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Knowledge brief

From Data to Green: The Path Towards Environmentally Conscious Medical Devices

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1 Project Overview and Objectives

The Dutch healthcare sector has a substantial environmental footprint[1], with medical devices playing a notable role. Transitioning to sustainable medical devices is therefore an essential measure in efforts to lower the sector's overall impact. To effectively address this challenge, it is important to systematically measure and assess the environmental impacts of medical devices throughout their life cycle.

Currently, efforts to assess and improve the sustainability of medical devices are often fragmented and hampered by a lack of standardized methods and practical guidance. Life Cycle Assessment (LCA) is a standardized method for quantifying the effects of products or processes across all stages of their life cycle on the environment.

The aim of this knowledge brief is to provide a clear introduction to LCA and how LCA can be applied in the context of medical devices, intended for standards developers, policy makers, or other stakeholders interested in applying or interpreting LCA studies. We therefore compare commonly applied LCA methodologies, address key challenges in applying LCA to medical devices, and present an illustrative categorization of medical devices to highlight how life cycle considerations can differ across device types. Furthermore, we summarize principal environmental indicators beyond carbon dioxide-based ones and provide practical considerations for improvement of data inventory and impact assessment methodologies.

To support a more harmonized approach in the sector, this knowledge brief offers practical guidance for both the assessment and the reporting of sustainability of medical devices. To this end, we address the following three principal questions: (i) what indicators exist and are widely used to determine the environmental sustainability of medical devices throughout their entire life cycle, (ii) which types of data are needed for each indicator and (iii) what are the most commonly used impact assessment methods to jointly map these indicators.

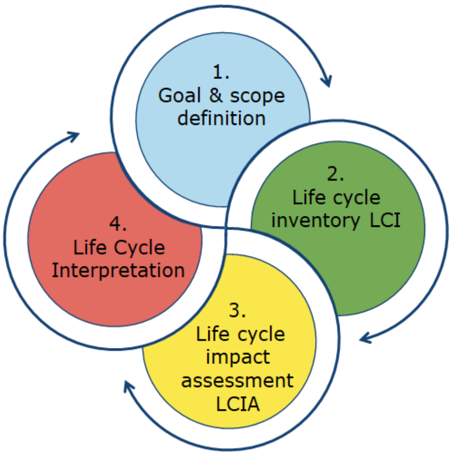
The scope of this knowledge brief is defined by the following key considerations. Throughout this document, "sustainability" refers exclusively to environmental sustainability; social and economic aspects are not considered, and the focus lies on the life cycle of medical devices as a product group, rather than individual products or specific treatments. This brief describes LCA for medical devices in general terms with generic examples, rather than detailing product- or treatment-specific cases. Therefore, topics such as the efficiency of particular treatments involving medical devices, or considerations of appropriate care[2] fall outside of the scope.

2 LCA of Medical Devices: Concepts and implementation

LCA is a scientifically established method for quantifying and evaluating inputs (e.g., raw materials, electricity), outputs (e.g., emissions, wastes), and potential environmental impacts (e.g., impact on climate change, water use) of a product or process throughout its entire life cycle[3,4]. By considering all stages—from raw material extraction, manufacturing, use, and distribution, to end-of-life disposal—LCA provides an overview of the environmental consequences, addressing multiple impact categories, such as climate change (CO_2), resource depletion, toxicity, and other relevant indicators (see chapter 2.3). This broader perspective is essential, as environmental sustainability is not fully captured by one indicator alone. Focusing on a single indicator (e.g., CO_2 emission) can overlook other important environmental effects and may even result into greenwashing or trade-offs[5].

Current LCA methodology is commonly defined by a set of International Organization for Standardization (ISO) standards, namely the ISO 14040 series[3,4]. These standards structure the LCA into four distinct phases:

1. **Goal and Scope Definition**: Establishes the purpose of the LCA study, the system boundaries, and the level of detail required.
2. **Inventory Analysis**: Involves collecting and quantifying data on material and energy flows into and out of the system.
3. **Life Cycle Impact Assessment**: Evaluates the potential environmental impacts based on the inventory data, using multiple impact categories (e.g., climate change, resource depletion, toxicity) to enable a thorough assessment.
4. **Life Cycle Interpretation**: Interprets the results, draws conclusions, and makes recommendations for decision-makers.



2.1 Goal & scope definition for medical devices:

The first phase, also known as the planning stage, of an LCA is the goal and scope definition. This is crucial to ensure that the assessment will be useful and relevant. This phase focusses on formulating the main research question(s), selecting the appropriate functional unit, and setting the context[6]. For a transparent, consistent, and comparable assessment, it is important to explicitly distinguish between the scope—which life cycle stages are included in the assessment—and the system boundaries, which determine how thoroughly each of these stages are analyzed. The environmental relevance of each life cycle stage can vary widely across medical device types; for example, the environmental impact of single-use gloves is concentrated in raw material extraction and production[7], while for a complex device such as an MRI, impacts could be more distributed across production, use, maintenance and end-of-life phases[8]. We next introduce a categorization of medical devices based on shared life cycle characteristics. This enables identification of typical sustainability challenges and opportunities for different device groups and can be used as initial guidance on topics (such as general hotspots) that should be considered. However, these topics are not always applicable or exhaustive. In some cases, additional topics may be relevant, or certain hotspots may not apply. Therefore, it is recommended to assess each device on a case-by-case basis. In the final part of this section, we discuss how system boundaries influence the depth of analysis for each life cycle stage.

