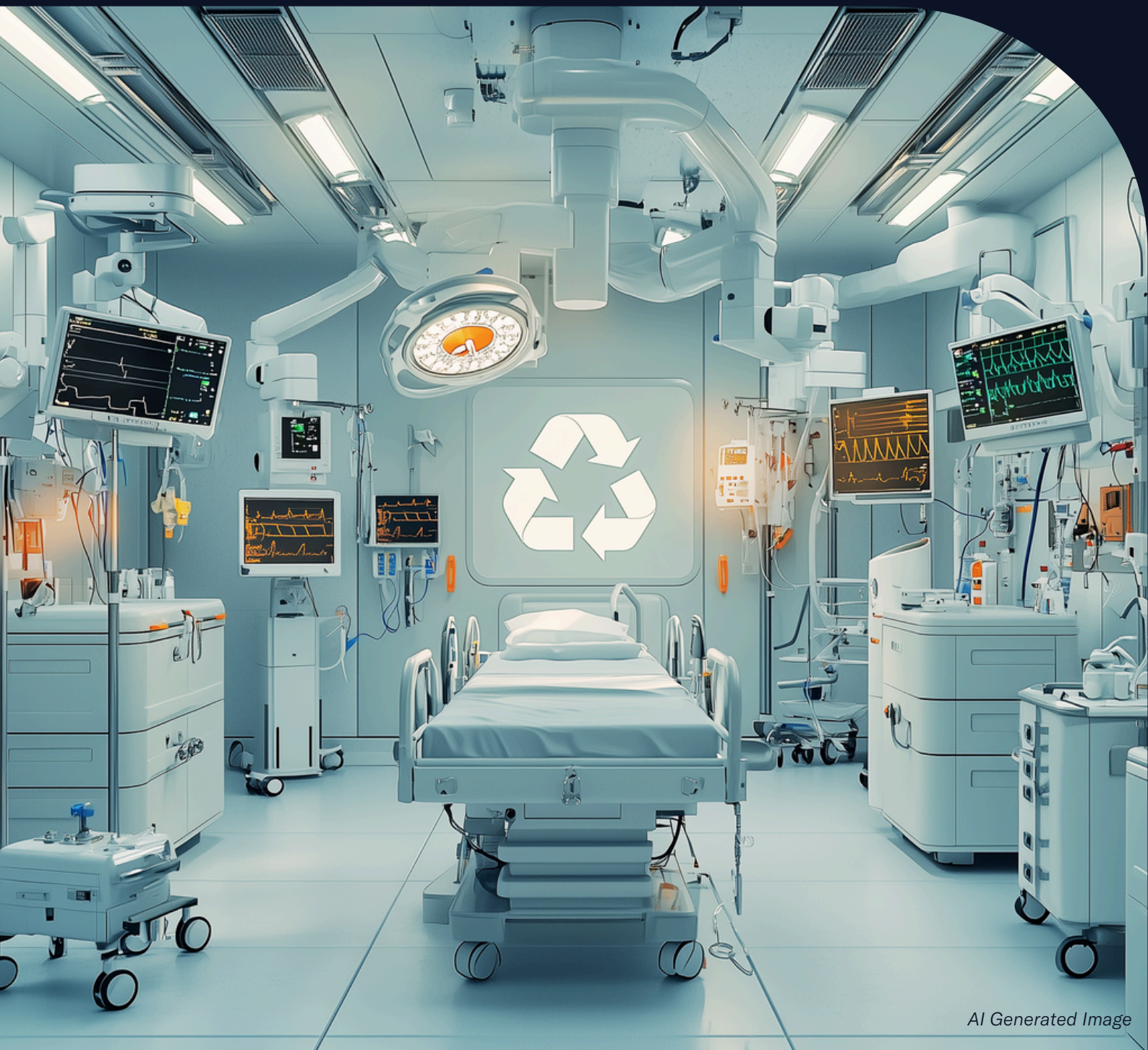
2024

INDEED Resourcify

FEASIBILITY CASE STUDY

Enabling Circular Economy in MedTech



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INDEED Resourcify®

A Circular Economy in MedTech

ensures that medical products and materials are used for as long as possible, extracting maximum value during their lifecycle and then recovering and regenerating them at the end.

A key challenge in achieving this vision is the economic feasibility of R-strategies (such as recycling, refurbishing, and remanufacturing) within a coalition of stakeholders. This aspect is often overlooked, yet it is crucial for building a sustainable and value-driven circular model in healthcare.

By addressing these economic aspects within a collaborative framework, the Circular Economy can become a financially viable and environmentally sound alternative to the traditional linear model of make-use-waste.

This white paper explores how to establish a circular medical value chain over the long-term by tackling economic, legal, and technical challenges.

Foreword

How can the medical technology industry continue innovating and improving patient care while reducing its environmental impact, in collaboration with regulatory institutions?

How can MedTech companies achieve sustainable growth while preserving natural resources and minimizing waste in an industry where single-use products and complex electronics are the norm?

These are the critical questions facing our sector today, and they demand transformative solutions. The Circular Economy concept is emerging as a key driver for the much-needed sustainable transition in healthcare, promising greater material efficiency, lower emissions, and new avenues for innovation and value creation.

The medical technology industry has long been at the forefront of improving human health and well-being. Now, we must apply that same innovative spirit to rethinking our approach to product design, manufacturing, and end-of-life management. With its concentration of expertise and resources, the medical technology industry holds immense potential to adopt circular, restorative practices where we no longer consider anything to be waste.

Therefore we initiated a Round Table of companies along the whole value chain. The result of our work is this feasibility case study. It represents a pioneering effort to catalyze the sharing of Circular Economy innovation across the MedTech ecosystem. This includes the active involvement of regulatory institutions.

We aim to create a collaborative platform for testing, validating, and implementing circular concepts at scale by bringing together manufacturers, healthcare providers, recyclers, and innovators.

This white paper provides a unique overview of our feasibility case study. It presents the so-called "White Dot" vision and roadmap, showcasing how the MedTech industry can viably implement Circular Economy principles. It outlines systemic changes at the product, company, and industry levels that can be scaled to create lasting impact.

We encourage MedTech executives, hospital administrators, policymakers, and researchers to join us on this journey toward a circular healthcare economy. Leveraging the model, tools, and collaborative approaches outlined in this white paper we aim to unlock the industry's potential to create sustainable medical technologies that benefit patients, society, and the planet.

Heiko Tullney
Executive Director at Indeed Innovation
h.tullney@indeed-innovation.com

Michael Leitl
Executive Director at Indeed Innovation
m.leitl@indeed-innovation.com

Key Findings

- As a step toward Circularity, we developed the "White Dot" system. It represents a paradigm shift in medical waste management, transforming a significant part of the 4.8 million tonnes of "waste" from 1,893 clinics into a valuable, sustainable resource. Companies must navigate multiple realities. While the current system is entrenched, the potential for innovation, value retention, and economic growth through refurbishment and reuse is immense.

- The economic model of the "White Dot" system has the potential to be cost-neutral or even profitable for manufacturers. By redirecting existing disposal costs and capturing embedded value in waste materials, companies can unlock action and commercial value. While achieving a competitive price point or extended margin may take time, once established, the "White Dot" system reduces environmental impact and improves operational efficiency and resilience.

