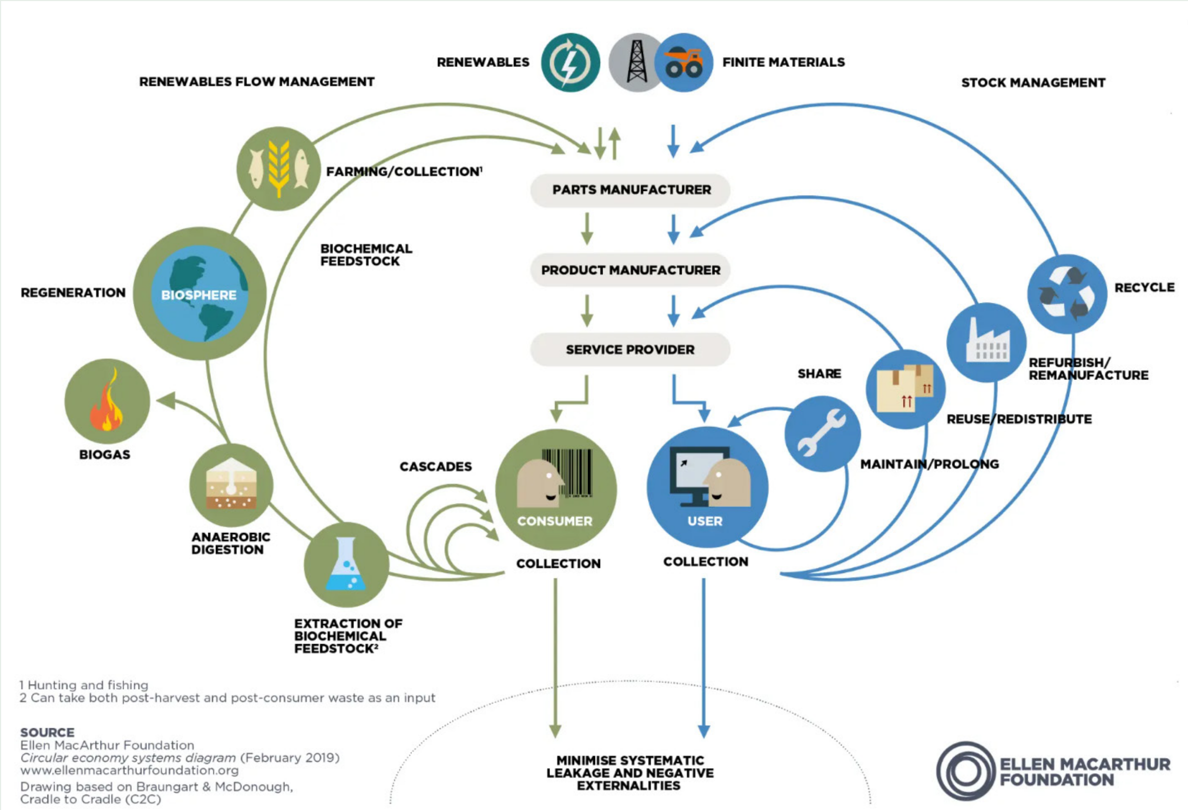


Figure 5: The Butterfly Diagram (Ellen MacArthur Foundation, 2019)

On the left side of the diagram is the biological cycle where biological materials that can be safely returned to the earth are depicted. Materials such cotton or wood for example, may be used repeatedly on the technical side before ending up in the biological side after they can no longer be used to make products.

On the right-hand side is the technical cycle for materials that are used rather than being consumed. These would include materials such as steel, titanium, copper, plastics etc.

In a linear economy many biological and technical materials are blended and become difficult and costly to separate so the value of both is lost, which again emphasises the importance of design in the CE.

1.3.4

Circular Business Models

Circular Business Models (CBMs) aim to minimise waste and extend product lifecycles by promoting the use of the R Strategies listed. In CBMs products are designed for durability, reduction of resource inputs and optimising resource recovery. For example, a Product-as-a-Service (PaaS) business model is where customers pay for the use or function of a product instead of outright ownership. In a PaaS model the company retains ownership of the product and is responsible for the product's maintenance, repair and end of life management. A PaaS model incentivises a company to design their products for durability and maintenance. The model also encourages longer relationships with customers and ensures a company's access to materials when the product reaches its end of life.

1.4 Circular Economy as a Prerequisite for the EU's 2050 Climate Neutrality Targets

1.4.1
Europe is warming fast

The Copernicus Climate Change Service (C3S), the EU's official weather and climate organization, and the World Meteorological Organization (WMO) released a joint report on the European State of the Climate (ESOTC) 2023 in which they reported that since the 1980s, Europe has warmed twice as fast as the global average. According to ESOTC 2023, the three warmest years on record for Europe have all occurred since 2020, and the ten warmest since 2007. They further reported that heat-related mortality has increased by around 30% in the past 20 years and heat-related deaths are estimated to have increased in 94% of the European regions monitored (Copernicus Climate Change Service, 2024).

The European Green Deal was established in 2019 with the aim of achieving no net emissions of greenhouse gases by 2050, economic growth decoupled from resource use and a fair transition in the process (European Commission, 2019).

The EU's Circular Economy Action Plan describes the transition to a CE as 'a prerequisite to achieve the EU's 2050 climate neutrality target and to halt biodiversity loss,' (European Commission, 2020) and the Corporate Sustainability Reporting Directive (CSRD) is a key instrument in steering that transition (European Union 2022).

1.4.2
The Corporate Sustainability Reporting Directive

As seen in Fig. 6, CSRD mainly targets large companies and listed entities, but SMEs will gradually be brought into scope. Smaller companies that might not fall within the scope of the directive but operate within the value chain of those that do, may need to provide them with Environmental, Social & Governance (ESG) data for their reporting.

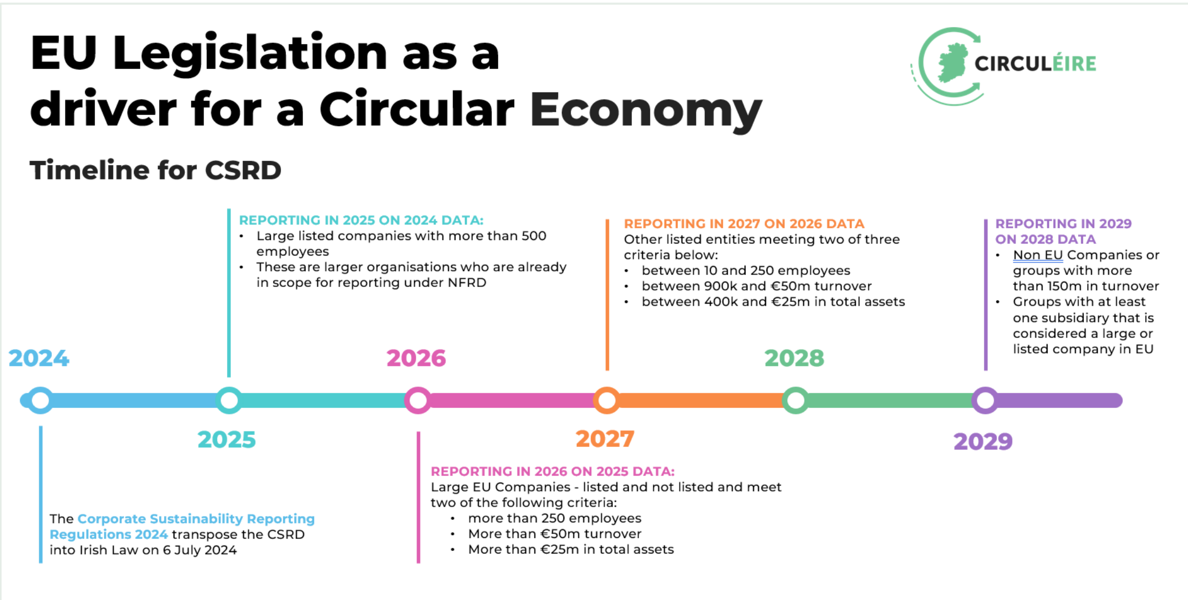


Figure 6: Timeline for the Corporate Sustainability Reporting Directive (CIRCULÉIRE, 2024).

The CSRD requires the use of the European Sustainability Reporting Standard (ESRS). The ESRS contain twelve standards which companies need to report on containing more than one thousand data points and it can take between twelve to eighteen months to collect the necessary data, which is no insignificant task.

Reporting under the ESRS begins with a 'double materiality' assessment. This is where companies must assess how ESG related matters will materially affect their financial performance and future viability (financial materiality), and also how company operations, including the value chain, will impact people and the planet (impact materiality).

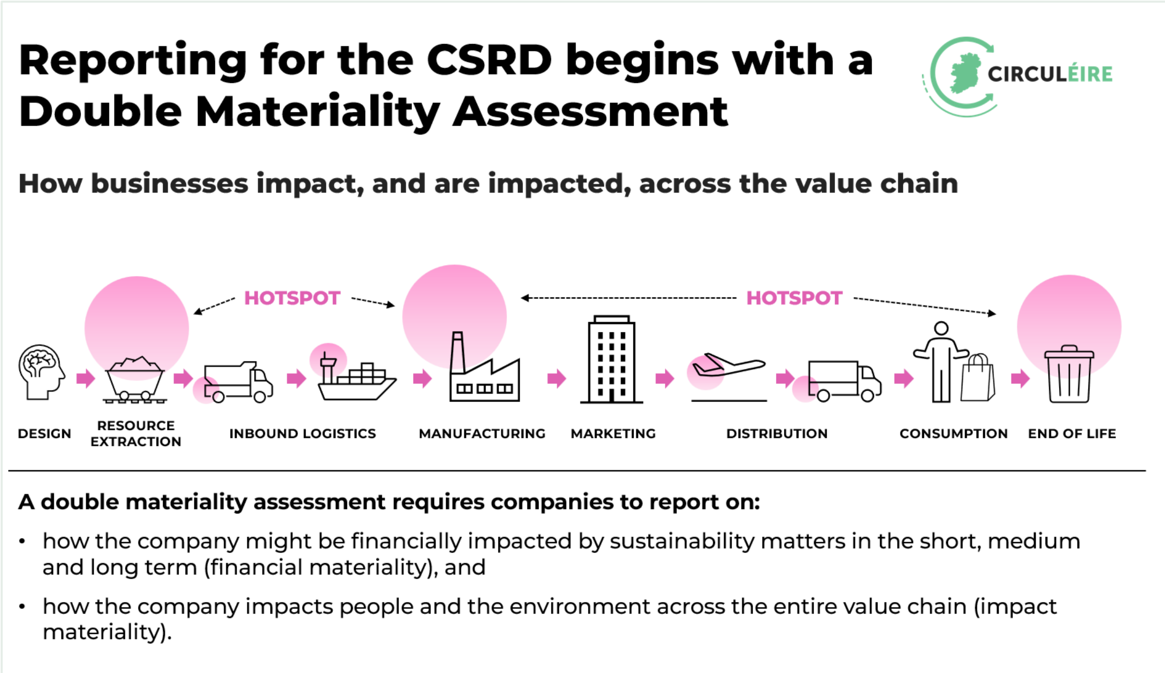


Figure 7: The Double Materiality Assessment (CIRCULÉIRE, 2024)

Completion of the double materiality assessment will direct companies to which of the remaining ten topical standards they must report on (Fig. 8). There are five **Environmental** standards (E1 to E5), four **Social** standards (S1 to S4) and one **Governance** standard (G1). The E5 standard relates to 'Resource use and the Circular Economy'.

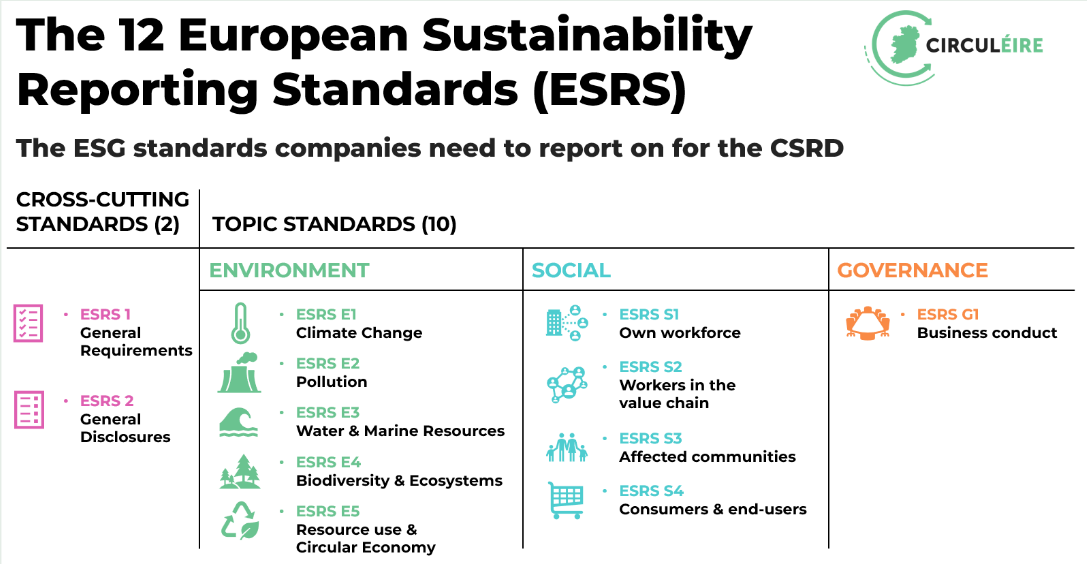


Figure 8: The 12 European Sustainability Reporting Standards (CIRCULEIRE, 2024)

Companies cannot pick and choose which standards they will report on as the double materiality assessment is subject to external assurance. If a company decides that 'Resource use and the Circular Economy' is not material to their operations it must provide a detailed explanation to justify its decision not to report.

