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To Dispose or to Reuse? Analyzing the Life Cycle Impacts and Costs of Disposal, Sterilization, and Reuse of Electrophysiological Catheters

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Abstract: Given the growing ecological footprint of anthropomorphic activities, considering the environmental impacts of any process is becoming increasingly important. This is especially true for the healthcare industry, whose objective of maintaining human health standards is impeded by its own unsustainable practices. To this end, life cycle analysis is particularly helpful. There have not been many life cycle analyses performed on a healthcare device or on medical procedures. Many medical devices are single use, which leads to a significant waste management problem, particularly as plastic is widely used in their composition. The objective of this study is to present a life-cycle-thinking-based approach to compare the environmental impacts associated with single-use electrophysiological catheters with the sterilization of reusable electrophysiological catheters using hydrogen peroxide, ethylene oxide, and peracetic acid. A life cycle assessment was conducted considering different use, disinfection, and disposal scenarios for electrophysiological catheters, using ReCiPe midpoint and endpoint analysis with the SimaPro software. The findings indicate that using single-use disposable electrophysiological catheters, instead of sterilizing a single catheter using either ETO or hydrogen peroxide and reusing multiple times, is preferable from a purely environmental perspective. However, the costs reduce drastically when equipment is sterilized and reused instead of disposing them after using one time. This in turn illustrates that depending on the process, sanitizing and reusing medical devices may not always be more resource-efficient than single device usage. From a cost perspective, ETO sterilization has the lowest costs, and yet it leads to an aggregate environmental impact of over 20 times compared to the single-use scenario, mainly due to the required detoxification process. The outcomes of this research will assist the health care industry in identifying the most suitable operational procedures considering patient safety, economics, and environmental stewardship, and in developing policies and guidelines for a more sustainable healthcare sector.

Keywords: medical devices; life cycle assessment; healthcare industry sustainability; eco-efficiency analysis

Citation: Lalman, C.; Karunathilake, H.; Ruparathna, R. To Dispose or to Reuse? Analyzing the Life Cycle Impacts and Costs of Disposal, Sterilization, and Reuse of Electrophysiological Catheters. *Sustainability* **2023**, *15*, 5363. https://doi.org/10.3390/su15065363

Academic Editor: Anna Mazzi

Received: 8 February 2023
Revised: 9 March 2023
Accepted: 12 March 2023
Published: 17 March 2023

1. Introduction

Environmental pollution and related impacts caused by anthropomorphic activities are widely acknowledged as one of the key concerns facing humanity at present. Several of the United Nations Sustainable Development Goals (SDG) center around minimizing greenhouse gas emissions and managing natural ecosystems [1]. Many countries have followed suit, introducing their own series of sustainability goals and guidelines. In Canada, federal development plans outline a variety of strategies that could potentially be implemented; these have been codified within the landmark policy Pan-Canadian Framework on Clean Growth and Climate Change. These programs include initiatives such as carbon pricing, the introduction of alternative fuel vehicles, energy efficiency, and the

integration of clean energy technologies [2,3]. However, the health sector does not receive adequate attention in Canada's climate change mitigation goals.

According to statistics published on the healthcare sector's climate footprint, the global healthcare industry produces approximately two gigatons of carbon dioxide each year [4]. This represents 4.4% of the world's total emissions. If the global healthcare industry was a country, it would rank within the top five highest emitters of greenhouse gases (GHG). The Canadian medical system in particular does no better than average, as it is the among the world's top three highest greenhouse gas emitters per capita [5]. According to Eckelman et al. (2018), the Canadian healthcare system contributes to 4.6% of Canada's GHG emissions [5]. The environmental footprint of the healthcare sector is not limited to GHG emissions. Hospitals around the world produce more than five million tons of waste each year [6], and the Canadian healthcare system specifically generates around 200,000 tons of waste products [5].

These emissions and waste have a negative impact on the environmental and human health around the world. According to the World Health Organization (WHO), the increase in the incidence of heat stress, malaria, malnutrition, and diarrhea attributable to climate change will cause an additional 250,000 deaths between 2030 to 2050 [7]. Medical waste is associated with a significant human health risk. For example, biohazardous waste, defined as substances that are infectious, toxic, or radioactive by the WHO, can spread a variety of infectious diseases, including tuberculosis and cholera [8]. Moreover, previous research estimates that the pollutants produced by the Canadian healthcare system can induce an accumulated 23,000 years of life lost from every resulting disability and early death [5]. While energy consumption might be one of the healthcare sector's most obvious contributors to environmental pollution, other aspects of the medical industry are also partially responsible. In the guidelines compiled by Ontario's Provincial Government, biomedical waste is defined to include human anatomical and blood waste, microbiology laboratory waste, sharps waste, and cytotoxic waste, among other things. A report from the Ontario Hospital Association estimates that hospitals produce around 1% of non-residential landfill waste. Around 20–33% of that amount is believed to come from hospital operating rooms [8].

The prevalence of single-use products in the healthcare industry is a key causal factor for both the high energy use and waste generation in this sector. As an example, a study published by Thiel et al. (2015) found that a single hysterectomy produced 20 lbs of waste, much of which came from single-use artifacts [9]. While this approach is spurred on by safety- and convenience-related reasons, replacing single-use items with reusable devices would lower the amount of waste produced in hospital settings. Furthermore, choosing to reprocess medical apparatuses instead of manufacturing new disposable objects leads to significant financial savings. A survey covering approximately 3000 hospitals in the United States found that medical device remanufacturing saves around $150 million every year [10]. Electrophysiological catheters are one of the medical devices that are the most popular for reprocessing. Electrophysiological laboratories save an estimated $150,000 annually by recycling their electrophysiological and imaging catheters. Not only that, but reprocessing medical devices is also cost-efficient from a waste management perspective. Since managing medical waste requires money, the less medical waste that is produced, the less money that needs to be spent to handle it. Therefore, reusing medical devices is becoming more common across the globe [11]. However, maintaining sterilized conditions, and by extension patient safety, is still necessary. Since sterilization methods themselves use energy and resources, and can negatively impact the environment in various ways, the benefits and drawbacks of these options need to be carefully weighed. Some previous studies have been carried out on the environmental impacts of sterilization in the context of medical waste disposal. Hospital waste must be properly managed before being reintroduced into the environment, after all.

The steam sterilization process is one of the most commonly used methods for the above application. This disinfection procedure involves exposing materials to steam at

a specified pressure and temperature for a given interval of time in an autoclave. Steam sterilization's microbicidal, sporicidal, and nontoxic properties make it the most common and dependable decontamination method [12]. However, steam sterilization is not the only sanitization procedure used in hospitals. Since the sterilization mechanism involves heated water vapor, many heat-labile products cannot be cleaned this way [12]. This includes any devices made of non-stainless steel, polystyrene, polyethylene, or polyurethane, along with any acids, bases, or organic solvents. In these cases, other techniques, such as ethylene oxide gas sterilization, hydrogen peroxide gas plasma sterilization, and peracetic acid sterilization are employed.

Ethylene oxide (ETO) sterilization consists of depositing articles in a vessel before adding a combination of ETO and chlorofluorocarbons (CFC), ETO and hydrochlorofluorocarbons (HCFC), ETO and carbon dioxide, or 100% ETO. CFCs have contributed to a substantial degradation of the ozone layer. A report compiled by the *National Research Council (US) Subcommittee to Review Toxicity of Alternatives to Chlorofluorocarbons* found that HCFCs, while less damaging to the ozone layer, can also considerably contribute to global warming [13]. Moreover, ETO is a known carcinogen and mutagen. A study, published in the International Journal of Environmental Research and Public Health, discovered that the ETO emissions of the largest medical sterilization center in Michigan gave rise to an additional cancer risk of one in 100 [14].

Hydrogen peroxide gas plasma sterilization is a more recent sterilization technology that consists of using gas plasmas along with the generation of free radicals to disinfect equipment. Devices that cannot tolerate high heat and humidity, including some types of plastics and electrical equipment, cannot be sterilized using hydrogen peroxide [12]. The advantages of using hydrogen peroxide sterilization instead of ETO sterilization have been studied. In a paper published by Bathina et al. (1998), researchers found that using hydrogen peroxide to sterilize nonlumen electrophysiology catheters could save around $2000 per catheter [15]. However, hydrogen peroxide sterilization has been identified as leaving small amounts of toxic residues on catheters; this is not a side-effect of ETO sterilization [12]. There has been very little research on the environmental impacts of hydrogen peroxide sterilization. Since hydrogen peroxide sterilization is a technique that relies on chemicals, its environmental impacts may be similar to those of ETO sterilization and may have similar effects on the human health in areas of close proximity to hospitals.