- Cross-manufacturer collaboration is crucial for the success of the "White Dot" initiative. Companies should neither underestimate nor be overwhelmed by the waves of disruption this collaborative approach brings. Those who recognize and embrace this shift are poised to succeed, much like the companies that successfully navigated the digital transformation.

- Hermitization and disinfection are key technological enablers for unlocking value in medical waste. No off-the-shelf blueprint exists so far, so all companies are learning on the go. However, by closely examining successful pilots and emerging technologies, we can see the outlines of a promising approach.

- The regulatory landscape presents both challenges and opportunities. Companies must be honest about internal barriers to change, such as a short-term focus or a mindset that sees sustainability as a cost. However, existing external barriers should not be used as excuses for inaction. Proactive engagement with regulators can open doors for innovative waste management solutions.

- The proposed roadmap offers a balanced approach to risk and opportunity. It reflects the best practical knowledge (proven in many European pilot projects) about what has worked for companies in the advanced stages of integrating sustainability. This proposal offers various entry points and works across entire companies and value chains.

- The approach can only be economically viable if all stakeholders join in the system. Our research showed, that individual collections do not lead to the significant economic break even but if qantities and values are pooled it works.

About the Round Table

The Round Table unites 14 key players from across the MedTech ecosystem into an alliance to drive circularity in healthcare. This diverse coalition blends deep industry knowledge, technical expertise, and innovative capabilities to address the complex challenges of implementing a Circular Economy in the MedTech sector.

By pooling resources and sharing risks, the Round Table overcomes the limitations that have hindered individual company efforts in the past, achieving the scale necessary to make circular approaches both economically and operationally viable.

Four types of organizations are part of the ecosystem:

- Healthcare providers and hospital networks, offering real-world insights on usage and disposal practices.
- Leading device and equipment manufacturers, bringing product knowledge and market reach.
- Innovation and circular experts partners, driving advanced tracking, data analytics, and process optimization.
- Recycling and logistics specialists, providing expertise in material recovery and reverse logistics.

PARTICIPANTS BUILDING THE VALUE CHAIN

Johnson&Johnson MedTech

OLYMPUS

PHILIPS

LÖWENSTEIN medical

People.Health.Care.

ZUKE GREEN

ALBIS

MARIEN KRANKENHAUS

UKE HAMBURG

Otto Krahn Group

Imperative for Change

A SECTOR AT A CROSSROADS

To understand the importance of this feasibility case study, it is crucial to first highlight the current landscape of the MedTech industry.

The sector stands at a crossroads, facing a convergence of challenges that necessitate new approaches and innovative solutions.

Rising Costs and Regulatory Burdens:

- Disposal costs for medical waste are increasing, with some estimates suggesting a 5-7% annual rise
- The Medical Devices Regulation (MDR) in Europe has significantly increased compliance costs, with some companies reporting 5-10% of revenue now dedicated to regulatory affairs

Supply Chain Vulnerabilities:

- The COVID-19 pandemic exposed critical weaknesses in medical supply chains
- Geopolitical tensions and trade disputes are further complicating access to raw materials and components

Environmental Regulations:

- The EU's Circular Economy Action Plan sets ambitious targets for waste reduction and material recovery
- Many countries are implementing extended producer responsibility (EPR) schemes for medical devices

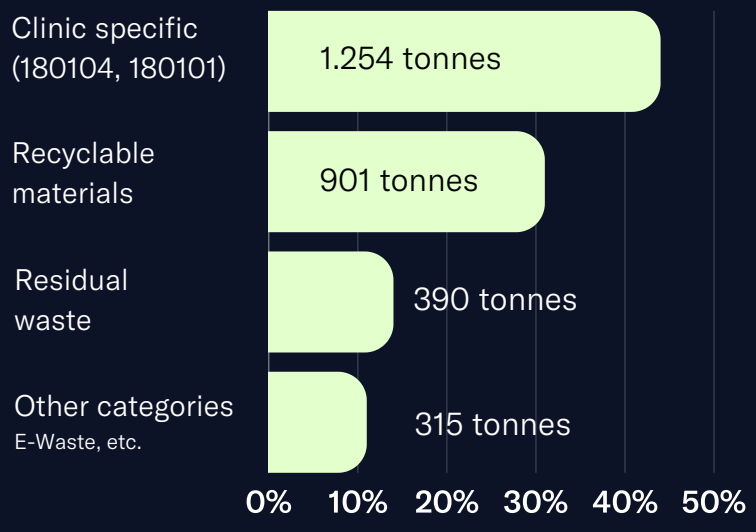
Market Demand:

- Healthcare providers are increasingly prioritizing sustainable procurement practices
- Patients and consumers are showing growing concern for the environmental impact of healthcare

THE OPPORTUNITY AND RESOURCE POTENTIAL:

An estimated **4,8 million tonnes of valuable materials from 1,893 clinics in Germany alone** are currently disposed as "waste" each year - only a fraction recycled. 422.000 tonnes are clinic specific waste which has to be incinerated. It contains valuable materials for example from single use devices. This represents a massive opportunity to retain economic and ecological value through smarter resource management.

Composition of waste volumes in tonnes in 2021 at the University Hospital in Dresden
Source: internal environmental report, fraunhofer.de.



This data highlights the significant volume of potentially recoverable materials currently being lost to incineration or landfill.

The White Dot

ECONOMIC POWER IN A DIGITALIZED NETWORK

The “White Dot” is a digitalized system that recovers economic value in the form of materials, hardware components, and products. It is an economic alliance (consortium) of leading stakeholders from manufacturers, users, and recyclers, e.g. in the form of a company participation.

The core of this concept is to remove medical products and their packaging from linear "disposal" by incineration, to save these costs and to preserve and return the embedded values:

For Manufacturers:

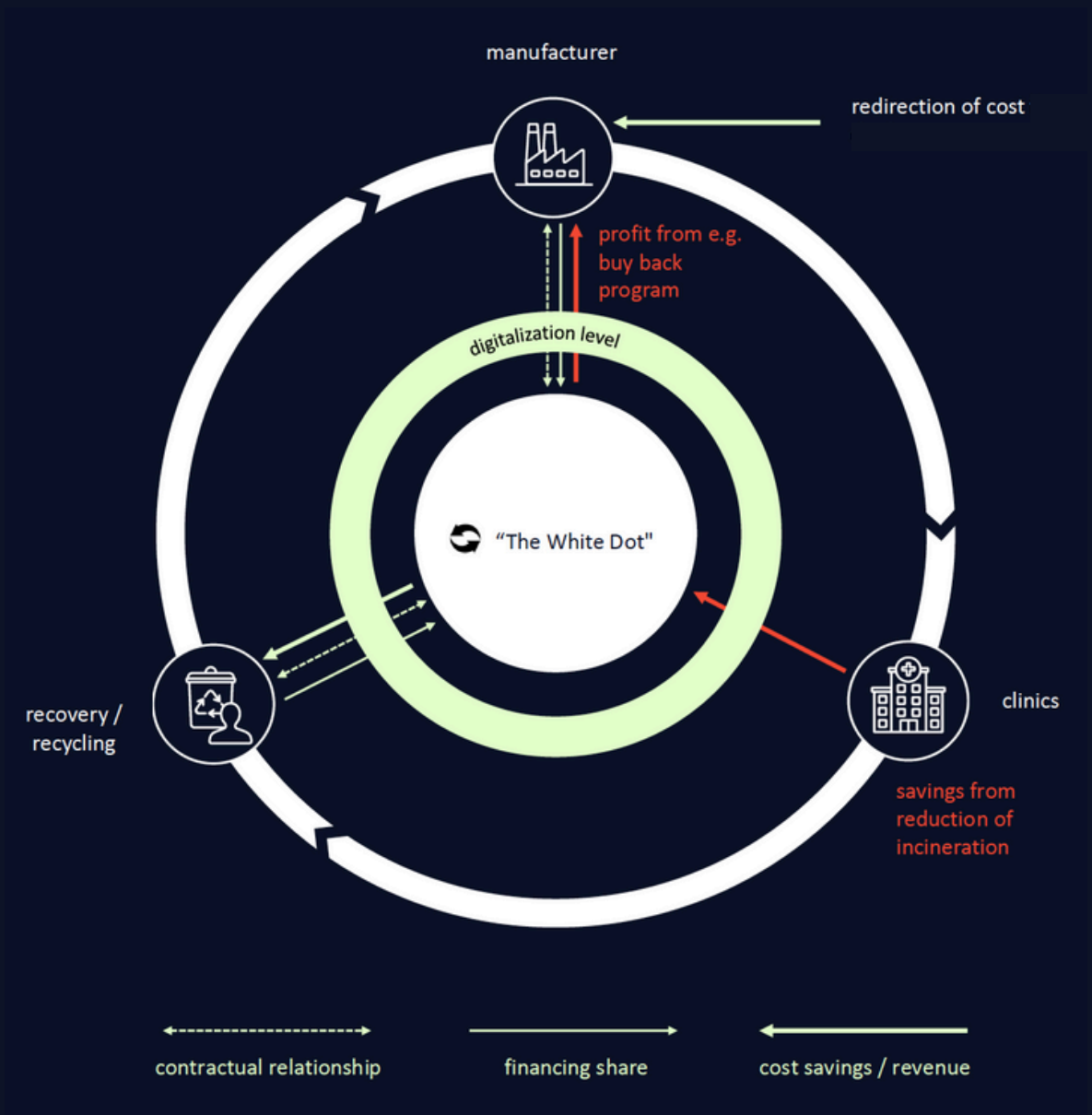
- Credit from savings on incineration
- Cost neutrality via redirecting disposal costs
- Profitability through buy-back programs

For Clinics:

- Process savings: unsorted disposal of "White Dot" products

For Recyclers:

- Economic viability through funding pool payments



Principles of Success

A SYSTEMATIC APPROACH TO CIRCULARITY

The “White Dot” Concept was developed by the founding members of the Round Table during an ideation workshop aimed at identifying opportunities to reduce waste volume in the healthcare sector.

This feasibility case study, conducted jointly by INDEED and RESOURCIFY, outlines a potential framework for establishing this system. The following components and processes are essential for its success.

CORE COMPONENTS:

Digital collection and tracking:
- RFID-enabled smart bins for product ID
- Blockchain for transparency and traceability
- Real-time inventory management

Centralized disinfection and processing:
- Advanced disinfection (e.g., electron beam)
- AI sorting for material separation
- Centralized collection to get needed quantities for economies of scale

Cross-manufacturer collaboration:
- Shared infrastructure for economies of scale
- Joint R&D on circular design and material standards
- Collective regulatory engagement

Revenue sharing:
- Redistributed cost savings from avoided incineration
- New revenue from recovered materials and refurbished products
- Incentives for healthcare providers

KEY PROCESSES:

Hermetic sealing and disinfection:
- Ensures safe handling and transport of used medical products
- Enables reclassification of waste streams for easier processing

AI-powered sorting:
- Computer vision and machine learning algorithms to identify and categorize products
- Enables efficient separation of materials for optimal recovery

Refurbishment and reprocessing:
- Cleaning, testing, and recertification of suitable devices for reuse
- Targeted at high-value capital equipment initially

Advanced recycling:
- Mechanical and chemical recycling processes tailored to medical-grade materials
- Focus on recovering high-value materials like surgical steel and rare earth elements

Reference Product: A Model for System Evaluation

A BENCHMARK FOR CIRCULAR ECONOMY

To assess the viability and potential of the “White Dot” system, we've created a standardized reference product - the “Joint Product”. This hypothetical item represents a *typical medical device* or *consumable*, incorporating common materials and components found in medical waste.

That means, it contains a cross-section of the typical 180104 material mix of different components, materials, and packaging. It represents single use materials like sheets as well as electronic components typically found in complex single use devices use for minimally invasive surgery and consumables.

By using this model, we can more easily calculate potential costs, savings, and value retention across different manufacturers and product types.

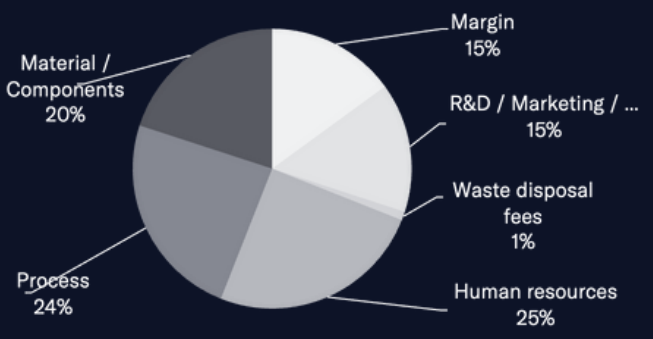
This reference product allows us to demonstrate the system's potential benefits without relying on any single company's proprietary information.

FOLLOW THE MONEY

The following charts illustrates several economic aspects like invested money to produce the Joint Product as well as the materials needed. The breakdown shows immediately that the materials itself represent just 20% in total, divided in packaging, plastic, steel and much more. This would result in minimal income if recycled. At the end, the greatest value is in the making... not in the material.

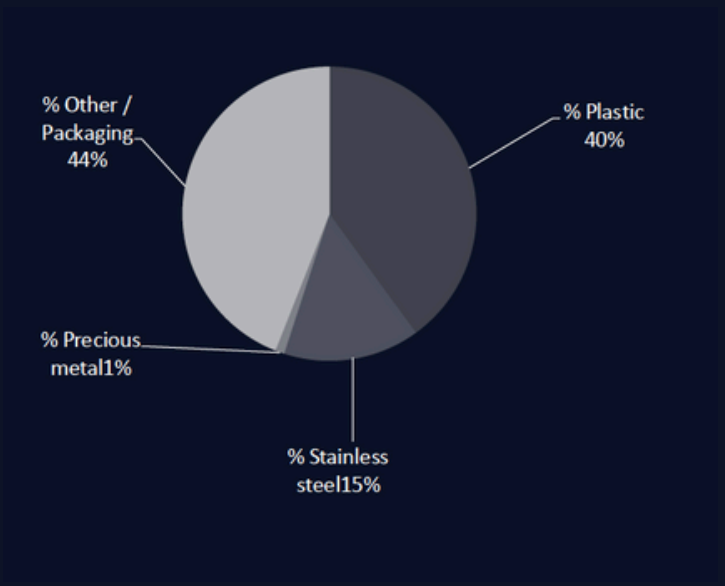
PRODUCT VALUE

This pie chart shows the distribution of costs within the 500 euro product.