This requirement of external assurance puts sustainability reporting on a level footing with financial reporting. Companies don't need to be sustainable to comply with the CSRD, but stakeholders and investors will be able to compare reports. Investors increasingly want to know how exposed a company might be to resource price-volatility and supply-chain shocks. Consumers want to make more sustainable choices and talent increasingly wants to work for more sustainable organisations.

1.5 Key Benefits to Businesses from a Circular Economy

There are numerous benefits to businesses in transitioning to a CE. Below are listed some key advantages from a business perspective:

REDUCED MATERIAL COSTS

When designed to be circular, products and components can be reused, repaired, refurbished, remanufactured or repurposed. Due to the resulting increase in usage, the desired service from the product will be more cost-effective. (Jensen, 2023)

When coupled with PaaS business models, companies can recover materials which can be reused to make new products or better maintain existing ones thereby lowering dependence on volatile raw material markets.

WASTE MANAGEMENT COST REDUCTION

By designing products and their components so that their materials can be easier recovered companies generate less waste. As such, costs related to waste disposal, such as landfill charges and regulatory compliance, can reduce.

INNOVATION AND COMPETITIVE ADVANTAGE

Through innovative circular design and business models, companies can differentiate themselves in the marketplace. Early-mover advantage can be gained by establishing a leadership position in sustainability and by getting ahead of increasing consumer and regulatory pressures for sustainable more practice.

IMPROVED BRAND IMAGE AND LOYALTY

Companies that have strong environmental performance can attract sustainability-conscious customers and increased customer loyalty. Customers who select PaaS subscription models can reduce their own environmental impacts and build more durable relationships with the brands they subscribe too.

This applies to employee loyalty too. In a global study of 3,700 students from 29 leading business schools conducted by Yale University, the World Business Council for Sustainable Development (WBCSD) and the Global Network for Advanced Management, 44 percent of students reporting a willingness to accept a lower salary to work for a company with better environmental practices. One-fifth of respondents reported an unwillingness to work for a company with bad environmental practices no matter what the salary (Cort et al., 2015).

REGULATORY COMPLIANCE AND RISK MITIGATION

Governments are increasingly enacting more stringent environmental legislation. As in the case of CSRD reporting requirements, businesses are having to look at the environmental performance of their entire value chain. Strong environmental performance can help businesses proactively comply with current and future regulations. It can also make a business a more attractive partner for other organisations looking to improve their own ESG performance across their own value chain.

RESOURCE SECURITY

'The circular economy is not only an environmental initiative, but also a risk mitigation imperative' (Circular Republic, 2024). The environmental crisis is worsening and will continue to do so until GHG emissions reach net-zero. As it worsens, the chance of supply chain disruption due to extreme weather events or geopolitical tensions increases. By embracing circular principles and circular business models, companies can reduce their exposure to such disruptions, which can lead to significant financial losses and operational downtime (Circular Republic, 2024).

NEW REVENUE STREAMS

Adopting circular business practices can create opportunities for new revenue streams, such as selling refurbished products or offering services like repair and maintenance. By recognizing the potential value of waste by-products companies also have the opportunity to monetise what would have been previously treated as waste.

Section 2: A Circular Economy of MedTech In Ireland

IN THIS SECTION:

- We define what MedTech means,
- We define a Medical Device
- We present an overview of the Irish MedTech sector,
- We present the environmental impact of the Medtech Sector in Ireland
- We examine what a circular economy in the Irish Medtech sector would look like
- We give an overview of the regulatory challenge facing the implementation of a circular economy in MedTech

2.1 What is MedTech?

The Irish Government's Department of Enterprise Trade and Employment (DETE) defines Medtech as follows:

'Medical technology, (Medtech), encompasses medical devices and technologies for diagnosis, monitoring or treatment of diseases or medical conditions.'

MedTech Europe, the European trade association for the medical technology industry including diagnostics, medical devices and digital health states:

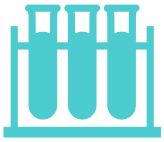
'Medical technologies are products, services or solutions used to save and improve people's lives.'

Medtech Europe further notes that these technologies are present at every phase of the patient pathway from prevention, diagnosis and monitoring to treatment and care

MedTech Europe provides a useful division of medical technologies into three main categories:

MEDICAL DEVICES

Products, services or solutions that prevent, diagnose, monitor, treat and care for people. (examples include minimally invasive technology, implanted devices, diagnostic equipment and imaging systems, surgical systems, dental equipment and devices, drug delivery devices, and ophthalmic and optical products and technology)



IN VITRO DIAGNOSTICS

Non-invasive tests used on biological samples (for example, blood, urine or tissues) to determine the status of a person's health.

DIGITAL HEALTH

Tools and services that use information and communication technologies (ICTs) to improve prevention, diagnosis, treatment, monitoring and management of a person's health and lifestyle. (examples include electronic health records, analytics, diagnostics and telecare/telemedicine)

For the purposes of these guidelines the term "medical devices" pertains to the medical devices and in vitro diagnostics categories defined above as these segments encompass the physical products, devices, materials and processes that have a greater environmental impact than the digital / electronic aspects of digital health and have a greater potential for the application of circular principles (while obviously acknowledging that the digital health segment can implement sustainable business practices many aspects of circularity also).

2.2 What is a Medical Device?

We use or interact with medical devices every day, sometimes without even realising it, as these devices range from objects commonly found in the home like sticking plasters, contact lenses, Covid-19 tests and crutches, to items we might more readily recognise as medical devices like implantable heart valves, pacemakers and replacement hip joints.

Regulation (EU) 2017/745 of the European Parliament on medical devices, more commonly called the **Medical Devices Regulation (MDR)** gives the following definition of medical devices:

'Medical Device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- **diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,**
- **diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,**
- **investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,**
- **providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,**

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

The following products shall also be deemed to be medical devices:

- **devices for the control or support of conception;**
- **products specifically intended for the cleaning, disinfection or sterilisation of devices as (...) referred to in the first paragraph of this point.**

Ireland is one of the main hubs for the production of medical devices in the world with a thriving MedTech sector supplying devices onto the global market.

2.3 Irelands MedTech Sector

The Irish MedTech sector is one of the top five global MedTech hubs (Government of Ireland, 2020) and is the third largest exporter of medical devices in Europe (MedTech Europe, 2023). According to Irish Development Authority (IDA) figures, over 50,000 people are employed in the MedTech sector in Ireland with 14 of the top 15 global MedTech companies having a presence here. The sector accounts for 8% of all exports from Ireland worth an estimated €14.9 billion with exports to over 100 countries worldwide. Ireland has the highest per capita proportion of people employed in MedTech industry in Europe (MedTech Europe, 2023).

There are some particularly notable examples of the Irish MedTech sector's contribution to the global supply of medical devices (Medical Technology Ireland, 2023):

- Ireland is the world's largest exporter of contact lenses.
- 80% of the stents used globally are manufactured in Ireland.
- 50% of world's ventilators are manufactured in Ireland.

The sector is decentralised in nature and distributed across the country with significant clusters along the western seaboard and in the midlands as well as around Dublin.

2.4 Environmental impact of Ireland's MedTech Sector

2.4.1
Single use devices as default

The healthcare sector encompasses all aspects of acute and community hospital, local care and home care settings, including the medical technology and devices used in the treatment of patients at these locations.

In the healthcare sector, patient safety is the primary consideration. Concerns regarding risk of infection or cross-contamination, especially since the Covid pandemic, has seen a significant rise in single-use devices as a model of product delivery. While this approach may be driven by a concern about infection, it has multiple negative consequences.

90% of medical device waste primarily consists of single-use devices

(Health and EY, 2024)

Medical device companies may come to regard single use as the default business model and consider that their customers have an expectation of single usage. This may inhibit investment in designing and producing devices that some components of the device could potentially be sterilised and can reused, repaired, refurbished or remanufactured.

Healthcare staff may also come to regard single use as the default. Without proper training they may not be aware that some elements of medical devices or packaging can be can be reused, repaired, refurbished remanufactured or recycled.

The Irish Health Service Executive Green Healthcare programme found that a third of medical waste placed in the biohazardous waste bin was not actually biohazardous waste and a further third of this waste could have been recycled.

In the absence of such training and appropriate recycling facilities, such as separate recycling streams and clearly labelled bins etc., staff may not be fully invested in the process. This may be especially true given the time pressures typical in the sector.

2.4.2
Competing and opposite pressures to change

Historically, there has been very little financial incentive for a device producer to invest in the creation of device recovery and reprocessing/remanufacturing systems.

The design and commercialisation process of a circular medical device may take longer than that of a single use device as significant consideration needs to go into creating a reverse logistics system for the collection, sterilisation, return, reprocessing/remanufacturing and recertification of used devices to reissue these products back into circulation.

This process typically involves an ecosystem of more stakeholders and "links in the chain" versus the linear, take-make-waste model of single use devices. It is therefore understandable, particularly in very price sensitive product sectors, why many companies would decide not to explore more sustainable or circular options.

However, this scenario is changing with legislation and regulations coming into effect which require companies to adopt more environmentally sustainable practices.

There is a movement among some healthcare professionals and patient groups to oppose the single use approach and highlight the lack of more sustainable options provided to them by device companies. For example, there is a growing opposition from Type 1 Diabetes patients to the amount of waste produced by continuous glucose monitors (PA Knowledge Limited, 2024)

Taking these factors into account, there are competing and opposite pressures on medical device companies when considering the design and provision of devices. While there is a move towards single use devices driven by a concern of infection control and sterility, there is also and increasing focus on the negative environmental impact of healthcare and the waste generated by the sector.

2.4.3
Energy consumption

As with all industry sectors involved in the creation of physical products from finite, non-renewable and abiotic (non-living) raw materials, the extraction, processing and manufacture of products requires vast amounts of energy – predominantly based on the burning of fossil fuels. Further energy consumption is required for the transportation and distribution of products, sometimes across long supply chains reaching across the globe. The production and transportation of medical devices is no different.

MedTech's rigorous safety standards often curtails the use of recycled materials in the production of devices, requiring the usage of virgin materials. After devices have been used many are classified as biohazardous waste and are typically incinerated requiring further inputs of energy in this end-of-life process.

2.4.4
Waste generation

In the Republic of Ireland, the Environmental Protection Agency (EPA) is the organisation "responsible for compiling national statistics on circular economy activities and the generation and management of waste" under statutory European and international reporting obligations.

According to the EPA's Circular Economy and Waste Statistics Highlights Report 2021 (Environmental Protection Agency, 2023), Ireland produced 3.17 million tonnes of municipal waste in 2021 (first year of breakdown figures by material type using European Waste Code). Of this, 20,000 tonnes were Health care and biological wastes (while there is no specific breakdown of the constituents of this waste, the figure includes medical devices).

Healthcare waste is categorised as either Healthcare Risk Waste or Healthcare Non-Risk Waste. Healthcare Risk Waste is classified as hazardous waste due to the risk posed by its potentially infectious or harmful nature.

Ireland produced 3.17 million tonnes of municipal waste in 2021. Of this, 20,000 tonnes were health care and biological wastes.
(EPA, 2023)

According to the EPA; "2021 was the first year in which more hazardous waste was treated in Ireland than was exported for treatment: 52% of hazardous waste was treated in Ireland and 48% exported.

The Green Healthcare programme (funded by Health Service Executive Capital & Estates through the Climate Action & Sustainability Office) seeks to reduce waste in Irish healthcare facilities. Green Healthcare information aimed at raising awareness among healthcare staff states that,

at least one third of the waste disposed of as healthcare risk waste is not actually risk waste and this misidentification costs €1.3 million per annum nationally.

Furthermore, at least a third of the material in general waste bins in healthcare settings could be recycled, costing another €0.5 million per annum.

While information is focussed on cost savings to individual healthcare institutions and the healthcare system, the potential environmental impact through the correct identification and disposal of items in healthcare settings is obvious.

2.4.5
Resource use, extraction and depletion

The typical business model for single use devices is the take-make-waste model of the linear economy. Within this model, due to current methods of waste disposal, a plethora of valuable materials and resources are wasted at the devices' end of life. Valuable and finite abiotic resources (metals and hydrocarbons) that are used in the production of the device are not recovered or reused, thereby losing the intrinsic value of the materials themselves. Also lost is the embodied value of the component they form - including the energy and resources that have gone into making them, assembling them and transporting them to the site of usage. They are also typically incinerated after use, thereby requiring more energy for their disposal and becoming a source of pollution through the release of toxins and other pollutants during incineration and requiring landfill of ash by-products.

In a partial or fully circular scenario, some or all of the resources, materials and energy required to produce a device would be saved.

2.4.6
Transport / global supply chains

Many of the major medical device companies located in Ireland produce a significant proportion of the global supply of different devices (for example Ireland is the largest exporter of contact lenses, produces 80% of the world's stents, and 50% of the worlds ventilators). Considering these items are produced in a small island on the western edge of Europe, they have lengthy global supply chains with the attendant energy usage that these supply chains involve.

While locating major manufacturing bases in one site allows companies to benefit from economies of scale (and in Ireland's case, a low corporation tax rate when compared internationally), this also means massive transportation and logistics operations to ship products all around the world, predominantly via fossil fuelled based modes of transportation. This can significantly increase the carbon emissions, pollution, resource usage and environmental impact of the products distribution.