2.1.1 Goal

Defining the goal is an essential starting point in an LCA. It should specify the intended application of the LCA study, the reasons for conducting the analysis, the target audience, and whether the results will be used for public comparisons[9]. Common LCA goals include **product improvement**, where LCA helps identify environmental hotspots. For example, a hospital aiming to reduce the environmental impact of a reusable surgical

scissor may discover that across all life cycle stages the sterilization process is the main contributor to CO_2 emissions (see Section 2.1.3). This insight enables us to adjust the protocol for greater sustainability. LCAs are also valuable **for product comparisons and procurement decisions**, such as when selecting the more sustainable option between two brands of disposable syringes. Additionally, LCA supports **communication efforts**. For example, an infusion bag manufacturer can substantiate an eco-label claim by demonstrating a lower-than-average carbon footprint. On a strategic level, LCA can inform **policy development**. For instance, an industry association might use LCA to determine which types of medical devices contribute most to the sector's overall environmental impact and develop targeted sustainability policies. Finally, LCA facilitates **accounting and monitoring.** A hospital may, for example, annually track the total carbon footprint of all its medical devices to assess progress towards sustainability goals.
To conduct an LCA, decisions need to be made about the functional unit that will be reported. The **functional unit** is a key concept in LCA, as it defines what is being measured and enables different products or systems to be compared in a meaningful way. Put simply, the function unit answers the question: "What service does a medical device provide, and how do we measure it"? For example, when comparing two types of surgical gloves, the functional unit could be "providing protection for one surgery of two hours." Alternatively, a study might use "100 pairs of gloves used in standard surgical procedures" as the functional unit. These examples show that even when assessing the same type of medical device, different choices of functional unit can make direct comparison across LCAs difficult.
To help ensure consistency, the ILCD Handbook[9] recommends that the function, quantity, duration, and quality of the functional unit are specified as precisely and transparently as possible. For medical devices, this means not only describing what the device does, but also how often, for how long, and to what quality level, including relevant technical specifications. For instance, the functional unit for a syringe could be defined as: "Delivering an accurate dose of 5 ml medication (function) in a single injection (quantity) over one administration moment (duration), with sterility maintained and no leakage (quality)". In summary, the functional unit acts as the common denominator, making it possible to fairly compare the environmental impacts of different products that perform the same medical task.

2.1.2 Scope (life cycle stages)

When defining the scope, it is important to specify which parts of the medical device life cycle are included in the assessment. The way life cycle stages are defined and classified can vary between studies. For example, some studies may include packaging as part of the production stage, while others consider it part of the packaging and distribution stage. Therefore, it is essential to clearly report which stages are included within the scope of each specific study. Table 1 shows typical life cycle stages.

Table 1 Overview of key life cycle stages of medical devices, including definitions and examples of relevant processes per stage.

STAGE	DEFINITION
1. RAW MATERIAL EXTRACTION	– Extraction and processing of metals, polymers, etc., and auxiliary materials that are needed to produce a medical device – Includes emissions and energy use in mining and refining
2. PRODUCTION & ASSEMBLY	– Manufacturing of components and modules – Assembly of the device (mechanical, electronic, chemical) – Supporting processes (energy supply, cooling water, lubricants)

STAGE	**DEFINITION**
3. PACKAGING & DISTRIBUTION	– Multiple layers of packaging (plastic, sterile barriers, etc.) – Transport between suppliers, manufactures, end-users, etc.
4. USE PHASE	– Direct use by healthcare professionals or patients – For electronic devices: electricity use, cooling systems, maintenance – For reusable devices: cleaning, sterilization, disinfection, washing and drying cycles – Maintenance and replacement parts
5. END-OF-LIFE (EOL)	– Waste management: incineration, landfill, recycling – Medical waste with infection risk (mandatory incineration) – Recovery of used products (reuse, recycling, energy recovery)

Depending on the scope of the LCA, the assessment may focus on all life cycle stages or only a selection of them. The most commonly used approaches are: stages 1–3 (**Cradle-to-Gate)** cover all processes from raw material extraction to the finished product leaving the manufacturing facility. This typically includes production and packaging but excludes distribution to end users or consumers. Stages 1–5 (**Cradle-to-Grave)** encompasses the entire life cycle, from raw material extraction to waste management. Stages 3–5 (**Cradle-to-Cradle)** are similar to cradle-to-grave but also considers the recovery of the product and its reintegration into new production cycles at end-of-life. Given the diversity in life cycle stages and their environmental relevance across medical devices, we introduce a structured categorization in the next section to better understand the sustainability challenges and opportunities for different types of medical devices.