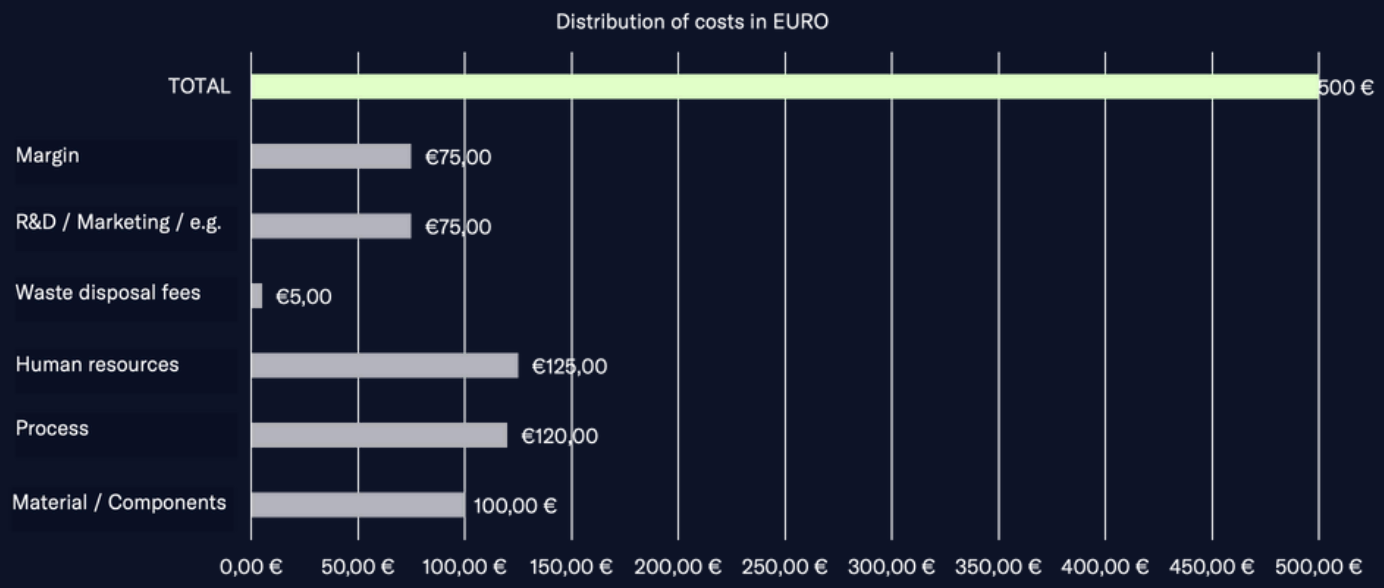
MATERIAL COMPOSITION

This pie chart illustrates the material content of the product



COST DISTRIBUTION IN EUROS

This horizontal bar chart breaks down the product's 500 euro price into specific cost categories.



IMPORTANT: all figures and calculations are based on assumptions, estimates and, in some cases, public data sources. The calculations do NOT show the economic reality but a possible vision.

Value Creation Potential

As illustrated in the previous page, the value is hidden in the creation process not in the materials. Therefore, our feasibility case study seeks to unlock this hidden value in medical products typically destined for incineration or landfills.

Through advanced processes of hermitization, disinfection, and recycling, the "White Dot" system aims to preserve materials, components, and even entire products, creating substantial economic and environmental benefits for all stakeholders in the medical industry.

By recovering embedded value, we aim to create a more sustainable and cost-effective industry that aligns with Circular Economy principles.

To achieve this goal we have to understand the entire system. How can the industry be transformed to sustain the hidden value and avoid value destruction through incineration?

UNDERSTANDING THE SYSTEM

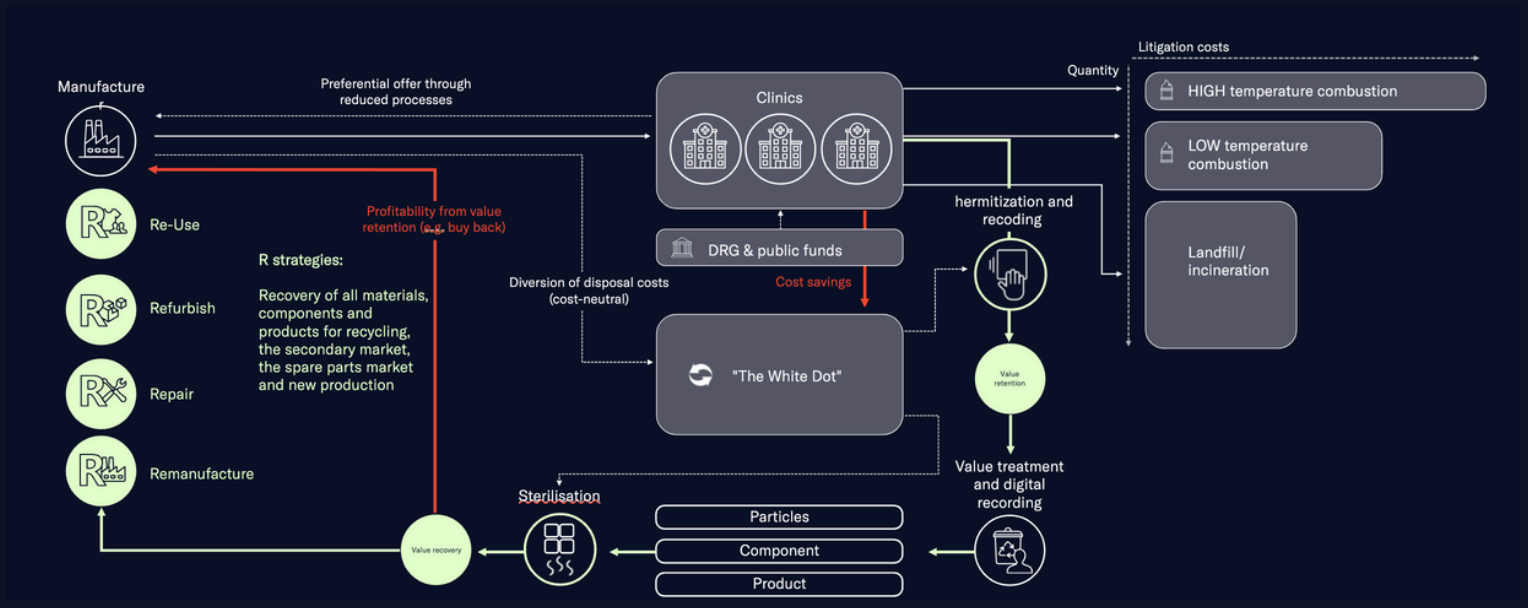
The system for recovering embedded value in MedTech involves several key stages that work together to ensure materials are efficiently collected, processed, and reintegrated into the production cycle.

The process begins with the collection of used medical devices and materials from healthcare providers including clinics, hospitals, and medical practices.

Once collected, these items undergo disassembly, where they are broken down into their individual components.

This step is crucial for identifying and separating valuable materials, such as metals, plastics, and electronics. After disassembly, materials are sorted based on their potential for reuse, recycling, or safe disposal.