In order to establish the comparative costs and benefits of single-use vs. reprocessed medical devices, the impact of sterilization needs to be holistically compared with those of waste disposal and management. A few studies in the past have used life cycle assessment in this task. Zhao et al. (2021), considered the environmental impacts of five different medical waste disposal strategies: rotary kiln incineration, pyrolysis incineration, plasma melting, steam sterilization, and microwave sterilization [16]. The different procedures were compared using energy recovery analysis (ERA), as well as LCA and LCC techniques, by collecting data from various medical institutions across several locations in China. Ultimately, it was determined that microwave sterilization followed by deposition in a landfill led to the lowest environmental impacts, while plasma melting had the highest environmental impact [16]. Additionally, pyrolysis incineration had the lowest economic cost, while plasma melting had the highest. In a similar study performed by Hong et al. (2018), a cost-coupled life cycle assessment was performed on three different types of medical waste disposal techniques: pyrolysis, steam sterilization, and chemical disinfection. The study found that steam sterilization and chemical disinfection led to the highest environmental impacts and the lowest economic burden [17]. Research has also been carried out specifically focusing on the reuse of electrophysiological catheters. For example, Schulte et al. performed life cycle analyses of reusable and disposable electrophysiological catheters. In this particular study, the reusable electrophysiological catheters were sterilized using a combination of ethylene oxide and carbon dioxide [18].

However, overall, very little research has been done to evaluate the benefits and drawbacks of different sterilization techniques when sanitizing medical devices for reuse

and to establish the comparative benefits of reusing medical devices instead of taking the single-use path. One issue in ascertaining the comparative sustainability of reusing medical equipment is that there is no one-size-fits-all answer for all types of equipment and procedures, and so impact assessments need to be individually carried out for different medical devices. Even among the existing studies, many have neglected to take a life cycle thinking approach in the impact assessment. In addition, a holistic perspective that combines economics with environmental considerations has not been adopted in most research carried out in this area. As such, there is a clear research gap related to the environmental impact assessment and eco-efficiency of sterilization procedures when used to disinfect medical devices.

The objective of this paper is to present a life cycle thinking based approach to compare the environmental impacts associated with single-use electrophysiological catheters with the sterilization of reusable electrophysiological catheters using hydrogen peroxide, ethylene oxide, and peracetic acid. The outcomes of this research will assist the health care industry in identifying the most suitable operational procedures considering patient safety, economics, and environmental stewardship, and in developing policies and guidelines for a more sustainable healthcare sector.

2. Literature Review

Life cycle analysis (LCA) along with life cycle cost assessments (LCCA) have been applied to a variety of concepts in the healthcare industry. Various LCA studies have been performed on medical processes, the packaging of medical devices, and the disposal of medical waste. For example, some studies have compared the environmental impacts of conventional cataract surgeries, hysterectomies, and caesarean births with their alternatives. One conclusion arising from the above studies is that reducing the production of disposable equipment would reduce the environmental footprint of these procedures [9,19,20]. Furthermore, a study analyzing cataract surgeries highlighted that maximizing medical device reprocessing would help reduce the greenhouse gases produced by the operation [19].

Some researchers have also considered the effects of different medical technologies on the environment, including a variety of instruments such as electrophysiological catheters, lumbar fusion surgery sets, and an assortment of regularly used hospital equipment. These studies mostly compared the environmental impacts of reusable and single-use devices. Researchers predominantly found that reusable devices were better for the environment than single-use devices, and that replacing single-use devices with remanufactured devices most often reduced global warming impacts along with resource consumption [18,21,22]. Further, it was identified that remanufacturing equipment and then recycling them a certain number of times saved considerable amounts of money.

However, in contrast, some research has indicated that the incremental resource use associated with sterilization, including water, electricity, and chemical disinfectants, has distinctly negative effects on the environment. It has been seen that, under certain circumstances, reprocessing medical devices has a more negative effect on human health impact categories than employing single-use equipment. This once again emphasizes the need to carry out detailed and holistic assessments of the environmental footprints of various sterilization techniques as well as reprocessing methods in general, in addition to the impacts of device manufacture itself, since the procedure chosen can decide which system is more advantageous [18,22].

In order to obtain a comprehensive vision of the impacts, LCA also needs to be performed on medical packaging, including shipping containers, sharps containers, and drug trays [23]. When considering reusable packaging materials against their disposable alternatives, it is usually found that employing reusable medical packaging produces fewer greenhouse gas emissions, consumes less water, and creates less landfill waste. Additionally, studies have found that reusable medical packaging is vastly cheaper than single-use materials [24]. In order to understand the impacts of medical equipment and procedures also been done on the disposal and management of medical waste. More

specifically, scientists have performed LCA analysis on the wastewater produced by the removal of pharmaceuticals and by hospital laundry, as well as solid waste treatment [23]. Ultimately, the study of the life cycle impacts of single-use vs. reusable medical devices needs to cover equipment manufacture and use, packaging, reprocessing methods, and waste disposal aspects.

2.1. Electrophysiological Catheters

Electrophysiological catheters are used in electrophysiology studies (EPS), which are medical tests that are used to differentiate between different types of arrhythmias, or abnormal heart rhythms. During the procedure, a catheter is inserted into a blood vessel that leads towards the heart. Then, electrical signals are sent through the catheter that change the heart's own electrical impulses by increasing or decreasing the heart rate. The altered electrical signals induced in the heart are recorded by the catheter in a process called cardiac mapping. This then allows a physician to identify the kind of arrythmia present [25]. Electrophysiological catheters consist of a set of insulated wires, an electrode, and a plug, which is usually attached to an external recording device. At the distal end of the catheter, each insulated wire is attached to an electrode, which is then allowed to come into contact with cardiac tissue. The electrodes are usually 1 to 2 mm in length. The proximal end is where the plug is located. Electrophysiological catheters are made of synthetic polymers, most commonly Dacron or polyurethane. The tips of electrophysiological catheters can be either fixed or deflectable. The following methods have been used for disinfecting catheters [26].

2.1.1. Standard Hydrogen Peroxide Sterilization Procedure

Typically, hydrogen peroxide disinfection requires a piece of equipment that consists of a sterilization chamber, a cassette through which hydrogen peroxide solution is injected, and a vent. The chamber of the sterilizer is first evacuated. Once hydrogen peroxide has been added to the sterilizer, it diffuses through the cassette and makes contact with the contaminated devices. The hydrogen peroxide gas saturates the chamber, which exposes all surfaces of the load to the chemical disinfectant and inactivates some microorganisms. Then, an electric field produced by radio waves or microwaves is applied to the chamber, creating hydrogen peroxide plasma. The plasma, which contains a high quantity of free radicals, is what is hypothesized to disinfect the medical devices. The proposed mechanism of action is that the hydroxyl and hydroproxyl free radicals strip electrons from any microbes present. The excess gas is removed during the final stage through the chamber's vent. At the same time, as high-efficiency filtered air is allowed inside the sterilization chamber, the load is slowly returned to atmospheric pressure. Since the by-products of this process, water vapor and oxygen, are both nontoxic, immediate aeration of the sterilized devices is unnecessary. Accordingly, any sterilized objects can be used immediately or stored.

A newer variation of this process involves separating the hydrogen peroxide diffusion and free radical generation into stages. This kind of hydrogen peroxide sterilization has been found to have a stronger germicidal activity. Hydrogen peroxide sterilization is able to inactivate a wide variety of microbes, including some kinds of bacterial spores, yeasts, fungi, and viruses. Items that are impaired by high temperatures and humidity can be sterilized by hydrogen peroxide [12]. As such, many devices that contain polyurethane, low-density and high-density polyethylene, polystyrene, and polyvinyl chloride as well as electrical devices and corrosion-susceptible metal alloys, which cannot be autoclaved, can be disinfected using hydrogen peroxide.

One study has been carried out on the safety of using hydrogen peroxide to sterilize nonlumen electrophysiological catheters, specifically [15]. The catheters were examined for sterility, mechanical and electrical integrity, and chemical residue. The study found that the catheters suffered no mechanical or electrical impairments after being sterilized. Upon light and scanning electron microscopic inspection, one catheter showed signs of insulation fraying at the insulation-electrode interface after being used for the fifth time. Additionally,

the glue adhering the electrode to the insulation was beginning to detach. Apart from this, no other visible defects were found. The microbe most resistant to hydrogen peroxide plasma sterilization was determined to be Bacillus stearothermophilus. However, even this organism was sterilized to levels lower than 10^{-6} after being exposed to hydrogen peroxide free radicals for 30 min. Moreover, after five days of incubation, no bacterial growth was discovered on any catheter tip or connector. Viral testing found that after 20 min of diffusion, both herpes and polio virus complexes were inactivated. The only chemical residual found on the catheters immediately after sterilization was 0.22% hydrogen peroxide. After a few minutes aeration, however, the residuals completely disappeared. Assuming three to five catheters are used per ablation procedure, around $6000 to $11,000 could be saved from every five ablation procedures performed.