2.1.3 Medical Devices Categories and Life Cycle Characteristics

Medical devices, as defined in the MDR[10], include a wide range of products for medical purposes such as instruments, equipment, software, implants, or diagnostic reagents. Given this diversity, grouping medical devices by similarities in their life cycle characteristics can provide a practical framework for exploring sustainability challenges and opportunities. In this overview, medical devices are organized into seven categories based on factors such as intended use, reusability, technological complexity, and the presence of electronic or implantable components.

Please note that these categories are neither exhaustive nor definitive; rather, they are intended to highlight common patterns and examples. For in-depth sustainability analysis, individual devices should be evaluated according to their particular use and life cycle context.

The classification was developed by reviewing the "MDCG guidance classification of medical devices"[11] and by identifying groups of devices with broadly similar life cycle profiles. Each category is accompanied by a description, along with illustrative examples and life cycle characteristics.

SINGLE-USE MEDICAL PRODUCTS - Devices, excluding implants, designed for single use only and disposal after use. These products are typically made from plastics, rubbers, or other disposable materials, and cannot be safely or economically reused.
Examples: Single-use syringe, injection needle, blood collection tube, surgical swab.
Life cycle characteristics: The life cycle of single-use medical products is generally characterized by the need for new material resources with each use, and the generation of waste after disposal. Environmental impacts are generally most relevant during the raw material extraction, manufacturing and end-of-life phases, while the use phase usually has little to no direct impact. The extent and nature of these impacts can differ depending on the product type and local waste management practices. At end-of-life,

these products contribute to healthcare waste streams and are generally challenging to remanufacture or refurbish due to contamination and design constraints.

REUSABLE MEDICAL PRODUCTS - Devices designed for repeated use after cleaning, disinfection, or sterilization. They are generally non-electronic and made from materials such as stainless steel or high-grade polymers.
Examples: Reusable surgical instruments, reusable scalpel handle, forceps, dental instrument set, orthopedic reamer.
Life cycle characteristics: Reusable medical products are designed for multiple uses, which can result in lower overall demand for raw materials and reduced product volumes over their lifespan, by avoiding production of new single use products[12], depending on use patterns. The use phase is more complex compared to single-use alternatives, as it involves repeated reprocessing (i.e. cleaning, disinfection, sterilization, and maintenance), which may require additional energy and resources. At end-of-life, these devices may be suitable for remanufacturing or refurbishment, potentially reducing environmental impact, although this depends on product design.

ACTIVE MEDICAL DEVICES - Devices that are externally powered, predominately by electricity, ranging from compact, portable equipment to large stationary systems. These devices are used across various healthcare settings, including hospitals, specialized clinics, and home environments. The scale and complexity of the devices within this category can vary widely, from handheld monitors to capital-intensive diagnostic and treatment systems.
Examples: ECG machine, infusion pump, blood pressure monitor, MRI scanner, CT scanner, anaesthesia machine.
Life cycle characteristics: Active medical devices typically rely on electrical power and contain electronic components, which require the extraction of critical raw materials. Some are battery-powered, the production of which can be energy-intensive[13]. While most active medical devices use external electricity, some rely on batteries or, less commonly, alternative sources like compressed air or gas. These differences in energy supply can affect the environmental profile of the device. Packaging and distribution impacts are generally more significant for smaller, portable devices and less so for larger, stationary systems produced in lower volumes. During use, energy consumption or battery use are key sustainability concerns, especially for high-powered or frequently used devices. At end-of-life, these devices create electronic and battery waste streams that contain hazardous and valuable materials.

ACTIVE IMPLANTABLE AND BODY-WORN MEDICAL DEVICES - Electrically-powered implants and body-worn medical devices are intended either to be implanted in the human body or worn externally, which require an internal power source, such as a battery. These devices typically contain electronic components and may provide stimulation, monitoring, functional support, or replacement of body parts.
Examples: Pacemaker, cochlear implant, implantable cardioverter defibrillator (ICD), neurostimulator, closed-loop insulin pump (implantable).
Life cycle characteristics: Electrically-powered implants and body-worn medical devices are typically small, specialized devices with long lifespans. Their life cycle starts with the extraction of critical materials for electronics and batteries, as well as medical-grade plastics. No peer-reviewed studies were identified that performed an LCA on this specific category of devices. However, given their small size and low production volumes, the environmental impact of packaging and transport is likely limited. Nevertheless, all associated surgical procedures (both for initial implantation and battery replacement or device removal or replacement) should be included in the LCA, as these can significantly

contribute to the environmental footprint. For body-worn devices, clinical handling and patient use may also influence the impact. During use, energy consumption is minimal, but battery replacement or recharging may be needed. At end-of-life, device removal, replacement or disposal creates electronic and battery waste containing hazardous and valuable materials.

