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From Design To Disposal: A Systematic Review Of Sustainability Practices In Medical Equipment Lifecycle Management

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Abstract

Modern healthcare critically depends on complex medical equipment, whose failure poses a direct and significant threat to patient safety, making a shift from traditional, reactive maintenance paradigms imperative. This systematic review synthesizes literature to critically evaluate risk management strategies in hospital-based operation and maintenance, comparing traditional methods (Corrective and scheduled Preventive Maintenance) against proactive, system-based approaches like Failure Mode and Effects Analysis (FMEA) and Reliability-Centered Maintenance (RCM). The findings demonstrate that while traditional maintenance is a necessary foundation, it is insufficient on its own to manage modern technology risk. Proactive methodologies—FMEA for component-level risk prioritization and RCM for the strategic design of function-oriented maintenance programs—provide a demonstrably more robust framework for prospectively identifying and mitigating equipment-related risks before they cause patient harm. Importantly, the ultimate success of any technical strategy is profoundly moderated by non-technical, organizational factors, including a strong, non-punitive safety culture, visible leadership support, and the strategic allocation of resources. Therefore, the most effective approach is an integrated one, which synergistically combines the predictive power of analytical tools like FMEA and RCM with robust operational practices, all underpinned by a committed organizational safety culture, reframing equipment management as a strategic imperative central to ensuring patient safety and quality of care. Modern

healthcare critically depends on complex medical equipment, whose failure poses a direct and significant threat to patient safety, making a shift from traditional, reactive maintenance paradigms imperative. This systematic review synthesizes literature to critically evaluate risk management strategies in hospital-based operation and maintenance, comparing traditional methods (Corrective and scheduled Preventive Maintenance) against proactive, system-based approaches like Failure Mode and Effects Analysis (FMEA) and Reliability-Centered Maintenance (RCM). The findings demonstrate that while traditional maintenance is a necessary foundation, it is insufficient on its own to manage modern technology risk. Proactive methodologies—FMEA for component-level risk prioritization and RCM for the strategic design of function-oriented maintenance programs—provide a demonstrably more robust framework for prospectively identifying and mitigating equipment-related risks before they cause patient harm. Importantly, the ultimate success of any technical strategy is profoundly moderated by non-technical, organizational factors, including a strong, non-punitive safety culture, visible leadership support, and the strategic allocation of resources. Therefore, the most effective approach is an integrated one, which synergistically combines the predictive power of analytical tools like FMEA and RCM with robust operational practices, all underpinned by a committed organizational safety culture, reframing equipment management as a strategic imperative central to ensuring patient safety and quality of care.

Introduction: The Imperative for Sustainable Medical Technology

The Healthcare Sector's Environmental Footprint: A Global Challenge

The global healthcare sector, while fundamentally dedicated to preserving and improving human life, paradoxically contributes significantly to environmental degradation, which in turn harms public health. The industry's environmental footprint is substantial and multifaceted, stemming from its resource-intensive operations, complex supply chains, and vast waste generation [1]. Globally, the healthcare sector is the fifth-largest carbon emitter, responsible for an estimated 4.4% of net global carbon emissions. The United States' healthcare system is a disproportionately large contributor, accounting for approximately 25% of this global healthcare total [2].

This environmental burden is driven by several factors. Hospitals are among the most energy-intensive commercial buildings, with a single hospital bed requiring as much power as three to four single-family homes [3]. Furthermore, healthcare facilities in the U.S. alone produce more than five million tons of waste each year [2]. A significant portion of this waste originates from the widespread use of medical equipment, particularly single-use devices (SUDs). A single operating room, for instance, can generate a volume of waste in one day equivalent to that of an average family of four in a week, with disposable items being the primary contributor [4]. This linear model of consumption—where devices are manufactured, used once, and discarded—results in enormous quantities of plastic and electronic waste, increased healthcare expenditures, and a supply chain that is highly vulnerable to disruption [5].

The environmental damage caused by the healthcare sector has direct and deleterious consequences for public health. Climate change, driven by greenhouse gas emissions, has clear implications for human health, including the exacerbation of respiratory and cardiovascular diseases, heat-related illnesses, and the spread of infectious diseases. This creates a damaging feedback loop: the sector's operations contribute to the very environmental conditions that fuel public health crises, which in turn increases the demand for healthcare services and further intensifies the industry's environmental impact [6]. This systemic paradox underscores the urgent need to embed sustainability into every facet of healthcare delivery, beginning with the tools and technologies it employs.

Defining Sustainability in Medical Equipment: Beyond Environmentalism to the Triple Bottom Line

The concept of sustainability, as defined by the United Nations World Commission on Environment and Development, entails "development that meets the needs of the present without compromising the ability

of future generations to meet their own needs" [2]. Within the context of medical equipment, this principle extends beyond mere environmentalism to encompass a holistic framework that balances environmental impact with the core healthcare tenets of safety, efficacy, and efficiency [7]. This integrated approach is often conceptualized as the "triple bottom line," which evaluates performance and value against three interdependent dimensions: environmental, social, and economic costs and impacts [8].

This broader definition reframes sustainability not as a peripheral corporate social responsibility initiative, but as a core domain of healthcare quality itself. A sustainable health service is one that can deliver high-quality care over time, considering the needs of both current and future patient populations [8]. From this perspective, value is redefined as health outcomes achieved relative to the total lifecycle cost, which includes not only financial expenditure but also environmental externalities and social consequences. Adopting sustainable practices is therefore not only an ethical imperative but also a strategic one. It can lead to significant long-term cost reductions through decreased energy consumption and waste management expenses, enhance a company's reputation and brand image, attract investors and top talent, and provide a significant competitive advantage in an increasingly environmentally conscious market [9].

This evolution of thought signifies a crucial paradigm shift. Sustainability is moving from an external constraint to an internal measure of operational excellence and long-term viability. It necessitates a culture of resource stewardship, ensuring that the right care is delivered with minimal financial cost and harmful environmental impact, while adding social value at every opportunity [8].

The Lifecycle Perspective: A Framework for Holistic Analysis

To comprehensively address the challenge of sustainability in medical technology, a holistic, lifecycle-based perspective is essential. This approach involves evaluating and managing the environmental, economic, and social impacts of a medical device at every stage of its existence—from the initial extraction of raw materials through design, manufacturing, distribution, use, and maintenance, to its final end-of-life (EoL) management, including recycling and disposal. This "cradle-to-grave" or, ideally, "cradle-to-cradle" analysis is the foundation of methodologies like Life Cycle Assessment (LCA), which serves as the primary quantitative tool for calculating a product's true environmental impact [10].