Advanced tracking and data analytics play a vital role in this system, ensuring that every step of the recovery process is optimized for efficiency and effectiveness. These tools monitor the condition of materials throughout their lifecycle and help to maximize the amount of recoverable value.



This image illustrates the flow of materials in the recovery process, visually mapping how embedded value is recaptured from used medical devices. An important component here is the hermetization of clinical waste for disposal. This allows protection the workforce and disinfection at a large scale. The cost will be shifted and distributed amongst the participants of the “White Dot” System.

Key stages depicted include:

Collection: Gathering used devices and materials from healthcare providers.

Disassembly: Separating products into their component parts for evaluation.

Sorting: Organizing materials based on their potential for reuse, recycling, or disposal.

Refurbishment/Recycling: Processing materials to extract and reintroduce their value into the manufacturing cycle.

“This system represents a paradigm shift from the current linear model of production, use, and disposal to a Circular Economy approach that maximizes resource efficiency and economic value while minimizing waste and environmental impact. Important to observe the collaboration between manufacturers, healthcare providers, and recycling experts is essential for this system to function effectively.“

Michael Leitl, INDEED Innovation

How to Make Profit

The following calculation demonstrates how a circular approach can generate new revenue while extending a product's life. Currently, we reduce the product's value to its energy content by incinerating it after use and selling the energy produced. When we recycle instead, we generate recyclates, with revenues comparable to those from energy sales during incineration.

For example, our reference product valued at €500 (1kg) costs about €0.20 to burn. The energy delevered (if it would be recovered like in standard waste incinerators) is just €0.30 worth of energy (electricity and heat). Alternatively, recycling the same product also costs €0.20 and yields about €0.30 in revenue from the sale of recyclates.
The value we can get through recycling is extremely low.

However, the proposed "White Dot" system aims to retain a higher proportion of the product's value through the reuse of components or the entire product.

Under this system, a €500 product (1kg) would incur a cost of €4 for cleaning and disinfection and €300 for restoration (including disassembly, reassembly, resale, and remarketing). The remanufactured product could then be sold again as new or a new business model like "Product as a Service" could be established, adding significant value and allowing for an increased profit margin.

Manufacturers and clinics can finance the recycling process by sharing some of the cost advantages, such as lower production costs and the elimination of incineration expenses.

This approach not only preserves more of the product's original value but also supports a more sustainable and profitable business model.

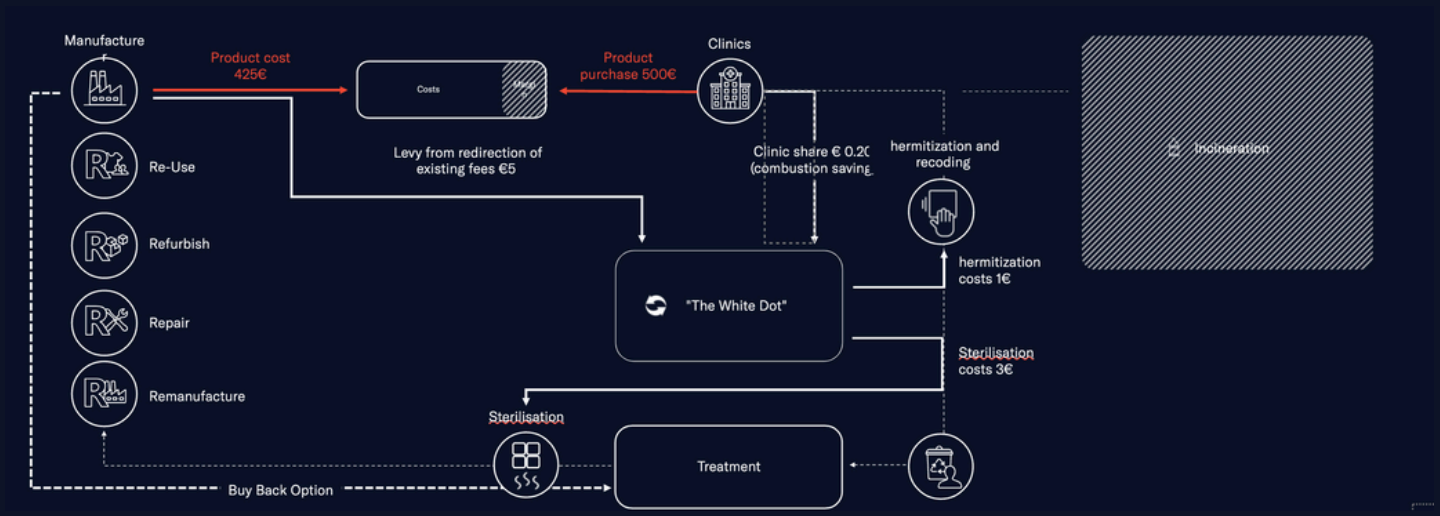
LINEAR VALUE DESTRUCTION [EUR]	
75 + 425	Margin 15 % and manufacturing costs of new product [1]
0,20 *	Disposal costs after use[2]

VALUE RETENTION CIRCULAR [EUR]	
500	Selling price of new product (margin and manufacturing cost) [3]
4	hermitization/cleaning for recoding [4]
300	Remanufacturing costs, utilisation of 50% of the parts [5]
5	Share of financing „White dot"
500	Selling price remanufactured product (as good as new) or as part of a Product as a Service Model[5]
175	Margin - here increased to 35% as an example

1) Margins in the medical technology sector according to the Roland Berger study "Global MedTech 2023 - How companies stem the tide" - https://www.rolandberger.com/en/Insights/Publications/Global-MedTech-2023-How-companies-stem-the-tide.html
2) Price of incineration / tonne = EUR 195 incl. transport according to Resourcify and clinic invoices, based on 1 kg of product.
3) Average value of various suppliers such as Ethicon, Olympus, Philipps for disposable electrical appliances
4) Assumption based on costs for small-scale cleaning by Resourcify's partners
5) 50% of the materials can be used; costs for remanufacturing at 70% of new production ■ Approximation by comparing industrial remanufacturing at Jungheinrich, operate profitable 2 plants - costs between 20 and 80 per cent of new equipment production, extension by 2-3 loops, 94 per cent reuse rate by design (https://www.jungheinrich.com/en/press-events/jungheinrich-opens-new-used-equipment-plant-1268426; https://www.jungheinrich.com/presse-events/jungheinrich-eroeffnet-neues-gebrauchtgeraetewerk-1108740) // Philipps: https://remanufacturing.eu/studies/fe7038c095524da69e15.pdf - Refurbished Systems are sold for 60 to 85% of the equivalent new system price, depending on the generation of the product and the developments of its life cycle. Refurbishment can be strategic from a marketing and market segmentation perspective. In addition, in this case, the system upgrade approach saves costs by up to 50% on the upgrade bill of materials. The upgrades provide a means for new revenue through new sales and service contracts.
6) see Part 3 - Technologies - Mechanical recycling - Plastics 1/2

Cost Neutrality as a USP

Under the assumptions made, the model could remain cost-neutral for manufacturers. The disposal portion of the product is transferred to the "White Dot" and bears the costs for hermitization and sterilization. This is additionally financed from the cost savings of the clinics (no disposal fees for white dot) and takes over the necessary economic processing with the entire income. The system in turn offers clinics the advantage of collecting unsorted waste simply and securely in the “White Dot" collection and handing it in hermetically sealed. This attractive advantage for clinics is reserved for participants and operators of the “White dot". They save also time and effort handling waste. In the future, this controlled collection of value may result in options for a circular buy-back program and thus increasing profitability.