NON-ACTIVE IMPLANTABLE AND BODY-WORN MEDICAL DEVICES - Non-active implants and body-worn devices are medical devices that are implanted in the body or worn externally and do not require an internal power source or electronics. They serve structural, replacement, or support functions. Implants are typically made from biocompatible metals, ceramics, or polymers while external prostheses may be made from a variety of materials such as plastics, metals, composites, and textiles.
Examples: Hip prosthesis, knee prosthesis, vascular stent, intra-ocular lens, reusable contact lens, dental implant, orthopedic brace.
Life cycle characteristics: As mentioned above, these devices are generally made from high-quality, biocompatible materials. The extraction and processing of these materials, along with precise manufacturing and assembly, typically account for the most significant environmental impacts in their life cycle[14]. Packaging and distribution impacts are usually minor, due to low product volumes and long device lifespans. For body-worn devices, packaging and transport impacts may be slightly higher, especially for products distributed in larger quantities or with shorter replacement cycles. The use phase varies depending on the device type; for implants, it is closely linked to the surgical implantation procedure, which can contribute substantially to the overall environmental footprint through resource use and waste generation in clinical settings. For body-worn devices, environmental impacts may arise from regular cleaning, maintenance, or associated consumables. End-of-life impacts are often limited, as many of these devices remain in the body. When devices are removed, they may offer potential for recycling or material recovery, depending on design, contamination, and local regulations.

HYBRID MEDICAL SYSTEMS - Hybrid or complex systems, in this context, refer to sets or combinations of devices, often comprising both disposable and reusable elements and sometimes including electronics. These systems are used in complex procedures and may be supplied as procedure packs or integrated solutions.
Examples: Dialysis set (including tubing, filters, and electronic components), procedure pack for surgery, endoscopy system (with camera and accessories), blood transfusion set, laparoscopic instrument set.
Life cycle characteristics: The life cycle of hybrid medical systems reflects the combined impacts of their disposable, reusable, and electronic components. Modular system design can create challenges for component separation, recycling, and waste management[15]. Packaging and distribution impacts vary based on the mix of single-use and durable elements. During use, the system may involve multiple devices and materials, resulting in diverse sustainability considerations. End-of-life management is complex, requiring effective separation and recycling of different materials and components, which is influenced by product design.

SOFTWARE AS A MEDICAL DEVICE (SAMD) - This category includes standalone software that meets the definition of a medical device, such as diagnostic, monitoring, or therapeutic applications. These products may run on standard computers, servers, tablets, or smartphones and are not tied to a specific hardware device.
Examples: Diabetes management app, AI-based radiology image analysis software, clinical decision support system, telemonitoring platform, ECG analysis app.
Life cycle characteristics: Software as a Medical Device (SaMD) does not involve

physical manufacturing, but its sustainability profile is primarily shaped by the energy use and resource consumption of the hardware and the infrastructure required to run the software, either locally or via cloud-based solutions. Servers, devices, and network capacity may be required, which involve indirect use of raw materials and energy during production and operation. The environmental impact during use is linked to the efficiency of data centers and local hardware, the volume of data processed, and the energy mix used by the cloud provider. End-of-life impact is mainly related to the potential for increased electronic waste if frequent updates drive hardware replacement.

Given the wide diversity of medical devices, as outlined above, categorizing devices by life cycle characteristics can provide an initial indication of which aspects are typically relevant for their environmental impact. Depending on the goal of the LCA study (e.g., comparing alternatives, identifying hotspots, or supporting policy decisions) one must determine which data are essential and how detailed this information should be for each life cycle stage of the specific device.

2.1.4 System Boundaries (level of detail)

The next step in the LCA process is to carefully define the system boundaries, to ensure that the analysis addresses the research question and captures the most relevant environmental effects. For each life stage, the system boundaries must be set with the right level of granularity, that is, the level of detail included in the analysis. A narrow boundary looks only at the most direct inputs and outputs, while a broad boundary includes supporting processes such as infrastructure, maintenance, packaging, and other secondary effects. Selecting the appropriate granularity ensures that the LCA is both relevant and manageable; it is not necessary to quantify inputs and outputs that will not significantly affect the overall study's conclusions[3]. Defining system boundaries is an iterative process, in which initial boundaries may need refinement as the study progresses.

System boundaries can be determined based on the study's goal, intended use and audience, underlying assumptions, available data and resources, input from involved stakeholders, and time and budget constraints. For example, when comparing a single-use medical device to a reusable alternative, the system boundary should be broad enough to capture all the relevant differences. For reusable instruments, this typically includes cleaning, sterilization, water and energy use, and required consumables[12]. Omitting these processes may systematically favor single-use devices and lead to misleading conclusions. In contrast, for an improvement-focused LCA aimed at identifying manufacturing hotspots in a complex medical device, it may be appropriate to focus the system boundary primarily on the manufacturing and assembly steps. The rationale for this narrower focus is to optimally allocate available resources to collect detailed and high-quality data for those stages where improvements are sought. These examples illustrate how system boundaries can vary widely depending on the specific medical device, goal, and scope of the LCA. Table 2 provides examples of narrow and broad system boundary definitions for each life cycle stage.

Table 2 Examples of narrow and broad system boundary definitions for each life cycle stage of medical devices.