This systemic viewpoint is gaining traction among regulatory bodies and management professionals. The U.S. Food and Drug Administration (FDA), for example, has reorganized to promote a "Total Product Life Cycle (TPLC)" approach, moving away from siloed oversight of premarket and postmarket activities to a more integrated model that considers all available information on a device's safety and effectiveness throughout its lifespan [11]. Similarly, the field of Healthcare Technology Management (HTM) utilizes lifecycle models to structure the practical management of equipment within clinical settings. These models typically delineate distinct phases, providing a clear framework for planning, procurement, operation, and disposal [2]. While the specific stages and terminology may vary across different models, they share a common recognition that decisions made at one stage have cascading consequences for all subsequent stages. The table below compares several prominent lifecycle models, illustrating the different lenses through which the lifespan of a medical device can be viewed.

Model Name	Key Stages	Primary Focus	Source(s)
Healthcare Technology Management (HTM) Model	Phase 1: Planning (Needs Assessment, Budgeting) Phase 2: Purchase (Selection, Procurement, Installation) Phase 3:	Operational and economic management within a healthcare facility.	[2]

	Lifetime (Training, Operation, Maintenance) Phase 4: End of Life (Decommissioning, Disposal)		
FDA Total Product Life Cycle (TPLC)	Device Design & Development -> Premarket Review -> Postmarket Surveillance & Compliance -> Real- World Use	Regulatory oversight, ensuring safety and effectiveness across the entire product lifespan from a holistic, integrated perspective.	[11]
Clinical Evidence Generation Model	i) Pre-clinical, pre- market ii) Clinical, pre- market iii) Diffusion, post-market iv) Obsolescence & replacement, post- market	Generation of clinical and economic evidence (HTA) to support regulatory approval, reimbursement, and adoption decisions.	[12]
Generic Product Development Model	Device Discovery & Concept -> Preclinical Research & Prototyping -> Pathway to Approval -> Market Release & Post-market Monitoring -> Obsolescence	The process of developing a new device from initial idea to market release and eventual decline, focusing on R&D and commercialization.	[12]

This systematic review adopts a synthesized lifecycle framework, integrating insights from these models to examine sustainability practices from initial design to final disposal. By analyzing each stage in detail, it is possible to identify key intervention points, understand the complex trade-offs involved, and formulate targeted strategies for creating a more sustainable and resilient medical technology ecosystem.

Foundational Concepts: Circular Economy and Life Cycle Assessment From Linear to Circular: Reimagining the Medical Device Economy

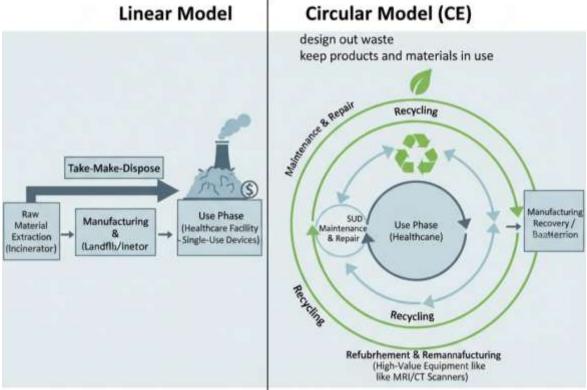
The prevailing economic model governing the medical device industry has been overwhelmingly linear, characterized by a "take-make-dispose" trajectory. In this system, raw materials are extracted, manufactured into products that are often designed for single use, and then discarded as waste. This linear approach is inherently unsustainable, leading not only to resource depletion and massive waste generation but also to significant economic inefficiencies and supply chain fragility. The heavy reliance on single-use disposables and "just-in-time" ordering systems creates a supply chain that is acutely vulnerable to disruptions, a weakness that was starkly exposed during the COVID-19 pandemic, which led to catastrophic failures in the provision of essential medical supplies [10].

In stark contrast, the Circular Economy (CE) offers a transformative alternative. The CE is a systemic framework that is "restorative or regenerative by design," with the overarching goal of maintaining

products, components, and materials at their highest utility and value at all times [10]. Its core principles are to design out waste and pollution, keep products and materials in use, and regenerate natural systems [13]. This is achieved by creating feedback loops that allow resources to be continuously circulated. These loops are often categorized as "slowing loops," which extend a product's longevity through strategies like designing for durability and reuse, and "closing loops," which create value from waste by finding new applications for used materials [10].

The transition to a circular model in healthcare is therefore not merely an environmental initiative; it is a critical strategy for building operational and economic resilience. By fostering local and regional loops of reuse, reprocessing, repair, and remanufacturing, a circular system inherently reduces dependence on long, complex, and often precarious global supply chains for new products [10]. This dual benefit—enhancing both environmental sustainability and supply chain security—forms a powerful business case for healthcare administrators and policymakers to champion the adoption of CE principles.

Figure 1. The Contrast Between Linear and Circular Economic Models in Medical Technology



The 'R' Strategies in a Healthcare Context: From Reduce and Reuse to Remanufacture and Recycle

The practical implementation of a circular economy is guided by a hierarchy of value-retention strategies, commonly known as the 'R' strategies. This framework prioritizes actions that keep products and materials in their most valuable state for as long as possible. The "inner loops" of the circular model, such as reducing consumption and reusing products, are considered the most effective and sustainable because they preserve the most embedded value (energy, labor, materials) within the product [14]. The "outer loops," such as recycling, are essential but less preferable, as they typically involve breaking a product down into its constituent materials, which requires significant energy and results in some value loss.

Table 1. Key strategies relevant to the medical equipment sector.