2.1.2. Standard Ethylene Oxide Sterilization Procedure

One ethylene oxide sterilization cycle usually consists of six stages: preconditioning, evacuation, humidification, gas introduction, postexposure gas purge, and heated aeration. Medical devices usually undergo preconditioning in a separate room that has been heated to a specific temperature. This ensures that the materials achieve the necessary internal temperature and moisture level before being placed within the sterilizer. This step is performed to reduce the influence of varying climate conditions, guaranteeing the sterility of the objects. Once preconditioning is complete, the devices are placed within a heated chamber. The chamber is then evacuated. At least 97% of the air present within the chamber is removed. This process, however, extracts a significant amount of the moisture in the medical devices as well. Accordingly, the water must be replaced, usually by steam injections. The materials are then allowed to rest in the steam to absorb the required amount of moisture. Afterwards, liquid ETO is vaporized and injected into the chamber.

Scientists hypothesize that ETO kills microorganisms by alkylating proteins, DNA, and RNA. This, in turn, prevents cell replication and the perpetuation of cellular metabolic processes. The products are allowed to sit in the chamber suffused with ETO for a specific amount of time. Then, once the medical devices have been exposed for long enough, the ETO is removed from the chamber using a series of post-vacuums and nitrogen backfills or washes. A sufficient number of washes are performed to minimize any ETO residuals. Finally, the medical devices are removed from the sterilizer and placed in a heated room to encourage additional ETO residual dissipation [27].

While ETO is a very effective microbicidal agent, able to inactivate a wide variety of microorganisms, it is toxic under a variety of contexts. Excessive ETO exposure can cause a diverse array of symptoms, including eye pain, sore throat, difficulty breathing, blurred vision, nausea, headache, convulsions, vomiting, and coughing. ETO has also been proven to be a carcinogen, and has been linked to spontaneous abortion, genetic damage, and peripheral paralysis in animal studies. Patient injuries have been associated with surgical implants sterilized using ETO [12]. As such, it is vital that the safety guidelines for ETO sterilization are followed rigorously, and any items sterilized using ETO be aerated so that lingering ETO residuals are vaporized. Ethylene oxide has been used to sterilize electrophysiological catheters before, and the safety of this process has been evaluated.

In one study conducted in 1997, researchers compared the levels of residual ethylene oxide found on electrophysiology catheters that had been sterilized using ETO followed by an aeration process wiht a method that incorporated a detoxification period [28]. The catheters were examined for residual ETO after the sterilization. The catheters that were disinfected using solely ETO sterilization (without detoxification) still had mean residual levels of ETO two- and seven-days post sterilization, which was above the FDA limit of 25 ppm. However, after 14 days, the amount of residual ETO on all ten catheters tested had decreased below 25 ppm. On the other hand, the catheters that were sterilized using ETO followed by a detoxification period contained much lower residual levels of ETO. However, only after a 15 h-long detoxification period did the ETO levels of all the catheters tested two days after disinfection drop below 25 ppm [28].

Table 1 presents published literature on sustainability assessments of sterilization methods. This summary indicates that life cycle costing has been incorporated in relatively fewer studies, and the medical waste aspect has also been neglected in many studies. There have been very few studies specifically studying the reuse of catheters, even though they are commonly subjected to reprocessing across the world.

Table 1. Current literature on sustainability assessment of sterilization methods.

References	Medical Waste	Life Cycle Assessment	Life Cycle Costing	Sterilization	Literature Review
An environmental life cycle assessment comparison of single-use and conventional process technology for the production of monoclonal antibodies [29]		✓	✓		
Life cycle assessment and costing methods for device procurement Comparing reusable and single-use disposable laryngoscopes [30]		✓	✓	✓	
Assessing the environmental, human health, and economic impacts of reprocessed medical devices in a Phoenix hospital's supply chain [21]		✓	✓	✓	
Assessment of the environmental impacts of medical devices [31]		✓			✓
Environmental impacts of surgical procedures: Life cycle assessment of hysterectomy in the United States [9]		✓	✓		
Clinical solid waste management practices and its impacts on human health and environment [32]	✓			✓	✓
Safety and efficacy of hydrogen peroxide plasma sterilization for repeated use of electrophysiology catheters [15]				✓	
Ethylene oxide exposure attribution and emissions quantification based on ambient air measurements near a sterilization facility [14]				✓	
Combining life cycle assessment and circularity assessment to analyze environmental impacts of the medical remanufacturing of electrophysiology catheters [18]		✓	✓	✓	
Energy, environment and economic assessment of medical waste disposal technologies in China [16]	✓	✓	✓	✓	
Life cycle assessment of a disposable and a reusable surgery instrument set for spinal fusion surgeries [22]		✓		✓	

Table 1. *Cont.*

References	Medical Waste	Life Cycle Assessment	Life Cycle Costing	Sterilization	Literature Review
Comparative life cycle assessment of emergency disposal scenarios for medical waste during the COVID-19 pandemic in China [33]	✓	✓		✓	
LCA as a decision support tool for environmental management in hospitals_ A literature review [34]		✓			✓
Clinical solid waste management practices and its impact on human health and environment—A review [32]	✓	✓		✓	✓
Impact on carbon footprint: a life cycle assessment of disposable versus reusable sharps containers in a large US hospital [24]		✓			
Cataract surgery and environmental sustainability: Waste and life cycle assessment of phacoemulsification at a private healthcare facility [19]	✓	✓			
Life Cycle Assessment Perspectives on Delivering an Infant in the US [20]		✓			
Ethylene Oxide Gas Sterilization of Medical Devices [35]				✓	✓
The financial and environmental costs of reusable and single-use plastic anaesthetic drug trays [36]		✓			
Ethylene Oxide on Electrophysiology Catheters Following Resterilization: Implications for Catheter Reuse [29]			✓	✓	

2.2. Eco-Efficiency Analysis

Eco-efficiency analysis is a composite indicator for decision-making that integrates the economic and environmental performance of a product or a process. In this study, eco-efficiency was calculated as the aggregated environmental impact per unit cost. Similar to LCA, life cycle cost assessments (LCCA) are not commonly used at present to evaluate the ecological impacts of medical devices and processes. However, LCCAs have been performed simultaneously with environmental impact assessments in certain LCA studies conducted for healthcare processes. These analyses have supplemented the LCAs that were performed, as the economic aspect of waste management and recycling is included. This in turn, provides people with a better understanding of the overall costs of using a particular object. One study, which considered the environmental impacts of single-use and reusable scissor tips, arthroscopic shavers, endoscopic trocars, ultrasonic scalpels, ligasures, pulse oximeters, and DVT compression sleeves, found that equipment reprocessing was less costly for all of these objects compared to simply disposing of them after one-time use [21].

3. Methodology

Based on the above literature review, the scope of the study was defined to compare and assess the relative benefits of reprocessing and reusing electrophysiological catheters instead of taking a single-use approach. The number of reuse turns was set at five, based on the findings of previous research that the insulation degraded after five turns in hydrogen peroxide sterilization [15]. A life cycle assessment and a life cycle costing were carried

out for different disposal, sterilization, and reuse scenarios as described in the following sections. The overall methodology is summarized in Figure 1.