In this model, cost neutrality is the focus. The product unit is produced by the manufacturers for 425 euros and clinics purchase it for 500 euros. After use, it goes into the return process via the white dot system. A redistribution of existing fees from manufacturers and clinics into the white dot system enables the financing of hermetisation, sterilisation and return transport.

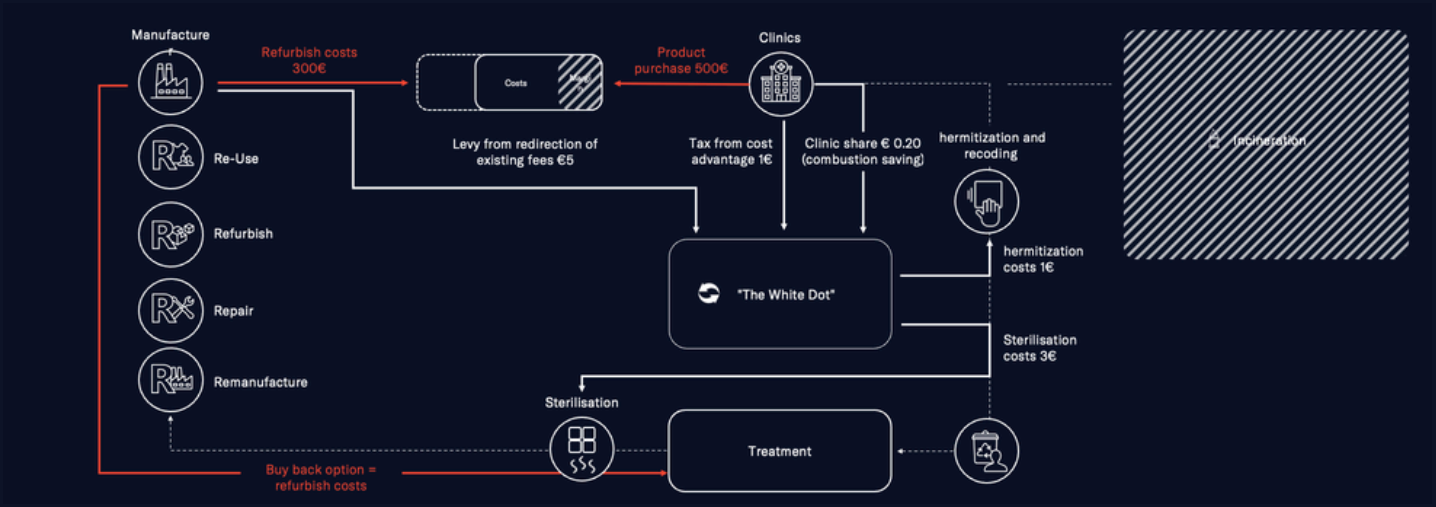
The actual mix of materials and products allows not much more than recycling, which destroys most of the value as we have seen before. To maintain the value of the products it is key to keep it in use. A fundamental change in product composition is the basic prerequisite for being able to apply circular principles such as remanufacture, reuse and repair. The model on the following page shows how this can be achieved.

IMPORTANT: all figures and calculations are based on assumptions, estimates and, in some cases, public data sources. The calculations do NOT show the economic reality but a possible vision.

Sales Growth Through Future Circularity

By optimizing the treatment of components, parts and entire products, the "white dot" offers several options for returning them to the economic cycle. A buy-back program could make use of these options. Refurbish processes could save manufacturing costs and the product could ultimately be offered at a lower price.

This would also be more sustainable, as materials would be reused and process energy would be reduced. Costs could be saved on every sales transaction, some of which could be passed on to customers. The whole White Dot System will be financed through the alliance of White Dot Participants - partly because it replaces the already existing fees for the packaging via “Duale System Deutschland”.



Here we see that the possibility of manufacturers buying back products creates a new usage cycle. The remanufacturing costs to restore the original value are, as the example calculation showed, considerably lower than new production.

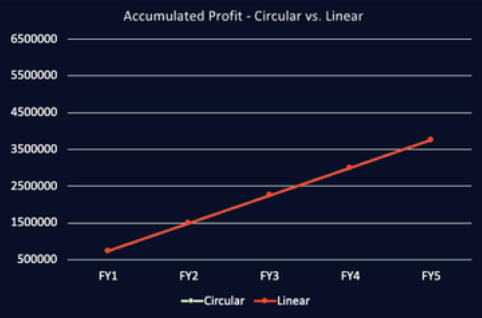
In this way, new business models can be developed, and a profitable circular system can be established. The following sample calculations illustrate the potential for developing new business models and building a profitable, circular system.

IMPORTANT: all figures and calculations are based on assumptions, estimates and, in some cases, public data sources. The calculations do NOT show the economic reality but a possible vision.

3 Scenarios for Sales Growth

We have compiled three comparative calculations to illustrate how the added value of an innovative, circular ecosystem can lead to a higher accumulated profit over five years: “Recycling”, “basic circularity”, and “advanced circularity”. These calculations assume 10,000 units of our “Reference Product” and shows the development of the accumulated profit over five years.

Below of each scenario the assumptions are listed, like Return Rate, Product Cost and Refurbishment Cost as well as the estimated savings for manufacturer and clinics.
Each case shows five years of profit development.



RECYCLING

Return rate: 0%

Product cost: 425 €

Sales price: 500 € (10,000 units)

Manufacturer:

- Cost-neutral profitability

Clinic:

- unchanged purchase
- Acceptance of the first disinfection

BASIC CIRCULARITY

Return rate: 50%

Refurbishment cost: 300 €

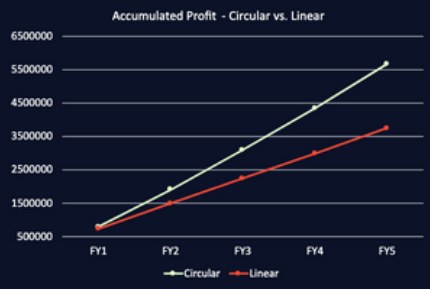
Sales price: 380 € (10,000 units)

Manufacturer:

- 30% Production costs
- Cost-neutral profitability

Clinic:

- 23% purchase price reduction
- Cost-neutral hermitization



ADVANCED CIRCULARITY

Return rate: 80%

Refurbishment cost: 300 €

Sales price: 400 € (10,000 units)

Manufacturer:

- 30% Production costs
- 2% costs per year due to automation

+ 50% accumulated profit after 5 years

Clinic:

- 20% purchase price reduction
- Cost-neutral hermitization

The comparison shows that, due to lower refurbishment cost than original product cost, manufacturers have 30% lower production costs (which corresponds to an average value based on other industries). Cost neutral profitability will be achieved with 50% return rate. In the case of advanced circularity savings could be even higher because of higher return rate and savings through automation.