'R' Strategy	Definition in Healthcare Context	Specific Medical Device Examples	Source(s)
R0: Refuse	Making a product redundant by adopting an alternative, more sustainable approach.	Implementing telemedicine to reduce the need for in-person diagnostic equipment use; choosing non-invasive procedures over those requiring disposable surgical tools.	[14]
R1: Rethink	Making a product's use more intensive, for example, through sharing or multifunctionality.	Shared equipment pools between hospital departments; leasing models (Product-as-a- Service) for large imaging systems.	[14]
R2: Reduce	Increasing the efficiency of a product by using fewer resources and materials in its design and manufacturing.	Lightweighting devices; using additive manufacturing (3D printing) to minimize material waste; minimalist, recyclable packaging.	[15]
R3: Reuse	Using a product again for the same function after cleaning, disinfection, and/or sterilization.	Reusable surgical gowns and drapes; reprocessing of single- use devices (SUDs) like laparoscopic trocars and pulse oximeter sensors.	[16]
R4: Repair	Fixing a broken or malfunctioning product to restore its original function and extend its lifespan.	In-house or third-party repair of infusion pumps, monitors, and other electronic equipment.	[15]
R5: Refurbish	Restoring a used product to a "like-new" condition, potentially with minor upgrades, to extend its use.	Refurbishment of high- value imaging equipment such as MRI, CT, and X-ray systems for resale.	[16]

R6: Remanufacture	Rebuilding a product to "as-new" specifications, often involving complete disassembly and replacement of worn parts.	OEM-led remanufacturing programs for complex diagnostic and surgical systems.	[15]
R7: Repurpose	Reusing a product or its components for a different function.	Using decommissioned medical equipment in training labs or veterinary clinics; harvesting functional parts from broken machines for use in other repairs.	[16]
R8: Recycle	Processing waste materials to recover their base components for use in new products.	Extracting precious metals from electronic circuit boards (e-waste); recycling non-contaminated plastics from device casings.	[15]
R9: Recover	Incinerating non-recyclable waste to generate energy.	Waste-to-energy processes for certain types of contaminated or mixed-material medical waste.	[14]

Life Cycle Assessment (LCA) as a Quantitative Tool for Environmental Impact Evaluation

To make informed, evidence-based decisions about which sustainability strategies to pursue, stakeholders require a robust method for quantifying and comparing the environmental impacts of different products and processes. The primary tool for this purpose is the Life Cycle Assessment (LCA), a standardized methodology governed by the ISO 14040 and 14044 standards [15]. An LCA provides a comprehensive evaluation of a product's environmental footprint "from cradle to grave," accounting for all resource inputs (e.g., energy, water, raw materials) and outputs (e.g., greenhouse gas emissions, waste streams) at every stage of its life [10].

By systematically mapping these flows, an LCA can identify environmental "hotspots"—the specific stages or components that contribute most significantly to the overall impact [17]. This data is invaluable for guiding eco-design efforts, informing procurement decisions, and validating sustainability claims. For example, LCAs are crucial for conducting a fair comparison between single-use and reusable devices, as they can quantify the trade-off between the high manufacturing impact of a disposable item and the resource-intensive reprocessing (water, energy, chemicals) required for a reusable one [18].

Despite its status as the gold standard for environmental analysis, the practical application of LCA in the medical device industry is fraught with challenges. The methodology is highly data-intensive, requiring detailed information about materials, manufacturing processes, and supply chain logistics that can be difficult to obtain [19]. The risk-averse and highly regulated nature of the industry, combined with the

proprietary status of many product designs and manufacturing techniques, creates significant barriers to the transparency and data sharing necessary for a comprehensive LCA [7]. This creates a fundamental tension: while the industry acknowledges the need for data-driven sustainability, its inherent structure often makes acquiring that data prohibitively complex and expensive. This suggests a critical need for the development of simplified LCA tools tailored to the medical sector, industry-wide databases for common materials and processes, and policies that encourage greater supply chain transparency.

The Design Phase: Embedding Sustainability at the Source

The design and development phase represents the most critical leverage point in the entire medical equipment lifecycle. Decisions made at this initial stage—regarding materials, architecture, and intended use—have profound and often irreversible consequences for the sustainability of all subsequent phases. It is estimated that up to 80% of a product's total environmental impact is determined during its design [20]. Therefore, embedding sustainability principles at the source is not merely an optimization but a fundamental prerequisite for meaningful lifecycle improvement.

Eco-Design Principles for Medical Devices: Proactive Impact Mitigation

Eco-design, also known as Design for the Environment (DfE), is a proactive approach that integrates environmental considerations into the product development process from its inception [21]. Rather than treating sustainability as an afterthought, eco-design holistically considers all aspects of a device's lifecycle, aiming to minimize its negative impacts while maximizing its value. Key principles include designing for reduced material and energy consumption (e.g., lightweighting), incorporating recycled content, and explicitly planning for end-of-life pathways such as serviceability, upgradability, modularity, and recyclability [22].

Historically, the medical device industry has been slow to adopt DfE practices [21]. The sector's highly regulated and risk-averse culture has traditionally prioritized patient safety and clinical efficacy above all other concerns, often creating a perception that sustainability is inherently at odds with these primary objectives. [22] A significant barrier has been the lack of a strong regulatory push for environmentally conscious design, leaving manufacturers with little incentive to innovate beyond core safety and performance requirements [6].

However, a significant paradigm shift is underway, driven by the convergence of traditional Health Technology Assessment (HTA) with environmental metrics. HTA is the process by which new technologies are evaluated for their clinical and cost-effectiveness to inform reimbursement and adoption decisions. The emerging field of "early HTA," or Health Technology Sustainability Assessment (HTSA), integrates sustainability considerations into this evaluation at the earliest stages of development. This approach argues that designing for sustainability not only maximizes the potential for impact reduction but can also enhance a device's overall "value proposition" [12]. By demonstrating a lower environmental footprint and a reduced total cost of ownership, a sustainably designed device may have a greater likelihood of gaining regulatory approval and favorable reimbursement, transforming sustainability from an ethical consideration into a strategic business advantage [20].

Innovations in Sustainable Materials: Bioplastics, Biodegradable Polymers, and Natural Compounds

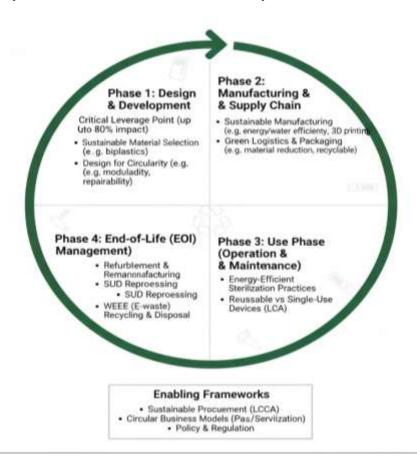
Material selection is one of the most impactful decisions made during the design phase [21]. The heavy reliance on petroleum-based, single-use plastics and energy-intensive metals is a primary driver of the healthcare sector's environmental footprint. Consequently, a major focus of sustainable innovation is the development and adoption of alternative materials with improved environmental profiles [9].