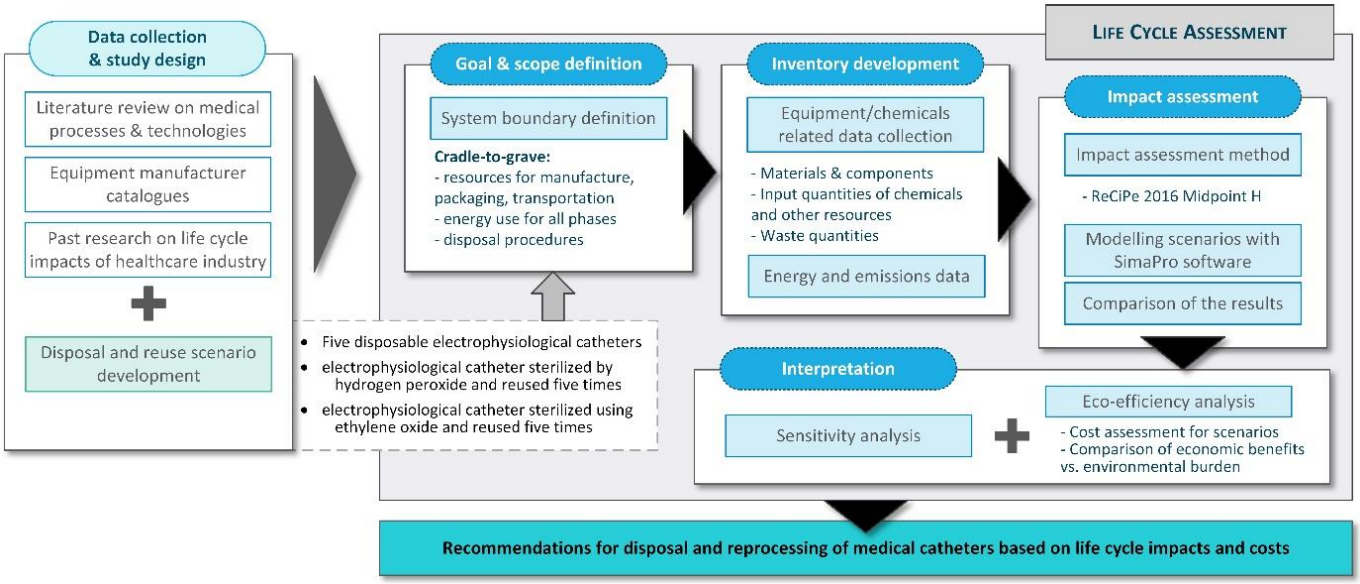

Figure 1. Overall Methodology.

3.1. Phase 1: Goal and Scope Definition

An LCA was performed to compare the environmental impacts of five disposable electrophysiological catheters: an electrophysiological catheter sterilized by hydrogen peroxide and reused five times and an electrophysiological catheter sterilized using ethylene oxide and reused five times. As such, the functional unit of this study was "the use of electrophysiological catheters five times", which corresponds to both using a new catheter each time and to disinfecting and reusing an electrophysiological catheter five times with a sterilization method. The hydrogen peroxide sterilization process followed that of the STERRAD 100NX sterilizer, while the ETO sterilization process followed that of the 3M^{TM} Steri-Vac^{TM} Sterilizer/Abator GS Series. As such, all inputs and wastes were chosen and calculated using the descriptions of these two disinfection processes.

The system boundary selected for this study was cradle to grave. This included the energy and resources necessary for the manufacturing, packaging, transportation, sterilization, and electricity necessary for each method, and disposal procedures. Since a second-order system boundary was considered in this study, capital goods were ignored in both environmental and economic analysis. Selecting a second-order system boundary is an accepted approach suggested in ISO 14044. The variable costs linked to logistics are not specific to a selected disposal and reuse scenario and can vary depending on the locally adopted practices. Since the focus of this study was to compare the relative environmental and economic costs and benefits of sterilization and reuse vs. single-use and disposal in medical equipment, this aspect was neglected in the present study.

The electrophysiological catheter process is the output of the single-use electrophysiological catheter raw materials' refinement and production, and manufacturing and packaging stages. The electrophysiological catheter process is then utilized as an input in the catheter sterilized by hydrogen peroxide and catheter sterilized by ETO sections. The hydrogen peroxide cassette portion of the H_2O_2 sterilization process and biological indicator process are both described by the cleaning supplies production stage in Figure 2. They both contribute to the sterilization step. Similarly, the ETO canister portion of the ETO sterilization process, and ETO chemical indicator process, are both described by the cleaning supplies production phase in the catheter sterilized by ETO portion of Figure 2. They all are elements of the sterilization stage. All the waste products in each stage were assumed to be disposed of by hospital incineration.

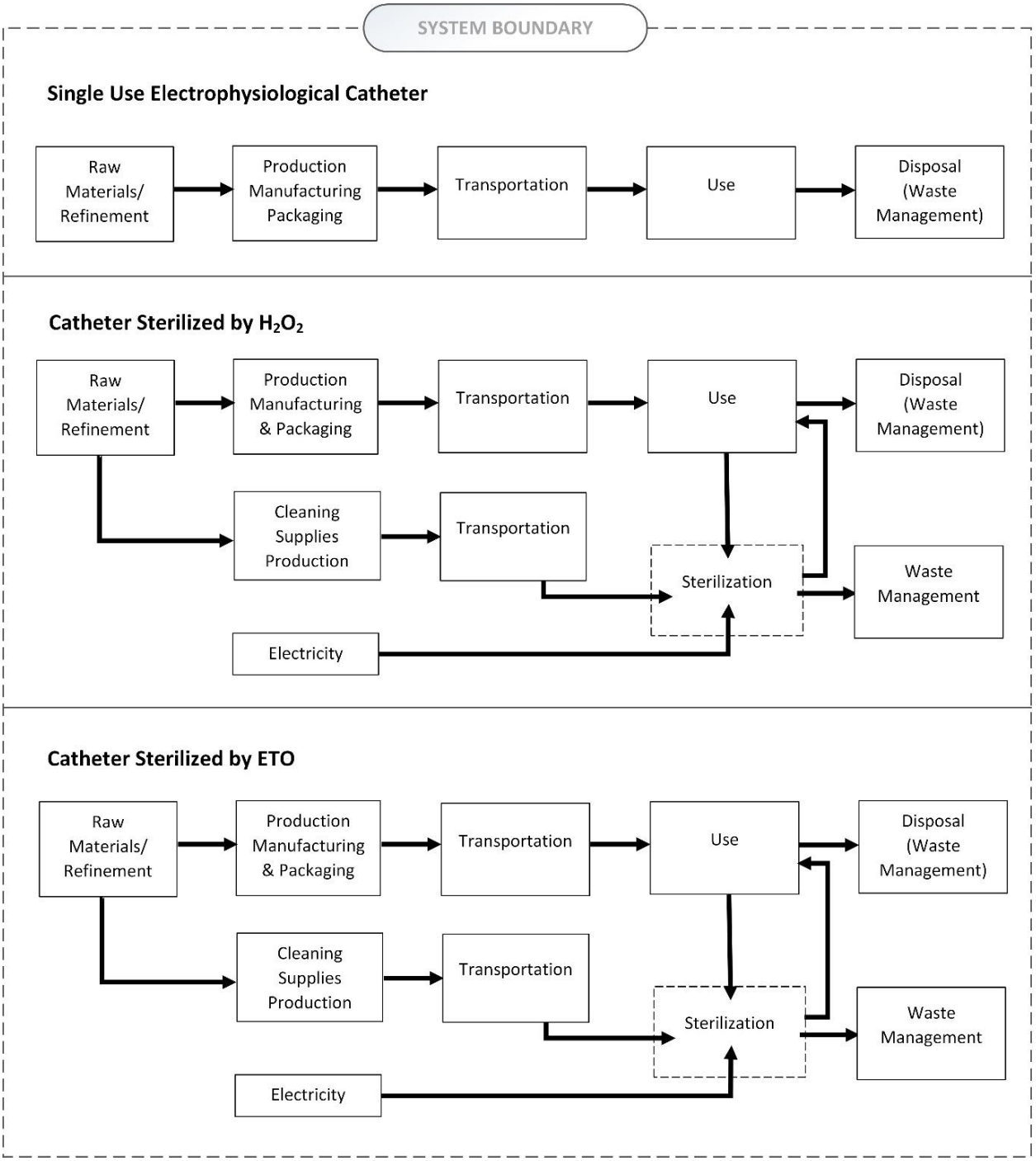

Figure 2. System boundaries of the life cycle analysis and eco-efficiency analysis for different scenarios.

Data was drawn from other studies, from manufacturers' manuals, and from medical distributor websites, and are summarized below. The details of the inputs and outputs of the processes under consideration are elaborated in the following sections.

3.2. Phase 2: Inventory Analysis

The life cycle inventory databases used in the study did not contain data on the different varieties of bacteria available as inputs. Since the hydrogen peroxide biological indicator and the ETO biological indicator were very similar, the same biological indicator was used for both the ETO sterilization and hydrogen peroxide sterilization processes.

Polyethylene terephthalate granulate was substituted for Tyvek. Fodder yeast was substituted for Bacillus stearothermophilus in the hydrogen peroxide biological indicator, and for Bacillus atropheus in the ETO biological indicator. Protein feed was substituted for the tryptone and yeast extract. The glass vial in the biological indicator was assumed to be a Premium Vials B4702-36 Glass Vial. The plastic components of the biological indicator were assumed to be made of the same materials as blood collection tubes, with a layer of polyethylene terephthalate granulate and polypropylene granulate. The material compositions for these processes were taken from manufacturers' models, which detailed the mass of the substances needed to produce them but did not specify the amount of electricity that would be needed for manufacture. However, the electricity consumption was neglected in the biological indicator, ETO chemical indicator, and hydrogen peroxide chemical indicator processes as the material use was determined to be the major contributor to the overall life cycle impact, while the electricity consumption of production was deemed to be negligible in comparison (as these items are produced in mass scale). The data on the manufacturing process of an electrophysiological catheter was obtained from a study done by Schulte et al. (2021) [18]. The values in Tables 2 and 3 were determined based on the information gathered from several sources [37–41].