In a scenario where some or all of a medical device could be reprocessed and reused, this could happen on a local scale or within country boundaries. This would mean that after an initial product purchase, the logistics and supply chains required to keep a product circulating in use would shorten and reduce the environmental impact of shipping brand new products from the same manufacturing site continuously.

2.5 Circular Economy in Irish MedTech

2.5.1
How does the Irish Medtech sector move from its current position to a more circular model?

While the intent of many businesses is to move towards more environmentally responsible practices, and there are financial incentives and regulatory imperatives that will direct companies towards these changes, it is also acknowledged that for a myriad of reasons, it can be challenging for companies to change long established processes, supplier relationships and production methods as well as a hesitancy to create any change that may affect customer expectations, satisfaction or service.

For companies that are evaluating their businesses with a view to the adoption and implementation of practices and methodologies that seek to reduce environmental impact, a pragmatic and realistic approach about the extent to which their products can be circular will help define clear and achievable goals to direct commercial strategy.

Due to the nature of the products they supply, some companies may not be able to achieve circularity in their end product ranges. For example, companies producing consumable devices such as contact lenses or implantable devices like orthopaedic joints, will not be able to retrieve and reuse these devices. However, the potential for positive environmental impact is not solely focussed on the products a company produces. Significant environmental impacts can be achieved in areas related to the sourcing, production, packaging and delivery of these products. By examining each step in the value chain, companies can identify areas of greatest potential impact, evaluate which of these areas are technically and commercially feasible, and develop a strategy to implement changes to existing business practice to realise these changes.

In that way companies can move incrementally through increasing levels of circularity in their business while acknowledging from the outset that, due to the nature of their product range, they may never be able to fully close-the-loop on their products or services.

For companies whose current or planned products lend themselves to a potentially circular approach (either partially or entirely), an important aspect for consideration is the shift in business strategy from a sales business model to a service model where the company (either through their own provision or through the engagement of third parties) creates a service proposition that allows the company to collect used products to reuse, repair, refurbish, remanufacture or repurpose them before repackaging and distributing within regulatory and legislative boundaries.

While creating a technically feasible and commercially viable circular service proposition is challenging, through examples and case studies, these guidelines hope to demonstrate the possibilities and opportunities that exist to operate successfully in circular MedTech.

2.5.2
Benefits of Circularising MedTech in Ireland

Circularising MedTech in Ireland would have the following benefits:

- A reduction in the amount of finite resources and raw materials, including rare earth metals, extracted from the earth to create new devices.

- A reduction in the fossil fuel consumption required for the processing, manufacturing and transportation of devices across global distribution networks.
- A reduction in the amount of energy required for, and the pollutants created by, the current end-of-life treatment of devices through incineration and landfill.
- The creation of an innovative circular MedTech hub for the design, production and delivery of circular medical devices and service models.
- Increase in Ireland's industrial competitiveness internationally.

To achieve these benefits the creation and activation of stake holder networks is key.

2.5.3
Key stake holders

At present, in a single use device scenario, many large medical device companies will produce products and handle the packaging, sterilisation and logistics themselves. This gives them control of the production and distribution elements of their business with the supply chain of raw materials and components being the only area outside of their direct control.

Smaller companies may design and specify bespoke components and assemblies, sometimes produced by third parties on a contract basis, and assemble these components in their own facilities, while again contracting out the sterilisation, packaging and transportation aspects of the business.

In an ideal circular scenario, there would be a network of interdependent stakeholders. The key members and roles of which are:

- **Raw material / component suppliers**
  Transparent supply chain
- **Medical device producers**
  Supplies product and creates circular service model
- **Healthcare professionals**
  Point of usage and initial step of device recovery
- **Packaging providers**
  (Re)labelling and (re)packaging of devices
- **Logistics providers**
  Reverse logistics systems to recover / redistribute devices
- **Reprocessing/remanufacturing facilities**
  Sterilisation and reprocessing / remanufacturing
- **Policy makers**
  Legislative framework for circular systems to operate
- **Regulatory bodies**
  Regulatory pathways for circular device certification

These stakeholders would work together and be invested in an eco-system that can produce, transport, use, recover, reprocess/remanufacture and redistribute devices in a certified and transparent eco-system that ensures patient safety and maximises the length of time that devices (or the main components of those devices) are in use through a number of certified reprocessing/remanufacturing cycles.

When a device reaches end-of-life, it would be designed in such a way that it can be disassembled easily and the majority of its components recycled appropriately in a safe manner.

This approach will require medical device producers to forge new relationships with third party service providers who will be responsible for part of the supply chain.

Performance and reliability will be key to create the levels of trust and operational efficiency required for this type of system to be successful.

There will also need to be changes to current policy, regulation and legislation to allow the classification, certification and approval of reprocessed / remanufactured devices and components as well as the harmonisation and streamlining of approaches to policy within and across jurisdictions to allow this scenario to operate safely and transparently.

There are exemplars of companies and service providers that are creating successful circular business propositions already (See Section 3). The likelihood is that more new innovative businesses will be created, and new competencies and services will be offered by existing adjacent companies to meet the demand for increased circularity and provide either an end-to-end service or provide services for specific links in the circularity chain.

2.5.4 Policy Drivers & Government Support

As a member of the EU, medical device companies operating in Ireland are subject to both EU and Irish regulation and legislation.

In addition, Irish medical device manufacturers which export their products to other countries must ensure that their products comply with the relevant regulations and legislation in the jurisdictions they are exporting to.

Due to increasing awareness of the negative environmental impact of our linear economy, the EU and individual governments of countries that are major markets for Irish MedTech companies (e.g. US and UK) have sought to implement policies that reduce the amount of waste produced by all sectors, promote sustainable practices and approaches in the production of products and increase transparency in the environmental claims made by companies

Adherence to developing regulations and policies will undoubtedly create challenges for Irish MedTech companies. However, there are also huge opportunities for progressive companies to position themselves at the forefront of what will only be a growing market shift towards more sustainable healthcare products and services pushed by worsening environmental factors, increasing regulation but also pulled by a more informed and demanding customer base.

To help Irish business capitalise on this opportunity and encourage sustainable business approaches the Irish Government offers supports coordinated by the National Enterprise Hub and provided through various agencies including Skillnet Ireland, Local Enterprise Offices, Enterprise Ireland, the Irish Development Authority (IDA), the Sustainable Energy Authority of Ireland (SEAI), Bord Bia (Irish Food Board) and more.

These supports range in intent and scale from specialised skills training on climate action and sustainability, and grants to invest in carbon-reducing technologies, to assistance in the implementation of sustainable practices for multinational organisations.

2.6 The Regulatory Challenge

In the MedTech industry, there is a complex regulatory landscape designed to ensure the safety, efficacy, and quality of medical devices.

Medical devices in Ireland are primarily regulated by the **European Union Medical Device Regulation (EU MDR 2017/745)** and the **In Vitro Diagnostic Regulation (IVDR 2017/746)**. These regulations ensure that medical devices meet strict safety, performance, and quality standards before they are placed on the market. In Ireland, the **Health Products Regulatory Authority (HPRA)** is responsible for enforcing these regulations.

While medical regulations traditionally prioritise patient safety and efficacy, new sustainability regulations such as **The Circular Economy Action Plan** are pushing for eco-friendly practices in all industries, including MedTech.

Medical devices intersect with several other sectors that have their own regulatory frameworks, such as **REACH, WEEE, ADR, GDP, Waste Framework Directive**, creating a multi-layered and highly regulated environment.

As the regulatory landscape is vast and complex, there is a tendency to generalise "the regulations" as a blanket obstacle to the adoption of circular economy principals without fully understanding the specific rules and opportunities for circularity.

Although incorporating circular economy principles, such as reprocessing, recycling, or remanufacturing medical devices can add significant regulatory complexities, there are many successful circular initiatives/businesses in the MedTech space operating within the current regulatory frameworks.

There is also potential for regulations to evolve in ways that support a circular economy in the MedTech sector.

For example:
The reprocessing of certain single-use medical devices is now allowed under Article 17 of EU MDR, provided it meets strict safety and performance criteria. When reprocessing/remanufacturing single use medical devices, manufacturers must show that the reprocessed/remanufactured device poses no additional risk. This requires proving that the reprocessed/remanufactured device can be effectively sterilised without compromising its functionality or safety, requiring extensive validation, clinical testing, and documentation to prove that the reprocessed/remanufactured device is as safe and effective as a new one.

However, it does not come without complexities/challenges.

In the EU there are two regulatory pathways to reprocessing/remanufacturing single use medical devices under the EU MDR.

- **Medical Remanufacturing with CE certification**
- **Medical Remanufacturing with CS certification**

There is a patchwork adoption and acceptance of these standards across EU as countries may choose how they implement these regulations. Some countries allow the reprocessing/remanufacturing of single-use devices according to both sets of standards, some by one or the other, while others prohibit it altogether or allow the reprocessing/remanufacturing but not the sale of such devices in their region.

For example, currently (as of November 2024): **Germany** permits reprocessing/remanufacturing under both sets of regulations and has established procedures in place in their own regulations (Section 4 of the Medical Devices Operator Ordinance (MPBetreibV)).

Spain, Portugal and Belgium take a similar approach with added restriction and prohibitions beyond the direct requirements of the MDR.

Iceland allows for both with no additional restriction and prohibitions.

France, Italy and 16 other EU counties prohibit the reprocessing/ remanufacturing of single use devices and their sale on their territory.

The Republic of Ireland and the Netherlands, allows for both the remanufacture and sale of reprocessed/ remanufactured single use devices under CE certification only.

In **Poland**, single use medical devices can be reprocessed/ remanufactured under CE certification only but not sold on their territory, only exported to counties which allow the use of Reprocessed/remanufactured single use medical devices under CE certification.

Croatia and Sweden allow the reprocessing/remanufacturing of Single Use Medical devices under CS certification only. They do not allow the reprocessing/ remanufacturing of singe use devices or their sale on their territory.

This fragmented approach means companies must navigate differing national regulations, which increases costs and complexity for businesses seeking to operate across multiple EU member states. The EU's goal of a seamless, borderless market is undermined by the inconsistent application of Article 17.

The inconsistent application of Article 17 under the EU MDR creates challenges for the MedTech sector, impacting market size, trade, operational efficiency, and sustainability. While complete harmonisation may not always be practical due to technical and financial constraints, greater regulatory alignment where feasible could enhance market accessibility, reduce trade barriers, and support the adoption of circular economy principles in MedTech across the EU.

The key MedTech regulations—like MDR, IDVR and ISO standards— are essential for protecting patient safety and can pose real challenges to the circular economy, but they aren't insurmountable.

By better understanding which regulations apply and how they can be navigated, the MedTech industry can innovate toward more sustainable, circular models while still ensuring patient safety.

Section 3: Circular Innovations in MedTech Ireland

IN THIS SECTION:

- **We present a series of international case studies showcasing innovative Circular Economy (CE) practices within the MedTech sector. While this guide is tailored to Ireland's MedTech industry, these global examples provide valuable insights and actionable lessons that can inform and inspire local implementation.**
- **The case studies have been clustered under key themes**
  - **Extending product lifecycles,**
  - **Design for circularity,**
  - **Material recovery and innovations, and**
  - **Sustainable packaging.**

  Each highlights strategies adopted by companies worldwide to address challenges, leverage opportunities, and align their operations with CE principles.
- **We also include a section on CIRCULÉIRE's 2022 Thematic Working Group on End-of-Waste & By-Products as it relates to the GE Healthcare case study.**
- **By examining these international examples, Ireland's MedTech stakeholders can identify transferable practices, adapt them to the unique context of the Irish market, and accelerate the sector's transition to a more sustainable and circular future. These case studies serve as a starting point for collaboration, innovation, and leadership in advancing CE within Ireland's MedTech sector.**

PLEASE NOTE

Because of the difference in measurement and evaluation techniques and methodologies it would be impossible in the scope of these guidelines to provide an accurate verification or comparison of information presented in the case studies below.

The information presented is taken from company source material publicly available on the companies' website, or from websites of third parties, along with the basis or reporting standard on which this information was generated (if available).

The accuracy of this information is taken in good faith and the presence of this information in the case studies does not constitute a verification of the accuracy of this information or an endorsement of the company or its activities on the part of the authors.

3.1 Cluster 1 - Extending Product Lifecycles

Extending the lifecycles of medical devices is a cornerstone of the Circular Economy (CE). This cluster explores how refurbishment, reprocessing, remanufacturing, and repair practices enable MedTech products to remain in use for longer, reducing waste and conserving resources. By maximising the functional lifespan of devices, these strategies not only align with CE principles but also offer cost-saving opportunities and environmental benefits while maintaining stringent safety and quality standards.

FEATURED CASE STUDIES:

- Royal Philips
- Vanguard AG

COMPANY: ROYAL PHILIPS

Royal Philips of the Netherlands is a leading health technology company specialising in diagnostic imaging, image-guided therapy, patient monitoring and health informatics, as well as in consumer health and home care.

One of the largest MedTech companies in the world, Philips recorded 3.64 billion euro in revenue from circular products and services in 2023. That amounts to 20% of their total 18.2 billion euro revenue for the year.

LEADERSHIP, STRATEGY, TARGETS & KPIS

Philips have long been a lighthouse example for the circular economy. The company's circular transformation journey began in 2012, a year after Frans van Houten took over as CEO. Under van Houten their first five-year strategy embedded circular economy explicitly into Philips' strategy, justifying it with a business rationale of increased competitiveness, cost savings and better customer relationships.