This trend involves a shift toward renewable and biodegradable resources. Natural organic materials (NM)—such as cellulose from plants, chitin from crustaceans, silk, and natural rubber latex—are gaining

significant attention. These materials often possess inherent biocompatibility and biodegradability, offering a sustainable alternative to conventional polymers [23]. Similarly, the field of bioplastics is rapidly advancing, with materials derived from renewable biomass like plant starch and cellulose, or from microorganisms that produce polymers like polyhydroxyalkanoate (PHA) [24]. These innovations are already being commercialized, as seen in examples like an FDA-approved biodegradable pregnancy test made from natural plant fibers that can be safely flushed [9]. Research is also exploring the use of biodegradable materials for transient electronics and sensors that naturally dissolve after their period of use, eliminating electronic waste [25].

However, the push for sustainable materials reveals a crucial and nuanced trade-off that designers must navigate. The ideal material characteristic is entirely dependent on the device's intended lifecycle pathway. For a single-use device designed for disposal, biodegradability is a highly desirable trait, as it minimizes landfill burden and pollution. In contrast, for a device intended for a circular pathway involving reuse, repair, or refurbishment, durability is paramount. Such a device must be made from high-quality, robust materials capable of withstanding repeated cycles of use, handling, and harsh sterilization processes [13]. A biodegradable material in a reusable surgical instrument would lead to catastrophic failure. Therefore, there is no single "best" sustainable material; the choice requires a strategic decision at the outset of the design process, aligning material properties with the intended end-of-life scenario. Further challenges remain in ensuring these novel materials can be produced at scale, meet stringent biocompatibility and safety standards, and maintain their integrity throughout required sterilization procedures [23].

Figure 2. A Synthesized Framework for Sustainability Across the Medical Device Lifecycle



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Designing for Circularity: Modularity, Repairability, and Ease of Disassembly

Beyond material choice, the architectural design of a device is fundamental to enabling a circular economy. Designing for circularity involves creating products in a way that facilitates their maintenance, reuse, and eventual recovery of components and materials [9]. This stands in direct contrast to traditional design, which often results in integrated, difficult-to-service products that are cheaper to replace than to repair.

Key strategies for circular design include:

- Modularity: Designing a device with interchangeable, independently functioning modules allows for easier and more cost-effective repairs and upgrades. Instead of replacing an entire system when one component fails or becomes obsolete, only the specific module needs to be swapped out [26]. This extends the overall lifespan of the core equipment and reduces waste. An exemplary case is Koninklijke Philips' Diamond Select line of high-value imaging equipment, such as X-ray machines. These systems are explicitly designed with a modular architecture to facilitate future upgrades, component refurbishment, and remanufacturing, allowing them to remain in service for extended periods [27].
- **Repairability:** This involves designing devices that can be easily diagnosed and repaired, both by official technicians and potentially by in-house biomedical engineering staff. This requires providing access to spare parts, service manuals, and diagnostic tools—a principle central to the "right-to-repair" movement [10].
- Ease of Disassembly: At the end of a product's life, its value can only be recovered if it can be taken apart efficiently. Designing for disassembly involves using screws instead of glue, avoiding complex composite materials, and clearly labeling components for easy identification [28]. This facilitates the harvesting of valuable functional components for reuse or refurbishment, as well as the separation of different material streams for high-quality recycling.

By integrating these principles from the very beginning, manufacturers can ensure that their products are not destined for the landfill but are instead designed to be valuable assets within a circular system.

Manufacturing and Supply Chain: Greening the Production Pathway

The transition from a sustainable design concept to a physical medical device involves the manufacturing and supply chain stages, both of which present significant opportunities for reducing environmental impact. While design sets the blueprint for a product's potential sustainability, manufacturing and distribution practices determine the actual footprint of its production and delivery.

Sustainable Manufacturing Processes: Energy Efficiency, Water Conservation, and Additive Manufacturing

Sustainable manufacturing aims to minimize negative environmental impacts while conserving energy and natural resources. Key practices in the medical device sector include reducing waste, improving energy and water efficiency, and adopting innovative production technologies [28]. Given that medical device production can be highly resource-intensive, requiring large amounts of energy for fabrication, cleanroom operations, and sterilization, implementing energy-efficient technologies and processes is a primary strategy for reducing a facility's carbon footprint [7].

One of the most promising technological shifts is the adoption of additive manufacturing, or 3D printing. Unlike traditional subtractive manufacturing methods, which start with a block of material and cut away the excess to create a part, 3D printing builds a product layer by layer from a digital file. This process can dramatically reduce material waste, particularly during the research and development and prototyping phases. The ultimate goal is to move towards "zero defect, waste-free manufacturing," where resources are used with maximum efficiency [9].

It is crucial to recognize that manufacturing sustainability is not an isolated activity but is systemically interdependent with choices made during the design phase. The selection of materials, the complexity of the device's architecture, and the specification of tolerances all have direct, cascading effects on the manufacturing process and its associated environmental burden. For instance, a designer who specifies a complex, multi-material composite may inadvertently preclude the use of energy-efficient manufacturing techniques and render end-of-life recycling impossible. Conversely, a product designed from the outset for 3D printing enables a fundamentally less wasteful production process. This deep interconnection highlights the necessity for robust, cross-functional collaboration between design engineers, manufacturing specialists, and sustainability experts from the earliest stages of product development to ensure that design intent can be translated into a sustainable production reality.

Reducing the Impact of Packaging and Distribution Logistics

The environmental impact of a medical device does not end at the factory gate. The packaging required to protect the device and maintain its sterility, as well as the logistics of transporting it to healthcare facilities, contribute significantly to its overall lifecycle footprint. Medical packaging is a major source of waste, particularly single-use plastics and sterilization wraps that are discarded in operating rooms and clinics [29].

Sustainable practices in this area focus on the principle of "Reduce, Reuse, Recycle" [29]. Strategies include:

- **Reducing:** Minimizing the amount of packaging material used to what is strictly necessary for safety and sterility. This is often seen as a more accessible opportunity for impact reduction than altering the materials of the device itself [30].
- **Switching Materials:** Replacing multi-material or non-recyclable plastics with more sustainable alternatives. This can include using single-material packaging that is easily recyclable, such as DuPont's Tyvek (made from high-density polyethylene), or exploring the use of bio-based or biodegradable materials for certain applications [9].
- **Reusing:** Implementing systems for reusable transport packaging or containers for bulk shipments between manufacturers and distributors or large healthcare systems.

In addition to packaging, the carbon footprint of distribution can be mitigated by optimizing supply chain logistics. This involves choosing more efficient modes of transportation (e.g., sea over air freight where feasible), consolidating shipments, and optimizing routes to reduce fuel consumption and associated emissions [28].