STAGE	**NARROW BOUNDARY EXAMPLE**	**BROAD BOUNDARY EXAMPLE**
1. RAW MATERIAL EXTRACTION	Only basic material quantities (e.g., kg polypropylene, stainless steel, titanium)	Includes mining activities, refining, chemical processing, transportation, machine emissions, by-products

STAGE	NARROW BOUNDARY EXAMPLE	BROAD BOUNDARY EXAMPLE
2. PRODUCTION & ASSEMBLY	Direct material and energy inputs for component production	Also includes production waste, cooling and cleaning agents, machine maintenance, facility construction and use
3. PACKAGING & DISTRIBUTION	Primary packaging (sterile plastic bag, blister), transport from factory to hospital	Secondary and tertiary packaging, sterilization packaging, global distribution network, refrigerated transport, internal hospital logistics
4. USE PHASE	Energy use during operation (e.g., MRI scanner kWh per scan or per hour)	Consumables (electrodes, tubing), sterilization/cleaning, water use, chemicals, maintenance and repairs
5. END-OF-LIFE (EOL)	Incineration or landfill of product	Sorting components, recycling processes, transport to waste processing, metal/energy recovery

Key considerations
Several challenges are common in defining the goal and scope (ILCD handbook[9]).
Exclusions: Prepare an initial list of exclusions from the LCA study, and justify these exclusions based on clear criteria.
System boundary diagram: Develop a schematic diagram of the system boundary, showing included life cycle stages and main processes.
Cut-off criteria: Set a minimum amount of materials, energy, or environmental impacts that must be covered (for example, at least 95% of total material use).
Consistency: Ensure all methods, data, and assumptions are applied consistently across all life cycle stages and processes.
Documentation: State intended application, target audience and the product system to be analyzed, including functional unit, system boundaries, and key assumptions.

2.2 Life Cycle Inventory

In the life cycle inventory (LCI) phase, all relevant input data (materials, energy, water) and output data (emissions, waste) are systematically collected and quantified for each stage of the medical device's life cycle[3,6]. The previously defined system boundaries determine which processes (i.e., the individual steps or activities in the medical device's life cycle, such as manufacturing, transport, or sterilization) and flows (i.e., the specific inputs and outputs, such as materials, energy, emissions, and waste, that move into, within, or out of these processes) are included in the inventory.

This knowledge brief outlines the types of data needed. In practice, LCA data collection involves several layers and types. **Foreground** (product) data relates directly to the medical device and includes all inputs and outputs within the defined product system (e.g., for disposable sharps containers[16]: quantity of plastic resin used, the electricity consumed by injection molding machines, etc.). Foreground data should be specific and accurate, as it forms the foundation for quantifying direct environmental impacts. **Background** (environmental) data refers to broader environmental processes that support the product system but occur outside its immediate boundaries (e.g., CO_2 emissions from upstream impacts of refining of oil for the plastic resin or the electricity mix used in the production process). This data is essential for translating the product's physical activities into measurable environmental impacts.

Both foreground and background data can be classified by source and accuracy. **Primary data** are direct, site-specific measurements or supplier information and are most accurate and representative; these should be prioritized, especially for components or stages identified as environmental hotspots (e.g., data from actual injection moulding manufacturing site, such as the exact energy consumption per batch). **Secondary data** come from external databases (such as the injection moulding dataset in Ecoinvent[17], literature, or industry reports. While less specific, secondary data is valuable for filling data gaps and providing context, particularly for background processes. **Proxy data** are estimates or data from similar products or processes, used when primary or secondary data are unavailable (e.g., using the injection moulding data from similar plastic products). Proxy data is the least accurate and should be used only when necessary, but it can be essential for rarely used materials or hard-to-model processes.

The effort and level of detail in data collection should be proportional to the significance of each component or process to the overall environmental footprint. For key contributors, that is, components, materials, or processes that have a major impact, it is crucial to collect high-quality primary data. For less critical elements, secondary or proxy data may suffice. For instance, the manufacturing process was identified as a major contributor to the environmental impact of the disposable sharps container, and therefore collecting detailed data on these components is important, whereas for the transportation, secondary or proxy data may suffice. However, whether and which type of data should be used can be highly medical device dependent and should always be clearly justified and documented based on the context and the relative importance of the component or process.

LCA is inherently an iterative process. After the initial inventory analysis, the results can reveal “hotspots”. These are life cycle stages, processes, or indicators that contribute disproportionately to the environmental impact of a medical device (such as the manufacturing phase of the disposable needles container). Identifying these hotspots enables the refinement of the scope, system boundaries, or data collection strategy in subsequent iterations of the LCA[18].

Key considerations

Several challenges are common in LCI, which can affect the reliability and transparency of the results:

Data Gaps and omission of data: Try to avoid missing data by collecting or estimating as much as possible. If data are missing and cannot be estimated, set them to zero and report this clearly.

Allocation: Decide how to split environmental impacts for processes with multiple outputs (e.g., by mass, energy, or value), as this can strongly influence results.

Data Quality and Consistency: Use harmonized data formats, units, and terminology, and document data sources and assumptions. Report the time period, geographic region, and technology level of the study.

System Complexity: Use flow diagrams and digital tools to manage complex system models.

Transparent documentation: Ensure all methods, data sources, assumptions and decisions are reported clearly for reproducibility.