Part of the value is passed on to the clinics as an incentive to buy the remanufactured products instead of new ones.
Therefore up to 50% accumulated profit is possible for manufacturers after 5 years through automation
As an addon comes the ecological benefit of using less raw material and, therefore, significantly lower Scope 1-3 emissions.

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How to Deal with Legislation

Successful implementation of the hospital waste recycling system hinges on navigating complex legislative requirements and leveraging cutting-edge technology. This section explores the key legal considerations and technological innovations that make this vision feasible.

By addressing these two crucial aspects, hospital waste can be transformed from a costly burden into a valuable resource, all while ensuring strict compliance with health and safety regulations.

LEGISLATION: TRANSFORMING HOSPITAL WASTE INTO A SOURCE OF VALUE

The current regulatory landscape, particularly LAGA 18 (Länderarbeitsgemeinschaft Abfall), generally mandates that products that have come into contact with patients must be incinerated. However, there is a crucial provision that allows for deviation from this recommendation, opening the door for innovative waste management solutions in the medical sector.

The key prerequisite for such deviation is obtaining confirmation from the competent authority that occupational health and safety requirements are met, and all health risks associated with blood and human excretions are adequately addressed. This exception has been successfully put into practice by Resourcify for Ethicon products, demonstrating the feasibility of alternative approaches within the existing legal framework.

To comply with occupational health, safety and hazardous goods regulations, the hermetic sealing of hospital waste until decontamination is crucial.

This process has been deemed proper and harmless within the meaning of Section 7 (3) of the Kreislaufwirtschaftsgesetz (KrWG), as confirmed by a detailed expert opinion from two lawyers.

While this approach incurs additional financial and personnel costs, it is the prerequisite for generating the financial added value that can support the model in the long term. These additional costs would be absorbed by the proposed "White Dot" system, supported by all stakeholders.

DATA PROTECTION AND COMPETITION LAW CONSIDERATIONS

The implementation of a cross-manufacturer recycling system to achieve economies of scale must navigate complex competition law requirements. Specifically, manufacturers are prohibited from accessing information about their competitors' quantities. Therefore, the technical platform must guarantee data security that protects both clinics and manufacturers.

Similarly, clinics must be protected from inadvertently learning each other's details. The system must be designed to ensure compliance with these legal requirements while still allowing for efficient waste collection and processing.

The Role of Technology

TECHNOLOGY: ENSURING CLINICAL PURITY AND EFFICIENT SORTING

The technological backbone of the "White Dot" system revolves around two key processes: hermitization and sorting.

HERMITIZATION

Hermetic sealing prior to transport, cleaning, and sorting of clinical waste (180104) is crucial for the feasibility of recycling and future re-use concepts. The primary goal is to ensure the reliable destruction of all bacteria, viruses, and spores.

Currently, autoclaves in conjunction with vacuum equipment have proven to be an effective method for this process. This approach has been tested and approved by Resourcify partners.

However, to reach the next value-added stage in closing the cycles, a new form of sterilization must be established in the medium term that does not destroy electronic devices. One promising solution is sterilization using low-energy electron radiation, which has been deemed suitable for recommended microelectronics by the Fraunhofer Institute and TÜV.

SORTING

Manual medical waste sorting is prohibitively expensive, necessitating automatic image recognition processes. Two potential solutions have been identified:

1. Greyparrot offers a complete solution for analyzing waste composition that automates the manual process of sampling and testing material through intelligent monitoring and analysis.
2. The Circular Digital Economy Lab at Ruhr West University of Applied Sciences is developing AI-controlled robots that can automatically dismantle electrical appliances.

These technological advancements are crucial for making the "White Dot" system economically viable and scalable.

The "White Dot" system aims to transform medical waste from a cost center into a valuable resource stream by addressing these legislative and technological challenges.

"In order to sustainably establish circular economy principles in the MedTech sector, the current regulations such as LAGA18 are currently the biggest obstacle. National authorities and European policymakers are called upon to create the regulatory conditions for a more circular economy in the MedTech sector."

Daniel Unger, Johnson & Johnson Medtech

Roadmap

IMMEDIATELY SUSTAINABLE AND PROFITABLE IN THE FUTURE

The transition from some initial recycling pilot to the fully realized "White Dot" system requires a strategic, phased approach. This roadmap outlines the key steps, financing strategies, and developmental stages necessary to bring our vision to fruition.

It makes sense to first establish the “White Dot" as a digitalized and centralized recycling system and thus also build it up as a brand (1). This phase takes place parallel to piloting (2).

Taking into account current authorization barriers (transport and recycling of, e.g., disposable materials) and established recycling technologies (e.g., e-waste recycling), the first step is to pilot SUP (single-use products) within one year (2).

This pilot system can then be extended to valuable tools (e.g. steel) and recyclable consumables (surgical drapes, packaging, etc.) (3)

To preserve as much value as possible, second markets for used high-quality devices should be established in addition to refurbish-services (4). With that everything is prepared to bring new generations of appliances to market, that are build to dissassemble or for multi-use.

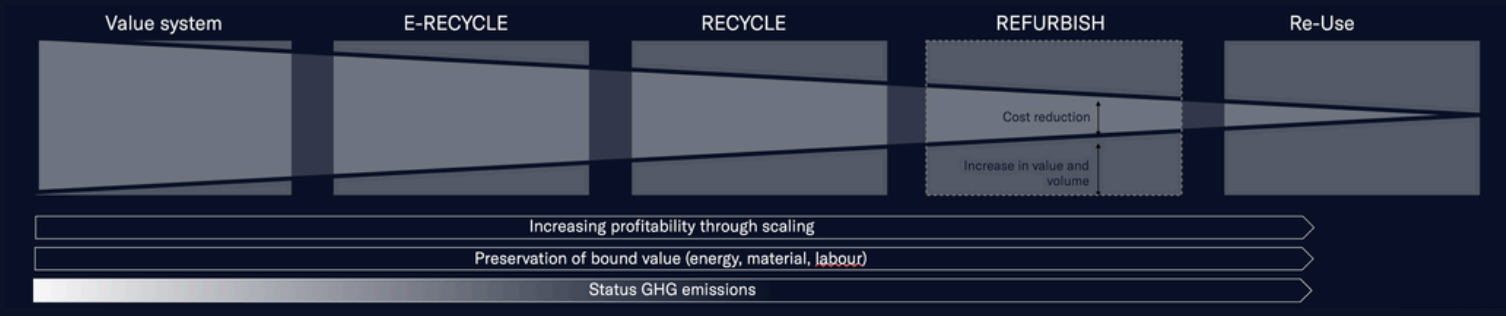
Infrastructure and financial model is established with a company supported by all / some stakeholders

Start with the recycling of SUD - largely single-variety, high quality possible, comparatively low costs

Addition of tools (metal/plastic) and textiles This results in higher volumes and better economies of scale, where possible, customization of materials in appliances (plastic) aiming for higher grade purity

Establishment of used market and Refurbish service for large appliances

New generations of appliances (horizon 2035) are channeled into the Refurbish - Re-Use section. This maximizes value retention and reduces the proportion of value-destroying recycling



Scaling Up

A fundamental system change such as this cannot be implemented alone as it is neither economically possible. To develop the prerequisites, limited cooperation between competitors is worthwhile. In this way, the costs can be spread across two dimensions. Firstly, the distribution of the burden among several companies, with the contribution of the individual companies becoming smaller the more they participate.