The Use Phase: Optimizing Operational Sustainability

Once a medical device is delivered to a healthcare facility, its operational life begins. This "use phase" is often the longest part of the equipment's lifecycle and can be a major contributor to its overall environmental impact, primarily through energy consumption and the resources required for maintenance and sterilization. Optimizing sustainability during this phase is critical and involves a combination of technological efficiency, procedural best practices, and behavioral change among clinical staff.

Energy-Efficient Operation of Medical Devices

Hospitals are exceptionally energy-intensive environments, ranking as the second most energy-intensive commercial building type in the United States, with HVAC systems alone accounting for over half of their energy use [31]. Medical equipment represents a substantial and rapidly growing portion of this consumption [32]. Even seemingly small and ubiquitous devices, such as infusion pumps and monitoring systems, can have a large aggregate energy footprint due to their sheer numbers and continuous operation.⁴⁹

A critical finding from recent studies is that many devices consume a significant amount of "vampire" or

"phantom" power even when not in active use. Research on anesthesia machines, for example, revealed that a device in standby mode consumed an average of 56.7 W, while a device that was fully switched off but still plugged in consumed 10.6 W. This analysis demonstrates that the most immediate and substantial energy savings may not come from costly technological upgrades but from simple, low-cost behavioral interventions. By implementing a policy to switch off 90% of its anesthesia machines after regular working hours, a single university medical center could save an estimated 24,687 kWh of electricity and 10.15 metric tons of CO₂ equivalent annually. The primary argument against this practice—that it would cause delays in emergency situations—is largely unfounded, as the study found the average time for a machine to become fully operational from a switched-off state was only 35.5 seconds [3].

This highlights a crucial point: a major barrier to operational sustainability is often not a lack of technology but a lack of awareness, training, and appropriate protocols for clinical staff. The "user factor" is a decisive element in any successful ecological transformation within a hospital [3]. Therefore, developing clear guidelines and educating staff on energy-saving practices, such as powering down equipment when not in use, represents a high-impact, low-cost strategy for reducing the operational footprint of medical devices.

Sustainable Maintenance, Calibration, and Sterilization Practices

Maintaining the functionality, safety, and sterility of medical equipment is a resource-intensive but essential aspect of healthcare operations. Sustainable practices in this domain focus on extending the useful life of equipment and choosing the least environmentally harmful methods for cleaning and sterilization.

Regular and proper maintenance, including visual inspections, cleaning, and performance calibration according to manufacturer specifications, is fundamental to preventing premature equipment failure and extending its operational lifespan [33]. This not only reduces the waste associated with early replacement but also ensures the device performs optimally, contributing to both patient safety and resource efficiency.

Sterilization is a particularly critical process with significant environmental implications. The choice of sterilization method involves a complex trade-off between microbial efficacy, material compatibility, cost, and environmental impact.

Table 2. A comparative analysis of common sterilization methods.

Sterilization Method	Mechanism	Environment al Impact	Cost- Effectiveness	Key Limitations	Source(s)
Steam Sterilization (Autoclave)	High-pressure saturated steam denatures proteins.	Low chemical toxicity; no harmful residues. High energy and water consumption.	Generally the most cost-effective method per cycle.	Not suitable for heat- or moisture- sensitive materials (e.g., many plastics, electronics).	[34]
Ethylene Oxide (EtO) Gas	Alkylation disrupts microbial DNA and proteins.	EtO is a toxic, carcinogenic, and flammable gas with significant air pollution concerns.	Higher operational costs due to gas, safety measures, and long cycle times.	Long cycle/aeration times (can be >15 hours). Health risks to staff. Environmental	[34]

		Requires long aeration times to remove residues.		hazards.	
Hydrogen Peroxide (\$H_2O_2\$) Gas Plasma	Creates a plasma state that generates free radicals to kill microbes.	Breaks down into non-toxic water and oxygen. Lower energy use than autoclaves.	Higher initial equipment cost and cycle cost than autoclaving.	Not suitable for cellulose-based materials (paper, linen), liquids, or powders. Can have limitations with long, narrow lumens.	[34]
Peracetic Acid (PA) Sterilization	Oxidation of microbial cell components.	Decomposes into acetic acid, oxygen, and water. Less toxic than EtO.	Can be cost- effective, especially in automated systems.	Corrosive to some metals. Suitable only for immersible items.	[34]

As the analysis shows, methods like steam autoclaving, where applicable, are often preferred from an environmental and cost perspective due to their lack of toxic chemical residues.⁵² For heat-sensitive devices, hydrogen peroxide gas plasma offers a safer alternative to ethylene oxide, which poses significant environmental and occupational health risks [35].

A Comparative Analysis of Single-Use vs. Reusable Devices

The proliferation of single-use devices (SUDs) has been a defining trend in modern healthcare, driven by convenience and concerns about cross-contamination [10]. However, this reliance on disposables is a primary contributor to the sector's massive waste stream and carbon footprint [4]. Consequently, there is a growing movement to reconsider and expand the use of reusable alternatives.

The debate between single-use and reusable options is complex, requiring a full lifecycle perspective to make a fair comparison. While reusable products require less material and energy in their production on a per-use basis, they necessitate resource-intensive reprocessing—including cleaning, disinfection, and sterilization—after each use, which consumes water, energy, and chemicals [18]. The perception among some clinicians that disposables are inherently cleaner or safer also presents a cultural barrier to the adoption of reusables [13].

Life Cycle Assessments (LCAs) are essential for quantifying these trade-offs. A systematic review of 27 comparative LCAs concluded that, on average, switching from single-use to reusable healthcare products is likely to reduce most environmental impacts, with the notable exception of water consumption, which often increases due to cleaning requirements [13]. Case studies provide more specific insights. An LCA of electrosurgical scalpels found that the reusable version had an 8.6-fold lower carbon footprint over one year of typical use compared to its single-use counterpart. The analysis revealed that 94% of the SUD's total carbon footprint was attributed to its raw material extraction and manufacturing, whereas 86% of the reusable device's footprint stemmed from the energy and resources used for its repeated sterilization. This

underscores that the primary environmental burden of disposables is front-loaded in production, while the burden of reusables is distributed across the use phase. The number of reuses is a critical factor; the more a reusable device is used, the lower its environmental impact per use becomes [36].

End-of-Life Pathways: Closing the Loop

The end-of-life (EoL) stage of a medical device's lifecycle is a critical juncture that determines whether its embedded value is lost to a landfill or preserved within a circular economy. Effective EoL management moves beyond simple disposal to prioritize pathways that close material and product loops, turning potential waste into valuable resources. These strategies range from high-value activities like refurbishment and remanufacturing to material-level recovery through recycling.