Circular KPIs were added to their 2016-2020 strategy and a concrete target of 15% of revenues from circular products and services was set.

For their 2021 - 2025 strategy Philips is committed to generating 25% of sales from circular products, services and solutions.

CULTURE CHANGE AND TRAINING

To instil a circular minded culture within the organisation, Philips uses storytelling to engage different audiences, created dedicated hubs across departments to share knowledge and expertise, and provides training for priority audiences such as product and service designers.

CIRCULAR BUSINESS MODELS

Philips reduces material use and builds lasting customers relationships through Product-as-a-Service offerings, Take-Back Schemes, plus upgrade and refurbishment programmes for medical imaging systems including, Mobile C-Arms, Ultrasound and Magnetic Resonance Imaging.

Philips offers refurbished MRIs at a price on average 25% lower versus a new system. Their refurbished systems come with the same warranty and service performance levels as a new system, reusing 79% of the average material weight.

Their MRIs are upgradeable and save up to 50% energy consumption versus similar systems.

FURTHER REFERENCES

- https://hollandcircularhotspot.nl/case/philips-healthcare-refurbished-systems/
- https://www.ellenmacarthurfoundation.org/circular-examples/pioneering-circularity-in-the-healthcare-industry-royal-philips

COMPANY: VANGUARD AG – MEDICAL REMANUFACTURING

Vanguard AG, a German company specialising in sustainable medical device reprocessing/remanufacturing, focuses on extending the life of single-use medical devices (SUDs) through reprocessing/remanufacturing.

Vanguard offer an extensive product portfolio of remanufactured products from the fields of electrophysiology and surgery. Vanguard's approach aims to reduce waste and environmental impact in healthcare, aligned with stringent European regulatory standards.

Vanguard AG's case demonstrates the feasibility and benefits of Circular Economy principles in the MedTech sector, showcasing how lifecycle extension, regulatory alignment, and financial incentives can converge to drive circularity in healthcare.

EXTENDING PRODUCT LIFECYCLES

Vanguard AG specialises in the remanufacturing of single-use medical devices (SUDs), such as electrophysiology catheters (typically designated as SUDs) which are costly to dispose of and resource-intensive to manufacture. Remanufacturing such devices extends their lifecycle. Through a closed-loop service, used devices are collected, inspected, decontaminated, remanufactured, sterilized, and redistributed. This approach reduces waste and decreases reliance on virgin materials.

Approximately 52.1% of collected devices are successfully remanufactured, delivering significant environmental and economic benefits. For example, remanufactured catheters reduce abiotic resource use by 28.8% and global warming impact by 50.4% compared to producing new devices.

Vanguard partners with both hospitals and original equipment manufacturers to provide medical devices reprocessing as a service.

REGULATORY COMPLIANCE

Vanguard adheres to the EU Medical Device Regulation (MDR) 2017/745 and follows related ISO standards, including EN ISO 13485 for quality management and ISO 14971 for risk management ensuring all reprocessed/ remanufactured devices meet (or exceed) regulatory requirements.

In the EU there are two regulatory pathways to reprocessing/ remanufacturing single use medical devices. Vanguard offers both to their clients, depending on their jurisdiction.

1. **Medical Remanufacturing with CE certification**
   - Legal basis Article 17(2) of the MDR
   - All manufacturer obligations of the MDR are taken over
2. **Medical Remanufacturing with CS certification**
   - Legal basis Article 17 (3) and (4) of the MDR in conjunction with Common Specifications (Common specifications are detailed practical rules setting out how particular types of devices should comply with certain requirements of MDR)
   - Core manufacturer obligations (except clinical testing, CE certification) are assumed.

Note: Medical Remanufacturing under CS certification is prohibited in Ireland.

FINANCIAL INCENTIVES

Vanguard's services offer healthcare providers a cost-effective alternative to purchasing new devices, reducing procurement costs by up to 30% in applicable areas. The remanufacturing model supports cost savings through lifecycle extension, reduced 'waste' generation and lower resource consumption, enabling hospitals to align financial efficiency with sustainability goals. These economic advantages, combined with the environmental benefits, have contributed to growing market acceptance and adoption of reprocessed SUDs.

Further References:

- https://www.mdpi.com/2071-1050/13/2/898
- https://www.vanguard.de/en/
- https://www.vanguard.de/en/fraunhofer-umsicht-has-published-these-remarkable-findings-in-sustainability-a-scientific-journal-dedicated-to-sustainability-and-sustainable-development/
- https://health.ec.europa.eu/medical-devices-topics-interest/reprocessing-medical-devices/national-rules-reprocessing-single-use-devices_en

Disclaimer:
Figures are based on internal and third-party studies, including LCA results (guided by ISO 14040 and 14044), and should be interpreted within context.

3.2 Cluster 2 - Design for Circularity

Designing products with circularity in mind ensures that sustainability is embedded from the start. This cluster highlights innovations in resource optimisation, modular design, and the integration of bio-based materials. It also examines how business models like Product-as-a-Service (PaaS) are enabling circularity by retaining control over products throughout their lifecycles. Together, these approaches reduce environmental impact and pave the way for a more efficient, flexible, and sustainable MedTech sector..

FEATURED CASE STUDIES:

- Stryker
- Zsquare
- Tympany Medical

COMPANY: STRYKER SUSTAINABILITY SOLUTIONS (SSS)

stryker®

Sustainability Solutions

Stryker, a global leader in medical technology, has embedded sustainability into its mission, emphasising environmental responsibility, resource conservation, and circular economy practices across its operations.

Stryker's Sustainability Solutions (SSS) offers an extensive range of reprocessed/ remanufactured medical devices, including their own, and those from other leading manufacturers, such as Abbott and Boston Scientific.

Stryker's 'Redesigned for Sustainability' philosophy demonstrate their commitment to reducing waste, conserving resources, and embedding sustainability into their business.

EXTENDING PRODUCT LIFECYCLES

Stryker offer you an extensive range of remanufactured medical devices consisting of their own original devices and devices from other medical device companies such as Abbott, Boston Scientific and Medtronic.

The reprocessed/ remanufactured Hologic MyoSure® hysteroscopic tissue removal suite is their flagship family of devices that incorporate Strykers 'Redesigned for Sustainability' philosophy.

Through rigorous processes including decontamination, disassembly, testing, and reassembly, Stryker ensures reprocessed devices meet or exceed original performance standards. Key elements include replacing substandard components with new parts and utilising advanced testing methods to guarantee safety and functionality.

FDA 510(k) clearance confirms that reprocessed/ remanufactured devices are as safe and effective as their OEM counterparts, fostering trust among healthcare providers.

DESIGN FOR CIRCULARITY

Stryker's 'Redesigned for Sustainability' philosophy exemplifies how circular design can reduce environmental impact throughout a product's lifecycle. This initiative incorporates innovative materials, thoughtful packaging, and efficient manufacturing processes to align with circular economy principles.

Materials Innovation
Key components of the MyoSure® device are replaced with sustainable alternatives, including bio-based plastics made from renewable softwood and PVC-free tubing to reduce chemical exposure.

Sustainable Packaging
Stryker reduced packaging weight by 34%, eliminating 53,000 pounds (approx. 24,000 kg) of material over five years. This not only minimises waste but also decreases transportation emissions.

Resource Efficiency in Manufacturing
By integrating water-efficient techniques, Stryker saves 164 gallons of water per batch of devices during cleaning, showcasing a commitment to sustainable production.

MARKET ADOPTION AND IMPACT

Stryker has successfully scaled its sustainability initiatives, earning the trust of over 3,000 hospitals worldwide. By combining environmental stewardship with cost-effective solutions, Stryker has driven widespread acceptance of reprocessed devices in a competitive market.

Environmental Benefits
Reducing manufacturing waste, raw material usage, and chemical exposure, Stryker's efforts align with the sustainability goals of healthcare facilities. Over 22 million devices have been diverted from landfills, significantly reducing waste while delivering more than $2 billion in cost savings to healthcare providers.

Economic Advantages
Reprocessed/remanufactured devices offer significant cost savings, supporting hospitals in managing budgets while achieving sustainability objectives.

FURTHER REFERENCES

- https://www.stryker.com/us/en/sustainability.html
- https://www.stryker.com/content/dam/stryker/about/annual-review/2023/Stryker-2023-Comprehensive-Report.pdf
- https://www.stryker.com/us/en/sustainability/products/myosure.html
- https://www.stryker.com/us/en/portfolios/medical-surgical-equipment/reprocessed-products.html
- https://www.stryker.com/content/dam/stryker/endoscopy/products/myosure/resources/MyoSure%20White%20Paper%20.pdf

Disclaimer:
Figures are based on internal studies and should be interpreted within context.

Company: Zsquare

Zsquare is an Israeli biomedical company that produces flexible single-use endoscopes that allow surgeons to view inside the body during minimally invasive surgical procedures across a range of surgical disciplines.

In 2022, Zsquare received approval from the Food and Drug Administration in the US to market their first product, the Zsquare ENT-Flex™ Rhinolaryngoscope.

The ENT-Flex is designed to visualise the internal cavities of the ear, airways, nose and sinus cavities during diagnostic endoscope procedures.

CHALLENGE ADDRESSED

Due to concerns about patient safety and possible cross contamination from incorrectly or inadequately sterilised reusable endoscopes, there has been a move towards single-use endoscopes for diagnostic and surgical procedures. Currently, these devices, which contain many electronic, optical and recyclable components and materials, are typically incinerated as biohazardous waste.

The design of Zsquare's ENT-Flex ensures that as much as possible of the endoscope is reused while also having a minimal single-use element so that patient safety is maintained.

SERVICE PROPOSITION

The Zsqure ENT-Flex is a modular platform consisting of a reusable control console, reusable imaging core, and different disposable single-use shells for each of the five surgical indications of Ear, Nose and Throat (ENT), urology, gynaecology, bronchoscopy and gastroenterology. The disposable sterile single-use shell contains a steerable shaft (inserted into the patient) housing optical components and imaging and illumination fibres. It is the only part that contacts the patient and physician, and is disposed of at the end of the procedure. After the procedure, the imaging core is disengaged from the single-use shell, is cleaned appropriately in-hospital and ready for reuse with a new single-use shell.

SUSTAINABILITY / CIRCULARITY BENEFITS

This is a good example of how a well-designed product system can meet circular objectives even though the product is not positioned on the market as a circular device.

The product is designed in a modular format where consideration has been given to the configuration of the components in each modular element of the overall product to maximise the reuse of valuable components and reduce waste as much as possible. The high value and high environmental impact components (electronics and vision processing elements) are contained in a sterilisable and reusable imaging core that is sheathed during surgical procedures and therefore protected from patient contact. This part clips into a range of single use endoscopic camera heads, each designed for specific surgical applications. Although the camera heads are disposed of after use (typically through incineration), this configuration significantly reduces the amount of waste compared to many current single use endoscopes where the entire device, including all the electronic components containing rare earth metals, is disposed of as biohazardous waste and incinerated.

FURTHER REFERENCES

- https://www.zsquaremedical.com/
- https://www.accessdata.fda.gov/cdrh_docs/pdf22/K220004.pdf

CIRCULÉIRE Member: Tympany Medical

Tympany Medical is a Galway-based medical technology company that develops sustainable ear, nose, and throat endoscopes.

Tympany Medical are the only start-up included in our selection. They are a CIRCULÉIRE member who have circularity at their core.

Endoscopy uses camera technology to improve the visualisation of hard-to-reach areas during surgery. Focused on reducing waste, the company created the Solascope, a sterile, reusable panoramic endoscope. By rethinking endoscope design, Tympany aims to lower the environmental impact of medical devices while improving surgical visibility.

BUSINESS ACTIVITIES

Single-use medical supplies account for about 80% of the industry's carbon footprint. Currently, discarded products that are disposable rather than reusable make up 85% of global medical waste. Tympany Medical addresses the environmental challenge posed by single-use medical devices. With traditional endoscopes, procedures require multiple scopes and extensive sterilization, generating significant waste. Tympany's Solascope device minimizes waste by encapsulating the core components, allowing for reuse, which reduces both environmental impact and costs associated with medical waste disposal.

RECIRCULATION APPROACH

Tympany medical has developed the next generation of endoscope called Solascope. The Solascope introduces a an encapsulation technology, allowing its complex internal components to be reused across procedures. Solascope's inbuilt lens-cleaning feature maintains a clear surgical view, enhancing efficiency. Through an integrated manufacturing and remanufacturing model, Tympany advances circular economy principles in medical devices.

IMPACT DATA

The Solascope's design reduces reliance on single-use devices, cutting costs of hazardous waste disposal, which can average €1,530 per tonne. This innovation also reduces the number of scopes required per surgery from 4 to 1, significantly cutting medical waste. Tympany Medical's approach not only lowers expenses for healthcare providers but also minimizes environmental impact.

FURTHER REFERENCES

- https://www.zsquaremedical.com/
- https://www.accessdata.fda.gov/cdrh_docs/pdf22/K220004.pdf

3.3 Cluster 3 - Material Recovery & Innovations

Efficient material recovery and innovative use of sustainable materials are key enablers of CE in MedTech. This cluster focuses on recycling processes, both internal and external, as well as advancements in biomaterials that reduce reliance on virgin resources. By closing material loops, MedTech companies can significantly reduce waste and create a more resilient, resource-efficient system that supports circular practices at scale.

FEATURED CASE STUDIES:

- GE Healthcare
- Envetec
- Novo Nordisk

COMPANY: GE HEALTHCARE

GE Healthcare, is an American multinational medical device provider that designs, develops, manufactures and distributes diagnostic imaging and clinical systems; products and services for drug discovery, biopharmaceutical manufacturing, and cellular technologies.