2.3 Life Cycle Impact Assessment

The life cycle impact assessment (LCIA) phase builds on the quantitative data collected in the LCI and transforms this complex list of inputs and outputs into potential environmental impacts[6]. Instead of evaluating hundreds or thousands of substances (i.e., materials, chemicals, or emissions) individually, LCIA groups these into key environmental themes, i.e., the impact categories—such as climate change, human toxicity, or resource depletion. For each impact category, inventory data are converted and aggregated into a common unit using scientifically derived characterization models and factors. For example, when performing an LCA on a disposable sharps container, the

LCIA phase translates all the greenhouse gas emissions from plastic production, energy used in the manufacturing facility, and emissions from incineration after use into a single "climate change" score, with "CO_2 equivalent" as the common unit[16]. This conversion process results in category indicator scores that provide a manageable overview of the environmental profile of a product or process.
Here, we address which indicators exist and are widely used to assess the environmental sustainability of medical devices throughout their entire life cycle. Indicators are measurable quantities used to express these impact scores. They can be defined at different points along the environmental cause-effect chain. This chain describes the sequence of events that starts with the release of substances or resource use (the "cause"), followed by intermediate environmental mechanisms, and ends with final impacts on human health, ecosystems, or resource availability (the "effect"). In other words, it traces how an initial environmental intervention can lead to broader consequences over time. **Midpoint indicators** (e.g., climate change, acidification) focus on specific environmental mechanisms, whereas **endpoint indicators** (e.g., damage to human health or ecosystems) reflect broader consequences further downstream[19].

2.3.1 Midpoint indicators

Environmental effects can be grouped into midpoint impact categories, which are then quantified by indicators[19]. Klöpffer and Grahl[20] describe a total of 91 impact categories, divided across eleven methodologies. Many of these categories are sector-specific and require additional, location-specific data, which limits their applicability in standard LCAs. Of the 91 listed impact categories, only the 12 below are directly applicable to the medical device life cycle (Table 3).

Table 3 Description of the main midpoint impact categories relevant for environmental assessment of medical devices[19,20]

MIDPOINT INDICATORS	**DESCRIPTION**
ABIOTIC RESOURCE USE	This impact category encompasses the use of non-renewable resources, such as metals and fossil fuels. Since these resources are limited and cannot be easily replenished, extensive use will result in reduced availability in the future, thereby contributing to resource scarcity. For example, many active medical devices that contain electronics depend on scarce resources, such as rare earth elements (e.g., neodymium, dysprosium).
ACIDIFICATION	Acidification occurs when substances like sulfur and nitrogen oxides, emitted from transport, industry, or agriculture, enter the air and deposit in soil or water, lowering the pH (this is also referred to as 'acid rain'). Acid rain can damage ecosystems, such as forests and lakes.
CLIMATE CHANGE	Climate change is mainly driven by the emission of greenhouse gases such as CO_2, methane, and nitrous oxide. These gases trap heat in the atmosphere, leading to global temperature rise, melting ice caps, rising sea levels, and ecosystem shifts. All processes that use fossil fuels contribute to this indicator, such as material transport or energy consumption. Certain medical gases, e.g., anaesthetic gases, have a global warming potential, and their release during use can disproportionately contribute to the climate change impact of devices[21].
ECO-TOXICITY	Ecotoxicity describes how toxic substances released by humans affect life in ecosystems. Chemicals such as pesticides, heavy metals, or industrial waste can be harmful to plants, animals, and microorganisms in water, soil, or air. This can lead to species extinction or disruption of food chains. Examples include fish deaths in rivers or the disappearance of insects due to pesticides.

MIDPOINT INDICATORS	**DESCRIPTION**
EUTROPHICATION	Eutrophication occurs when too many nutrients, especially nitrogen and phosphorus, enter water or soil, often through manure, fertilizers, or sewage. The result is rapid algae growth, which leads to oxygen depletion and the death of fish and other organisms. Well-known examples are green, foul-smelling ditches or 'dead zones' in the sea where no life is possible, and the current nitrogen surplus problem in the Netherlands.
HUMAN TOXICITY	This category looks at the harmful effects of substances on humans. Substances like heavy metals, pesticides, and industrial chemicals can enter our bodies via air, water, food, or skin contact, causing diseases or poisoning. Examples include lead in drinking water and pesticide residues on vegetables.
LAND USE	Land use concerns how humans use land for agriculture, construction, or mining, and what this means for nature. Converting natural areas into farmland or cities leads to loss of biodiversity and disruption of ecosystems. This affects the availability of natural resources, soil quality, and, for example, the ability of nature to purify water.
PARTICULATE MATTER FORMATION	Particulate matter formation refers to the production of very small particles in the air, originating from sources such as traffic, industry, or wood stoves. These particles can penetrate deep into the lungs and are harmful to health: they increase the risk of lung diseases and heart problems and can even lead to premature death. This is a major issue, especially in cities and near busy roads.
PHOTOCHEMICAL OZONE FORMATION	Smog formation occurs when substances from exhaust gases and industry react in the air under the influence of sunlight, forming ozone close to the ground. This ozone is harmful to our health (e.g., respiratory problems) and to plants and crops. On warm summer days, this can lead to smog, especially in urban areas.
STRATOSPHERIC OZONE DEPLETION	The depletion of the ozone layer is mainly caused by substances like CFCs from old refrigerators and spray cans. The ozone layer protects us from harmful UV radiation emitted by the sun. If this layer becomes thinner, the risk of skin cancer in humans increases, and plants and animals can be harmed by excessive UV exposure.
WATER USE	Water use looks at how much water is consumed and whether this can lead to water shortages. This is especially a problem in dry areas, where large amounts of water are used for agriculture, industry, or households. Excessive water use can lead to drought, reduced water availability for nature, and problems for future generations.
IONIZING RADIATION	Ionizing radiation refers to subatomic particles or electromagnetic waves with enough energy to remove electrons from atoms or molecules, causing ionization. It is mainly emitted from anthropogenic sources such as nuclear power and certain industrial activities, and exposure can damage DNA and lead to adverse health effects such as cancer. Ionizing radiation is included only in certain impact assessment methods, such as ReCiPe and Environmental Footprint. It is not listed among the 11 main impact categories described by Guinée[19]. However, the use of radioactive materials is not uncommon in medical devices or in procedures involving medical devices. Therefore, it is recommended to incorporate this impact category into the LCA.