Table 2. Input values for one electrophysiological catheter.

Material	Amount	Description
Carbon dioxide	2.82×10^{-3} kg	Ingredient of sterilization gas
Corrugated board	0.14 kg	Secondary packaging
Ethylene oxide	1.80×10^{-4} kg	Ingredient of sterilization gas
Polyamide 6 fibres (PA 6)	3.20×10^{-3} kg	Component of PEBAX shaft
Polyethylene granulate (PEI)	0.11 kg	Plug and handle
Polyethylene glycol (PEG)	1.25×10^{-3} kg	Component of PEBAX shaft
Polyethylene high density granulate	0.02 kg	Primary packaging
Polyethylene low density granulate	3.00×10^{-4} kg	Shaft stiffener
Polyurethane flexible foam (PU)	8.00×10^{-4} kg	Curvature and loop
Water (desalinated; deionized)	2.00×10^{-3} kg	Process water
Electricity; consumption mix	0.36 kWh	Electricity needed except for plastic production

Table 3. Input values for one biological indicator.

Polyethylene terephthalate, granulate	3.8 g	Plastic tube and filter material
Polypropylene granulate	3.4 g	Plastic tube material
Glass tube, borosilicate	70.02 g	Vial for test organism
Fodder yeast	0.016 g	Indicator organisms
Protein feed	0.02 g	Media component
Sodium chloride, powder	0.165 g	Media component
Water, ultrapure	1.65 g	Media component

The plastic the indicator ink was printed on was assumed to be unsaturated polyester resin. Ethylene glycol monoethyl ether was substituted for BKUA-2370 phenol-formaldehyde resin. Epoxy resin was substituted for E-3558 polyamide curing agent. O-nitrophenol was substituted for 2,6-dinitrophenol. Aniline was substituted for Janus Blue. Propylene glycol was substituted for Dowanol PNP. Powdered carboxymethyl cellulose was substituted for thickener. The electricity necessary to construct the indicator out of its inputs was not considered.

The data in Table 4 was acquired from the data published by equipment suppliers [42,43] and a patent paper [44].

Table 4. Input values for one ETO chemical indicator.

Unsaturated polyester resin	0.14 g	Strip Material [42,43]
Deionised water	2.88 g	Ingredient of indicator [44]
Epoxy resin	0.8 g	Ingredient of indicator [44]
Titanium dioxide	0.72 g	Ingredient of indicator [44]
Citric acid	0.09 g	Ingredient of indicator [44]
Potassium chloride	0.02 g	Ingredient of indicator [44]
Non-ionic surfactant	0086 g	Ingredient of indicator [44]
Powdered Carboxymethyl cellulose	0.28 g	Ingredient of indicator [44]
O-nitrophenol	0.079 g	Ingredient of indicator [44]
Propylene glycol	0.24 g	Ingredient of indicator [44]
Aniline	0.393 g	Ingredient of indicator [44]
Ethylene glycol monoethyl ether	2.63 g	Ingredient of indicator [44]

Aluminum sheet was substituted for the tin-plated steel cap. The electricity needed to manufacture the ETO cartridge, as well as the Tyvek packaging, was not included.

The data in Table 5 was collected from Advances in Technical Nonwovens [45], equipment manufacturers 3M [46] and Getinge [47], and the United States Environmental Protection Agency [48].

Table 5. Input values for the ETO sterilization process.

Ethylene oxide	100 g	Sterilization gas
Aluminium sheet	30 g	Cartridge material
High density granulated polyethylene	5.326 g	Component of sterilization packaging
Granulate Polyethylene terephthalate	1.388 g	Component of sterilization packaging
Electrophysiological catheter	1	
Ethylene Oxide Chemical Indicator	1	
Biological Indicator	1	
Electricity	64.9 kWh	Electricity needed

The plastic the indicator ink was printed on was assumed to be unsaturated polyester resin. Ethylene glycol monoethyl ether was substituted for BKUA 2370. Epoxy resin was substituted for E-3558 polyamide curing agent. Non-ionic surfactant was substituted for sodium laurel sulfate. Powdered carboxylmethyl cellulose was substituted for cellulosic. Aniline was substituted for Janus Green B. The electricity needed to construct the indicator was not included. The data in Table 6 was acquired from equipment suppliers [42], patent paper [44], and multiple literature sources [45,47,49].

The hydrogen peroxide cassettes along with the cassette collection boxes for disposal were assumed to be made of polypropylene [50]. The energy needed to manufacture the hydrogen peroxide cassette along with the Tyvek packaging was not considered. Table 7 presents input values for the hydrogen peroxide sterilization process.

Table 6. Input values for one hydrogen peroxide chemical indicator.

Unsaturated polyester resin	0.14 g	Strip material
Ethylene glycol monoethyl ether	3.42 g	Ingredient of indicator
Deionised water	2.97 g	Ingredient of indicator
Titanium dioxide	1.03 g	Ingredient of indicator
Epoxy resin	0.25 g	Ingredient of indicator
Non-ionic surfactant	0.086 g	Ingredient of indicator
Powdered carboxymethyl cellulose	0.024 g	Ingredient of indicator
Aniline	0.079 g	Ingredient of indicator

Table 7. Input values for the hydrogen peroxide sterilization process.

50% Hydrogen peroxide solution without water	18.166 g	Ingredient of sterilization solution
Deionised water	4.536 g	Ingredient of sterilization solution
Polypropylene granulate	22.6576 g	Cassette material
Polyethylene terephthalate granulate	1.388 g	Component of sterilization packaging
High-density polyethylene granulate	5.326 g	Component of sterilization packaging
Electrophysiological catheter	1	
Biological indicator	1	
Hydrogen peroxide chemical indicator	1	
Electricity	4.888 kWh	Electricity needed

3.3. Phase 3: Life Cycle Impact Assessment

ReCiPe 2016 Heirarchist (H) technique was used for environmental impact assessment under both midpoint and endpoint indicators. The characterization factors of ReCiPe 2016 are representative for the global scale, which is more appropriate for a study of this type [51]. In life cycle assessment, impacts can be quantified under midpoint or endpoint impact categories. While midpoints are oriented towards problems, midpoint indicators are damage-oriented and can provide a quantification of the damages from a product, process, or system in a form more relatable to the general public [52,53]. Endpoint approaches are also more valuable in decision-making applications where aggregation is needed, and thus have higher relevance for decision support [53]. ReCiPe method has both endpoint and midpoint impact categories, and is harmonised in terms of modelling principles and choices [54]. It is one of the newer and up-to-date impact assessment methods available for LCA studies [55]. The Heirarchist perspective is the consensus model that is usually considered to be the default approach, as it is based on the most common policy principles on issues such as timeframe [51,56]. The impact assessment modeling was done through SimaPro software, which is the most widely used state-of-the-art LCA tool today. The endpoint damages were aggregated under three main categories: ecosystems, human health, and resources.

For further transparency and clarity of the data, the midpoints were also assessed and presented. Midpoints are considered to be more certain and accurate compared to endpoints, with a higher level of transparency and the lower complexity in modeling. Experts recommend both midpoint and endpoint indicators to be presented in parallel for better decision making [53]. The 22 impact categories that were considered under this approach are as follows:

1. Global warming, human health (kg CO_2-eq to air);
2. Global warming, terrestrial ecosystems (species·yr/kg CO_2-eq to air);
3. Global warming, freshwater ecosystems (species·yr/kg CO_2-Eq);
4. Stratospheric ozone depletion (kg CFC-11-eq to air);
5. Ionizing radiation (kBq Co-60-eq to air);
6. Ozone formation, human health (yr/kg NOx to air);
7. Fine particulate matter formation (yr/kg PM2.5 to air);
8. Ozone formation, terrestrial ecosystems (yr/kg NOx to air);
9. Terrestrial acidification (yr/kg SO_2 to air);
10. Freshwater eutrophication (species·yr/kg P to fresh water);
11. Marine eutrophication (species·yr/kg N to marine water);
12. Terrestrial ecotoxicity (species·yr/kg 1,4-DCB to industrial soil);
13. Freshwater ecotoxicity (species·yr/kg 1,4-DCB to fresh water);
14. Marine ecotoxicity (species·yr/kg 1,4-DCB);
15. Human carcinogenic toxicity (yr/kg 1,4-DCB to air);
16. Human non-carcinogenic toxicity (yr/kg 1,4-DCB to air);
17. Land use; mineral resource scarcity (US2013 $/kg Cu);
18. Fossil resource scarcity (US2013 $/kg crude oil);
19. Water consumption (species·yr/m^3 water consumed);
20. Water consumption-Human health (yr/m^3 water);
21. Water consumption, terrestrial ecosystems (species·yr/m^3 water consumed);
22. Water consumption, aquatic ecosystems (species·yr/m^3 water consumed).