Circular EoL Strategies: The Value Proposition of Refurbishment and Remanufacturing

For complex and high-value medical equipment, refurbishment and remanufacturing are premier circular strategies that extend product life and maximize resource productivity. Though often used interchangeably, they represent distinct levels of restoration:

- **Refurbishment** is the process of restoring a used device to a "like-new" quality, ensuring it meets original safety and performance specifications without significantly changing its intended use [37]. This typically involves inspection, cleaning, repair of any broken parts, and cosmetic restoration. It is a common practice for capital-intensive equipment like MRI machines, CT scanners, and ultrasound systems [16].
- Remanufacturing is a more comprehensive industrial process that restores a used device to a condition of "as-new" or even better quality and performance [37]. It may involve complete disassembly, replacement of all worn components (regardless of whether they have failed), and technology upgrades.

The primary barrier to the widespread adoption of these circular strategies lies in the complex and often ambiguous regulatory landscape. The U.S. FDA, for example, draws a critical line between "servicing" (which returns a device to its original OEM specifications) and "remanufacturing." An entity is considered a remanufacturer if its actions "significantly change the finished device's performance or safety specifications or intended use". This distinction is crucial because a remanufacturer is subject to the full suite of regulatory requirements applicable to an original equipment manufacturer (OEM), including registration, listing, adverse event reporting, and quality system regulations [38]. This regulatory ambiguity creates considerable uncertainty and risk for third-party entities, who may inadvertently cross the line from servicing to remanufacturing. This lack of clarity can stifle innovation and investment in the circular EoL market, as organizations are hesitant to engage in activities that could subject them to unforeseen and burdensome regulatory obligations [39].

Despite these challenges, the benefits are substantial. Both refurbishment and remanufacturing offer significant cost savings for healthcare providers, with restored devices often costing 25-40% less than new ones, without compromising quality or safety [40]. Environmentally, they are vastly superior to manufacturing a new device, as they preserve the immense amount of energy, materials, and labor embedded in the original product.

The Single-Use Device Challenge: The Role and Regulation of Reprocessing

While refurbishment and remanufacturing apply to durable equipment, a different circular strategy addresses the immense waste stream from single-use devices (SUDs): reprocessing. Reprocessing is a regulated and validated process whereby certain devices labeled for single use are collected from healthcare facilities, rigorously cleaned, decontaminated, inspected, function-tested, sterilized, and repackaged for another safe use [41].

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In jurisdictions like the United States and the European Union, commercial reprocessing is a highly regulated industry. The FDA requires third-party reprocessors to meet the same stringent regulatory requirements as the OEMs of new devices, ensuring that a reprocessed device is as safe and effective as the original [10]. This includes submitting extensive data to prove that the cleaning and sterilization processes are effective and that the device's material integrity and functionality are not compromised. The practice is governed by standards such as FDA 21 CFR Part 820 (Quality System Regulation), ISO 13485 (Quality Management for Medical Devices), and AAMI ST98 (Standards for Reprocessing of SUDs) [42].

The impact of SUD reprocessing is significant. Environmentally, it diverts tons of waste from landfills and incinerators and dramatically reduces the carbon footprint associated with manufacturing new devices; one study found that using reprocessed devices can cut climate-changing emissions by half or more. Economically, it provides substantial cost savings to hospitals, which can purchase reprocessed devices for a fraction of the cost of new ones. This practice is increasingly recognized as a key strategy for achieving healthcare sustainability goals, with organizations like the UK's National Health Service (NHS) identifying SUD remanufacturing as critical to its net-zero ambitions [43].

Recycling and Disposal: Managing Medical E-Waste (WEEE) and Hazardous Components

For devices and components that cannot be kept in higher-value circular loops, recycling and safe disposal represent the final EoL pathways. Medical equipment, particularly electronic devices, is a significant and growing contributor to the global stream of Waste Electrical and Electronic Equipment (WEEE), or e-waste [44]. This waste stream is uniquely complex, containing a mixture of valuable materials (e.g., gold, copper, palladium) and hazardous substances (e.g., lead, mercury, brominated flame retardants) [45].

Proper management of medical WEEE is therefore critical for both resource conservation and environmental protection. Regulatory frameworks like the European Union's WEEE Directive mandate the separate collection of e-waste and establish targets for collection, recovery, and recycling [44]. These policies aim to promote a circular economy for electronics by recovering valuable secondary raw materials and to prevent environmental contamination by ensuring hazardous components are treated properly. However, significant challenges remain. The heterogeneous nature of WEEE makes it difficult to automate disassembly and material separation. Furthermore, there are vast global disparities in waste management infrastructure. A large portion of e-waste from developed nations is illegally exported to low- and middle-income countries, where it is often processed in informal sectors using unsafe methods that expose workers and communities to toxic substances [46].

For components that are non-recyclable or contaminated with biohazardous materials, safe disposal is paramount. This requires strict adherence to regulated medical waste management protocols. Practices include the use of designated, clearly labeled, leak-proof, and puncture-resistant containers for sharps and other hazardous items. Treatment methods are employed to decontaminate the waste and render it safe for final disposal. These methods include steam sterilization (autoclaving), incineration, or chemical disinfection, each with its own environmental profile and suitability for different waste types [47].

Enabling Frameworks: Procurement, Business Models, and Policy

The transition to a sustainable medical equipment lifecycle cannot be achieved solely through technological innovation or improved EoL management. It requires a systemic shift supported by enabling frameworks that align economic incentives, corporate strategies, and public policy with sustainability goals. Three of the most powerful levers for change are sustainable procurement, innovative business models like servitization, and a coherent global regulatory landscape.

The Power of the Purchaser: Sustainable Procurement Frameworks (ISO 20400) and Life Cycle Cost Analysis (LCCA)

Healthcare organizations wield immense purchasing power, and their procurement decisions can significantly influence the market, creating demand for sustainable products and pressuring suppliers to improve their environmental and social performance [48]. Sustainable procurement, or Green Public Procurement (GPP), is a process whereby organizations seek to procure goods and services with a reduced impact throughout their lifecycle [49]. This represents a shift in focus from a narrow consideration of upfront purchase price to a holistic evaluation of a product's long-term value and impact.

Frameworks such as the ISO 20400 standard provide guidance for organizations to integrate sustainability into their procurement processes, covering aspects from policy and strategy to supplier selection and contract management [50]. A critical tool for implementing sustainable procurement is Life Cycle Cost Analysis (LCCA). LCCA is an economic method that assesses the total cost of ownership of an asset over its entire lifespan, including not only the initial acquisition cost but also all subsequent costs related to operation (e.g., energy and water consumption), maintenance, and end-of-life disposal [49].