Seeing the value in waste trimmings from blood-pressure cuffs, GE saved landfill and disposal costs, while creating a new revenue stream and providing a valuable feedstock for a shoe manufacturer.

FINDING THE VALUE IN WASTE

In GE HealthCare's manufacturing plant in Ciudad Juárez, Mexico 1.4 million blood pressure cuffs are produced every week. Part of the production process involves trimming the edge of each cuff and 566 metric tonnes of PVC trimmings are produced every year. Those trimmings were previously returned to the U.S. from Mexico for landfilling at a cost of $52,000 per annum.

Recilogic, an industrial symbiosis facilitator and secondary materials processor had prior knowledge of GE's PVC waste, and approached GE's Environmental Health, and Safety (EHS) Manager at the Mexico plant, and their Border Ops Plant Manager in Texas about finding a use for it.

Due to the cleanliness and quality requirements for materials used in the the MedTech sector, by-product material can be a high-grade and desirable feedstock for other companies.

INDUSTRIAL SYMBIOSIS IN PRACTICE

Testing the PVC with a manufacturer in Mexico, Recilogic found that a mixture of 60% of the trimmings, combined with resins and adhesives, formed a strong and flexible shoe sole.

GE Healthcare staff began collecting the trimmings in bins before supplying them to Recilogic for shredding. Recilogic then supplied a shoemaker with clean medical grade PVC for use in the manufacture of their shoe soles.

Recognising the value in what was previously consider waste helped save GE Healthcare $52k per annum in disposal costs while diverting 566 tonnes of waste from landfill. This simultaneously provided a new revenue stream for GE and further benefitted their ESG goals. The experienced has inspired GE to search for uses of other by-products creating the potential for additional future revenue.

The shoe manufacturer gained access to clean medical grade PVC, which avoids the need for virgin PVC and its inherent environmental extraction and processing costs.

GE's EHS Manager had been searching for other MedTech uses for their by-products for some time but had run into challenges with regulatory requirements. The partnership with Recilogic helped GE find a company outside of the MedTech sector with a need for their material. While MedTech by-products maybe be difficult to use within MedTech there may be opportunities in other industries.

Further References
https://www.gehealthcare.com/insights/article/hoping-to-do-their-part-in-the-circular-economy-a-new-program-in-mexico-turns-scraps-into-shoes

Disclaimer:
Figures are based on internal and third-party studies and should be interpreted within context.

3.4 By-Products & End of Waste

As seen in the GE Healthcare case study, a by-product is a residue left over from the production of another product.

In Ireland, Regulation 27 of the Waste Directive sets out the circumstances in which a material can be considered a by-product and not a waste.

It is essential you notify the EPA to determine if your material satisfies the criteria of a by-product. The EPA will confirm if it can be categorised as a by-product or if it must be categorised as a waste.

If the substance is classified as a 'waste' then it may need to achieve End-of-Waste status via Article 28 of the Waste Directive to be kept in use as a resource.

In 2022, CIRCULÉIRE organised a Thematic Working Group (TWG) to demystify End-of-Waste & By-Products for industry. Several resources were produced based on the learnings from that TWG. You can access those resources at the links below:

CIRCULÉIRE's End-of-Waste and By-Products TWG Seminar
During this 2-hour virtual seminar, Karl Hylands of RE-MINE Ltd. provided panel members with an overview of the key terminology and considerations for industry when making an End-of-Waste By-Product application. Caitriona Collins (EPA) provided attendees with an overview of the EPA's approach to End-of-Waste & By-Product regulations and clarified the role and responsibilities of key agencies - alongside the EPA – in this domain.
https://wks.circuleire.ie/public/artefact/b5076829-a1d8-4468-90f5-78b59d55c06e

Industry Fact Sheet: End of Waste, By-products and Waste Licensing Pathfinders
Co-Delivered by Re-Mine Limited and Irish Manufacturing Research (IMR). This Industry Fact Sheet summarises the key insights from this TWG for Irish businesses looking to prepare an end-of-waste or by-product submission.
https://wks.circuleire.ie/public/artefact/feb7fd23-66d5-4236-aabd-352ccab9a66d

Self-guided Worksheet for End-of-Waste and By-Products Application Preparation
This worksheet is intended to guide you with the initial prompts to understand whether your material is an End-of-Waste or a By-Product, and what initial steps you'll need to take to prepare an application.
https://wks.circuleire.ie/public/artefact/9fd15ad3-1d78-44a5-a089-f7bb832b7f00

Policy Briefing: End-of-Waste, By-products and Waste Licensing Pathfinders
This policy briefing summarises the key challenges identified by CIRCULEIRE's End-of-Waste, By-products and Waste Licensing Pathfinders Thematic Working Group. Based on the Thematic Working Group Ideation Workshops, it then sets out a number of proposals for Irish business and Government and Regulators that were co-developed with input by CIRCULÉIRE's multi-sectoral panel members which could play a critical role in advancing the national End-of-Waste and By-product regime for a circular economy in Ireland.

https://wks.circuleire.ie/public/artefact/c0742665-38e4-4b54-a1dd-15d9f10b203e

Synthesis Report: End of Waste, By-products and Waste Licensing Pathfinders
Co-Delivered by Re-Mine Limited and Irish Manufacturing Research (IMR), this synthesis report outlines the key findings and recommendations from CIRCULÉIRE's 2022 End of Waste, By-products and Waste Licensing Pathfinders Thematic Working Group.
https://wks.circuleire.ie/public/artefact/9c5c3b79-9f98-4e7e-97dc-c29cb5761dbc

CIRCULÉIRE (2022) End of Waste, By-Products & Waste Licensing Pathfinders Public Webinar
This webinar, hosted by CIRCULÉIRE on 14 September 2022, presented the key results and innovation opportunities identified by CIRCULÉIRE End of Waste, By-Products & Waste Licensing Pathfinders Thematic Working Group. Expert Facilitators, Re-Mine Limited, presented the main findings of the working group including:

- The state of play of Ireland's end of waste and by-product policy context, and the role that this plays in driving Ireland towards circularity
- What key lessons industry can apply when looking to prepare strong end-of-waste and/or by-product applications;
- Major barriers to circularising Ireland's economy using these specific tools, and the recommendations identified on what's needed to overcome them;
- Innovation opportunities identified by CIRCULÉIRE's cross-sectoral Thematic Working Group Panel Members about how Ireland's end of waste and by-product regimes might be optimised for a circular economy.

https://wks.circuleire.ie/public/artefact/adfe5645-f9bb-40f4-ba47-bfc92209a5fe

COMPANY: ENVETEC

Envetec is an Irish company founded in 2021 as a spin-out from Technopath Clinical Diagnostics. Envetec's stated mission is "to assist all laboratories to achieve their sustainability goals".

Envetec provides GENERATIONS Clean Technology, an on-site non-thermal technology for the life sciences sector that treats biohazardous waste produced by laboratories and allows the recovery of waste materials for recycling.

CHALLENGE ADDRESSED

According to Envetec figures, laboratories globally produce 42 million kgs of waste every day, 90% of which is plastic. Current treatment methods of biohazardous waste produce approx. 6 million metric tonnes of CO_2 per annum as they require large amounts of energy and water as well as transport of the waste to and from the treatment facilities.

Typically, this treated waste is either landfilled or transported to another facility for incineration requiring further energy inputs and producing harmful gases. The waste ash produced by incineration is then landfilled.

SERVICE PROPOSITION

Envetec provides a service to its customers that allows them to treat biohazardous waste in a more sustainable and energy efficient manner that current methods. The GENERATIONS technology consists of an onsite unit that processes (shredding) and treats biohazardous waste, converting this (predominantly plastic) waste into a flake material for recycling. The technology uses an added chemical to kill microbes and pathogens during the shredding process. The effluent from this process is filtered to remove any solids or microplastics.

According to information on the Envetec website the GENERATIONS technology has the following benefits:

- reduces biohazardous waste treatment emissions by 90% on average (comprising scope 1, 2 & 3 emissions) when compared to traditional treatment processes.
- non-thermal treatment and shredding of single use plastics produces a clean polymer flake that is suitable for recycling.
- reduces transport emissions associated with biohazardous waste disposal by 94% through onsite treatment.
- uses 70% less water on average when compared to autoclave and other onsite treatment methods.
- the filtration and neutralisation technology ensures that all wastewater is compatible with municipal release standards.
- removes public health and brand reputational risks associated with the transport of untreated biohazardous waste.

CIRCULAR BUSINESS MODEL

Envetec GENERATIONS is a good example of a technology solution that has been developed through the consideration of all the challenges, inputs and outputs of current industrial practice.

Through this careful consideration and identification of key problem target areas, Envetec has developed a solution with the ability to significantly improve several sustainability objectives in a streamlined service provision – reduction of energy usage, reduction of chemicals used and produced, reduction of transportation required, reduction of health risk, recycling of materials. This solution demonstrates the end-to-end systems level and process thinking required in the design and provision of sustainable technologies that can effect change to existing methods.

FURTHER REFERENCES

- https://envetec.com/
- https://envetec.com/knowledge/carbon-action-comparative-ghg-study-summary-report/
- https://actdatabase.mygreenlab.org/details/896

COMPANY: NOVO NORDISK

Novo Nordisk is a Danish pharmaceutical and healthcare company that produces pre-filled insulin injection pens. The company has committed to net zero emissions across their entire value chain by 2045 at the latest.

PenCycle is a UK-based take-back initiative by Novo Nordisk in association with Alliance Healthcare (a distributor and wholesale supplier of pharmaceutical and healthcare products) to collect medical injection pens and recycle the materials into useful products.

CHALLENGE ADDRESSED

With an increasing and ageing global population and increases in lifestyle related diseases like diabetes and obesity, millions of people around the world are dependent on medical injection pens to treat chronic diseases. However, after use, millions of these pens end up in landfill or are incinerated with all the associated negative environmental impacts.

In the UK, Novo Nordisk estimate that 23 million medical pens are sent to landfill or are incinerated annually. To address this issue, Novo Nordisk ran a successful pilot of the PenCycle scheme in November 2021 that led to the UK national roll-out of the scheme in October 2022.

SERVICE PROPOSITION

Medical injection pens are used by patients with conditions like diabetes and obesity to self-administer insulin and other medications in the home. Through the PenCycle scheme, patients can return used pens (with needles removed) in return boxes containing 12 used pens to participating pharmacies (3,700 community pharmacies in the UK are registered to participate in the pen return scheme). The collected pens are returned to Denmark where the plastic is then recycled into a range of items, including furniture, and glass is re-used to make products including lamps.

As of August 2023, over 30,000 pens were being returned monthly through the scheme.

SUSTAINABILITY / CIRCULARITY BENEFITS

This collect and return scheme is beneficial as it diverts the used pens away from potential incineration or landfill and also creates a stream of relatively homogenous and clean components for recycling.

FURTHER REFERENCES

- https://www.novonordisk.com/sustainable-business/zero-environmental-impact/recycling-used-devices.html
- https://www.alliance-healthcare.co.uk/sites/g/files/xpfdlm151/files/2022-01/1015_NN_PenCycle_Introduction-letter_Manchester.pdf
- https://pharmaceutical-journal.com/article/news/first-ever-injection-pen-recycling-pilot-rolled-out-nationally-across-pharmacies
- https://pharmaceutical-journal.com/article/news/patients-return-200000-injection-pens-through-recycling-scheme
- https://matter.health/uploads/The-Business-Case-for-a-Circular-MedTech-Sector-LR.pdf

3.5 Cluster 4 - Sustainable Packaging

Sustainable packaging solutions are vital to reducing the environmental footprint of MedTech products. This cluster examines innovations in both non-sterile and sterile packaging, addressing primary and secondary packaging needs. Strategies such as lightweight designs, recyclable materials, and reusable packaging systems contribute to waste reduction while ensuring the integrity and safety of medical devices. These advancements illustrate how circular principles can be integrated even into essential protective materials, particularly for companies unable to fully circularise their products, innovations in the area of sustainable packaging solutions can create an immediate and impactful pathway to align with Circular Economy principles.

FEATURED CASE STUDIES:

- KLÖCKNER PENTAPLAST - KP FILMS
- PLASTIC INGENUITY WITH MERIT MEDICAL

COMPANY: KLÖCKNER PENTAPLAST - KP FILMS

Global manufacturer of sustainable and recyclable plastic films and high-barrier protective packaging for food, pharmaceutical, health products.

KP Films created am innovative medical grade PETg with up to 50%* Certified recycled content. It is suitable for medical devices packaging with properties equal to virgin resin.

It is further suitable for extensive applications across various medical specialties including sterile barrier packaging films for class I, IIa, IIb, and III medical devices.

MATERIAL INNOVATION

kp Films' SecondLife® MD packaging incorporates up to 50%* certified recycled content derived from landfill-diverted plastics. These films are chemically recycled to produce PETg materials with properties equivalent to virgin plastics, ensuring they meet the rigorous demands of medical-grade packaging.

The "Second Life" range adheres to the **EN ISO 11607** standard for sterile barrier packaging, a critical certification for medical-grade packaging.

This innovation reduces dependency on virgin resources while maintaining compatibility with key sterilisation methods such as EtO, gamma, e-beam, and steam.

ENVIRONMENTAL AND INDUSTRY IMPACT

SecondLife® MD films transform waste into value by repurposing post-consumer materials for use in medical packaging, significantly reducing plastic waste and carbon emissions.