The aggregation of the impacts into a single overall endpoint indicator was carried out through the default model, i.e., the heirarchist version of ReCiPe with average weighting (H/A) in SimaPro [51]. The H/A option uses the average result from all three ReCiPe impact assessment perspectives. Here, a higher relative importance was assigned to the ecosystem damage category. The weighting was done at the endpoint level (damage-oriented), and the heirarchist value choices were accepted both scientifically and politically in general, thus making it suitable for this application, which aimed to define best practices for the healthcare industry [51]. The scores are indicated in the units mega points (MPt) [57]. The life cycle impact assessment was performed using the Eco-invent 3.8 database.

3.4. Phase 4: Interpretation

Certain components of both the ETO and hydrogen peroxide sterilization processes had some uncertainty. More specifically, the weight specifications for the Tyvek packaging were printed in a range. As such, sensitivity analyses were performed for both ETO and hydrogen peroxide disinfection.

Eco-Efficiency Analysis

An eco-efficiency analysis was performed so that the economic impacts of each process could be evaluated. The system boundaries of the eco-efficiency analysis were similar to those for the LCA. However, the eco-efficiency analysis did not include the cost of any sterilization machinery used, including the ETO Abator that converted any residual ETO into carbon dioxide and water for the ETO sterilization process. Furthermore, the life cycle of the machine and any repair costs included were not considered. The prices of various medical instruments and sterilization equipment were obtained from various medical retail websites. All prices were given or were converted to Canadian dollars using the conversion rate of 1 USD being equivalent to 1.26 CAD, which was the rate recorded on 21 April 2022.

Since the price for the electrophysiological catheters were found in a range, the average of the minimum and maximum prices was taken to represent the cost of one catheter. Similarly, because the electricity providers in Ontario, Canada charge customers using a tiered scale, the average of all the rates was taken and used to calculate the cost of the electricity necessary for each process. The price of each component of the processes considered are below, compiled in Tables 8 and 9.

Table 8. Prices of components of the hydrogen peroxide sterilization process.

Item	Price (CAD)
Sterrad 100 NX Sterilant Cassettes (Case of 2)	$502.74
Tyvek pouches (100 per case)	$52.00
Hydrogen peroxide chemical indicator strips (250 per box)	$54.86
Hydrogen peroxide biological indicator (30 per box)	$970.52
Cassette Collection Box for the Sterrad 100 NX (10 per case)	$364.14

Table 9. Prices of components of the ETO sterilization process.

Item	Price (CAD)
3M Steri-Gas 4XL or 5XL EO Cartridge	$191.49
Tyvek pouches (100 per case)	$52.00
3M Attest Biological Indicators for Ethylene Oxide (400 per case)	$1067.16
3M Comply EO Chemical Indicator (240 per box, 4 boxes per case)	$120.07

Electricity in Ontario is provided using a tiered system in which off-peak hours, mid-peak hours, and on-peak hours have different rates. An average was taken of the three different prices published on the Ontario Energy Board, effective since 8 February 2022 [58]. This information was used in assessing the costs of energy use for sterilization.

One octapolar (8-electrode) catheter costs between $3824.1–4214.7 CAD [59]. Five catheters were assumed to be used in the eco-efficiency assessment for the disposable process. The use of one catheter was considered in the assessment for both the hydrogen peroxide sterilization procedure and the ETO sterilization procedure. The component price values in Table 8 were gathered from the websites of several medical equipment suppliers [60–63].

Table 9 represents price data of the components for the ETO sterilization process, collected from the medical equipment supplier websites [61,64,65].

A different brand of biological indicator was substituted for the STERRAD Velocity hydrogen peroxide biological indicator, as a price for the latter could not be found. As well, a different size of Tyvek pouch was substituted for the Tyvek pouch used in the LCA.

Using the above data, the total cost of each disposal and reuse process was determined for the same functional unit (the use of electrophysiological catheters five times). Taking the single-use scenario as the base case, the monetary cost and the environmental benefit of the different sterilization and reuse scenarios were investigated. One important metric calculated in this analysis is the potential increase or decrease in overall impacts under different scenarios per dollar of cost reduced.

4. Results

The results obtained from the LCA and the eco-efficiency analysis are presented below. These results can be used to conduct a comparative assessment of the environmental and economic sustainability of the different disposal and reuse scenarios.

4.1. Life Cycle Impact Assessment Results

Both midpoint and endpoint results can be observed in Figures 3 and 4. Here, the scores for different disposal and reuse scenarios are compared on a percentage basis. It should be noted that the higher the indicator score, the higher the environmental impact and therefore the lower the environmental sustainability.

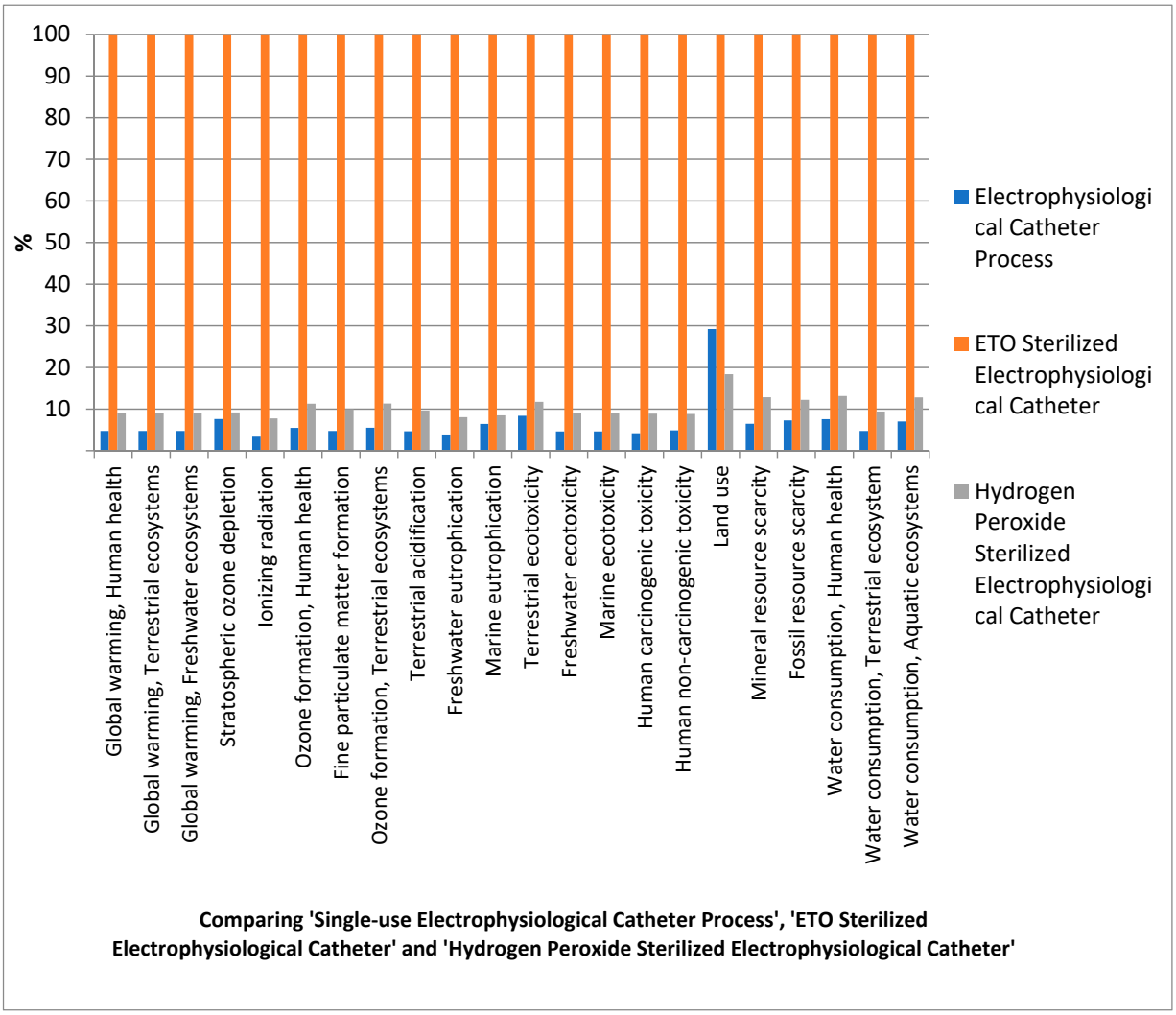

Figure 3. Environmental impact comparison of different disposal and reuse scenarios (midpoint level).