By employing LCCA, a procurement department can transform its role from a tactical cost center focused on minimizing initial expenditure to a strategic driver of both organizational sustainability and long-term financial health. For example, an LCCA might demonstrate that a more expensive, energy-efficient MRI machine will have a lower total cost of ownership over its 10-year life due to significantly reduced electricity costs, making it the more financially prudent choice despite its higher purchase price [51]. Given that over 70% of a health system's greenhouse gas emissions are embedded in the products and services it buys, procurement is the single most impactful lever for reducing an organization's environmental footprint [52]. By making purchasing decisions based on comprehensive sustainability criteria and total lifecycle cost, procurement becomes a strategic function that creates long-term value for the organization and the community it serves.

The Shift to Servitization: Product-as-a-Service (PaaS) and Leasing Models

Perhaps the most transformative enabler of a circular economy for medical equipment is the shift in business models away from transactional product sales toward "servitization." Servitization involves companies providing integrated, outcome-based solutions rather than just physical products. A key manifestation of this is the Product-as-a-Service (PaaS) model, where a customer pays for the use or outcome of a device—such as a "per-scan" fee for an MRI machine—while the manufacturer retains ownership of the physical asset [53].

This change in ownership fundamentally realigns economic incentives with the principles of sustainability and circularity. In a traditional sales model, a manufacturer's profit is maximized by selling more new units, creating a perverse incentive for planned obsolescence and discouraging durability [10]. In a PaaS model, the manufacturer's revenue is tied to the continued, reliable, and efficient performance of their asset over an extended period. This reversal of incentives makes a circular economy economically viable for the manufacturer. It is now in their direct financial interest to:

- **Design for Durability and Reliability:** To minimize service calls and downtime.
- Design for Modularity and Upgradability: To extend the asset's useful life and keep it technologically current.
- Invest in Predictive Maintenance: To prevent failures before they occur.
- Establish Robust Refurbishment and Remanufacturing Programs: To efficiently redeploy their own assets and continue generating revenue from them.

Companies like Philips Healthcare are already pioneering this shift, moving from simply selling imaging equipment to providing comprehensive imaging and data management solutions [10]. Leasing and other financing mechanisms are crucial components of this model, as they facilitate the separation of use from ownership [54]. Ultimately, servitization provides the missing economic engine that makes the engineering

principles of circular design—durability, repairability, and modularity—not just an environmental goal but a profitable business strategy.

The Global Regulatory Landscape: Navigating FDA, EU MDR, and WEEE Directives

The regulatory landscape for medical devices plays a dual and often conflicting role in the transition to sustainability. On one hand, environmental regulations act as powerful drivers for change. Directives such as the European Union's Waste Electrical and Electronic Equipment (WEEE) Directive and the Restriction of Hazardous Substances (RoHS) Directive compel manufacturers to take responsibility for their products at end-of-life and to phase out the use of certain toxic materials [44]. These policies have been instrumental in promoting e-waste recycling and designing for material recovery.

On the other hand, the stringent safety and quality regulations that govern the medical device industry can act as significant barriers to sustainable innovation. Regulations like the EU's Medical Device Regulation (MDR) and the FDA's quality system requirements are designed to be risk-averse to protect patient safety [2]. While essential, this rigorous approach can make it incredibly slow, complex, and expensive to gain approval for new, sustainable materials or to validate the safety and efficacy of reusable or reprocessed devices [6]. This creates a fundamental tension: the need to ensure absolute patient safety can inadvertently stifle the adoption of more environmentally friendly technologies. Navigating this complex interplay between environmental and medical safety regulations is one of the central challenges for manufacturers, healthcare providers, and policymakers alike.

Overcoming Barriers and Charting the Future

The path toward a fully sustainable and circular medical equipment lifecycle is impeded by a complex web of interconnected barriers. However, a confluence of powerful drivers is accelerating the pace of change, while emerging innovations offer a glimpse into a more sustainable future for healthcare technology. Acknowledging these challenges, harnessing the drivers, and investing in innovation will be key to navigating this transition.

Analysis of Key Challenges: A Synthesis

Across the entire lifecycle, stakeholders face significant hurdles that slow the adoption of sustainable practices. These can be categorized as regulatory, economic, cultural, and technical. A particularly acute set of challenges exists in low- and middle-income countries (LMICs), where systemic issues often compound the problem.

Table 3. Primary barriers and corresponding drivers at each stage of the medical device lifecycle.

Lifecycle Stage	Key Barriers	Key Drivers
Design & Development	- High cost and regulatory hurdles for novel biomaterials [7] Risk-averse culture prioritizing safety over sustainability [21] Lack of regulatory push for eco-design [6].	- Integration of sustainability into Health Technology Assessment (HTSA) [20] Market demand for "green" products and corporate brand image [55] Potential for long-term cost savings and competitive advantage [9].
Manufacturing & Supply Chain	- High energy and resource intensity of production processes [55].	Rising energy costs create incentive for efficiency [3].Regulations on emissions and

	- Complex, global supply chains with limited transparency [56] Cost of investing in energy-efficient technologies [56].	industrial waste (e.g., RoHS) [57] Operational efficiency and cost savings from waste reduction [55].
Use Phase (Operation & Maintenance)	 User perception that disposables are safer or cleaner [30]. Lack of staff awareness, training, and protocols for sustainable use [1]. High water and energy use for sterilization of reusables [18]. 	- Significant potential for cost savings from energy efficiency [3] Institutional net-zero and sustainability goals (e.g., NHS) [40] Growing evidence (LCAs) showing environmental benefits of reusables [18].
End-of-Life Management	 - Ambiguous regulations for refurbishment vs. remanufacturing [58]. - Technical difficulty of recycling complex, composite materials [55]. - Global disparities in waste management infrastructure and illegal e-waste trade [46]. 	- WEEE Directive and similar e-waste regulations [44] Economic value of recovered materials and components [45] Growth of regulated SUD reprocessing industry [40].
Systemic/Overarching	- Procurement models focused on low initial purchase price [7] - Business models incentivizing product sales over longevity (planned obsolescence) [10] LMIC-Specific: Lack of maintenance infrastructure, trained personnel, and spare parts; prevalence of inappropriate donated equipment [56].	- Shift to sustainable procurement frameworks (ISO 20400) and LCCA [49] Emergence of circular business models (PaaS, servitization) [59] Increased global awareness and international development aid focused on sustainable infrastructure [60].