Environmental Impact
Landfill-diverted plastics reduce the environmental footprint of packaging production. It also demonstrates the feasibility of creating value from what was once considered waste for use in the MedTech space.

Industry Milestones
kp Films' Montabaur facility was the first in Europe to achieve ISCC Plus certification, setting a benchmark for sustainable innovation in medical packaging.

Circular Economy Insights
This initiative demonstrates how recycled polymers can be successfully integrated into MedTech packaging, highlighting the potential for sustainability even in highly regulated industries.

LEADERSHIP, STRATEGY, TARGETS & KPIS / CULTURE CHANGE AND TRAINING

Klöckner Pentaplast (kp) has embedded sustainability at the core of its operations through its "Investing in Better" strategy, which focuses on three objectives: Close the Loop, Work Smarter, and Act Responsibly.

In 2023, kp offered a recyclable alternative for 68% of their product portfolio and used 25% of PCR material in the plastic packaging they produced. Using recycled rather than virgin material in their operations equates to more than 321,000 tonnes of avoided CO2 emissions.

They have achieved zero waste to landfill on all their sites, where legally possible.

kp has established clear sustainability targets that provide measurable milestones such as Zero Waste to Landfill - Achieve zero waste to landfill or incineration without energy recovery, with 24 sites already meeting this goal by 2022.

kp fosters a culture of sustainability by prioritising employee engagement and training.

This robust combination of leadership, strategy, KPIs, and cultural transformation exemplifies how MedTech companies can drive sustainability while maintaining operational excellence.

FURTHER REFERENCES

- https://marketing.kpfilms.com/
- https://marketing.kpfilms.com/acton/media/43553/sustainable-medical-device-packaging-films--secondlife
- https://www.kpfilms.com/en/pharma-medical/medical-device-packaging-films/sustainable-rigid-films#/SecondLife%C2%AE%20MD
- https://www.kpfilms.com/en/sustainability/our-strategy/

Disclaimer:
Figures are based on internal and third-party studies and should be interpreted within context.

COMPANY: PLASTIC INGENUITY WITH MERIT MEDICAL

Merit Medical Systems, Inc., a manufacturer of single-use medical devices for interventional and diagnostic procedures, turned to Plastic Ingenuity to design a solution to eliminate shipping damage, decrease material waste, and reduce packaging costs.

Plastic Ingenuity collaborated with Merit Medical Systems to develop a custom solution for sustainable packaging.

This case study demonstrates how innovative materials, thoughtful design and collaboration, can drive significant environmental and economic benefits in MedTech packaging.

MATERIAL INNOVATION

Plastic Ingenuity collaborated with Merit Medical Systems to develop a groundbreaking solution for sustainable packaging. The key innovation was the use of Eastalite, a foamed PETG material that outperforms traditional high-impact polystyrene (HIPS) in multiple ways.

Lower Density
Eastalite offers reduced weight, making it more efficient for transport while maintaining durability.

Enhanced Protection
The material provides superior abrasion resistance, shock absorption, and impact strength, ensuring the safety of delicate medical devices during transit.

Reusable Design
The universal transport tray designed by Plastic Ingenuity can be reused at least four times, extending the lifecycle of the packaging and reducing waste.

ENVIRONMENTAL IMPACT

The switch to Eastalite and the redesign of the packaging significantly reduced Merit Medical's environmental footprint.

Transport Efficiencies
The redesigned tray improved cube utilization by 133%, allowing 1,400 devices per pallet compared to the previous 600. This optimisation reduced transatlantic freight requirements and associated emissions.

Waste Reduction Through Reuse
With the ability to reuse the packaging multiple times, the solution aligns with Circular Economy principles, reducing the demand for new materials.

FINANCIAL INCENTIVES

Beyond its environmental benefits, the new more sustainable packaging solution delivered substantial cost savings.

Reduced Packaging Costs
Material innovations decreased packaging material costs by 52%, a significant saving for Merit Medical.

Lower Freight Costs
The improved pallet utilisation reduced transatlantic freight costs by 57%, highlighting the economic value of efficient design.

Further References

- https://www.plasticingenuity.com/customer-story/custom-healthcare-packaging-universal-transport-tray/

Disclaimer:
Figures are based on internal studies and should be interpreted within context.

Section 4: What is needed to Circularise MedTech in Ireland

This section is designed to present key enablers and barriers and then provide actionable recommendations to encourage a circular transition in Ireland's MedTech sector. These come from a combination of practitioner/industry and academic literature.

4.1 Key Enablers/Drivers:

The transition to a Circular Economy (CE) in the MedTech sector requires a robust foundation of enabling factors that drive innovation, foster collaboration, and create the conditions necessary for change. Key enablers such as collaboration, visionary leadership, sustainable/green/circular procurement practices, supportive regulatory frameworks, and technological innovations form the backbone of this transition.

Each enabler plays a unique role in addressing the challenges of CE adoption while unlocking opportunities for sustainable growth. Collaboration fosters shared responsibility and knowledge exchange across sectors, while strong leadership ensures alignment and action. Green and more specifically circular procurement and clear regulatory drivers incentivise circular practices, creating a market and policy landscape conducive to sustainability. Meanwhile, technological advancements in materials science, manufacturing, and digital tools provide the practical means to design, produce, and manage circular MedTech devices.

By harnessing these enablers collectively, the MedTech sector in Ireland can accelerate its journey toward a circular future.

4.1.1
Collaboration

Cross-sector partnerships and industry collaboration drive innovation and inspire action for transitioning to a Circular Economy.

INDUSTRY PARTNERSHIPS

Collaboration through industry partnerships is one of the most powerful enablers of a Circular Economy (CE) in the MedTech sector. It allows stakeholders to pool resources, share knowledge, and overcome common barriers, driving innovation and efficiency at a scale that individual actors might not achieve alone.

PUBLIC-PRIVATE PARTNERSHIPS

Collaborating with research institutions, universities, and government agencies enhances access to cutting-edge knowledge, resources, and solutions tailored to MedTech.

CROSS-SECTORAL INITIATIVES & SECTORAL KNOWLEDGE HUBS

Sharing knowledge across industries can provide valuable insights into best practices and technical approaches – and because waste valorisation opportunities often present outside the sector or supply-chain where the waste is generated.

Moreover, cross-sectoral industry associations and networks dedicated to demystifying and scaling circularity, like CIRCULÉIRE, are positioned to facilitate cross-sectoral insights AND sectoral best-practice sharing – both of which are required to drive circular economy innovations across the economy.

Plastic Ingenuity's partnership with Merit Medical highlights the value of cross-sector collaboration in achieving reusable circular packaging solutions that benefit both companies and the environment.

In the case of GE Healthcare a collaborative relationship was found between GE and Recilogic, an industrial symbiosis facilitator and secondary materials processor. Recilogic had prior knowledge of GE's PVC by-product without which the relationship may not have happened. In addition, GE's by-product found its use outside of the MedTech sector so it is important to consider possible collaborations beyond MedTech.

The PenCycle case study is another good example of collaboration (PenCycle is the name of the initiative in the UK but is part of a wider set of initiatives, currently available in 7 countries, under the umbrella ReMed). In Denmark, the system is called Returpen and pens from Lilly, Sanofi and Merck can also be returned under the Novo Nordisk scheme showing collaboration across companies.

A further example of industry collaboration is The Alliance to Zero group, which was established to facilitate the transition of the pharmaceutical industry to compliance with net zero emission targets. Though the Alliance consists of mainly pharma companies, its pilot study focused on the manufacture of injection devices, and their secondary packaging. The Alliance established multiple working groups which worked in collaboration with subject matter experts, to develop guidelines and facilitate more productive interactions towards more sustainable outcomes for the industry. (Alliance to Zero, 2024)

'Collaboration and joined up thinking on green procurement across industry, HSE and policymakers, plus the appointment of a Sustainability Leader in the HSE are key calls to action building on existing stakeholder networks.' (HealthTech Ireland & Davy Horizons, 2023)

"*Collaboration between device manufacturers, healthcare providers, and policymakers is essential to create effective circular models in the medical device sector, where cross-sector partnerships can unlock innovation and sustainability*." (Benedettini, 2022).

4.1.2
Leadership

Visionary leadership across stakeholders inspires action, aligns goals, and establishes the strategic direction for transitioning to a Circular Economy.

INDUSTRY AND EXECUTIVE-LEVEL SUPPORT FOR CIRCULAR STRATEGIES

Top-down support from industry leaders is crucial to prioritise circular initiatives, set sustainability KPIs, and foster a company-wide culture of innovation and climate responsibility.

HEALTHCARE PROVIDERS AND HSE

The Health Service Executive (HSE), Health Innovation Ireland, and healthcare professionals can support circular practices by promoting and prioritising sustainable products and circular procurement strategies. Clinicians can lead by advocating for sustainable /green procurement policies which support the adoption of circular products.

ACADEMIC AND RESEARCH PARTNERS

Academics also play a key role in embedding CE principles into education and training programs, preparing the current and future workforce to implement circular practices.

REGULATORS & POLICYMAKERS

Public sector leadership is fundamental for creating an enabling environment for CE through policy design, implementation, incentivisation and creating regulatory harmony. Policymakers can lead by embedding CE principles into national strategies and frameworks, providing clarity on the long-term goals for MedTech circularity and therefore helps align industry efforts.

"Visionary leadership is necessary to drive the systemic changes needed for the adoption of circular practices in the healthcare sector." (Østerle & Danse, 2020)

Leadership in CE practices can be seen across all of the case studies listed in Section 3. In particular, the benefits of early leadership in CE can be seen in the Philips Royal case study. Beginning their CE journey in 2012, under CEO Frans van Houten, their first five-year strategy embedded circular economy explicitly into Philips' strategy. Circular KPIs were added to their 2016-2020 strategy and currently they are targeting 25% of sales from circular products, services and solution for 2025. Realising 3.64 billion euro in revenue from circular products in 2023 is a clear example that early leadership pays.

It is important for leadership at the highest organisational levels to recognise that the transition to a CE is an important goal for the EU and vital to the success of European net-zero targets. Delay in engaging exposes companies to risk of vital materials becoming unavailable due to supply chain issues, exacerbated by increasing geopolitical instability and worsening climate conditions.

As seen in the Philip's case study embedding CE into an organisation's strategy gives clear direction signalling within the organisation and justifies investment and effort within the CE space.

4.1.3
Circular Procurement

Sustainable/green procurement practices prioritise circular and sustainability criteria, encouraging the adoption of MedTech products that can be reused, repaired, refurbished, remanufactured, repurposed and/or recycled, creating a market for Circular medical devices.

CIRCULAR PROCUREMENT CRITERIA

Public and private healthcare providers can include circular requirements in procurement tenders, such as prioritising devices which are designed for reuse, repair, refurbishment or remanufacture.

LIFE-CYCLE COSTING IN PURCHASING DECISIONS

Encouraging life-cycle costing (LCC) instead of focusing solely on upfront costs can promote the sourcing of longer-lasting products, reducing waste and total cost over time.

"Integrating circularity into procurement strategies is crucial, as it drives demand for products that are reusable, repairable, and recyclable." (CE Hub, 2024).

PROCUREMENT AND THE CORPORATE SUSTAINABILITY REPORTING DIRECTIVE (CSRD)

From Jan 2025, the first companies will begin reporting under the CSRD. CSRD requires reporting across a company's value chain and under the CSRD's ESRS E5 'Resource use & Circular Economy' standard, it will be necessary to gather data on material resource inflows and outflows. Procurement departments can benefit by taking proactive steps to integrate corporate sustainability reporting principles into their operations.

4.1.4
Regulatory and Policy Drivers

Clear, supportive policies and aligned global regulations provide the framework and incentives necessary for circular innovations to thrive.

EU POLICIES AND DIRECTIVES

The European Commission adopted the Circular Economy Action Plan (CEAP) in 2020 as one of the main building blocks of the European Green Deal (European Commission, 2020).

In 2021, the Corporate Sustainability Reporting Directive (CSRD) was adopted by the EU commission in line with further commitments made under the Green Deal. Under the CSRD's ESRS E5 'Resource use & Circular Economy' standard, it will be necessary to gather data on material resource inflows and outflows and to define policies, actions, resources and targets for the transition to a circular economy. The first companies will begin reporting under CSRD in Jan 2025. CSRD aims to bring the same level of transparency and assurance to ESG reporting as is normal with financial reporting.

The Eco-design for Sustainable Products Regulation (ESPR), entered into force in 2024 as part of a package of measures central to achieving the aims of the CEAP. The ESPR enables the setting of eco-design requirements for almost all categories of physical goods (European Commission, 2023). The ESPR also introduces a Digital Product Passport (DPP), a digital identity card for products, components, and materials, which will store relevant information to support products' sustainability, promote their circularity and strengthen legal compliance (European Commission, 2023).

Medical devices do fall within the scope of the ESPR, once the regulation can ensure that it does not negatively affect patients' health and safety. While there is no indication yet when ESPR or DPP will apply to medical devices, embracing circularity by aligning with their requirements will help the sector remain future fit.

ALIGNMENT WITH SAFETY AND COMPLIANCE STANDARDS

Regulations encouraging safe reuse, repair, refurbishment, remanufacture, and recycling practices within healthcare settings will be critical to harmonise with circular principles.

INCENTIVES FOR RD&I IN SUSTAINABLE MATERIALS

Incentives for innovation and research, particularly around sustainable materials and advanced manufacturing techniques, can speed up the transition to circularity in the MedTech sector.

4.1.5
Technological Innovations

Advancements in materials science, digital tools, and manufacturing technologies enable more circular design, production, and lifecycle management of MedTech devices.