The selection of relevant impact categories, indicators, and calculation methods is crucial, as it determines which environmental aspects are highlighted and how results are interpreted and compared. This choice is especially important for policy decisions and product comparisons, as illustrated by a study comparing the environmental impact of two medical staplers[22]: while steel input dominates the global warming impact, plastic disposal is more significant for ecotoxicity and eutrophication. Relying on a single indicator, such as climate change, risks overlooking other important environmental effects. Therefore, using a broad set of indicators is essential for identifying actual environmental hotspots and supporting effective decision-making.

In practice, climate change is the most commonly used and reported indicator, due to the widespread availability of data and policy focus. However, Smurthwaite et al.[23] demonstrate that this focus leads to a narrow perspective: while all LCAs report impacts on climate change, other indicators listed in Table 3 are significantly underrepresented. As a result, effects such as toxicity and resource depletion (often) remain unaddressed. These are essential for topics such as planetary health, as well as for considering the consumption of (critical) raw materials.

2.3.2 Endpoint indicators

Even when multiple relevant impact categories are included in a study, it remains challenging to determine which category is most significant. Keil et al.[24] illustrate this issue by showing that reusable healthcare products generally perform better across most indicators than single-use alternatives, except for water use. However, this does not mean that water use is inherently a "critical" indicator for reusable products. To understand its overall significance, one needs to know how water use affects damage at the **endpoint level**—such as ecosystem degradation—relative to other impact categories[25].

While midpoint indicators describe specific environmental mechanisms, endpoint indicators quantify the resulting damage to human health, ecosystems, or resource availability. Methods such as ReCiPe 2016[26] and Eco-indicator 99[27] link midpoint flows to these higher-level damage categories through cause–effect chains. These endpoint models make it possible to compare different midpoint indicators on a common scale—for example, in terms of Disability-Adjusted Life Years (DALYs) or species loss. However, the ISO standard for LCA[3] places certain restrictions on its use. This is because weighting and combining impacts on human health, ecosystems, and resources into a single index inevitably involves value judgments. Although the calculation of midpoint-to-endpoint factors is grounded in scientific models, important choices—such as time horizon, level of precaution, and which effects to include—reflect underlying value judgments. For instance, ReCiPe 2016 explicitly uses three "cultural perspectives" (individualist, hierarchist, and egalitarian) to represent different sets of assumptions and priorities[26]. Thus, subjective choices are always part of the weighting process, as emphasized in the ISO standard[3]. Moreover, this scientific field continues to evolve: ongoing research aims to make these underlying choices more scientifically robust and to further develop or add new indicators, reflecting advances in knowledge and methodology.

2.3.3 LCA methods

In this knowledge brief, we list the most used impact assessment methods to jointly map the indicators. Several methodologies are available to calculate the impact of environmental indicators in LCA; each differs in the definition of impact categories, characterization models, and whether environmental impacts are expressed at the midpoint or endpoint level. Some methods focus on a single impact category (e.g., USEtox[28] for toxicity) while others cover a broad set of environmental categories (e.g., ReCiPe 2016[26], CML 2012[29], IMPACT 2002+[30], Environmental Footprint (EF)[31]). Furthermore, endpoint methods can aggregate results into a single score (e.g., Eco-Indicator 99[27]). According to Wahl[32], the most used global multi-impact LCIA methods at the midpoint level are ReCiPe, followed by ILCD 2011, CML 2012, and IMPACT 2002+. The choice of LCIA method depends on the study's goal, regional context, and target audience. For example, TRACI[34] is tailored to North America, USEtox is suitable for products with toxicity concerns, and Eco-Indicator 99 provides single aggregated scores but involves subjective weighting. Methods like ReCiPe 2016, EF, CML 2012, and IMPACT 2002+ each include multiple impact categories, offering a broad environmental coverage. For medical devices, as discussed in chapter 2.3.1, multiple indicators are relevant. It is therefore recommended to use a multi-impact LCIA method. Among the methods mentioned above, only ReCiPe 2016 and EF cover all the relevant impact categories described in Table 3. Applying these methods helps ensure that no important environmental impact category is overlooked.