In LMICs, these challenges are magnified. A staggering 40% to 70% of medical equipment in these regions is estimated to be out of service, often due to a lack of trained biomedical engineers, unavailable spare parts, or because donated equipment was incompatible with the local infrastructure (e.g., power supply) in the first place [61]. This represents a massive waste of resources and a critical failure to provide sustainable healthcare solutions where they are needed most.

Identifying Key Drivers for Change

Despite the formidable barriers, a powerful confluence of drivers is pushing the medical technology industry toward greater sustainability. Evolving environmental regulations, such as net-zero mandates and extended producer responsibility laws, are creating a compliance imperative [7]. Simultaneously, there is a growing recognition of the strong economic case for sustainability. Practices like energy efficiency, waste reduction, and product life extension can lead to significant long-term cost savings, providing a clear financial incentive [3]. Furthermore, in an increasingly conscious market, a strong commitment to environmental and social responsibility can enhance corporate brand image, attract and retain talent, and

serve as a key competitive differentiator [7]. Perhaps most importantly, large healthcare providers, such as the NHS, are beginning to leverage their immense procurement power by setting ambitious sustainability targets for themselves and their suppliers, effectively creating market-based demand for greener products and services [40].

Future Outlook and Emerging Innovations

The future of sustainable medical technology will likely be shaped by the integration of digital technologies and continued advancements in material science. Key emerging trends include:

- **Digital Health and Telemedicine:** Technologies like remote monitoring and virtual consultations can significantly reduce the environmental impact of healthcare delivery by minimizing patient and provider travel, optimizing resource allocation in hospitals, and in some cases, reducing the need for certain types of diagnostic equipment [7].
- AI and the Internet of Things (IoT): The integration of smart sensors (IoT) and artificial intelligence (AI) into medical equipment can enable predictive maintenance, alerting technicians to a potential failure before it occurs. This maximizes uptime, extends equipment life, and reduces waste from premature replacement. AI can also be used to optimize energy consumption and manage resources more efficiently within a hospital setting [7].
- Advanced Materials and Manufacturing: Ongoing research into smart biomaterials, which can respond to biological cues, and advancements in 3D bioprinting, which could one day create custom tissues and organs on demand, hold the potential to revolutionize medical treatment while minimizing environmental impact [62].

Conclusion and Strategic Recommendations

This systematic review has demonstrated that integrating sustainability into the lifecycle management of medical equipment is a complex but imperative endeavor. The healthcare sector's significant environmental footprint creates a paradoxical cycle wherein the act of healing contributes to the very public health crises it seeks to solve. A transition from a linear "take-make-dispose" model to a circular, regenerative one is essential not only for environmental stewardship but also for building economic and supply chain resilience. This transition requires a holistic, systems-thinking approach that addresses every stage of the product lifecycle, from initial design to final disposal. While significant barriers—regulatory, economic, and cultural—remain, a powerful combination of policy drivers, economic incentives, and technological innovation is accelerating the shift toward a more sustainable future for medical technology.

Based on the synthesis of the evidence, the following strategic recommendations are proposed for key stakeholder groups.

Recommendations for Medical Device Manufacturers

- 1. Adopt a "Sustainability-by-Design" Mandate: Integrate sustainability as a core requirement, alongside safety and efficacy, from the earliest stages of product development. Mandate the use of Life Cycle Assessment (LCA) and eco-design principles to proactively mitigate environmental impact. Prioritize designing for circularity through modularity, repairability, and ease of disassembly.
- 2. **Invest in Sustainable Material Innovation:** Accelerate research and development into viable, scalable, and safe alternative materials, including biodegradable polymers for single-use applications and highly durable, recyclable composites for reusable devices. Collaborate with regulatory bodies to establish streamlined pathways for the validation and approval of these new materials.
- 3. **Transition to Circular Business Models:** Strategically pivot from transactional product sales to servitization and Product-as-a-Service (PaaS) models. This shift aligns corporate profitability with product longevity, creating a powerful internal incentive to design durable, maintainable, and upgradable equipment and to invest in robust refurbishment and remanufacturing programs.

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Recommendations for Healthcare Providers and Procurement Bodies

- 1. **Institutionalize Sustainable Procurement:** Formally adopt sustainable procurement policies based on internationally recognized frameworks such as ISO 20400. Establish multidisciplinary procurement committees that include clinical, financial, and sustainability experts to ensure holistic decision-making.
- 2. **Prioritize Total Cost of Ownership over Purchase Price:** Mandate the use of Life Cycle Cost Analysis (LCCA) for all significant capital equipment acquisitions. This will provide a more accurate financial picture and justify investment in products that may have a higher upfront cost but offer long-term savings through greater energy efficiency, lower maintenance needs, and higher residual value.
- 3. Invest in Staff Education and Circular Infrastructure: Develop and implement comprehensive training programs for clinical staff on energy-efficient equipment operation, proper waste segregation, and the safe handling of reusable devices. Invest in the necessary infrastructure to support circularity, such as expanding Central Sterile Services Department (CSSD) capacity and establishing dedicated collection systems for devices intended for reprocessing or remanufacturing.
- 4. **Expand Regulated Reprocessing Programs:** Partner with reputable, regulated third-party reprocessors to identify and expand the range of single-use devices that can be safely reprocessed. This is a proven, high-impact strategy for immediately reducing waste, carbon emissions, and supply chain costs.

Recommendations for Policymakers and Regulatory Agencies

- 1. Harmonize and Clarify Regulations for Circular Pathways: Develop clear, internationally harmonized definitions and regulatory pathways for servicing, refurbishment, and remanufacturing. Reducing ambiguity and legal risk will encourage investment and growth in the third-party market for circular EoL services.
- 2. **Incentivize Sustainable Innovation:** Create policy and fiscal incentives to encourage sustainability in the medical device sector. This could include tax credits for manufacturers investing in circular design or PaaS models, streamlined regulatory "sandboxes" for testing novel sustainable materials, and public funding for research in green medical technology.
- 3. **Strengthen Global E-Waste Management:** Enhance and enforce regulations, such as the WEEE Directive, to ensure the responsible management of medical e-waste. This must include robust measures to combat the illegal export of hazardous e-waste to developing countries and to support the development of safe, formal recycling infrastructure globally.
- 4. **Promote Sustainable Healthcare in LMICs:** Shift the focus of international aid and donation programs from simply providing equipment to building sustainable healthcare technology ecosystems. This includes funding for training biomedical engineers, establishing maintenance infrastructure, ensuring the availability of spare parts, and adhering to WHO guidelines for appropriate and context-specific equipment donation.

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