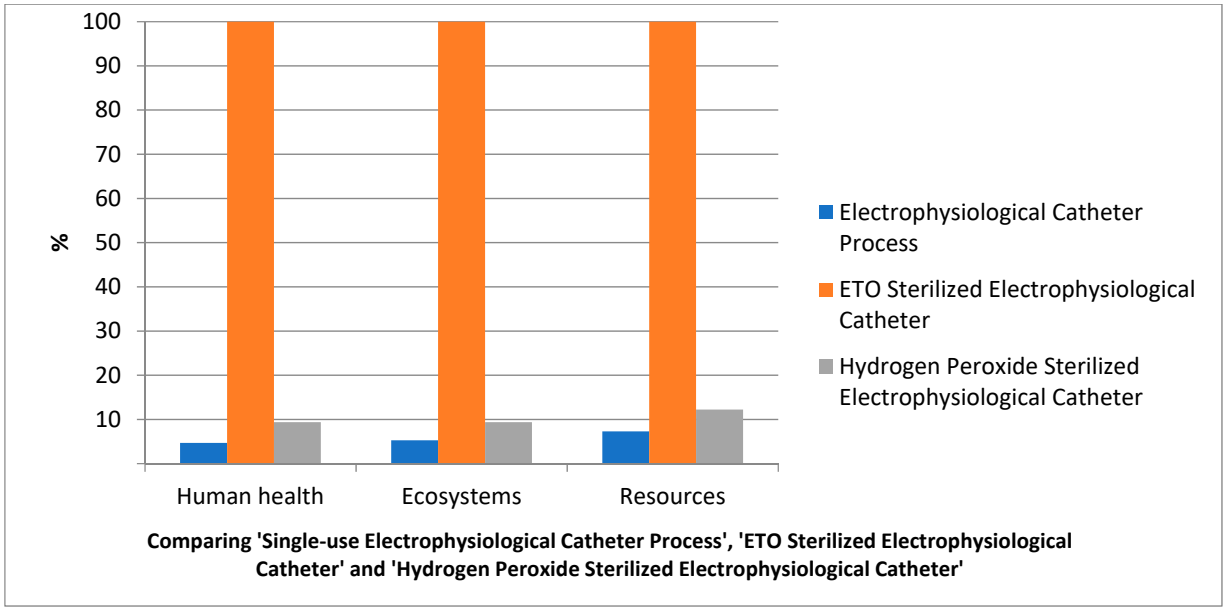

Figure 4. Damage assessment comparison of different disposal and reuse scenarios (endpoint level).

Figure 5 depicts the aggregated score of the endpoint damage scores under all three scenarios.

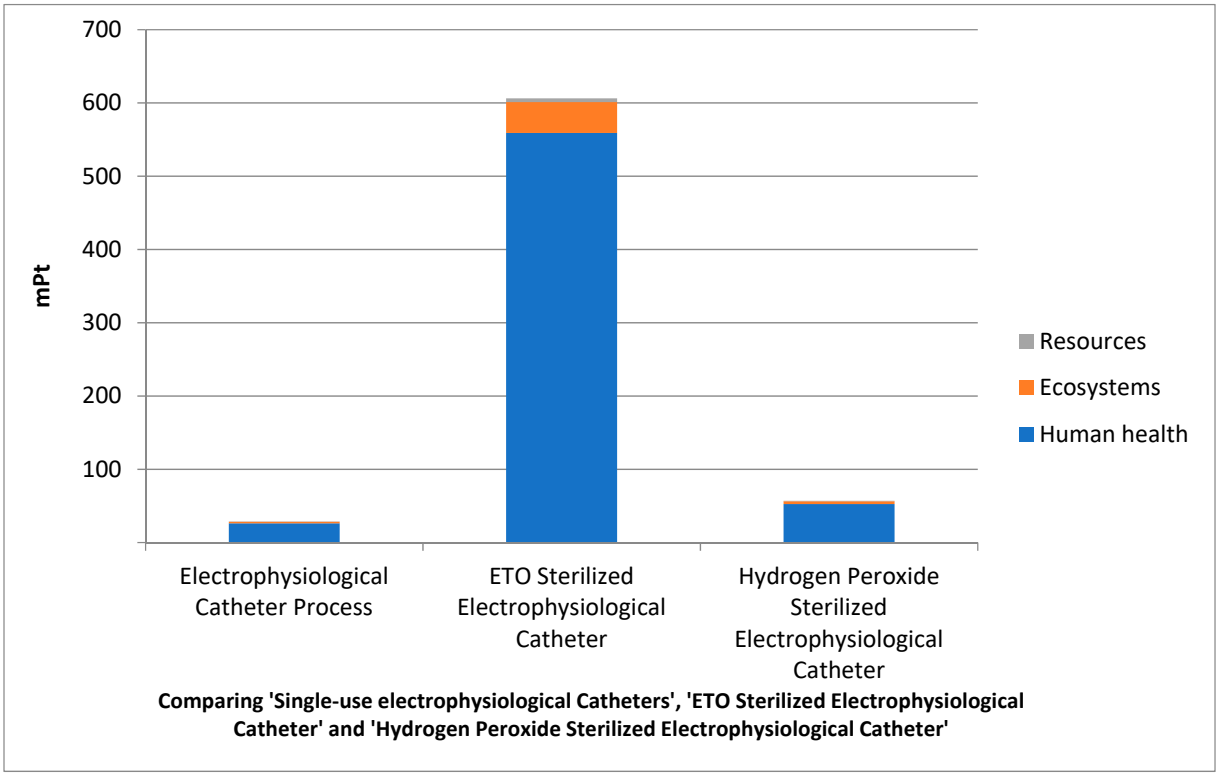

Figure 5. Single aggregated score of the environmental impacts of different disposal and reuse scenarios.

In all these graphical representations, it is clear that the ETO sterilised electrophysiological catheter had the highest environmental impacts.

LCA Impacts of ETO Sterilization of one Electrophysiological Catheter: Ethylene oxide sterilization had the highest impact in each of the 22 midpoint impact categories considered and had the highest single-score environmental impact. This scenario had a score of approximately 600 mPt, more than 12 and 24 times those of hydrogen peroxide sterilization and single-use electrophysiological catheters, respectively.

LCA Impacts of Hydrogen Peroxide Sterilization of one Electrophysiological Catheter: Hydrogen peroxide sterilization had an intermediate effect on the impact categories considered, scoring below ethylene oxide sterilization but above disposable electrophysiological catheters in all but the land use category. However, the differences between the land use scores for hydrogen peroxide and single-use electrophysiological catheters were not very large, averaging around 10%. As well, hydrogen peroxide sterilization had the second highest single score and damage assessment.

The best process from a purely environmental perspective would be to employ single-use electrophysiological catheters. Disposing of used electrophysiological catheters had the lowest environmental impact in all but one of the impact categories considered (i.e., land use). Moreover, disposing of each electrophysiological catheter had the lowest single score as well as the lowest damage assessment.

4.2. Eco-Efficiency Analysis

The total cost of disinfecting one electrophysiological catheter using hydrogen peroxide so that it can be reused five times is $5885.52, as indicated in Table 10. The total cost of sanitizing one electrophysiological catheter for reusing up to five times using ETO is $4064.22. Finally, five disposable catheters cost $20,097 in total. From a cost perspective, using five disposable catheters instead of sterilizing and reusing them appears to be suboptimal.

Table 10. Eco-efficiency of different scenarios.

Scenarios	Aggregate Environmental Impacts (mPt)	Cost ($)	Cost Per Unit of Impacts ($/mPt)	Cost Reduction ($)	Impact Increase	Environmental Impacts Increase Per a Dollar of Cost Reduced (mPt/$)
Five single use catheters	28.7509	20,097	699.00	-	-	-
Catheter sterilized using hydrogen peroxide (reused five times)	56.9762	5885.50	103.30	14,211.50	98%	1.99×10^{-3}
Catheter sterilized using ETO (reused five times)	606.2411	4064.22	6.70	16,032.78	2009%	3.60×10^{-2}

Taking the single-use scenario as the base case, the effect of reusing on environmental impacts and cost has been explored. The results indicate that while the cost is the lowest in sterilizing catheters using ETO (reused five times), the environmental impacts increase drastically under this scenario. Compared to an impact increase of 98% for hydrogen peroxide sterilization, the impact increase is 2009% for the ETO sterilization. For each dxollar of cost reduction, the aggregate environmental impacts increase by 3.60×10^{-2} mPt for the ETO sterilization scenario.