Secondly, distribution over time. The earlier the conversion is started, the lower the costs are per year.
For this reason, the roadmap presented divides the development of the system over a time horizon of one decade. This corresponds to the approval of new medical devices. In this way, the goal of circular design for disposable products can also be implemented within a realistic framework.

ADDED VALUE

The idea of the Round Table enables the following added value through cross-manufacturer collaboration, among other things:

1. Quantity advantage/scale effects through cross-manufacturer waste collection.
2. System control and economic transparency through digitalization level; digital collection enables better control and transparency in the system.
3. System controlled by the economy (the manufacturers, politically independent). This creates planning security.
4. EU competitive advantage through process cost savings for system participants (clinics) through simplified waste collection in the "Weißer Punkt" system for participating products and brands only.
5. Shared value access and shared efforts for all parties involved.
6. Measurable reduction of downstream Scope 3 emissions by 3kg/kg product as a documentable parameter in ESG reporting*.
7. Better business performance (through open collaboration)**.

PREREQUISITES

The following cooperative and technical aspects are necessary for a successful scaling of the concept over all five phases:

1. *Coopetition* 2.0 - cooperation between competitors and with stakeholders (see Gassmann, O.; Collaborative Advantage: How Open Organisations Thrive in Volatility; University of St. Gallen).
2. Development of a scalable, efficient hermitization strategy.
3. Medium to long-term perspective to spread costs.
4. Preparation of a financially and ecologically sustainable business model with the option of developing new service models.
5. Looking for strategies like reuse or remanufacturing instead of recycling to remain profitable.
6. Standardization of materials and components for cross-manufacturer reuse (for economies of scale).
7. New sterilization technology, e.g. with the aid of low-energy electron radiation (suitable for recommended microelectronics according to the Fraunhofer Institute and TÜV)***.

Sources:
* Measurement in pilot tests by Resourcify, feasibility case study p. 27
** "Companies from Daimler to 3M, Google and IBM have built some of their most iconic success stories on the systematic use of alliances, networks and ecosystems" Oliver Gassmann, University of St. Gallen "Collaborative Advantage: How open organisations thrive in volatility"
*** https://www.fep.fraunhofer.de/content/dam/fep/de/documents/Themenflyer/N15_Sterilisation_medizinischer_Produkte_DE_net.pdf

Recommendations

The concept has been developed, and the plan is in place. Now, it is up to you, as a company in the medical technology sector, to take the next steps. We have mapped out three possible paths:

Face It: Familiarize yourself with circularity.
Connect: Seek to join forces.
Do It: Implement sub-projects together in the Round Table Group.

FACE IT:
Boosting Circularity.

Now it's time for action. Sustainability is a business imperative, and Circularity is the lever that propels us forward. Embracing circularity is a strategic business advantage.

Begin by:

- Assessing current practices: Identify areas for improvement in your waste management.
- Exploring reusability.
- Working towards more sustainable product designs and packaging.

CONNECT:
Join the Network.

The power of collaboration is at the heart of the "White Dot" initiative.

By joining our network, you'll benefit from:

- Shared value of leading industry players.
- Cost Distribution: Share the financial burden of developing innovative solutions.
- Regulatory influence: Be part of a unified voice to influence policy changes on national and EU level.
- Track waste production and recycling rates, setting improvement targets.

DO IT:
Join a White Dot Pilot.

Participate in shaping the future of medical waste management:

- Influence system development.
- Access expertise: Benefit from collective knowledge in hermitization, sorting, and recycling.
- Contribute to research: Help generate data to inform improvements and policy changes.
- Realize economic benefits: Capture embedded value in waste streams, potentially reducing costs and creating new revenue.

GET IN TOUCH TO LEARN MORE

Conclusion

The transition to a Circular Economy is essential for the MedTech industry, particularly as Europe strives to become climate-neutral by 2050. Achieving this goal requires a fundamental shift in how the healthcare ecosystem manages resources. Currently, with 4.8 million tonnes of waste produced annually, a fully Circular Economy in MedTech seems out of reach. These materials, particularly electronic waste and those containing plastics and metals, are often destined for thermal utilization or disposal rather than being efficiently recycled.

However, the foundation for a sustainable model can be established today through systemic and collaborative efforts of the Round Table. By launching pilot projects under the "White Dot" initiative, we have the opportunity to create scalable take-back systems across Germany, setting a precedent for broader implementation across Europe. These systems would, for the first time, include all manufacturers, allowing for the comprehensive recovery and recycling of valuable materials.

Key factors identified through structured interviews with stakeholders highlight the challenges and opportunities in this transition. Sterilization and logistics are critical hurdles, as current regulations often require incineration for the reclassification and transport of medical materials. Clinics face financial constraints that limit their ability to implement sustainable practices, while regulators have integrated exemptions for the medical sector into laws, buying valuable time for the development of the "White Dot."

Despite these challenges, there are promising signs. Pilot projects f.e. at TU Delft and University Clinic Leuven have demonstrated that circular practices can be achieved at zero cost or even at a profit, though not necessarily in short term . However, it's clear that for raw materials and parts to be used economically, they must be collected in significant quantities, mostly in the range of numerous tonnes.

For this vision to succeed, one solution could be to update the LAGA recommendations for action to support circular practices. Or develop secure hermetization systems to meet current legal requirements. Also the technical and logistical infrastructure for material recycling must be significantly expanded. By leveraging the potential of nearly 1,900 clinics, 100,000 medical practices, and 427 medical laboratories, Germany can establish a model that not only transforms its own healthcare waste management but also serves as a blueprint for other EU countries.

In conclusion, while the path to a Circular Economy in MedTech is challenging, the Round Table's efforts today will lay the groundwork for a more sustainable and economically viable future. By working together and overcoming initial hurdles, we can take decisive steps towards a Circular Economy, driving innovation and setting a powerful example for the global healthcare industry.

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Authors

Michael Leitl
Executive Director Indeed Innovation
m.leitl@indeed-innovation.com

Heiko Tullney
Executive Director Indeed Innovation
h.tullney@indeed-innovation.com

Florian Körner
Circularity Manager at Resourcify
florian.koerner@resourcify.com

Contributors

Chris Willcock - Lohmann & Rauscher
Christoph Hauke - Olympus
Cornelia Peško - Olympus
Daniel Unger - Johnson & Johnson
Daniela Mandt - Lohmann & Rauscher
Denise Seyhan - Olympus
Dominique Pfeiffer - Philips
Erik Steinlechner - Lohmann & Rauscher
Francesca Martinelli - Philips
Laura Frühwirth - Lohmann & Rauscher
Stefan Jung - Olympus
Stephanie Simonis - Lohmann & Rauscher
Tim Wunderlich - Löwenstein Medical

Andreas Haase - ALBIS
Annika Ossenkopf - Asklepios Kliniken
Frank Zukowski - UKE
Lea Eggers - Marienkrankenhaus Hamburg
Matthias Schulz - Otto Krahn New Business
Mike Freudenstein - ALBIS
Nicole Krojer - Zuke Green
Stefan Vellekoop - Otto Krahn Group
Ulrike Schwerig - ALBIS

The Round Table