Technological innovations, particularly in material science and manufacturing, are key enablers for achieving CE in MedTech. By leveraging biodegradable materials, adopting advanced production techniques the sector can design, produce, and manage devices that are safer, more efficient, and aligned with sustainability goals.

These advancements ensure that circular practices become economically viable and operationally feasible while maintaining high standards of patient safety and care.

MATERIAL SCIENCE ADVANCEMENTS

Biodegradable, recyclable, and non-toxic materials are critical enablers of a Circular Economy by reducing waste, facilitating material recovery, and decreasing dependency on finite virgin resources.

ADVANCED MANUFACTURING TECHNIQUES

Technologies such as 3D printing, additive manufacturing, and precision machining enable waste reduction by using only the exact amount of material needed. They also support modular and repairable designs, making products easier to disassemble, refurbish, or recycle.

Stryker's use of water-efficient manufacturing processes showcases how technological innovations in material science and manufacturing can enable more sustainable practices in MedTech.

4.2 Key barriers / Challenges

The transition to a Circular Economy (CE) in the MedTech sector faces several challenges that can hinder its progress. These barriers span regulatory, economic, technological, and cultural domains, reflecting the complexity of integrating circular practices into a highly regulated and safety-critical industry. Addressing these barriers will be key to unlocking the full potential of Circular Economy for the MedTech sector in Ireland.

4.2.1 Regulatory Compliance & Guidance

The MedTech sector operates within necessary but stringent regulatory frameworks, which can make the adoption of circular practices complex.

UNDERSTANDING & INTERPRETING REGULATIONS

The complexity and diversity of regulations ranging from product safety and waste management to material compliance can create confusion for companies looking to align their operations with circular economy principles. Moreover, the lack of product and sector-specific guidance, can hinder innovation and slow adoption of circular practices.

COMPLEX REGULATORY LANDSCAPE

Regulatory requirements vary across countries and are understandably strict for MedTech to reduce risk to human health, however, the varied requirements make it challenging to embed circular practices/design principles in products serving global markets.

MULTIPLE REGULATORY COMPLIANCE REQUIREMENTS

Scaling circularity principles in MedTech products is further complicated by overlapping regulations in healthcare, environmental protection, and medical safety. Different regulations often prioritise distinct objectives. For example, healthcare regulations prioritise strict sterility standards to prevent healthcare-associated infections (HAIs), so reusing products or recycled materials often requires rigorous sterilization processes. Such processes can sometimes degrade materials or introduce contamination risks.

FRAGMENTED GLOBAL COMPLIANCE

Regulatory requirements differ across countries, making it challenging to align circular strategies globally, especially in cross-border operations.

Vanguard's case highlights the challenges of navigating the complex regulatory landscape, particularly in relation to Article 17 of the EU MDR and the fragmented acceptance of reprocessing/remanufacturing standards across EU member states.

In the GE Healthcare case, their EHS manager had looked into using leftover Thermadrape (a type of warming blanket) to help children in Central American hospitals, but the rules regarding medical products were too stringent and he was unable to get the project approved. It was only when looking outside the MedTech sector that a use case was discovered – highlighting the cross-sectoral nature of circular opportunities particular at a material level.

"*The adoption of circular principles in medical device design is contingent upon developing regulatory frameworks that align with sustainability goals* *without compromising patient safety"* (Hoveling et al., 2024).

4.2.2
Supply Chain Complexities

Globalised supply chains add layers of complexity to implementing circular practices, particularly for material recovery and reverse logistics.

GLOBALISED SUPPLY CHAINS

Long, complex supply chains present challenges for tracking materials, ensuring responsible sourcing, and implementing reverse logistics.

CROSS-BORDER MATERIAL RECOVERY AND REVERSE LOGISTICS

Variability in waste management and recycling regulations across borders makes material recovery complex and costly.

4.2.3
Technological & Material Limitations

Technical and material challenges, particularly in meeting safety and efficacy standards, can hinder adoption of CE practices in MedTech.

SAFETY AND QUALITY CONSTRAINTS

Necessarily stringent safety standards can limit material reuse, with biocompatibility and sterility requirements constraining sustainable material options.

LIMITED AVAILABILITY OF CIRCULAR MATERIALS

Biodegradable or recyclable materials that meet medical standards are still under development and not widely available. Developing materials that meet safety and environmental requirements while being easy to recycle or biodegrade remains a challenge.

END-OF-LIFE CHALLENGES

Technologies for disassembling complex devices and recovering high-value materials, such as rare metals, are not yet cost-effective or widely accessible.

While Stryker has made advancements with bio-based plastics and PVC-free tubing, challenges still exist in sourcing sustainable materials that meet all medical device standards.

"*Developing circular solutions for medical devices is often limited by the availability of materials that meet both safety and environmental standards*." (Health Affairs, 2020)

4.2.4
Economic and Financial Barriers

The cost of transitioning to CE, combined with the lack of economic incentives, is currently a significant deterrent for many organizations.

HIGH INITIAL COSTS FOR CIRCULAR TRANSITION

Developing circular products, processes, and infrastructures often requires significant upfront investment. Transitioning existing MedTech products to circular models, not only necessitates redesigning them, but also re-certifying them with regulatory bodies including testing for biocompatibility, sterility, and performance, which are costly and time-intensive and can be prohibitive.

INCENTIVES AND FUNDING GAPS

The absence of tax breaks, subsidies, or funding dedicated specifically to circular initiatives in MedTech may limit progress.

"One of the most significant barriers to adopting circularity in healthcare is the lack of financial incentives, particularly for small and medium-sized enterprises (SMEs)." (Zhang et al., 2017)

4.2.5

Cultural Shift in Healthcare

A key barrier to circular economy adoption in healthcare is the sector's strong reliance on single-use devices, driven by perceptions of safety and convenience. This cultural preference, along with (legitimate) concerns over patient safety and limited awareness of circular benefits, hampers the transition to more sustainable practices.

HEALTHCARE SECTOR'S CULTURAL DEPENDENCE ON SUDS

Single-use devices (SUDs) are often seen as safer or more convenient, leading to resistance to reprocessing / remanufacturing or using reusables.

PATIENT SAFETY VS. CIRCULARITY

Circular devices with proven clinical reliability (supported by research and evidence) still need to overcome understandable concerns regarding the perceived safety and efficacy of reusable/refurbished/remanufactured devices. Such perceptions can be challenging to change and as a result can deter the adoption of circular practices.

AWARENESS AND ACCEPTANCE

Limited awareness among healthcare professionals and patients about the environmental impacts of MedTech/healthcare and the benefits of circular options can hinder adoption.

"*The primary challenge in implementing circularity is the perception that it compromises patient safety, and overcoming this requires stringent compliance with safety and regulatory standards*" (Hoveling et al., 2024).

4.2.6

"Waste"

The classification, management, and perception of waste in healthcare presents unique challenges for the transition to a Circular Economy for the MedTech sector.

HAZARDOUS WASTE CLASSIFICATION AND REGULATION

Due to infection control and patient safety requirements, many medical devices are designated for single use, resulting in substantial waste. Often, MedTech waste is classified as hazardous due to potential contamination risks, necessitating specialised handling and disposal protocols. This classification can limit or complicate recovery options resulting in high-value materials being incinerated or landfilled.

While infection control is paramount, overly broad classifications prevent the recovery of materials that may pose no additional risk post-sterilisation.

"Implementing circular practices in healthcare requires significant changes in infrastructure, including better waste management and material recovery systems" (Østerle & Danse, 2020).

4.3 Recommendations:

The following recommendations outline actionable steps to support the MedTech sector in Ireland's transition to a Circular Economy. These strategies aim to address current barriers, and leverage enablers.

4.3.1
Adopt Circular Design Principles Early in Product Development

Designing for circularity ensures products are optimized for reuse, repair, refurbishment, remanufacture, repurposing and recycling from the outset.

ECO-DESIGN & ESPR

Embed CE principles into the design process for MedTech devices to minimize resource use, extend product lifecycles, and enhance recyclability as outlined in the ESPR for other product categories.

Medical devices fall within the scope of the ESPR and aligning with its requirements early will help the sector remain future fit.

MATERIALS INNOVATION

Prioritise the use of advanced, sustainable materials such as biodegradable or recyclable polymers to reduce environmental impact while maintaining safety and compliance standards.

Stryker's 'Redesigned for Sustainability' philosophy exemplifies how integrating circular design principles at the outset can lead to more sustainable devices.

Plastic Ingenuity's use of Eastalite, a foamed PETG material, is an example of designing for circularity by selecting sustainable materials that improve product protection while reducing environmental impact.

Philips provides training for priority audiences within the organisation such as product and service designers.

"A key opportunity lies in the redesign of products for easier disassembly, refurbishment, and recycling, which can significantly reduce the lifecycle impact of medical devices" (Hoveling et al., 2024).

4.3.2
Advocate for Policy Support and Clear Standards

Policy alignment is critical to enabling circular practices within a regulated industry.

DRIVE CIRCULAR PROCUREMENT

The MedTech sector should work with policymakers and healthcare providers to embed circularity requirements into procurement frameworks, creating demand for circular MedTech products.

ALIGN STANDARDS FOR CIRCULAR PRACTICES

Advocate for harmonised global standards on material recovery, device reuse, repair, refurbishment, remanufacture, repurposing and recycling, plus reverse logistics to simplify compliance and foster innovation.

4.3.3
Strengthen Financial Incentives and Access to Funding

Economic support is vital to encourage investment in CE innovation and infrastructure in the MedTech Sector.

GREEN FUNDING OPPORTUNITIES

Expand access to grants and funding programs, such as EU Horizon Europe, for companies pioneering CE initiatives in the MedTech Sector.

TAX INCENTIVES FOR INNOVATION

Introduce tax breaks or credits for investments in CE-related research in the MedTech Sector.

Stryker's cost savings, such as the reduction in packaging weight and energy savings in manufacturing, align with the recommendation to incentivize sustainability through economic benefits.

4.3.4
Foster Leadership

Leadership at all levels is essential to inspire action, align stakeholder efforts, and establish the strategic direction needed to advance the transition to a Circular Economy in the Irish MedTech sector.

EMPOWER INDUSTRY LEADERSHIP

Encourage MedTech companies to embed CE into their organisational strategies, led by executive-level commitment. This includes setting measurable sustainability KPIs, appointing CE champions within leadership teams, and fostering a culture of innovation focused on circular solutions.

STRENGTHEN LEADERSHIP IN HEALTHCARE PROVIDERS AND HSE

Healthcare organisations, including the Health Service Executive (HSE) and Health Innovation Ireland, should demonstrate leadership by integrating CE principles into procurement policies, prioritizing sustainable and circular medical devices. Clinicians can play a vital role by advocating for these practices and highlighting their alignment with patient care goals.

4.3.5
Enhance Collaboration

Collaboration fosters shared responsibility, resource efficiency, and accelerated adoption of circular practices.

PUBLIC-PRIVATE PARTNERSHIPS & KNOWLEDGE SHARING

Strengthen and leverage existing partnerships (like CIRCULÉIRE amongst others) between industry, academia, and government to co-develop circular solutions tailored to MedTech's unique challenges and share best practices, case studies, and technical expertise.

TRAINING AND SKILLS DEVELOPMENT

Provide training programs focused on CE principles, empowering professionals across the value chain to implement sustainable practices.

4.3.6
Encourage Circularity in Education (Training and skills development)

Educating the next generation of professionals ensures a lasting cultural shift toward sustainability.

INTEGRATE CE IN EDUCATION

Collaborate with academic institutions to embed CE concepts into MedTech, engineering, and healthcare curricula.

TARGETED TRAINING FOR DESIGNERS

Offer specialised training for product designers to incorporate circular principles into medical device development.

FUTURE SKILLS

The **Talent to Thrive: The Future Skills Report for Ireland's Medtech Sector, 2024 - 2028** , prepared by KPMG Ireland in collaboration with Irish Medtech Skillnet, Irish Medtech, and Skillnet Ireland mentions circularity 23 times, highlighting it as a key trend shaping sustainability (Skillsnet, 2024).

'Regulatory Affairs and Quality will need new skills around the regulation of end-of-life disposal, whether around recycling, remanufacturing, or sterilisation. Manufacturing will need skills training to implement device recycling, remanufacturing, and novel packaging materials and methods, while the RD&I team will need to be skilled in thinking sustainably, designing for efficient use, and end-oflife considerations.' (Skillsnet, 2024).

"Embedding circular economy principles in medical education will be pivotal in developing future leaders capable of designing and implementing sustainable practices in MedTech." (Benedettini, 2022)

4.3.7
Implement and Scale Up Circular Business Models

Adopting innovative business models creates opportunities to close the loop and retain value.

PILOT CIRCULAR INITIATIVES:

Begin with small-scale trials of circular strategies to demonstrate feasibility and build confidence.

PRODUCT-AS-A-SERVICE

Transition from ownership-based models to service-based approaches, enabling greater control over product lifecycles and material recovery.

The Philips case study clearly highlights that there is an appetite for service based models in MedTech, and significant to revenue to be generated as well as environmental gains.

"Adopting circular business models, such as Product-as-a-Service, can help MedTech companies regain control over product lifecycles, enabling better resource recovery and reducing waste." (Benedettini, 2022)

4.3.8
Establish Metrics and Monitoring Systems

Tracking progress is essential to evaluate the effectiveness of CE strategies and for reporting under the Corporate Sustainability Reporting Directive and will be required if ESPR and DPP are expanded in the future to MedTech devices.