The manufacturer's report on the Tyvek pouches mentioned that there was some variation in the weight and dimensions of each pouch. A sensitivity analysis was conducted to analyse the effect of this variation on the LCA results. The analysis found however, that this uncertainty had a small effect on the LCA results, most likely since the weight of the Tyvek pouches along with the resources necessary to produce them were relatively minor in comparison to the other inputs.

5. Discussion

Based on the above results, the key takeaway is that while sterilization and reuse can lead to economic benefits, the overall life cycle impacts of the electrophysiological catheters increase due to this (when compared to the single-use scenario). The single-use disposal scenario scored the lowest in life cycle impacts under almost every impact category. ETO sterilization and reuse, while leading to a higher cost reduction compared to hydrogen peroxide sterilization, causes the environmental impacts to increase by over 20 times.

5.1. Environmental Impacts Comparison

The results seem to indicate that from a purely environmental perspective, employing disposable electrophysiological catheters does not have much of a positive outcome. As mentioned before, single-use electrophysiological catheters had the lowest environmental impact in every category except land use, in which hydrogen peroxide sterilization had the lowest impact. This might be due to the fact that more resources are necessary to produce five new catheters than are necessary to disinfect one catheter. However, surprisingly, using ETO to sterilize the electrophysiological catheters had the highest environmental impact in every category considered. This is partially attributable to the fact that a significant amount of electricity is consumed in every ETO sterilization cycle. These extended cycle times in turn are necessary because of the toxicity of the residual quantities of ETO; the lengthy aeration periods are needed so that enough ETO dissipates before the next use. Furthermore, because ETO is a toxic compound proven to be a carcinogen, an additional apparatus is needed for detoxification in order to convert any remaining ETO to carbon dioxide and water. This instrument too required electricity to operate. The hydrogen peroxide disinfection scenario also consumes energy and chemicals for the disinfection

process. However, due to the lower toxicity compared to ETO, there is no need for such a stringent detoxification process. This means that the disinfection-process-related impacts are lower in hydrogen peroxide sterilization.

Another interesting aspect that comes up in this analysis is how the energy sources used to supply the energy needs of human activities can change the overall impacts significantly. The energy used for sterilization and detoxification is a major reason for the drastic increase in the environmental impacts in disinfection and reuse scenarios. By shifting to cleaner energy sources with lower impacts, this situation can be improved. However, the costs and benefits of that clean energy transition should also be performed with a life cycle perspective, as many supposedly "zero-emission" and "clean" energy technologies have high embodied impacts and pollution issues during the disposal phase.

These results once again underscore a theme that has appeared in many LCAs applied to medical technology: while reprocessing may seem more environmentally friendly, the particular resources necessary for certain sterilization techniques might in fact make them less environmentally favorable than simply disposing of used material. Single-use does mean that a significant amount of medical waste is generated, leading to waste management problems and other environmental impacts due to pollution. However, in the medical sector, it is quite challenging to respond to this problem via recycling as is done in other industries. Particularly when it comes to catheters, they are generally difficult to recycle as they come into contact with bodily fluids, including urine and other biomedical waste. However, certain material components such as platinum can be recovered through a carefully handled sorting, separation, and recycling process. The other key alternative to reducing the environmental impacts of medical devices is the use of biodegradable materials. Various research initiatives are ongoing to produce biodegradable or dissolvable catheters and other medical devices.

5.2. Comparison of Environmental Impacts against the Costs and Health and Safety Benefits

From a perspective based purely on cost, ETO sterilization is the best option due to having the lost cost of all three scenarios. This may be due to the fact that producing new electrophysiological catheters is much more expensive than the process of ETO sterilization: the price of a single Octapolar catheter can be anywhere from $3824.1 to $4214.7. Along the same lines, hydrogen peroxide biological indicators are much more expensive than their ETO counterparts. This may explain why hydrogen peroxide sterilization is more costly, given that the two processes share many other similarly priced inputs. Finally, the quantity of electricity necessary for ETO sterilization, which may be responsible for most of its high environmental impacts, is actually one of the least costly components of the process. However, hydrogen peroxide sterilization is a non-toxic, relatively environmentally friendly option, while also being more time-efficient compared to ETO [66]. On the other hand, while ETO sterilization has the disadvantages of lengthy cycle time and potential hazards, it is highly effective in sterilizing heat- and moisture-sensitive medical devices [67].

Due to the high costs for new electrophysiological catheters, it seems favorable to either sanitize and then reuse catheters using a process similar to those detailed in this study, or recycle them, in which electrophysiological catheters are disassembled, sanitized, and then reprocessed and sent back to medical facilities. However, because sterilizing electrophysiological catheters can, in fact, have a greater environmental impact than simply using disposable catheters, all processes should be carefully considered. Nevertheless, it may be difficult to weigh the economic downsides of the single-use approach against the potential environmental benefits.

One other aspect that may further complicate this scenario is that it is essential to disinfect multiple-use electrophysiological catheters thoroughly and safely to prevent the spread of communicable diseases. When using single-use catheters, this is not as much of a concern, as new catheters should be sterile. However, because sterilizing catheters may, in fact, affect the environment in ways that negatively impact human health, it may be better to choose to utilize disposable catheters.

5.3. Limitations

The study outcomes are subject to some uncertainty due to some material substitutions and approximations, which had to be made while gathering data for the inventory analysis. Furthermore, some of the components of the chemical indicators and biological indicators were not available within the life cycle databases available with the SimaPro software used for this LCA.

The electricity inputs used in synthesizing the Tyvek packaging, the ETO chemical indicator, the hydrogen peroxide chemical indicator, and the biological indicator from their respective constituents were not included in the scope of the LCA. Moreover, the electricity required to incinerate any waste produced from these items was not included as well. If these values had been also incorporated into the assessment, then the environmental impacts of both sterilization processes would have been higher.

Not including the costs of the sterilization machinery used for either disinfection process in the eco-efficiency analysis is another limitation of this study. If the prices for that equipment had been included, then the eco-efficiency values of ETO sterilization and hydrogen peroxide sterilization would change, as the increase in the environmental impacts per dollar of cost reduction would decrease by a small amount. However, the sterilization machines are used for many rounds of sterilization for multiple catheters over their lifetime. Therefore, the machine-related impacts per reused scenario were deemed to be quite limited, and therefore were not included within the system boundary.

Another limitation of this study is the fact that the transportation-related impacts of the electrophysiological catheters and the sterilization process inputs was not included within the system boundaries. If transportation had been included, then the environmental impacts of all three processes would most likely have increased. The number of process components increases for hydrogen peroxide sterilization scenario and increases even more for ETO sterilization compared to the base case. However, the transportation impact allocatable to a single catheter is likely to be quite small and therefore negligible.

6. Conclusions

The results show that, in general, using disposable electrophysiological catheters instead of sterilizing a single catheter using either ETO or hydrogen peroxide and reusing multiple times is preferable from a purely environmental perspective. However, in terms of the monetary cost, ETO sterilization is the best option, while disposable electrophysiological catheters are the least economical (with four to five times the cost of sterilization for the process unit "*use of electrophysiological catheters five times*"). Thus, while the costs of medical devices can be reduced by sterilizing and reusing the equipment, it can lead to an increase in the environmental impacts. This is mainly due to the energy consumed in disinfecting and detoxifying the equipment between each usage cycle. Thus, while it is possible to avoid the use of virgin material extraction and end-of-life waste disposal by replacing single-use devices with disinfection and reuse options, it may not lead to the environmental benefit expected in the long run and may actually have a net negative effect. This represents a dilemma in which medical administrators must carefully consider the advantages and disadvantages of each process. By considering the economic impacts of the long-term environmental damage, this analysis can be extended further. Additionally, this once again illustrates that recycling methods are not always more favorable than single-use devices. As such, it is important to carefully consider the resources necessary for and outputs of each process; to this end, life cycle analysis can be a very helpful tool. The outcomes of this type of analysis is quite important in making decisions and developing regulations on sustainability initiatives, operational procedures, and waste management practices, not only in the medical sector but also in other domains.

Author Contributions: Conceptualization, C.L., H.K. and R.R.; methodology, C.L. and H.K.; software, C.L.; formal analysis, C.L.; investigation, C.L. and R.R.; resources, R.R.; data curation, C.L.; writing—original draft preparation, C.L.; writing—review and editing, H.K. and R.R.; visualization, C.L.; supervision, R.R.; project administration, R.R. All authors have read and agreed to the published version of the manuscript.

Funding: This research received no external funding.

Conflicts of Interest: The authors declare no conflict of interest.

Nomenclature

GHG	Greenhouse gas
LCA	Life cycle assessment
LCC	Life cycle costing
LCI	Life cycle inventory
LCIA	Life cycle impact assessment

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