It has also been demonstrated that the use of a specific LCIA method can significantly influence the interpretation of LCA results, especially for specific impact categories and subcategories. For example, in a biorefinery case study, consistent outcomes were found for the climate change category across 42 subcategories and 12 different LCIA methods[35]. However, for Eutrophication Potential and Water Use, substantial differences were observed between methods and subcategories. This sometimes leads to contradictory trends and changing conclusions about which scenario performed best or worst. Key reasons for these differences are that each method may use different calculation approaches or definitions for certain categories. For example, methods might treat how nutrients affect water quality or how water use is measured differently. This highlights the importance of transparency: it is crucial to always clearly state which LCIA method (and version) has been used. In addition, it is recommended to compare multiple LCIA methods in scenario analyses, so that any differences in results are made visible and can be explained. This contributes to the reliability and reproducibility of LCAs and makes methodological choices transparent.

Key considerations

Use multiple indicators: Relying on a broad set of impact categories prevents important environmental effects from being overlooked and improves the comprehensiveness of the assessment.

Identify key indicators by mid- to endpoint contribution analysis: Analyze which indicators contribute most to overall impacts at both midpoint and endpoint levels to prioritize data collection and interpretation.

Use multi-impact life cycle impact assessment methods: Select LCIA methods that cover a wide range of impact categories to capture the full spectrum of potential environmental burdens.

Apply multiple impact assessment methods as part of uncertainty analysis: Comparing results from different LCIA methodologies helps to understand the robustness of findings and identify uncertainties or methodological biases.

2.4 Life Cycle Interpretation

In the above, we focused on three key aspects of LCA for medical devices: indicators, data inventory, and impact assessment methods. The life cycle interpretation phase, while a crucial part of LCA for translating results into decision-making guidance[36], is not addressed here, as it falls outside the scope of our research questions. Further guidance on life cycle interpretation may be addressed in future studies or complementary publications.

3 Discussions

LCA is a valuable tool for advancing sustainability in the medical sector, offering a comprehensive framework to evaluate the environmental impacts of medical devices throughout their entire life cycle. However, its application needs careful attention because of the wide variability in device types, materials, design, and function. The categorization of devices presented in this knowledge brief can support better overview and transparency by pragmatically grouping devices with shared life cycle characteristics, enabling more consistent and relevant sustainability assessments. Nevertheless, it is important to recognize that each type of medical device is unique, and specific assessments should always take into account the individual characteristics and context of the device in question. In addition, an assessment is always done with a relevant goal and scope, which may or may not be applicable to other settings.

This knowledge brief has summarized a list of suitable indicators that are recommended for inclusion in the LCA of medical devices. To determine which of these indicators are most critical, endpoint modelling within the LCA is necessary to analyze their respective contributions to ecosystems, human health, and other areas of concern. To assess the most important indicators for medical devices as a group or by category, the literature on medical device LCAs must be sufficient, reliable, comparable, and transparent, while using multiple indicators. A systematic review of peer-reviewed LCAs of medical devices is therefore essential to analyze the current state of the field; a similar study has recently been conducted for the pharmaceutical industry[18].

Transparency in reporting methods, data sources, and assumptions or choices is essential for robust and reproducible results and to prevent greenwashing and counterproductive investments. LCAs may be conducted by manufacturers, researchers, or third parties, each with different motivations and constraints. For manufacturers, strict regulatory requirements are focused on patient safety, and as a result environmental (effect) data is often lacking. Additionally, implementing sustainable alternatives may be challenging, as changes to the manufacturing process may require additional testing and approval.

Data requirements are highly device- and study-specific. While several healthcare LCA databases have emerged, such as Groene Zorg database[37] and the international HealthcareLCA database[38], methodological and contextual differences between studies remain a barrier for reliable comparison. Upcoming initiatives like the Lancet MedZero database[39] (to be launched in 2026) aim to improve global coverage and comparability, but achieving full harmonization will require reliable and transparent data, consistent methodological alignment, and international collaboration.

Standardization and harmonization can further improve the usefulness and comparability of LCA results. Standardization could help address issues such as inconsistent use of indicators, difficulties in comparing results, and notable data gaps, often linked to differences in scope, methodology, and data availability. The challenges described in this knowledge brief underline the need for mandatory multi-indicator reporting, harmonized LCIA methods, and transparent reporting. This will require an iterative science-based collaborative process with the medical device sector, given the sector’s complexity and diversity. Some degree of flexibility and case-specific adaptation will likely be necessary.

4 Conclusions

Environmental assessments of medical devices are essential for advancing sustainability in healthcare, a sector increasingly affected by environmental challenges. This knowledge brief introduces a device categorization based on life cycle characteristics and recommends a set of twelve key indicators for LCA of medical devices. Reliable LCAs require both product-specific and general data, with transparency about data sources, assumptions, and uncertainties. The iterative nature of LCA and careful selection of impact categories, indicators, and assessment methods help to identify environmental hotspots and support meaningful improvements.

Moving beyond a single-indicator approach and adopting harmonized, multi-indicator LCAs tailored to device diversity is crucial. Transparent reporting and thoughtful methodological choices help to prevent greenwashing.

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