SET CIRCULARITY KPIS

Define key performance indicators, such as the percentage of recycled materials used or the volume of remanufactured / refurbished products sold.

MEASURE AND REPORT PROGRESS

Regularly monitor and report on circularity efforts, aligning with frameworks like the Corporate Sustainability Reporting Directive (CSRD).

Under the ESRS E5 'Resource use & Circular Economy' reporting standard it will be necessary to gather data on material resource inflows and outflows. It can take between 12 to 18 months to gather the necessary data so every organisation should begin gathering the information now if they have not already started. Explore ESPR and what it means for device evolution to ensure products are future fit should it be expanded to all products placed on the EU market.

"Measuring and reporting circularity through clear metrics, such as the percentage of recycled materials used or the reduction in carbon footprint, is crucial for tracking progress and ensuring accountability in the MedTech sector." (Benedettini, 2022)

By adopting these recommendations, the MedTech sector in Ireland can accelerate its transition to a Circular Economy, balancing regulatory compliance, patient safety, and environmental sustainability.

References

1. Alliance to Zero (2024). 'Net Zero Requires Circularity'. Available at: https://alliancetozero.com/wp-content/uploads/2024/07/alliance-to-zero-net-zero-requires-circularity-final-23-07-2024.pdf
2. Barbella, M. (2023). Medtech's Supply Chain: From Disruption to Opportunity. [online] Medical Product Outsourcing. Available at: https://www.mpo-mag.com/medtechs-supply-chain-from-disruption-to-opportunity/ [Accessed 8 Nov. 2024].
3. Benedettini, O. (2022) 'Green Servitization in the Single-Use Medical Device Industry: How Device OEMs Create Supply Chain Circularity through Reprocessing', Sustainability, 14(19), p. 12670. Available at: https://www.mdpi.com/2071-1050/14/19/12670
4. Circular Republic. (2024). *CIRCULAR REPUBLIC | The Business Case for a Circular Economy*. [online] Available at: https://www.circular-republic.org/ce-business-case-whitepaper [Accessed 17 Nov. 2024].
5. Copernicus Climate Change Service (2024) European State of the Climate 2023, Full report: https://www.climate.copernicus.eu/ESOTC/2023
6. Caesar*, L., Sakschewski*, B., Andersen, L. S., Beringer, T., Braun, J., Dennis, D., Gerten, D. Heilemann, A., Kaiser, J. Kitzmann, N.H., Loriani, S., Lucht, W., Ludescher, J., Martin, M., Mathesius, S., Paolucci, A., te Wierik, S., Rockström, J. (2024). Planetary Health Check Report 2024. Potsdam Institute for Climate Impact Research, Potsdam, Germany. (*equal contributors to this work and designated as co-first authors). Available at: https://www.planetaryhealthcheck.org/storyblok-cdn/f/301438/x/a4efc3f6d5/planetaryhealthcheck2024_report.pdf
7. CE Hub (2024) 'Circular Economy in the Medical Technology Sector'. Available at: https://ce-hub.org.
8. Cort, C.; Franceschini, L.; Wang, J. (2015). *Rising Leaders on Environmental Sustainability and Climate Change*. Yale Center for Business and the Environment. https://cbey.yale.edu/research/rising-leaders-on-environmental-sustainability-and-climate-change
9. Ellen MacArthur Foundation (2017). *Circular Economy Introduction*. [online] Ellen MacArthur Foundation. Available at: https://www.ellenmacarthurfoundation.org/topics/circular-economy-introduction/overview.
10. Ellen Macarthur Foundation (2019). The butterfly diagram: visualising the circular economy. [online] ellenmacarthurfoundation.org. Available at: https://www.ellenmacarthurfoundation.org/circular-economy-diagram.
11. Ellen MacArthur Foundation (2021). *Completing the plcture: How the circular economy tackles climate change*. Available at: https://emf.thirdlight.com/file/24/XoGiOySXvopGQ9Xo4d6XnKIvUh/Completing%20the%20picture%20-%20%20Executive%20summary.pdf
12. Environmental Protection Agency (2003). National waste statistics. [online] www.epa.ie. Available at: https://www.epa.ie/publications/monitoring--

assessment/waste/national-waste-statistics/circular-economy-and-waste-statistics-highlights-report-2021.php.

13. European Commission (2019). *The European Green Deal*. [online] European Commission. Available at: https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/european-green-deal_en.
14. European Commission (2020). *Circular Economy Action Plan*. [online] environment.ec.europa.eu. Available at: https://environment.ec.europa.eu/strategy/circular-economy-action-plan_en.
15. European Commission (2020). *Critical Raw Materials Resilience: Charting a Path towards greater Security and Sustainability*. [online] environment.ec.europa.eu. Available at: eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0474
16. *European Commission (2023). Ecodesign for Sustainable Products Regulation. [online] European Commission. Available at: https://commission.europa.eu/energy-climate-change-environment/standards-tools-and-labels/products-labelling-rules-and-requirements/ecodesign-sustainable-products-regulation_en.*
17. European Commission. (n.d.) *National rules on reprocessing single-use medical devices*. Available at: https://health.ec.europa.eu/medical-devices-topics-interest/reprocessing-medical-devices/national-rules-reprocessing-single-use-devices_en (Accessed: 1 November 2024).
18. European Commission. (n.d.) *Common Specifications for the MDR*. Available at: https://health.ec.europa.eu (Accessed: 1 November 2024).
19. European Parliament (2023). *Circular economy: definition, importance and benefits | Topics | European Parliament*. [online] www.europarl.europa.eu. Available at: https://www.europarl.europa.eu/topics/en/article/20151201STO05603/circular-economy-definition-importance-and-benefits.
20. European Union (2022). *Directive (EU) 2022/2464 of the European Parliament and of the Council of 14 December 2022 amending Regulation (EU) No 537/2014, Directive 2004/109/EC, Directive 2006/43/EC and Directive 2013/34/EU, as regards corporate sustainability reporting (Text with EEA relevance)*. [online] EUR-Lex. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32022L2464.
21. European Union. (2017) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices. Official Journal of the European Union. Available at: https://eur-lex.europa.eu (Accessed: 1 November 2024).
22. European Union. (2017) Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices. Official Journal of the European Union. Available at: https://eur-lex.europa.eu (Accessed: 1 November 2024).
23. Figge, F., Givry, P., Canning, L., Franklin-Johnson, E. and Thorpe, A. (2017). Eco-efficiency of Virgin Resources: A Measure at the Interface Between Micro and Macro Levels. *Ecological Economics*, 138, pp.12–21. doi:https://doi.org/10.1016/j.ecolecon.2017.03.016.
24. Government of Ireland, (2020). 'Focus on Medical Technologies'. Available at : https://enterprise.gov.ie/en/publications/publication-files/focus-on-medical-technologies-2020.pdf

25. Guterres, A. (2024). Following three hottest days on record, secretary-general launches global action call to care for most vulnerable, protect workers, boost resilience using data, science United Nations (25 July 2024). Available at: https://press.un.org/en/2024/sgsm22319.doc.htm
26. Hardwick, A. (2024). The State of European Supply Chains 2024: A deep dive into visibility, digitalisation, sustainability and resilience. A survey-led report in partnership with Maersk. [online] reutersevents.com. Reuters. Available at: https://1.reutersevents.com/LP=36871#:~:text=The%20State%20of%20European%20Supply%20Chains%202024&text=Focused%20on%20Visibility%2C%20Digitalisation%2C%20Sustainability,what%20is%20powering%20Supply%20Chains. [Accessed 8 Nov. 2024].
27. Health, A. and EY, T. (2024). *Driving Innovation in MedTech: The Power of Circularity and Sustainable Product Design*. [online] Ey.com. Available at: https://www.ey.com/en_ch/insights/health/driving-innovation-in-medtech-the-power-of-circularity-and-sustainable-product-design.
28. Health Affairs (2020) 'Circular Economy in Healthcare: The Missing Link to Sustainability', *Health Affairs*, 39(6), pp. 1024-1032. Available at: https://www.healthaffairs.org/doi/10.1377/hlthaff.2020.01118 (Accessed: 1 November 2024).
29. Health Service Executive, (2024). Green Healthcare Programme. Available at: https://greenhealthcare.ie/
30. HealthTech Ireland & Davy Horizons (2023) 'Driving Sustainability in Health Tech Supply Chains through Procurement – An Irish Leadership Opportunity'. Available at: hti-sustainable-procurement-paper-1.pdf
31. Hopkinson, P., Hopkins, G., Charnley, F., Dawson, T., Zils, M., Nidhi, A., & Akeredolu-Ale, M. (2024). MedTech Spotlight Report: Accelerating circular economy adoption. . [online] *CE-Hub.org*. CE-Hub. Available at: https://ce-hub.org/knowledge-hub/circular-economy-medtech/
32. Hoveling, T., Nijdam, A.S., Monincx, M., Faludi, J. and Bakker, C. (2024) 'Circular economy for medical devices: Barriers, opportunities and best practices from a design perspective', Resources, Conservation and Recycling, 208, p. 107719. Available at: https://www.sciencedirect.com/science/article/pii/S0921344924003136
33. IPBES (2019), Global assessment report of the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services, Brondízio, E. S., Available at: https://www.ipbes.net/global-assessment
34. IUCN. (2024). *More than one in three tree species worldwide faces extinction - IUCN Red List*. [online] Available at: https://iucn.org/press-release/202410/more-one-three-tree-species-worldwide-faces-extinction-iucn-red-list.
35. Jensen, H.H. (2023). *8 ways the circular economy outperforms linear businesses*. [online] World Economic Forum. Available at: https://www.weforum.org/stories/2023/03/8-ways-the-circular-economy-outperforms-traditional-business-models/.
36. 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.

37. Medical Technology Ireland, (2023). 'Building on Ireland's MedTech Success to Drive Future Growth'. Available at: https://www.medicaltechnologyireland.com/news/building-on-irelands-medtech-success-to-drive-future-growth
38. MedTech Europe, (2023). 'The European Medical Technology Industry in figures. Available at: https://www.medtecheurope.org/wp-content/uploads/2023/10/the-european-medical-technology-industry-in-figures_2023-1.pdf
39. Østerle, L., & Danse, S. (2020) 'Barriers and drivers for circular economy in the healthcare sector', *Sustainability*, 12(5), p. 1712
40. PA Knowledge Limited, (2024). 'Reimagining sustainable medtech'. Available at: https://www.paconsulting.com/industries/life-sciences/reimagining-sustainable-medtech
41. Potting J, Hekkert M, Worrell E and Hanemaaijer A, (2016). Circular Economy: Measuring innovation in product chains. PBL Netherlands Environmental Assessment Agency, The Hague.
42. Ripple, W.J., Wolf, C., Gregg, J.W., Rockström, J., Mann, M.E., Oreskes, N., Lenton, T.M., Rahmstorf, S., Newsome, T.M., Xu, C., Svenning, J.-C., Pereira, C.C., Law, B.E. and Crowther, T.W. (2024). The 2024 state of the climate report: Perilous times on planet Earth. *BioScience*. doi:https://doi.org/10.1093/biosci/biae087.
43. Settele, J., Díaz, S., Ngo, H. T. (eds). IPBES secretariat, Bonn, Germany. 1144 pages. ISBN: 978-3-947851-20-1
44. Skillnet Ireland (2024). *Talent to Thrive: The Future Skills Report for Ireland's Medtech Sector 2024 – 2028*. [online] Available at: https://www.skillnetireland.ie/insights/Talent_to_Thrive_The_Future_Skills_Report_for_Irelands_Medtech_Sector_2024-2028.
45. UNEP (2021). *Air Pollution Note – Data you need to know*. [online] www.unep.org. Available at: https://www.unep.org/interactives/air-pollution-note/.
46. United Nations Environment Programme (2024): Global Resources Outlook 2024: Bend the Trend – Pathways to a liveable planet as resource use spikes. International Resource Panel. Nairobi. https://wedocs.unep.org/20.500.11822/44901
47. WWF (2024) Living Planet Report 2024 – A System in Peril. WWF, Gland, Switzerland. / Available at: https://livingplanet.panda.org/en-us/.
48. Zhang, Y., Xu, S., & Liu, S. (2017) 'Towards green strategies for circular medical products', *Resources, Conservation and Recycling*, 127, pp. 1-13. Available at: https://www.sciencedirect.com/science/article/pii/S0921344917302094?via%3Dihub

CIRCULÉIRE

DISCLAIMER

Although every effort has been made to ensure the accuracy of the material contained in this Sectoral Guide is complete, accuracy cannot be guaranteed. The author(s) do not accept any responsibility whatsoever for loss or damage occasioned or claimed to have been occasioned, in part or in full, as a consequence of any person acting, or refraining from acting, as a result of a matter contained in this publication. Irish Manufacturing Research do not make any warranty, express or implied, including warranties of merchantability and fitness for a particular purpose, nor does it assume any legal liability or responsibility for the accuracy, completeness, or usefulness of any information, apparatus, product, or process disclosed, nor does it represent that its use would not infringe privately owned rights. References in this guide to any specific commercial products, process, government policies (both EU and Irish) or service by trade name, trademark, manufacturer, or otherwise, does not necessarily constitute or imply its endorsement, recommendation, or favouring by Irish Manufacturing Research. The views and opinions of authors expressed herein do not necessarily state or reflect those of Irish Manufacturing Research and shall not be used for advertising or product endorsement purposes.

IRISH MANUFACTURING RESEARCH

Roinn Cumarsáide, Gníomhaithe ar son na hAeráide & Comhshaoil
Department of Communications, Climate Action & Environment